European Commission

Ex-post Evaluation of the Health Programme (2008-2013)

Annexes to the
Final report

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with the support of Cemka-Eval, and Economisti Associati.

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EUROPEAN COMMISSION

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Directorate-General for Health and Food Safety
Health Programme

2015

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1. TASK SPECIFICATIONS

1.1.CONTEXT OF THE ASSIGNMENT

Short presentation of the Health Programme 2008-2013

The EU is required by its founding treaty[1] to ensure that human health is protected as part of all its policies, and to work with the EU countries to improve public health, prevent human illness and eliminate sources of danger to physical and mental health.

The Second Programme of Community Action in the Field of Health 2008-2013 (referred to here as the Health Programme), came into force on 1 January 2008 with Decision No 1350/2007/EC[2] of the European Parliament and of the Council of 23 October 2007.

The Decision provides for a **total budget of 321.5 million euros**. Most of the Health Programme budget will finance projects to complement, support and add value to national policies. It should boost solidarity and prosperity in the EU by protecting and promoting human health and safety and improving public health.

The Health Programme is managed by the Commission with the **assistance of the Executive Agency for Health and Consumers (EAHC)**. A specific Committee, called the **Programme Committee[3],** assists the Commission in monitoring progress in the light of the Programme's objectives.

Actions under the Programme are intended to **complement national policies of the Member States with a European added-value.** This means that they should involve actors from different participating countries and the results should be able to be applied in other countries and regions across Europe and in its neighbourhood.

The Health Programme is part of a broader strategy aimed at improving and protecting public health. **The Health Strategy: "Together for Health: A Strategic Approach for the EU 2008-2013"** was published in 2007 and aims to provide an overarching strategic framework spanning core issues in health as well as health in all policies and global health issues. The Health Programme is the main financial instrument the European Commission uses to support implementation of the EU Health Strategy.

The objectives of the Health Programme

According to the above-mentioned legal basis of the Health Programme, its three objectives may be summarised as follows:

First objective: Improve citizens' health security

- Protect citizens against health threats by developing the capacity of the EU community to respond to communicable and non-communicable diseases and health threats from physical, chemical and biological sources, including bio-terrorism; for example with emergency planning and preparedness measures;

[1] Article 168 of the Treaty on the European Union (Official Journal C 83 of 30 March 2010 pp. 122-124)

[2] Official Journal L 301 of 20.11.2007, pp. 3-13.

[3] See Article 10 of Decision 1350/2007/EC establishing a second programme of Community action in the field of health (2008-13).

- Improve citizens' safety by promoting actions related to patient safety through high quality and safe healthcare, scientific advice and risk assessment, safety and quality of organs, substances of human origin and blood.

Second objective: Promote health and reduce health inequalities

- Action on key health factors such as nutrition and physical activity, drug consumption, sexual health, focusing on key settings such as education and the workplace;
- Measures on the prevention of major diseases with a focus on EU added-value action in areas such as gender issues, children's health or rare diseases;
- Promote healthier ways of life and reduce health inequalities, thus increasing healthy life years and promoting healthy ageing;
- Promote and improve physical and mental health;
- Address the health effects of social and environmental determinants.

Third objective: Generate and disseminate health information and health knowledge

- Exchange knowledge and best practice on health issues supporting the coordination of European reference networks, Member States' public health policies and progress;
- Collect, analyse and disseminate health information focusing on health monitoring system with appropriate indicators and ways of disseminating information to citizens such as Health Portal, conferences and regular reports on health status in the EU.

Health priorities and criteria

To meet the above-mentioned Programme objectives, an Annual Work Plan (AWP) is prepared each year. It sets out health priority areas and the criteria for funding activities under the Programme. Preparing the Annual Work Plans[4] is the responsibility of the Commission and they are adopted after approval by the Members States represented in the Programme Committee.

The financial mechanisms

A wide range of financial mechanisms is offered to support the implementation of the Health Programme. These are:

- Grant agreements for actions: they are awarded to projects involving several partners, usually public health bodies and NGOs. The rate of EC contribution is 60%.

[4] Decision 2008/170/EC (*Official Journal* L56 of 29.02.2008); Decision 2009/158/EC (*Official Journal* L53 of 26.02.2009) and Decision 2009/964/EU (*Official Journal* L340 of 22.12.2009) refer to the annual work plans 2008, 2009 and 2010. The links to these decisions for the annual work plans are given in Chapter 4. of the current Task specifications.

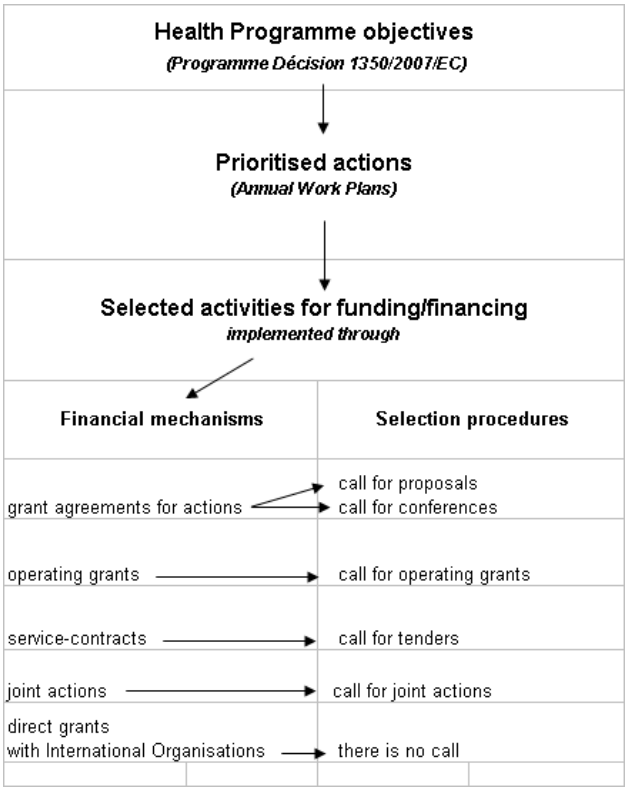
- Service-contracts: services (studies, data, etc.) are purchased after procurement procedures. The cost is fully covered by the Health Programme budget.
- Joint actions with the Member States: funding for projects jointly designed and financed by the EU with one or more Member States authorities or bodies associated. EC contribution rate is 50%.
- Direct grant agreements with international organisations: these are traditionally awarded to OECD, WHO, European Observatory on Health policies and health systems, Council of Europe and the International Agency for Research on Cancer to develop projects of common interest. The rate of EC contribution is 60%.
- Operating grants: EC contribution at 60% of the annual operating costs of a non-governmental organisation or a specialised network in the field of health; such bodies must be non-governmental, non-profit making, independent from industry or other conflicting interests and have as their primary objectives one or more goals of the Programme.
- Grants for conferences: co-financing at a rate of 50% EC contribution for conferences on public health issues organised by the Presidency and for conferences organised by European public or non-profit organisations.

All of the above-mentioned mechanisms are announced yearly in the AWPs indicating priorities and are subject to competitive selection procedures via

- calls for proposals for projects;
- calls for conferences;
- call for operating grants;
- call for joint actions;
- call for tenders.

The calls are published in the Official Journal and the selection process followed, except for tenders, involves external experts as evaluators.

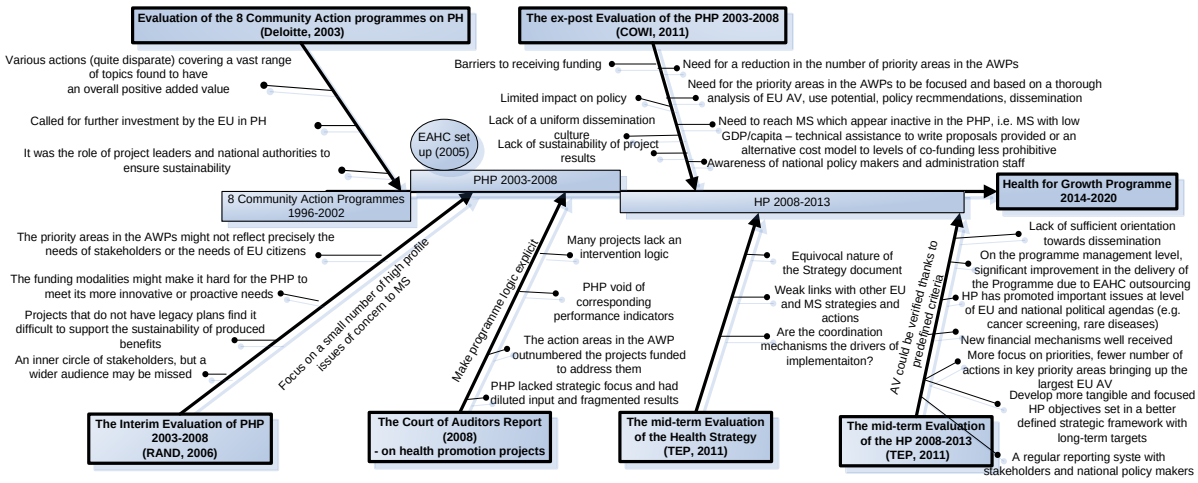
Figure 1



The past Programme evaluations

A mid-term review of the 2nd Health Programme in 2010, confirmed conclusions already known by the two previous evaluations made on the 1st Health Programme; it has also tested and validated the seven criteria for the EU added value while pointed out a series of recommendations concerning changes needed in the design of the Programme, in dissemination of the Programme, the management including the monitoring and evaluation indicators.

The below Ishikawa diagram summarises all the recommendations from previous evaluations and audits



A large number of those recommendations fitted into the conception of the new 3rd Health Programme 2014-2020. This Programme is expected to be adopted soon (February-March 2014). Given the fact that the mid-term evaluation of this new Programme is requested to be delivered by mid-2017 and certainly there will not be enough mass of actions and outcomes to assess, it is clear that the present ex-post evaluation will be of meaningful contribution in the decisions to be taken for a successor Programme after 2020.

1.2. THE ASSIGNMENT

Legal obligation

Article 13 (3)(c) of Decision No 1350/2007/EC establishing the Health Programme 2008-2013 requests the Commission to submit, no later than 31 December 2015, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions an external and independent ex-post evaluation report covering the implementation and results of the Programme.

The report should make it possible to assess the impact of measures on all countries.

The report should contain an executive summary of the main findings and conclusions in both French and English, and it might be accompanied by remarks by the Commission.

The Commission should make the results of the evaluation undertaken pursuant to this Decision publicly available and ensure their dissemination.

Duration of the evaluation

The evaluation is scheduled to start in February 2014 and be completed by the end of year 2014 (overall duration of 10 months).

Budget

For indicative purposes the maximum available budget is 200 000 euros.

1.3.DESCRIPTION OF THE ASSIGNMENT

Purpose and objective of the evaluation

The purpose of this evaluation is to inform on main outcomes and results achieved by the second Health Programme 2008-2013 as well as main problems and solutions with regards to its implementation, not least in relation to the taking up of results of the last health programme evaluations.

The objectives of the evaluation are, inter alia:

(a) alignment of implementation with the objectives defined in the legal base, including the annex;

(b) assess the impact of the Health Programme in support of Member States with an emphasis on Joint Actions;

(c) assess the dissemination practices undertaken for the Programme, including via bibliometric studies;

(d) assess the management tools including the different financing mechanisms in place for the Programme implementation and provide recommendations for improved effectiveness

Scope of the evaluation

The evaluation should address the functioning of the entire programme while explicitly avoiding repeating earlier evaluation work that was executed to impact on the design of the health for growth programme, while giving an overview of the major achievements. It should address issues that have been insufficiently explored in past exercises such as the relationship with the research programmes, the rationale for the programme intervention and the effectiveness of new funding modalities such as the joint actions.

It will cover all Member States and other participating countries and encompass relevant stakeholders (in particular: the Programme Committee members and national Focal points, various policy committees, social partners, national authorities and bodies and key EU civil society organisations).

Where the deliverables of the financed activities are not yet available, the evaluation should focus on interim and prospective outcomes, selection procedures and criteria, contracting documents and any other information that indicates the financed activity's objectives and results.

Evaluation questions

The evaluation questions are organised in four main blocs: (a) the Programme management tools, (b) the Programme dissemination practices, (c) Assessing the impact of the Health Programme, (d) Establishing synergies with other services and programmes

The questions are specific and synthetic. They have to be approached through the classical evaluation points of view (relevance, effectiveness, efficiency, coherence and utility of the Health Programme. For instance the relevance of the Programme is addressed through question ix, the efficiency through questions iv and viii (in terms of better monitoring and dissemination). These were two aspects that the Programme should have improved according to the previous mid-term evaluation.

The list of questions is not at present exhaustive and evaluators may raise additional points in order to assess more fully the Health Programme. It is to be stated that basic data and judgment on the classical evaluation points have already been gathered by earlier exercises on the programme. The evaluation of the effectiveness has also been part of the external evaluation of the EAHC. All these findings and conclusions are publicly available and may be used again to give the full picture of the Programme which is now at its end.

(a) The Programme management tools

The mid-term evaluation in 2010-2011 resulted to a series of recommendations for improved management of the Health Programme. These were the definition of a strategic multi-annual planning, the continuation of the existing variety of financial mechanisms, the provision of technical assistance to potential applicants, the creation of a nomenclature for explaining the EU added value, the scientific evidence etc and to share it with the Programme stakeholders and potential beneficiaries, the simplification and rationalisation of procedures. The following questions are to measure the progress made in terms of effectiveness

i. To what extent have the recommendations of the mid-term evaluation concerning the management and the design of the Programme been implemented?

ii. How effective have recent changes in the emphasis on and use of specific funding mechanisms (i.e. use of Joint Actions, balance between calls for proposals and calls for tender) been in delivering policy-related outputs, and what was the impact on the geographical distribution of beneficiaries?

iii. To what extent did the implementation of previous recommendations influence the Programme's other operations, including the recruitment of beneficiaries and the level of participation of all Member States in Programme actions (including the facilitation of participation from low GNI countries)?

iv. What are the state of the art tools in terms of monitoring project outputs that could be applied to the Programme, what are the expected benefits against costs and how could they be implemented?

(b) The Programme dissemination practices

The dissemination of the Programme results attracted the attention of the external evaluators in the mid-term evaluation. They have recommended to foster the dissemination of projects' results and to organise exchange of information on project results between EAHC-Commission officials-policy makers in MS-other stakeholders. Moreover, the recent negotiations with Council and European Parliament on the next health Programme 2014-2020 confirmed the important role dissemination plays in the optimisation of Programmes' impact.

It is expected that the replies to the following questions and the subsequent recommendations could help to improve further the dissemination strategies and so to satisfy explicit obligations in the new Health Programme Regulation (see Article 13 point 4).[5]

The following questions are therefore about effectiveness, efficiency and utility.

v. a) To what extent have the actions/outcomes/results of the Second Health Programme been published? To what extent are they (made) accessible to the international scientific and health community, to health policy makers, civil society, and to the wider public in the EU?

b) Are the results published and disseminated in a sustainable way?

c) How useful is the CHAFEA (EAHC) database in this context? How can it be improved?

d) Which other tools would be useful in this context?

vi. What is the relation between the publications/activity reporting and the Member State participation in the Second Health Programme, the number of health scientists, public health specialists and physicians per Member States? Are patterns identifiable? Have dissemination activities been undertaken in way to overcome possible geographical imbalances in certain actions?

vii. To what extent do stakeholders other than Member State governments (subnational regional organisations, civil society, social partners etc.) promote

[5] The Commission shall make the results of actions undertaken pursuant to this Regulation publicly available and shall ensure they are widely disseminated in order to contribute to improving health in the EU.

Programme outcomes and results, and via which channels? This should consider both organisations funded by the programme, and others.

viii. How could the current dissemination practices be improved to increase return on investment?

(c) Assessing the impact of the Programme

Given the difficulty to assess the impact of a small Programme against the tremendous needs in health in Europe, the following questions are focused first on the relevance of the Programme actions vis-à-vis the Union mandate in health and secondly to the short-term and mid-term progress achieved in specific areas. However, the questions triggering also some elements for better understanding of how the Programme could influence health policies in MS. This will be of use in the next Programme period.

ix. How and to what extent has the Second Health Programme supported Member States' health policy and actions (in relation to the provisions on support, cooperation and coordination in Article 168 of the Treaty)?

x. Which are the main health policy areas in which progress has been achieved due to the support of the Health Programme, and what constitutes this progress?

xi. What are reasonable assumptions on the way to measure the impact of the programme in terms of timelines a) short-term, b) middle-term, c) long-term and d) in relation to average project trajectories?

xii. Which factors/reasons may intervene and influence positively or negatively the impact of the Programme?

xiii. What are the main lessons than can be drawn to ensure an overall successful transition from the second to the third Health Programme?

(d) Synergies with other services and programmes

The success of the Programme depends also on the synergies with other Programmes in the area of health. The following question refers to coherence and consistency and focuses in principle on the two major Programmes with substantial EU funding and interest for MS. However other synergies with smaller ones are also covered as the question is also about Commission's general objectives for economic growth and social inclusion.

xiv. What synergies are there with other policies and programmes of the Commission such as the European Structural and Cohesion Funds, the programmes managed by DG RTD, other DGs (in particular EMPL, CNECT) and to what extent did the Health Programme underpin the Commission's general objectives-focus on Europe 2020 and their objectives related to social policy (e.g. the renewed Social Agenda) and economic growth (research and innovation, competitiveness)?

Organisational framework and methodology

The evaluation will be organised through a specific framework contract with the Directorate-General for Health and Consumers. As part of the bid, the contractor should identify the team of evaluators to be involved, describe their skills and qualifications, quantify the input of each member of the team in terms of days and explain the distribution of tasks between the different evaluators. The team must have the capacity to work in the different fields and languages needed. It must have proven experience in

evaluation related to health policies and a wide range of experts on their various aspects at national and EU level. As part of the tender documentation, the team to be involved should be identified, describing their skills and qualifications, qualifying the inputs of each member of the team and quantifying them in terms of days and showing the distribution of tasks between the consultants involved. All staff-related issues will be clarified during the kick-off meeting.

The contractor may propose methods and tools that are considered appropriate to answer the evaluation questions, suggest benchmarks and define suitable indicators. Contractors can propose other tools for data collection and analysis as they see fit, including desk research, use of tracers, case studies, workshops, bibliometrics, focus group interviews, concept mapping, Delphi methods etc. It would be appropriate to concentrate the present evaluation work more on desk work, case studies and research scrutinising relevant internal documents such as Annual Work Plans, call documents, project evaluation reports, project deliverables and not reduce it to only e-surveys and interviews.

Methods and tools for answering each evaluation question should be proposed in the bid and further developed in the inception report.

The ex-post evaluation of the Health Programme must comply with the quality criteria and the state of the art in the field, and assessments should be well argued on the basis of rigorous qualitative and quantitative analysis. It should also be conducted in such a way that the results can be used to improve policy decision-making and thus improve action taken in future.

The evaluators are expected to develop an appropriate method to address the evaluation questions as laid down above, not losing sight of the following transversal issues:

- Health Programme intervention logic; (see figure 2, this intervention logic should be verified and completed)
- Causality factors;
- Partnership strategies;
- Programme management.
- In addition to above mentioned evaluation questions to which evaluators should provide their input and build their conclusions and recommendations, overall conclusions covering shortly the relevance, effectiveness, efficiency, EU-added value, utility and coherence-consistency of the Health Programme 2008-2013 are also expected.

Methodological considerations per evaluation question

The following non-exclusive and non-exhaustive approach is suggested in relation to the different evaluation questions. As often, a sound mix of different methods is essential:

i. Desk research and interviews;

ii. Desk research, database searches and interviews;

iii. Desk research, database searches and interviews;

iv. Survey of relevant examples of monitoring in other European and international programmes in addition to a cost-benefit analysis/ considerations of required IT investments;

v. A bibliometric study and a relatively precise stakeholder analysis to establish a baseline are expected as well as possibly further instruments measuring effective accessibility able to generate precise data;

vi. An assets assessment of the presently existing capacity is expected, allowing to draw conclusions on specific capacity building needs and good comparison of data with participation patterns in the EU health research programme;

vii. An programme assets assessment, a stakeholder analysis and establishment of a baseline including a survey to the National Focal Points;

viii. A close examination of innovative practices that are currently generally in use, as well as the current level dissemination for Joint Actions, potential options for recommendations: FWC on dissemination, activating multipliers in the civil society, etc.;

ix. An analysis of concrete cases in each of the three Programme's main areas with a baseline for the new policy areas, including transitional elements to the Health for Growth programme to underpin strategic thematic adjustment decisions;

x. Screening of health policy areas using the same criteria as in the mid-term evaluation (7 EU Added Value criteria) in order to define case studies for deeper investigation and improve understanding of the additionality of the support given to MS action in terms of coordination and cooperation;

xi. and xii. A clear picture is expected on how the Programme impact can be documented, giving due attention to confounding variables from competing actors, issues of allocative and productive efficiency, frequently used metrics for measuring return on investment and application in a number of case studies taken out of the Programme;

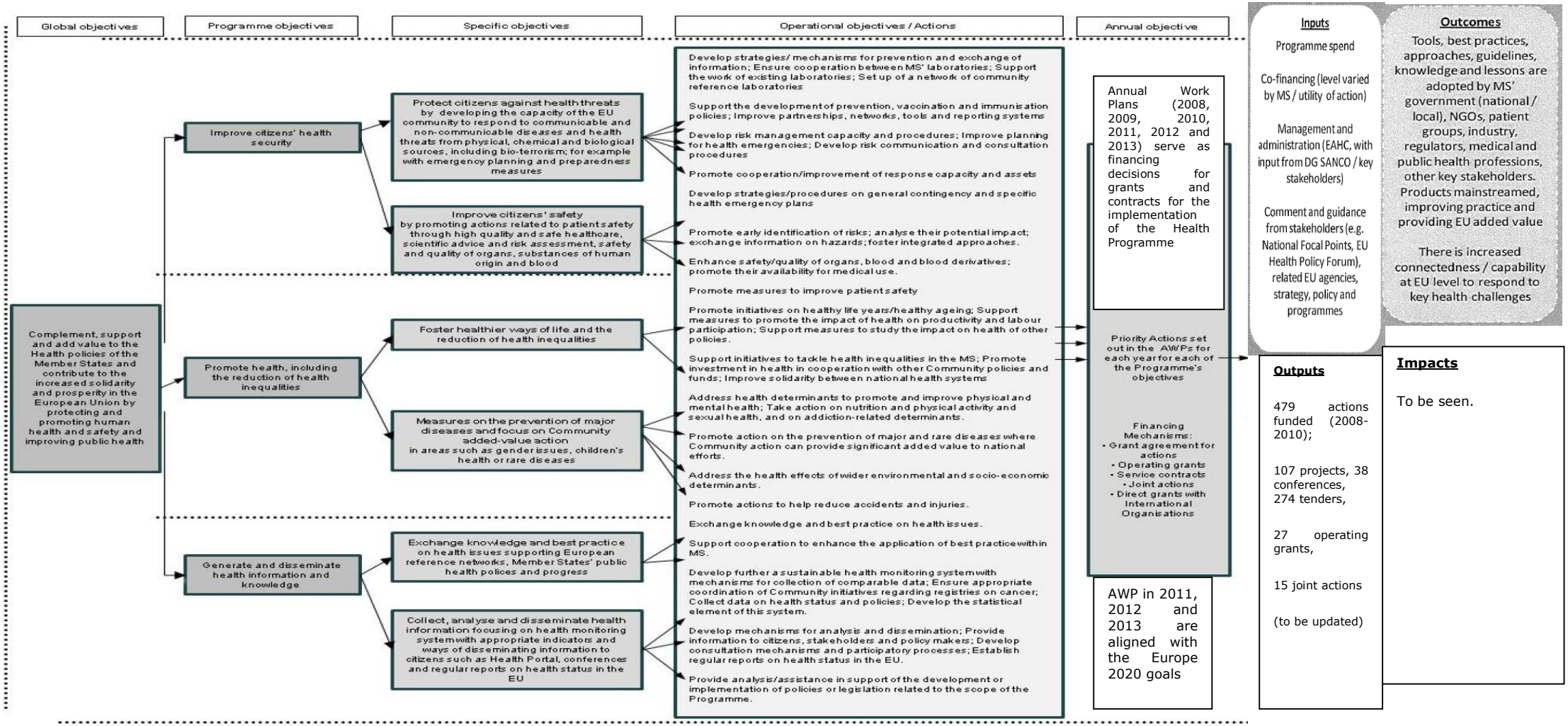
xiii. This part of the exercise may address the different dimensions of sustainability, the potential disappearance of networks and potential gains/ losses of efficiency in areas where the Health Programme has secured successes, etc.;

xiv. It is expected that the focus in this question will be on major instruments of the Commission to which the programme has a potentially synergistic/leverage effects. Eventually should there also be a more comprehensive exercise than earlier ones on these questions that were based on narrow issues and rather anecdotal evidence. A full perspective on the relationship with the major policy areas is expected allowing a deepened understanding of the role of the programme in leveraging interventions at larger scale.

Figure 2: Intervention Logic

Context to the Intervention: The EU is required by its founding treaty to ensure that human health is protected as part of all its policies and to work with EU countries to improve public health, prevent illness and eliminate sources of danger to physical and mental health.

Rationale for the Intervention: Many of the challenges cannot be addressed at the MS level. There is therefore a need for EU action to complement MS' efforts, focusing on common challenges where there is scope for EU added value to make progress on EU 2020 goals.



While the contractor is expected to develop his own stakeholder analysis for this assignment, a non-exhaustive and non-mandatory list of key stakeholders will be provided . The contractor should refrain from identifying stakeholders as clients only and not restrict himself to working with a core group of stakeholders.

The evaluation methods, the final version of the evaluation questions and indicators, and the choice of tools to be used and stakeholders to be consulted, will be formally agreed upon with the Steering Group during the inception phase.

Expertise required

The contractor is requested to constitute a strong and experienced team for this evaluation exercise. Since the areas in Public health covered by the programme as well as the number of countries participating are widespread, the experts should be able to demonstrate familiarity with the entirety of the substance the Programme is dealing with.

The submission should therefore contain details on at least two well experienced experts (at least ten years) in evaluation of EU/other international funding programmes and at least two well (at least ten years) experienced experts in the areas of public health where the programme is active and with, in addition, a good record of project/programme evaluation. Such experts should be fully committed to the work commissioned and can be complemented by other experienced experts tasked to specific missions. All experts contributing to the contract will be asked to declare the extent of their contribution and sign the reports.

Reporting and deliverables

The assignment includes the submission of a series of deliverables: reports and presentations.

The evaluators will deliver the following reports at key stages of the evaluation process: inception report, interim progress report, draft final report and final report. Each report should be written in English, professionally edited, and critically assessed as it provides the basis for tracking the quality of the work done by the evaluator. The contractor will attend four to five specific meetings with the Steering Group to present and discuss the progress of the evaluation work after the inception report, the interim report and the draft final report. These meetings will be held in Luxembourg or Brussels. The contractor is requested to take notes at the meetings and to submit them to the Steering Group for adoption the week following the meeting.

More precisely, the following reports and presentations shall be delivered:

Kick-off meeting report

Members of the contractor'evaluation team will attend a kick-off meeting with the Steering Group. The purpose of this meeting is to verify:

- the team's understanding of the Task Specifications;
- the proposed general approach to the work (methodology, scope, etc.);
- the composition of the full evaluation team.

Inception report – within 1 month of signing the contract

The inception report completes the structuring phase of the evaluation. It aims to describe the organisation of the work, and to adapt and substantiate the overall approach, the methodology required for each evaluation question and the work plan outlined in the proposal. It should set out in detail how the proposed methodology will be implemented, and in particular lay out clearly in tabular form how the method

allows each evaluation question to be answered via establishment of judgement criteria and within these, of evaluation indicators. In addition the table should have a further column indicating the evaluation tools chosen. The inception report should include enough detail for the Steering Group to gain a good understanding of the evaluation tools and related methodological steps proposed.

The report may supplement and/or suggest additional evaluation questions the contractors consider suitable (see above paragraph 3.3). As such, this document will provide an opportunity to make a final check on the feasibility of the method proposed and the extent to which it corresponds with the task specifications.

The known sources of information, use of tracers, case studies, contact persons in MS, as well as the way the contractor will interact with MS representatives will be fully clarified at this stage.

The inception report will be submitted to the Steering Group which will discuss on this basis with the contractor and may request changes and improvements. The final versions of evaluation questions suggested by the contractor and the evaluation indicators to be used will be validated by the Steering Group at this stage. After the meeting the contractor will submit a final version.

Intermediate report – 3 months after the inception report

This report will provide information on the initial analysis of data collected. The evaluator should already be in a position to provide: a) aggregate data and overview of the first three years of the implementation of the Health Programme, b) preliminary findings related to the three objectives of the evaluation undertaken (see above paragraph 3.1), and c) answers to the evaluation questions.

The report will provide the evaluation manager and the Steering Group with an opportunity to check whether the evaluation is on track and whether it has focused on the specified information needs.

The contractor will submit a final interim report with the necessary updates after discussion with the Steering Group in a specific meeting. At this meeting, the contractor will define in agreement with the evaluation manager and the Steering Group the table of contents and structure of the draft final report. A document outlining the latter must be submitted in advance of the meeting by the contractor. It will serve as a basis for the discussion.

Draft final report – 3 months after the interim report

This document will provide the preliminary conclusions of the evaluator in respect of the evaluation questions in the task specifications. These will be based on evidence generated through the evaluation. Any judgements provided should be clear and explicit. The draft final report should also contain substantiated recommendations made on the basis of the conclusions reached by the evaluator. It will also provide a technical overview of the evaluation process, highlighting limitations and possible bias therein.

The draft final report should be structured along the lines of common Evaluation Standards and include an executive summary of not more than 10 pages (factual data concerning the implementation of the Programme and summary of analyses and conclusions)in FR and EN , the main report (presenting the results of the analyses in full, conclusions and recommendations) and technical annexes (one of which will be the Task Specifications) and a draft one-page summary on the Key Messages (conclusions and recommendations in bullet form) of the evaluation.

Final report – to be submitted 1 month after communication of comments made by the SG on the draft final report

The final report should have the same structure as the draft final report. It will take account of the results of the comments and discussions with the Steering Group regarding the draft final report insofar as they do not interfere with the autonomy of the evaluators in respect to their conclusions.

It is essential that all the reports be clear, unambiguous and comprehensive. They should also be understandable for non-specialists. The reports should be provided to the European Commission in Word format with the charts in Excel. They should be accompanied, where requested, by appropriate annexes. All reports and presentations are to be submitted in electronic format in accordance with the deadlines set in the time-schedule specified below.

The contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes. At the request of the Commission, the contractor should provide a maximum of two presentations to interested stakeholder groups. The Commission will hold the copyright of the reports.

Quality assessment

In order to ensure the necessary level of quality for the independent evaluation requested by the Decision on the Health Programme, contractors should always bear in mind that:

- the evaluation must respond to the information needs, in particular as expressed in the Task Specifications and following discussions with the Steering Group;
- the methodology and design must be appropriate for obtaining the results needed to answer the evaluation questions;
- the collected data must be appropriate for their intended use and their reliability must be ascertained;
- data must be analysed systematically to answer the evaluation questions and to cover all the information needs in a valid manner;
- findings must follow logically from and be justified by, the data/information analysis and interpretations based on the pre-established criteria and rationale;
- To be valid, conclusions must be non-biased and fully based on findings;
- Particular attention will be given to the recommendations. These must be practical and helpful. All areas which need improvements must be identified in conformity with the conclusions, and the suggested options must be realistic and impartial.

Time schedule

The Service order has a duration of 9 to 10 months. It is due to start in early February 2014.

A detailed work plan should be submitted together with the bid building on the time-schedule summarised below. It should be updated with the Inception Report.

What	(By) when?
Kick-off meeting with the contractor	April 2014
Inception report	May 2014

Inception meeting	May 2014
Interim Report	August 2014
Meeting for the interim report	Beginning of September 2014
Draft final report	October 2014
Meeting on the draft final report	November 2014
Final report	December 2014

1.4.References

Useful web-links

- Decision No 1350/2007/EC establishing a second programme of Community action in the field of health (2008-13) (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF)
- White paper "Together for Health: A Strategic Approach for the EU 2008-2013" (http://ec.europa.eu/health-eu/doc/whitepaper_en.pdf)
- Consolidated version of the Treaty on the functioning of the European Union (more specifically article 168) (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0047:0200:EN:PDF)
- Annual Work Plans, Awarding Decisions and Annual Reports on Programme implementation (http://ec.europa.eu/health/programme/policy/index_en.htm)
- Executive Agency for Health and Consumers (database) (http://ec.europa.eu/eahc/projects/database.html)
- Executive Agency: Brochures on the Health Programme (http://ec.europa.eu/eahc/publications/publications_for_health_programme.html)

- DG Health and Consumers (http://ec.europa.eu/health/index_en.htm)
- Consumer , Health , Agriculture and Food Executive Agency (Executive Agency for health and Consumers) (http://ec.europa.eu/eahc/)

Other documentation available

- Tables mapping financed activities against prioritised actions
- Interim Evaluation of the 2nd Health Programme 2008-2013
- Interim Evaluation of the Public Health Programme 2003-2008
- Ex-post final Evaluation of the Public Health Programme 2003-2008
- Audit Report of the Court of Auditors "The European Union's Public Health Programme: an effective way to improve health?"
- Mid-term Evaluation of the EU Health Strategy 2008-2013, August 2011, including annexe
- Study to measure the implementation of EU health policies at national, regional and local levels, assessing the utility of existing indicators for this task and developing new indicators where necessary, August 2012

2. DATA ON SECOND HEALTH PROGRAMME

This section presents an analysis of data on the implementation of the Health Programme, with a view towards providing insight into the extent to which recommendations made in the mid-term evaluation (as well as evaluations of the 1st Health Programme) have been taken on board. In particular, we focus on the aim of diversifying the use of funding mechanisms to ensure that the benefits of the Programme are spread equitably across the EU.

What follows are key findings from an analysis of funds allocated (overall and by year, by objective / sub objective and via the different funding mechanisms)[6] as well as an overview of the spread of actions across the Member States and the kinds of organisation engaged in the implementation of the Programme.

2.1.Funding and actions

The second half of the Programme was marked by a shift in emphasis in terms of types of actions funded coupled with efforts to extend the use of diversified funding mechanisms to broad the reach of the Programme across all MS. The ensuing paragraphs briefly summarise key features of the Programme's operational budget, followed by a discussion of the types of action funded. The data serve to highlight the shift in focus from projects towards joint actions starting in 2010.

Operational funding over the course of the Programme

The operational budget was fairly consistent throughout the life of the programme, averaging EUR 49 million - Table 1.

[6] The data presented here are based on information drawn from the CHAFEA database which is a composite of information provided by DG BUDGET (via application forms for funding) and DG SANTE. Annual Implementation Reports were also consulted. DG SANTE provided additional information on service contracts and funding for the entire Programme (i.e. including administrative support and support for the functioning of CHAFEA).

Table 1: Health Programme spending by year (millions, EUR)[7]

	2008	2009	2010	2011	2012	2013	TOTAL
Operational budget	45.2	51.05[8]	45.7	47.1	48.3	49.8	283.1
EFTA and Croatia contribution	1.08	1.128	1.15	1.12	1.26	1.39	7.128
Total available operational budget[9]	46.28	52.308	47.23	48.87	51.7	51.99	298.378
Operational budget committed	45.9	50.8	46.9	47.3	51.4	51.6	293.9

Source: data provided directly by DG SANTE

Funding and number of actions by funding mechanism

During the life of the Programme, projects were by far the most utilised funding mechanism. Between 2008 and 2013, over EUR 100 million was committed to projects, while service contracts and joint actions were the next most utilised types of actions. Operating grants and direct grant agreements took a much smaller share of the budget. Grants for conferences totalled 5.3 million EUR over the period (Table 2).

[7] Note that funding available under the second Health Programme was not solely used for operational purposes. In the region of 10% was reserved for administrative support for actions (8.9 million EUR) and funding for the functioning of CHAFEA (26.2 million EUR). See poster on second Health Programme: http://ec.europa.eu/health/programme/docs/ev_20120503_programme_en.pdf

[8] 4.05 million EUR was allocated as an additional sum to support action against the flu pandemic

[9] including revenues and excluding transfers

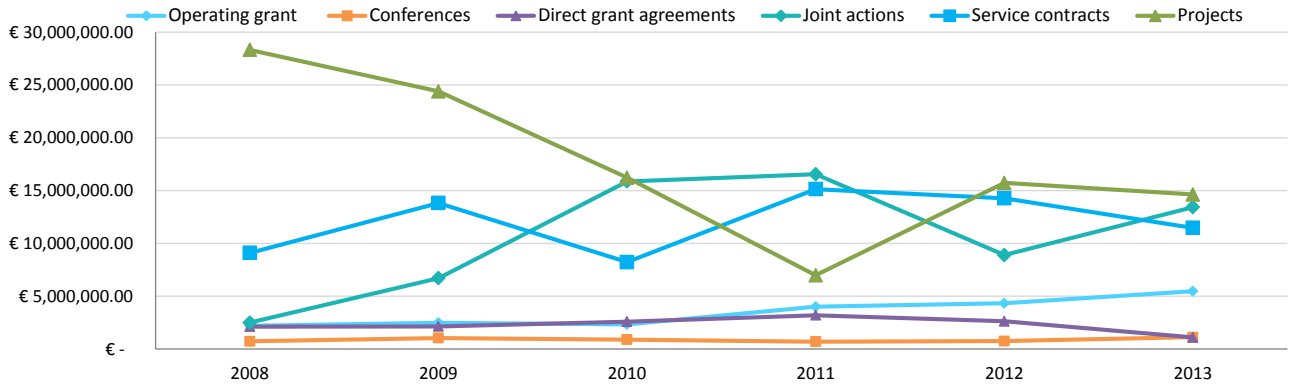
Table 2: Health Programme (2008 – 2013) spending by funding mechanism[10]

Funding mechanism	Total	%
Projects	€ 106,293,671.24	36%
Service Contracts	€ 72,053,873.45	25%
Joint Actions	€ 63,962,704.38	22%
Operating Grants	€ 20,825,185.85	7%
Direct Grant Agreements	€ 13,805,987.00	5%
Grants for conferences	€ 5,268,308.14	2%
Other[11]	€ 11,693,227.81	4%
Total	€ 293,902,957.87	100%

Source: Annual Implementation Reports

However, the aggregate figures mask substantial shifts over time. The amount of funding dedicated to projects declined dramatically after 2008 and 2009, while other instruments, especially service contracts and joint actions gained in relative prominence. Funding for operating grants grew steadily from 2008-2013, while for direct grant agreements it fell from 2011 onwards (Figure 3 and Table 3).

Figure 3: Health Programme spending by funding mechanism (2008 – 2013)



Source: Annual Implementation Reports

Due to the varying sizes of individual actions, spending and numbers of actions did not align precisely. Service contracts accounted for a significant proportion of spending (around a quarter overall) but a much more significant share of total actions (just over half). The vast majority of these were actions that supported mechanisms for analysis and dissemination of information, and many were related to IT services. The opposite was true of joint actions, which accounted for 23% of funding but only 4% of the number of actions. Moreover, the upwards trend in funding awarded to joint actions

[10] Note that the total spending on service contracts is a composite of the spending on CHAFEA tenders, CHAFEA specific contracts and DG SANTE service contracts.

[11] Note "other" includes actions signed and committed by DG SANTE and CHAFEA, such as special indemnities to experts for their participation in and work for EU Scientific Committees, an administrative agreement with the Joint Research Centre (JRC), publications and various communication initiatives to promote the second Health Programme, subdelegations to Eurostat, etc.

(Figure 3), was not "matched" by an upwards trend in the number of joint actions funded (Table 3), indicating that the scale of the joint actions (rather than the number) has grown relative to 2010. Overall, the data show that the number of services contracts and operating grants has trended upwards, while the number of projects per year has declined markedly over time.

Table 3: Total number of actions supported by funding mechanism (2008 – 2013)

	2008	2009	2010	2011	2012	2013	Total
Service contracts	26	71	70	90	56	107	**420**
Projects	50	37	20	10	19	11	**147**
Operating grants	10	8	9	16	19	22	**84**
Grants for conferences	12	14	11	9	9	16	**71**
Direct grant agreements	6	6	5	9	4	6	**36**
Joint actions	2	3	10	5	5	5	**30**
Total	**106**	**139**	**125**	**139**	**112**	**168**	**788**

Source: CHAFEA database, Annual Implementation reports and data provided by DG SANTE

2.2.Funding and number of actions by thematic priority[12]

In terms of the breakdown of thematic priorities: the data shows that more than half of funding was geared towards "health promotion" (with the remainder split more or less equally between support for heath security/threats and information) and that this saw grew in importance more or less continuously over time. This reflects the Programme's focus on tackling health inequalities and health determinants. Looking at the number of actions pursued under each theme shows a slightly different picture, with the three themes more equally represented. However, as discussed below, we note that the sheer number of service contracts falling (mainly) under health information, is a key explanation for this.

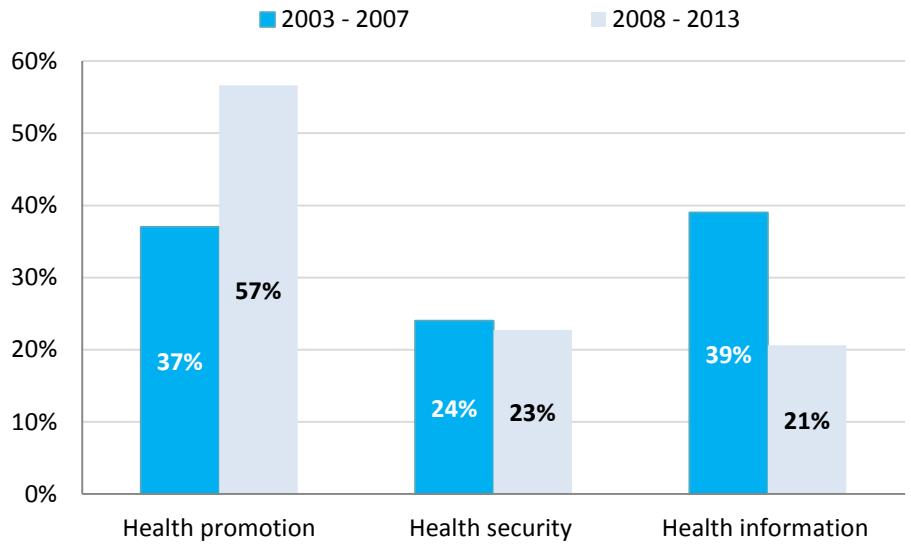
Funding by thematic priority

Health programme actions each address a theme, and within themes, a specific priority and sub-priority (as defined in the HP Decision). Of the three themes addressed under the second Health Programme actions supporting **health promotion** made up the lion's share of spending. This reflects a shift towards addressing health determinants and promoting healthy ageing, as well as reducing health inequalities. Indeed, the available data show that over half of the operational budget supported actions falling under the health promotion objective compared to 37% in the previous Health Programme – Figure 4. By contrast, spending on health security and health information took up 23% and 21% respectively of the budget under the second Health Programme.[13]

[12] Note that under the second Health Programme, funding can be categorised under a thematic priority for most actions (projects, joint actions, direct grant agreements and service contracts). This is not the case for conferences and operating grants since these tend to address multiple objectives. The total sum of funding which can be attributable to strand/priority/sub-priority is 246,851,494.52 EUR. The analysis in this section is based on available information concerning amounts paid and - where this information was not yet available - on amounts committed. There are therefore small discrepancies (less than 3% of the total) with the amounts presented in table 3 above, which are based purely on commitments as reported in the Annual Implementation Reports.

[13] Please note that due to rounding, these numbers do not add up to 100%.

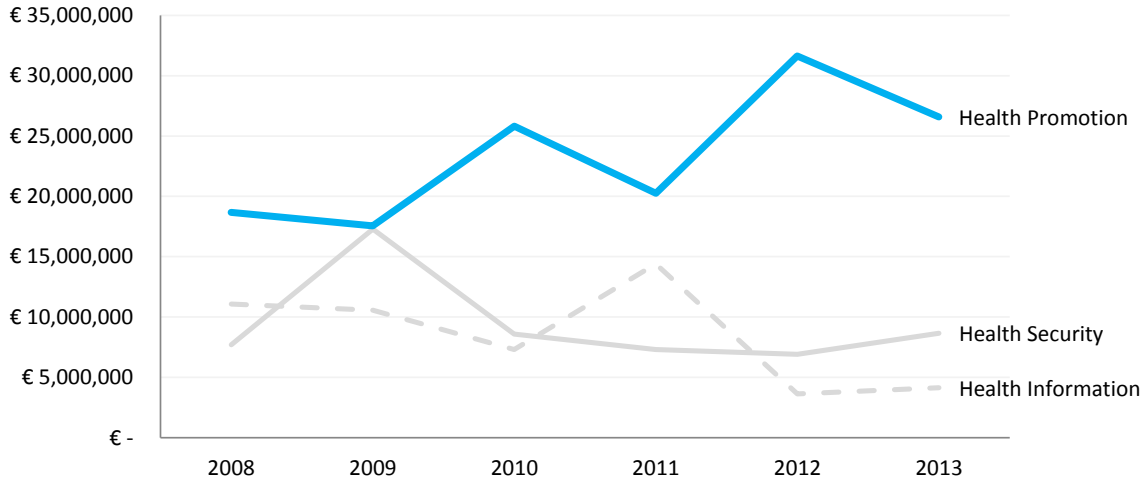
Figure 4: First Health Programme (2003 – 2007) and second Health Programme (2008 – 2013) spending by thematic priority where available[14]



Source: CHAFEA database, Annual Implementation Reports and DG SANTE

As shown in Figure 5, the proportion of spending on Health Promotion followed an upwards trend over the course of the programme, while spending on Health Information declined and spending on Health Security was more or less stable (with the exception of an increase in 2009).

Figure 5: Spending by thematic priority (2008 – 2013)



Source: CHAFEA database, Annual Implementation Reports and DG SANTE

In terms of the more detailed level – the three themes are further broken down to pursue two *priority areas* each and a series of more specific *sub-priorities* within them (Table 3). As you might expect, the priority area which received the most funding fell under the health promotion theme: actions which aim to support "health

[14] Ibid.

determinants" received 41% of funding (or close to 103 million EUR). Furthermore, within this priority area, actions that aimed to "address health determinants and promote healthy lifestyles" received just under a quarter of funding (or 60 million EUR) making it the highest-supported sub-priority absolute terms.

Table 4: Proportion of funding by strand, priority and sub-priority (2008 – 2013) based on total of 248 million EUR[15]

	Priority	Sub-priority	Funding awarded (%)		
Health Security	Health threats	(Non-) communicable diseases & health threats	6%	13%	23%
		Prevention, vaccination & immunisation policies	2%		
		Risk management / preparedness health emergencies	3%		
		Response capacity & assets	1%		
		General contingency & specific health emergency plans	1%		
	Improve safety	Scientific advice & risk assessment	2%	10%	
		Organs & substances of human origin, blood & blood derivatives	4%		
		Patient safety	4%		
Health Promotion	Healthy lifestyles & reduced health inequalities	Increase healthy life years & promote healthy ageing	8%	15%	**57%**
		Identify the causes of, address & reduce health inequalities	7%		
	Health determinant	**Address health determinants & promote healthy lifestyles**	**24%**	**41%**	
		Prevention of major & rare diseases	16%		
		Health effects of wider environmental determinants	1%		
		Promote actions to help reduce accidents & injuries	1%		
Health Information	Exchange knowledge	Exchange knowledge & best practice on health issues	2%	2%	21%
		Enhance the application of best practice within MS	0%		
	Collect, analyse & disseminate	Health monitoring & comparable data	11%	18%	
		Mechanisms for analysis & dissemination of information	5%		
		Development / implementation of policies / legislation	2%		

Source: CHAFEA database and DG SANTE

Number of actions by thematic priority

Compared to the clear emphasis on health promotion visible through the receipt of funding, the spread of individual actions is somewhat different. Slightly more actions were found to support health information (specifically, the priority to "collect, analyse and disseminate data" and the sub-priority "Development / implementation of policies / legislation") (Table 5).

[15] Please note percentages are given to nearest whole number. Due to rounding, the totals do not necessarily add up to 100%.

Table 5: Percentage of actions funded by strand, priority and sub-priority (2008 - 2013), based on total of 618 actions[16]

Obj	Priority	Sub-priority	% of actions		
Health Information	Exchange knowledge	Exchange knowledge & best practice on health issues	1%	1%	38 %
		Enhance the application of best practice within MS	0%		
	Collect, analyse & disseminate	Health monitoring & comparable data	6%	37%	
		Mechanisms for analysis & dissemination of information	27 %		
		Development / implementation of policies / legislation	4%		
Health Promotion	Healthy lifestyles & reduced health inequalities	Increase healthy life years & promote healthy ageing	4%	9%	37 %
		Identify the causes of, address & reduce health inequalities	6%		
	Health determinants	Address health determinants & promote healthy lifestyles	19 %	27%	
		Prevention of major & rare diseases	6%		
		Health effects of wider environmental determinants	1%		
		Promote actions to help reduce accidents & injuries	1%		
Health Security	Health threats	(Non-) communicable diseases & health threats	4%	12%	26 %
		Prevention, vaccination & immunisation policies	1%		
		Risk management / preparedness health emergencies	5%		
		Response capacity & assets	1%		
		General contingency & specific health emergency plans	1%		
	Improve safety	Scientific advice & risk assessment	8%	13%	
		Organs & substances of human origin, blood & blood derivatives	5%		
		Patient safety	2%		

Source: CHAFEA database and DG SANTE

However, it should be noted that service contracts (which account for over half of the number of actions, but only around a quarter of funding) skew the findings. Table 6 shows that 39% service contracts (or 159) were in support of mechanisms for the analysis and dissemination of information. This pulls the aggregate figure in the same direction. Projects tended to reflect the emphasis on health promotion. More specially, over one third of projects focused on health determinants and the sub-priority of the promotion of healthy lifestyles (Table 6).

[16] Ibid.

Table 6: Percentage of actions by sub-priority and funding mechanism, 2008 - 2013[17]

Obj	Priority	Sub-priority	SC	PJ	JA	DGA
Health Information	Exchange knowledge	Exchange knowledge & best practice	0%	3%	3%	6%
		Enhance application of best practice within MS	0%	0%	0%	0%
	Collect, analyse & disseminate	Health monitoring & comparable data	5%	5%	20%	**19%**
		Mechanisms for analysis & dissemination of information	**39%**	1%	0%	14%
		Develop / implement policies / legislation	5%	0%	0%	6%
Health Promotion	Healthy lifestyles &lower health inequality	Increase healthy life years & promote healthy ageing	2%	10%	3%	0%
		Identify the causes of, address & reduce health inequalities	5%	5%	10%	8%
	Health determinants	Address health determinants & promote healthy lifestyles	15%	**36%**	7%	17%
		Prevention of major & rare diseases	1%	16%	**23%**	11%
		Health effects of wider environmental determinants	1%	1%	0%	0%
		Promote actions to reduce accidents & injuries	0%	1%	0%	3%
Health Security	Health threats	(Non-) communicable diseases & health threats	2%	6%	10%	3%
		Prevention, vaccination & immunisation policies	1%	3%	0%	0%
		Risk management / preparedness health emergencies	8%	0%	0%	0%
		Response capacity & assets	0%	2%	0%	0%
		General & specific health emergency plans	1%	1%	0%	0%
	Improve safety	Scientific advice & risk assessment	10%	3%	3%	0%
		Organs & substances of human origin etc.	3%	4%	13%	11%
		Patient safety	0%	3%	7%	3%
Total (n=)			405	147	30	36

Source: CHAFEA database and DG SANTE

By comparison, Table 7 indicates the proportion of *funding* by action type and how this differs to the number of actions by priority. For example, 35% funding on service contracts (or 23.4 million EUR) and 29% of funding on projects (30.9 million EUR) was spent on addressing health determinants and promote healthy lifestyles. Again, this pulls the aggregate figure in the same direction. Joint tended to reflect the emphasis on health promotion, as well.

Table 7: Proportion of funding by action type (2008 – 2013)[18]

			% Total funding			
Obj	Priority	Sub-priority	SC	PJ	JA	DGA
Health Security	Health threats	(Non-) communicable diseases & health threats	2%	7%	11%	5%
		Prevention, vaccination & immunisation	1%	4%	-	-

[17] Please note percentages are given to nearest whole number. Due to rounding, the totals do not necessarily add up to 100%.

[18] Please note percentages are given to nearest whole number. Due to rounding, the totals do not necessarily add up to 100%.

		policies				
		Risk management / preparedness health emergencies	10%	-	-	-
		Response capacity & assets	1%	1%	-	-
		General contingency & specific health emergency plans	2%	1%	-	-
	Improve safety	Scientific advice & risk assessment	1%	2%	5%	-
		Organs & substances of human origin, blood & blood derivatives	3%	3%	6%	3%
		Patient safety	0.1%	3%	11%	1%
Health Promotion	Healthy lifestyles & reduced health inequalities	Increase healthy life years & promote healthy ageing	2%	13%	7%	-
		Identify the causes of, address & reduce health inequalities	7%	7%	7%	13%
	Health determinant	Address health determinants & promote healthy lifestyles	**35%**	**29%**	5%	18%
		Prevention of major & rare diseases	2%	20%	**24%**	15%
		Health effects of wider environmental determinants	0.2%	1%	-	0%
		Promote actions to help reduce accidents & injuries	0.3%	2%	-	3%
Health Information	Exchange knowledge	Exchange knowledge & best practice on health issues	-	4%	2%	3%
		Enhance the application of best practice within MS	-	-	-	-
	Collect, analyse & disseminate	Health monitoring & comparable data	10%	4%	22%	**22%**
		Mechanisms for analysis & dissemination of information	18%	1%	-	13%
		Development / implementation of policies / legislation	5%	-	-	4%
Based on funding (million EUR) of:			66.24	105.07	62.35	15.13

Source: CHAFEA database and DG SANTE

2.3.Beneficiaries

The second Health Programme emphasised tackling health inequalities and promoting the transfer of knowledge towards the newer MS (EU12). This section examines these issues through the lens of participation in the Programme. More specifically, the following paragraphs analyse participation in the Programme in terms of the spread of actions and funding across (groups of) MS (and other participating countries, see Table 8) and funding mechanisms, with a view to understanding how the benefits of the Programme were distributed, and why.[19]

[19] As in the previous section, the analysis of funding by (groups of) beneficiaries is based on available information concerning amounts paid and - where this information was not yet available - on amounts committed. There are therefore small discrepancies (less than 3% of the total) with the amounts presented in table 3 above, which are based purely on commitments as reported in the Annual Implementation Reports.

Table 8: List of MS groupings and non-MS used for beneficiary analysis

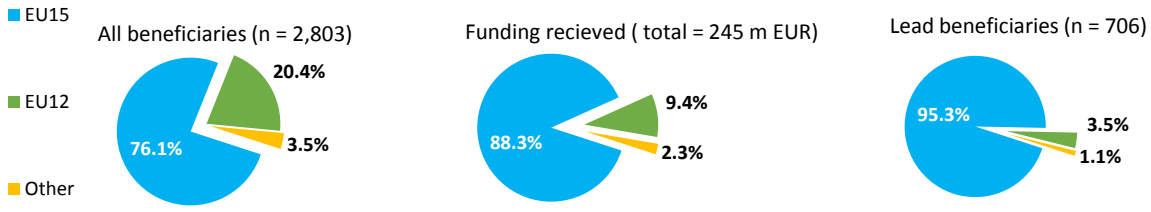
Groups	List of countries
EU 15	BE, DE, DK, IE, GR, ES, FR, IT, LU, NL, AT, PT, FI, SE, UK
EU 12	BG, CZ, EE, CY, LV, LT, HU, MT, PL, RO, SI, SK,
Other	HR[20], IC, NO, (CH[21])

Spread of actions and funding across Member States[22]

In terms of number of beneficiary organisations, participation in the Programme aligned with differences in population. Just over three fourths (76%) of beneficiaries were based in the EU15, while the EU12 accounted for 20%.[23] There is a disparity in terms of the allocation of funding, with 88% of funding going to organisations from the EU15 and 9% going to those based in the EU12. This is likely due in part to differences in wages and labour costs.[24]

However, the difference between EU15 and EU12 is far more pronounced when considering the spread of *lead* beneficiaries, of which an overwhelming 95% were based on the EU15, with only 4% based in the EU12. This prevalence was especially acute in service contracts, projects and operating grants, for which nearly all lead partners were based in the EU15. However, 15% of lead partners for grants for conferences (11 of 71) and 10% for joint actions (three of 30) were based in the EU12. This breakdown is presented in Figure 6 below.

Figure 6: Proportion of beneficiaries (total/lead) and funding received in EU15/EU12 (2008 – 2013)[25]



Source: CHAFEA database and DG SANTE

[20] Croatia is included in "Other" given it officially acceded to the EU only on 1st July 2013, at the tail end of the second Health Programme, and was therefore not an EU member for the vast majority of the funding period.

[21] Note that Switzerland was not a participating country. Its inclusion is due to one DG SANTE contract being based there, as the procurement is open to countries having signed the WTO agreement.

[22] The spread of actions/funding received across the Member States includes amounts committed for DG SANTE-managed tenders where applicable and available. Direct grant agreements (which are received by international organisations) are not included since due to their nature they cannot be attributed to a particular Member State. All figures for Chafea contract/grants are based on a combination of paid and committed funding (rather than amounts allocated in the annual work plans).

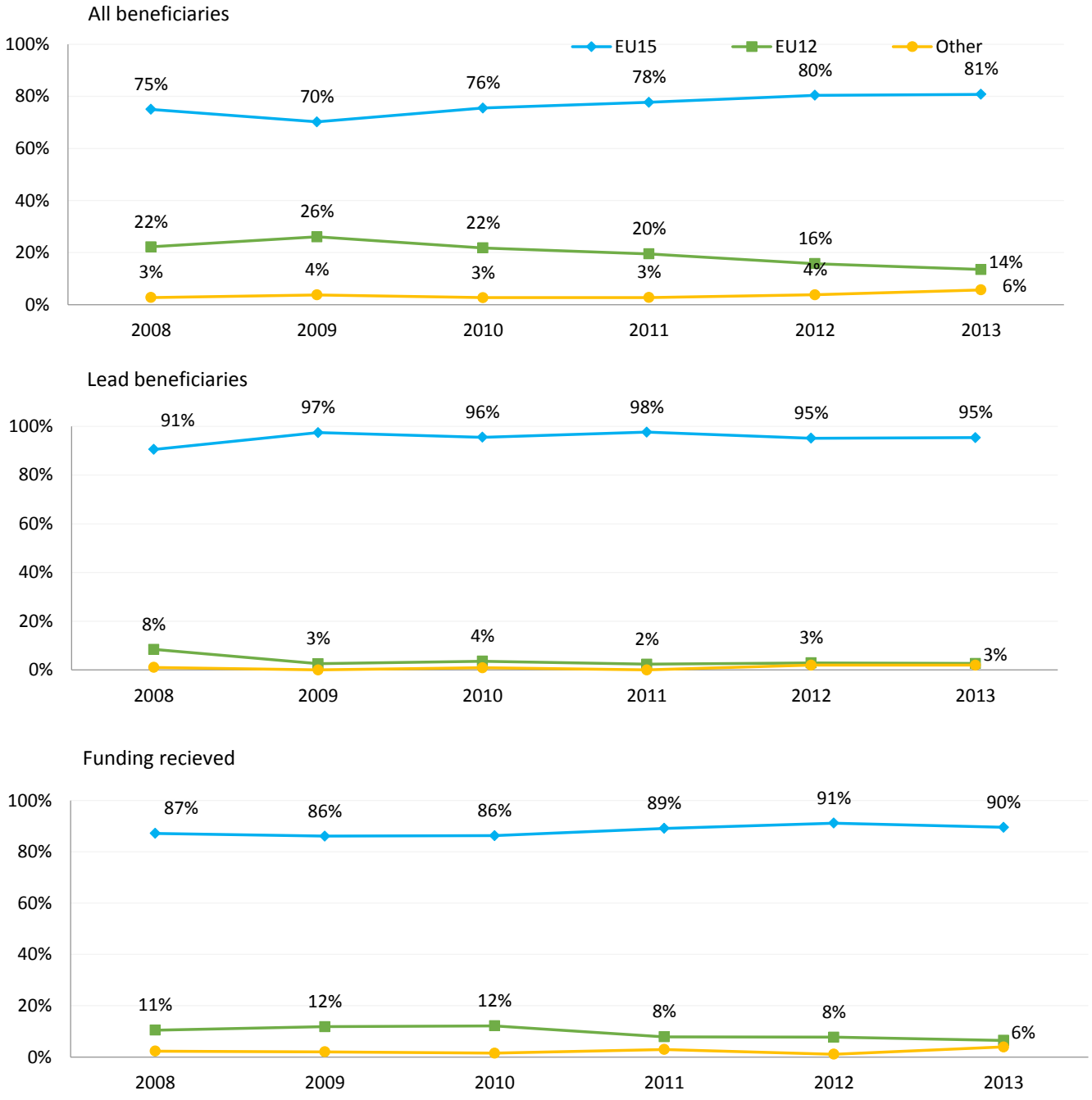
[23] According to Eurostat data, in 2011 the total population of the EU was 501 million, of which 404 million (81%) lived in the EU15 and 97 million (19%) lived in the EU12.

[24] According to Eurostat data, wages and labour costs in the EU12 are about one third of those in the EU15, on average.

[25] As noted in the footnotes on the previous page, the data on which these graphs are based includes a combination of paid and committed amounts for all funding instruments *except* direct grant agreements (to IOs, so not attributable to a MS per se) and certain DG SANTE service contracts for which information on the attribution of the funds to a specific country was not available.

All three measures have been relatively constant throughout the life of the Programme, though there are a few noteworthy trends. Regarding beneficiaries, the proportion of organisations from the EU12 has actually declined over time, falling gradually from 22% for actions awarded funding in 2008, to 14% in 2013. The proportion of lead beneficiaries from the EU12 also fell after initially comprising 8% of the total in 2008. There was also a drop for the EU12 in terms of funding received, from a maximum of 12% in 2010 to 6% in 2013.

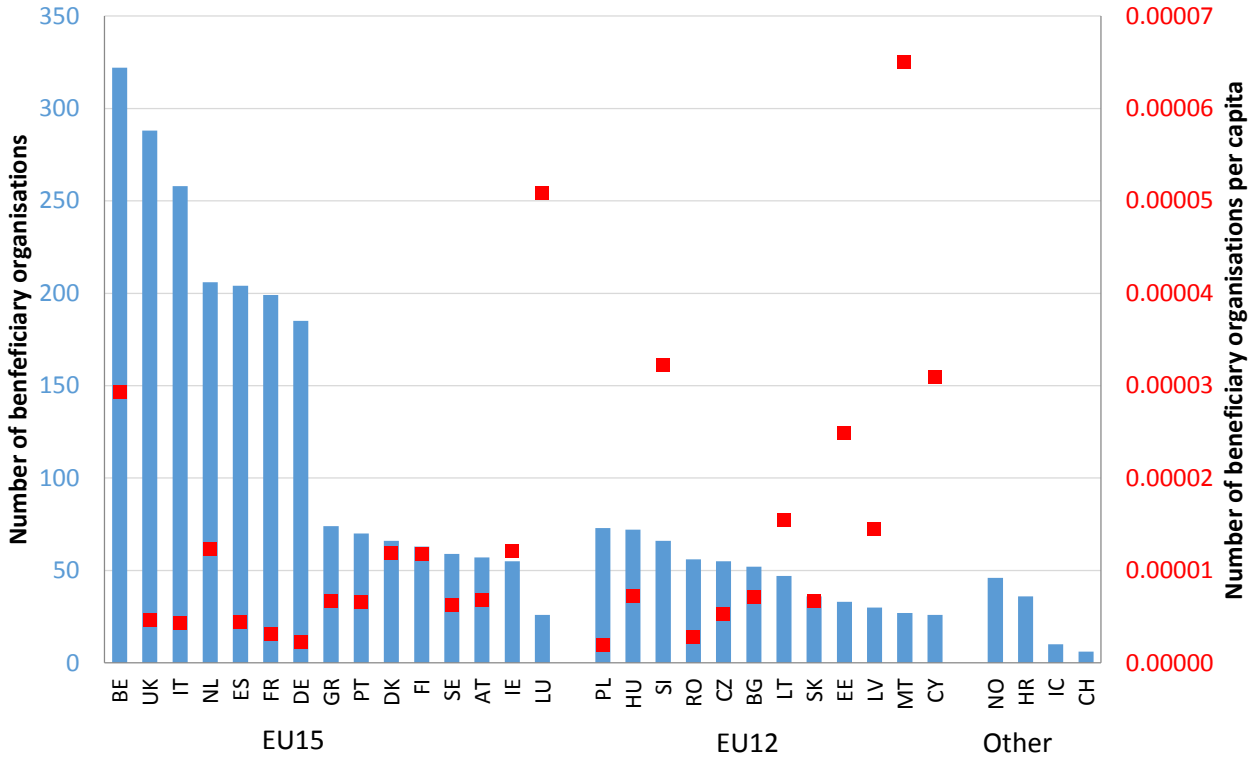
Figure 7: Proportion of beneficiaries (lead/associated) in EU15 and EU12 over time



Source: CHAFEA database and DG SANTE

Looking at participation in the Programme at the country level shows that the size of a given MS is a more important determinant than whether it sits within the EU15 or EU12, with smaller MS tending to have a smaller number of beneficiaries in absolute terms, but a higher number per capita. In terms of number of beneficiaries per capita, Luxembourg, Malta, Slovenia, Estonia and Cyprus stand out as doing disproportionately "well", while countries such as the UK, Germany, Poland and Romania are at the lower end of the scale (Figure 8).

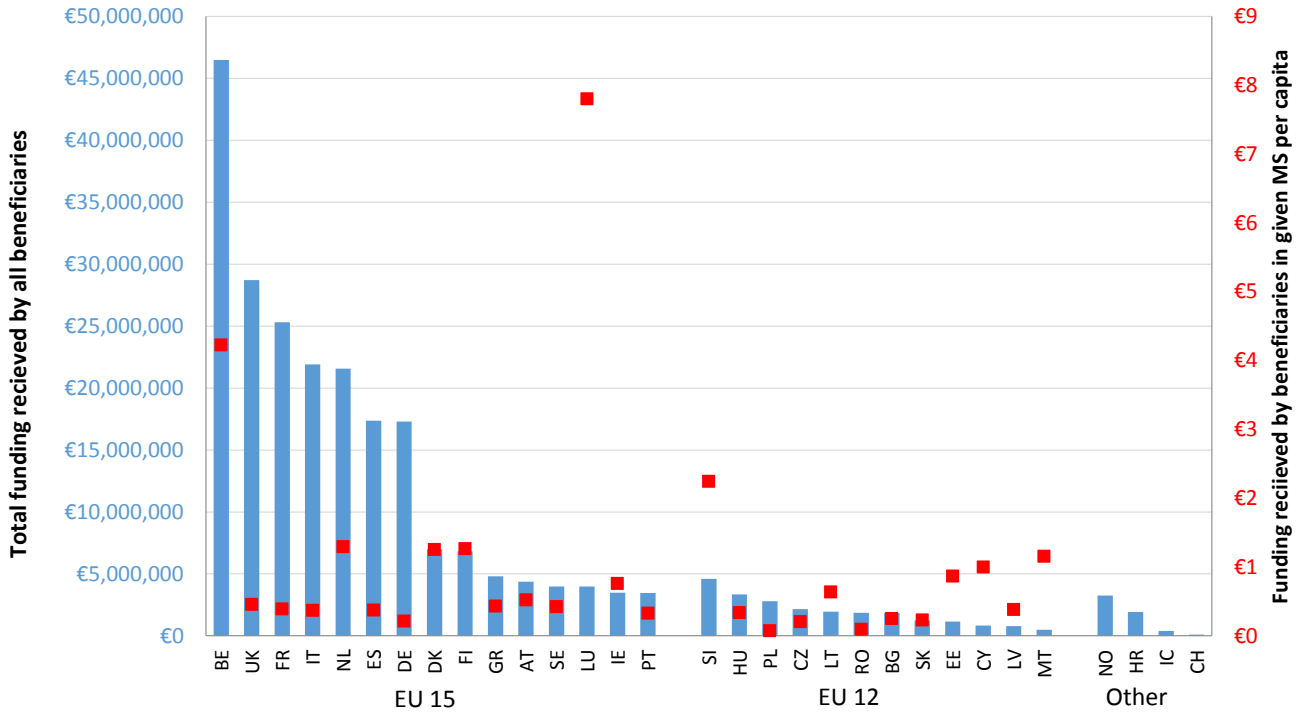
Figure 8: Number of HP beneficiaries by country, in absolute terms and per capita (2008 – 2013)



Source: CHAFEA database and DG SANTE

While a similar logic in favour of small countries holds in terms of the distribution of funding, the picture is more nuanced. For example, Belgium receives far more funding in absolute terms than any other country, and significantly more than its population would suggest. Luxembourg receives the most in per capita terms, followed by Belgium and Slovenia, while Poland, Romania and Germany receive the least (Figure 9).

Figure 9: HP funding received by country, in absolute terms and per capita (2008 – 2013)



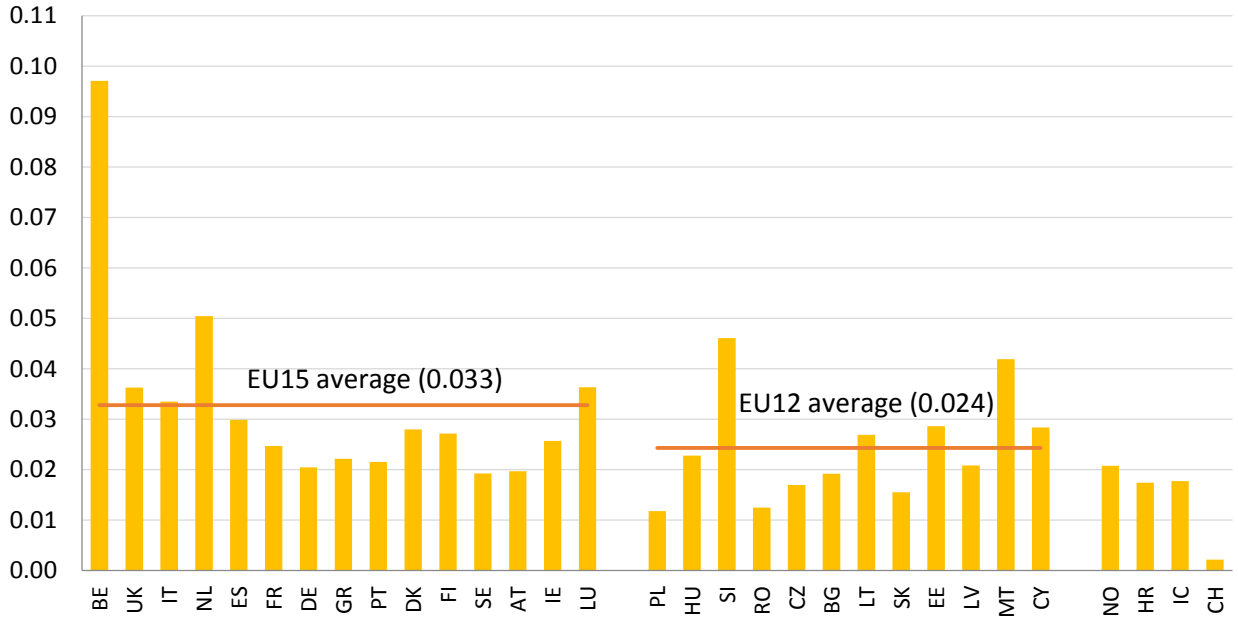
Source: CHAFEA database and DG SANTE

However, relying on per capita figures is potentially misleading. The public health landscape of a given country differs according to its size (among other factors), and this means that the natural (or optimal) level of participation in the Programme is also likely to vary. In order to control for this natural level of variation, it is useful to apply a 'degressively proportional'[26] analysis that holds up participation in the Programme against the square root of population rather than using per capita terms. This means that the size of a country's population matters, but less so than if per capita values are used.

In terms of number of beneficiaries, this analysis shows that the Netherlands and Belgium indeed benefit disproportionately (in the case of Belgium this is primarily due to the large number of service contracts that are awarded by DG SANTE to service providers based in Belgium, and to a lesser extent, to operating grants for international and pan-European organisations that are based there), while Luxembourg is closer to the EU15 average. Within the EU12, Slovenia does particularly well, even better than some EU15 countries (of which Austria and Sweden are lagging the furthest behind), while Poland, Romania and Slovakia participate relatively little (Figure 10).

[26] This approach also forms the basis of how the number of MEPs per MS is decided.

Figure 10: Number of HP beneficiaries by country, per square root of the population (2008 – 2013)[27]



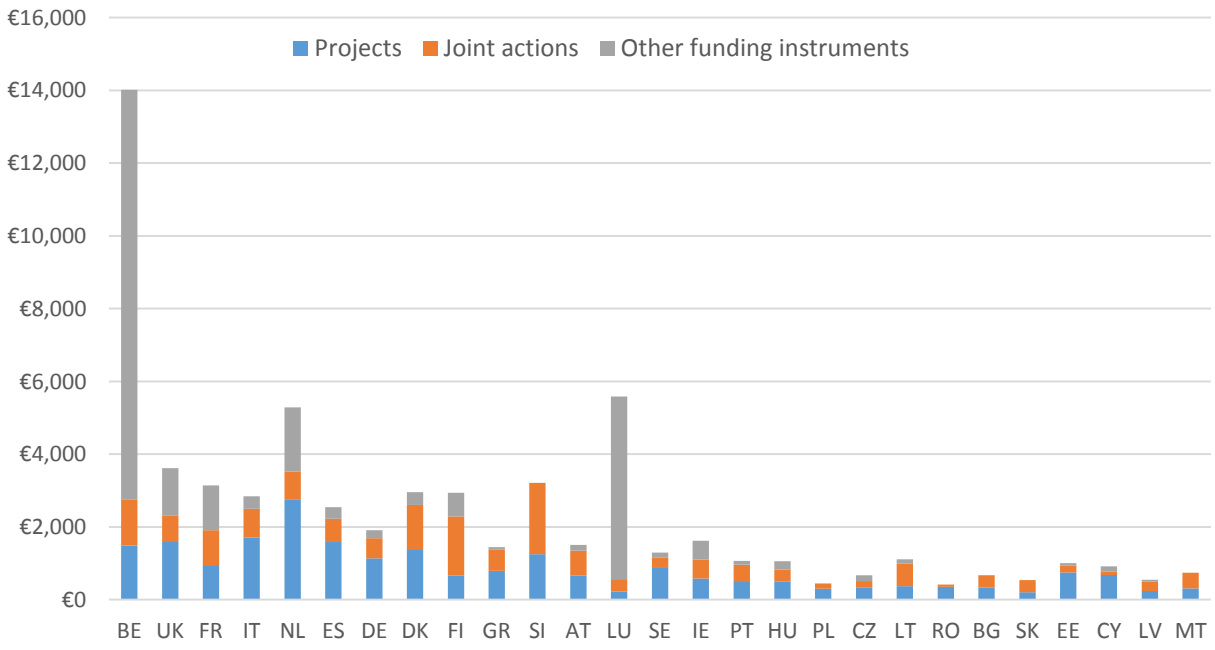
Source: CHAFEA database and DG SANTE

Funding per square root of population emphasises the extent to which Belgium, the Netherlands, Luxembourg, the UK and Slovenia benefit from the Programme, while showing that many countries participate relatively little in monetary terms. Again, differences between MS are not easily ascribed to whether they belong to the EU15 or EU12; eleven EU15 MS receive less funding per square root of population than Slovenia. There are also wide disparities in the funding mechanisms used by organisations in the different MS. In Belgium and Luxembourg, for example, the vast majority of funding came from service contracts. Organisations involved with projects used the most funding in the Netherlands, Spain, Italy, Estonia and Cyprus. In Slovenia, Finland, Denmark and Lithuania, Joint Actions were the most important. The data also show that funding for EU12 MS was focused on projects and joint actions, while they benefited very little from other actions, particularly operating grants (for which they received no funding) and service contracts (for which they received very little).[28]

[27] Please note that the order in which the countries are shown is the same as that for the equivalent graphs above (i.e. total number of beneficiaries / funding), so as to highlight how the order differs when using the "degressively proportional" approach.

[28] The available data on the number and success rates of funding applications / proposals submitted (see Annex 6) suggests that this is mainly due to the fact that entities from EU12 MS submit very few applications / proposals for service contracts or operating grants.

Figure 11: HP funding received by country, per square root of population (2008 – 2013)



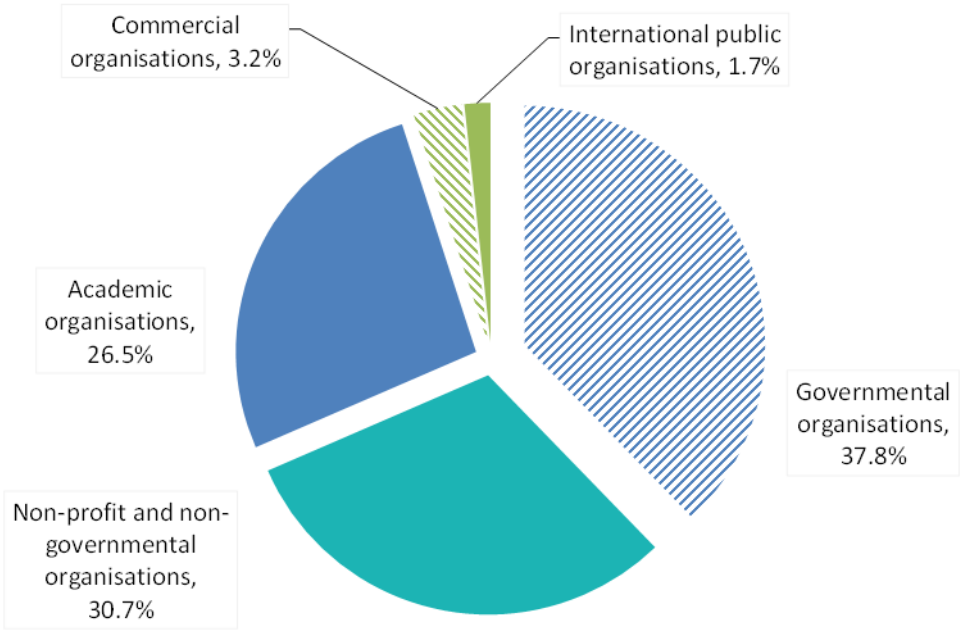
Source: CHAFEA database and DG SANTE
NB: countries listed in order of amount of funding received in absolute terms

Organisation type

We have also analysed data on CHAFEA-managed actions in terms of the types of organisations that receive funding. Please note that the breakdown is based on the categories provided by CHAFEA, and reflects how beneficiaries define themselves. As a result, it is not quite clear if there is a material difference between "non-profit" and "non-governmental" organisations; in our view, the two groups should best be viewed as one (and are therefore combined in the graph below). The in-depth review (see Annex 8) looks more closely at a more refined sub-set of organisation types for the sample of 80 actions.

The graph below shows the number of recipients of grant funding across all funding instruments (service contracts, which are not grants as such, are excluded). Governmental organisations (ranging from health ministries to public health operators) make up the largest proportion of beneficiaries (38%), followed by non-profit and non-governmental organisations (31%) and academic organisations (27%). Only 3% of beneficiaries are classified as commercial organisations, and less than 2% as international public organisations.

Figure 12: Organisations (by type) receiving grant funding from the Health Programme 2008-2013 [29]



Source: CHAFEA database

Taking each type of organisation in turn, there are noticeable patterns which show certain funding mechanisms are more likely to support particular types of organisations. For example, the majority of **international public organisations** receiving grants are supported through direct grant agreements (indeed, all 36 direct grant agreements were awarded to international public organisations since this is the target group for the funding mechanism). Most **commercial organisations** receive grants through projects, and this is also true for **academic**, **non-governmental** and **non-profit organisations**. This is somewhat expected since projects are the most numerous and – over the course of the Programme – have received the most in terms of funding. Joint actions and projects make up the vast proportion of access grants for **government organisations**, as well. Looking at different funding mechanisms and the proportion of organisations in receipt of grants shows the following:

- 75 out of 84 (or 89%) operating grants, were awarded to non-governmental/non-profit organisations;
- Two thirds of grantees for joint actions were governmental organisations (or 66%);
- Recipients in projects were split more evenly between: academic organisations (34%); governmental organisations (28%) and non-profit/non-governmental organisations (33%);
- Presidential conferences were awarded to governmental organisations but grants for conferences were most likely to involve non-governmental/non-profit organisations (i.e. 71%);
- Direct grant agreements were the preserve of international intergovernmental organisations.

[29] Please note that the breakdown includes all funding instruments except service contracts.

Summary

In terms of participation in the Health Programme, the data suggests that the issues of health inequalities and knowledge transfer towards the EU12 MS have partly been addressed, but also begs several questions about how equitable the HP participation patterns of different (groups of) MS are. For example, while organisations from the EU12 participate in the Health Programme at a level commensurate with their population (both in terms of numbers of organisations involved as well as funding received, taking into account differences in wage and labour costs), they are far less likely than organisations from the EU15 to act as lead partners in funded actions. More positively, it appears that the shift towards joint actions during the second half of the Health Programme has helped channel funding towards organisations from the EU12 (although in terms of the overall share of funding, this positive trend seems to have been cancelled out by the proliferation of service contracts, which favour entities from the EU15). There are also exceptions to the general trends at the level of specific countries and action types that are difficult to explain using the data alone. To understand these issues in more depth, we analysing the Programme's dissemination practices, particularly regarding the relationship between the Programme and public health capacity.

3. SURVEY OF NATIONAL FOCAL POINTS

This section provides a summary of the perspectives gathered through an online survey, which was distributed to 30 National Focal Point (NFPs) on 17th July 2014. The survey sought to gain feedback from NFPs on four main areas: 1) management of the 2nd Health Programme, 2) dissemination practices, 3) impact of the 2nd Health Programme, and 4) synergies with other relevant programmes.

3.1.Profile

Responses were provided by twenty-three NFPs (77%), covering the countries listed in the table below. Following the launch of the survey, three follow up emails were sent to respondents in order to encourage participation, with the survey closing on Thursday 25th September.

Table 9: Survey respondents

	EU-15 Member States	EU-12 Member States	Other participating countries
Respondents	Austria	Cyprus	Iceland
	Belgium	Czech Republic	Norway
	Denmark	Estonia	
	Finland	Latvia	
	Germany	Lithuania	
	Greece	Malta	
	Ireland	Poland	
	Italy	Slovakia	
	Portugal	Slovenia	
	Spain		
	Sweden		
	United Kingdom		
No response	France	Bulgaria	Croatia
	Luxembourg	Hungary	
	Netherlands	Romania	

Source: SQW e-survey

3.2.Findings

Management

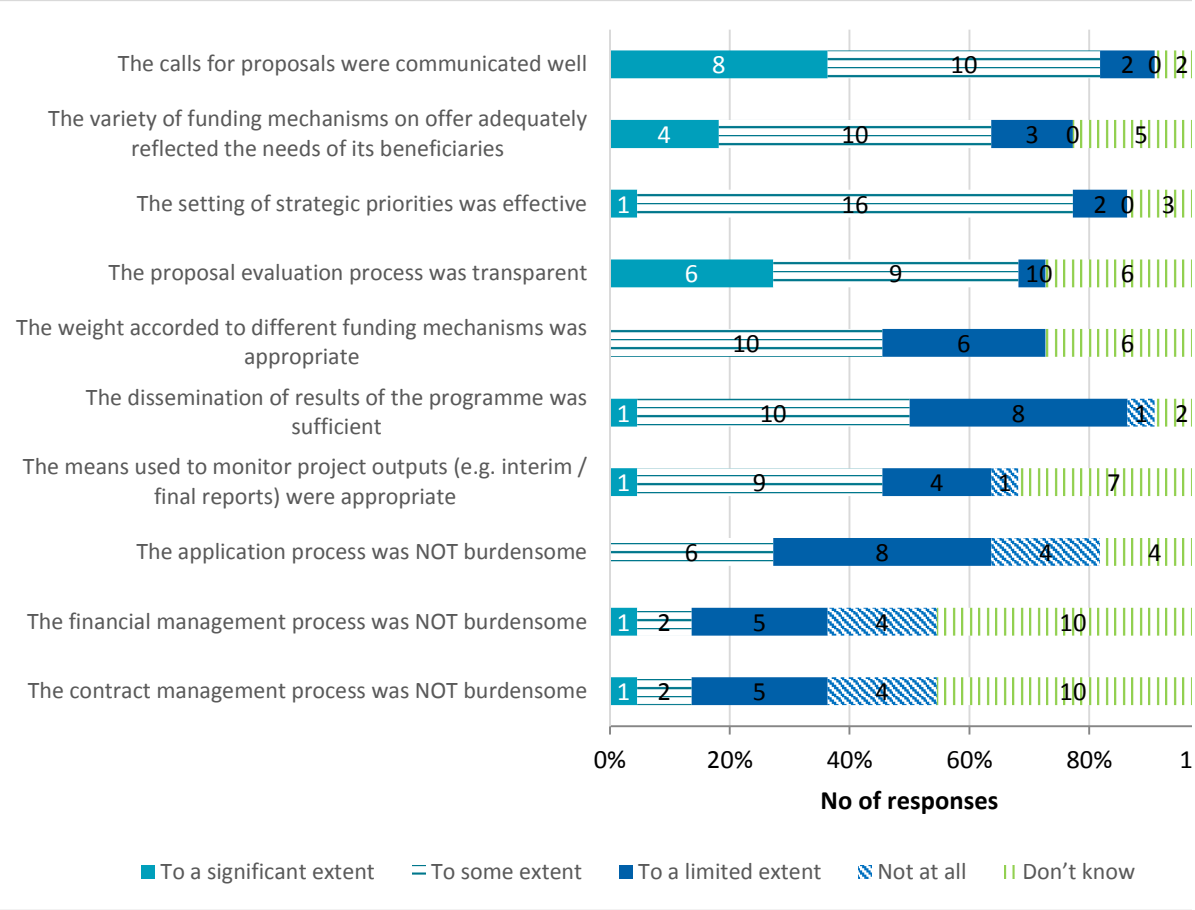
The time required to conduct NFP activities varied across countries, although approximately half of respondents (n= 12) reported spending over 10 days a year undertaking their responsibilities. A further five respondents reported spending between 6 and 10 days on NFP activities, while another six spent five or less days performing this role. On the whole, NFPs made use of this time through the following activities: disseminating information on the HP in general (n= 21), and on calls for proposals specifically (n= 20), providing guidance and support to applicants (n= 20), and attending NFP network meetings (n= 19).

As illustrated in Figure 13, there was wide consensus that the calls for proposals were effectively communicated, that funding mechanisms were well suited to beneficiaries, and that the setting of strategic priorities had been effective, with over half of respondents stating that they agreed at least to some extent with these statements. Nearly two thirds of respondents (n=15) also felt that the evaluation process had been transparent.

Conversely, more mixed responses were provided in regards to the dissemination of programme results (36% of respondents felt that dissemination had been limited),

and level of burden associated with administration. Further analysis revealed that respondents from the EU-15 MS were slightly more likely than those from EU-12 MS to state that administrative processes were burdensome and that dissemination of results had been limited, although given the small sample sizes and several "don't know" responses, these results should be considered at best indicative.

Figure 13: NFP perceptions of a number of elements of HP management



Source: evaluation e-survey (n=22)

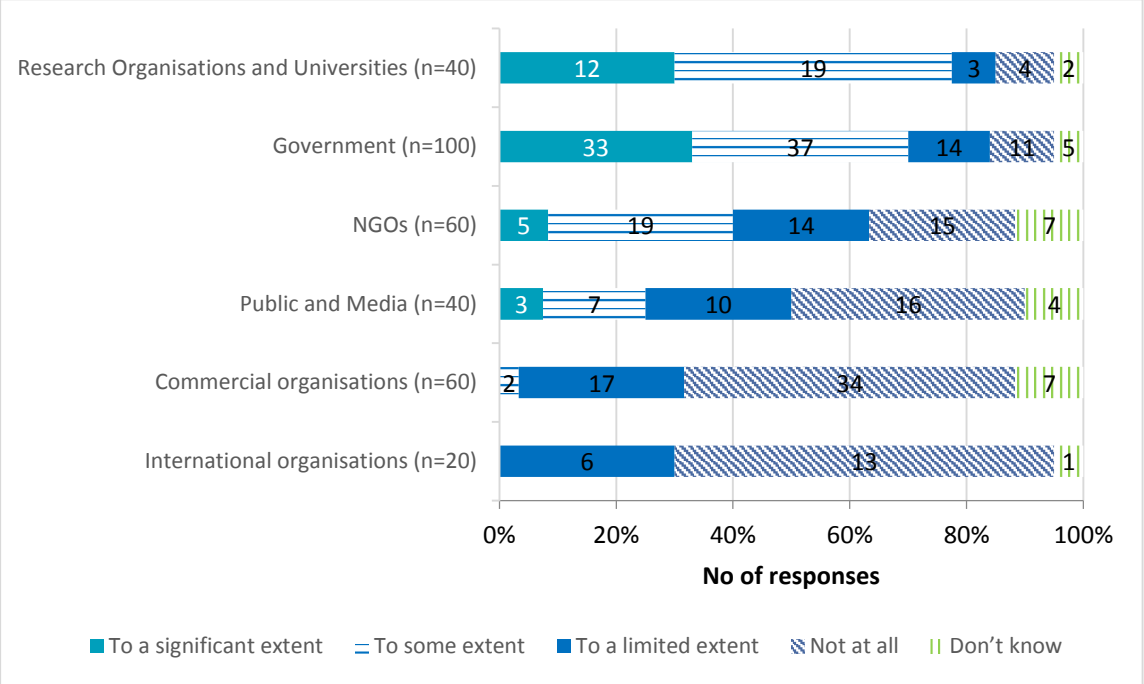
In regard to the **effectiveness of the EC and executive agency**, the response was generally positive, with over 75% of respondents stating that DG SANTE and Chafea were "fairly effective" or "very effective". In contrast, feedback provided on the Programme Committee was more mixed. Only a half of NFPs felt that the Programme Committtee had been "fairly" or "very effective", suggesting some room for improvement. These views undoubtedly reflected the NFP's interaction with the Programme Committee, as well as DG SANTE and Chafea. When asked how satisfied they had been with their interaction during the 2nd HP, 65% stated that they had been at least "fairly satisfied" with interaction with DG SANTE, and likewise 78% with Chafea, and 56% with the Programme Committee.

Dissemination

NFP respondents were asked about the degree to which their dissemination activity had targeted different stakeholder groups (based on the categories used in the stakeholder analysis). As indicated in Figure 14, **general awareness** activity had

targeted mainly on Government Institutions, Research Organisations, and Universities. Commercial and international organisations were least likely to be targeted via general awareness raising, as well as Public and Media organisations to a lesser extent.

Figure 14: Targets of NFP general awareness raising activities



Source: evaluation e-survey (n=20)

Moving to other reasons for dissemination, the survey responses revealed that:

- Government Institutions, Research Organisations and Universities had also been the main target audiences for **information on concrete funding opportunities**, followed by NGOs. Commercial Organisations had been targeted much less actively, aligning with the stakeholder analysis results which indicated that Commercial Organisations tend to undertake contracts alone;

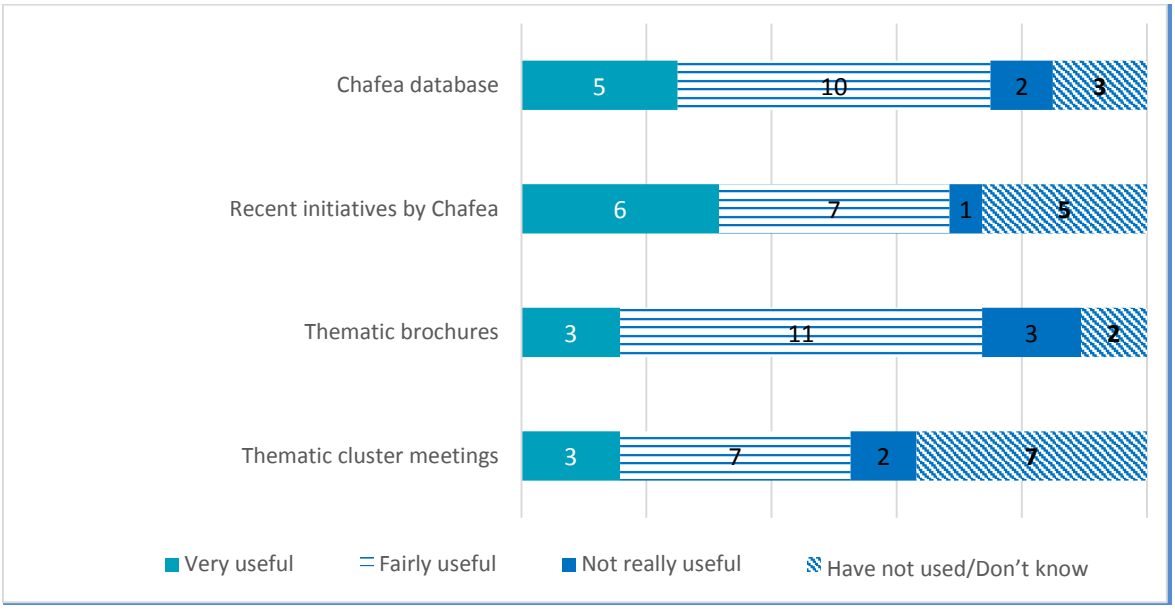
- **Information on programme outputs and outcomes** had been disseminated to stakeholders to a much lesser extent. The same pattern in dissemination was maintained (in terms of key target audiences), but only half of NFPs stated that they targeted Government Institutions to at least some extent, compared to over two thirds for both concrete funding opportunities and general awareness raising. Nearly two thirds of NFPs also had not targeted Commercial Organisations "at all" in terms of outputs and outcomes.

In regard to the mechanisms used to disseminate information through the 2nd HP (see Figure 16), feedback from the NFPs suggested that they had found the Chafea database a useful resource, as they had the thematic brochures and other recent initiatives by Chafea to encourage dissemination (e.g. roadmap exercise). Slightly less positive feedback was provided on the thematic cluster meetings organised by Chafea, however the general consensus was that support with dissemination was welcome, and should be encouraged as much as possible. The following ideas were shared as to how dissemination could be improved going forward:

- Develop more tailored approached to dissemination in MS – reflecting the different institutional and political-economic landscapes;
- Ensure that the Chafea database contains up to date contact details and as much information on actions as possible, and that information is generally accessible online;
- Consider the potential to create a database that can be used to search for partners during calls for proposals.

Gaining further insights from the NFPs on how the Chafea database could be improved would also be recommended. Whilst most NFPs had found the database useful, reported usage was quite low, with 73% (n=11) stating that they only used the database once every 6-12 months.

Figure 15: The usefulness of different dissemination channels

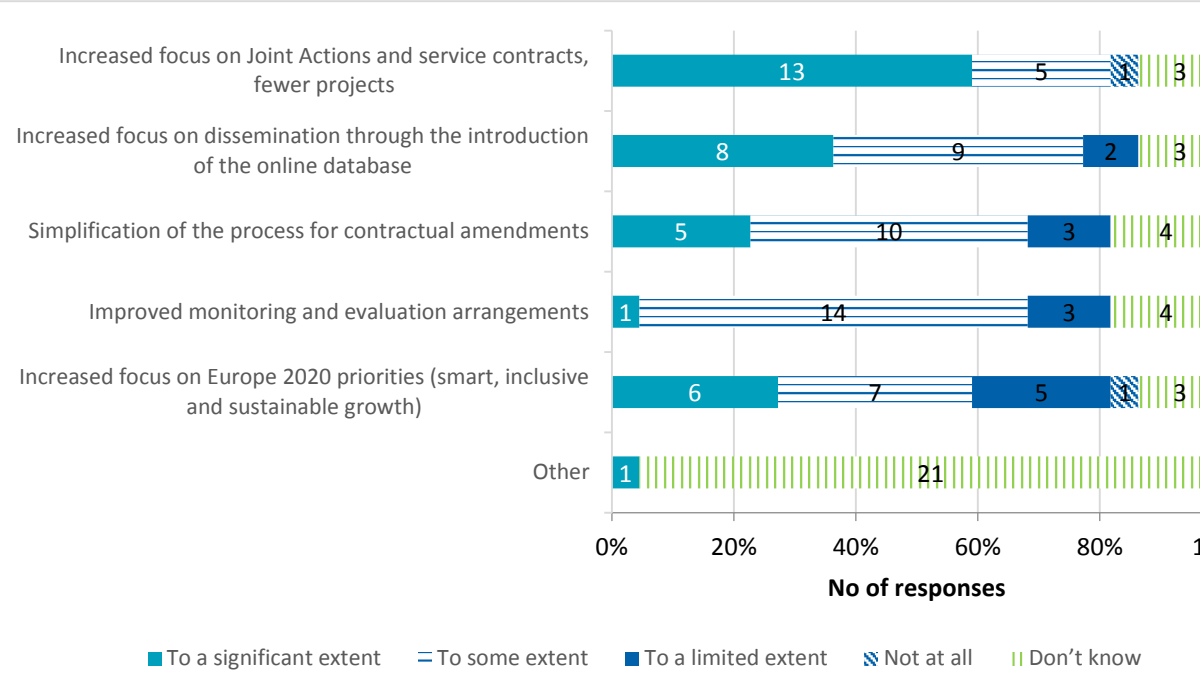


Source: evaluation e-survey (n=20)

Impact

The 2nd Health Programme includes a number of alterations from the 1st Health Programme. One of the issues the survey sought to explore was whether and to what extent NFPs approved of recent changes to the health programme, such as the increased focus on Joint Actions, and dissemination through the online database. As shown in Figure 16, the focus on Joint Actions was considered to have significantly contributed to improving the Health Programme by 13 of the 22 respondents. An 'Other' response category was included to capture additional changes, for which one respondent identified an improved definition of the term 'European added-value' as a significant contribution to improving the programme.

Figure 16: The extent to which changes that were implemented over the course of the second Health Programme have contributed to improvements in the programme's effectiveness

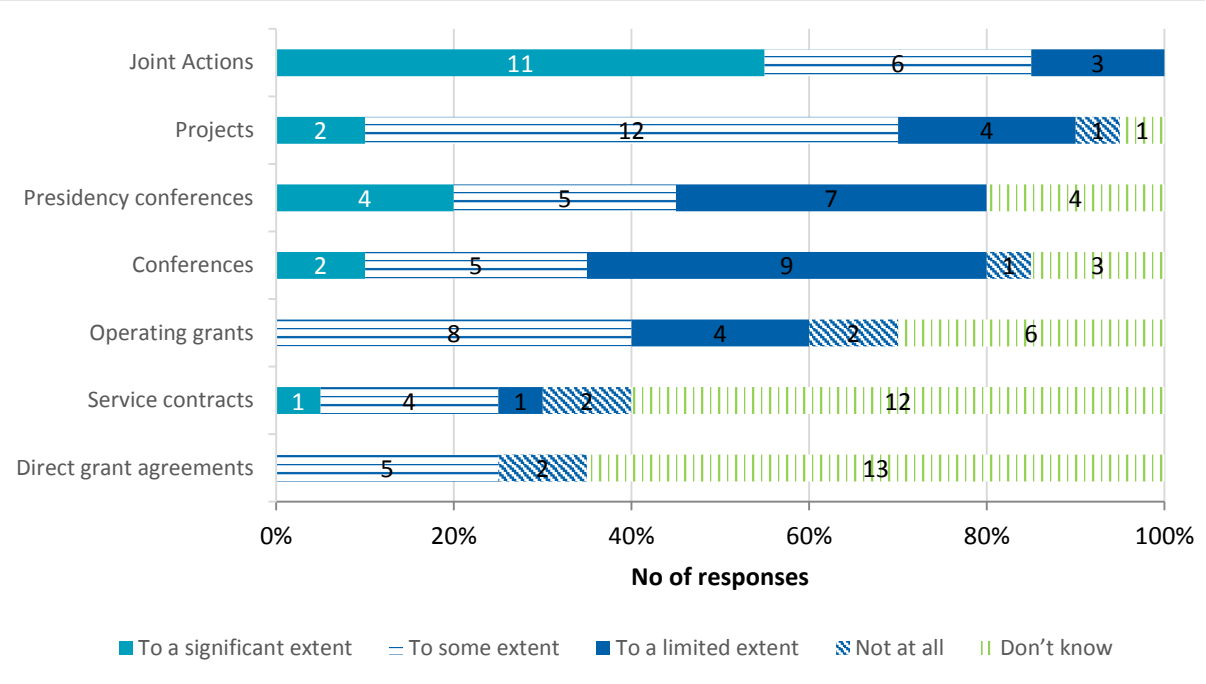


Source: evaluation e-survey (n=20)

NFPs were asked for their views on the extent to which the outputs produced through the second HP had been relevant to policy in your country. The majority believed that they had to at least some extent, although NFPs from EU-12 MS were more likely to provide this response than those from EU-15 (42% of which stated that the outputs had not been relevant at all, or only to a limited extent).

Figure 17 shows a breakdown of NFP views on the extent to which the HP has supported national health policies according to the five different types of action. Joint Actions were believed to be most effective at complementing national health policies, followed by projects, presidency conferences and conferences (it should be noted this response may be partly motivated by the fact that NFPs work for governmental organisations at the national level, which are the main beneficiary of JAs). Over half of responses did not feel able to comment on whether Direct Grant Agreements and Service Contracts had contributed to national health policies.

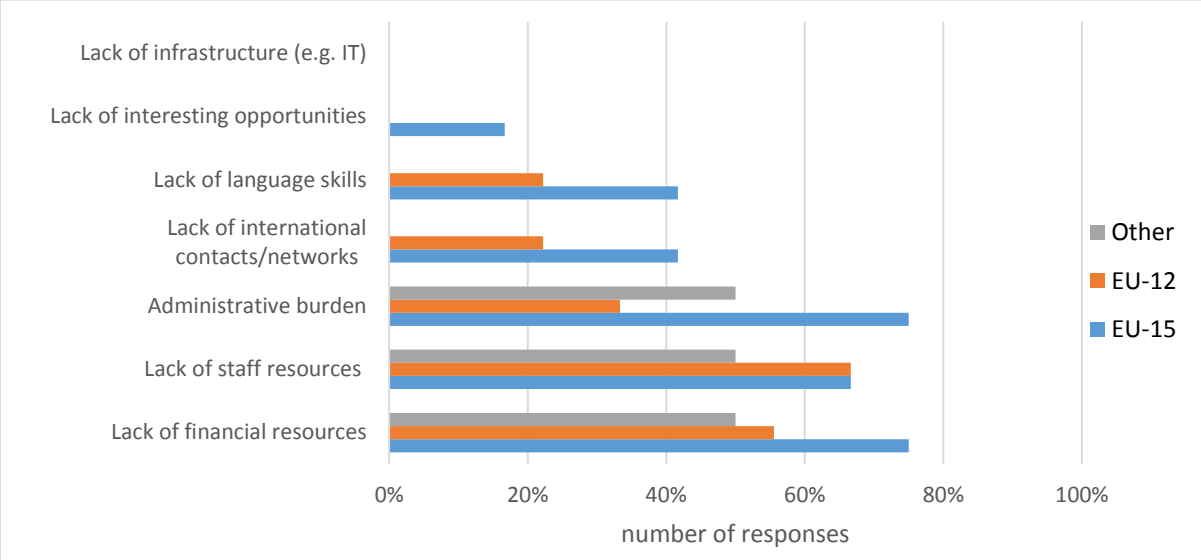
Figure 17: Actions and their effectiveness in complementing, supporting and adding value to national health policies



Source: evaluation e-survey (n=20)

NPFs were also asked to express their views on barriers to Health Programme participation, as shown in Figure 18. The perceived barriers were mostly internal and related to the administrative burden and lack of financial and/or human resources, while external barriers were considered relatively minor. Interestingly, EU-15 MS were more likely than EU-12 MS to state these barriers, with two thirds of EU-15 respondents reporting lack of financial resources and administration as a burden, compared to approximately one third of EU-12 MS. The same trend continued across the range of possible options, with a much higher proportion of EU-15 MS reporting barriers. This is an interesting finding, which may reflect the fact that in spite of the question being focused on barriers to participation broadly in their country, NFPs' responses reflected their own personal experiences of administration. NFPs may also interpret their role differently, and their responses may be a reflection of the extent to which they engage with, and are therefore aware of the barriers faced by, applicants from different types of organisations and with different financing mechanisms.

Figure 18: The main barriers to the participation of organisations from your country in the Health Programme

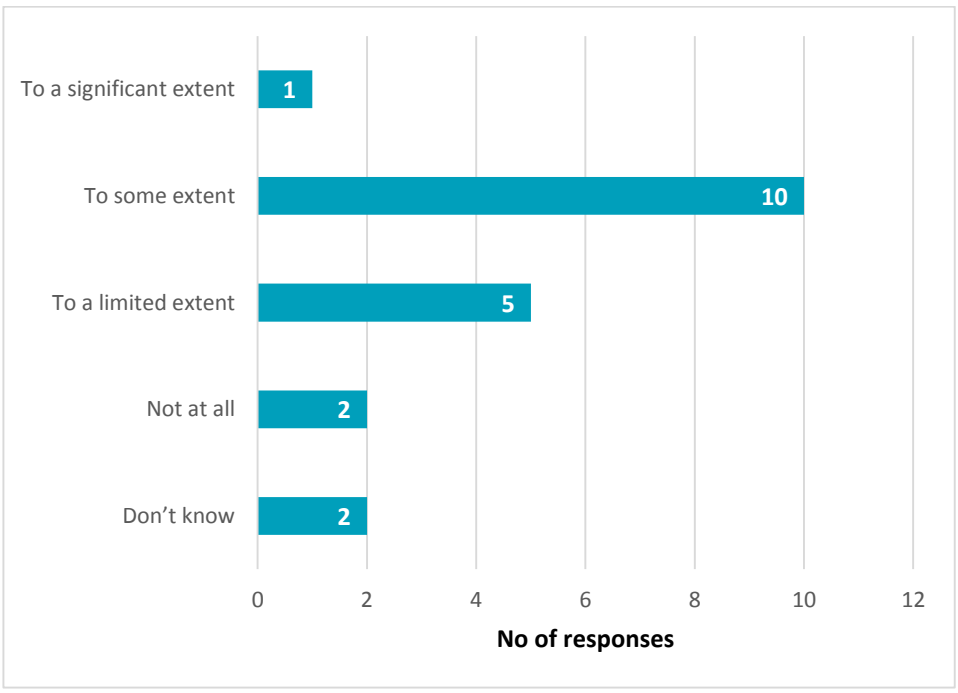


Source: evaluation e-survey

Synergies

According to most NFPs, synergies exist between the EU 2nd Health Programme and other EU Programmes, although they did not feel strongly about this, with just one reporting that they exist to a significant extent. As shown in Figure 19, 15 of the 20 respondents indicated that synergies exist to some or a limited extent.

Figure 19: The extent of Synergies between the EU 2nd Health Programme and other EU Programmes



Source: evaluation e-survey

Following the question depicted in Figure 19, there was an optional open text follow-up question. Just under half of the respondents took the opportunity to convey further ideas for improving Health Programme synergies. Six of them felt that there could be more information and knowledge sharing provided about different EU health related programmes. Possible solutions to this ranged from calls for more and better quality information to be provided to NFPs on other EU programmes, to the development of an EU dissemination mechanism, to building greater linkages into all EU programme design. Respondents also suggested changes specific to their role, such as specific training for NFPs to teach them how best to facilitate synergies and direct applicants to the most useful programmes, and conducting joint meetings between all NFPs. It was also expressed that there could be more clarity about the allocation of responsibilities and funding for the programme, with two respondents noting a disconnect between research activities and public health activities, and two respondents commenting on how the Health Programme could be made compatible with structural funds.

3.3.Summary

Overall, the preliminary survey results are encouraging. Most importantly, the responses indicated that the increased focus on Joint Actions and dissemination activities has been well received by NFPs, who felt that both have made positive contributions to the Health Programme. Joint Actions were also seen to compliment and add value to national health policies, as were projects and conferences, to a more limited extent.

On the other hand, the responses also indicated that dissemination activities are being targeted at quite a narrow range of stakeholders, notably Government Institutions, Research Organisations, and Universities. Whilst the focus on government stakeholders is unsurprising given that actions (in particular Joint Actions) are seen to compliment national policy, it remains to be seen whether dissemination activities could be better targeted at other stakeholders. In addition, a number of barriers to participation were suggested, including administrative burden, and lack of financial and human resources, particularly by NFPs from EU-15 MS.

4. SUMMARY OF INTERVIEWS

4.1.Introduction

A total of 25 interviews were conducted; consisting of seven interviews with external stakeholders (MEPs, NGOs and international IOs); six EC officials and twelve National Focal Point contacts (NFPs).

Table 10 – Interviews conducted

Stakeholder group	Interviews conducted	Notes
External stakeholders:		
MEP (assistant)	2	Interviews were originally foreseen with MEPs themselves, who provded unavailable. Therefore, two assistants of MEPs who played important roles in the transition from the 1st – 2nd or 2nd – 3rd Health Programme were interviewed.
NGOs	4	
Intergovernmental IO	1	The interview was conducted with a representative of the OECD.
EC officials:		
DG SANTE	4	
CHAFEA	2	
NFP contacts:	12	
Total	25	

The interviews were conducted between May 2014 and January 2015, mostly by telephone, and typically lasted between 30 and 60 minutes. The sample of interviews we spoke to during the interview programme reflects a balance that was struck in consultation with DG SANTE. While more individuals from each stakeholder group would have made suitable interviewees, the selection is reasonably representative given the limited number of interviews that could be included in the study. It should be noted that a considerable quantity of interviews were also conducted in the context of the research for the cases studies (see Annex 9).

The following text presents the results of the interviews conducted with each group in turn. It reflects the views of those interviewed rather than the evaluators; our interpretation of the findings is presented, alongside other evidence, in the main report in terms of answers to the evaluation questions, conclusions and recommendations.

4.2.Interviews with external stakeholders

Interviews were conducted with two groups of external stakeholders, as detailed below.

- **Assistants to MEPs** in order to provide insights into the Health Programme's aims and objectives from a policy maker's perspective;
- **NGOs** which received funding under the second Health Programme provided insight into experiences of implementation of funding and actions supported by the Programme;
- The Head of Health at the OECD - an **international Intergovernmental organisation** - was interviewed which allowed for insight into the funding

awarded through direct grant agreements in particular but also the strategic value of the Health Programme more broadly. The OECD has received a number of direct grants through the second Health Programme.[30]

In the event, it proved very difficult to secure interviews with MEPs (or their assistants) however the two we did interview were well placed to provide insight into the Programme. One was rapporteur for the second Health Programme, while the other was rapporteur for the third and also involved in the negotiations for the transition from the second to the third Heath Programme.

The non-governmental organisations we interviewed are detailed below:

- **HOPE**: the European Hospital and Healthcare Federation is an international not-for-profit association. Its acronym - HOPE – stands for **H**ospitals for Eur**OPE**. HOPE has been involved in a number of projects and joint actions, for example the European Union Network for Patient Safety (EUNetPaS)[31] and the European Health Workforce Planning and Forecasting (EUHWforce)[32] and the European Partnership for Action Against Cancer (EPAAC)[33];
- **EUREGHA**: EUREGHA is a network of 13 European Regional and Local Health Authorities focused on public health. Its primary focus is on working together for more sustainable and efficient health care systems. EUREGHA has been involved in the second Health Programme also through EPAAC as well as European Regions Enforcing Actions Against Suicide (EUREGENAS)[34] and was also in receipt of an operating grant;
- **EuroHealthNet** is a not for profit partnership of organisations, agencies and statutory bodies. Examples of their involvement with the second Health Programme include: an EU Consortium for Action on Socio-Economic Determinants of Health (DETERMINE) and Capacity Building for Public Health and Health Promotion in Central and Eastern European Member States and Candidate Countries of the European Union (CABPH)[35];
- **EHMA**: a membership organisation made up of 170 members across more than 30 countries which aims to build the capacity and raise the quality of health management in Europe. The members range from hospitals to universities, from ministries of health to primary care providers, from management education schools to consultancies. EHMA was awarded several operating grants under the second Health Programme.[36]

The following text presents the interview findings in relation to the four blocks or themes explored as part of this evaluation, namely the Programme's management, dissemination, impact and synergies.

[30] For example: "Refinement and new manual of the System of Health Accounts for actions not covered by the Community Statistical Programme" (in 2008); and "Multiannual framework to further develop and improve data, indicators and analysis relating to health and in particular health care in cooperation with the OECD, in support of the work of the Health Committee of the OECD" (in 2009).
[31] http://www.eunetpas.eu/
[32] http://ec.europa.eu/chafea/projects/database.html?prjno=20122201
[33] http://www.epaac.eu/
[34] http://www.euregenas.eu/
[35] http://ec.europa.eu/chafea/projects/database.html?prjno=2005301
[36] http://www.ehma.org/?q=node/971

Programme management

Interviewees discussed the evolution of the Programme over time in relation to the management of the Programme in general, in relation to applications made for funding and their experiences.

In relation to the first of these, interviewees reported considerable issues in dealing with DG SANTE and Chafea, because it was "not always clear where the authority lies". More specifically, one interviewee felt problems in communication were due to Chafea's heavy workload, and attributed problems to the agency being overloaded by projects, joint actions and not having sufficient capacity to handle queries in a timely manner.

Overall, while interviewees thought that **the work of the management had improved over time**, they acknowledged that relations were **not as smooth as they might ideally be.**

Take up of recommendations from mid-term evaluation

Interviewees were asked specifically about the take up of recommendations from the mid-term evaluations including the process for submitting applications and receiving funds. We heard from multiple sources that – compared to other EU programmes – the Health Programme was considered **inflexible and overly bureaucratic, particularly with regard to operating grants,** and that efforts to simplify procedures had been unsuccessful for this funding mechanism. For example, we heard complaints from organisations regarding the restrictive terms of payment, tied payment, lack of flexibility and administrative burden which was considered disproportionate for the level of funding. Interviewees suggested several **ways to address the problems in the context of operating grants**, for example to select organisations which operate in an area which the Commission wishes to support and letting them determine what the funding is spent on, or indeed offering a two-tiered application process so that organisations which are unlikely to be funded do not spend time and resources compiling applications.

Effectiveness of shift towards joint actions and service contracts

Interviewees were asked to comment on the decision to fund more joints actions and service contracts. We found that joint actions had been **very well received** and even that developing this funding mechanisms was highlighted as representing the most significant and successful element of the evolution of the second Health Programme. This is expressed in the following comment: "The most progress in the second Health Programme was the joint actions. Even though the budget is rather modest, it brings the right people together… Joint actions are brilliant." One of the side-effects of the focus on joint actions was that it became more difficult for non-governmental, research and academic organisations (which were not affiliated with the ministry of health or equivalent) to participate in the programme. These organisations are more likely to participate through projects, operating grants or service contracts. In spite of this, associations were positive about the shift and recognised the importance of involving Member State authorities.

Despite a consensus that a greater focus on joint actions was a positive development, there was also concern about how the ability for joint actions to re-apply and continue to receive funding led to some unease regarding sustainability (see more in impact section below).

Programme dissemination

Stakeholders were asked about their experiences and thoughts regarding programme dissemination; how this could be improved and how it impacts on other aspects of the

Programme, such as the level of engagement with beneficiaries in different geographical areas.

Contribution to reducing geographical imbalances

The dissemination of results of actions could be seen as a means to redress geographical imbalances in the participation of the scheme. Interviewees emphasised that **language remains an important barrier** in any attempts to reach those who might be considered hardest to reach. Translating results into national languages needs to be considered as a way to address this. However there is the question of who should take responsibility for this: should this be part of the dissemination budget for all actions? Should national authorities take charge? What if national resources are not available?

Role of organisations (not MS government/authorities) in promoting Programme outcomes and results

Organisations explained the mechanisms they used to disseminate information, which included making use of their networks to share information across their member organisations. This, however, was described as extremely difficult partly due to **language barriers and the varying abilities of members** to translate but also the "fragmentation of healthcare across Europe". This last point concerns the importance of reaching national, regional and even local level organisations; these organisations are much harder to reach than, say, European level organisations.

The one **exception was the OECD** which reported to have considerable organisational resources for dissemination activities, translating their reports to most EU languages and working directly with national competent authorities.

Scope for improvements in dissemination

Interviewees were clear on the benefits of effective dissemination but we heard that it **could be substantially improved**.

One specific idea involved **earmarking a certain proportion of funding** exclusively for dissemination. However we note that this is somewhat contradictory to earlier comments (see "Take up of recommendations from mid-term evaluation) which pointed to a need to reduce tied funding (specifically in the context of operating grants).

In terms of **what methods could be explored further**, we specifically heard arguments for activities which support networking and relationship building, making better/more use of the (specialised) press and NFPs to communicate what has been achieved (as well as available funding). Furthermore, more targeted dissemination was also discussed by interviewees. For example targeting certain journals and adapting the message to specific audiences.

The importance of ownership for the **sustainability of results** was emphasised during interviews, for example: "In a project, you have to have a dissemination plan for the duration of a project but who is the owner of the project results and in 10 years how we will make sure that they are used / who is the end user?" This concern for long-term planning is important as a means to secure the impact of the Programme over time (see also discussion under Impact of the Programme).

Impact of the Programme

Interviewees were asked about their perception of the impact of the second Health Programme. We heard frequently that despite very interesting research and results through Health Programme funding, **the take up of the findings and the tools**

created is reportedly rare and that the reason for this was at least in part due to low visibility of results and tools. For example we heard the following statements from organisations:

- "The truth be told no one actually uses the tools created. They should focus on dissemination."
- "There are good results but to be honest we don't see them."

Indeed, when asked about specific points on what constitutes the main strengths and weaknesses of the Programme, **long-term efforts in dissemination was cited as a weakness**. This was acknowledged by the interviewee from the OECD who described how their dissemination strategy was changing as a result. In an effort to keep findings 'alive', the OECD was now planning dissemination on longer time scale, not concentrated around the publication of their findings. At the same time, **the move towards joint actions was heralded as a strength** since it signalled a shift towards a programme "with policy relevance". Yet, we also heard concern regarding the number of joint actions, which was seen as obscuring their individual value.

Impact on MS health policy and actions; main policy areas in which progress has been achieved, and what constitutes progress

Interviewees struggled to point to specific areas where progress had been made, especially given that each stakeholder tends to have quite a niche angle from which to assess the impact of the Programme. However, as reported by one MEP, there had been a noticeable increase in awareness (among citizens) in four areas in particular: protecting citizens against health threats, health determinants, major/rare diseases, and the exchange of knowledge and best practice. We also heard from another stakeholder that health inequalities saw important progress, specifically through joint actions, which "give the public authority the chance to sit together with others and that is very valuable". Indeed, more broadly, the Programme was viewed to have had an "effect on national health policy" which was a significant achievement as compared to the previous programme, which was less successful in this respect.

Of the external stakeholders, the OECD, reported to have the closest contact with policy makers on a Member State level, in large part because OECD provides a forum for governments to compare and analyse policies. The interviewee also emphasised the close cooperation with competent authorities and policy makers made it possible to create 'tailored' evidence to support national policy decisions. Furthermore, the work OECD did on health was described as an important way of coordinating domestic and international priorities and identifying best practices across MS. For example, the increased use of generic drugs among MS was credited to reports published by the OECD.

What factors intervene to (+/-) impact the Programme

Interviewees shared their ideas on what determines the impact of actions funded through the Programme. These can be grouped under the following themes:

- **Relevance**: the policy relevance should, ideally, be clear from the outset and the results should be geared towards a concrete policy objective (where applicable);
- **Dissemination**: this was felt to be a significant determinant of the impact of an action but an area which could be improved;
- **Strategy for sustainability**: one suggestion was that actions need to have a vision / strategy which sets out how they will continue to have an impact after the funding ends and who will take up the results. This vision would be built in to the assessment of whether the action is funded;

- **Topic and scope**: another specific comment argued that the topic itself is an important determinant of the level of impact, for example a joint action on patient safety has a better chance of "a clear impact" than other health issues. In a similar vein, we heard that barriers to impact were when the topic is "too wide or too technical" and the action is too small to really make a difference. Oftentimes actions can be "too ambitious" and that there are problems when time is not taken to analyse the issue before "jumping into" actions in that field.

Main lessons drawn for successful transition from the second to the third Health Programme

MEPs we spoke to felt that **the third Health Programme was better organised**. Indeed, simplifying and streamlining the Programme had been a key objective in the negotiations for the transition from the second to the third Health Programme.

In addition, the Health Programme plays an important part in facilitating EU cooperation in areas where the EU either has already or may be likely to establish legislation (such as cross border health), and in driving innovation. As such, these aspects are addressed and supported by the third Health Programme.

Synergy

With regards to synergies, few comments were made. However from a policy perspective, we heard that more integration across the difference Directorate-Generals (DGs) would be desirable, as expressed in the following statement: "It would be good if (maybe in the fourth Health Programme) we have much more cooperation between different DGs. Health also concerns DG AGRI, DG EAC, DG RESEARCH, etc."

The OECD provides an example of the creation of a setting for governments to compare policy and seek answers to common problems. Since it works directly with MS it can be considered an effective platform for supporting policy decisions on a trans-governmental basis.

4.3.Interviews with EC officials

Over the course of the evaluation six interviews were conducted with officials from the DG SANTE and Chafea. The interviews explored the Programme management, its impact, dissemination strategy and synergies. The interviewees conducted were with the following individuals:

Table 11- Interviews conducted

Position and organisation
Chafea, Head of Unit - Health
DG SANTE, Head of Unit –C1- Health Programme & diseases
Chafea, NFP coordinator
Policy Officer, previously in Health determinants
Policy Officer, Health Information
Policy Officer, Health threats

This section sets out the findings from these conversations.

Please note that in addition to the above, 13 officials (5 from DG SANTE and 8 from Chafea) were interviewed as part of the research for the case studies.

Programme management

Commission officials we spoke with were generally very positive about the management of the Programme, with some exceptions or minor grievances regarding for example, confusion regarding lines of responsibility. Essentially, from the point of view of DG SANTE and Chafea, there is a clear demarcation of responsibility; but there are some who seem to find this confusing. We heard from Chafea that there is now better coordination with DG SANTE, for example through more regular meetings.

Take up of recommendations from mid-term evaluation

There have been efforts to respond to criticisms raised in the mid-term evaluation, notably in the following areas: strategic focus of the Programme; dissemination of the results; flexibility in terms of management and modernisation of processes. Each of these is discussed in turn below.

Over the last two years in particular, there have been effort to **increase strategic focus** – using the Europe 2020 objectives as a method of prioritisation and also including more input from senior DG SANTE personnel to replace the bottom up development process. In doing so, however, the following constraints were noted:

- ensuring MS buy in to policies;
- a very broad remit which is matched by a small budget;
- many different funding mechanisms.

There was consensus that more focus of efforts had been spent on ensuring **effective dissemination of results** (see Programme dissemination section below).

Since the mid-term evaluation there have been efforts to simplify and improve **the flexibility of administrative procedures**, for example reducing the need for amendments to contracts in specific circumstances (previously an amendment was required to change the cost category of a team member but this is no longer required). Generally, there is now "more professionalism in treatment" of beneficiaries and applicants, because there is a team experienced in public procurement.

Indeed, **administrative procedures have been significantly modernised under the third Health Programme**. The first major break from the past is that now grants (i.e. deliverables) are managed electronically, there is no paper exchanged between a successful applicant and Chafea. For procurement management, an online system is being developed and should be in place for 2015 calls. In the words of one interviewee: "It is a revolution for applicants, the agency and DG SANTE, as we will have access to all tools, deliverables at any time". The second major break from the past is the introduction of simplification measures, for example electronic signatures are now used and there are other tools to help with the preparation of amendments.

Effectiveness of shift towards joint actions

In terms of the shift towards a greater focus on joint actions, one interviewee was keen to point out that as a funding mechanism they are not really innovative, however they do involve a more conscious focus on MS and there are essentially **two reasons for the increased focus**: a desire to involve more MS (for sustainability reasons), and to concentrate funding on fewer but larger activities (in order to improve value for money through greater level of match funding).

Joint actions are proving to be **an effective way to further progress at the MS level in specific policy fields**, especially where collaboration between MS is required. For example, the SHIPSAN ACT joint action[37] – which was preceded by the SHIPSAN project and SHIPSAN TRAINET, aims to safeguard the health of travellers and crew of passenger and cargo ships to prevent the cross-border spread of diseases by working with port authorities and supporting the effective implementation of national legislation (based on the National Single Window - Directive 2010/65/EU - in relation to Maritime Declaration of Health).

In terms of **value for money, we heard two warnings from interviewees**: the first was about the sustainability of funding, we heard that when funding is drying up (towards the end of the action) experts and participants begin to look elsewhere for funding which means that – for example – an action lasting three years will only involve two years of actual work. The second warning was about the topics which up being funded as a joint action, there is a risk that joint actions will be set up (driven by MS) in areas that are inappropriate.

Recruitment of beneficiaries from new Member States

Although efforts have been made to recruit beneficiaries from new MS in particular, for example by ensuring calls for proposals are disseminated in all MS and offering training on how to lead projects in some MS, **structural barriers remain**. For example, certain funding mechanisms simply do not reach new MS (for example, no operating grants have been awarded to organisations based in new MS (partly) because the requirements to have organisations based in multiple MS effectively rules out most organisations). According to one interviewee there are other hidden barriers as well; many MS don't even trust national procurement procedures, which mean not many contracts are signed in new MS.

To increase new MS participation the following suggestions were made: make sure the tools (i.e. the funding mechanisms) are right and dissemination efforts are proactive but also that the content of the calls are specific to new MS.

Programme dissemination

There was consensus that more focus of efforts had been spent on ensuring **effective dissemination of results**. Given that there is a relatively small budget for dissemination efforts, all parties are keen to ensure that this budget is used strategically. For example, there was a "huge effort to improve the **Chafea database** in order to bring it (more) up to date and add the backlog of projects which were not previously included". In addition, we were informed of the development of a search function to make it easier to source information on individual projects. The result has been an increase in hits. At same time, **efforts in other areas** were stepped up, for example brochures were produced covering broad range of actions, grouped under thematic areas in close collaboration with NFPs.

Dissemination contribution to reducing imbalances

As discussed above, under Programme management, there have been efforts to ensure dissemination of calls across all MS, especially new MS. However, the problem is more systemic, there are other barriers besides awareness. In addition to those mentioned above (conditions attached to funding instruments, for example) there is also the problem of language barriers.

[37] http://www.shipsan.eu/

Scope for improvements in dissemination

Looking ahead, interviewees had a number of ideas for what needs to be done to improve dissemination. The first relates to the abundance of information available on the actions funded by the Health Programme and the sustainability of those efforts. There was concern at the proliferation of action websites which are not guaranteed after funding ends. The suggestion voiced by some was there should be a one-stop-shop for information on actions (perhaps based on the Chafea database, hosted by the Commission) which would enable information to be available even after the funding ends. Others ideas for improvements were: to base more of Chafea awareness raising activities in-country (at present most Chafea dissemination is organised in Luxembourg); to try to engage stakeholders – for example EU Health Policy Forum members - to be more proactive in disseminating information/results; and finally to adopt mechanisms to encourage MS to endorse best practices.

Under the third Health Programme simplifications (and automation) of certain procedural aspects of the Health Programme (see more under Programme management) are hoped to help facilitate a refocus of resources towards dissemination activities.

Impact of the Programme

With regards to the impact of the Programme, although there was a sense that the Programme did have an impact, the general consensus was that **this impact could be much greater**. We were given examples (such as the ECHI indicators, or the injury database, the use of healthy life years, as well as joint actions which had succeeded in having tangible results[38]) of instances where research and results were being used and the impact was visible. But we were also told that more could be done to ensure that the relatively small budget (compared to say the Framework Programme/Horizon2020) was used to maximise impact. Indeed, while some interviewees expressed concern that funding was "too little" to have an impact, we also heard that more money wasn't necessarily the right answer. Rather, a better long-term strategy (i.e. map out the programme design for 5-10 years) which includes some flexibility to respond to specific developments, could be adopted to make the best use of the funds available.

In relation to the **transfer of capacity and know how to new MS**, there was concern that this is not guaranteed even through the participation in actions. In order to ensure that this transfer does occur, actions need to be designed to ensure that knowledge and capacity transfer is an obligatory component and that beneficiaries can be held accountable.

Timeline for expecting impact

In terms of what time period would be reasonable to expect to see some impact, the feedback indicated that there is no universal standard but that some factors which determine the speed at which results are picked up. For example, whether there is a string and accepted evidence base, whether there are strong economic interests in pushing forward, who needs to take action and whether they are on board. At one extreme, 1 – 1.5 years might be enough, but it is often more likely to be somewhere between 5-6 years but at the other extreme could be 20 years.

One example of a factor which can intervene (negatively) to reduce the impact of an action is the 6-monthly rotation of the EU presidency. Depending on the nature of the

[38] Examples given were SHIPSAN ACT and HTA.

issues addressed by an action (i.e. more generic/more specific) this could be problematic.

Synergies

Regarding the extent to which synergies across the Commission DGs (for example DG EMPL, AGRI, CONNECT, etc.) as well as other funding programmes (especially the Framework Programmes/Horizon2020) were exploited we heard evidence of good practice as well as evidence of room for improvement. With respect to the exploitation of synergies, there was evidence that in the development of indicators collaboration across the Commission had been crucial, this was also true for the development of tools to improve the administration of the Programme at Chafea. Where there seems to be most scope for improvement – according to interviewees – is with relevant funding programmes (FP7 and Horizon2020). A key barrier to better collaboration is communication.

4.4.Interviews with National Focal Point contacts

This section sets out the findings of the in-depth interviews programme with National Focal Point contacts (NFPs). In total **12 interviews were conducted with NFPs** from across the EU and one EFTA country, Norway. The sample was chosen to be representative of different levels of the participation in the Health Programme (HP) with the aim to get a geographic spread of countries and a range of participation rates.

Table 12 – Selection of NFPs interviewed

Category	Country
EU 15	Belgium
	Finland
	Greece
	Italy
	Spain
	Sweden
	United Kingdom
EU 12	Cyprus
	Poland
	Romania
	Slovakia
	Slovenia
EFTA	Norway

The interviewees explained the background of their work, their contact with stakeholders and their overall role as NFPs. Their workload was variable, increasing significantly when calls to tenders and the Annual Work Plan were launched. Several interviewees estimated that NFP tasks took around five to ten per cent of their workload over a given year. A number of interviewees explained that one of the most challenging aspects of their role was **negotiating time to fulfil their duties as NFP.** Interviewees emphasised that high staff turnover impacted on the effectiveness of NFPs in their role.

In most countries the NFP role was fulfilled by voluntary nomination, usually undertaken by representatives of the statutory organisation (Ministry of Health or equivalent). In comparison with other programmes such as Horizon 2020, interviewees described the HP as drawing the "short straw" in terms of funding and resources dedicated to the Programme.

NFP tasks included disseminating information (results and applications) and providing guidance, several NFPs also noted that they would give advice on proposals and on rare occasions help draft proposals. Several of the NFPs (mostly EU15) also reported having previous experience working on joint actions.

Programme management

There was a clear agreement among NFPs that the management and organisation of the HP had improved over time; as one interviewee put it: 'There has **been considerable progress in the management of the HP over the years**, for example clarification of roles'. Nonetheless, many believed there was room for more improvement. Interviewees credited Chafea as being responsive, rapidly answering questions and communicating well. There were however a number of interviewees that felt frustrated by the high expectations of Chafea on NFPs. Especially in amount of tasks that Chafea expected NFPs to comply with. This issue will be treated more extensively under the relevant headings.

Extent to which Annual Work Plan was developed in consultation with NFPs

A number of NFPs were concerned about the lack of consultation about the Annual Work Plan (AWP) priorities. Several NFPs spoke of how DG SANTE largely dominated the agenda setting of the HP, leaving very little room and time for comments on draft AWP from MS. This had resulted in little incentive to engage with and comment on AWP drafts, since this was perceived to have little impact on priorities.

One NFP, however, argued that as HP became more a reflection of DG SANTE's priorities this had resulted in the HP becoming a more focused tool to direct health policy in MS. However, in the process it had lost transparency and democratic credibility. Other NFPs had (unsuccessfully) raised this issue with the Programme Committee in an attempt to develop a more formal and inclusive consultation mechanism. As one interviewee described it: "An agreed procedure is very time consuming, but **a step by step approach for defining priorities would give more consistency and more support to implementation by MS**." In other words, the interviewee called for a more deliberative process that would better take into account MS needs when defining HP priorities.

Aligning MS strategies and HP strategy was not considered to be an easy task but interviewees argued that it would be beneficial for the impact and transparency of the Programme.

Extent to which clear guidelines are provided

Several NFPs noted that substantial paperwork is involved in proposals with the administrative burden reportedly deterring some applicants. Understanding the requirements was sometimes difficult since the AWP was a 'complicated' and 'abstract' document.

Interviewees also reported that since the bureaucracy was perceived to be less burdensome in other EU funding programmes and that the information provided not in their native language, that it prevented participation. As one interviewee put it: "People prefer to apply to projects funded from structural fund resources or other aid programmes. This programme is too complicated and procedures are not familiar, every document and guideline is in English […]"

For interviewees where language was not an issue, understanding the AWP was still difficult and abstract. One suggestion was to use a similar application form as employed by Horizon 2020. Though a couple of NFPs stated that guidelines had become less complicated over time, most agreed that there was substantial room for improved accessibility.

Extent to which Programme application and procedures have been simplified

Some NFPs had experience in the implementation of HP actions (specifically joint actions) and were able to provide comments on the procedures involved. Interviewees saw significant hurdles in the start-up of the action as well as through its lifetime. Interviewees also highlighted the importance of joint actions building on previous work as an important success factor increasing its ambition and impact.

The main criticisms voiced by interviewees were:

- **Action budgets were perceived as inflexible with cost categories overlapping** (e.g. travel and subsistence) and little variation allowed against cost categories running the risk that costs will not be refunded;
- Most action participants were public bodies and since **Value Added Tax was a non-eligible cost, they needed to use their own budget to cover the expenses**;
- **Work plans were inflexible** resulting in having to deliver outputs agreed at the proposal stage with little regard to emergent findings and evidence based delivery; this also dis-incentivises organisations from aspiring to achieve ambitious targets, as they don't want to run the risk (financial/reputational) of not achieving them.

Finally, a number of interviewees described how the time to respond to Chafea requests was too short, for example to comply with certain requests NFPs would have to drop all other tasks. As such, **Chafea's expectations were described as unrealistic**; the role of NFP was only a small part of the representative's workload. As one interviewee put it: "There is some **disconnect and unrealistic expectations from the EU level, Chafea, all the way down to NFPs**. Expectations are unrealistic from a resource, infrastructure and logistical perspective…"

Recruitment of beneficiaries/ impact of geographical balance

There was awareness among interviewees that DG SANTE and Chafea were aiming to **improve the involvement of newer MS and increasing the emphasis on joint actions**. Interviewees acknowledged this as reasonable and **a good way of achieving "clear European added value".**

There was however awareness that involving new MS was at times difficult. As one interviewee commented "It's not always easy because they [newer MS] do not always have **the capacities or possibilities to lead or participate"**. It was seen as a balancing act of not discouraging "new-comers" but also maintaining high quality results and ensuring the capacity to deliver. Similarly, countries with more experience working with EU projects were believed to benefit more because of greater capabilities and resources.

Another point raised by some interviewees was that the older EU countries received most of the leading roles in actions. Many proposals were described as already having assigned the core roles before other MS were invited to participate. This effectively prevented EU12 countries who don't have already established professional links to the leading countries from contributing important functions. One interviewee suggested that if Chafea wanted to increase participation they would need to take more risks with funding and possibly provide extra support when more inexperienced countries took the lead on actions.

Similarly, several interviewees **believed that the focus on joint actions was more beneficial for bigger organisations with more experience and expertise**. They argued that the composition of beneficiaries would largely stay the same, funding would go to those who are well known, have the expertise, capabilities and experience of working with EU actions. One interviewee noted that even the AWP is addressed to

those with knowledge of EU policies. The AWP was described to be "self-selecting", since, to be able to access and understand it, potential applicants needed to be familiar with the institution and language. The same interviewee also argued that this was not necessarily an argument for increased EU12 participation. Requiring participants to have experience of the EU environment was a way of focusing actions and increasing the capacity to deliver.

One interviewee suggested that the **co-financing was problematic for the participation of competent authorities in joint actions**. In the case of Poland, budgets were usually prepared up to six months before the fiscal year which made it hard to plan co-financing expenditure without having a decision in place. This was also described as results of "procedures in Polish law" complicating the situation. Another reason given by interviewees was the preference of using structural funds and other aid programmes since they were perceived as less complicated in terms of documentation, accounting and reporting.

With regard to countries that receive less funding in general, interviewees had differing explanations; one interviewee described it in terms of a **"clash" between national health policy and the HP priorities.** Specifically, in one case, the HP was considered to be more focused on addressing health outcomes where the national health policy was more focused on health promotion and prevention. The wider point being that there was little alignment between HP priorities and recipient national health policy targets and research priorities, precluding economies of scale and synergy opportunities.

Finally, we also heard that some actors were "intimidated" by the administration required without enough reward; potential participants were described as seeing greater value in pure research funding since it didn't require co-financing.

Effectiveness of shift towards joint actions and service contracts

The majority of NFPs were very positive towards joint actions. Newer MS especially felt that they provided an opportunity for competent authorities to actively participate and to play more of a leading role. Language was however still described by some interviewees as a barrier to participation.

Interviewees also described how the subjects of joint actions were more high profile, especially since NFP's own institutions were often involved. In turn, joint action results were more widely acknowledged by the policy making institutions, increasing their potential policy impact. As one interviewee put it: "The **focus on joint actions is appreciated since many other actions didn't reach Ministry of Health**, which is where policy is actually determined. Eastern and southern countries were also better represented in these too."

Another key benefit described by interviewees of joint actions was the value of having governments' committing resources to a field of work and creating the necessary stability to progress key issues for an extended period of time.

There was however awareness that the **shift towards joint actions resulted in winners and losers in terms of funding**. The main target of joint actions was considered to be government agencies and other larger national actors which inevitably led to "smaller players" not being able to participate. In some cases interviewees noted that these "smaller players" were the ones in most frequent contact with NFPs, looking for funding opportunities. For example, projects were described as a useful avenue to explore ideas and build an evidence base for future actions (and these have decreased over the course of the HP). Interviewees did however acknowledge projects had their own drawbacks for example, they were not always focused and the results were (at times) poorly communicated.

Operating grants and service contracts were not discussed in great depth by interviewees. In regards to **operating grants**, interviewees **from EU12 countries expressed concerns** that national non-governmental organisations (NGOs) were **not eligible since they were not active in half of the MS**. This was perceived to result in NGOs from more established EU countries being the primary beneficiaries of operating grants.

In terms of service contracts, not many interviewees had much experience in dealing with the funding mechanism. Although not representative of opinions in general, we heard concern from one NFP regarding the accessibility of information on service contracts, which was described as "less clear" than information on Calls for proposals on projects.

Programme dissemination

Interviewees found dissemination particularly challenging, especially from a time and resource perspective and in relation to the expectations from Chafea. To this effect, some interviewees suggested that there should be a more strategic and coordinated approach to dissemination at a national level. Especially among different agencies and other stakeholders involved that were not perceived to coordinate communication activities effectively. Other interviewees confirmed that regional events involving neighbouring countries were useful from a dissemination perspective. Language barriers were commonly cited as presenting difficulties for NFPs in their attempt to disseminate information (which is generally in English) on calls for proposals as well as results and findings.

Several interviewees also noted how there was a lack of awareness of who was actually involved in actions and what progress was being made. The information flow from Chafea and the Programme Committee was not always smooth and the usefulness of the Chafea database was also limited.

Extent to which results are accessible to stakeholders

Most NFPs reported using a standard set of tools and channels such as national information days, email lists and websites to publicise results, calls for proposals and to reach stakeholders.

Many interviewees reported their role in disseminating information was their main challenge. As one interviewee explained: "The main challenge in my NFP role is the difficulty to reach all the target groups… We are doing our best but our resources are too limited to reach the millions of stakeholders we have." With regards to reaching stakeholders, some of the NFPs from new MS reported how there was little contact with NGOs in general, indeed the only contact was through the annual information days. The opposite was reported true for Nordic countries, who reported a high interest from NGOs.

NFPs pointed out that there remains a lack of awareness about the role that they play among stakeholders in their country. Furthermore, several NFPs highlighted the fact that they did not have "stakeholder networks" in place (these were described as taking significant time to develop). As such, the expectations placed on NFPs from Chafea in this regard were thought to be slightly unrealistic by interviewees, especially in light of NFP coordination duties often being a smaller part of their workload.

Moreover, one interviewee suggested that there might be a need for a **strategic coordination of dissemination at the national level, possible through ministries.** Especially since in the bigger actions there could be several agencies involved. In addition, the same interviewee argued that there was no real guidance on "what makes good dissemination" or standardised dissemination mechanisms across actions, since there were a multitude of actors involved.

Interviewees also raised the issue of **not "being in the loop"**, with a lack of awareness of who actually was involved and what progress was being made in funded actions on a national level. Similarly, interviewees also expressed confusion in regards to the communication between Programme Committee and NFPs, where information was not always passed on, with the flow of information being unsatisfactory. One interviewee raised the need for NFPs to be part of the meetings with the Programme Committee to get a better idea of the policy development in the HP. This was also reported to be the case in little under half of the Member States.

Regional coordination of dissemination activities among NFPs was **experienced as highly effective**. By pooling resources, networking and framing the issues in a regional context dissemination was considered more effective. For example, Nordic NFPs had regular high-level meetings (including officials from the Ministry of Health) to disseminate results and Slovakia, Czech Republic, Hungary and Poland had an conference on rare diseases where relevant actions could present results.

Finally, an issue raised by several interviewees was that **language was at times a significant barrier.** Getting stakeholders engaged was difficult since in some countries if outputs were in English only. One of the roles as an NFP was described by an interviewee as, "translate" information produced by DG SANTE and Chafea.

Usefulness of Chafea database

A number of interviewees raised the issue of improving the Chafea database, highlighting the importance of increased functionality, including:

- The need for not only names of partners participating in actions to be available but the **actual contact details of the person leading the action for each institution;**
- **Ability to do a partner search**; having credentials, interests and contact details so coordinators for projects can match with partners;
- **Make use the database as a dissemination tool**, including updates on progress in actions, list of stakeholders and dissemination methods.

Impact of the Programme

Interviewees struggled with giving concrete examples of how the Health Programme had direct impact on their national health policy. The joint action on cancer, European Partnership for Action against Cancer[39], was mentioned several interviewees as being particularly successful. As one interviewee put it: "Impact on National Health Policy is difficult to attribute, but for example cancer; we have a national strategy on this. Through our participation in the joint action for cancer [European Partnership for Action Against Cancer], it helped us to implement some of the objectives of our strategy."

The success of the joint action on cancer was largely explained by the previous widespread cooperation and expertise available in the field. To this extent, interviewees perceived that joint actions were more likely to impact policy, especially since the competent authorities is where "policy is determined". Furthermore, interviewees noted that involving MS and competent authorities was a good way of increasing access to EU policy development information and cooperation between states, and that joint actions worked on "higher level" compared to other actions. As a result, joint actions were reported to give a more tangible connection to European issues and a sense of cohesiveness around shared challenges.

[39] http://www.siope.eu/activities/eu-projects/european-partnership-for-action-against-cancer-epaac/

Interviewees were also aware that progress was different for different health policy areas which affected the potential impact actions could have. As one interviewee put it: "We are not at the same state of the art in all topics, quite different levels of expertise and cooperation in different areas."

Interviewees with experience of joint actions also noted **that the information and knowledge sharing was one of the greatest benefits**. In addition, understanding the complexity of being part of an EU project was especially useful in their role as NFP. It being an "issue in itself"; transferring the results to the national context and being able to navigate the different requirements imposed.

The cooperation between MS through joint actions was also emphasized by interviewees, suggesting that **involving more MS resulted in economies of scale, pooling of resources with results that could benefit all MS**. As one interviewee put it: "The benefits of the Health Programme are drawing attention to common EU health issues, fostering collaboration, shared learning and networking." It is also an opportunity for Member States and Ministries of Health to collaborate on concrete measures. Interviewees noted that finding these "common problems" that have wide applicability was an easy argument for European collaboration, which also made for an easy intervention logic.

Finally, less tangible but still important, a few interviewees emphasised the creation of a "European atmosphere" among participants.

What factors intervene to influence the impact of the Programme

The interviewees were asked about barriers that influenced the impact of the HP. Continuing difficulties were felt to exist in the **alignment between national health policies and the priorities in the HP**; and, in general, the **overall budget available**.

In regards to the alignment between HP and national health policies, interviewees did not perceive a clear connection. Though joint actions provided a "bridge", this is one of many funding mechanisms and the link should be more consistent across all types of actions. A similar criticism was that interviewees **didn't see a clear connection from the broad topics described in the regulation to the individual priorities.** Rather, this was seen as a reflection of the Commission's priorities.

Some interviewees also described how they felt a **lack of involvement and cohesiveness**, with both the Commission (Chafea and DG SANTE) and fellow NFPs. There were several suggestions to improve this, including: the use of webinars, regular workshops to understand the AWP and having regular "catch-up" sessions with Chafea and well as networking events for NFPs to improve their relationships.

Synergies

Several interviewees gave suggestions on how to exploit potential synergies:

- One avenue suggested to increase synergies across research programmes was **establishing a clear link to Horizon 2020**, so innovative results could be directly implemented through the HP;
- **Increased cooperation with DG Research** was suggested as a means to avoid overlap in actions and research. Interviewees also noted that there might be possible synergies implementing results from Horizon 2020 projects through the HP; and

There was some evidence that different programmes were also competing over limited resources of NFPs and applicants. For NFPs this was particularly true when covering several research programmes, in these cases it was the HP which received less priority

due to the size of the funding available. The same was reported for applicants, who were more interested in applying to research programmes since it was where the most funding was available and was perceived as less complicated.

5. BIBLIOMETRIC ANALYSIS

Bibliometric analysis techniques were used to evaluate the dissemination of the results of HP actions specifically via scientific publications. The analysis followed a three-step approach: (1) sample selection, (2) identify relevant articles, and (3) assess their visibility / impact in terms of citations.

Step 1

To prepare the ground for the bibliometric analysis, we screened (as part of the in-depth review, see annex 8) a sample of 80 actions for their potential / likelihood of resulting in scientific publications.[40] Based on this we selected 25 actions, and (in agreement with DG SANTE) added five further actions that were not included in the original sample of 80 but appeared particularly interesting / relevant for inclusion in the analysis. Thus, the final sample for the bibliometric analysis included 30 actions, of which eight were joint actions and 22 projects.

Step 2

We then undertook a series of systematic searches on PubMed[41] to identify relevant articles for each of these actions. After testing different search strategies and terms, and following consultation with DG SANTE, the following approach was used:

1. Definition of search terms for each action: We used key words related to the subject, the names of the most likely authors (namely the action coordinator and the leaders of the non-horizontal work packages[42]), and the action timeframe, connected with Boolean operators (AND/OR) as per the table below.

2. Systematic searches: Using the terms below, we ran the searches and recorded all hits in a database.

3. Search for acronyms: We also ran a separate search for the acronym of each action, and recorded the relevant[43] results separately.

4. Screening of results: We then manually screened the results in order to determine whether it seemed likely they resulted directly or indirectly from the respective HP-funded actions. For this, we considered the first names / initials of the authors, and the content of the articles based on their titles and, where available, abstracts.

[40] The criteria used for judging the potential / likelihood of actions resulting in scientific publications included (1) a strategic focus on research (at least partly); (2) the involvement of academic and research partners; (3) the subject matter and stated objectives of the action; and (4) information on (planned) publications found on the action website and/or CHAFEA database.

[41] PubMed comprises more than 24 million citations for biomedical literature from MEDLINE, life science journals, and online books. URL: http://www.ncbi.nlm.nih.gov/pubmed/

[42] Please note: To identify the names of the WP leaders, we had to contact the action coordinators, as this information is not centrally held by CHAFEA. 28 of the 30 actions got back to us and provided names; the other two failed to respond, and could therefore not be included in the analysis.

[43] Please note: Some action acronyms are common words or terms, such as "PHASE" or "MODE". Searching for these terms resulted in a very large number of hits, which were discarded since they were clearly irrelevant.

Table 13: Criteria for searching for articles resulting from selected HP actions on PubMed

Criterion	Subject	Authors	Timeframe
Search terms	Two to three key words taken from action title, plus up to one synonym per word (where necessary), connected with AND / OR as appropriate	Last names of up to a maximum of ten potential authors, namely the action coordinator and relevant work package leaders, connected with OR	From 1 January of the year after the year in which funding was awarded, until 1 September 2014
Search field	Title/Abstract	Author	Date – Publication

It should be noted that this represented the most robust approach possible given the circumstances, but the results are subject to certain limitations:

- The list of potential authors that was included is not comprehensive. In some cases, it seems likely that participants other than the WP leaders published articles. However, within the confines of the evaluation it was not possible to assemble a comprehensive list of all participants for each action, so the use of only WP leaders represents a pragmatic and systematic approach that is replicable in the future, although the results are not comprehensive.

- The screening of articles for their relevance necessarily involved an element of subjectivity. In many cases it was clear beyond a doubt that articles were directly related to the action in question, but in many others it was less obvious. In these cases, the key question we asked to judge the relevance was whether it appeared likely, based on the content of the article and the author(s), that it was at least partly inspired by the HP-funded action.

In total, we identified 151 relevant articles, as shown in the table below. More details, including the search terms that were used as well as the results of the analysis for each individual action, are presented overleaf.

Table 14: Scientific publications by a sample of HP-funded actions

Action type / strand		Number of actions reviewed	Actions for which at least 1 publication was found	Total publications	Avg. publications per action
By funding instrument	Projects	21	13	103	4.9
	Joint Actions	7	6	48	6.9
By strand	Health Security	8	6	29	3.6
	Health Promotion	16	10	77	4.8
	Health Information	4	3	45	11.3
All actions		**28**	**19**	**151**	**5.4**

Table 15: Search terms and results of the article search per HP-funded action

Action			Search terms			Hits using search terms			(D) Relevant hits for acronym only	Total relevant hits (B+D)
Acronym	Instr.	Project	Subject	Authors	Timeframe	(A) No. of hits on PubMed	(B) of which classified as relevant	(C) of which included acronym		
PROMISE	PJ	Promoting Mental Health Minimising Mental Illness and Integrating Social Inclusion through Education	Mental AND (health OR illness) AND education	Ryan OR Plette OR Machin OR Urek OR Greacen OR Flores	2009/01/01 to 2014/09/01	14	0	0	0	0
INEQCITIES	PJ	Socioeconomic Inequalities in Mortality: evidence and policies in cities of Europe	Inequalities AND (cities OR urban) AND (Europe OR European)	Borrell OR Saez OR Hoffmann OR Kovács	2009/01/01 to 2014/09/01	26	8	2	0	8
EUMUSC.NET	PJ	European Musculoskeletal Conditions Surveillance and Information Network	Musculoskeletal AND (conditions OR issues)	Woolf OR Erwin OR Smolen OR Stamm OR Stoffer OR Petterson OR Vlieland OR Uhlig OR Moe	2009/01/01 to 2014/09/01	12	2	0	5	7
Climate-TRAP	PJ	Climate Change Adaptation by Training, Assessment and Preparedness	Climate AND change AND (training OR preparedness OR assessment)	Van den Hazel OR Moshammer OR Forsberg OR Böse OR van Loenhout	2009/01/01 to 2014/09/01	2	2	0	0	2
DOVE	PJ	Domestic violence against women/men in Europe: prevalence, determinants, effects and policies/practices (DOVE)	Domestic AND (violence OR abuse)	Barros OR Sundin OR Lindert OR Torres-Gonzáles OR Toth OR David OR Verhaegen	2009/01/01 to 2014/09/01	2	0	0	0	0
EURO-GBD-SE	PJ	The potential for reduction of health inequalities in Europe	Health AND inequalities AND (Europe OR European)	Mackenbach OR Hoffmann OR Menvielle OR Judge OR Lundberg OR Martikainen OR Eikemo OR Costa	2009/01/01 to 2014/09/01	43	32	3	5	37
Vintage	PJ	Good health into older age	Health AND age	Scafato OR van Schayck OR Colom	2009/01/01 to 2014/09/01	14	4	3	0	4

Action			Search terms			Hits using search terms			(D) Relevant hits for acronym only	Total relevant hits (B+D)
Acronym	Instr.	Project	Subject	Authors	Timeframe	(A) No. of hits on PubMed	(B) of which classified as relevant	(C) of which included acronym		
RDTF Scientific Support	JA	Scientific support to the Rare Disease Task Force activities	Rare diseases	Aymé OR Fregonese OR Devereau	2009/01/01 to 2014/09/01	10	1	0	0	1
Healthy children	PJ	Healthy children in healthy families	Healthy AND children AND (families OR parents)	Hansen OR Holstein OR Atkinson OR Larsen OR Sobotik-Paven	2010/01/01 to 2014/09/01	7	0	0	0	0
RDPortal2	PJ	Development of Orphanet: The Rare Diseases Portal	(Orphanet OR portal) AND rare diseases	Aymé	2010/01/01 to 2014/09/01	2	2	0	0	2
IMPLEMENT	PJ	Implementing Strategic Bundles for Infection prevention and Management	Infection AND prevention AND management	Frank OR Borg OR Lambert OR Tacconelli OR Wollersheim OR Schumacher	2010/01/01 to 2014/09/01	7	3	1	0	3
COORENOR	PJ	Coordinating a European initiative among national organizations for organ transplantation	(European OR Europe) AND organ AND (transplantation OR transplant)	Costa OR Font-Sala OR Rowiński OR Brezovsky	2010/01/01 to 2014/09/01	4	2	0	0	2
Daysafe	PJ	Improving Patient Safety of Hospital Care through Day Surgery	Patient safety AND (surgery OR hospital)	Bellentani OR Lemos OR Bontemps OR Toftgaard OR VanOutryve	2010/01/01 to 2014/09/01	0	0	0	0	0
NANOGENOTOX	JA	Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard	(Nanomaterials OR nanotechnology OR nanoparticles) AND (safety OR evaluation OR hazard)	Elreedy OR Jensen OR Norppa OR Fessard OR De Jong	2010/01/01 to 2014/09/01	10	6	0	0	6
EUnetHTA JA	JA	European Network for Health Technology Assessment (JA1)	European AND (HTA or health technology)	Kristensen OR Lampe OR Goettsch OR Mertens OR Meyer OR Wild	2010/01/01 to 2014/09/01	10	9	2	1	10

Action			Search terms			Hits using search terms			(D) Relevant hits for acronym only	Total relevant hits (B+D)
Acronym	Instr.	Project	Subject	Authors	Timeframe	(A) No. of hits on PubMed	(B) of which classified as relevant	(C) of which included acronym		
PHASE	PJ	Public Health Adaptation Strategies to Extreme weather events	Public health AND (weather OR climate)	Michelozzi OR Murray OR Bone OR Maesano OR Katsouyanni OR Forsbery	2011/01/01 to 2014/09/01	15	6	0	0	6
YouthSexualViolence	PJ	Understanding and addressing youth sexual coercion and violence as a threat to young people's sexual health in Europe	Sexual health AND (youth OR young) AND (coercion OR threat OR violence)	Vanwesenbeeck OR Krahé OR Diesen	2011/01/01 to 2014/09/01	59	0	0	0	0
EuroHeart II	PJ	European Heart Health Strategy II	(Europe OR European) AND health AND heart	Kestens OR Rayner OR Capewell OR Critchley OR Logstrup OR Gabriel	2011/01/01 to 2014/09/01	5	2	0	0	2
EPAAC	JA	European Partnership for Action Against Cancer	(Europe OR European) AND cancer	Krnel OR Lipuscek OR Yared OR Anttila OR Borras OR Van den Nucker OR Sant OR Albreht	2011/01/01 to 2014/09/01	30	18	1	2	20
MODE	JA	Mutual Organ Donation and transplantation Exchanges: improving and developing cadaveric organ donation and transplantation programs	Organ AND (transplantation OR donation)	Costa OR Brezovsky OR Matesanz	2011/01/01 to 2014/09/01	46	10	2	0	10
RARECARENet	PJ	Information network on rare cancers	Information AND rare AND (cancers OR cancer)	Gatta OR Capocaccia OR De Angelis OR Siesling OR Licitra OR De Lorenzo	2012/01/01 to 2014/09/01	8	7	6	9	16
TACTICS	PJ	Tools to Address Childhood Trauma, Injury and Children's Safety	(Childhood OR children) AND (trauma OR injury OR safety)	Vincenten OR McKay OR Rigby OR Lyons OR Brand	2012/01/01 to 2014/09/01	17	0	0	0	0
BISTAIRS	PJ	Good practice on Brief Interventions in the Treatment of Alcohol use disorders In Relevant Settings	Alcohol AND (intervention OR interventions)	Reimer OR Anderson OR Gual OR Scafato	2012/01/01 to 2014/09/01	17	8	0	0	8

Action			Search terms			Hits using search terms			(D) Relevant hits for acronym only	Total relevant hits (B+D)
Acronym	Instr.	Project	Subject	Authors	Timeframe	(A) No. of hits on PubMed	(B) of which classified as relevant	(C) of which included acronym		
Parent	JA	Cross-Border Patient Registries Initiative	(Cross-border OR international) AND patient AND (registries OR registry)	Meglic OR Pristaš OR Zalatel OR Doupi	2012/01/01 to 2014/09/01	1	1	1	0	1
ICARE4EU	PJ	Innovating care for people with multiple chronic conditions in Europe	Care AND multiple chronic	Rijken OR Schellevis OR Rissanen OR Melchiorre OR Busse OR Ginneken	2013/01/01 to 2014/09/01	0	0	0	0	0
HEPCOM	PJ	Promoting healthy eating and physical activity in local communities	(Overweight OR obesity OR obese) AND (children OR young people)	Buijs OR Paulus OR Felder-Puig OR Jourdan OR Simovska	2013/01/01 to 2014/09/01	0	0	0	0	0
BENCH-CAN	PJ	Benchmarking comprehensive cancer care that provides interdisciplinary treatment for patients, and yield examples of best practice in comprehensive cancer care	Cancer AND care	Lombardo OR van Harten OR Kasler OR Nefkens OR Saghatchian	2013/01/01 to 2014/09/01	12	6	0	0	6
SHIPSAN ACT	JA	The impact on maritime transport of health threats due to biological, chemical & radiological agents, including communicable diseases	(Maritime OR ship) AND transport AND health	Hadjichristodoulou OR Martinez OR Davidson OR Pirnat OR Otorepec OR von Munster OR Lavruvianec	2013/01/01 to 2014/09/01	1	0	0	0	0
					Total	**374**	**129**	**21**	**22**	**151**

Step 3

The third and final step consisted of a search for citations of a sub-sample of the relevant articles to determine their visibility / impact.

For this, we selected 11 out of the 28 HP-funded actions that were used for step 2. This included all eight actions for which we had found a medium number of relevant publications (between six and ten), as well as one action with a very high number (20), and two with a low number (one or two). This resulted in a good coverage of funding instruments (six projects, five joint actions) and Health Programme strands (six actions on health promotion, three on health security, and two on health information)

The search for citations was carried out via Web of Science.[44] A separate search had to be conducted for each of the 84 articles related to the 11 actions. The results are shown in the table below. 57% of all articles we identified were cited at least once. Of these, around a quarter can be classified as relatively impactful based on their h-index of 3 or higher.[45] Six out of the 11 actions in the sample had at least one such article. This suggests a reasonable amount of coverage and visibility overall, although it should also be noted that this varies very significantly from action to action.

Table 16: Citation analysis of a sample of relevant articles

Action Acronym	Instrument	Strand	Year funding awarded	Relevant articles found on PubMed	Articles with 1 or more citations	% articles cited	Total number of citations	Number of articles with h-index of…			Citations per article	Citations per *cited* article
								5 or higher	3 or higher	1 or higher		
EPAAC	JA	HP	2010	20	8	40%	108	0	2	7	5.4	13.5
EUnetHTA JA	JA	HP	2009	10	5	50%	30	0	2	5	3.0	6.0
MODE	JA	HS	2010	10	9	90%	121	3	4	7	12.1	13.4
BISTAIRS	PJ	HP	2011	8	2	25%	10	0	0	2	1.3	5.0
INEQCITIES	PJ	HP	2008	8	6	75%	16	0	0	3	2.0	2.7
EUMUSC.NET	PJ	HI	2008	7	5	71%	35	0	1	4	5.0	7.0
BENCH-CAN	PJ	HP	2012	6	2	33%	7	0	0	1	1.2	3.5
NANOGENOTOX	JA	HS	2009	6	5	83%	62	1	3	4	10.3	12.4
PHASE	PJ	HS	2010	6	4	67%	16	0	0	3	2.7	4.0
RDPortal2	PJ	HP	2009	2	2	100%	29	1	1	2	14.5	14.5
PARENT	JA	HI	2011	1	0	0%	0	0	0	0	0.0	N/A
Totals				**84**	**48**	**57%**	**434**	**5**	**13**	**38**	**5.2**	**9.0**

[44] Thomson Reuters (formerly ISI) Web of Science is a subscription-based multidisciplinary research platform. URL: http://thomsonreuters.com/thomson-reuters-web-of-science/

[45] The h-index (named after its inventor Jorge E. Hirsch) is an attempt to measure both the productivity and the citation impact of a published body of work. Put in simple terms, articles with an h-index of 3 or higher were cited by at least three articles, each of which in turn was cited at least three times by other articles.

6. ANALYSIS OF HP PARTICIPATION RATES AND PUBLIC HEALTH CAPACITY

One of the issues the evaluation was tasked to explore was the relationship between HP participation, relevant publications, and the public health capacity of Member States, to identify any patterns that may exist, and assess to what extent these have been – or could be – addressed via relevant dissemination activities.

Detailed data on **HP participation patterns** is shown in Annex 2. It suggests that the participation of different (groups of) Member States varies considerably, and that the concerns around the participation of organisations from "new" Member States have only partly been addressed. We therefore set out to investigate further where differences in participation rates come from, and how they might best be addressed going forward.

It should be emphasised that "**public health capacity**" is not an easy concept to pin down, and there is no widely accepted practical way of measuring it. We have therefore conducted desk-based research to identify potentially relevant indicators in a number of areas[46], and review and compile existing data from various sources. This data has been assessed and tested for correlations between the different indicators and HP funding awarded to different participating countries by both DG SANTE and the evaluation team. The initial results were somewhat inconclusive, partly because of the small sample size of only 27 observations (countries).

Nonetheless, when **certain adjustments** are made, potentially interesting patterns do begin to emerge. We have adjusted the HP funding data as follows:

- **Degressively proportional approach**: Rather than per capita funding, we have based the analysis on funding per square root of population size. This is based on the assumption / expectation that, due to the nature of the HP, and the desire to involve all participating countries, funding should be roughly "degressively proportional to population size". This means that the size of countries does matter (so that for instance Germany can be expected to receive more funding than Malta), but not quite in proportion with the size of their populations (i.e. we would not expect Germany to absorb almost 200 times as much funding as Malta). Similar considerations are used to determining the number of MEPs per country. Based on using the square root of the population, we would expect Germany to receive approximately 14 times more funding than Malta. We would like to emphasise that this is not an exact formula for determining what distribution of funds would be "natural" or "desirable", but it provides a useful starting point for the analysis – certainly more useful than absolute amounts (which unsurprisingly show that large MS benefit the most) or per capita amounts (which favour small MS, and would mean that all of the larger MS are under-represented).

- **Exclusion of some funding instruments**: The analysis of HP funding data reveals that the way the funding for some instruments is distributed among beneficiaries from different Member States is highly irregular, and responds to considerations that seem to have very little to do with national public health capacity.[47] Therefore, we have run the further analysis based on the funding

[46] These included wealth (GNI / GDP), health research spending, health publications, health expenditure, healthcare resources, health outcomes, and healthcare performance.

[47] The reason for the omission of the other funding instruments (service contracts, operating grants, and presidency conferences) is that the funding patterns are highly irregular, and seem to respond more to specific considerations than to any possible measure of public health capacity:

only for projects and joint actions, which together represent 67% of all funding that is attributable to a MS (Direct Grants to international organisations are not).

Having made these adjustments, we analysed the correlation between the resulting funding patterns for the 27 EU Member States[48] with various potential indicators of public health capacity.[49] The full results (in the form of scatter diagrams) are shown the diagrams below. Interestingly, we can observe a **relatively strong correlation** (confirmed by the R squared values[50]) between funding patterns and indicators related to health *research*, and (to a slightly lesser extent) healthcare systems. All of these provide a better correlation with HP funding than the Gross National Income (GNI). The best correlation is with the number of health publications. This suggests that health research capacity in particular does affect the extent to which countries are able to benefit from HP funding.

- Service contracts (17% of HP funding): More than half (55%) of the funding for service contracts went to entities established in Belgium. 17% went to the UK, and 8% to France. Less than 2% went to EU-12 Member States.
- Operating grants (8% of HP funding): 59% of the funding went to entities based in the Benelux countries; 23% went to France. Not a single beneficiary of an operating grant was based in an EU-12 country.
- Presidency conferences (less than 1% of HP funding): The funding patterns for these respond to which Member States happened to hold the EU Council Presidency during the period in question, rather than any other considerations.
- (Non-Presidency) conferences (2% of HP funding: Such conferences are no longer eligible for funding under the 3rd HP. We chose to omit them in order to focus attention on funding instruments and patterns that remain relevant going forward.

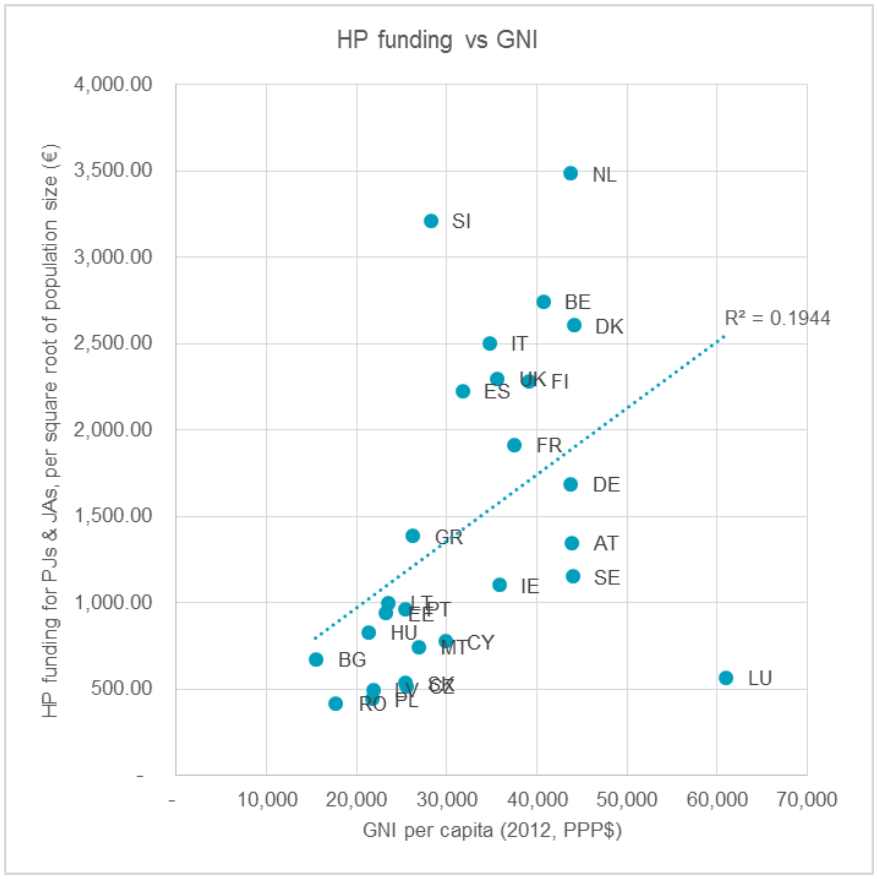
[48] Croatia was not included in this analysis because it only became an EU member in 2013, at the very end of the funding period. Although it participated in the HP since 2008, its status as a non-member of the EU may have led to lower than usual participation rates, and thus skew the analysis.

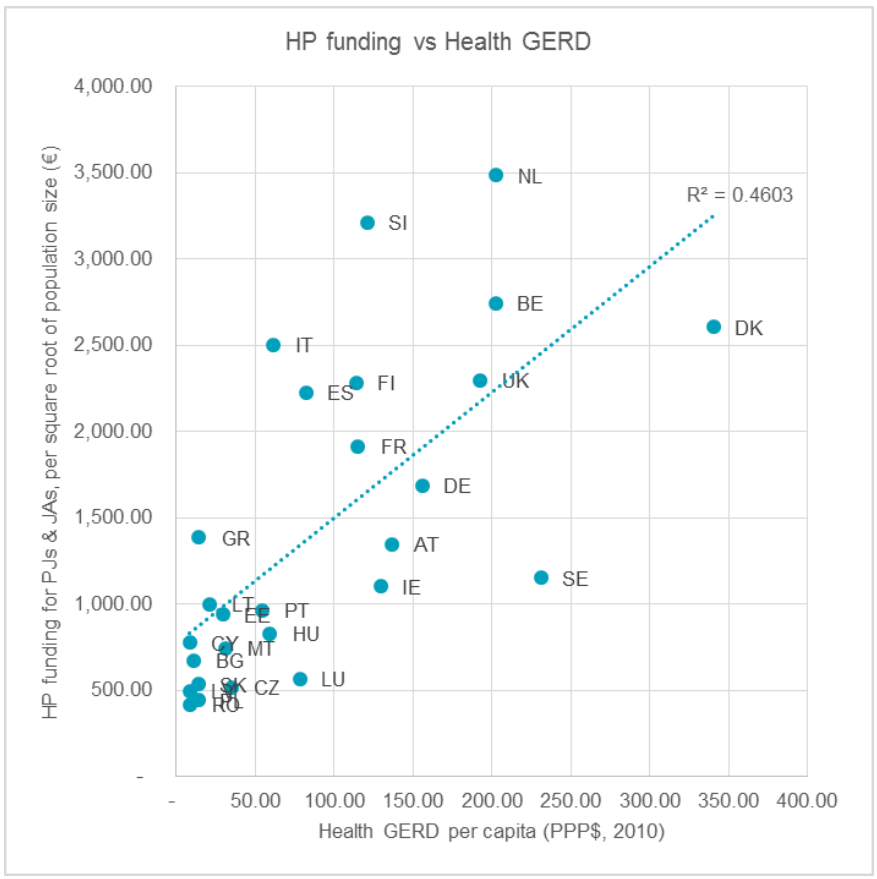
[49] These indicators were:

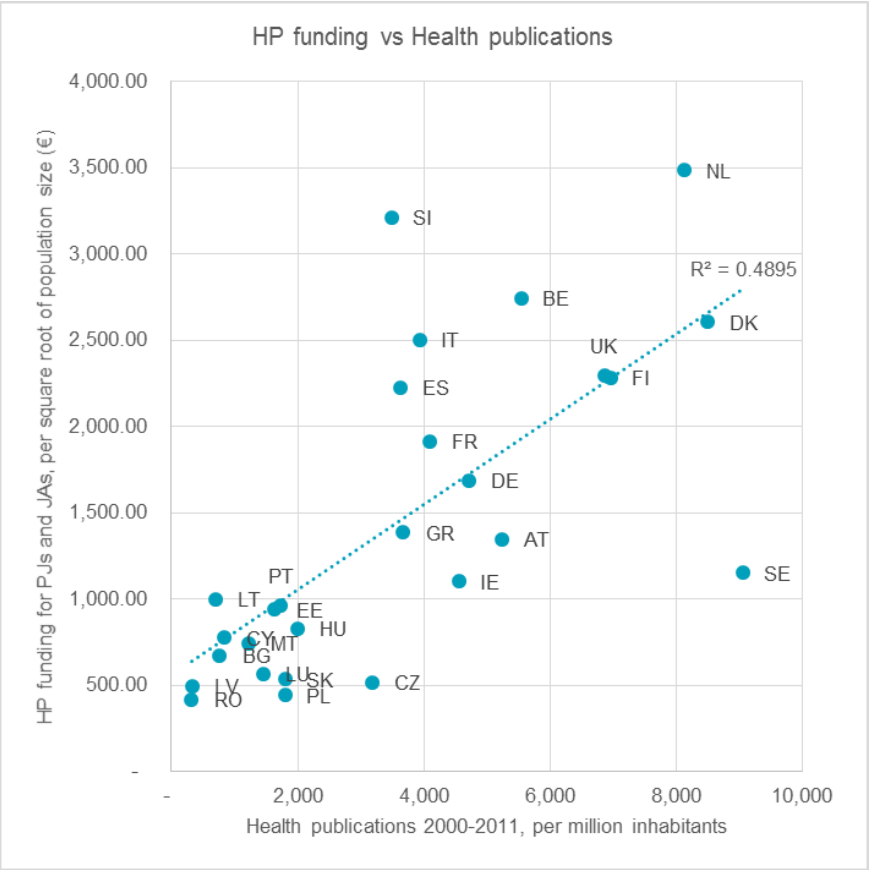
- Gross National Income (source: World Bank)
- Health GERD (source: Rottingen J et al: Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory? in The Lancet, Vol. 382, October 12, 2013)
- Health publications (source: Science Metrix Inc for DG RTD: Country and Regional Scientific Production Profiles. Luxembourg 2013)
- Health expenditure (source: OECD Health at a Glance 2012)
- Healthcare performance based on the EHCI score (source: Health Consumer Powerhouse)
- Number of medical doctors (source: OECD Health at a Glance 2012)

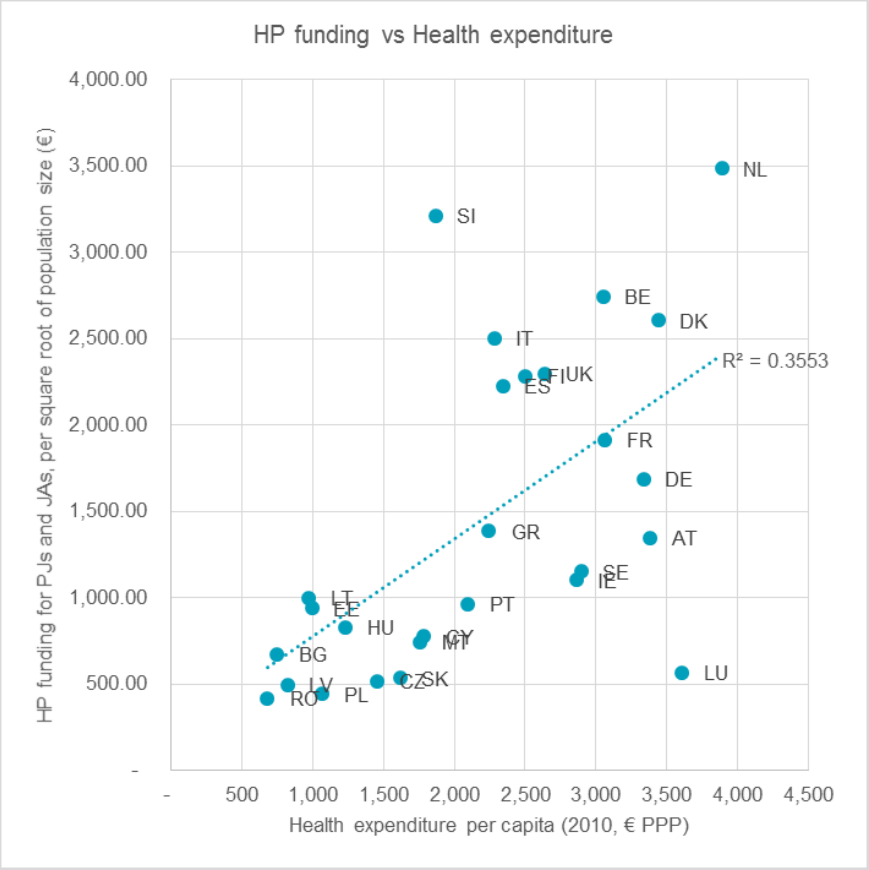
[50] R squared quantifies "goodness of fit". It is a fraction between 0.0 and 1.0, and has no units. Higher values indicate that the model fits the data better.

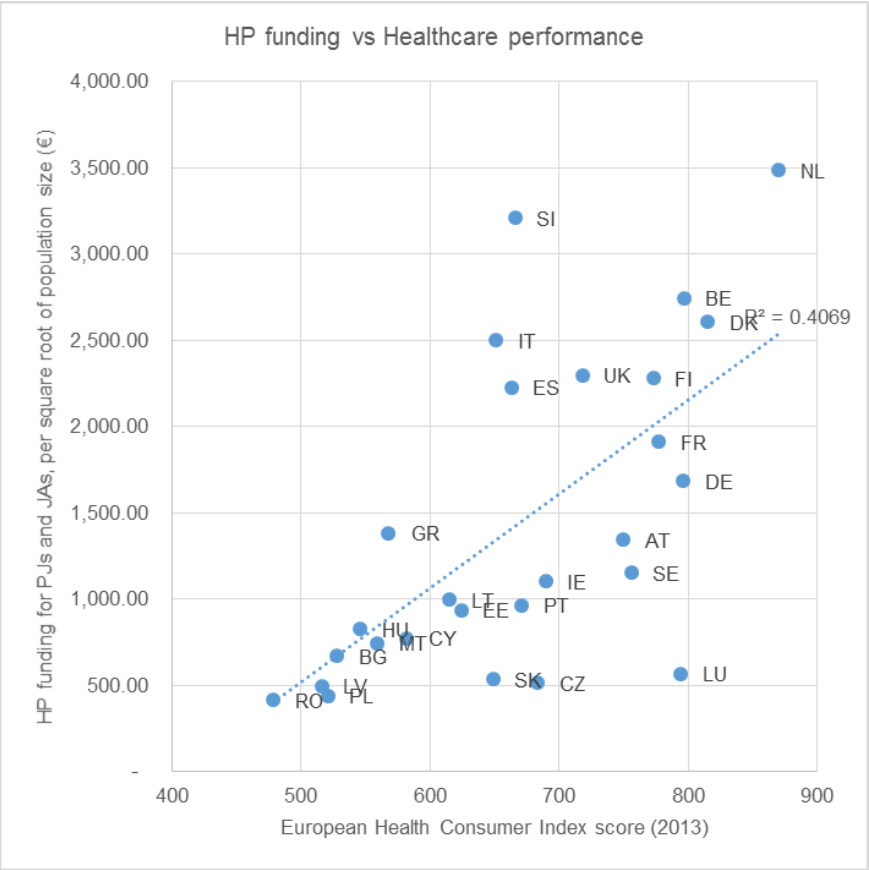
Figure 20: Correlation between HP funding and various measures of public health capacity

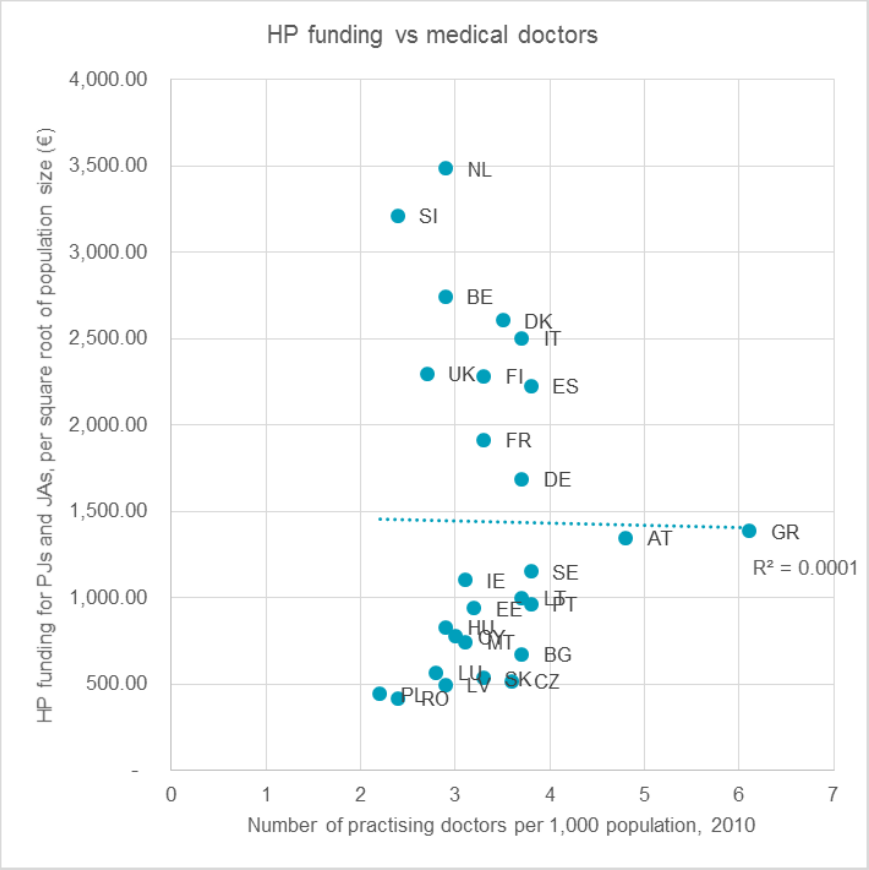





HP funding vs Health publications
HP funding for PJs and JAs, per square root of population size (€)
4,000.00
3,500.00
3,000.00
2,500.00
2,000.00
1,500.00
1,000.00
500.00
-
2,000
4,000
6,000
8,000
10,000
Health publications 2000-2011, per million inhabitants
R² = 0.4895
NL
SI
BE
DK
IT
UK
FI
ES
FR
DE
GR
AT
SE
IE
PT
LT
EE
HU
CY
MT
BG
LU
SK
CZ
LV
RO
PL


HP funding vs Health expenditure
HP funding for PJs and JAs, per square root of population size (€)
4,000.00
3,500.00
3,000.00
2,500.00
2,000.00
1,500.00
1,000.00
500.00
-
500
1,000
1,500
2,000
2,500
3,000
3,500
4,000
4,500
Health expenditure per capita (2010, € PPP)
R² = 0.3553
NL
SI
BE
DK
IT
FI
UK
ES
FR
DE
GR
AT
SE
IE
LT
EE
PT
HU
CY
MT
BG
LU
LV
CZ
SK
RO
PL


HP funding vs Healthcare performance
HP funding for PJs and JAs, per square root of population size (€)
4,000.00
3,500.00
3,000.00
2,500.00
2,000.00
1,500.00
1,000.00
500.00
-
400
500
600
700
800
900
European Health Consumer Index score (2013)
R² = 0.4069
NL
SI
BE
DK
IT
ES
UK
FI
FR
DE
GR
AT
SE
IE
LT
EE
PT
HU
MT
CY
BG
LV
RO
PL
SK
CZ
LU


HP funding vs medical doctors
HP funding for PJs and JAs, per square root of population size (€)
4,000.00
3,500.00
3,000.00
2,500.00
2,000.00
1,500.00
1,000.00
500.00
-
0
1
2
3
4
5
6
7
Number of practising doctors per 1,000 population, 2010
R² = 0.0001
NL
SI
BE
DK
IT
UK
FI
ES
FR
DE
GR
AT
IE
SE
LT
EE
PT
HU
CY
MT
BG
LU
SK
CZ
LV
PL
RO

The correlations detected in the analysis thus provide an (imperfect but nonetheless meaningful) explanation of different countries' HP participation rates. For example, the fact that Denmark manages to obtain relatively more funding from HP projects and joint actions than Greece is likely to be due at least in part to its higher health *research* capacity (as both countries lie very close to the trend line for HP funding vs Health publication). At the same time, the analysis suggests that some Member States absorb significantly higher amounts of HP funding than one would expect based on the various indicators (i.e. are situated well above the trend line), while others do less well (i.e. lie below). In very broad terms, **most EU-12 countries seem to benefit less** from the HP than would seem to correspond to them, but the same is true of several EU-15 countries.

In view of this, we proceeded by **focussing on the outliers**, i.e. those countries that lie the farthest from the trend lines (in other words, those cases where their health research capacity, as expressed by the number of publications and health research budgets, fails to explain their – particularly high or low – participation rates), and looked into other information on public health capacity, as well as factors that are specifically related to the HP, in order to attempt to identify the likely reasons behind this. Some of the countries that best fit this description – based on the correlations shown above –are:

- Member States that receive **more** HP funding than one would expect: Belgium, the Netherlands, Slovenia, Italy and Spain;
- Member States that receive **less** HP funding than one would expect: Sweden, Poland, the Czech Republic, Slovakia and Romania.

Potentially interesting observations on these countries – drawn from various data sets generated or reviewed for this evaluation – are summarised below.

Firstly, **data on funding applied for and received** for projects and JAs paints a somewhat diverse picture, but some interesting findings emerge:

- All of the most successful countries (in terms of funding levels that would seem to be in excess of their capacity) are very active participants in JAs, whereas the opposite is true of the least successful ones. Slovenia in particular stands out, as it has led three separate JAs, more than any other country except France and the UK (the coordinator in all three cases was the National Institute of Public Health Slovenia).
- As regards projects, the successful countries all have above-average success rates on the proposals they lead, with the exception of Italy, which makes up for its low success rate by submitting by far the highest number of proposals of all countries. On the other hand, the less successful countries submit few project proposals as lead partners, and when they do, their success rate is consistently below average.

Table 17: HP participation, selected countries

Country	Rank for project funding amounts*	% of all HP project applications	Project application success rate	Rank for JA funding amounts*	Number of JAs led
Belgium	5	5%	30%	3	1
Netherlands	1	7%	40%	7	1
Slovenia	7	2%	31%	1	3
Italy	2	25%	14%	6	2
Spain	4	11%	26%	10	2

** Rank among EU-27 MS, based on amounts per square root of population*

Country	Rank for project funding amounts*	% of all HP project applications	Project application success rate	Rank for JA funding amounts*	Number of JAs led
Sweden	10	3%	19%	21	0
Poland	24	3%	17%	25	0
Czech Republic	22	1%	0%	24	0
Slovakia	27	0%	0%	20	0
Romania	20	2%	0%	27	0

** Rank among EU-27 MS, based on amounts per square root of population*

This suggests that **low levels of engagement typically go hand in hand with low levels of capacity**. In other words, to help the worst performing MS to achieve higher levels of HP funding, one would need to address both their engagement (in terms of applying for funding, especially in a lead role) and their capacity to submit winning proposals.

Trying to identify reasons for the apparent lack of engagement and capacity based on **pertinent literature on EU MS' public health capacity** proved to be a relatively fruitless task. The potentially most interesting recent study in this respect[51] relied on expert judgments (with their inherent biases and limitations); rather than publish any rankings or scores, it only provides a list of strengths, weaknesses and recommendations per country. The diverse nature of these makes it very difficult to identify any significant commonalities; nonetheless, potentially relevant points include:

- The "high performing" MS all seem to have relatively well-developed public health institutions. However, the same is reportedly the case in some of the low performing MS, in particular Sweden.
- The high performing MS also tend to have explicit policies and objectives that make public health a priority. This seems to be the case to a much lesser extent in the less well performing countries, where the report notes issues such as:
    - Strategic planning for public health services has not been a government priority (Czech Republic);
    - Although policies for public health are in place, responsibilities are unclear and there are no funding schemes developed to implement the policies (Slovakia);
    - Public health policies, plans and regulations are rarely reviewed or revised to address changing trends in health priorities (Romania).
- There also seem to be problems with the public health workforce, in particular regarding a lack of strategies to guide its systematic development and deployment, and/or a definition of competencies and/or career paths, in most of the low-performing countries (including the Czech Republic, Poland, Slovakia and Sweden).

[51] Aluttis CA, Chiotan C, Michelsen M, Costongs C, Brand H, on behalf of the public health capacity consortium (2013). Review of Public Health Capacity in the EU. Published by the European Commission Directorate General for Health and Consumers. Luxembourg, 2013.

- When comparing the EU-12 MS, it is striking that health promotion and health determinants, including social determinants / health inequalities, seems to be a much higher priority in Slovenia than in any of the other "new" MS.

We also attempted to address the differences in HP participation levels and possible reasons behind these during the **interviews with NFPs and beneficiaries** (the latter as part of the case studies). Partly due to the small sample size, but also because most interviewees lacked a full appreciation of the public health landscape in their respective countries (much less other countries), this did not provide any conclusive evidence either. However, some interesting thoughts and views did emerge, in particular:

- Some interviewees noted that in many EU-12 MS, there is an insufficient division between the political and the technical levels, which often means that technical capacity in public health struggles to develop independently of political preferences and priorities, and that changes in government often lead to changes in leadership personnel and the structure of public health institutions, to the detriment of continuity (and thereby ability to build capacity, and be a reliable long-term partner in collaborative international projects).

- It was felt that the "success story" of Slovenia in terms of HP participation (especially in JAs) was at least partly due to the initiative of the National Institute of Public Health Slovenia, and of certain key individuals within it, who have made international collaboration a priority, and do not shy away from the exposure that comes with playing a leading role.

- In the case of Italy, the high level of activity in terms of submitting project applications seems to be a result of this being "pushed" relatively hard by the relevant national authorities, which have set targets in terms of the funding Italian organisations are meant to receive from different EU programmes (including the HP), and are quite active in pushing information about funding opportunities to potentially interested parties and providing support for applying.

- In the Swedish case, possible reasons offered for the low level of interest in the HP (in particular from relevant government organisations - cp. the low level of participation in JAs) included structural issues (lacking links between different potentially relevant Swedish actors), political issues (reportedly lack of convergence between Swedish and EU health policy in some areas), and the view that generous funding is available from Swedish sources, thus reducing the need for EU funding that is perceived as being tied to rather bureaucratic processes and requirements.

- In a few cases (including Poland), there was a suggestion that participation in EU projects can be seen as a burden by staff of relevant institutions, as it increases their workload without providing financial incentives. Furthermore, the lack of planning security was noted as a problem, as (annual) budgets often need to be prepared before a decision on project applications have been made. Complex national legal and accounting rules reportedly further diminish the attractiveness of EU funding through the HP.

- Finally, language was cited by several NFPs as a significant barrier to participation.

Overall, the picture that emerges is one of **various contributing factors, including issues related to capacity but also administrative / organisational culture**. It seems that the extent to which relevant national authorities "push" institutions or individuals in their respective countries and organisations to get involved varies

significantly. This may be the one key factor that rivals public health capacity as a determinant of success (in terms of funding levels) – simply put, where some see opportunities, others seem to see mainly problems and barriers.

7. STAKEHOLDER ANALYSIS

Introduction

There is long-standing recognition that health system reform (and by extension, the sorts of issues that are addressed by the HP) has both technical and political dimensions, and hence that data on stakeholder power, positions and interests is critical to effective policy- and decision-making. Stakeholder analysis, "an approach, tool or set of tools for generating knowledge about actors – individuals or organisations – so as to understand their behaviour, intentions, inter-relations and interests; and for assessing the influence and resources they bring to bear on decision-making or implementation processes" (Gilson et al, 2012), is the most commonly recommended analytical tool for gathering information on these issues.

As the impact and added value generated through the HP is dependent on the actions and activities of stakeholders in the MS, stakeholder analysis was undertaken to explore what different stakeholders brought to bear on the second HP and importantly, how their engagement could be strengthened in future through appropriate dissemination mechanisms. The analysis followed three key steps:

1. Identifying the main **groups of stakeholders** relevant to the policy issue of focus – through a stakeholder audit. This formed part of the in-depth review of 80 actions, and was carried out using a list of categories defined in the inception phase. For each of the 80 actions, we identified the direct and indirect stakeholders (i.e. partners and target audiences), and classified them according to pre-defined criteria, both from a thematic and geographical perspective. The 10 most frequent target audiences (i.e. those addressed by the highest number of actions in the sample; see Annex 8, **Error! Reference ource not found.**) were retained for the ensuing steps;

2. Determining the current position, in terms of **extent and focus of involvement** in the HP of each stakeholder on the issue (ranked according to high, medium and low);

3. Determining the relative **interest of each stakeholder (e.g. sharing best practice, accessing evidence to inform policy-making)**, and their influence in terms of policy making and implementation (ranked according to high, medium and low).

Whilst this approach followed well-established methodology (see Roberts et al, 2008; Gilson et al, 2012), the wide geographical/ thematic scope of the HP, diversity of actions and funding instruments used, and different stakeholder landscapes in each MS, made it challenging to factor in the political-economic and cultural context, which is seen as critical to any traditional stakeholder analysis. We sought to address this by structuring the analysis by focusing on the top 10 target audiences[52] (identified in step 1), investigating each by strand (based on 4-5 case studies each), and considering the geographical spread of organisations; although it was still not possible to carry out the analysis in as much detail were we to have undertaken it on a specific intervention in a specific locality.

Below, we present an overview of the findings for each of the strands. This includes a summary of the findings for steps 2 and 3, as well as their implications on dissemination (in terms of the extent to which they should be prioritised through

[52] Following further analysis of the specific types or organisations within each of the 10 groups (steps 2 and 3), we consolidated the groups to 8 – all with distinct levels of involvement, influence and interest.

dissemination, and recommendation on the best mechanisms/ communication channels to do so).

Stakeholder analysis – health security

The actions funded under the health security strand of the HP were typically focused on undertaking research and sharing information/ best practice on either health threats (e.g. epidemics) or safety improvement issues (particularly of organs and substances of human origin, such blood transplantation). The case studies on which this stakeholder analysis were based were broadly representative of the themes covered under the health security strands, with a project and joint action on organ donation and transplantation, and two further joint actions on genotoxicity and infectious pathogens. The relatively high number of joint actions included in the sample has been taken into account in the analysis.

The stakeholders targeted by the health security actions differed quite substantially for the two themes (health threats and safety improvement). **Scientists and academics**, as well as **specialised public health institutions** (e.g. transplantation and organ donation research centres) tended to be more involved in actions on health threats (particularly where the action involved research), whereas non-technical groups, notably **patient organisations,** were more engaged in those focused on safety improvement (particularly information-sharing/ networking actions).

By and large, most of the dissemination efforts were focused on academic/research organisations and public health institutions, with scientific publications, presentations at health symposiums, databases and websites (including information repositories) among the channels used. Whilst important, doing so meant that policy-makers were often overlooked, except where they were engaged strategically in actions (e.g. through representation on the advisory boards of joint actions). This is important as although interest in health security actions may not be high among policy-makers, they have a relatively high level of influence on the implementation of results. Following on from this, the key messages of the stakeholder analysis are that:

- The main groups with the highest level of interest in health security are **health professionals, health providers/commissioners** and **general public health institutions.** Like policy makers, health professionals (and providers/ commissioners) have not been typically targeted through HP dissemination strategies, and yet in working on the "frontline", they can have an important influence in ensuring that policy gets translated into practice. Better targeting them in actions should therefore be seen as a priority;

- Interest among **patient groups** about health security issues can be high (particularly around safety improvement issues, but such groups have a medium-level influence on the implementation of results, as their involvement tends to be focused on advocacy/ lobbying. Dissemination efforts should reflect this, with a "light touch" strategy used (e.g. keeping informed via social media) in most instances;

- **International organisations'** interest in health security actions is variable, depending on the scale/ severity of the issue in question (e.g. higher interest for cross-border issues such as epidemics). At times though, these organisations can have a significant influence on the use made of results (e.g. establishing international agreements or policy frameworks), which dissemination efforts need to reflect.

Table 18 Stakeholder analysis, Health Security

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
1. Governmental org. - Health policy makers and regulators	Ministries / departments of health	Croatian Ministry of Health	Limited involvement, as tends to be led by public health organisations with more technical/ specialist knowledge (e.g. transplantation/ disease specialist centres), although likely responsible for decision-making	Access to robust scientific expertise and evidence to inform policy and prevent health threats/ risks (e.g. infectious diseases) Collaboration on cross-border issues Share learning/ best practice amongst member states	Low. Most interest in area of health threats / risks	High, including cross-border influence through bilateral agreements.	Keep satisfied - about new research developments (increasing engagement in the case of health threats)	Presentations at conferences/ events Press releases Action website, associated websites and social media activities Reports, policy guidelines, strategic frameworks
2. Governmental org. - Healthcare providers, funders and commissioners	Providers of healthcare services (incl. insurance funds)	NHS Blood and Transplant (UK Department of Health), Lithuanian National Transplant Bureau	Limited involvement, except where issue is not focused on health threats (e.g. organ transplantation)	Learn about good practices Clear protocols/ guidelines/ infrastructure in place Influence healthcare decision-making processes	High. Particularly so for patient safety (compared to health threats).	Medium. Particularly so for patient safety (compared to health threats).	Manage closely (priority for dissemination of results)	Reports, policy guidelines, strategic frameworks Presentations at conferences/ events Press releases Action website, associated websites and social media activities
3. Health and social care professionals	Associations of healthcare professionals (including lab	N/A	Very limited involvement, except through healthcare	Learn about good practices Clear protocols/ guidelines/	Medium	Medium. Particularly so for patient safety	Manage closely (priority for dissemination of results)	Reports, policy guidelines, strategic frameworks

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
	technicians)		providers (category 2)	infrastructure in place Influence healthcare decision-making processes		(compared to health threats).		Presentations at conferences/ events Press releases Action website, associated websites and social media activities
4. Governmental org. - public health organisations / institutions	Technical agencies undertaking research, implementing policy and delivering programmes in the area of public health	Bulgarian National Center of Infectious and Parasitic Disease, Italian Istituto Superiore di Sanità (ISS), Norwegian Institute of Public Health, Swedish Institute for Communicable Disease Control	Heavily involved as partners, in both joint actions and projects, and across EU-15 and EU-12 member states. Particularly the case where action has a strong networking function (e.g. QUANDHIP)	Develop robust scientific expertise and evidence to inform policy and prevent health threats/ risks Collaboration on cross-border issues Share learning/ best practice amongst MS	Very high	Medium	Manage closely (priority for dissemination of results)	Participation in training/ workshops Guidelines/ protocols Databases/ repositories Scientific papers Action website and associated websites Reports
5. General public	Citizens and consumers	N/A	No involvement in delivery	Information about health threats/ risks/ security issues	Low	Very low	Monitor	Newsletters, posters, flyers Press releases
6. International organisations	Global or European organisations that are active in the field of public health policy	N/A	Very limited involvement in delivery – engagement more informative	Collaboration on cross-border issues (e.g. development or European protocols/ infrastructure)	Medium, particularly where the issue is international in scope (e.g. global health threat).	Medium, where legislation/ international policy is enacted/ required	Engagement varied according to topic/ policy area/ scale and severity of issue	Presentations at conferences/ events Press releases Reports, policy guidelines, strategic

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
				European experiences/ data that may inform policy				frameworks
7. Academic and research org. – Universities and research organisations/ institutes	Higher education institutions	Technical University of Denmark, Riga East University Hospital, Slovak Medical University	Moderately involved, where focus has been on scientific/ clinical research (NANOGETOX), rather than collaboration (QUANDHIP)	Increase scientific knowledge (including risk factors, interventions)	Medium, where the focus is on research/ developing the evidence base	Low (dependent upon the focus of the action)	Keep informed – about new research developments, funding opportunities, opportunities to collaborate etc	
8. Patients and service users (NGOs)	Includes patient, service user, carer or voluntary organisations, or charities, that directly or indirectly represent the public health or disease prevention interests of people	Eurotransplant International Foundation	Limited involvement, largely focused on patient safety issues (EFRETOS)	Information about health threats/ risks/ security issues Provide information that can be used for lobbying	Medium, particularly where issue relates to a citizen safety/ security	Low	Keep informed – about new research developments, legislation, risk factors etc.	Newsletters, posters, flyers Press releases Briefings/ conferences

Stakeholder analysis – health promotion

Within health promotion, the majority of actions funded through the HP focused on developing the evidence base to inform policy-making and delivery, through the undertaking of specific studies, networking/ dissemination and advocacy activities. Actions addressed a wide range of policy issues, covering health protection (e.g. food safety), social determinants and inequalities (e.g. obesity, alcohol consumption) and disease prevention. The case studies that informed this analysis are reasonably representative of the relevant HP-funded actions, including a joint action and two projects on disease prevention (covering rare diseases, cardiovascular disease and food reformulation respectively), and a service contract on the information present on alcoholic beverage labels.

Although the health promotion actions often involved clinical or technical research, the **main target audiences tended to be policy-makers** (at the European, national and local levels), as well as **health professionals and other non-technical audiences** (e.g. SMEs). Technical stakeholders (e.g. academic institutions) were often involved in delivery (including leading on the delivery of Joint Actions), but the extent to which they were targeted was more varied, according to the nature of the action (e.g. larger extent for research studies, lesser extent for actions focused on sharing best practice/ informing policy).

The **targeting of policy makers was relatively successful**, particularly for joint actions, where linkages with policy makers tended to be more established. In these cases, the mechanisms through which the outcomes of actions could influence and inform policy-making were generally effective, with formal governance mechanisms established (e.g. the EUCERD), reports/ briefing papers issued, and workshops organised. That said, there was indication that more of the latter (workshops/ networking events) would have been helpful, rather than the focus being on research outputs (e.g. scientific papers). The targeting of policy makers also varied across countries, with a greater focus on those from EU-15 MS. As interest in health promotion (particularly social determinants and health inequalities) can be limited by resource availability, the political-economic context and other variables – meaning that it is considered a "nice to have" rather than a "must have" – this finding is not surprising. In countries where the importance of health promotion is recognised, policy makers need to be informed and kept satisfied, whereas in countries where it less so, they need to be targeted more intensively, in order to raise awareness of its importance.

Further key findings identified through the analysis were:

- Similar to health security actions, the groups with the highest level of interest in health promotion actions are **health professionals, health providers/ commissioners** and **general public health institutions.** These groups can also have a strong influence on the uptake of results, particularly health professionals given that they are working on the "frontline". Dissemination efforts need to better reflect this, through the use of more non-technical (i.e. practical) outputs (e.g. guidelines, toolkits);
- Interest in health promotion among **patient/ service user groups**, and the **general public** more widely, can be high (particularly around safety improvement issues), but such groups often have a medium-low influence on the use that is made of the results, which should be factored into the development of dissemination strategies;
- Technical audiences (e.g. academics, research institutes) had also been effectively targeted where the focus of the action was on research, with a clear dissemination strategy often in place, which was based around scientific publications, conferences etc. Whilst positive, the influence of these groups on the delivery of health promotion activities can be low, and so it is critical that they are not considered the main (or only) key audience.

Table 19 Stakeholder analysis, Health Promotion

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
1. Governmental org. - Health policy makers and regulators	Ministries / departments of health	EU Committee of Experts on Rare Diseases (EUCERD), Finnish Ministry of Social Affairs and Health, Spanish Ministry of Health, Social Policy and Equality Committee on National Alcohol Policy and Action, Members of the European Parliament (MEP)	Low level of involvement, largely through participation on policy committees (e.g. EUCERD) and greater for Joint Actions than projects. Only involved in delivery where no specialised / dedicated institution (e.g. research institute) exists.	Access to robust scientific expertise and evidence to inform policy Share learning/ best practice amongst member states Foster and support evidence-based decision making and policies	Low (although varies across topic and potentially member state (with EU-15 member states having a stronger interest)	High	Keep satisfied – keeping up to date with recent developments in research	Representation in policy committees Presentations at conferences/ events Participation in training/ workshops Participation in research (e.g. surveys) Guidelines/ syntheses of study results Action website and associated websites Reports Newsletters, posters, flyers Press releases
2. Governmental org. - Healthcare providers, funders and commissioners	Providers of healthcare services (incl. insurance funds)	N/A	Very low level of involvement (limited to delivery of a few Work Packages)	Access to new healthcare innovations Share learning/ best practice among member states	High, as exposed to the issues associated with low health promotion (e.g. obesity, smoking related diseases)	Medium. Dependent on the scale of involvement. Influence likely to be much higher for frontline (i.e. primary care) providers	Manage closely (priority for dissemination of results)	Presentations at medical congresses/ events Scientific papers Fact sheets, guidelines and tool-kits Action website and associated websites

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
								Reports Newsletters, posters, flyers
3. Health and social care professionals	Associations of healthcare professionals	European Society of Cardiology (ESC), British Heart Foundation (BHF)	Medium involvement, largely through delivery of Work Packages	Access to new innovations in healthcare Understand and influence healthcare decision-making processes Improved awareness of health promotion among patients/ service users, so as to reduce service demand	High, as working on the frontline and exposed to the issues associated with low health promotion (e.g. obesity, smoking related diseases)	High, although could be higher if more professionals were involved in the HP actions	Manage closely (priority for dissemination of results)	Presentations at medical congresses/ events Scientific papers Fact sheets, guidelines and tool-kits Action website and associated websites Reports Newsletters, posters, flyers
4. Governmental org. - public health organisations / institutions	Technical agencies undertaking research, implementing policy and delivering programmes in the area of public health generally	French National Institute of Health and Medical Research (INSERM), Portuguese Instituto Nacional de Saúde Doutor Ricardo Jorge (INSA), Italian Istituto Superiore di Sanità (ISS)	Heavily involved as partners, in both JAs and projects, particularly from countries where there is sufficient resource and policy support in place.	Access to robust scientific expertise and evidence to inform policy Share learning/ best practice amongst member states Foster and support evidence-based decision making and policies	Very high, although varies across EU-15/ EU-12 countries, based on resources/ policies in place	Medium, as inform, but do not implement policies/ legislation	Manage closely (priority for dissemination of results)	Representation on policy committees Presentations at conferences/ events Scientific papers Participation in training/ workshops Participation in research (e.g. surveys) Guidelines/ syntheses of study results Action website

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
								and associated websites Reports Newsletters, posters, flyers Press releases
5. General public	Citizens and consumers	N/A	No involvement/ engagement, expect through patient organisations (see category 8)	Access to new research findings	Medium, although focused on more widespread issues (e.g. smoking, physical activity, obesity), rather than specific/ technical issues (e.g. rare diseases)	Very low	Keep informed – about new research developments, legislation, risk factors etc.	
6. International organisations	Global or European organisations that are active in the field of public health policy	World Health Organisation (WHO), Organisation for Economic and Cooperative Development (OECD)	Low involvement, restricted to specific Work Packages with an international dimension (e.g. development of international nomenclature)	European experiences/ data that may inform international policy frameworks	Medium	Medium	Engagement varied according to topic/ policy area/ scale and severity of issue	Participation at conferences/ events Reports, Guidelines/ syntheses of study results Scientific papers
7. Academic and research org. – Universities and research organisations/ institutes	Higher education institutions	University of Newcastle (UNEW), Johann Wolfgang Goethe Universität Frankfurt am Main (GUF)	Heavily involved as partners, from countries where there is sufficient resource and policy support in	Development of scientific evidence base Innovations in healthcare Funding opportunities	Medium	Low, as findings often limited to academic/ scientific circles. Higher where there are established links between	Keep informed – about new research developments, funding opportunities, opportunities to	Presentations at conferences/ events Training/ workshops Scientific papers Guidelines/

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
		Centro de Investigación Biomédica en Red de Enfermedades Raras (CIBERER), Saint Georges Hospital Medical School (SGUL), University of Oxford (UOXF)	place.	Share learning/ best practice amongst member states		academics and policy-makers (e.g. EUCERD)	collaborate etc	syntheses of study results Action website and associated websites Reports Newsletters, posters, flyers Press releases
8. Patients and service users (NGOs)	Includes patient, service user, carer or voluntary organisations, or charities, that directly or indirectly represent the public health or disease prevention interests of people	European Organisation for Rare Diseases (EURORDIS), EU Platform for Action on Diet, European Heart Network	Heavily involved through representation on committees, involvement in delivery etc. Often represented through one main organisation (e.g. European Heart Network)	Sharing learning/ best practice Improved patient experience and voice Increased awareness of health promotion	High, although focused on more widespread issues (e.g. smoking, physical activity, obesity), rather than specific/ technical issues (e.g. rare diseases)	Low	Keep informed – about new research developments, legislation, risk factors etc.	Networking and dissemination) Participation at conferences/ events Action website and associated websites Reports Newsletters, posters, flyers Press releases

Stakeholder analysis – health information

The majority of HP-funded actions (as well as the bulk of the funding) in the area of health information (strand 3 of the HP) dealt with developing pan-European **monitoring systems** or approaches to **define indicators**, and collect, analyse and/or **disseminate comparable (statistical) data and information** across (some or all) Member States. Actions addressed information on a wide range of aspects of public health, including specific conditions or diseases, but also analytical approaches and techniques such as health technology assessment (HTA). The case studies, on which the ensuing stakeholder analysis is based, provided a reasonably representative cross-section of relevant HP-funded actions, including two projects on information systems for musculoskeletal conditions and neonatal care (respectively), a joint action on HTA, and a service contract on policies relating to the reimbursement of medicinal products.

By their very nature, health information actions tend to be aimed at (and relevant for) primarily a **technical audience**, be it specific public health institutions (e.g. HTA agencies), healthcare providers (e.g. neonatal intensive care units), and/or academic / research institutions (e.g. university hospitals). As a result, most of the dissemination effort tends to focus on such specialist audiences. The extent to which other groups (notably policy makers, health professionals, patients) are also engaged and involved varies significantly, depending partly on the subject (which can be very narrow, or relatively broadly defined) as well as on the funding instrument (it seems that JAs tend to fare better when it comes to establishing linkages with policy makers).

The case studies suggest that the **absence of a strategy to engage relevant groups beyond the purely technical core group significantly reduces the chances of success of actions**. To be effective, health monitoring and information exchange usually requires the participation of as many units / countries as possible, which in turn implies a need to bring on board non-participants as well as generate support among potential backers and funders of such schemes. At the same time, care should be taken to not waste efforts and resources on target groups that have neither a strong interest nor any influence on the use of the results.

Following on from this, the key messages that emerge from the stakeholder analysis in the area of health information are:

- The main groups for which health information actions and the results thereof tend to be of most interest are (in descending order) **public health institutions, academic and research organisations, and healthcare providers and commissioners**. These are the natural target groups of the dissemination efforts in this area;

- All of these have, on average, a medium level of influence on the implementation of the results, which indicates that the systematic application of health information indicators, tools, data etc. requires a complex interplay (and therefore engagement) of several actors in order to be effective;

- **Policy makers** are the key to implementation, but their level of interest in most health information actions is limited, as they tend to be technical and rather far removed from day-to-day political priorities. In countries where the need for evidence-based health policy-making is widely accepted, they need to be informed and kept satisfied. Where evidence-based policy-making is less firmly rooted, they need to be targeted more intensely, so as to facilitate implementation of relevant results;

- The results of HI actions are typically of limited interest to **health professionals**, and even more so to patients or even the general public. These groups also have relatively little (indirect) influence on the use that is made of the results, and the dissemination effort should reflect this.

Table 20 Stakeholder analysis – Health Information

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
1. Governmental org. - Health policy makers and regulators	National Ministries / Departments of health	Ministry of Health of Cyprus Ministry of Health of the Czech Republic Spanish Ministry of Health, Social Services and Equality	Typically only involved as (collaborating or associated) partners in JAs where no specialised / dedicated institutions (e.g. HTA agency) exists, or in Federal systems where the relevant competence lies with the regional level	Benchmark performance of national healthcare system against other countries Foster and support evidence-based decision making for sustainable, equitable choices in healthcare Build national analytical capacity	Low (Not a top priority on the political agenda of most MS – though some variation depending on priority a government attached to evidence-based policy-making)	High	Keep satisfied, but attempt to stimulate interest in relevant HI issues, by maximising opportunities to raise awareness and generate buy-in, so as to improve the framework conditions for EU-wide implementation of results But no direct participation (NB: ministries often do not have the required expertise in-house to add value to technical projects directly; collaboration works best when specialised institutions are involved)	Presentations in policy groups (e.g. HTA Network meetings) Summary reports / policy papers Briefings and press releases Conferences

Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
2. Governmental org. - Healthcare providers and commissioners	Healthcare providers, such as hospitals or trusts, but also payers (statutory health insurance)	Royal Cornwall Hospital Trust Paediatric hospital Bambino Gesù Assistance Publique - Hôpitaux de Paris International European Social Insurance Platform (ESIP) European Hospital and Healthcare Federation (HOPE)	Main beneficiaries (alongside research institutions) in projects focusing on specific diseases / conditions. Consulted and informed (as members of the Stakeholder Forum)	For individual providers (e.g. hospitals): Establish international cooperation Gain knowledge Benchmark / eventually improve service delivery Obtain funding For associations: Understand and influence healthcare decision-making processes Ensure specific themes and concerns of relevance to the sector are covered	Medium (potentially high, but non-participants may lack incentives / resources to accommodate / apply new data collection and sharing approaches)	Medium (High within their specific units, but lower in terms of ensuring wider application)	Keep informed, consult on key issues Highlight key benefits of pan-European information exchange, provide arguments to convince policy makers in the respective jurisdictions	Summary reports / policy papers Briefings Conferences Guidelines, toolkits Training
3. Health and social care professionals	(Associations of) Healthcare professionals	Standing Committee of European Doctors (CPME) European Society of Cardiology (ESC)	In some cases, consulted and informed (e.g. HTA: as members of the Stakeholder Forum)	Learn about key performance issues and good practices Understand and influence healthcare decision-making processes Ensure specific	Low (Passive interest, but individual professionals will typically not be able to make much use of the monitoring data as such, unless it is first translated	Low (Collection and use of data typically not driven by individual professionals)	Keep informed, consult on key issues	Summary reports / policy papers Briefings Conferences Guidelines Consultation fora / events (where sufficient

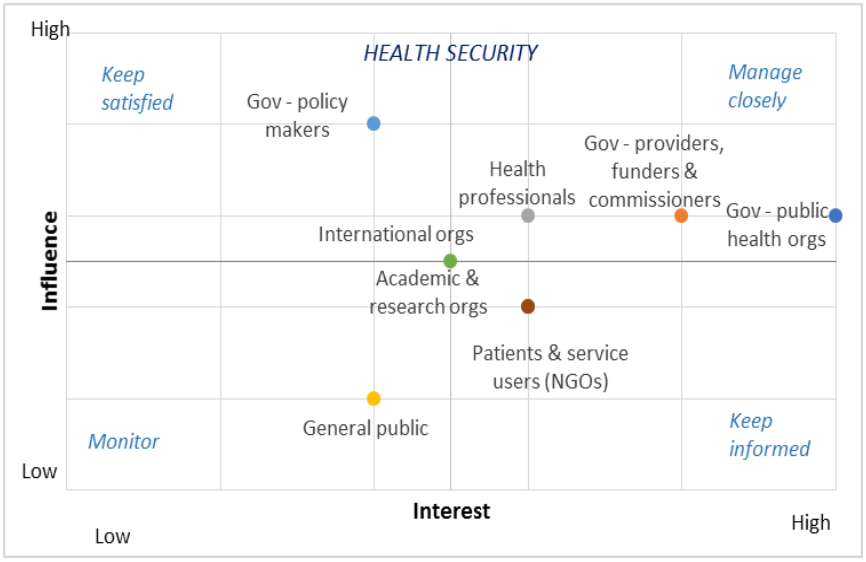
Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
				themes and concerns of relevance to health professionals are covered	into guidelines / approaches / policy)			interest exists) Direct engagement with EU umbrella organisations
4. Governmental org. - Public health organisations / institutions	Dedicated HTA agencies, and other (executive) agencies that include HTA among their responsibilities	Danish Health and Medicines Authority Finland's National Institute for Health and Welfare National Institute of Public Health of Slovenia National Institute for Health and Care Excellence (UK) Polish Agency for Health Technology Assessment German Institute for Quality and	Heavily involved as partners in JAs on 'strategic' issues (such as HTA); far less involved in projects	Networking with other specialised organisations across Europe Mutual learning and exchange of experiences Capacity building / technical assistance Exchange of technical / scientific information Common tools and approaches to facilitate joint working	Very high	Medium (can be higher depending on the exact subject – e.g. HTA – but these institutions typically play more of an advisory role to governments when it comes to policy	Manage closely Engage directly in actions Where not directly involved, make key target audience for dissemination of results	Action deliverables Conferences / events / workshops / training Thematic brochures
5. General public	Citizens of EU Member States	N/A	No involvement / engagement, except through patient organisations	None	Very low (specific issues may be of interest to patients, see below)	Very low	Largely ignore (health monitoring / information is of limited direct	N/A

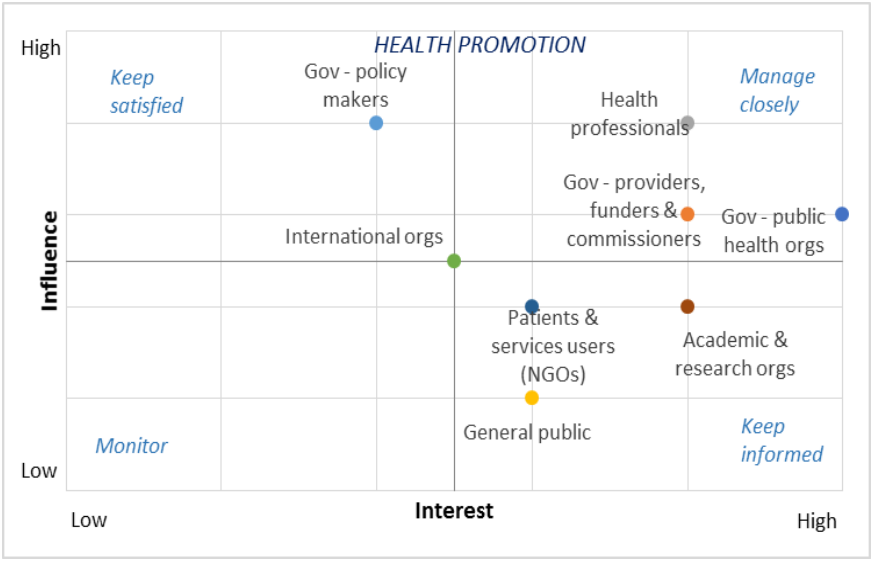
Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
							interest to citizens)	
6. Academic and research organisations and institutes	Universities, faculties / schools of (public) health, or university hospitals Not-for-profit organisations focused on research, technology and innovation (e.g. research councils and commercial research providers)	Basque Foundation for Health Innovation and Research Medical University Vienna University of Ulm Children's Hospital Department of Public Health of the University of Tartu University of Roma Tor Vergata	Main beneficiaries (alongside healthcare providers) in projects focusing on specific diseases / conditions. Involved as partners (minority of countries) or associates in HTA JA.	Increase body of evidence / data on issues of interest Learning about / feeding in scientific knowledge about relevant methods and approaches Prestige of international collaboration Funding opportunities	High (Comparable information across countries is highly relevant / useful for research purposes, as is knowledge on methods etc.)	Medium (some influence on collecting data, developing indicators / tools / datasets / methods, and contributing to their use)	Engage as project partners where appropriate Keep informed of key results, methods and approaches, data issues	Scientific publications Conferences, seminars
7. International organisations	Global or European organisations that are active in the field of public health policy	N/A	No involvement	European experiences / data that may inform policy	Low – Medium (Some interest in comparable data)	Low - Medium	Monitor; engage where specific issues warrant it	
8. Patients and service users (NGOs)	Patient and healthcare consumer organisations	Swedish Rheumatism Association European League against Rheumatism (EULAR)	Rarely involved as project partners In some cases, consulted and informed (e.g.	Further the evidence base on issues of specific concern to patients Provide information that	Low (except when it comes to diseases / conditions of direct concern to specific organisations)	Very low (HI not an area where much lobbying tends to occur)	Keep informed of key results	Summary reports / policy papers Briefings and press releases Conferences Consultation

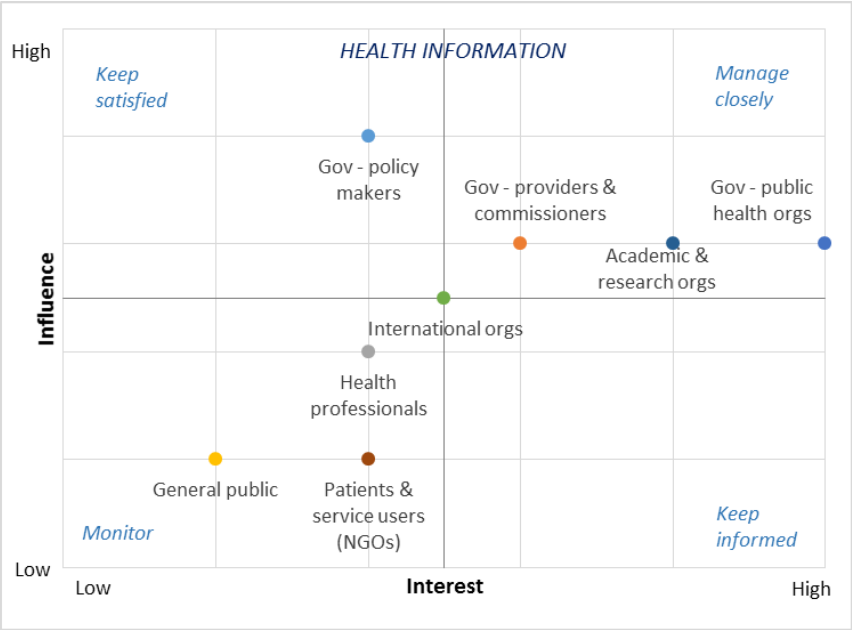
Description of stakeholder group				Assessment of interest and influence			Recommended engagement / dissemination strategies	
Main group	Specific types of organisations	Examples of organisations	Extent and focus of involvement	Key relevant interests	Overall level of interest in the action (the HP strand)	Influence on take up/ implementation of results	Priority for engagement and dissemination	Dissemination strategies (of results)
		European Consumer Organisation (BEUC) European Patients Forum (EPF) The European Rare Diseases Organisation (EURORDIS)	EUMUSC.NET: patient-oriented standards of care)	can be used for lobbying Understand and influence healthcare decision-making processes Ensure specific themes/ concerns of relevance to patients are appropriately covered				fora / events (where sufficient interest exists) Direct engagement with EU umbrella organisations

Overall results

A summary of the findings of the stakeholder analysis are presented in the figures below, which map the level of interest and influence of the key stakeholders across the three strands. In principle, stakeholders towards the right of the matrixes are potential target audiences, whilst those to the top are (potentially) effective disseminators of information. At the same time, stakeholders in the top left quadrant need to be looked at carefully: it may be worth exploring ways in which their interest could be maximised so as to take advantage of their high levels of influence.







When interpreting these results, it is important to be mindful of the limitations of applying the stakeholder analysis approach to an intervention that is as broad and multi-faceted as the Health Programme. Even though breaking the analysis down by strands helps to makes things a little more homogeneous, it remains the case that the position of stakeholders is different from topic to topic and from action to action. Nonetheless, the analysis provides a useful way of conceptualising the strategic position of key groups, and reveals some interesting high-level trends, some of which could be explored further and applied to specific priorities or topic areas under the 3rd HP to help guide the dissemination and engagement effort going forward.

As the matrixes illustrate, there are a small group of stakeholders whose high degree of interest cuts across two, if not all of the strands. These are: public health institutions (highest across the piece), academic and research organisations (particularly for health promotion and health information), healthcare providers and commissioners (across the piece), and health professionals (particularly for health promotion and health security).

All of these stakeholders have, on average, a medium level of influence on the implementation of the results, and should therefore be considered in any dissemination and engagement efforts. In order to do so, the development of robust dissemination strategies, which take into account the complex interplay of the different actors' motivations, resources and influence are required. Under the second HP, the effectiveness of dissemination activities differed according to different actors, with technical audiences (e.g. academics and research organisations) often better targeted than non-technical ones. Whilst scientific publications, medical congresses, and other tried-and-tested methods can be important in communicating the outcomes of HP actions, they sometimes need to be complemented by more practical tools (e.g. professional manuals, toolkits and training), which enable practitioners to be better engaged.

The targeting of policy makers has also varied in extent and effectiveness, in spite of the fact that these groups can have a high degree of influence on the implementation of actions across all three of the strands. Going forward, the HP needs to better engage these groups, by maximising opportunities to raise awareness and generate buy-in, so as to improve the framework conditions for EU-wide implementation of results. Where policy makers have been involved (e.g. through representation on policy committees as part of joint actions), the outcome has generally been positive, although it should be noted that strategic engagement has been most effective, and indeed ministries often do not have the required in-house expertise to participate

directly in any technical projects (here, the involvement of specialised institutions works better).

Finally, the importance of taking a flexible approach to dissemination needs to be noted, given that the interests and influences of stakeholders can change dynamically over time. Whilst it is important to establish a clear dissemination strategy at the outset, the strategy needs to be refreshed continually during the lifetime of any action, in order that influence ongoing delivery.

8. IN-DEPTH REVIEW OF 80 HP-FUNDED ACTIONS

This section provides the results of an in-depth review that was conducted of 80 actions, followed by an analysis of these actions' EU added value.

8.1.In-depth review

The sample

The tables below provide an overview of the 80 actions included in the in-depth review. The task involved the categorisation of this sample actions along the lines presented in Annex 2. Analysis of this review is presented below.

Table 21: Overview of actions included in the in-depth review

Funding instrument	Health security	Health promotion	Health information	Total
Projects	10	26	3	39
Service contracts	5	2	3	10
Joint Actions	7	9	5	21
Operating grants	N/A	N/A	N/A	10
Total	22	37	11	80

Table 22: Overview of actions included in the in-depth review - by instrument, strand and sub-priorities (including the three most important)

Strand	Priority	Sub-priority	Project	Joint Action	Service contract	Total
Health Security	1.1 Health threats	1.1.1 (Non-) communicable diseases & health threats	4			4
		1.1.3 Risk management / preparedness health emergencies			1	1
	1.2 Improve safety	1.2.2 Organs & substances of human origin etc.		3		3
	Other – random selection		6	4	4	14
Health Promotion	2.2 Health determinants	2.2.1 Address health determinants & promote healthy lifestyles	14		1	15
		2.2.2 Prevention of major & rare diseases	6	5		11
	Other – random selection		6	4	1	11
Health Information	3.2 Collect, analyse & disseminate	3.2.1 Health monitoring & comparable data		4		4
		3.2.2 Mechanisms for analysis & dissemination of information			2	2
	Other – random selection		3	1	1	5
Total			39	21	10	80

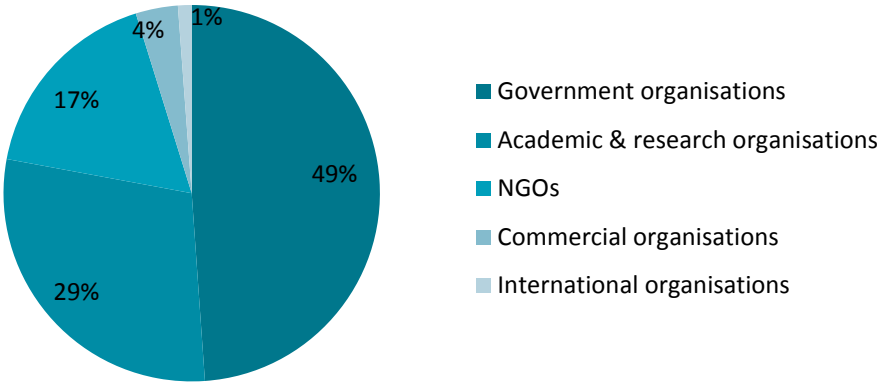
Findings

The analysis presented here is based on an assessment of the data available from the in-depth review. The analysis focuses on three main areas covered by the in-depth review, namely partners, results and objectives, and dissemination.

Management

The in-depth review includes substantial information regarding the partners involved in the implementation of the actions funded through the Programme, information which is relevant to assessing the inclusiveness of and geographical / sectorial linkages formed as part of the Programme. The analysis here begins by establishing what kinds of organisations are involved in the delivery of actions funded through the Programme, particularly since we have more detailed information for our sample compared to the information to hand for all actions. Secondly, the geographical mix/balance between organisations based in EU15 and EU13 Member States overall and by action type in our sample is laid out showing that it broadly mirrors the findings of the Programme as a whole. Finally, the number of partners and the degree of cross-sectorial collaboration involved in actions is briefly explored to show how this differs by action type.

Figure 21: Types of partner organisations involved in HP actions

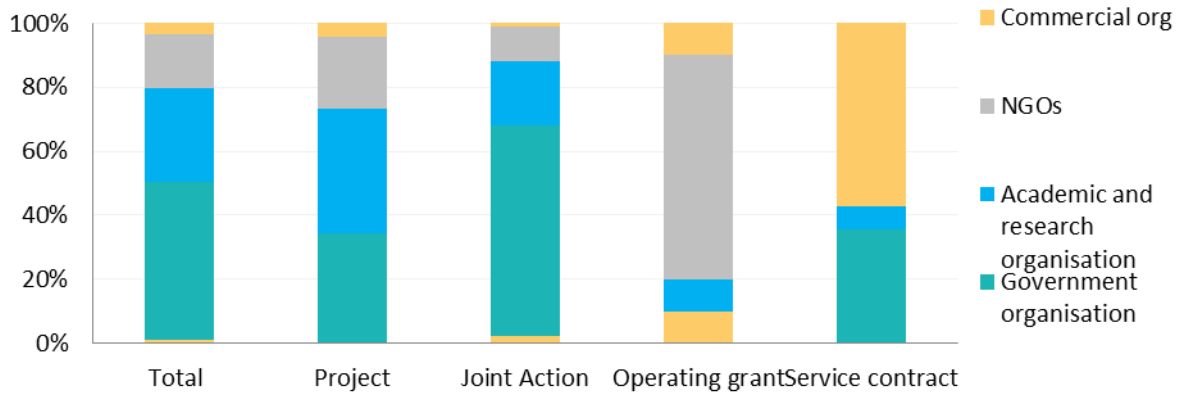


When viewed against all actions funded under the second Health Programme (see Annex 2), the sample is broadly representative in terms of the types of beneficiaries, although more government organisations were included in the IDR sample (49%, compared to 39% for actions overall), and fewer NGOs (17%, compared to 31% for actions overall). This is not surprising given the high number of joint actions included in sample (which NGOs tend to participate in relatively little).

When the IDR sample is analysed according to different types of action, these findings are further elaborated:

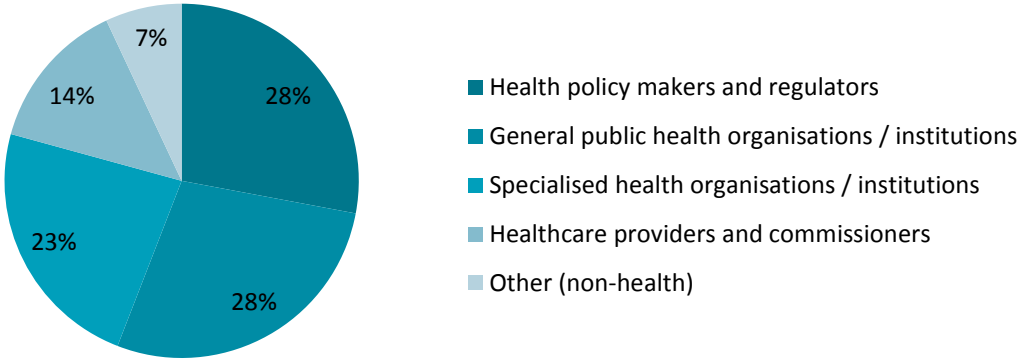
- Government organisations have a much greater stake in joint actions than in other actions, and particularly those relating to health security and health information;
- Academic and research organisations are more involved in projects than government organisations, with the level of involvement approximately the same across all three stands of the health programme;
- NGOs predominate in terms of operating grants, and commercial organisations in terms of service contracts.

Figure 22: Partner organisations involved in different types of HP actions



As part of the IDR, we also broke down the broad types of organisations into various sub-types in order to arrive at a more fine-grained understanding of who is funded. A closer look at the breakdown of the kinds of governmental organisations involved in the delivery of the Programme shows that within this group, "policy makers and regulators", as well as "general public health organisations/institutions" were the most sizable constituents (making up 28% of each - Figure 23). Specialised health organisations and institutes were close behind, accounting for 23% of government organisations.

Figure 23: Breakdown of types of government organisations involved in the delivery of the Health Programme



The table below provides a ranking of the 17 different sub-groups of stakeholders that were defined at the outset, according to the frequency with which they have been involved in actions, and shows these trends clearly. In addition, while the ranking illustrates that those stakeholders involved to a significant degree in some actions are more than likely to be involved significantly in other actions, there are discrepancies. Universities and most types of NGOs are more strongly represented in projects, while governmental organisations (in particular health policy makers and regulators) are more likely to participate in joint actions. Commercial organisations are, for example, significantly engaged in operating grants and service contracts, but less so in projects and joint actions – a trend that is also reflected in non-health NGOs. This information is relevant in particular as a basis for the stakeholder analysis (see Annex 7).

Table 23: Ranking of partners involved in HP actions

Stakeholders - main and associated partners	Over all	PJ	JA	OG	SC
Academic and research org. - Universities	1	1	3	N/A	4
Governmental org. - General public health organisations / institutions	2	3	2	N/A	3
Governmental org. - Health policy makers and regulators	3	8	1	N/A	2
Governmental org. - Specialised health organisations / institutions	4	2	4	N/A	N/A
Governmental org. - Healthcare providers and commissioners	5	7	5	N/A	N/A
Academic and research org. - Research organisations and institutes	6	6	6	3	N/A
NGOs - Health and social care professionals	7	5	7	1	N/A
NGOs - Patients and service users	8	4	10	1	N/A
Governmental org. - Other (non-health)	9	8	9	N/A	N/A
NGOs - Hybrid (healthcare professionals and users)	10	11	8	N/A	N/A
Commercial org. - Other	11	10	N/A	3	1
NGOs - Other NGOs (non-health)	12	12	12	3	N/A
International organisations	13	N/A	10	3	N/A
Commercial org. - Industries relevant to public health	14	14	13	N/A	N/A
Commercial org. - Private healthcare providers	14	13	14	N/A	N/A

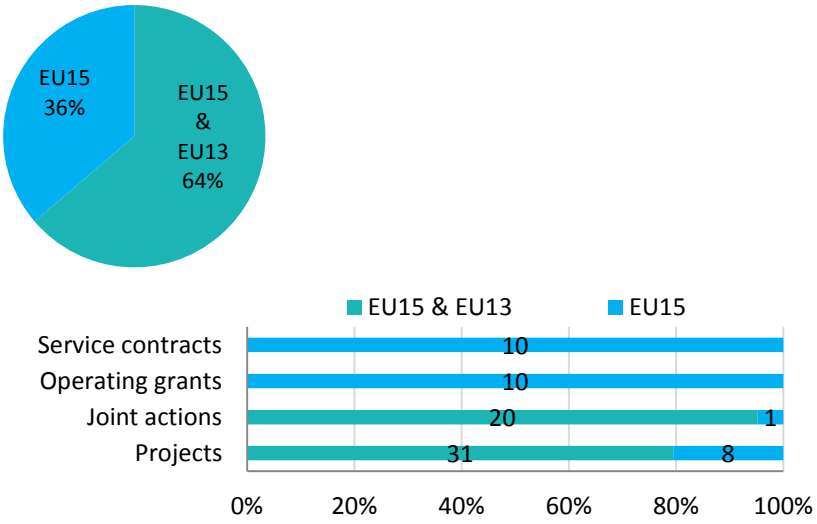
* NB: N/A denotes stakeholder types that were not involved in any actions of a particular type that were reviewed. The three stakeholder categories – media, general public, and others (see annex H) – that were not involved as partners or beneficiaries in any of the actions at all are not included in the table.

Geographical spread of organisations

An analysis of the geographical spread of the sample shows that the vast majority of the 80 actions reviewed included partners from both EU13 and EU15 (64%). However, over a third of these actions (36%) did not include partners from EU13 countries (Figure 24). This trend was observed for all types of actions reviewed, but it is worth reiterating that, as was the case for the Programme as a whole (see Annex 2), service contracts and operating grants (of which there were ten each) stand out since there was not a single organisation based in an EU13 Member State (Figure 24).[53]

[53] In the case of operating grants, one of the criteria for operating grants is that they involve non-governmental bodies and specialised networks coordinated by a public body or non-profit body, with members in at least half of the MS and a balanced geographical coverage across the EU.

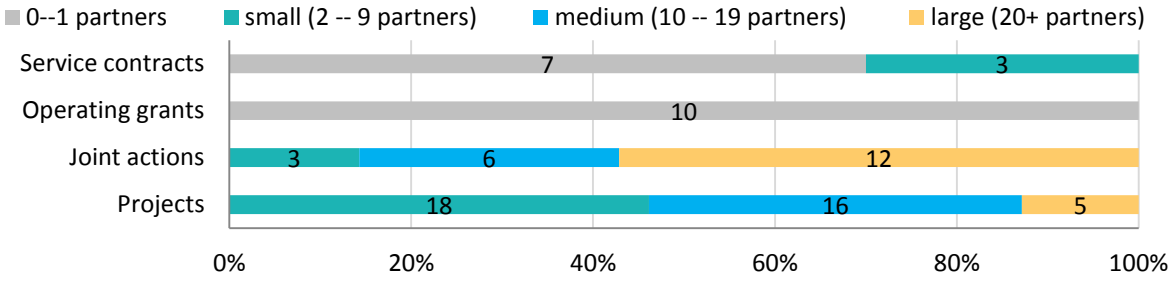
Figure 24: Geographical spread of main and associated partners involved in the delivery of actions, by action type



Number of partners

The average number of organisations varied considerably depending on the type of action (Figure 25) with both service contracts and operating grants tending towards the lower end of the scale. On average, joint actions had more partners than other action types; just over half of those reviewed had over 20 partners. When considering the objective of joint actions this is perhaps unsurprising; while there are – on average – just five joint actions a year, they target areas where the value of EU-level involvement is high. In doing so, they aim to bring together Member State authorities or associated bodies to design and implement actions in a collaborative way. Projects, which are also collaborative by definition, are much more focused, and goal-orientated. As such, they tended to have a "small" number of partners (between two and nine) or a "medium" number of partners (between ten and 19).

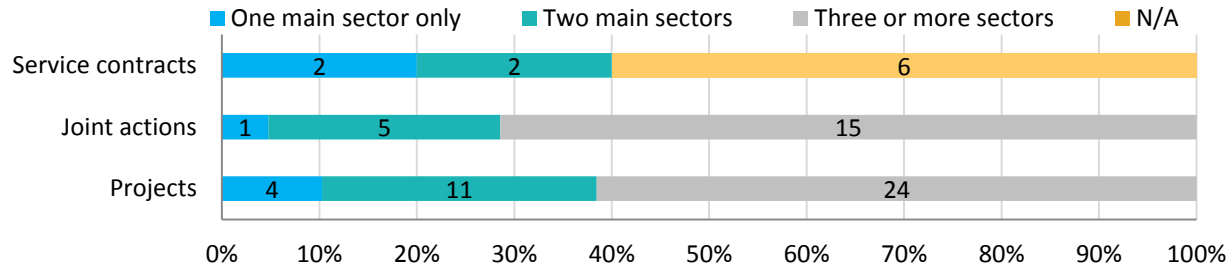
Figure 25: Number of partners per action (main and associated), by action type



Degree of cross-sectorial partner collaboration

Following from this, the degree of cross-sectorial collaboration reflects a similar pattern in that service contracts only showed limited cross-sectoral collaboration whereas projects and joint actions – by virtue of having more partners – were much more likely to exhibit collaboration across different sectors (Figure 26).

Figure 26: Cross-sectorial cooperation by action type (excluding operating grants which only had one main sector listed)



Impact

An assessment of the focus, objectives, activities and results of the 80 actions reviewed will assist in ascertaining the nature and degree of (potential) impact of the Programme. In fact, the 80 actions were assessed for area(s) of focus (i.e. research, development, implementation, or a combination of these); these findings are presented below for the sample as a whole, as well as by funding instrument. The desired results of the actions have also been assessed and the actions rated in relation to the extent to which having an impact on national policy was important for action success. The findings of this exercise are presented below for the sample as a whole, as well as by funding instrument. Further analysis will be undertaken as part of the second half of the data collection phase on the actions' activities and outputs, for example.

Focus of actions

The focus of a given action was determined based on definitions from DG SANTE's categorisation of projects[54], namely:

- **Research**: To increase knowledge that can serve as a basis for evidence-based decisions.
- **Development**: To develop and pre-test an intervention to address a particular problem in a particular population or target group.
- **Implementation**: To achieve wider dissemination and implementation of an existing intervention in a particular population or target group.

Since not all actions will necessarily fit neatly into these three categories, for the purposes of the review the categorisation was a sliding scale, i.e. an action could be classified as "research/development" or "development/implementation", or indeed "all three".

Taking all 80 actions sampled for the review into consideration, shows that "development" was covered (either specifically, or together with research and/or implementation) for 75% of actions assessed (Table 24); while over half dealt with implementation and nearly half (44%) involved an element of research.

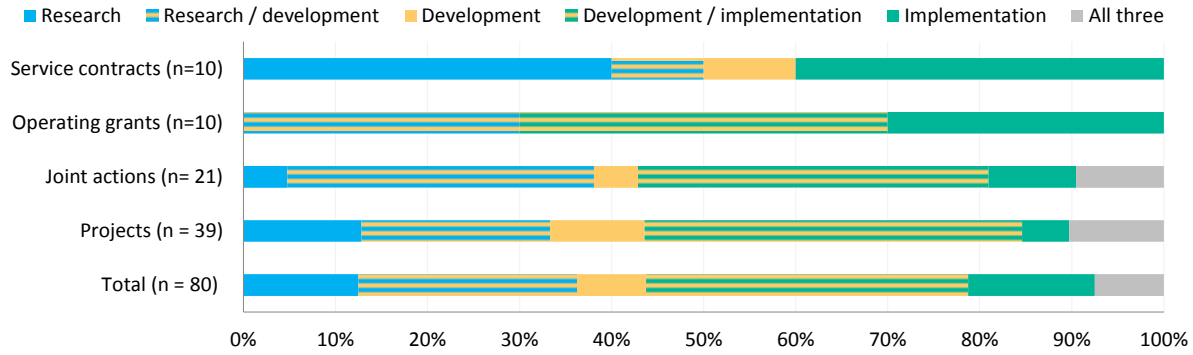
[54] As outlined in the Project Management in Public Health in Europe, 2011

Table 24: Number of actions by focus area

	Number of actions which involve…	% of total
…research	35	44%
…development	60	75%
…implementation	45	56%

In terms of the findings by action type, though the sample of service contracts and operating grants was limited to ten each, it seems those service contracts reviewed as part of the sample dealt largely with "research" or "implementation", while operating grants were most likely to be directed at "implementation" (either with or without an element of "development"). As regards projects and joint actions (of which considerably more were reviewed, 39 and 21, respectively), both follow the overall trend: development is most important (although this is slightly more accentuated for joint actions).

Figure 27: Focus of actions, overall and by action type

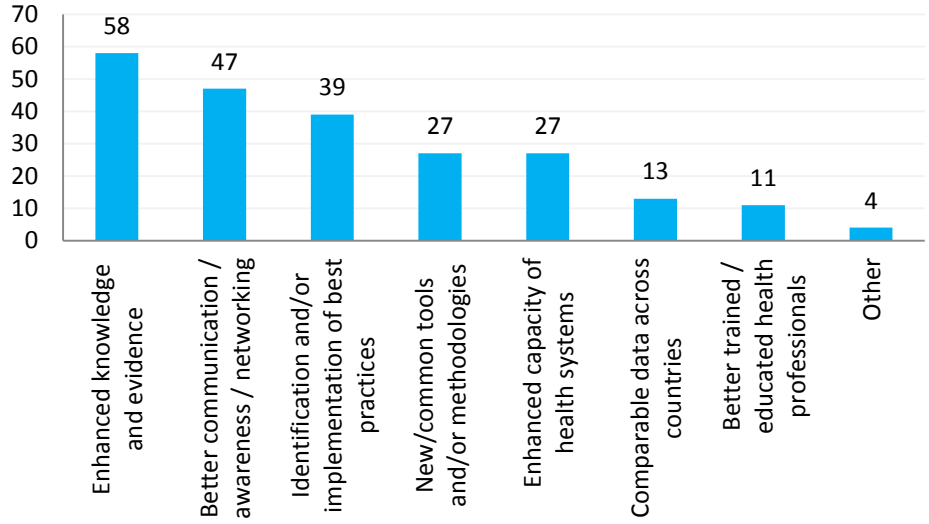


Desired results

Desired results were assessed by the evaluation team according to eight categories formulated for the mid-term evaluation. Importantly, the results reflect the extent to which we considered a project to be designed for achieving one of the eight criteria rather than areas where they were likely to achieve impact (which is assessed more in the EU added value analysis and case studies).

The results of the in-depth review show that most actions (around three quarters) aimed to "enhance knowledge and evidence". More than half were classified as seeking to achieve "better communication, awareness and networking", while just short of half were considered to involve the "identification/implementation of best practices". One third of actions reviewed seek to "build capacity" either "by developing new common tools and methodologies" and/or through "enhancing the capacity of health systems". Actions aimed at "developing comparable data across countries" and/or "better trained/educated health professionals" were found to be the least common.

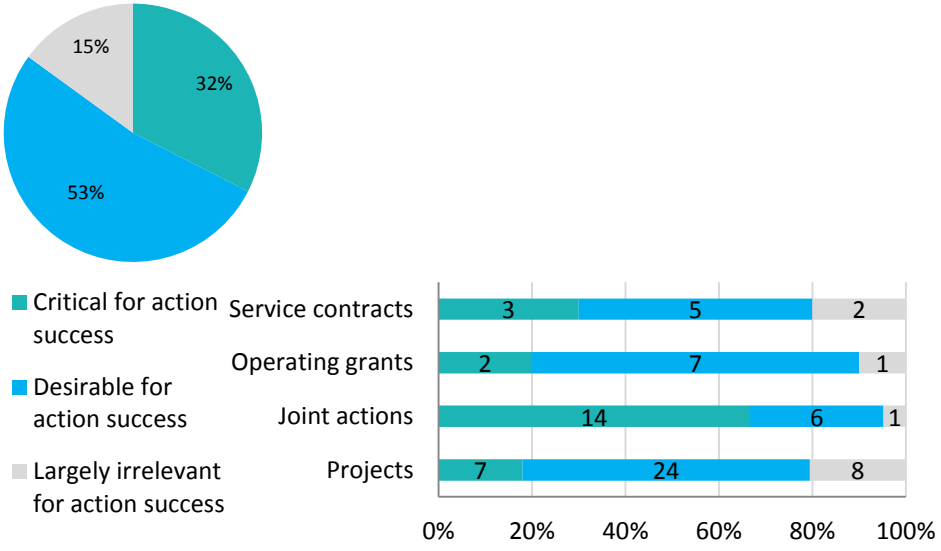
Figure 28: Desired results of actions



Potential impact on national policy

The assessment showed that having an impact on national policy was at least 'to some extent' relevant for the success of most actions (85% - Figure 29), while for nearly one third of actions, it was judged as critical for action success. Perhaps reflecting the stakeholders involved, the extent to which influencing national policy was considered important for an action's success was most pronounced for joint actions (Figure 29). All but one joint action reviewed was seen to depend on influencing national policy for success and for two thirds of these (14 out of the 21), it was seen as "critical". For all other action types, impact on national policy was deemed relevant but more often as "desirable", not "critical".

Figure 29: Extent to which "Impact on national policy" determines the success of an action, overall and by action type



Dissemination

As part of the in-depth review, the specific dimensions of the dissemination approach of each action were assessed. For instance, whether a dissemination plan was available, who the main target audiences were and how they might be reached (activities). In terms of target stakeholders, the IDR analysis revealed that (see table below):

- Government organisations were most frequently among the target audiences, across all four types of action. Within this group, policy makers and regulators (e.g. ministries of health) predominated, being the prime target audience across all four actions;
- NGOs were the second largest target audience on the whole (when broken into the broad stakeholder categories), although NGOs representing health and social care professionals were much more prolific than those representing service users, or covering non-health issues;
- Academic and research organisations were the third largest target audiences. They were targeted slightly more through joint actions, than other action types;
- Commercial organisations were less of a target audience priority, although they were identified as a key target for service contracts (particularly private healthcare providers), and to a lesser extent projects.

Table 25: Key target audiences for HP actions

Stakeholders – target audiences	Overall	PJ	JA	OG	SC
Governmental org. - Health policy makers and regulators	1	1	1	1	1
Governmental org. - Healthcare providers and commissioners	2	2	11	3	2
NGOs - Health and social care professionals	3	3	6	5	8
Governmental org. - Specialised health organisations / institutions	4	6	2	2	2
General public	5	3	9	3	N/A
Academic and research org. - Research organisations and institutes	6	5	4	13	5
Governmental org. - General public health organisations / institutions	7	7	2	7	N/A
International organisations	8	11	4	7	2
Academic and research org. - Universities	9	7	8	7	8
NGOs - Patients and service users	10	9	7	5	8
Commercial org. - Private healthcare providers	11	9	13	13	5
NGOs - Hybrid (healthcare professionals and users)	12	15	11	7	N/A
Commercial org. - Industries relevant to public health	13	13	13	7	N/A
Governmental org. - Other (non-health)	14	17	9	N/A	N/A
Media	14	11	13	N/A	N/A
NGOs - Other NGOs (non-health)	16	14	N/A	13	N/A
Commercial org. - Other	16	15	N/A	N/A	5
Others	18	17	N/A	7	N/A

* NB: N/A denotes stakeholder types that were not involved in any actions of a particular type that were reviewed.

In addition, the dissemination tools and activities undertaken for each action were also analysed; the table below provides the results:

Table 26: Dissemination activities and tools used by a sample of HP-funded actions

Dissemination activities and tools	TOTAL (n=80)	JA (n=21)	PJ (n=39)	SC (n=10)	OG (n=10)
Dedicated website	70%	90%	77%	0%	70%
Conferences / events	58%	76%	62%	10%	50%
Reports / guidelines for specialist audiences	48%	67%	41%	40%	40%
Newsletter	44%	67%	33%	0%	80%
Print promotion materials (brochures, leaflets)	29%	52%	26%	0%	20%
Presence on other websites (e.g. Wikipedia)	24%	33%	21%	20%	20%
Scientific publications	20%	29%	23%	0%	10%
Social media activities	10%	24%	5%	0%	10%
Press releases	9%	19%	3%	10%	10%
Briefings for policy makers	9%	19%	3%	0%	10%
Other	8%	0%	15%	0%	0%
Audio-visual materials	3%	5%	3%	0%	0%
Average number of activities and tools per action	3.3	4.8	3.1	0.8	3.2

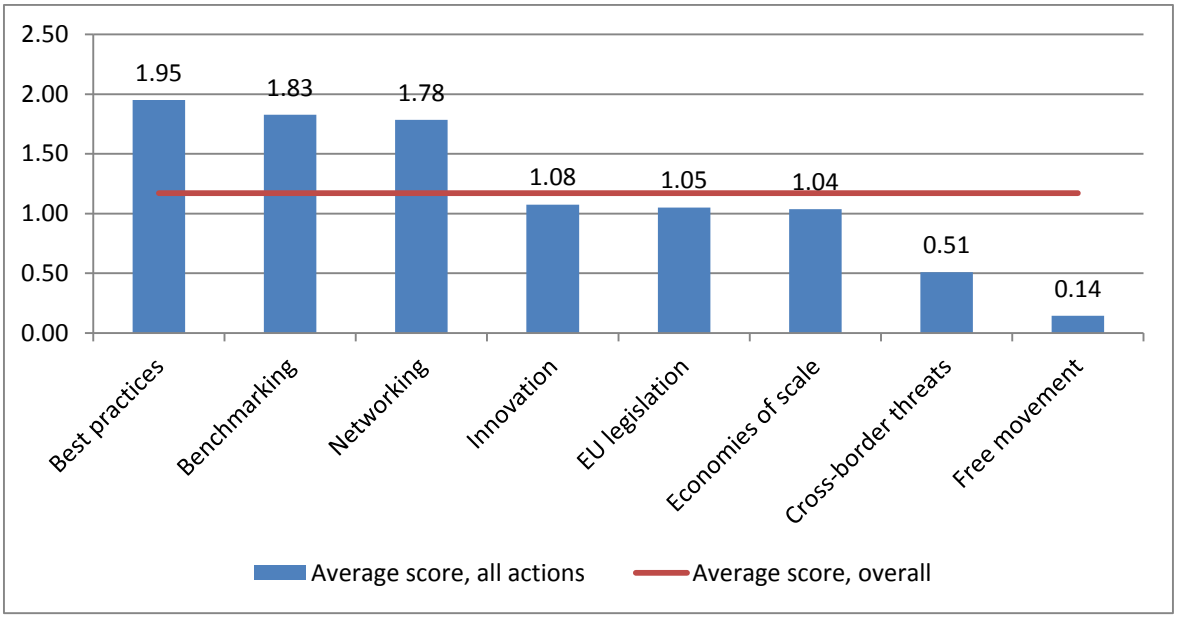
8.2.EU added value analysis of a sample of HP-funded actions

The EU's soft competence in the field of health, in addition to the fact that the health situation in Europe is affected by a huge multiplicity of actors, point the Health Programme's supporting role. To assess the extent to which programme is fulfilling that role, we carried out an EU added value analysis of the 80 actions selected for the in-depth review. The following provides a report on the results.

Analysis by EU added value criteria

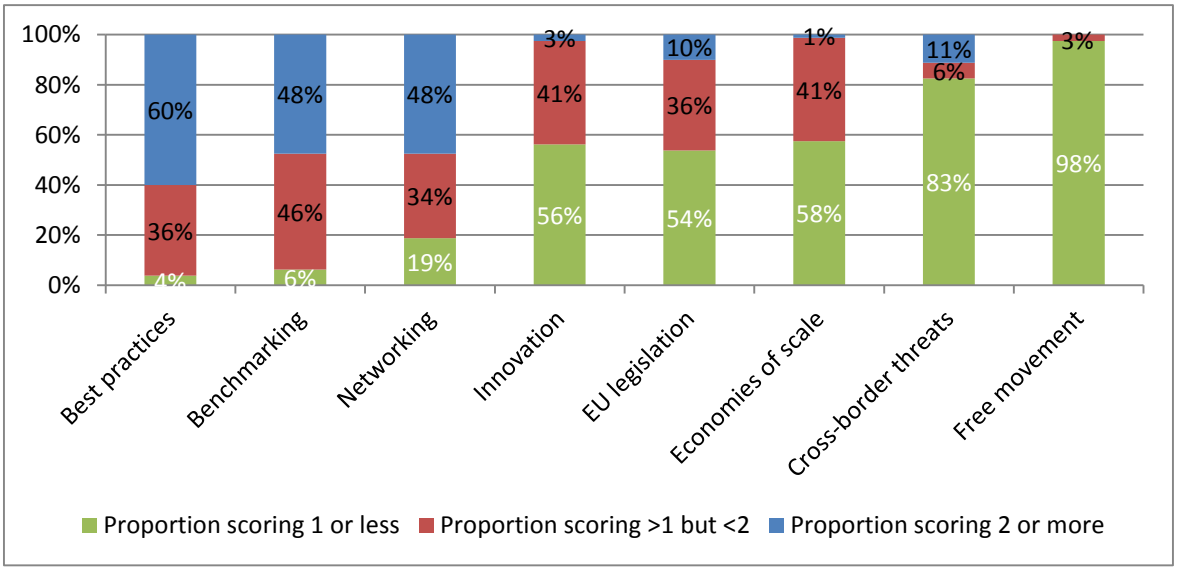
On average, actions scored 1.2 across the eight EU added value criteria. However, there were huge swings depending on the criterion in question. As shown in the chart below, for the criteria relating to the spread of best practices, benchmarking for decision making and networking, average scores neared two (EU added value likely), while for the innovation, implementation of EU legislation and economies of scale criteria they were closer to one (EU added value possible). The potential for actions to add value in dealing with cross-border threats or facilitating the free movement of persons was significantly lower, and in the case of the latter was close to zero.

Figure 30: Average scores by EU added value criteria, all actions



While such averages risk downplaying the EU added value (or lack thereof) of individual actions, further examination shows that these trends do not only hold true for individual actions, but are further pronounced. This is shown in the next chart, which divides actions according into three groups: those receiving low average scores of 1 or less, those receiving medium scores between 1 and 2 and those receiving high scores of 2 or more. The chart emphasises that a far larger proportion of actions scored highly (two or more on average) for the best practices, benchmarking and networking criteria than for any of the others. Indeed, while very few actions scored two or more for the other criteria, large majorities scored one or less. This implies that the programme's EU added value is highly concentrated across just three criteria.

Figure 31: Proportion of actions averaging scores of 2.0 or more and 1.0 or less, by EU added value criteria

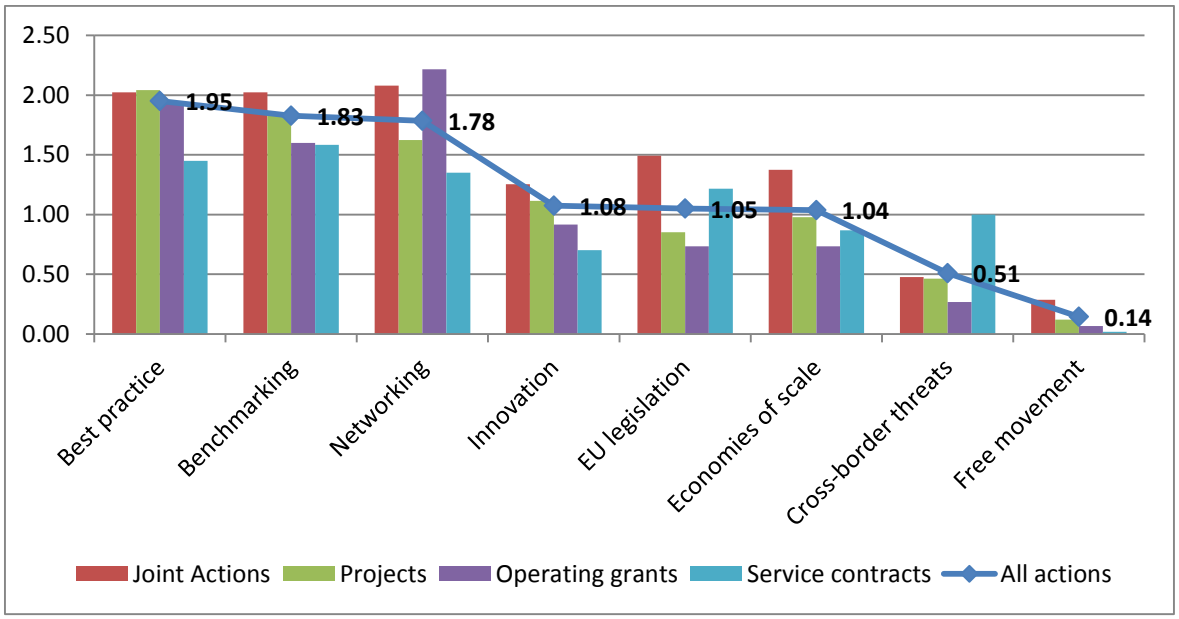


Analysis by action type and strand

Examining the data by action type is less revealing, if only because the EU added value criteria appear more closely linked to the scores than any other factors. However, there are clear trends that are worth reporting. Most importantly, on

average the experts found joint actions considerably more likely to provide EU added value than the other action types. This applied in aggregate as well as across EU added value criteria. As shown in the chart, joint actions scored higher than average across all criteria. The only exceptions related to the cross-border threats and free movement of persons criteria, where scores in any case were relatively low. Indeed, the relatively high score of service contracts in the area of cross-border threats was linked to one action[55] that received the highest possible score.

Figure 32: EU added value per action type

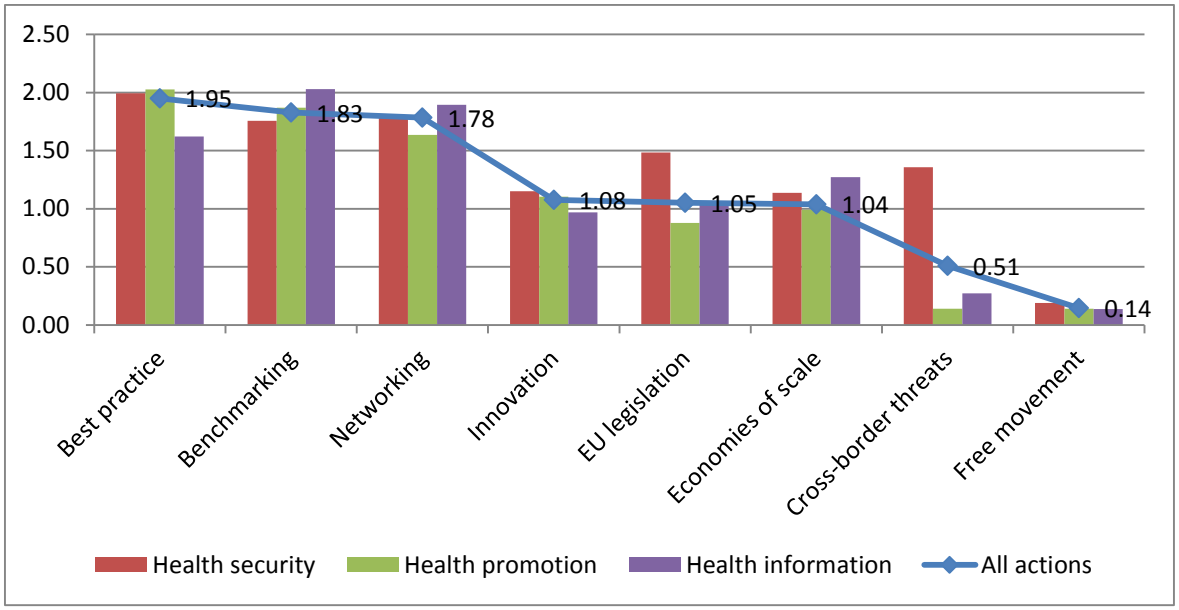


Analysis by strand

Some patterns were also apparent from our analysis by strand, but they were even less marked than for the other factors examined above. On average, actions aimed at Health Security scored higher (at 1.36) than those pursuing either Health Information (1.16) or Health Promotion. As the chart below makes clear, scores related much more closely to specific EU added value criteria than to strand, with patterns very similar to those already described above. Deviations, such as the higher-than-average score for Health Security actions aimed at cross-border threats, can be attributed to a small number of individual projects rather than a general alignment of certain strands and types of EU added value.

[55] Due in part to its status as an outlier, we have suggested that this service contract, 'Organisation of two regional training seminars with Member State public health authorities relating to a new Decision on serious threats to cross-border health', be examined in depth as one of the 13 case studies.

Figure 33: EU added value per strand



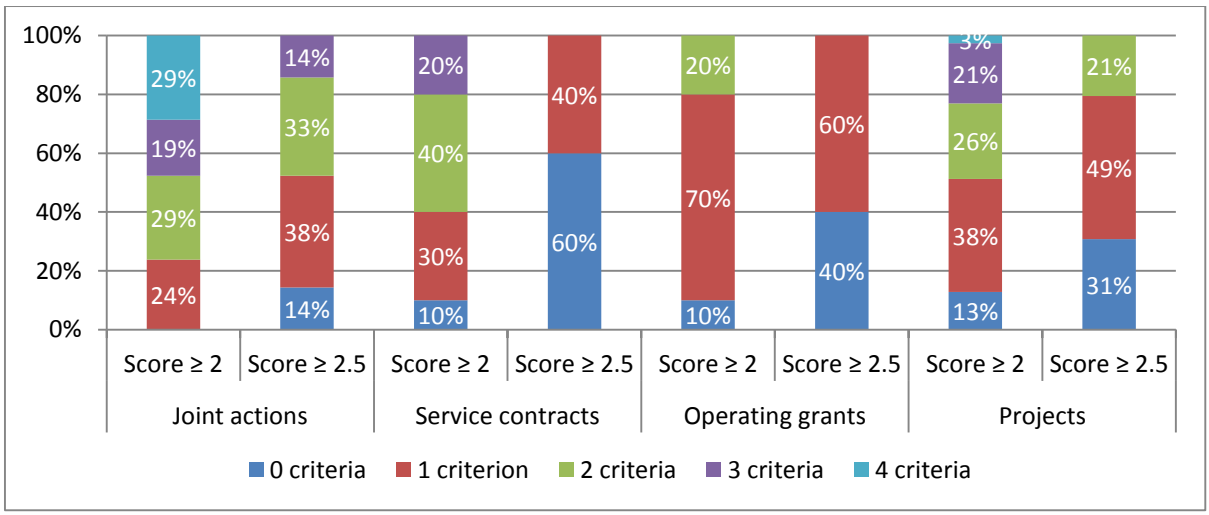
Characteristics of high scoring actions

Leading from the general analysis above, we examined the data to look for characteristics of actions that were relatively successful in terms of their potential to provide EU added value. Of the actions in our analysis, nearly all (96%) were scored a two or higher for at least one EU added value criterion. This demonstrates that the vast majority of actions were considered likely to provide EU added value in a meaningful and substantial way.

However, some actions scored highly across several criteria, with nearly 30% of joint actions being awarded two or higher for four EU added value criteria. This contrasted with the other action types, which were all considerably more focused. As shown in the chart on the next page, while nearly 50% of joint actions scored highly for three or four criteria, less than 25% of service contracts, operating grants or projects were thought likely to have such a wide impact.

Actions scoring 2.5 or higher for any of the EU added value criteria were much rarer and serve to highlight the high perceived added value of joint actions. While nearly half of joint actions were allocated 2.5 or higher for at least 2 criteria, this was only the case for 21% of projects and no service contracts or operating grants.

Figure 34: Proportion of actions scoring 2 or higher or 2.5 or higher, per action type



Divergent views within the expert panel

The scores assigned by the three members of the expert panel were generally consistent across given actions, adding validity to the findings. We examined divergence in two ways. First, we looked at how much the experts' opinions varied across all eight criteria for single actions. To do this, we looked at the spread between the maximum and minimum scores allocated for given actions, and then counted the number of criteria for which the spread was greater than two[56]. For about two thirds of actions, such divergence was limited to one criterion or fewer, and for 90% of actions it was limited to a maximum of two criteria.

We also looked at the scale of the divergence with regard to specific added value criteria, noting instances where there was a spread of three points. This only occurred for 10% of actions and never for more than one criterion at a time. Moreover, there were no discernible patters in terms of the actions types, strand or EU added value criteria involved. Rather than casting doubt on the robustness of the exercise, the actions for which views diverged flagged up issues meriting further exploration. These were taken into account in the selection of 13 actions for case studies.

Summary

The findings from the EU added value analysis allow us to draw out two main themes.

- The first of these is that spreading best practices, benchmarking for policy making and networking are considered by far the main ways for the programme to provide EU added value. In these areas nearly all actions were considered likely to provide substantial value, while for the other criteria such contributions were only perceived as possible at best.
- The second theme relates to the perceived success of joint actions. Joint Actions were seen to spread high amounts of EU added value across a larger number of criteria than other action types. While Joint Actions averaged high scores (greater than 2.0) for three of the EU added value criteria, no other action types achieved such scores for more than one criterion. Projects were shown to add significant value but in a more narrow and focused way. They scored highly for the spread of best practices, but less so for other criteria. Average scores for service contracts and operating grants were lower, but in the cases of a small number of individual projects they allowed the programme to add value against certain criteria, such as cross-border threats, where other actions appeared unlikely to contribute strongly in terms of the scores allocated by the expert panel.

[56] The maximum spread for each score would be three, if one expert allocated a three and another a zero.

9. CASE STUDIES

Overview

During the second half of the evaluation we undertook 13 case studies of actions funded through the Health Programme. The purpose of the exercise was to improve our understanding of how the given actions could contribute to the objectives of the HP and maximise strategic value given the EU's soft competence in health policy and the relatively limited budgets involved.

The case studies applied a highly focused methodology to explore factors and barriers to success and the paths to generating impact for funded actions, with a view to identifying aspects applicable at Programme (rather than individual action) level. In other words, the case studies can be conceptualised as tools for looking at the HP as a whole. By identifying recurring and significant themes, we were able to draw out relevant issues with a high degree of confidence.[57]

Leading from this, the case studies focused on the following areas in particular:

- Design: relevance of the action and potential impact on policy;
- Implementation: examination of whether and to what extent the action was delivered as planned, particularly with regard to conducting activities, achieving proposed milestones and targets, relationships between partners and engagement with other actors;
- Dissemination: appropriateness of the dissemination strategy, particularly with regard to the identification and suitability of target groups;
- Results / impacts: discussion of whether and to what extent the action realised (or was likely to realise) its potential in terms of leveraging the limited budget available, achieving results with wider applicability and making a difference beyond an inner circle of key stakeholders to affect policy.
- EU added value: investigation of the EU added value criteria where the potential impact (allocated by our panel of public health experts as part of the in-depth review of 80 actions, see explanation below) of an action was deemed most likely. Rather than revisiting or reformulating the scores, the ideas was to assess whether and to what extent EU added value for given criteria was achieved in practice.

Methodology

Each case study varied slightly due to the diverse nature of the subject matter. Nonetheless, the nature of the research was the same and consisted of the following sources:

- **Documentation review**: DG SANTE provided documentation as requested (including but not limited to: the proposal, interim and final reports for each action and in some cases evaluation reports). Where relevant and feasible, this was supplemented by additional documentation like publications, conference materials and visiting the action website;

[57] This is not to say that case studies did not reveal salient features about individual actions. However, their performance was examined in more depth in the comprehensive monitoring and (independent) evaluation reports that were produced with such issues in mind.

- **Telephone interviews**: interviews were conducted with relevant stakeholders including action coordinators, associated partners, beneficiaries and DG SANTE / Chafea (see below for more details);
- **Public health expert involvement**: each action was designated an expert who provided support in two phases. The first allowed consisted of an informal exchange (through email and telephone calls) whereby the responsible evaluator provided initial ideas about the theory driving a particular action. This allowed the experts to sense check our preliminary views and raise issues worth investigating in the interviews and other research. The second phase was a more formal quality assurance role that consisted of a review by the expert of a draft version of the case study report.

Based on the research, the team drafted concise reports on the 13 actions. As part of this, we also **allocated scores** to the actions in various aspects of the areas of focus mentioned above (with the exception of EU added value). The scores were then aggregated so that each case study had an average score for design, implementation and so on. While this was not an exact science, scoring the actions facilitated comparison and helped identify key success factors and barriers that applied at a level beyond single actions.

In practical terms, scores were allocated on a 1-3 scale, with 1 meaning 'poor', 2 meaning 'good' and 3 meaning 'excellent'. For example, an action receiving a 3 for impact on policy would imply a high likelihood of achieving a large-scale impact; a 1 would imply that the (necessarily limited) evidence did not support a strong case for future impact. Importantly, the scores should be viewed in light of the purpose and limitations of the case study methodology, and *not* as substitutes for comprehensive evaluations of individual action performance.

Note that scores for **EU added value** were allocated as part of in-depth review of 80 actions[58] contained in Annex 8. In brief, this entailed reviewing each of the actions against a set of eight criteria developed by Chafea that informed the evaluation of funding applications. The criteria are summarised in the table below

Table 27 – EU added value criteria

Criteria	Definition
Implementing EU legislation	To ensure that the funded actions are contributing to the development and/or implementation of EU legislation
Economies of scale	To save money and provide a better service to citizens by avoiding a duplication of efforts and by cooperating across national health systems
Promotion of best practice	To apply best practice in all participating Member States, e.g. by identifying procedures, approaches, methods or tools that could be applied by healthcare professionals or others
Benchmarking for decision making	To facilitate evidence-based decision making, e.g. by providing scientific information, real time data for comparison, and/or indicators that can impact on decision making at a higher political / policy level
Cross border threats	To reduce risks and to mitigate the consequences of cross border health threats by establishing relevant structures for coordination
Free movement of persons	To increase the movement of patients and healthcare personnel between EU Member States, thereby contributing to a better match between supply and demand

[58] Any case study actions not included as part of the in-depth review were scored for EU added value using the same process.

Networking	To make sure that networking activities among stakeholders, which contribute to knowledge sharing and building health capacity in the EU, are supported and sustained
Unlocking the potential of innovation	To support the deployment of innovative solutions for healthcare provision, in terms of both products and services

The actions were scored on a three-point red-amber-green scale as per the table below, with 0 representing 'no EU added value foreseen' and 3 equating to 'EU added value almost certain'. Half scores (e.g. 2.5) were permitted where the experts saw fit.

0	**No EU Added value foreseen**	**Not a result** of the Action based on the Action's objectives / intended effects
1	EU added value **possible**	**Not an explicit result of the Action, but limited EU added value may arise as a bi-product** based on the Action's objectives / intended effects
2	EU added value **likely**	**A likely result** of the Action based on the Action's objectives / intended effects
3	EU added value **almost certain**	A **most definite result** of the Action based on the Action's objectives / intended effects

Sample and implementation

The sample of 13 actions was restricted to joint actions, projects and service contracts and was chosen purposefully in collaboration with DG SANTE and Chafea. It consisted of the following actions.

Table 28 – Case study actions

Action type	Action name	Strand	Action status
Joint actions	EUnetHTA JA	Health information	Finalised (2013 end)
	EJA	Health promotion	Ongoing (Oct 2012 start / 42 months)
	QUANDHIP	Health security	Finalised (Aug 2014 end)
	FOEDUS	Health security	Ongoing (May 2013 start)
	NANOGENOTOX	Health security	Finalised (March 2013 end)
Projects	Salux	Health promotion	Finalised (Aug 2014 end)
	EURONEOSTAT II	Health information	Finalised (Nov 2012 end)
	EuroHeart 2	Health promotion	Finalised (Aug 2014 end)
	EUMUSC.NET	Health information	Finalised (Feb-2010 start)
	EFRETOS	Health security	Finalised (Jan 2013 end)
Service contracts	Reimburse med prod	Health information	Finalised
	RFS 2	Health security	Finalised (April 2014 end)
	Harm Alcohol	Health promotion	Finalised (December 2013)

For the research, interviews were conducted with 41 organisations (or individuals representing organisations in the case of Chafea and DG SANTE). Project coordinators were interviewed for all actions, as were the relevant project officers at Chafea (two out of the eight officers interviewed were responsible for multiple actions). Where relevant and possible, we also interviewed associated partners, in addition to DG SANTE officials and beneficiaries (such as users of action deliverables) as applicable.

Table 29 – interviews conducted as part of case study

Interviewee roles	Number of interviewees
Chafea Project officer responsible for action	8
Lead partner organisation in charge of coordination work package (along with others)	14[59]
Associated partners	13
DG SANTE officials	5
Beneficiaries	1
Total	41

Summary

As noted above, we allocated scores between 1-3 (with 1 being 'poor', 2 being 'good' and 3 being 'excellent') to the case study actions in the key areas of interest. While the scores should not be used in isolation to assess the performance of individual actions, for the purposes of comparability, the summary scores are reproduced in the table on the next page. The following subsections then contain the full case study reports.

Table 30 – Case study score summary

Action type	Action name	Design	Implementation / outputs	Dissemination	Results / impacts
Joint actions	EUnetHTA JA	2.7	2.7	2.5	2.2
	EJA	2.3	2.0	2.7	2.0
	QUANDHIP	2.7	2.5	2.0	2.7
	FOEDUS	2.2	2.3	1.5	2.0
	NANOGENOTOX	2.0	2.7	2.3	2.0
Projects	Salux	2.2	1.8	1.3	1.3
	EURONEOSTAT II	1.7	2.0	1.7	1.7
	EuroHeart 2	2.3	2.2	2.5	1.8
	EUMUSC.NET	2.7	2.2	2.3	2.0
	EFRETOS	2.3	2.3	2.2	2.0
Service contracts	Reimburse med prod	2.7	2.5	1.3	1.5
	RFS 2	2.7	2.8	2.2	1.2
	Harm Alcohol	2.3	2.0	2.6	1.4

[59] For one action, FOEDUS, coordination was shared between two organisations, thereby requiring two interviews.

9.1. EUnetHTA JA - European Network for Health Technology Assessment (Joint action)

Summary

The first EUnetHTA JA (which was preceded by a HP-funded project and followed by a second JA) illustrates how a joint action can work in the best of circumstances: it addressed a highly relevant topic where there was a real appetite for cooperation between MS, was well managed, coordinated and implemented by an effective partnership of national HTA agencies and other relevant organisations from nearly all MS, engaged stakeholders to a significant extent, and achieved real progress in terms of developing and testing common tools and approaches. Thanks to all this, there is significant potential for increased use of HTAs across Europe (including in "weaker" MS), and for cost savings for national HTA agencies from joint working and avoiding duplication of efforts. This in turn has the potential to foster innovation and lead to more evidence-based national health policy making.

However, the JA has also shown that achieving this is a long process, as considerable technical, methodological, cultural and others barriers need to be overcome before the common tools are usable, and there is sufficient commitment and trust among MS to put them into practice on a significant scale. In the case of EUnetHTA, this has required nine years and more than €11 million of EU funding so far, and while there are first tentative signs of an increasing acceptance and use of the results, and the return on the investment may finally begin to materialise, cooperation on HTA still seems far from having reached a sustainable state, and how the network can be turned into a permanent structure remains an open question.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

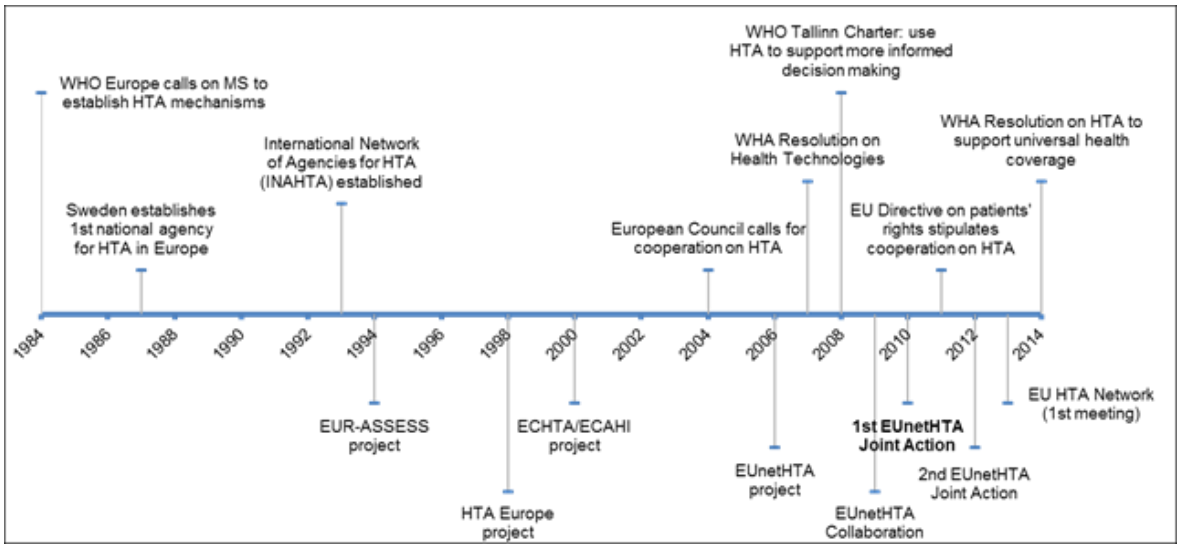
Evaluation area	Average score (1-3)	Explanation
Design	2.7	A very relevant, well-structured and designed action, in an area where previous projects had already shown the potential benefits of collaboration between MS.
Implementation / outputs	2.7	Effectively and efficiently implemented and managed, making use of the collective expertise and commitment of all key players in Europe, with a focus on practical results.
Dissemination	2.5	Technical action aimed mainly at a specialist audience, but with significant efforts to raise awareness among and engage policy makers as well as relevant stakeholders.
Results / impacts	2.2	Good progress made with developing, testing and fine-tuning tools and methods, but in spite of increasing buy-in from MS, their uptake and application in practice is a slow process, and sustainability is a concern as a third and final JA is currently being discussed.

Introduction

Health Technology Assessment (HTA) began to gain prominence in the 1980s, and has been a focus of attention for the EU since around the mid-1990s. According to the WHO, HTA refers to "the systematic evaluation of properties, effects, and/or impacts of health technology (defined as the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life). It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making".[60]

Between 1994 and 2002, the EU funded three major projects that sought to support collaboration on HTA methods and working. Following a call from the European Council in 2004 for systematic EU-wide cooperation to enhance the exchange of expertise and information, the EUnetHTA project was funded under the first EU Health Programme (HP) in 2006 to establish an effective and sustainable European Network for HTA. Its work was continued and expanded by two Joint Actions (JAs) funded under the second HP. The first of these (JA1), which was meant to "ensure the continuation and development of [HTA] in the EU, including work on relative effectiveness (RE) of drugs"[61], is the subject of this case study.

Figure 35: Key milestones on Health Technology Assessment in Europe



According to the final report, the broad intent of EUnetHTA JA1 was to take forward the prior developments of the EUnetHTA Project[62], and bring them to a level that enables a genuine collaboration that is implemented in practice. To do so, the JA1 aimed to examine and overcome barriers to collaboration; develop a practice of stakeholder involvement; improve the EUnetHTA tools through further testing and

[60] Health Technology Assessment, WHO. URL: http://www.who.int/medical_devices/assessment/en/

[61] Commission Decision 2009/158/EC on the adoption of the Work Plan for 2009 for the implementation of the second programme of Community action in the field of health (2008 to 2013)

[62] Key development prior to the EUnetHTA JA1 include the HTA Core Model, a framework for producing and sharing structured HTA information, which had been developed and tested in two projects; an Adaptation Toolkit and an Adaptation Glossary; the first version of a database for new technologies requiring additional evidence generation, called EIFFEL; a series of websites and e-tools; and substantial developments in the area of coordination and management.

user feed-back, and promote their actual implementation in the everyday practice of European HTA organisations (thereby reducing duplication of efforts in the production of HTAs); and further develop the collaboration management structures. In this context, it is worth mentioning Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (CBHC Directive), which was adopted while the JA1 was ongoing, and stipulated the implementation of a permanent European network for HTA.

Just like the EUnetHTA project before it (as well as the second JA after it), the first EUnetHTA JA was led and coordinated by the Danish Health and Medicines Authority (DHMA). It included 33 associated partners (government appointed organisations from almost all EU Member States, Norway and Croatia) and 26 collaborating partners (including regional agencies and not-for-profit organisations that produce or contribute to HTA). It covered the period from 2010 to 2012, and received a grant from the HP totalling almost € 3 million.

Table 31: Key features of the action

Full name	European Network for Health Technology Assessment Joint Action
Acronym	EUnetHTA JA
Funding instrument	Joint Action
Action number	20092302
HP strand	3. Health information
Priority	3.2. Collect, analyse and disseminate health information
Sub-priority	3.2.1. Develop a sustainable health monitoring system and collect comparable data
Maximum EC contribution	€ 2,903,898
Actual start date	1 January 2010
Duration (in months)	37
Status	Finalised
Lead partner	Danish Health and Medicines Authority (DHMA)
No. of associated partners	33
No. of collaborating partners	26

Table 32: Work packages and partners

WP	Work Package Description	Lead institution
1	Coordination	Danish Health and Medicines Authority (DHMA)
2	Dissemination	Institute of Public Health of the Republic of Slovenia (IPH-RS)
3	Evaluation	NIHR, Evaluation, Trials and Studies Coordinating Centre (NETSCC), UK
4	Core HTA	The National Institute for Health and Welfare (THL), Finland
5	Relative Effectiveness Assessment of Pharmaceuticals	National Health Care Institute, Netherlands
6	Information Management System	Belgian Health Care Knowledge Centre (KCE)
7	New Technologies	French National Authority for Health (HAS), France

8	Strategy and business model development	Danish Health and Medicines Authority (DHMA)

The analysis in the remainder of this case study report is based on a review of relevant project documentation (proposal and deliverables), as well as interviews conducted in December 2014 with three partners (leaders of work packages 1, 2 and 4) and the responsible CHAFEA project officer.

Design

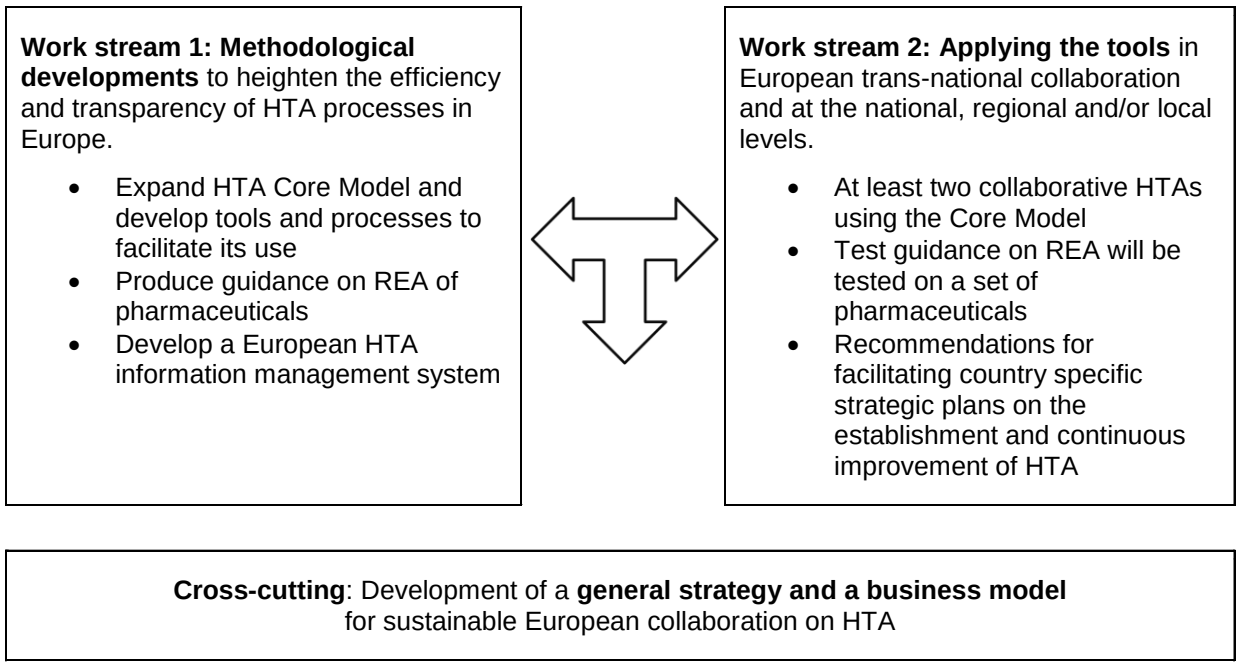
Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	3
Feasibility of implementation plan	2

The **relevance** of HTA is underlined by the continued interest from the WHO and a large number of national (and in some cases regional) governments. The case for European collaboration seems clear: the JA1 grew out of and built on the work undertaken during the previous project. When this came to an end in 2008, a number of Member States continued to work together – without EU funding – in 2009 through the so-called EUnetHTA "collaboration". This fact alone confirms the relevance of the issue to Member States, who felt that the tools and approaches developed during the project needed to be taken forward. During the interviews, it was noted that pan-European cooperation on HTA is especially (but not exclusively) relevant for smaller countries that may not have the resources to systematically assess all new health technologies that become available.

Work on the **design** of the JA1 was mostly undertaken during 2009. The Danish competent authority, which had already coordinated the project, took the lead again, since although the amount of work involved was reportedly considerable, the DHMA had the capacity to lead and felt that doing so would be useful and beneficial both from a European and from a national perspective. Other countries' competent authorities were actively involved in planning and designing the JA, as was DG SANTE. The national partners were nominated by the governments of Member States; the core of partners was the same as for the predecessor project, with some new partners joining (partly because of the fact that the JA1 covered Relative Effectiveness Assessment (REA) of pharmaceuticals, an issue which emerged from the High Level Pharmaceutical Forum (2005-2008)). There appear to have been no problems finding partners to lead the various WPs. The representatives of the partners who were interviewed were satisfied with the process; it required intense discussions to flesh out the WPs and decide on the proportions between the different activities, but in the end a good balance was struck.

The work of the JA1 can perhaps best be understood as two separate but closely related **work streams**, as per the diagram below. On the one hand, the methods and processes that had been developed during the project were further fine-tuned, and certain new tools developed. In parallel, these tools and approaches were piloted in collaboration between various partners so as to ensure their applicability and appropriateness. In addition, and cutting across these streams, the work on developing a strategy and business model to achieve sustainable European collaboration on HTA continued. The underlying logic, and the way the work was organised, seem very robust, and the implementation and results (see below) confirm the plans were largely appropriate and feasible.

Figure 36: EUnetHTA JA1 main work streams



Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2.5
Fostering of collaboration and partnerships	3
Engagement with other actors (incl. DG SANTE / CHAFEA)	2.5

The information retrieved via the interviews and review of documentation suggests that, in spite of the challenges posed by the size and scope of the action and the large number of partners involved, the JA was **implemented in a very professional, effective and efficient way**. The work plan was described as conceptually and practically sound, and by and large, adequate funding was available for the different activities. Therefore, no major difficulties with conducting the activities and producing the outputs in accordance with the plan were reported (although, as noted in the final report, some deliverables or objectives were changed for well-founded reasons). Interviewees explained that CHAFEA had repeatedly pointed to this JA as a model for others to emulate.

Interviewees also felt that, far from losing momentum (as could perhaps be expected of a JA that follows in the footsteps of four years of previous work), the action actually generated what was described as a **'snowball effect'**, as there were plenty of good and relevant tasks and ideas still to pursue to build on and operationalise what had been produced before. According to some interviewees, it was notable how as the work proceeded, buy-in from MS increased and they adopted a more and more collaborative attitude. Whereas during the project, there was reportedly still a significant amount of concern and sometimes negativity in WP meetings about what EUnetHTA would do and whether standardisation would go too far, these were largely resolved during the JA1, as attitudes became more positive and constructive, and participants increasingly understood "it's about mutual support, not complete standardisation".

The **partnership** also broadened during theJA1: although one Associated Partner went inactive during the JA (from the Czech Republic), two new organisations joined the JA (from Slovakia, Croatia) and participated actively and at their own expense. A number of organisations also joined the original list of the Collaborating Partners. The few MS that were not represented among the Associated Partners of the JA1 (Cyprus, Luxembourg, Romania) did eventually nominate organisations to participate in the EUnetHTA JA2, effectively bringing the coverage of EU MS to 100%.

The **key success factors** of the JA1 included first and foremost:

- A relevant topic, where pan-European collaboration is possible (although not necessarily straight-forward) and the added value of participating is relatively clear to all. In the evaluation survey for the JA that was conducted in 2012, 80% of the respondents found the collaboration very useful.
- The nature of the partnership, which included a core of relevant institutions that had a good understanding of the issues at hand and how collaboration would help. All the most important institutions in Europe were represented, and there was reportedly "a lot of expertise around the table".
- A focus on producing practical results and creating value; the coordinator but also other partners emphasised pragmatism and the need to produce results that would be useful and applicable in a real-world setting by participants.
- The development of an effective management structure, with a Technical Secretariat, a Plenary Assembly, and an Executive Committee. DG SANTE participated in the latter, which reportedly added value in terms of overall management and governance. A Stakeholder Forum was also set up to foster engagement with a broad range of stakeholders, including patient organisations, healthcare providers, payers (statutory health insurance) and the industry.
- Solid project management, which required a dedicated and competent coordinator with a good understanding of and the capacity to implement effective processes and systems.

In terms of the **administrative aspects**, interviewees noticed surprisingly little difference between the JA and the previous project in practice. Most felt that it was essentially the same for most intents and purposes. The collaboration with CHAFEA was assessed positively; it was said to function effectively in terms of financial and other administrative processes, provide help when needed, and also be prepared to listen and at least try to address most problems that arise. The only problems that were mentioned were (1) a certain lack of flexibility imposed by the need to budget up front for the full three years, and the relatively onerous procedure for the (inevitable) re-budgeting as the action progressed; and (2) the fact that national officials were considered to be both a contribution and an expense in the budget, which was said to have led to inequality and in some cases, "perverse" incentives. [NB: Both of these issues have reportedly been addressed and resolved with the launch of the 3rd HP.]

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	2.5
Effectiveness of tools and channels used	2.5
Sustainability of dissemination activities (incl. use of multipliers)	2.5

The **target groups** were very clearly defined at the outset. This was an action aimed primarily at a very specific technical audience, and only indirectly at a (still relatively narrow) audience of policy makers and stakeholders:

- The primary target groups of the EUnetHTA JA were the producers of HTA and bodies assessing the relative effectiveness of pharmaceuticals in Europe.
- The secondary, more indirect target group comprises those who fund, commission or in other ways are users of HTA reports – the policy-makers and decision-makers who use the HTA information in their formulation of policies and decisions.

Interviewees confirmed that HTA is a topic for specialists (i.e. HTA producers and users), but that the JA still sought to address decision makers and stakeholders (patient and healthcare consumer organisations, healthcare providers, payers (statutory health insurance) and the industry) as much as possible, since it was deemed important to raise awareness of HTA and its benefits among these groups.

A number of tools and activities were used for dissemination, including a number of **electronic media** such as newsletters, an entry on Wikipedia and, interestingly, a presence on social media. The JA experimented with LinkedIn, Facebook and Twitter; however, without a dedicated person to generate content, these groups / accounts were never very active, and their use was discontinued. A video on HTA was also produced, as were physical promotion materials such as leaflets, all using a recognisable logo.

A large **conference** with around 300 participants was held in 2011 in Gdansk. The fact that it was possible to organise such an event in the second (and not the third and final) year of the JA was due to the progress already made during the preceding project and collaboration, which meant that plenty of results could be presented, as well as providing an opportunity to discuss next steps, and feed into the parallel process of finalisation of the CBHC Directive and its implementation. The conference was described as very successful and timely by interviewees, who further noted that JA participants also gave a great many presentations to different audiences, and were "quite liberal" in saying yes to invitations and requests to present about EUnetHTA. The key stakeholder groups were also involved and engaged directly via the dedicated **Stakeholder Forum** (which met three times per year) and the stakeholder advisory groups within WPs 4, 5 and 7.

A series of more than ten **scientific articles** were written about the (results of) the JA1. At the time of writing, these had been accepted by a peer-reviewed scientific journal, the International Journal of Technology Assessment in Health Care (IJTAHC), and their publication in a dedicated EUnetHTA theme section was imminent. Interviewees noted that this is typical of the long delays (in this case, nearly three years) that often occur between an action and related publications.

Overall, the dissemination effort appears **adequate and broadly successful** in view of the nature of the JA. **Sustainability** is guaranteed by the subsequent JA2, which means inter alia the website continues to be updated, another conference was held in 2014, etc. Nonetheless, an interviewee who was directly involved with WP2 felt that **more could have been achieved** if partners had prioritised and engaged with communication and dissemination more, and if more resources had been available. It was noted that dissemination should be a key feature of each WP, and not only something that is outsourced to a horizontal WP (which brings with it the risk that technical WP leaders forget about dissemination to some extent).

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2.5
Impact on policy	2
Robustness of evaluation strategy and reporting	2

An "**independent internal evaluation**" of the JA1 was conducted under WP3. It was based primarily on a series of annual surveys of JA participants, Plenary Assembly members, and Stakeholder Forum members. In line with the distinction between the two main work streams outlined above, the key evaluation results[63] can be summed up as follows:

- **Methods and tools development**: The Core HTA Model (which was first developed during the project and refined and added to during the JA1) was intended to overcome the barriers to collaboration between HTA agencies from different countries and cultures (due to variation in assessment practices, preferred report structure, use of research methods and language) by providing a structure that allows selecting only important and shareable assessment elements (and leaving the country specific or controversial issues out of the joint assessment) and by providing methodological guidance for users. The evaluation survey in 2012 found that 60% of respondents had used the HTA Core Model, and an additional 28% considered using it in the future. The proportion of partners who regularly updated their planned and on-going projects to the POP database (thereby enabling HTA agencies from other countries to be aware of HTAs that are ongoing or have been completed) rose from 0 to almost 80 % during the JA1 and the number of project entries in POP was 1267 by the end of year 2012. Overall, approximately half of the 2012 survey respondents perceived the tools as "very useful".
- **Applying the tools**: Three pilot assessments using the HTA Core Model were undertaken as part of the JA1, as well as 12 shared traditional rapid HTA projects. These exposed different perceptions and practices in the use of methods, but there was a willingness to listen and adopt the ideas of others, reflecting an overall confidence that was increasing towards the end of most activities. It is important to note that the pilot projects did not reflect the everyday practices of the partner organisations. Therefore, the evaluation concluded that it was still too early to assess the benefit of the tools in practice, although prediction of use was described as encouraging.

Overall, the internal evaluation concluded that the EUnetHTA did put into practice an **effective collaboration that is sustainable**. This is reflected by the fact that a follow-up EUnetHTA JA2 was considered needed and appropriate to sustain collaboration before the establishment of any permanent network. Most of the high-level objectives of the WPs were achieved. However, in spite of the overall positive impression, there was also a clear **need for further improvements**, both of the tools and the management of the collaborative projects. The quality and relevance of the HTA information produced was one of the major issues brought up. It was felt that the JA1 was **not yet able to clearly demonstrate the added value** of participation for the agencies themselves, namely that it eventually reduces the overall expenses and resources required by partners because of the access to HTA information provided by others on other topics.

[63] EUnetHTA Joint Action Final Technical Report, May 2013, pp. 16-24

The interviews broadly confirmed these views, but also provided a **longer-term perspective**, since they were able to take into account further developments in the nearly two years since the JA1 had ended. Interviewees emphasised the overall usefulness and value of the tools, especially the Core HTA Model, and noted that from around 2013-2014, **some national HTA agencies are finally using the Model in the way it was intended**, i.e. producing national HTAs in this way, and using relevant bits of information produced either within the JA or by another MS as part of the national HTA. Use of the POP database has also been incorporated into the standard procedure in some countries, so that HTA agencies that are considering starting a national HTA increasingly check the database, and may contact other agencies that are (considering) working on the same topic, with a view to exploring potential for joint working or using each other's results.

It was felt the reasons why it had taken so long was that many HTA agencies have existed for years and developed their own approaches, and it has taken time for them to grasp the benefits of the international (i.e. more coordinated and harmonised) approach. Now that the tools are finally being used in a real-world setting, feedback is reportedly mostly positive; there still remain challenges to overcome, but the overall value of the approach is rarely being questioned anymore. Interviewees noted that the timeframe for the first impacts to emerge – at least five years from the initial work on developing the Model, to pilot testing and refining it, to its actual use in a real-world setting – seemed fairly typical in an environment fraught with methodological, institutional and cultural complexities. At the same time, it was noted that some countries still lack the institutional capabilities to conduct effective HTAs, and therefore are not in a position to take full advantage of the opportunities provided by the common tools.

Regarding the JA's potential impact on policy, interviewees emphasised that EUnetHTA plays a technical and scientific role, whereas policy cooperation takes place within the EU HTA Network that was established following the adoption of the CBHC Directive in 2011 and met for the first time in October 2013. Nonetheless, interviewees were adamant that the work under the JA1 and its successor has helped considerably in bringing the scientific level and the policy level of HTA closer to each other, and that thanks to EUnetHTA, policy makers have become more conscious of HTA activities in different countries. Therefore, the JA has affected policy, and prepared the ground for more evidence-based policy making in the area of health technologies.

A final issue that is worth discussing is that of sustainability. As noted previously, the JA1 followed in the footsteps of a previous project, and was followed by a second JA (with a significantly larger EC contribution). In total, EUnetHTA will have absorbed over €11 million of EU funding between 2006 and 2015. There are currently even discussions about the need for a third JA for the period from 2016 to 2019, as in spite of all the progress that has been made, the collaboration and the tools are unlikely to reach a sustainable end point by the time the JA2 comes to an end. Some interviewees voiced concerns over the fact that it is still unclear how exactly cooperation between MS on HTA can be organised and funded in the future, and the inherent risk of the need for continuing EU funding with no end in sight. On the other hand, interviewees explained that it was very clear to all participants that a possible JA3 would definitely be the last one, and would have to be used to find a permanent solution. They noted that EUnetHTA was reaching a crossroads, and expressed the hope that MS would recognise the value of European collaboration on HTA, and increasingly be willing to invest their own resources.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the JA against eight pre-defined criteria as shown in the table below. In

what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	1.2
Economies of scale	**1.7**
Promotion of best practice	1.5
Benchmarking for decision making	**2.0**
Cross border threats	0.2
Free movement of persons	0.0
Networking	**2.7**
Unlocking the potential of innovation	**1.8**

Criteria 1: Networking

Networking was clearly one of the main benefits of the JA, both according to interviewees and to the internal evaluation survey in 2012, which suggested that the 'added value' from networking was even greater than that of the tools that were developed. The JA was very successful in facilitating networking because it was supportive and aware of the needs of MS, and supports decision making processes not at the EU level but at MS level. As such, it is an example of how EU cooperation can work even in areas of exclusive MS competence.

Criteria 2: Benchmarking for decision making

The EU added value in the area of benchmarking is potentially very significant, and mainly has to do with building HTA capacity in "weaker" MS, so that these can conduct their own HTAs and access those produced by other MS, and use the results for evidence-based decision-making. Capacity building is an ongoing challenge (and needs to go hand in hand with institutional development), but progress is reportedly being made. To build on this, it was suggested that a possible future JA3 could include measures such as training, exchanges, and/or fellowships for knowledge transfer.

Criteria 3: Unlocking the potential of innovation

HTA can lead to the greater use of innovative health technologies by enabling decision-makers to identify innovations that really make a difference. Therefore, a more widespread and systematic use of HTA across Europe is likely to lead to a wider use of the most impactful and cost-effective innovations.

Criteria 4: Economies of scale

Overlapping and double work performed in HTA agencies in Europe has been one of the main drivers of developing the collaboration. EUnetHTA aimed and aims to enable MS to use the work undertaken by others as part of their own national (or in some cases regional) HTAs, which would lead to significant cost savings. According to interviewees, after a long period of methodological development and building trust and commitment, this is finally starting to happen, and there are the first examples (e.g. on colorectal cancer screening) where national HTA agencies are taking the work of others as a starting point for their HTAs.

Conclusions and lessons learned

EUnetHTA (including the project, JA1 and JA2) is an example of where HP funding has facilitated **successful collaboration between MS** on an issue – health technology assessment – where the **potential added value is clear** (primarily in terms of eventual cost savings from joint working and avoiding duplication of efforts, and the adoption of more evidence-based approaches to health policy making across Europe, including MS with a weaker tradition in this field). **Key success factors** include a very relevant topic, a partnership involving all the key institutions and bringing to the table very significant technical expertise, and a focus on pragmatically working towards results that would be directly applicable by and useful to national HTA agencies. This was facilitated by sound project management and effective governance structures, and appropriate budget for all key areas. The Joint Action was a very appropriate funding instrument in this case, as it facilitated a very specific and targeted design of the action, with active involvement of relevant institutions designated by the governments of nearly all Member States.

The JA has led to **significant progress** in terms of developing common tools and collaborative approaches, which – after a long period of pilot testing and fine-tuning – are finally starting to be used in a real world setting by some national HTA agencies, so that the significant investment on the part of the EU but also MS may be beginning to pay dividends. At the same time, it is important to highlight that even after nine years of almost continuous EU funding for EUnetHTA, it still has not reached a point where all difficulties have been overcome, and the tools and approaches are not yet in wide-spread use. With the prospect of a third JA looming, **sustainability is a concern**, and a permanent structure to put the collaboration on a stable footing has yet to be found. This illustrates the challenges inherent in achieving effective cooperation between MS with their different approaches, traditions, cultures, methodological preferences, and available resources. Even with a very well-designed, well-resourced and well-implemented JA, and increasing buy-in from MS, it takes many years until the return on investment materialises – and there is still a risk that it may never be in a position to continue and prosper without some form of EU funding.

9.2.EUCERD (Joint action)

Summary

The EUCERD Joint Action (EJA)'s contribution to the European rare disease (RD) agenda was important, particularly in terms of informing European Commission (EC) policy and promoting the sharing of best practice. However, whilst the design and dissemination activity undertaken through the EJA was strong, there were some issues in implementation and in achieving outcomes.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2.3	Built on previous JA, but insufficient 'groundwork' undertaken to inform management arrangements and technical focus (including development of clear aims and objectives).
Implementation / outputs	2.0	Relatively good management, but mixed performance on each of work packages.
Dissemination	2.7	Strong dissemination and communication strategy in place, including linkages with other relevant initiatives, however information to local policy-makers not always practical enough.
Results / impacts	2.0	Good level of impact on European policy, but insufficient flexibility to develop evolving areas of interest, and mixed impact generated through other work packages – reducing the value for money.

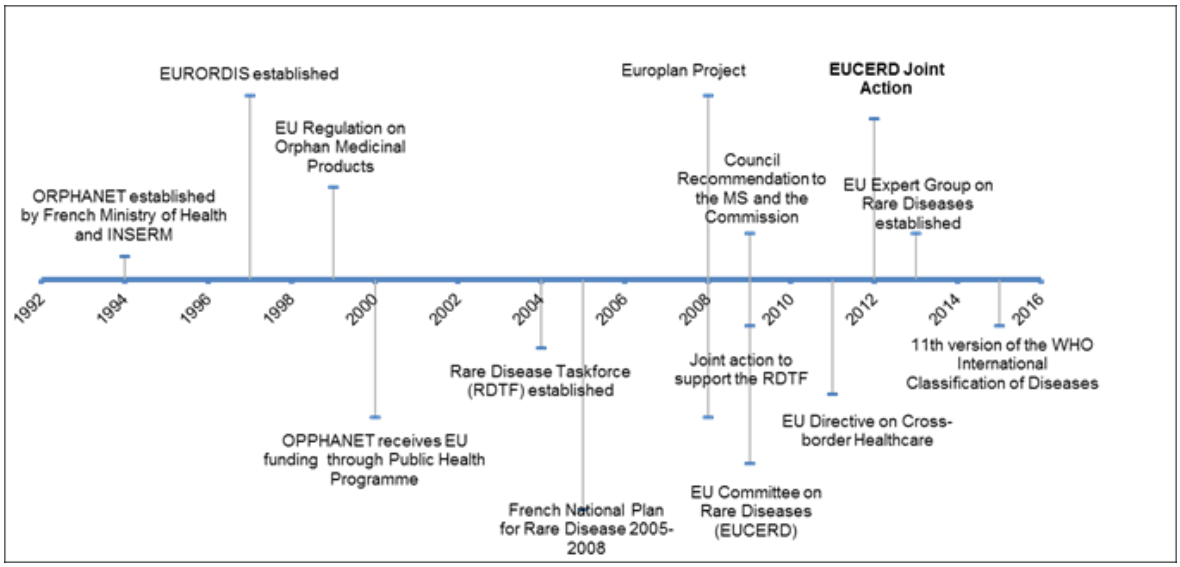
Introduction

The need for better management of rare diseases (RD)[64] first came to the fore in Europe in the early 1990s, with the establishment of Orphanet; a reference portal set up by the French Ministry of Health and National Institute of Health and Medical Research (INSERM)) to *"help improve the diagnosis, care and treatment of patients with rare diseases".* In 2000, the issue entered the European policy arena when the *EU Regulation on Orphan Medicinal Products* (Regulation EC n° 141/2000) was published. This listed RD as a key priority, and signalled the European Commission's (EC) continued investment in the area.

64 Defined as life-threatening or chronically debilitating diseases - mostly inherited - that affect so few people that combined efforts are needed to: reduce the number of people contracting the diseases; prevent newborns and young children dying from them; preserve sufferers' quality of life and socio-economic potential. http://www.eurocat-network.eu/pagecontent.aspx?tree=aboutus/eurarediseasespolicy.

Over the last decade (since Orphanet first received EU funding in 2000, under the Programme for Community Action on Rare Diseases), a number of interventions have been established in RD, many funded under the second EU Health Programme. Key examples include the Europlan project, EURORDIS, the Rare Disease Task Force (RDTF) and various RD EU funded European reference networks. In addition, EC policies on RD have also been adopted, through the *"Rare Diseases: Europe's challenges"* (November 2008) and subsequently the *"Recommendation from the Council to the Member States"* (June 2009). These key policy documents set out a number of tools and instruments that Member States (MS) were expected to adopt, as well as a road map defining key priorities and actions going forward (including the recommendation that all MS have a national plan in place for RD by 2013).

Table 33: Timeline for development of the EJA



The EUCERD Joint Action (EJA): Working for Rare Diseases was established in 2012 to support the body responsible for overseeing implementation of EU priorities and actions relating to RD – the *EU Committee of Experts on Rare Diseases (EUCERD).*[65] It built on the previous Joint Action (2009-11) in place to support the Rare Disease Task Force (RDTF), the precursor to the EUCERD, and sought to fulfil three main purposes:

1. Enhancing the visibility and recognition of RD
2. Contributing to the development and dissemination of knowledge on RD, from specialized research, through to the support of the healthcare professionals and the empowerment of patients
3. Contributing to improvements in access to quality services and care, from diagnosis, through to care and social support and innovative therapies.

It was expected that five main areas of work would be undertaken to achieve these goals:

1. Promoting the implementation of plans and strategies for RD at national level (collaboration here with Europlan);
2. The standardisation of RD nomenclature at international level;

[65] The EUCERD is mandated to assist the EC in formulating and implementing the Community's activities in the rare disease field, to foster exchanges of relevant experience, policies and practices between the MS and stakeholders.

3. Mapping the provision of specialised social services and promoting integration of RD into mainstream social policies and services;
4. Mapping national initiatives to address the quality of care in the field of RD across the continuum of care;
5. The integration of RD initiatives across thematic areas and across MS.

Further details of the EJA, including the main work packages (WP) and partners, are detailed in the table below.

Table 34: Overview of the EJA

Full name	EU COMMITTEE OF EXPERTS OF RARE DISEASES JOINT ACTION
Acronym	EJA
Funding instrument	Joint Action
Action number	20112201
HP strand	2 - Health promotion
Priority	2.2 Reduce major diseases and injuries by tackling health determinants
Sub-priority	2.2.2 Prevent major diseases of particular significance, and rare diseases
Maximum EC contribution	€ 2 994 023,00
Actual start date	October 2012
Duration (in months)	42
Status	Ongoing
Lead partner	University of Newcastle upon Tyne (UNEW), UK
No. of associated partners	8
No. of collaborating partners	15

Table 35: Work packages and partners

WP	Work Package Description	Lead institution
1	Coordination	UNEW, UK
2	Dissemination	Institut National de la Santé et de la Recherche Médicale (INSERM), France
3	Evaluation	Instituto Nacional de Saúde Doutor Ricardo Jorge (INSA), Portugal
4	Support for the implementation of plans or strategies at MS level	Istituto Superiore di Sanità (ISS), Italy, working with the European Organisation for Rare Diseases (EURORDIS)
5	Standardisation of rare diseases nomenclatures	INSERM, France
6	Specialised social services and integration of RD into social policies and services	EURORDIS, France
7	Mapping national initiatives	Ministry of Health, Social Policy and Equality (MSPSI), Spain, changed to Centro de Investigación Biomédica en Red de Enfermedades Raras (CIBERER)
8	Integration of RD initiatives	UNEW, UK

This case study explores the delivery of the EJA, its impact, EU Added Value and the dissemination activities undertaken, drawing on the following sources to do so:

- Four telephone interviews – with representatives from UNEW, INSERM and Chafea;
- Review of key documentation – including the Proposal, Terms of Reference, Communications Strategy and Annual Evaluation Report;
- Review of EJA website and wider dissemination materials.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	2

By its nature, the EJA was designed to **build on the previous JA**, although its scope was wider due to the fact that the EUCERD was a much more formal structure than the RDTF (with representation from across Europe, rather than from a small number of MS (e.g. Denmark, France, Sweden)). At a strategic level, the same objectives were set (e.g. to provide scientific expertise to support the work of the Committee) and many of the existing partners involved (e.g. INSERM, EURORDIS, ISS). However, at a thematic level, the areas covered through the EJA were much broader than in its predecessor.

The **design process** commenced with a 'policy paper' drafted by DG SANTE, which sought to map out the broad areas of work that it was expected the EJA would focus on. A professional partners meeting was subsequently held (in December 2010), which brought together the RDTF, DG SANTE and interested stakeholders from the MS, to discuss the initiative and structure its design going forward.

The University of Newcastle (UNEW) led these discussions, having been designated the action leader early on in the design process. Collaboratively, the EJA was designed to ensure that:

- It had **clear links with policy-making** – the EJA was, by its nature, set up to support policy-making, with rare diseases specified as one of two priority diseases in the 2011 work programme (the other being cancer). DG SANTE's and the RDTF's engagement, as well as the fact that many of the partners involved had experience of working with EU policy makers (through the RDTF and other initiatives) helped to ensure its potential to impact on policy;
- It **built on the previous JA and aligned initiatives** – in particular, WP 4 was incorporated to support the implementation of national plans, which had been developed through Europlan; WP 5 was included to help standardise RD nomenclature, building on work that was already underway by INSERM through Orphanet;
- It had a strong **communication and knowledge sharing** component – with existing communication channels continued (e.g. annual State of the Art Report of Rare Diseases, monthly newsletter) and a strong focus placed on ensuring that workshops, conferences and events were held to discuss pertinent issues;
- It provided some **flexibility** to enable the EJA to be able to support the evolving needs of the EUCERD – WP 8 was seen as the main way through which this flexibility could be achieved.

Unlike its predecessor, the EJA was also designed to incorporate some **research elements** – WP 6 and WP 7 were introduced to explore the development of national initiatives and best practice, in the areas of health and social care respectively. Whilst clearly related to RD, suggestion was made during the interviews that these areas of work were not necessarily relevant to what the EJA was set up to support, and may have been more appropriate in a DG Research funded project. It was also felt that the drive to undertake them may have come from the interests and lobbying efforts of the large number of MS and organisations (e.g. EURORDIS) involved, some of which were accommodated, but not wholly justifiable.

Certainly, the **level of clarity associated with each of the WP** differed. The aims and implementation plans for WP 3 (dissemination), WP 4 (support to implement national plans) and WP 5 (standardisation of RD nomenclature) were well-defined, as they built on work that was already being undertaken through the RDTF, Europlan and Orphanet. On the other hand, clarity on the other WPs was arguably more limited – partly this was to provide flexibility in working with the EUCERD, however it was also seen to reflect inadequate 'groundwork' undertaken to understand what appetite and interest there was in the MS for the work proposed. Indeed, a few design issues were identified during the interviews, notably:

- **Limited scoping work** being undertaken during the design process – as well as there being insufficient knowledge of the needs and interests of MS vis-à-vis the activities proposed, it was felt that the governance and management arrangements for the EJA were not scoped out as effectively as they could have been. This, in turn, was seen to have impacted on the degree to which WP 1 (coordination) was defined;
- **Partners selected** – meaning that the action leader (or consortium more widely) was not able to select who worked on the EJA. Whilst this worked out in the majority of cases (due to good management on the part of the action leader), it meant that in one case (WP 7) a partner had to be replaced early on in the implementation phase, as the original lead (the Ministry of Health, Social Policy and Equality) did not have the technical expertise to deliver.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2
Fostering of collaboration and partnerships	2
Engagement with other actors (incl. DG SANTE / CHAFEA)	2

Overall, the implementation of the EJA was seen to have gone relatively well. The **clear direction** provided by the EUCERD and DG SANTE, as well as the **expertise** of those involved (many of whom were renowned experts in their field and had been involved in RD policy for some time) were seen to have facilitated implementation. **Strong relationships** were also described with associated initiatives (e.g. Europlan, TREAT-NMD, E-RARE). Specific examples of collaboration included:

- Liaising with the EUnetHTA to explore mechanisms for sharing data (RD data) across MS, by studying the HTA Core Model;
- Attending conferences organised by RARECAREnet, to share guidance on rare cancers, and discuss the potential to harmonise certain indicators/ recommendations pertaining to national RD plans and National Cancer plans.

The 'close knit' and dynamic nature of the RD community, and specifically the fact that many of those working on the EJA were also working on the aligned initiatives (e.g. the UNEW lead was contributing to RARE-Bestpractice), had helped to enable this

collaboration. Reference was made to good professional relationships being in place, and strong input from academic partners.

On the other hand, a few mixed messages were given on the effectiveness of the coordinating organisation. Whilst it was recognised that the action leader had done a good job at managing the various partners, the level of **internal communication** was seen as an issue at times. According to the Year 1 Evaluation Report, regular meetings (e.g. annual partner meetings, min-WP meetings), agreed action points (discussed and agreed at the annual meetings), and 'update reports' (distributed every 6 weeks to track new reports/ activities/ workshops) were among the tools used to encourage communication, but one interviewee felt that internal correspondence had been too limited. It was also recognised that the **extent to which the WPs were delivered according to plan had differed** (as detailed in the table below), and that this had not always been addressed sufficiently by the action leader.

Table 36: Progress in delivering individual Work Packages

WP	Work Package	Feedback on implementation
1	Coordination	Implemented to plan, although concern raised that coordination had not always been as effective as it could have been – particularly in terms of communicating lessons/ plans, and addressing performance management issues
2	Dissemination	Seen across the board to have been implemented effectively. Included development of an annual report, fortnightly newsletter and website. The website was migrated to another host site in 2014, which has created some logistical challenges, but nothing significant.
3	Evaluation	Seen to have been implemented effectively.
4	Support for the implementation of plans or strategies at MS level	Positive feedback, although had to be revised. Initial plan to provide tailored support to MS in implementing their plans was revised due to limited appetite among MS for such support. Resources instead used to organise national conferences, which were effective, although the reallocation of resources caused contractual tensions between the partners, and was not always delivered in a timely manner (e.g. some events were held after national plans had been produced).
5	Standardisation of rare diseases nomenclatures	Very well executed and had a good level of impact and EU added value. The main output of this WP was the development of a comprehensive coding of RD, and associated workshops and information leaflets.
6	Specialised social services and integration of RD into social policies and services	Mixed feedback – usefulness of better understanding the evidence base recognised, but questionable what overall outcome would be achieved, given that many MS focus on basic services through their social policies, rather than RD. Outputs generated through this WP included: • Fact sheets on Therapeutic Recreation Programmes and Respite Care Services • Fact sheets for Adapted Housing Services and Resource Centres • Workshops at EURORDIS Membership: 'Specialised Social Services: need, policy, case studies' and 'Social & medical services initiated by patient organisations'.

7	Mapping national initiatives	Mixed feedback – usefulness of better understanding the evidence base recognised, although seen as too research-focused.
8	Integration of RD initiatives	Mixed feedback – again quite research focused, and delays caused by linkages with other programmes (e.g. collaboration with the EuroGentest (EuGT) project, the sustainability of which was in question during the first year of work).

Building on the point made in the design section above, it was felt that where progress had been more limited, it was due to **insufficient scoping work** having been done – in terms of putting in place management/ governance arrangements, gaining an understanding of the needs / interests of the MS (in order to respond to them accordingly) and an awareness of what was being undertaken through other initiatives (to reduce duplication). One interviewee questioned, for example, the extent to which WP 6 (focused on social services) was relevant to the MS, given that social services in most countries were more interested in basic needs. Another suggested that the changing nature of European cross-border directives meant that other expert groups were doing very similar work to what was being undertaken as part of WP 8, which had led to some duplication.

In addition, a number of **other challenges and barriers** were identified through the case study, which were seen to have impacted upon implementation:

- Mixed level of **engagement from national health authorities** – with scientific experts in some MS playing a much more leading role in implementation (e.g. France, UK, Finland);
- **Inadequate flexibility** with some of the WPs – it was felt that the EJA was still not always able to sufficiently respond to the emerging needs of the EUCERD. To illustrate this point, the example was provided of the input into the World Health Organisation's (WHO) International Classification of Diseases (summarised in the EUCERD Recommendations on Core Indicators for Rare Disease National Plans), which was achieved through workshops organised as part of WP 5. Several interviewees stated that the EU added value in this work was significant, but could have been maximised further if more opportunities to do such work had been available. Going forward, it was felt that much more flexibility was required (including in the Terms of Reference), in order to respond to the field, as it evolves in line with the implementation of national plans;
- **Performance issues** with some of the partners – although the action leader was complemented for managing to navigate some challenging partner dynamics at times, it was felt that performance issues were not always adequately addressed, such as deliverables not produced to time / specification (e.g. WP 4 and WP 8). According to one interviewee, this reflected the fact that it was a JA (rather than a project) and hence that partners were not purposefully selected by other partners in the consortium, which introduced a different partner dynamic;
- **Delayed contracting arrangements** at times – contract amendments sometimes took longer to process than was anticipated.

Moreover, it was noted that the change in the expert group – from the EUCERD to the EC Expert Group on Rare Diseases – which commenced in 2014, had impacted upon delivery. Whilst this could not have been foreseen, the institutional change led to a 12 month "period of unknown" (2013-14), which in turn led to some momentum for implementation being lost.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	3
Effectiveness of tools and channels used	2
Sustainability of dissemination activities (incl. use of multipliers)	2

Although the EJA Proposal stated that "this joint action ultimately targets the patients with the 5000-8000 recognized rare diseases across Europe, their families and patient organizations"[66], it was widely recognised that the **main target audiences** of the EJA were the scientific community and policy makers (as well as the national and international societies with representation in RD (e.g. European Society on Human Genetics (ESHG)).

Here, the aims of the initiative were **ambitious**. As stated in the EJA Proposal: "In addition there is interest from outside the EU to participate in activities relating to rare disease policy as indicated by the application to the EUCERD for non-MS countries to receive EUCERD documentation and participate in meetings…. The challenges faced by RD have a global reach and dimension. Through its participative approach and integrative actions, the proposed JA builds a bridge between EU action and MS activities, further strengthening the sustainability of current initiatives, while ensuring the best possible outcomes for future action."[67]

A number of **communication and dissemination channels** were used to achieve these aims, including:

- A newsletter for the EUCERD Committee (Orphanews Europe) – produced every 2 weeks by INSERM, providing a review of relevant scientific literature, press reviews of policy developments at Europe and MS level etc. The newsletter was described as high quality, relevant and well-regarded. It has a wide readership base (16,000 subscribed readers);
- The Annual "State of the Art in Rare Diseases" Report – produced by INSERM in July 2012, July 2013 and July 2014, and providing an update on RD activities in Europe (the report was also produced as part of the previous JA). Approximately 15,000 people download the report each year, which was again described as comprehensive, well-written and high-quality;
- EJA Website – including a members section for partners to exchange information and lessons. The website was online from September 2012, and transferred to a new site hosted by the Commission in 2014: http://ec.europa.eu/health/rare_diseases/expert_group/index_en.htm[68];
- A series of events and conferences – organised across Europe, and structured around five main themes: national plans/strategies for RD; RD in international nomenclatures; specialised social services; quality of care/centres of expertise; and integration of RD activities. Representatives of the EJA also attended numerous 'external' conferences, including the meeting of the Council of National Alliances and Council of European Federations (October 2012).

[66] Joint Actions Application Form: EUCERD Joint Action, p. 18
[67] Ibid., p. 22.
[68] The original website can also still be accessed at: http://www.eucerd.eu/.

Other vehicles for communication and dissemination included academic articles[69] and press releases. Broadly speaking, these dissemination activities were seen as **highly effective**. They were underwritten by a clear communication strategy, which was developed following a stakeholder analysis in collaboration with the key groups (e.g. parent associations). They aligned with other relevant structures (e.g. the Orphanet database of RD and expert services, the RD information networks, collaboration between MS authorities initiated through the Europlan project) to enable sustainability; and they had benefitted from the expertise of those working on the EJA, and the EUCERD "brand" more broadly. Strong engagement with the patient alliances was also reported. As a case in point, the patient alliance had helped to organise a conference to discuss implementation of the national plans, which one interviewee stated *"has gone well… it has been really empowering in some countries and helped to move things forward".*

At the same time, some issues with dissemination were highlighted. In particular, **challenges** were reported in engaging with some stakeholders, including practitioners. Although the JA originally sought to provide practical information and advice to those working in the RD field, it was felt that other initiatives (e.g. Orphanet) were more suited to this purpose, and in fact EJA should have focused its efforts on policy makers, where its main value was held. A similar view was shared for patients, as although the JA sought to *"reach new groups of RD patients with appropriate levels of diagnosis and care, as well as to facilitate access to novel therapies as these are developed"*[70], it was felt by some to be unrealistic, and again as detracting from the prime goal of providing scientific expertise to policy-makers.

A few issues were also reported in regard to the **website**, which had been migrated to the EUCERD website when the institutional structure of the EUCERD had changed. This was felt to have had a bigger impact on internal dynamics (e.g. sharing information) than external, although there was suggestion that it could have been prevented if the website had been affiliated with the institutional agency (i.e. the EUCERD), rather than the EJA in the first place.

Finally, further **areas for improvement** were highlighted regarding dissemination to policy makers. Specifically, suggestion was made that outputs needed to be more practical – enabling those working in government ministries and departments to have very practical recommendations about what works and does not, developed through workshops and guidelines. The need to translate specific outputs (notably the Committee Regulations) in other languages was also deemed necessary, in order than those in non-English speaking languages could access the information.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2
Impact on policy	2
Robustness of evaluation strategy and reporting	2

The EJA was set up to support the EUCERD by achieving **three main objectives**:

- Enhancing the visibility and recognition of RD;

[69] See, for example: *The European Union Committee of Experts on Rare Diseases: three productive years at the service of the rare disease community*
Ségolène Aymé and Charlotte Rodwell, Orphanet Journal of Rare Diseases 2014, 9:30.
[70] Joint Actions Application Form: EUCERD Joint Action, p. 18.

- Contributing to the development and dissemination of knowledge on RD, from specialized research, through to the support of the healthcare professionals and the empowerment of patients;
- Contributing to improvements in access to quality services and care, from diagnosis, through to care and social support and innovative therapies.

Generally speaking, it was felt that the JA had been successful at meeting these objectives. The following **outcomes and impacts** were highlighted during the case study:

- **Influence on European policy** – by assisting the Commission to draw up reports, guidelines and recommendations (defined in the Commission Communication and in the Council Recommendation), and providing advice as required. This was crucial in helping the Commission to prepare for deliberations, although further impact could have been generated if the outcomes had been translated into other languages, and more flexibility had been available to explore areas of policy interest (e.g. the use of technology to address RD);
- **Continued engagement** on RD – the State of the Art of Rare Disease reports (2012, 2013 and 2014), and numerous workshops and events organised through the communications, and individual WPs, helped to build engagement in RD;
- **Informing international best practice**, notably around the classification of health indicators – highlighted as a "real success", this work informed the 11th version of the International Classification of Diseases (ICD-11) by providing a coding of RA and a classification in the framework of the revision process defined by the WHO, thereby helping to assure the traceability of RD in health information systems;
- **Influence on some decision-making by local and regional policy makers** – by providing technical and scientific support to the development and implementation of national plans, firstly through tailored expertise/ capacity building workshops (delivered by ISS), and secondly national conferences (organised by EURORDIS and national patient alliances). Due to limited interest among MS for the former activity, resources were diverted to the national conferences;
- **Development of evidence base** on RD, relating to both health and social care – drawing on the insights of leading scientists, local policy makers, patient groups and other stakeholders. Examples included the *'Guiding Principles on Training for Social Services Providers'* (published in April 2014), and mapping of national initiatives undertaken with directors of services. The outcome of this work was seen as helpful in developing the evidence base, although it was suggested that the strong research focus may mean that it is less likely to impact on policy- and decision-making.

On the whole it was felt that some activities (e.g. classification of RD; implementation of national plans through national conferences) had been more impactful than others (e.g. mapping of national initiatives; integration of RD initiatives), and that **the WPs that had been better defined, and more focused on development and implementation (rather than research) had represented better value for money**. Going forward, it was suggested that work is undertaken to translate the research and learning gathered through the EJA into more practical recommendations and guidelines for regional and local policy-makers – and that workshops and events, used to discuss key issues and best practice, would be a good place to do so.

In terms of **monitoring and evaluation**, this had seemingly been well executed, however it was questioned whether the performance issues raised has been adequately addressed. Partly this resulted from the institutional change in EUCERD, which could not have been anticipated, but had an impact on programme momentum

and partner engagement. Partly it resulted from the nature of the EJA – and namely the fact that the partners were selected by the MS (rather than the lead partner/ consortium), meaning that it took time to get relationships off the ground.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	**2.5**
Economies of scale	1.7
Promotion of best practice	**2.7**
Benchmarking for decision making	**2.3**
Cross border threats	0.3
Free movement of persons	0
Networking	**2.3**
Unlocking the potential of innovation	1.5

The areas assigned the highest *potential* EU Added Value were the *promotion of best practice, implementation of EU legislation, networking,* and *benchmarking for decision-making*. In this section, a summary is provided of the extent to which this potential materialised, based on the findings of the case study research.

Promotion of best practice

Taking the first point – the promotion of best practice – the evidence gathered justified the score assigned. Through the JA, numerous opportunities were provided to share best practice, particularly around the further development and implementation of national plans, and the standardisation of RD nomenclatures. These were facilitated by the strong engagement and credibility of many of the key partners (e.g. UNEW, INSERM, EURORDIS and the patient alliances), the infrastructure already in place to share learning (e.g. European reference networks, Orphanews Europe, State of the Art reports), and good linkages with other relevant initiatives (including other EU programmes). For the centres with limited expertise, the value generated through this work was particularly high.

Efforts were also made to share best practice around social care and health initiatives (including the development of collaborative tools and expertise), although the extent to which this was successful, and in turn informed national plans and local decision making is questionable. Going forward, it will be important to take stock of the efforts achieved, and where possible embed them into policy to ensure sustainability.

Implementation of EU legislation

Moving to the second point – implementation of EU legislation – the EU added value was clear. The EJA is the main source of scientific support to the EUCERD, providing a range of technical expertise, from developing recommendations in key areas (e.g. indicators for national plans, improving informed decisions based on the clinical added value of orphan medicinal products) to drafting the annual State of the Art report (a key source of information for policy-makers, academics, patient groups and the

scientific community). It allows expert opinions to be sought from a broad range of areas, and for information sharing to be achieved at a European scale. Going forward though, it was felt that more flexibility could be helpful – in order to respond more effectively to the needs of the EUCERD as and when they emerge.

Networking

Good feedback was also provided on the extent to which the EJA had enabled networking, which again had been facilitated by the institutions and infrastructure in place, as well as by the fact that the EUCERD itself was well recognised. It was felt that more internal networking would have been helpful however (including potentially an internal newsletter), and that more efforts could have been undertaken to provide more opportunities to discuss the practicalities of the information/ learning developed through the initiative, and better engage the EU-12 MS.

Benchmarking for decision-making

The EU Added Value generated in benchmarking for decision-making was really generated through WP 5 – the Standardisation of RD nomenclatures. Here, the impact was reported among MS, as well as internationally (through incorporation in the WHO's International Classification of Diseases.

Conclusions and lessons learned

The EJA's contribution to RD debates was wide-ranging, and influenced policy in a number of ways. It built upon the expertise of a number of key institutions, who had a track record of working together, and strong links with policy-makers. It also provided a good opportunity to share expertise and lessons on topics including national planning, standardisation of RD, cross-border directives, and patient registries. During the case study, a number of lessons learned were identified, which may be helpful in informing the next JA (which is expected to bring together the EJA and Orphanet):

- Importance of having sufficient specialist knowledge and capacity to inform policy – without the EJA, it was clear that the Commission's ability to oversee RD policy would have been significantly diminished;
- Importance of having sufficient flexibility in delivery – the need for the EJA to be able to respond to the EUCERD's needs, as and when they arise. For example, during the lifetime of the initiative, technology emerged as an area of interest, which could have been explored, had there been budget to do so
- The need to balance policy / practice and research – the value added generated by the EJA really came from its work in developing policy (through recommendations, guidelines etc.) rather than research (which a DG Research funded project may be more suitable for);
- The need to have done sufficient groundwork in preparing an action – including developing strong management / governance processes, and a clear understanding of what support MS require, which was seen to have caused delays in start-up and implementation;
- Importance of having a strong clinical leader and strong linkages with the EC – particularly the case as the institutional structure has changed.

9.3.QUANDHIP - Quality assurance exercises and networking on detection of highly infectious pathogens

Summary

QUANDHIP is an example of a Joint Action (JA) that provided real added value to the EU via its contribution to enhancing public health security. It achieved this by creating a network of laboratories working with high threat bacteria and viruses in 22 Member States (MS) and providing them with an opportunity to exchange information and learn from each other. This resulted in an increased laboratory capacity to prepare for, detect and respond to highly infectious pathogens - produced naturally or due to deliberate release - that can spread quickly across borders. The wide EU coverage, the commitment and interest of the partners, the strong project management and delivery, and the reliance on experience and knowledge gained in the implementation of prior EU-funded projects were key success factors of the implementation of this JA.

However, QUANDHIP also showed that ensuring the participation of all MS, as well as the strong involvement of the relevant public health and security authorities at national and EU level is key for the full realisation of its results and impacts and, consequently, for further enhancing Europe's preparedness to responding to outbreaks of highly infectious diseases.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Avg. score (1-3)	Explanation
Design	2.7	The JA addressed a highly relevant topic, was well designed and planned, and was managed by highly competent and experienced organisations. Its actual impact on policy though, could be hindered by a number of MS that were not part of the action, as well as by the fragile involvement of relevant national authorities.
Implementation / outputs	2.5	The JA was implemented successfully and delivered its outputs as envisaged. It was based on a network of highly competent and specialised partners in a broad range of countries that, in spite of some initial difficulties, committed strongly to it.
Dissemination	2.0	The dissemination plan was executed successfully by the partners; however the ties established with the policy level were fragile and additional efforts to increase awareness of the network among relevant national authorities are needed.
Results / impacts	2.7	The JA achieved some very important results in terms of capacity-building, standardisation of best practices and networking. It also added value to prior established networks at EU and addressed issues that could have not been addressed by MS on their own.

Introduction

Since the late 1990s, and drawing from a number of events[71] that influenced the international health security landscape, protecting citizens from natural and deliberate biological health threats has been a focus of attention for the EU.

In 2002, the European Council took the first steps towards addressing the chemical, biological, radiological and nuclear (CBRN) threat at EU level when it adopted the "Programme to improve cooperation in the EU for preventing and limiting the consequences of CBRN terrorist threats". Following the attacks in Madrid in 2004, the Programme was widened, revised and replaced by the Council and European Commission's (EC) EU Solidarity Programme on the consequences of terrorist threats and attacks.[72] The relevant elements of this Programme were included in the overall Strategy and Action Plan on Combating Terrorism established in 2005 after the London attacks.

Later in 2007, the Justice and Home Affairs (JHA) Council adopted specific Conclusions calling for further EU level work on CBRN security. Consequently, in 2009, the EC established a policy package composed of the Communication on "Strengthening CBRN Security in the EU" and an Action Plan with horizontal and specific measures for preventing, detecting and responding to incidents.[73] The third component was the Staff Working Document "Bridging Security and Health" which focused on the cooperation between public health and law enforcement authorities at national level, between MS and at EU level.[74] In line with this, in 2013, the EU adopted a Decision to support cooperation and coordination between the MS and improve preparedness to combat cross-border threats to health.[75]

Whilst the responsibility for responding to CBRN incidents rests with the MS, throughout the years, several procedures and tools were established at EU level to support them in case of a crisis with cross-border implications. For example, the Health Security Committee (HSC)[76] which plays a major role in terms of crisis preparation, exercises on CBRN events, as well as in drawing up a list of pathogens and chemicals which pose a health threat. In addition, the European Centre for Disease prevention and Control (ECDC)[77] provides risk assessments for communicable diseases and biological incidents.

[71] For example, the 1995 sarin gas attack in the Tokyo subway, the 9/11 terrorist attacks and mailing of anthrax spores in the United States in 2001, the emergence of the Severe Acute Respiratory Syndrome (SARS) in 2003, the 2009 H1N1 Pandemic, the accident at TEPCO's Fukushima nuclear power station in Japan, and the Ebola virus outbreak in 2014.

[72] EU Solidarity Programme on the consequences of terrorist threats and attacks (revised/widened CBRN Programme). A *draft* version of the document is available at: http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2015480%202004%20INIT (the final version of the document was not found online at the time of writing)

[73] http://ec.europa.eu/home-affairs/summary/docs/com_2009_0273_en.pdf

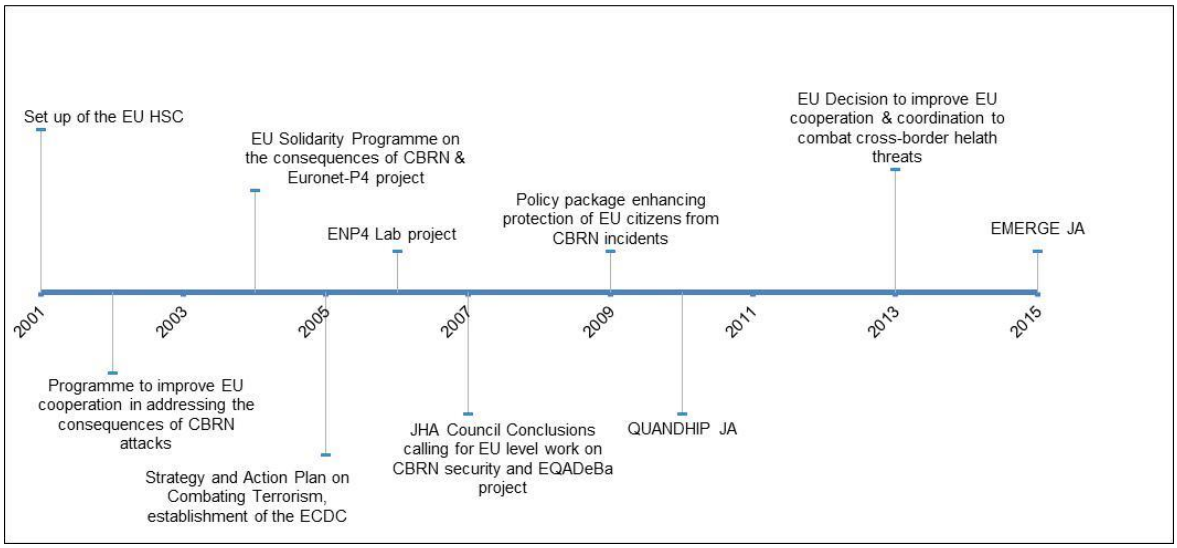
[74] http://ec.europa.eu/health/ph_threats/com/preparedness/docs/bridging_en.pdf

[75] http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf

[76] The HSC was set up in 2001. It is composed of representatives from each MS, DG SANTE and other relevant EC organisations.

[77] The ECDC was established in Stockholm, Sweden, in 2005 with the aim of strengthening Europe's defences against infectious diseases.

Figure 37: Key milestones on health security in Europe



Laboratory preparedness for a correct and rapid diagnosis of highly infectious pathogens is understood as one crucial element when managing outbreaks of these pathogens. In the framework of the first and second EU Health Programmes (HP), the EU funded three projects related to this. One was the Euronet-P4 project (2004-2006) which was targeted at Biosafety Level 4 (BSL 4) laboratories. In 2006, this was funded an additional three years to continue its activities under the ENP4Lab project.[78] The third project was EQADeBa[79] (2007-2009), which was aimed at laboratories working with pathogenic agents under BSL 3 conditions.[80]

QUANDHIP built on these prior projects. It was funded under the 2010 Work Plan[81] which called for a JA that would increase capacity building for joint law enforcement of security and health authorities on the basis of the mentioned Working Paper "Bridging Security and Health". The JA would help to achieve this by strengthening EU BSL 3 and 4 laboratories capacity to detect highly infectious pathogens on a sustainable and long-term basis. The JA was co-led by the Robert Koch-Institut (RKI) in Germany and the L. Spallanzani National Institute for Infectious Diseases (INMI) in Italy. For a summary of the project's key parameters and work packages (WP), see the tables below.

Table 37: Key features of the actions

Full name	Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens
Acronym	QUANDHIP
Funding instrument	Joint Action
Action number	20102102
HP strand	1 - Health security

[78] European Network of P4 laboratories, coordinated by L.Spallanzani National Institute for Infectious Diseases (INMI) in Italy (http://www.euronetp4.eu/)

[79] Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk, coordinated by the Robert Koch-Institut (RKI) in Germany

[80] The 'Biosafety Level' (BSL) is a level of the biocontainment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. The levels of containment range from the lowest biosafety level 1 (BSL 1) to the highest at level 4 (BSL 4). In the EU, biosafety levels are defined in the Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work.

[81] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:340:0001:0046:EN:PDF

Priority	1.1 Protect citizens against health threats
Sub-priority	1.1.1 Diseases and health threats from physical, chemical or biological sources
Maximum EC contribution	€ 3,315981.96
Actual start date	August 2011
Duration (in months)	42[82]
Status	On-going
Lead partner	Robert Koch-Institut
No. of associated partners	33
No. of collaborating partners	4

Table 38: Work packages and partners

WP	Work Package Description	Lead institution(s)
1	Coordination	RKI and INMI
2	Dissemination	INMI
3	Evaluation	Philipps Universität Marburg (Germany)
4	External Quality Assurance Exercises (EQAEs)	RKI
5	Setting up of Repositories for Reference materials	RKI
6	Training on best diagnostic practices and biosafety/biosecurity	Norwegian Institute of Public Health (Norway)
7	Application and further improvement of checklists for biosafety and biosecurity evaluation	RKI
8	Support to coordination of laboratory response to cross-border events with highly infectious pathogens	INMI

This case study is based on a review of relevant project documentation (proposal, grant agreement, and deliverables) and a series of interviews conducted in December 2014 with the action's coordinator and co-coordinator, one partner organisation, and the project official at CHAFEA.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	3

[82] QUANDHIP was originally planned to end in July 2014. However, it was extended to 31 January 2015 so that it could support the detection of Ebola-fever cases. No additional funding was granted for this.

QUANDHIP addressed a **highly relevant topic** (laboratory preparedness and response to outbreaks of highly infectious agents) within the broader area of health security, contributing to realising one of the HP's main objectives i.e. protecting citizens against diseases and health threats from physical, chemical or biological sources.

The logic under this JA indicated that by **combining two existing networks** of BSL 3 and 4 laboratories (ENHPB[83] and ENP4Lab[84]), QUANDHIP would establish a universal exchange of best diagnostic practices that would strengthen laboratories diagnostic capacity, reliability and safety. In line with this, the JA included the development of a pan-European quality assurance scheme for the diagnosis of highly infectious pathogens and the expansion of a bio-diverse repository of reference materials that could be used by all MS, candidate countries or globally for the development and evaluation of new diagnostic assays, kits or instruments. Via the exchange of best practices between the networks and the implementation of practical trainings, QUANDHIP was also meant to address one of the shortcomings identified in the prior EU-funded projects: the different levels of laboratory preparedness in European countries for responding to outbreaks. Another key aspect of the JA was that it would increase biosafety and biosecurity levels in laboratories by improving and applying checklists for the evaluation of safe and secure laboratory management, reducing the risk of laboratory based and accidental transmission of highly infectious pathogens. Moreover, in accordance with the HP's 2010 Work Plan, QUANDHIP would provide European health and security authorities with an integrated laboratory infrastructure able to respond to cross-border health threats and outbreaks.

According to the proposal's evaluation panel and our own examination of it, the action's design was **appropriate to its logic** and adequate to achieve its goals. Its objectives and expected outcomes were formulated clearly and the different WPs were in line with them. The JA also benefited from highly competent coordinators with proven track record on the delivery of EU-funded projects, who proposed a shared technical and managerial coordination. In addition, QUANDHIP's planning was well described in the proposal, and the steps and actions to be taken where judged to be **feasible and realistic** by the proposal's evaluation panel and CHAFEA.

Drawing from this, as well as from its relevance to the EU policy context, one could expect the JA to have a real impact on policy. This was actually the first intent of **bridging efforts** for laboratory diagnostics for both high threat bacteria and viruses. According to the stakeholders consulted, the cooperation of the bacteria and viruses networks had the potential to encourage cross-disciplinary and cross-border expertise, as well as to provide a unique EU platform for rapid response, detection and epidemiological investigation of such pathogens.

However, there are two aspects that should be pointed out regarding the JA's design. In order to ensure that the network actually supported Europe's preparedness and response to outbreaks, all MS and competent national authorities (from both the health and security fields) would have to be **aware of and engaged** in the QUANDHIP network in some way. Even though all MS and EEA/EFTA countries were invited by the EC to participate in the JA, there were a few that did not join. (see Implementations/ outputs). In addition, the fact that laboratories participation in the consortium depended on national authorities' approval (which means that the link with the policy level was a pre-condition), may not have been enough to ensure that all relevant authorities in each country were aware of the existence of the network and

[83] The European Network for Highly Pathogenic Bacteria (ENHPB) was created in the framework of the EQADeBa project.

[84] The European Network of P4 laboratories (ENP4Lab) was created in the framework of the ENP4Lab project.

considered it a point of contact/reference in the case of a suspected case of a highly infectious disease (see Dissemination). Moreover, it is worth noting that there were no specific objectives (or indicators) related to this aspect.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	3
Fostering of collaboration and partnerships	2.5
Engagement with other actors (incl. DG SANTE / CHAFEA)	2.5

QUANDHIP was implemented as planned, with all intended deliverables and milestones achieved **timely and with a high quality**. The activities under the different WPs were executed successfully and with no major delays. The project reports also show that the JA even delivered more than was originally planned. For example, it conducted an additional EQAE for the viruses' network, worked with a higher number of samples than planned during the EQAEs for the bacteria network, and set up three Working Groups for studying specific issues that aroused during the EQAEs.

The JA's partnership was **extensive and diverse**, both from a geographical and technical perspective. It included BSL 3 labs from 22 Member States (both EU-15 and EU-13 MS) and all existing BSL 4 labs in Europe (5 labs). Moreover, in relation to the prior networks, the partnership was expanded to include also members from the veterinary and military fields as a way of ensuring an appropriate mix of skills and experiences in addressing common issues of biosafety and biosecurity.

In our view, QUANDHIP's **geographical coverage** was one of the action's main strengths, but also one of the main areas for improvement. The partnership was built on the members of the existing laboratory networks (ENHPB and ENP4Lab) and was extended by contacting the list of National Focal Points (NFPs) in all MS and EEA/EFTA countries provided by DG SANTE. All were invited to designate a laboratory to participate in the consortium. In spite of this, few countries did not respond to the invitation or said they did not have the resources needed to participate (i.e. Cyprus, Denmark, Luxembourg, Malta, and Romania).[85]It could be argued that without all MS on board, there is a risk that QUANDHIP would benefit the countries involved in it only. This could **potentially restrict** the JA's contribution to ensuring Europe's preparedness for responding effectively to outbreaks of infectious pathogens.

In relation to the collaboration between the two networks that formed the partnership, this worked very well, despite some **initial difficulties**. According to the stakeholders consulted, changing, opening up and disseminating information to laboratories from the other network was sometimes challenging in this JA. This related to the fact that the networks had been working quite independently until the JA, but, more importantly, because they worked with different pathogens. Each network had diagnostic processes, methods, and standards that were not always applicable to the other network.

[85] It should be noted that the laboratories that joined the consortium participated as associated partners or collaborators. Being an associated partner implied that human resources and equipment would be allocated to the project. As collaborators, laboratories could participate in meetings and follow-up the progress and results of the project without having to allocate resources to it (except for covering travel expenses).

However, there were also other factors that, in the end, resulted in a fruitful cooperation. First, many laboratories from the different networks knew each other well and had developed joint projects in the past. In addition to this, there were **common needs and interests** between the two networks, particularly in terms of exchanging knowledge, experiences, and best practices. Another factor that enabled cooperation was the strong project management by the coordinators, as well as the implementation of joint meetings to align objectives, expectations and procedures between the two networks. According to the project's partners, the training courses were also an important element for establishing collaboration and mutual support between laboratories.

The engagement of other actors happened mainly via the Advisory Board, which included CHAFEA, DG SANTE, DG HOME, ECDC and WHO. These helped to raise awareness of the JA among relevant stakeholders and link it to other EU and international initiatives (see EU added value).

The partners consulted were positive about CHAFEA's involvement in the project; however they also mentioned some **discrepancies** regarding WP 8. During the evaluation of the JA's proposal, CHAFEA identified a potential overlap between the original WP 8 – which seek to support the creation of a mobile laboratory - with a DG DEVCO project (EMLab).[86] After various negotiations and discussions, CHAFEA and QUANDHIP's coordinators agreed that WP 8 would be amended to focus on the response aspect. More concretely, QUANDHIP would assess laboratories current capacity to respond to outbreaks, would respond to outbreaks at request from the EC and, when no outbreak occurred, would work to develop a simulation exercise. Yet, during the implementation of the WP, there were some disagreements particularly in relation to QUANDHIP's real role in responding to outbreaks. From the coordinators' perspective, their involvement in outbreak response was more *'theoretical'* than practical and would basically cover the production of guidelines and recommendations. When the HSC (via DG SANTE's request) asked the network to coordinate the response to some suspected cases of highly infectious pathogens, QUANDHIP's partners thought it was unclear what was actually expected from that coordination. In relation to this, CHAFEA mentioned that there were several meetings to clarify this and that the tasks agreed were, for example, the provision of guidelines for sample transportation and the performance of diagnostic, including confirmatory tests. One additional challenge mentioned by the QUANDHIP's coordinators was that they were not given enough flexibility to move resources from preparedness to response activities, causing some delays that, in the event of a real outbreak, would ultimately compromise response.

According to the public health expert involved in the development of this case study, QUANDHIP's role in Europe's response to outbreaks is a **difficult topic** and should be given further thought as there are various organisations involved (e.g. ECDC, HSC, EC, MS etc.). In order to avoid any potential overlaps or inconsistencies in response, it would be important that it is clear for all which organisation should lead the response and what role should each of the other organisations/networks play in it.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	2.5
Effectiveness of tools and channels used	2
Sustainability of dissemination activities (incl. use of multipliers)	1.5

[86] http://www.emlab.eu/

Because of the JA's main topic (health security), much of the information produced **could not be revealed** to the general public and had to be retained by the scientific community or specific stakeholder groups. At the outset of the project, this was judged pertinent by CHAFEA, although it was recommended to the consortium that the information was shared widely whenever possible through the production of public versions of the confidential outputs.

Consequently, the action's dissemination strategy clearly identified **different target groups and different products** for each of them, as well as different channels to reach them. The primary group were the network's laboratories (and their workers), as well as biosafety experts, first responders, and clinical and security forces in the different MS. The main tools for reaching these people were basically the documents developed in the framework of the JA which were circulated around and uploaded in a restricted section of the website which was only accessible to them. The project partners also delivered a number of presentations, hosted conferences and participated in events organised by other stakeholders. The project also issued a leaflet and various documents and publications that were made available to the general public via the (open) website.

A secondary target group were **public health and security authorities** at EU and national level. Some representatives of this group were directly involved in the JA via the Advisory Board (see Implementation / output). The national authorities were engaged and informed of QUANDHIP by the partners, who were asked to identify the relevant bodies and keep them updated on the action's progress and results. These were also granted access to the restricted section of the website from where they could download additional documentation. Despite of the efforts made, the ties established with the policy level were fragile.

Overall, QUANDHIP had **good visibility**, which increased during its participation in responding to (potential) outbreaks of highly infectious diseases that occurred during the implementation of the JA.[87] However, according to the project's partners, not all national authorities are aware that part of the activities that took place in their countries were connected to the JA. It can be taken as a positive sign that many countries know about the existence of the network now and that new countries will be joining the new JA. Nevertheless, it is important that all relevant health and security authorities (and professionals) that may have to deal with suspected cases of highly infectious pathogens know about the existence of the QUANDHIP network and, more importantly, know what to do (or who to contact) in these cases. Despite the consortium's dissemination efforts, this **has not been achieved yet**. Public health agencies, including public defence bodies, could be further involved in and/or informed of this JA.

In the case of the next JA, QUANDHIP's coordinators should focus more on following up the partners' strategies and actions to disseminate information to their respective national authorities, as well as on collecting information on the results of these efforts. There are also some actions that CHAFEA could undertake in order to support the JA and help to increase awareness and visibility (taking into account that this is responsibility of the JA's partners). For example, it could provide the contact details of relevant stakeholders who could be given access to the restricted part of the JA's website.

Results / impacts

[87] Hantavirus, Novel Coronavirus, Anthrax, and Ebola-fever.

Results / impacts	Score (1-3)
Wider applicability of results	3
Impact on policy	3
Robustness of evaluation strategy and reporting	2

Even though it is too early to gauge any wide impact of QUANDHIP on the target groups and/or policy, it is possible to highlight some **key contributions** to realising the HP's objectives. These have been (will be) fully realised in the short, medium or long-term, as follows:

***Short-term results**:* QUANDHIP increased and extended **laboratories preparedness** to detect highly infectious pathogens. The EQAEs and practical trainings implemented were the main factors responsible for this improvement, as evidenced by the action's internal evaluation of these exercises. The project coordinators highlighted that laboratories' response capacity was strengthened too, as they were able to shorten the response time to present data on suspected cases from 15 to 5 hours.

QUANDHIP provided the **EU dimension** needed for running effective EQAEs. The broad network of laboratories involved in the project allowed the comparison and discussion of results, as well as the identification of areas for improvement. According to the stakeholders consulted, due to the rare occurrence of highly infectious agents, as well as to the complexity of the mentioned exercises, the partners could not have performed these alone, in their own countries. Moreover, some of the partners served as multipliers at the national level by using the samples for assessing additional national laboratories for their quality of diagnostics. This constitutes evidence that the JA outputs have wider applicability, which is a major benefit.

QUANDHIP trained and prepared the participating laboratories to detect Ebola-fever cases, allowing them to **provide concrete support** to the diagnosis of suspected cases that occurred in Europe during the JA's implementation.[88] In addition, all BSL 4 laboratories in the QUANDHIP network were made available to receive samples from any European country that needed a diagnosis (or confirmation of it). The JA also developed guidelines on how to collect, inactivate and transfer the samples for diagnosis. Partners confirmed that in the absence of the QUANDHIP project, the European laboratories would have depended on reference laboratories in the United States or Africa to send the samples for diagnosis. This constitutes concrete evidence of how the network could help to ensure global health security in the longer-term the network's activities continue and is extended to also include other pathogens and laboratories.

QUANDHIP contributed to the **standardisation of key practices** for laboratory management. Previous to the JA, the viruses and bacteria laboratory networks had their own biosafety and biosecurity checklists for assessing laboratory management. In the framework of the JA, these were contrasted, compared and combined to produce common checklists for the QUANDHIP network. The checklists were then incorporated into the training programme and applied during the preparation for the EQAEs. In the internal evaluation of the project, partners expressed that the checklists

[88] Six months before the Ebola-fever outbreak, the partners had conducted an EQAE that included Ebola-fever Zaire samples which had been obtained due to the collaboration established with African laboratories through the EMLab project. Thus, at the moment of the outbreak, there were European laboratories that had been trained and were prepared to detect Ebola cases.

were a very helpful tool and that it should become an applicable document for all laboratories.

***Medium-term results**:* QUANDHIP proved that combining the two networks was an **innovative and cost-effective** approach. According to the project's coordinators, due to the networking and levelling of laboratories preparedness generated by the JA, now there are countries with BSL 3 labs that can inactivate samples and send them to another BSL 4 lab for diagnosis (either in the same country or abroad). A broader impact could be achieved in the medium- or longer-term if all MS became part of the network.

QUANDHIP provided a number of countries with **new reference laboratories** for diagnosing specific pathogens (e.g. Greece, Portugal and Spain). Laboratories in these countries were given access to samples (via the repository of reference samples), which allowed them to validate their diagnostic methods (via the EQAEs and training programme). This enabled them to be designated as national reference labs. The full realisation of this result would require that all MS were part of the network and that qualified BSL 3 laboratories in the missing countries could become national reference labs too.

Long-term results: QUANDHIP helped to identify topics where **further scientific research** is needed. During the EQAEs, the partners noted that there was a low level of knowledge about antibiotic susceptibility of high pathogenic bacteria and that further testing was needed. Thus, they constituted a Working Group specifically aimed at studying this. The European Committee on Antimicrobial Susceptibility Testing (EUCAST) was interested in this research and started working together with the JA's partners. The results of this research will be probably realised in the longer-term.

According to the JA's coordinators, QUANDHIP also showed that maintaining (and further improving) the high quality level of laboratories diagnostic capacity requires **continuous EQAEs and training**. Moreover, they explained that there are factors that can negatively affect the level of diagnosis achieved so far if they are not properly addressed; for example, technology progresses, the evolution of the pathogenecity of organisms and the turn-over of specialist staff. This means that the future allocation of resources to the QUANDHIP network is central for the full realisation of its objectives.

Finally, in terms of QUANDHIP's evaluation strategy and reporting, it consisted mainly of regular meetings and evaluation forms for meetings, training activities, and EQAEs. This was judged as more than adequate by the external experts that examined the proposal. By the end of the project, the consortium had fulfilled all monitoring requirements and had delivered the interim report on due date. The final report was still under preparation at the time of the current case study. It should be noted though, that the evaluation conducted was more of a **process evaluation** aimed at verifying if the JA had been implemented as planned and reached its objectives. But no attempts were made to collect evidence regarding QUANDHIP's broader outcomes or impacts, and how these contributed to the realisation of the HP's objectives.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	1.5
Economies of scale	1.0
Promotion of best practice	**2.2**
Benchmarking for decision-making	2.0
Cross border threats	**2.5**
Free movement of persons	0
Networking	**2.6**
Unlocking the potential of innovation	1.5

Criteria 1: Promotion of best practice

The JA developed common biosafety and biosecurity checklists for self-evaluation of BSL 3 and 4 laboratories, based on laboratories own experience and best practice. Partners considered that the new checklists could become an applicable document for all BSL 3 and 4 laboratories in Europe. QUANDHIP's training activities were central for the dissemination of these checklists, as well for the exchange of other best practices among the network partners. A key aspect of these trainings was that they were very practical and focused on concrete needs and interests. According to participants, they provided high benefit to them and were conducive to the optimisation of laboratory practices for both diagnostic and biosafety/biosecurity procedures.

Finally, the EQAEs also helped to bring best practices to fruition in the participating countries. These proficiency tests allowed laboratories to assess the quality of their diagnostic procedures and methods against the practice and the performance of more experienced ones (present in their own countries or abroad) and identify their main areas for improvement. As was explained before, some partners also used the samples from the EQAEs to assess the diagnostic quality of other national laboratories not included in the partnership.

Criteria 2: Cross-border threats

QUANDHIP contributed to reducing risks and mitigating the consequences of cross-border health threats by establishing relevant structures for coordination, preparedness, detection and response. According to the documentation consulted and the interviews conducted, by merging the two existing laboratory networks, the JA offered a cross-border and cross-disciplinary opportunity for evaluating and improving the accuracy, safety and suitability of laboratories assays, methods, data interpretation and safe transportation of samples. The result is an enhanced laboratory system capable of responding to cross-border health threats. It also created a sound base on which to establish a structure for coordinating that response. Moreover, the JA also provided an infrastructure and strategy for EQAEs, which are an essential tool for ensuring a robust and sustainable early diagnostic system. It is worth noting that in order to fully realise these outcomes at an EU level, it would be necessary that all MS are included in the network.

Criteria 3: Networking

QUANDHIP built a network of BSL 3 and 4 laboratories spread across Europe. Over the course of this case study we presented concrete outputs generated thanks to cooperation and networking between the laboratories involved (e.g. the biosecurity/biosafety checklists, training activities, EQAEs etc.). The key success factors of these networking activities were that partners knew each other for a long time, had experience working together, had common interests and needs and were very interested in learning from each other.

Moreover, there is evidence that partners will continue using the network and will collaborate with each other even after the end of the JA. For example, one of QUANDHIP's coordinators recently connected an Italian laboratory that needed to do some particular virus testing with a partner in Spain that agreed to cooperate. In addition, some laboratories from the viruses and bacteria side have established bilateral collaborations for specific research projects. According to the JA's coordinators, members are very motivated to continue with these activities.

Finally, QUANDHIP also established links with other initiatives at EU level dealing with the management of health threats and with reinforcing global health security such as the European Research Infrastructure on Highly Pathogenic Agents (ERINHA)[89] funded by DG RTD/ENTR; EMLab; the European Network for Diagnostics of Imported Viral Diseases (ENIVD)[90] and the European Committee on Antimicrobial Susceptibility Testing (EUCAST)[91], the last two supported by the ECDC. The JA was also represented by its coordinators in other global initiatives such as the Global Health Security Action Group Laboratory Network (GHSAG-LN).[92]

Conclusions and lessons learned

QUANDHIP was a relevant and comprehensive JA addressing a particular priority for the EU in relation to ensuring global health security. It was considered a unique project by the consortium partners, the EC, and the public health experts that participated in the development of this case study.

The main achievement of this JA was making previously established viruses and bacteria laboratory networks cooperate and create channels for exchanging information and best practices. This resulted in an increased and extended preparedness to detect and respond to potential outbreaks of highly infectious pathogens. QUANDHIP also provided information and a valuable structure for coordinating the response to cross-border health threats.

QUANDHIP's actions can be replicable and transferable and, a number of its outputs (for example, the repository of reference material and biosafety/biosecurity checklists) would be useful to leverage the capacity of laboratories in MS which are not currently included in the network, in candidate countries or even internationally. As mentioned before, QUANDHIP's broad partnership is one of the action's main strengths, but also one important area for improvement. It is fundamental that all EU MS are involved in the network and that they all count with high quality and safe laboratory diagnostic capacities.

Finally, feedback collected during this case study confirms that it is highly desirable that the QUANDHIP network is sustained and, more importantly, extended. It can be taken as a positive sign that a new JA will most likely be developed during 2015 and that new MS will be joining. In relation to this, it is also important that the network remains open to other laboratories not currently involved, including from the EU, EEA/EFTA and acceding countries and that it establishes stronger links with national authorities, in particular with those key links in the chain of command for responding to outbreaks.

[89] http://www.erinha.eu/
[90] http://www.enivd.de/index.htm
[91] http://www.eucast.org/
[92] http://www.ghsi.ca/english/background.asp

9.4.FOEDUS – Facilitating exchange of organs donated in EU Member States (Joint Action)

Summary

The Joint Action FOEDUS addresses a highly relevant topic (cross-border exchange of donor organs for transplantation), in an area where the Commission is called upon to complement national policies. Even though the action is currently on-going, its design is very pertinent and its implementation has met with no significant obstacles to date. Expectations on the results and impacts of the Joint Action are high, but the success of the action relies on a stronger engagement of collaborating partners in particular, but also of partners not tasked with leading the work packages. Critical to the sustainability of the Joint Action will be the operationalization of a common EU-wide approach to the exchange of organs, through the use of the common donor forms and the IT portal, as well as of the communication manual.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Avg. score (1-3)	Explanation
Design	2.2	The Joint Action addresses a very relevant topic in an area that is of high priority for the EU. The action and its general objectives are clearly aligned with EU actions and legislation They also complement previous and on-going funded actions. The specific objectives are less clear and not entirely aligned with one another, as they are formulated at different levels.
Implementation / outputs	2.3	The size and composition of the consortium are highly adequate to meet the objectives of the Joint Action, but are also challenging in terms of implementation. Challenges with regards to the size of the action and to the potential political and economic changes at national level that may impact on the work of the partners are identified as inherent risks of the action. Implementation to date has run smoothly though some logical delays were experienced.
Dissemination	1.5	Dissemination of the results of the Joint Action ultimately relies on the work of the partners at national level. Even though competent authorities and supranational organisations receive regular updates on the state of play of the Joint Action, stronger levels of engagement of collaborating partners are recommendable on an on-going basis to foster the future use of the common tools and guidelines developed. Dissemination should ultimately aim at reinforcing commitment of competent authorities with the outputs of the Joint Action, and it is still early to fully assess this element.
Results /	2	The results of the Joint Action are expected to positively impact cross-border exchanges of donor organs.

impacts		However, with the project halfway through it is still too early to jump to anticipated conclusions and scores have been assigned accordingly. Critical to the sustainability of the action will be the commitment of Member States to use the common donor forms and the IT portal, as well as the communication manual. These tools will be useful to improve organ availability but they are outside the scope of EU legislation, therefore their implementation will rely upon political willingness and the development of internal capacities at national level. Adaptations to the national contexts might also be required.

Introduction

Organ shortage is a common problem that affects all European countries. The number of organ donors is insufficient across the EU Member States, as is the number of organs that are used per donor. "Surplus donor organs" that are not allocated at national level because of lack of suitable recipients on national waiting lists are currently wasted in many cases even though they could be used in other EU countries.

Whilst the management of waiting lists is a national competence, there are different types of mechanisms to exchange donor organs between EU countries. There are a number of Member States that have partially delegated this task to European organisations, like Eurotransplant and Scandiatransplant.[93] Bilateral cooperation between specific countries, which foresees a more flexible type of collaboration, is also taking place between countries like Spain, Italy, France, Portugal, the Czech Republic and Switzerland, members of the recently established South Alliance for Transplants (SAT). However organ exchanges continue to be problematic for some EU countries in particular for Member States who have accessed the EU more recently or for smaller countries with underdeveloped national transplant programmes in place or with weak communication about organ donation and transplantation.

According to recent figures on organ donation and transplantation, more than 63,000 patients were officially placed on organs' waiting lists in December 2013 for an organ transplant in the European Union. The figures for 2013 were lower than those registered in 2012 (63,800 patients) but higher than numbers for 2011 (61,500 patients). Of these nearly 80% were waiting for a kidney, about 10% for a liver, and several thousands for other organs such as a heart or lungs.[94]

Whilst the number of organs transplanted for the EU has registered a steady increase in the last 10 years (from 26,340 in 2004 to 31,165 in 2013), there is still a substantial amount of EU patients on the waiting list to receive donor organs. Data for 2013 registered 4,100 patients who died in the EU while officially waiting for an organ transplant.

With regard to EU action in this field, article 168 of the Lisbon Treaty (former article 152) calls on the Commission to adopt harmonising measures to ensure organ safety and quality, and states that Community action should complement national policies directed towards improving public health.

[93] Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia are members of Eurotransplant. The Nordic Member States Denmark, Finland and Sweden, plus Norway and Iceland are members of Scandiatransplant.

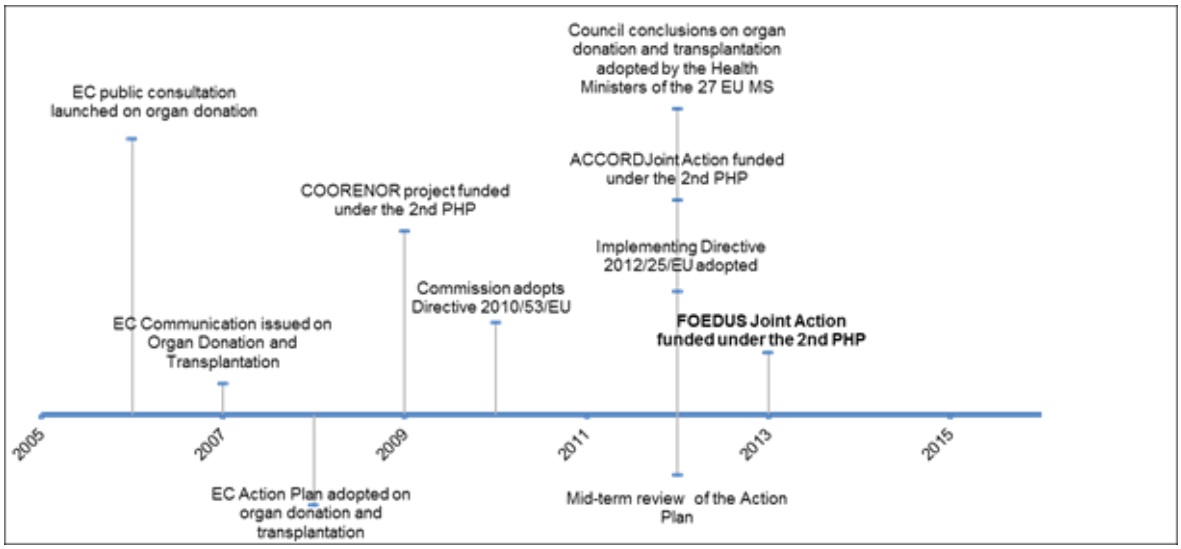
[94] Source: Council of Europe Transplant Newsletter 2014

The Communication on organ donation and transplantation[95] adopted by the Commission in 2007 and the accompanying Impact Assessment[96] identified a series of challenges and suggested a number of actions at Community and Member State levels to help increase the supply of organ donors across the EU and ensure the quality and safety of the procedures.

Following the adoption of this Communication, a public consultation with national experts and stakeholders was launched by the Commission which resulted in the adoption of an Action Plan on organ donation and transplantation[97] for the period 2009-2015 and of the following two Directives setting up the EU legal framework for standards of quality and safety of human organs intended for transplantation (general framework) and for information procedures in case of cross-border exchange of donor organs: Directive 2010/53/EU[98] and Commission Implementing Directive 2012/25/EU.[99]

The Action Plan (duly called "Strengthened Cooperation between Member States"), which aims at enhancing cooperation between Member States, identifies 10 priority actions to be achieved by Member States and by the Commission. In particular, the Commission can support the Member States through the use of different Community tools, including actions funded under the EU Health Programme 2008-2013, working groups on different topics, and journalists' workshops on organ donation and transplantation (organised by the Commission).

Figure 38: Key milestones on organ donation and transplantation



The FOEDUS Joint Action is a direct response to two of the ten key priorities of the Action Plan 2009-2015, namely Priority Action 4 (improving the knowledge and communication skills of health professionals and patient support groups on organ transplantation) and Priority Action 8 (development of a structured system for

[95] SEC (2007) 704 – SEC(2007) 705

[96] Impact Assessment on organ donation and transplantation: policy actions at EU level, available at: http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

[97] Action Plan on organ donation & transplantation (2009-2015): Strengthened Cooperation between Member States

[98] Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

[99] Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation

exchanges of surplus organs between Member States). In line with these two priorities of the Action Plan, the 2012 work programme for the HP[100] called for a Joint Action to support Member States in organising, via cross-border arrangements, optimal allocation and use/transplantation of donated organs through multilateral and bilateral agreements and through transplantation in other Member States.

The Joint Action that was selected for co-funding, led by the Italian National Transplant Centre (CNT), aims to better practice of exchange of organs with the end objective of increasing bilateral agreements, and an overall approach that includes raising awareness and preventing misunderstandings.. Key objectives that the JA is set to achieve are brought ahead by the four core work packages, including: analysis of the possible barriers and obstacles which hinder the exchange of organs (WP4); drafting of a consolidated proposal for a common donor form to be used during organ exchanges based on the consensus reached during the COORENOR project (WP5); development of the IT portal set up under the COORENOR project to enable quick exchange of information/offers (WP6); and improved communication and awareness raising around organ donation and cross-border organ donation (WP7). For a summary of the action's key parameters and work packages, see the tables below.

Table 39: FOEDUS project key parameters

Full name	Facilitating exchange of organs donated in EU member states
Acronym	FOEDUS
Funding instrument	Joint Action
Action number	20122101
HP strand	1 – Improve citizens' health security
Priority	1.2. Improve citizens' safety
Sub-priority	1.2.2. Help to enhance the safety and quality of organs and substances of human origin, blood, and blood derivatives; promote their availability, traceability and accessibility for medical use while respecting Member States' responsibilities as set out in Article 152(5) of the Treaty. [now Article 168]
Maximum EC contribution	€ 1,149,902.30
Actual start date	May 2013
Duration (in months)	36
Status	On-going
Lead partner	Centro Nazionale Trapianti, Istituto Superiore di Sanità (CNT/ISS)
No. of associated partners	17
No. of collaborating partners	7

[100] Commission implementing decision 2011/C 358/06 of 1 December 2011 on the adoption of the 2012 work plan

Table 40: FOEDUS JA work packages

WP	Work Package Description	Lead institution
1	Coordination	Centro Nazionale Trapianti, Istituto Superiore di Sanità (Italy)
2	Dissemination	OVSZ– Országos Vérellátó Szolgálat (Hungary)
3	Evaluation	EOM – Hellenic Transplant Organization (Greece)
4	Guidelines for organ exchange and bilateral agreements	ETI – Eurotransplant International Foundation
5	Consensus on donor medical information recommended for international organ exchanges	ABM – Agence de la Biomedecine (France)
6	Upgrading IT Platform for cross-border exchange of organs	KST – Koordinacni stredisko transplantaci (Czech Republic)
7	Communication and public Awareness	ST – Institute for Transplantation of organs and tissues of the Republic of Slovenia (Slovenia) DSO - Deutsche Stiftung Organtransplantation (Germany)

This case study is based on a review of relevant documentation on the Joint Action (including the proposal, grant agreement, and project presentations) and a series of interviews with the JA coordinator, the lead partners for two of the work packages, and officials of DG SANTE and CHAFEA.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	1.5
Feasibility of implementation plan	2

The FOEDUS Joint Action is meant to complement Member State policies in the field of organ donation and transplantation and is **clearly aligned to the EU priorities** set by the EU Action Plan on organ donation & transplantation (2009-2015), the Directive 2010/53/EU and by the Implementing Directive 2012/25/EU. In December 2012, under the Cypriot Presidency of the European Union, Member States came to common conclusions and recommendations on organ donation and transplantation that were largely supported by the Commission. In its conclusions, the Council openly invited the Member States *"to engage in operational cross-border exchange of organs, including through the participation in a Joint Action (i.e. FOEDUS) dedicated to cross-border exchange agreements"*.[101] The Commission's report on the mid-term review of the Action Plan, made available in April 2014, also placed high emphasis on the potential of FOEDUS to support the objectives and priorities of the Action Plan in the coming years, in particular in relation to Priorities 4 and 8 of the plan, but also (to a lesser

[101] Council conclusions on organ donation and transplantation (2012/C 396/03) of December 2012

extent) covering priorities 5 (facilitating the identification of organ donors across Europe and cross-border donation) and 6 (enhancing organisational models of organ donation and transplantation).

In terms of its **design**, FOEDUS is the result of a former EU funded project (COORENOR), which resulted in the establishment of the first European tool for international exchange of organs, freely accessible for all national competent authorities established by Directive 2010/53/EU (whether or not they are partners within FOEDUS). Designed as a Joint Action, FOEDUS expands on the work of COORENOR, which was restricted to a small number of countries[102]. Its broad geographical scope (21 EU Member States + 3 non-EU countries + 1 international organisation) and the participation and financial involvement of the national competent authorities for organs (as partners in the JA) enable a more powerful implementation directly at national level. In terms of participating countries, the JA features a good mix of big countries with big donor pools and smaller countries with less developed programmes (and therefore less chances to transplant all organs from their donors), which increases opportunities for cross-border organ exchange). Another key strength of the action's design is the participation of a number of organisations who took part in the COORENOR project, which guarantees continuity and a previous history of joint collaboration between partners.

The **general objectives** of the Joint Action are robust and in line with EU legislation and actions. The main aim of the Joint Action, as per the proposal, is to contribute to a better practice of exchange of organs in order to increase the number of operational exchanges and agreements between EU countries. The ultimate aim is to increase the number of transplanted organs and to develop a better approach to communication in this field. The specific objectives developed in the proposal are less clear and not entirely aligned with one another, as they are formulated at different levels. Some of the objectives would be more appropriate if formulated as outputs or even longer term outcomes. For example, the development of common donor forms (Specific Objective number 3 in the proposal) cannot be aligned at the same level as an increase in number of bi-lateral/ multilateral agreements for cross-border organ exchanges (Objective 4) or an increase in the number of exchanged organs (Objective 5). The intervention logic of the Joint Action could be strengthened by reviewing / reformulating the different levels.

Taking into account the size of the consortium, the **implementation plan** of the Joint Action relies on well experienced partners and work package leaders with a common history of collaboration in previous EU-funded actions and within the network of authorities set by Article 19 of Directive 2010/53/EU. The fact that the four core work packages are scheduled to run almost in parallel is also positive in that the tasks are not relying or excessively dependent on one another. In terms of implementation drawbacks, one of the key challenges is linked to the size of the consortium, which is intrinsically more challenging to manage than a smaller consortium with fewer partners. The other main challenge is related to the changes in the political and economic situation in partner countries, which may lead to staff changes at the level of national competent authorities with possible impacts on the implementation. Political risks are also inherent in that countries not involved in the JA (or involved only in some Work Packages) may not want to cooperate with all activities, thus mining some of the results. All of these challenges are highlighted in the proposal and contingency strategies are presented (including strong coordination mechanisms, regular communication among partners, and the set-up of an Advisory Board). In practice however, regular communication has been taking place mostly among active partners (those leading the different work packages). The composition of the Advisory

[102] Given that CORENOR was funded after a "call for proposals", the selected consortium counted several EU Member States, but fewer than in a larger "Joint Action".

Board includes representatives of countries other than work package leaders with the objective of achieving a stronger involvement of the JA's partners.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2
Fostering of collaboration and partnerships	2.5
Engagement with other actors (incl. DG SANTE / CHAFEA)	2.5

The Joint Action was launched in May 2013 and is only half-way through, so **implementation is still on-going** with many deliverables yet to be produced. To date, overall implementation of the action has run smoothly despite some delays that have called for a number of adjustments. The three horizontal work packages (WPs 1 to 3 dealing with coordination, dissemination and evaluation) are running according to schedule. In terms of the core work packages, WP4 (definition of guidelines in cross-border organ exchange and analysis of barriers and obstacles) has been the most problematic so far in terms of delays. In particular, the activities were affected by changes in the staff of Eurotransplant (WP4 coordinator) and by the fact that the questionnaire developed and circulated among 31 countries and international organisations collected 67% of responses so it was agreed to give a longer time frame in order to collect more responses. The other work package that has experienced some delays is WP6 (upgrading the IT organ exchange platform). It was agreed that the portal has to be developed according to the requirements of the Commission's IT department in case that, at the end of the action, national authorities agree to leave the portal to be managed directly by the Commission. WP5 (consensus on donor medical information) and WP7 (communication and awareness raising) have developed according to plan.

The **partnership** set up for the Joint Action is geographically broad, with twelve out of the 13 new EU Member States represented (all except Latvia), and 9 former EU Member States taking part.[103] FOEDUS also includes three non-EU countries (Norway, Iceland and Moldova) and the supranational organisation Eurotransplant as coordinator of one of the work packages. The composition of the action is highlighted in the proposal and by interviewees as one of its key enabling features, given that it is integrated by the relevant institutional and governmental bodies that implement national policies in the field of organ donation and transplantation. Challenges are also identified, in particular with regards to the size of the action and to the potential political and economic changes at national level that may impact on the work of the partners. The Joint Action is a natural continuation of the former COORENOR project and also complements other completed and/or on-going projects (DOPKI, ALLIANCE O, ETPOD, EFRETOS) and Joint Actions (MODE, ACCORD) in the field. The two partners interviewed highlighted the relevance for their countries / national governments of participating in the Joint Action. Participating countries benefit not only from the work and results of the JA, but also from the informal networking and information exchange generated via meetings and contacts.

In terms of **engagement with other actors**, collaboration and links between FOEDUS and the Commission are fluent and of a positive nature. The Joint Action leader highlights that DG SANTE and CHAFEA are kept continuously updated on the on-going activities and any relevant issues that come up related to the action. Twice a year, the Joint Action leader provides an update to EU representatives and to the

[103] Sweden, Denmark, Finland, Austria, Ireland and Luxembourg are not taking part in the Joint Action.

whole network of national competent authorities at the meetings of competent national authorities. Commission officials interviewed confirmed their overall levels of satisfaction with the management and implementation of the Joint Action to date, even though they mention the challenges and delays faced by WP4 and WP6 in particular. DG SANTE and CHAFEA interviewees also highlighted concerns that they had at the outset of the Joint Action in relation to the relevance and management of WP7, and which were dissipated as the work package moved along and progress was achieved.

The seven collaborating partners integrate the **Advisory Board** of the Joint Action, together with Swisstransplant which has been invited as an external member of the board. The role of the board is to participate in the action's general meetings, provide advice if and when needed and to evaluate the outcomes of the Joint Action. In view of DG SANTE and CHAFEA, the composition of the Advisory Board is good, in particular as it helps to keep on board the countries represented by the collaborating partners. Comments were raised that the board should be more informed and become more involved in the follow up of the Joint Action.

Overall **implementation of FOEDUS is going well** despite some delays, which are being addressed and which don't seem to affect the general functioning of the Joint Action. The commitment of the action leader and of the work package leaders is key to maintain the action on track and to encourage the other partners to comply with the tasks and agreed deadlines. Communication between partners is fluent and there is willingness and interest from the countries involved to move forward with the work packages and the key deliverables. The evaluation work package is meant to detect weaknesses and obstacles as the action moves along and to propose recommendations in the context of open discussions with a view to improving the quality of the project and project outcomes. Collaboration with DG SANTE and CHAFEA is perceived positively on both sides.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	1.5
Effectiveness of tools and channels used	1.5
Sustainability of dissemination activities (incl. use of multipliers)	1.5

The **main target groups** of the Joint Action are the partners, including the national organisations in charge of organ exchange and the national competent authorities (in many cases the same organisations). Regular updates of the work carried out are made during the meetings of the competent authorities for organs; thus, the Action's progress and messages are more widely disseminated to all competent authorities aside from the JA partners. FOEDUS is also addressed at other institutional and professional actors, including intensive care and transplant professionals, hospital administrations and organ donor associations. Indirectly, the general public –in particular patients waiting for a transplant who are affected by the benefits or organ exchange– are also targeted by FOEDUS. Communication with patient associations and journalists is instrumental to reaching out to citizens.

To this end, work package 2 is dedicated to the dissemination of the Joint Action results. Each partner is responsible for dissemination in its own country by attending conferences in order to present key results and outcomes and by communicating the findings to national authorities and policy makers. A dissemination plan was developed by the coordinator of WP2 and discussed / approved by the partners featuring the main dissemination objectives, target groups, dissemination tools and a timeline.

In view of the dissemination work package leader, the biggest dissemination challenge faced by the Joint Action lies in motivating the partners to communicate about the action in their countries on a regular basis. Work package leaders are more informed and committed to disseminating the findings, and hence are more active communicators. Efforts from the action leader and work package coordinator have been very important during the initial years of the action, but in the future it is recommended to encourage a more active involvement of partners to communicating with target audiences in their countries in order to succeed in reaching the objectives in all the countries that take part in the Joint Action.

With regards to the **tools and channels used**, a layman's brochure and the official dedicated website were produced and launched by the action, though dissemination of these two tools at national level relies on the work of the partners. The website has a private area that works as an information exchange platform between partners. The official documents of the Joint Action are stored in this domain, as well as examples of dissemination activities organised by partners. In addition to the brochure and the website, partners are required to communicate with their target audiences via social media channels, and to attend conferences and present papers. It will be important to continue keeping a regular track record of the work in this area, to follow up with partners who are not actively involved, and to exchange experiences in terms of tools and channels that work well and those that do not.

Future actions as part of WP2 include the creation of a newsletter that will be available in paper and online versions, and the development of short videos targeted at the general public on the main aspects of organ donation to be uploaded on YouTube. A final layman's brochure will also be produced and disseminated by the action. As mentioned before, it remains critical that the tools produced are effectively disseminated with the relevant audiences at national and international level. The commitment of partners is important to identify the most relevant opportunities for communication.

In terms of the sustainability of dissemination activities, one of the key features of the Joint Action is the work package (WP7) on communication and awareness-raising which aims at developing a specific approach to communicate about organ donation to general public with special focus on cross border organ exchange. This work package is running in close collaboration with WP2 as there are obvious links between the two, and its final output is the development of a **manual for national competent authorities** on how to communicate with the media in the field of organ donation and transplantation. The content of the manual will be the result of widespread consultation and analysis of positive and negative communication experiences, exchanges with journalists and experts, and surveys with citizens in five countries. It is expected that the manual will be widely used by national authorities on a daily basis when the Joint Action comes to an end.

Dissemination is also expected to take place through the CHAFEA website ('projects' database', 'News') and the European Commission website (e.g. pages of the Journalist Workshops: FOEDUS included in the document 'useful links') and through the national websites of the partners, who are likely to be the key multipliers of results and outcomes when the action finalises. In addition, relevant information and reports will be distributed among the associated partners and key target groups.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2
Impact on policy	2
Robustness of evaluation strategy and reporting	2

The text below (and the scoring assigned to the different areas) should be read with the caveat that FOEDUS is halfway through, so it is only possible to reflect on expected results and impacts based on initial findings and impressions collected.

FOEDUS is expected to produce the following **outputs**:

- Study describing different types of barriers to cross-border organ exchange, and proposals to overcome them. Possibly also templates of contracts and guidelines to support countries engaging in multilateral or bilateral agreements (WP4). This output is linked to the first challenge of the Commission's Action Plan, which is to increase organ availability, and is also in line with the two EU Directives in place.
- Consensus on organ specific forms to be used for international cross-border exchanges and on guidelines for items recommended for donor evaluation (WP5). This output is also linked the first challenge of the Action Plan (increasing organ availability), and is in line with EU legislation (Annex to the Directive 2010/53/EU).
- Consolidate and test the IT tool developed in the COORENOR project to manage cross-border exchange of organs, check feasibility and compliance by the European Organ Exchange Organisations and expand the pool of users (WP6). This output is linked to the first challenge of the Commission's Action Plan (increase organ availability), and is also in line with the two EU Directives in place.
- Manual for national competent authorities on how to communicate about organ donation and cross border exchanges (WP7). This output is linked to the first challenge of the Commission's Action Plan (increase organ availability) and complementary to the communication work carried out by the Commission (Journalists Workshops on organ donation and transplantation).

The outputs are expected to assist Member States in concluding bilateral and multilateral agreements and in communicating to the wider public about cross-border exchange of organs for transplantation, resulting in an increase in the number of organs exchanged. FOEDUS partners and Commission officials interviewed agree that all of the **outputs are directly applicable and usable**, and this is reinforced by the fact that FOEDUS partners are the main target audiences who will be expected to make use of the tools developed and tested. There are of course political factors that may affect the implementation of the results, but there is consensus about the relevance of the action both for the Commission and for the countries involved.

At this stage, it is expected that the results of the Joint Action will have a **significant impact on policy**. In particular, the establishment of a tool for cross-border organ exchange will bring the EU one step closer to having a common policy at least for special cases such a paediatric, urgencies and hyper sensitized patients. Increasing the availability of organs is also expected to stimulate Member States to invest resources to develop their own transplant programmes with a view to achieving self-sufficiency and meeting their own patient requirements. The manual on how to communicate with media is likely to help in raising awareness and addressing mistrust among EU citizens with consequences on donation rates.

Impacts are of course dependent on the use of the common donor forms, the IT portal and the manual developed, and all of this will be closely linked to the uses that each partner gives to the outputs of the Joint Action at national level. Impact is likely to be stronger for small countries or new Member States with gaps or deficiencies in their national transplant programmes, or with weaknesses in communicating about organ donation.

As regards **evaluation**, a system was developed by the leader of work package 3 at the outset of FOEDUS to evaluate the action, and the members of the Advisory Board

–integrated by the action's collaborating partners– were nominated. The system that was developed includes regular evaluation and monitoring mechanisms to improve the work in progress and ensure the success of the Joint Action, and a final evaluation performed near the end of the action to provide evidence of the achievements. The leader of the evaluation work package will report on progress achieved and results at every general meeting, and the Advisory Board will contribute to both elements, with a stronger focus on the final evaluation report. Whilst it is early to assess the success of this work package, the mix of formative and summative elements seems to be appropriate, though it will be difficult to measure impacts at the end of the Joint Action. The other factor that was raised by DG SANTE and CHAFEA officials interviewed is the need for stronger involvement of the Advisory Board, supported by a more continuous information flow.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	**2.2**
Economies of scale	1.5
Promotion of best practice	**2.0**
Benchmarking for decision making	**2.0**
Cross border threats	0.2
Free movement of persons	1.7
Networking	**2.0**
Unlocking the potential of innovation	1.0

Criteria 1: Implementing EU legislation

The FOEDUS Joint Action was designed to facilitate collaboration on organ donation among national authorities in the EU, as prescribed in the Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation and in the Action Plan 2009 – 2015 set by the Commission. The action and its intended outputs are also clearly aligned with Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation. The main rationale of the action is to align Member States' practices with the EU legal framework, so that available organs can be exchanged cross-borders without unnecessary problems or delays.

Criteria 2: Promotion of best practice

Whilst not an explicit objective of the Joint Action, two of the four core work packages of FOEDUS (WPs 4 and 7) are clearly focussed on identifying procedures, approaches, methods or tools to be applied by Member States in the field of cross-border exchange of organs. Work package 4 aims at defining guidelines on basic principles for organ exchanges and recommendations to overcome obstacles and barriers that hinder the development of these exchanges. The guidelines are the result of an analysis of the current exchange practice, including key challenges and an inventory of bilateral and

multilateral agreements in place. Work package 7 aims at developing a specific approach in communication about organ donation to the general public with a special focus on cross-border organ exchange. To this end, positive and negative communication examples will be analysed and shared with partners, and close collaboration with journalists and communication experts will be instrumented with a view to developing a manual that can be used by national authorities on how to communicate about organ donation and cross-border exchanges.

Criteria 3: Benchmarking for decision making

A key underlying objective of FOEDUS is to provide partners with experience and knowledge in the field of organ exchange so that the outputs, skills and information acquired can serve as the basis for future recommendations at European level that will extend the benefit of the Joint Action beyond its lifespan. The action provides new guidelines, a common donor form and a communication manual that are expected to impact on decision making and ultimately on an increase and a more efficient use of the number of organs exchanged.

Criteria 4: Networking

FOEDUS has a strong networking component that, if successful, will strengthen cooperation between Member States in the longer term, in line with EU legislation requirements. FOEDUS work packages and expected outcomes are largely linked to the direct involvement of national competent authorities from nearly all Member States as partners in the Joint Action. Of course the links between FOEDUS partners precedes the EU funded action, but the mechanisms and tools that are being developed under this action are meant to reinforce cross-border collaboration in this field and to support the set-up of an EU-wide common approach to the issue of organ exchanges.

Conclusions and lessons learned

FOEDUS is halfway through at the time of writing this report, so much of what has been written is dependent on the successful implementation and completion of the action, and on the degree to which the participating countries make use of the outputs developed. The preliminary analysis shows that the Joint Action is a very relevant tool that is intended to help achieve priorities 4 and 8 of the Commission's Action Plan on organ donation and transplantation, and is also instrumental to the transposition of the two EU Directives in this field.

The design of the action, including the instrument selected for funding as well as the size and composition of the consortium, are highly instrumental for the legitimacy and sustainability of the outputs. FOEDUS is integrated by the national competent authorities in charge of organ donation in each country, so having them on board is in itself a signal of commitment. Whilst many of the partners have worked together in the past, there are countries that are new joiners and the ample geographical coverage and mix of countries is intended to benefit networking and exchanges between Member States.

The horizontal work packages, namely those linked to the implementation and dissemination of the Joint Action will be critical to achieving the desired outcomes and impact, and to guaranteeing the sustainability of the action. In particular, it will be important to encourage stronger participation and commitment of all the partners, as their involvement is likely to result in more regular exchanges in the future.

9.5.NANOGENOTOX JA - Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard (Joint action)

Summary

This "safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard" was highly technical in content. It addressed a topic which is highly relevant for the both the industrial sector of the EU economy and health security of EU citizens. However, there were some concerns regarding the design and in terms of the impacts, however the implementation and dissemination were strong.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2	The project is relevant and clearly an important area for public health security, however it is incredibly specific and highly focused. Despite clearly having aspects which make it well suited to a joint action at EU level, its fit with the Health Programme (compared to say, a DG Research project) was challenged.
Implementation / outputs	2.7	Despite delays in getting started, the outputs were delivered as envisaged.
Dissemination	2.3	Dissemination was effective and well managed, especially through the linkages and consultation of stakeholders.
Results / impacts	2	Besides further work to ensure regulation in this field, there is limited evidence of the impact of the action at the policy level (although this was not the primary objective of the action). Nonetheless, there have been relationships developed; paving the way for future collaboration and within this specific topic area the results were significant. Although currently this is mainly limited to technical research/results.

Introduction

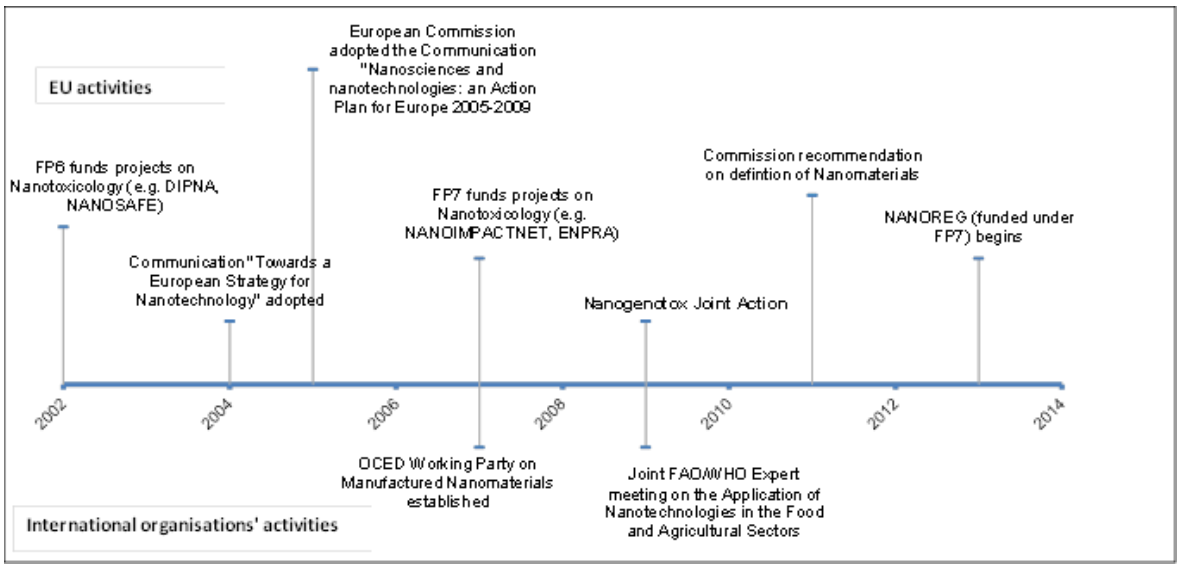
Manufactured Nanomaterials (MN) are increasingly important for the industrial and economic sector. They are used in a range of consumer products, for example in cosmetics, some food products, clothing, packaging, etc. Human exposure to MNs in consumer products can occur at various stages: synthesis, production and inclusion in the products to the release of MNs to the environment. Nano geno- toxicology - the study of the damage to DNA caused by toxicity of nanomaterials - is becoming increasingly relevant for governments worldwide, especially since without sound evidence on the impact of MN on human health and the environment, regulation is difficult.

There has been a lot of work and research related to nanomaterials funded and led by the European Commission. In this context, an important milestone was the adoption of the "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009" by

the European Commission, Council and Parliament in 2005 which built on the Commission's Communication "Towards a European Strategy for Nanotechnology" from 12 May 2004. Both aimed to reinforce the EU's leading position in nanoscience and nanotechnology whilst addressing concerns for environmental, health and safety concerns. There have been a series of projects funded by the European Union under the 6th and 7th Framework Programme for Research and Technological Development (FP6 and FP7 running 2002 – 2007 and 2007 – 2013 respectively) which included, for example, investigations into methods for testing toxicity and eco-toxicity and risk assessment. In 2009, under the 2nd Health Programme, a Joint Action was funded to conduct a "Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard". This joint action is the subject of this case study. We note that, there continue to be actions under FP7 and Horizon2020 (previously known as FP8) which build on previous work, for example "NANOREG"[104], which was funded under FP7 began March 2013 (to last 42 months) and builds on NANOGENTOX with a specific focus on regulation.

The objective of the Joint Action (JA) was to work together towards establishing a robust (specific and sensitive) **methodology** to assess the potential genotoxicity of MNs and to **generate data** on the genotoxic effect of selected commonly used MNs materials.

Figure 39: Key milestones on Nanomaterials in Europe



The 2009 work programme for the HP[105] called specifically for a "Joint Action on the safety of nanomaterials" with the following objectives:

- "to strengthen, expand, and share the knowledge required for the assessment of the hazard, exposure, and overall risk of nanomaterials;
- to accelerate the exploitation of existing data and the exchange of best practices in risk assessment and management; and
- to promote the establishment of robust methodologies throughout the EU."

The Joint Action was led by French Agency for Food, Environmental and Occupational Health & Safety (ANSES).[106] For a summary of the project's key parameters and work packages, see the tables below.

[104] http://nanoreg.eu/images/NANoREG_FACTSHEET_final_100613.pdf
[105] Commission Decision (2009/158/EC)

Table 41: NANOGENTOX key parameters

Full name	Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard
Acronym	NANOGENOTOX
Funding instrument	Joint Action
Action number	20092101
HP strand	1 - Health security
Priority	1.2 Improve citizens' safety
Sub-priority	1.2.1 Scientific advice and risk assessment
Maximum EC contribution	€ 2,809,268
Actual start date	03/2009
Duration (in months)	36
Status	Finalised
Lead partner	Agence française de sécurité sanitaire de l'environnement et du travail – ANSES
No. of associated partners	16
No. of collaborating partners	10

Table 42: NANOGENTOX work packages and lead institutions

WP #	Work Package Description	Lead institution
1	Coordination	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
2	Dissemination	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
3	Scientific evaluation of the Joint Action	Federal Institute for Risk Assessment (BfR)
4	Characterisation	The National Research Centre for the Working Environment
5	In vitro testing	Finnish Institute of occupational health (FIOH)
6	In vivo testing	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
7	Toxicokinetics	National Institute for Public Health and Environment (RIVM)

This case study is based on a review of relevant project documentation (including the proposal, grant agreement, and project deliverables) and interviews.

[106] This organisation is the product of a merging of two separate organisations (AFSSET "Agence Francaise de securite sanitaire de l'environnement et du travail" and AFSSA "Agence Francaise de Securite Sanitaire des Aliments" – which occurred during the course of the action, July 1st 2010)

Design

Design	Score (1-3)
Fit within programme and policy context	2
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	2

An array of policy initiatives have been led by the EU and a significant body of research has been funded (primarily under the Framework Programme FP6 and FP7) over the past decade to advance the understanding of how to ensure the safe use of MN. The (increasing) importance of MN in the production of goods in the EU combined with some amount of inconsistency surrounding the application of definitions and uncertainty regarding the risks involved makes their regulation very difficult and thus the topic of the safety of MN **very relevant for the safety of EU citizens and important for the EU growth agenda (Europe 2020)**.

In terms of fit within the programme, the Joint Action was set up to explore the safety of MN under the Health Programme objective to improve citizen's health security and safety[107]. It should be noted that we heard concern regarding the highly focused nature of the study which was deemed by a representative of Chafea to be inappropriate for a Joint Action funded under the Health Programme and possibly more suited to funding by DG Research. There was suggestion that in order for this kind of work to be funded by the Health Programme, it would have been more appropriate to answer a wider, more generic question such as: how can research related to new products (such as NM) be used to address and ensure the safety of public health at EU level?

As with all joint actions, leadership from Member States is important since their design is the product of a collaborative partnership with DG SANTE and the actions are joint-funded by Member State organisations. As such, leadership and ownership from Member States is critical in setting both the direction and ensuing the success of a Joint Action for its implementation. For NANOGENOX, we heard that it was the French representative in the Programme Committee who had led the original idea for the joint action, and secured its place in the 2009 work plan. Once it was in the work plan, there was no reason to question it.

We heard from the lead organisation responsible for the action that important aspects of the design of the action illustrate how careful consideration went into ensuring not only that methodologies and results were obtained but that the way they were obtained was through *collaborative* working which supported *the transfer of knowledge and best practice* in an area which is increasingly important for health safety and security. We heard how the added value of conducting this research / developing methodologies collaboratively meant that duplication was avoided. These features make the action different from a regular research project.

Indeed, the importance of conducting this research collaboratively and at the EU level is summarised in the general objective of the action, which was: "to complement, support and add value to the Member States' policies and to contribute to increasing the safe use of MNs in the European Union".

[107] see Annex to Decision 1350/2007/EC, point 1.2.1 "Support and enhance scientific advice and risk assessment by promoting the early identification of risks; analyse their potential impact."

The tasks and design of the action are based around **highly technical work packages**. These packages are formulated in order to produce the necessary information on which to determine (how to assess) the potential genotoxicity of MN. Indeed, ultimately, "the joint action will provide quick, reliable and economical tests to assess potential genotoxicity of MNs with alert signals useful for society and industries", as well as data on the potential genotoxicity of commonly used MN.

In terms of the implementation plan itself, a series of risks were identified at the proposal stage and mitigation strategies were identified. One risk in particular - namely delays in receiving material turned into a significant problem (see next section for discussion on this point). In order to execute the tasks within the joint action, the standard operating procedures (SOP) developed and used will be audited to ensure their consistent application and where necessary, training will be provided. The proposal specified when a new Member State would be involved, but also recognised certain tasks were best undertaken by the more experienced partners.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2.5
Fostering of collaboration and partnerships	2.5
Engagement with other actors (incl. DG SANTE / CHAFEA)	3

Although everything did not go according to plan, contingency plans were put in place and due to both the professionalism and effective management of the lead firm meant that ultimately this did not jeopardise the outputs of the action.

There were significant setbacks in getting the action started due to **delays in the receipt of materials for testing** (the industry was not forthcoming and in the end the Commission's Joint Research Council (JRC)[108] and the Danish National Research Centre for the Working Environment (NRCWE) provided the materials to facilitate the work). These delays meant that some experiments were on-going at the point when results were supposed to be presented. There were also greater needs for training to ensure consistency of approach than originally envisaged. Despite the delays and the extra training required, Chafea reported that the outputs were delivered as expected. This was facilitated by a professional and effective lead organisation. In addition to the work planned, towards the end of the action Chafea realised recommendations for how to take the work forwards would be useful. These are included in the final report and facilitate the on-going improvement of efforts to ensure the safety of MN.

This joint action involved 16 associated partners (from 11 Member States; 2 of which were "new" Member States, Bulgaria and Poland) and 10 collaborating partners. According to the evaluation report, the collaboration between laboratories was good but was not excellent throughout. As stated in the final report "The participation of a large number of scientific teams from various EU Member States enabled the development of a common methodology and should contribute to its uptake and implementation". In addition, the report stated that "the JA has contributed to the creation of a network of laboratories within the partner institutes that will hopefully continue to work together".

[108] The Commission's in-house science service, which is charged with the mission of providing the EU with independent, evidence-based scientific and technical support throughout the policy cycle (https://ec.europa.eu/jrc/)

We were informed that this has, indeed, been the case. "NANOREG" which was launched under FP7 in March 2013 and aimed at linked scientific knowledge of the toxicity of MN to the need for regulation, builds not only on the findings (and is broader) but also the partnerships established under NANOGENOTOX. NANOREG involves 9 partner organisations which were associated partners for NANOGENOTOX. We do note, however, that neither of the "new" Member States (Bulgaria and Poland) have been involved in NANOREG. Nonetheless, this development is evidence of the effectiveness of NANOGENOTOX in building a real network and partnerships which have endured.

Engagement with other actors was an important part of the work carried out as well as looking ahead to how the results are used. Of particular note, the involvement of the JRC as a collaborating partner was deemed critical to the success of the action. First and foremost, it was the JRC which stepped in when the industry were reluctant to provide the MN for testing, purchasing the necessary samples and providing them to the team. There was also significant collaboration with the OECD's Working Party on Manufactured Nanomaterials' (WPMN), facilitated by the scientific coordinator of the joint action who was also a member of the OECD's WPMN. As per the final report: "All the results of the project will be shared with the OECD's Working Party on Manufactured Nanomaterials' (WPMN) sponsorship programme for the testing of MNs" and "Synergy was also developed with other European and international activities like ISO TC229 and FP7 funded projects and networks (ENPRA, NanoSafetyCluster, Nanodevice, Q-nano etc." We were also informed that certain decisions were taken in order to facilitate collaboration. For example, the final conference was timed to coincide with an OECD meeting which would have brought scientists from around the world to Paris and made it much easier for them to partake in the final conference.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	2.5
Effectiveness of tools and channels used	2
Sustainability of dissemination activities (incl. use of multipliers)	2.5

The dissemination work package was led by ANSES, the organisation which led the coordination of the action as a whole.

The target groups identified for this action in the proposal were: the general public; regulatory authorities and market surveillance bodies; industries which could apply the developed methodology before marketing their MN or products which use them and policy-making bodies. As noted by Chafea, the work undertaken is probably too technical to be interesting for the general public, however relevant it is for their safety. The main direct target groups were really those identified through the stakeholder analysis. The main stakeholders were identified early on in the action and then a stakeholder consultation (in the form of a questionnaire completed via telephone or in writing) of five categories of stakeholders (EU risk assessors and policy-makers; members of the scientific community; professional federations representing companies; non-governmental organisations (NGOs) and trade unions) was undertaken 10 months into the action. The findings were then fed back to the project partners. Two years into the action, another consultation, this time a workshop, was conducted to share the preliminary results and knowledge acquired with the stakeholders. According to the action coordinator, the relation built up with the stakeholders was a strong and active component of the action.

Traditional mechanisms for awareness-raising were used. There was a dedicated website (which is still active[109]), production of a leaflet[110], newsletters[111], a final report (which was made public[112]), partners presented at national and international conferences and scientific publications are expected for each scientific work package. According to the final report, the website was visited 7000 times (not necessarily unique visitors, however) and 2000 downloads were made.[113] The action coordinator was keen to emphasise that the joint action resulted in many publications to a worldwide audience, not just within the EU. Indeed, the final conference was held in Paris in February 2013 and arranged to fit with an OECD meeting related to MN which was a strategic tool to make sure that scientists who were already in Paris could attend both meetings. Given the highly specialised nature of this project, it is debatable whether the spending on project website and branding etc. was really necessary. However, websites are a somewhat routine and arguably important for effective dissemination in the context of transnational work; as such this criticism is not specific to this action.

In terms of the sustainability of dissemination activities, collaborative working and the transfer of knowledge between national teams were successful features of the project and seemed to be effective, providing important elements for network's construction and some first results towards sustainability (NANOREG project involving most of NANOGENOTOX partners).

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2
Impact on policy	2
Robustness of evaluation strategy and reporting	2

The final report states that "policy-makers, the OECD WPMN and the EC DG SANTE representatives confirmed that the results and lessons coming out from NANOGENOTOX can be built upon for risk assessment and risk management purposes". However, it is highly questionable that the results of this action have applicability outside the specialised topic area involving MN. Indeed, the most important outcomes are very specific to MN, namely: sets of standard procedures for rapid characterisation of types of nanomaterials, the method for producing suitable media for exposure to NM, and the data sets of physic-chemical properties. Nonetheless, the recommendations do connect the action with public health concerns despite their focus on how to advance risk assessment in the field of nanotechnology. According to a publication on joint actions: "its [NANOGENOTOX'] response to the needs expressed by regulators, industry and society … made a significant contribution to ensuring the further protection of human health".[114]

In terms of impact on policy, the Chafea official we spoke to was fairly conservative in their assessment of the impact of the action on policy. However, they conceded that where there may have been some impact was through the recommendations made. As

[109] http://www.nanogenotox.eu/
[110] http://www.nanogenotox.eu/files/PDF/nanogenotox_leaflet.pdf
[111] http://www.nanogenotox.eu/index.php?option=com_content&view=article&id=124&Itemid=157
[112] http://www.nanogenotox.eu/files/PDF/nanogenotox_web.pdf
[113] See p.25 of final report
[114] http://ec.europa.eu/health/programme/docs/joint_actions_2008_2011_en.pdf

per the final report: "The proposed method may be used by MS and EU and international (e.g. OECD) human health risk assessment and regulatory bodies, industries, consumer or worker protection associations and others, thereby improving public health in the EU". A regulatory review in 2012 outlined the Commission's plans to improve EU law and its application to ensure the safe use of nanomaterials. The accompanying Staff Working Paper references NANOGENTOX, among many others. Aside from this, there is little concrete evidence of the impact of the joint action on policy.

WP3 constituted "Scientific evaluation of the Joint Action", coordinated by a Bundesinstitut für Riskobewertung (BfR). The evaluation process involved both process and outcome evaluation, an internal evaluation team (comprising the WP leaders) and an external evaluation team (comprising ten technical experts). Despite some delays and recognised deficiencies in the design of the evaluation methodology, the teams were able to provide the steer needed and lessons were learnt.

The evaluation results state that given that this action was able to identify "major methodological problems" involved in testing the potential genotoxicity of MN. As such, the action provides lessons for further research and demonstrates certain key considerations in taking this research forward.

EU added value

As part of the in-depth review of the actions, a panel of three public health experts assessed the potential EU added value of the joint action against eight pre-defined criteria as shown in the table below. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.This action was also reviewed as part of the Mid-term Evaluation of the second Health Programme in 2011, against all but the last criterion (unlocking the potential for innovation). The results show a similar - not identical - pattern. Indeed, the highest scoring criteria are the same, namely promotion of best practice and benchmarking for decision making (although as previously mentioned, unlocking the potential for innovation is a new criterion so does not appear in the previous assessment).

In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice.

Criteria	Average score
Implementing EU legislation	1.7
Economies of scale	1.7
Promotion of best practice	**2.2**
Benchmarking for decision making	**2.3**
Cross border threats	1.3
Free movement of persons	0
Networking	1.5
Unlocking the potential of innovation	**2.2**

Criteria 1: Promotion of best practice

The promotion of best practice does seem to have been achieved to significant extent, as expressed by the following statement: "As a multi-partner initiative, the JA has accelerated the exchange of best practice for in vivo and in vitro genotoxity studies, as well as physico-chemical characterisation of nanomaterials"

Criteria 2: Benchmarking for decision making

In terms of benchmarking for decision-making the action seems to have made a good level of progress through developing a common methodology for industry stakeholders who can use the methodology before marketing their nanomaterials – either directly or in consumer products.

Criteria 3: Unlocking the potential of innovation

The area is new and establishing better processes for testing the safety of new techniques and the use of new materials could be seen as a way to unlock the potential for innovation. The joint action mainly involved scientific research that may lead to an innovative methodology to assess the potential genotoxicity of MNs.

Conclusions and lessons learned

NANOGENOTOX is an example of an action which addresses a topic with clear health and policy relevance and was designed in a way to deliver useful, applicable deliverables. As a joint action, it was also successful in facilitating collaboration between MS as well as EU partners and international organisations. In terms of the work carried out, there were obvious cost savings from collaborative efforts, avoiding duplication of efforts, facilitating sustainable and future collaboration in this field and bringing together organisations with less expertise and lower capacity to transfer knowledge and best practice. There were also synergies with previous and current/future work in this area under the 7th Framework Programme (and Horizon 2020). The success of the joint action was facilitated by effective management of the joint action. Indeed, when problems arose, contingency plans were made. In terms of lesson learnt, although the problems in acquiring the materials for testing were surmounted and a contingency plan was put in place, perhaps there could have been more scoping in the run up to avoid these logistical problems.

The actual impact of the work carried out is difficult to know without expertise in this specific and highly technical work streams. However, there are indications that the results have been picked up and taken forwards with a new action (NANOREG) which focuses on regulation with some of the members of the consortium implementing this joint action.

9.6.SALUX – A European Network to Follow-Up the Reformulation of Food; Identification and Exchange of Good Practices for SMEs and Consumers (Project)

Summary

Although the project addressed a highly relevant and pertinent topic (food reformulation in SMEs), and was mostly well implemented by a broad, varied and engaged group of actors, the results seem unlikely to have a significant impact either on SMEs themselves or on policy makers. A key reason for this seems to have been a certain lack of focus (trying to do too much for a variety of audiences), which led to the inclusion of elements in the work plan that were not fully feasible, outputs that do not quite meet the needs of the audiences, and a less than clear dissemination strategy.[115]

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Avg. score (1-3)	Explanation
Design	2.2	The project addressed a very relevant topic, and was based on a solid logic containing a good mix of research and development type activities. However, too broad and unspecific objectives, partly caused by the nebulous formulation "follow-up" and the addition of a new WP following the evaluation of the proposal, had a negative effect on the clarity and feasibility of the intervention logic.
Implementation / outputs	1.8	The project was mostly implemented well by a diverse partnership of private and academic organisations. However, obtaining sufficient feedback from SMEs presented a challenge, and some of the deliverables do not seem fully in line with expectations / needs of the target audiences.
Dissemination	1.3	The identification / prioritisation of target audiences was not sufficiently systematic / specific, in particular as regards the extent to which the action results are mainly targeted at SMEs themselves, or at other stakeholders. Although the fact that deliverables were translated into several languages is a positive, their structure and presentation is not conducive to dissemination.
Results /	1.3	Although the project adds to the evidence base on

[115] Please note that the review of the project results by a panel of three external evaluators under the auspices of CHAFEA revealed significant differences of opinion between the evaluators, which ranged from "very high" [sic] to "poor". The consensus report rated the results as "fair". This illustrates the potential for disagreement as regards the quality and usefulness of the results. This case study report attempts to take a balanced view, but reflects the fact that, having reviewed the deliverables, the author has significant concerns as regards the quality of some of the results and the way in which they have been presented.

impacts		reformulation, the good practices identified, tools developed, conclusions drawn and recommendations made remain rather general, and seem unlikely to be directly applicable by either SMEs or policy makers. The impact seems likely to remain limited.

Introduction

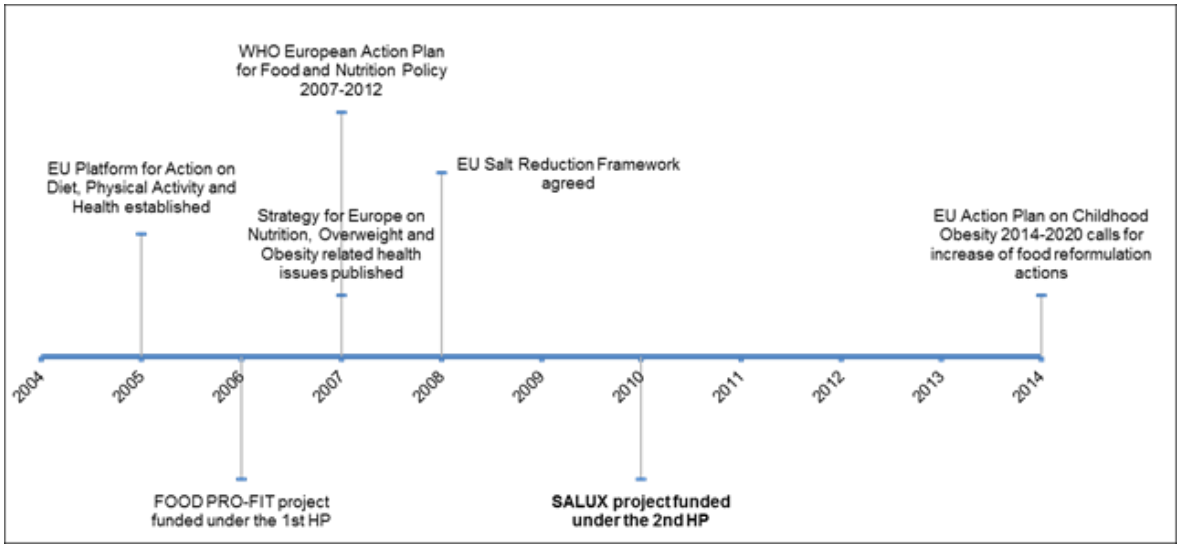
The last three decades have seen the levels of overweight and obesity in Europe rise dramatically, particularly among children, due mainly to a worsening trend of poor diets and low physical activity levels. Part of the problem is that European diets have evolved towards a higher proportion of prepared foods, including heavily processed food. Such foods can contain high levels of 'unhealthy' nutrients such as salt, saturated fat and (added) sugars. To a large extent, consumers' intake of nutrients in prepared and processed foods is unknowing; as a result, "as consumer demand for convenience food has grown, so intakes of these nutrients have reached beyond [the] recommended maximum levels".[116] In light of this, many public health actors argue that interventions to educate and inform consumers are not enough to address poor nutrition, and have called on food manufacturers to reduce the content of energy and "unhealthy" nutrients in their products. This is referred to as reformulation. Among others, the WHO European Action Plan for Food and Nutrition Policy 2007-2012 stated that "reformulation of food is considered as one of the key options for achieving dietary goals."[117]

Recent years have also seen the EU become increasingly active in trying to work with the food industry as well as other public and private actors on reformulation. The 2007 Strategy for Europe on Nutrition, Overweight and Obesity related health issues[118] notes that there is "growing interest in the composition of manufactured foods and the role that reformulation can play to make diets healthier", and that the food industry "could make demonstrable improvements in areas such as the reformulation of foods in terms of salt, fats, particularly saturated and trans fats, and sugars for consumers across the EU." In 2008, the EU Member States agreed to the creation of a common EU Framework on voluntary national salt reduction initiatives; since 2012, this is gradually being expanded to cover saturated fat.

A key initiative that pre-dates the publication of the EU Strategy is the EU Platform for Action on Diet, Physical Activity and Health, which was launched in March 2005 to bring together representatives of relevant industry sectors (including food and beverages, catering and vending, and advertising) and civil society (including health NGOs, consumer groups, and many others). The Platform is meant to contribute to progress in the fight against obesity by facilitating dialogue and voluntary commitments by stakeholders. Between them, Platform members have made close to 300 concrete commitments, including 31 in the category "Composition of Foods (Reformulation)". A background paper prepared by an expert for the Platform in 2009 identified a series of significant technical issues and barriers for reformulation. It concluded inter alia that support for SMEs is needed through networking and guidance.[119]

[116] EATWELL consortium (2012), p. 47
[117] http://www.euro.who.int/__data/assets/pdf_file/0017/74402/E91153.pdf
[118] COM(2007) 279 final
[119] Jacqui Webster: Reformulating food products for health: context and key issues for moving forward in Europe (paper prepared for the EU Platform for Action., November 2009)

Figure 40: Key milestones on Food Reformulation in Europe



The SALUX project needs to be seen in this context. The 2010 work programme for the HP[120] called specifically for a project on "Follow-up of the reformulation of manufactured foods — exchange of good practice with regard to the reduction of the levels of fat, saturated and trans fats, salt and sugar in manufactured foods focusing on the technical and economic aspects of reformulations in small and medium sized enterprises" in order to support the implementation of the 2007 EU Strategy. The project that was eventually selected for co-funding, submitted by a consortium led by the Italian firm Tecnogranda, aimed to achieve this by a series of actions / tasks including an analysis of the local context in a series of Member States, and the development of practical tools to support SMEs in their reformulation efforts. For a summary of the project's key parameters and work packages, see the tables below.

Table 43: SALUX project key parameters

Full name	A European network to follow-up the reformulation of food; identification and exchange of good practices for SMEs and consumers
Acronym	SALUX
Funding instrument	Project
Action number	20101210
HP strand	2 - Health promotion
Priority	2.2 Reduce major diseases and injuries by tackling health determinants
Sub-priority	2.2.1 Address health determinants and promote healthy lifestyles
Maximum EC contribution	€ 834,688
Actual start date	August 2011
Duration (in months)	36
Status	Finalised
Lead partner	Tecnogranda SpA
No. of associated	14

[120] Commission Decision 2009/964/EU

partners	
No. of collaborating partners	None

Table 44: SALUX project work packages

WP	Work Package Description	Lead institution
1	Coordination	Tecnogranda SpA, Italy
2	Dissemination	Critt Agro-Alimentaire de Haute-Normandie (France)
3	Evaluation	MTT Agrifood Research Finland
4	Analysis of the local context	IBA - National Institute of Research & Development for Food and Bioresources (Romania)
5	Definition and exchange of good practices	State Food and Veterinary Service of the Republic of Lithuania
6	Organization of the follow-up of the food reformulation among SMEs	BOKU – Universität für Bodenkultur Wien (Austria)
7	Cost-Effectiveness Analysis (CEA) of the major reformulations identified	Tecnogranda SpA (Italy)
8	European Clearing House for agri-food SMEs and consumers	ISES – European Institute for Socio-Economic Development, Italy

This case study is based on a review of relevant project documentation (including the proposal, grant agreement, and project deliverables) and a series of interviews with the project coordinator, the lead partners for two of the work packages, and officials of DG SANTE and CHAFEA.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	1.5

The project addressed a **very relevant topic** within the broader area of nutrition and physical activity. The 2007 White Paper highlighted the role reformulation can play in making diets healthier and thereby combating nutrition, obesity and overweight related health issues, and called on the various actors to do more in this area. This call for increased action was renewed in the 2014 Action Plan on Child Obesity, confirming its continued relevance. More specifically, interviewees (including from DG SANTE) emphasised the importance of enabling and motivating SMEs to reformulate, since there are significant (economic, technical, cultural etc.) barriers to successful reformulation that tend to be harder for SME to overcome. It was therefore felt that any project that can provide support to SMEs and put them in a position to meet the growing demand for healthier food products could have not only a significant impact on the health of Europe's population, but also enhance their competitiveness, and thus contribute to various policy objectives (including the Europe 2020 smart growth objective).

As regards the **project design and structure**, there is a good mix of analytical, consultative and development tasks. However, the fact that the proposal retained the rather unspecific formulation from the 2010 HP work programme – namely the "follow-up" to food reformulation – and turned it into its *general* objective (as well as the title of one of the key work packages) may have led to some uncertainties as to what exactly it was intended to achieve. The *specific* objectives, as per the initial project proposal, included not only the identification and exchange of good practices, but also to "evaluate the impact of [reformulation] programmes and policies", the "promotion" of reformulation, and the organisation of a "European information and awareness campaign for consumers" (this objective was subsequently removed, see below). The broad nature of these objectives suggests that the original proposal may have been more driven by a desire to cover all aspects that *may be* relevant, rather than as clear and focused an intervention logic as would have ideally been desirable.

Certain **changes were made to the proposal** following a review by a panel of three external experts. Most importantly, the information campaign was dropped (as it was deemed unnecessary and risk leading to a dilution of efforts), and instead a new work package was introduced to analyse the cost-effectiveness of the major reformulations identified (and thereby focus the project more on the difficulties faced by SMEs). In the end, the inherent logic of the project was fairly clear, moving from a series of analytical tasks to explore the local (which in this context actually means national) context (WP4) and good practice interventions to facilitate reformulation (WP5) in each participating country, to a direct consultation of SMEs primarily via s survey (WP6), on to the development of practical tools (WP7 and WP8). Nonetheless, it would seem that the *initial* lack of clarity, and the re-orientation of the work programme, may have caused some problems during project delivery (see below). In a similar vein, it is worth noting that the target groups defined in the proposal[121] are rather all-encompassing and not particularly well-defined (e.g. ministries and food manufacturers are included in the same group), and do not explicitly mention SMEs as such (whereas during the interviews with project partners, most did feel that SMEs were the main target audience).

The design of the project was (rightly) assessed positively by the proposal evaluation panel ("plans are clear and well thought out, ambitious but achievable and structured in such a way as one step leads to the next"). However, in hindsight, the eventual implementation showed that some of the project objectives may have been **overly ambitious** and were not fully achieved (see the following sections for more detail). This was particularly the case of WP7, which was added to replace the consumer information campaign, but failed to deliver an actual cost-effectiveness analysis, and instead produced a "Short Guidebook on Reformulation" and a "Cost [but notably not effectiveness] Evaluation Tool". Both of these are meant to directly support SMEs in their reformulation efforts, which – as noted above – were not originally explicitly defined as a key target audience. This suggests the project may have tried too hard to "be all things to all people", with the inherent risk that objectives were not defined sharply enough, and resources spread too thinly. The interviews with project partners also suggest it was not easy to find the right balance between the research components (which were emphasised by some as *the* core activities) and providing practical support to SMEs (which others felt was the key desired outcome).

[121] These were: 1. Universities and/or Research centres dealing with the project issues; 2. Technical staff from ministries of health and representatives from food manufacturers; 3. Professional associations and Catering industry representatives; 4. Nongovernmental organizations (NGOs): consumers rights/interests protection, agri-food associations; and 5. Consumers. NB: The last group (consumers) was dropped from the final version of the proposal that was annexed to the grant agreement.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	1.5
Fostering of collaboration and partnerships	2.5
Engagement with other actors (incl. DG SANTE / CHAFEA)	1.5

By and large, the project implementation went well. With a few notable exceptions (see below), the project schedule was adhered to, and deliverables were submitted in accordance with the plans laid out at project inception. The earlier work packages in particular (WP4 and WP5) went smoothly and produced a wealth of relevant information. Interviewees provided very positive feedback on the professional and effective way the project was managed by the coordinator, and on the collaboration between partners more generally. The **partnership** set up for the project was very broad and diverse, which proved a definite positive, although it was at times also a challenge to coordinate, since the partnership is relatively large in view of the budget). It included a mix of private companies and academic / public research organisations from 12 Member States covering all parts of the EU, including five "newer" (EU-12) countries, which were described as very engaged. It was also noted that contacts were established with other related European and national projects[122], which further added value.

SALUX produced a series of significant **outputs**, including a report on local (i.e. national) contexts, a report on good practices, a report on the "follow-up" (i.e. survey) of SMEs, a "Short Guidebook on Reformulation" and a "Cost Evaluation Tool" for SMEs, and a "clearing house" (i.e. online database) of documentation related to reformulation. As such, it has delivered all of the outputs that were envisaged (with the exception of a cost-effectiveness analysis, which turned out to be not feasible – see below).

The **main difficulty** encountered by the project, according to the interviewed partners, was engaging with and **obtaining feedback from SMEs**. This was reportedly due to two main factors. First, the subject area is highly complex and often technical, especially for those SMEs that had not engaged actively with reformulation before. Others had reformulated products, but using a "health by stealth" approach (i.e. not advertised the reformulation), and thus may have been reluctant to share information. This made it difficult for them to provide the requested feedback, in particular on the issue of cost-effectiveness (WP7), but to some extent also the main survey (WP6), which achieved a response rate of 587 (out of over 6,700 companies contacted), well below the target of 1,000 responses. One interviewee noted that the target was perhaps over-ambitious to begin with, seeing as response rates of around 10-20% are typical for online business surveys. Furthermore, one interviewee noted that survey fatigue may have set in, as some of the same SMEs were contacted several times for different WPs, and their willingness to engage and respond tended to decrease with each attempt. It was suggested that better coordination across WPs could have partly addressed this problem.

It is also worth noting that **WP7** – the cost-effectiveness analysis – **failed to fully meet its objective**. While a "Cost Evaluation Tool" was developed (and according to

[122] Including TERIFIQ (Combining Technologies to achieve significant binary Reductions in Sodium, Fat and Sugar content in everyday foods whilst optimizing their nutritional Quality) and PLEASURE (Novel Processing approaches for the development of food products low in fat, salt and sugar reduced), both funded under the EU's FP7.

the final report, "can be used to predict the total costs the Company is going to sustain for a given reformulation process and according to a chosen strategy"), it was not possible to include the benefits in the model, as it turned out to be "nearly impossible to get analytic data on said benefits across the EU (at least within the time and budget constraints of the project Salux)."[123] This was again partly due to the lack of input from SMEs (although 57 did test / validate the tool), but perhaps also to unrealistic expectations at the outset. There was also a suggestion that the failure was partly due to a lack of the necessary (economic) skills within the project team; while this may have been the case, it does appear that the benefits of reformulation depend on many factors – in particular the quality of the reformulated product and its acceptance by customers – that are inherently difficult to predict as part of an economic model.

Finally, it is worth mentioning divergent views between project partners and CHAFEA over the role played by the latter, in particular whether some of the changes to the deliverables that were requested by CHAFEA were justified or not in view of the quality of certain deliverables (for more on these see below. Interviewees also mentioned certain difficult and time-consuming administrative procedures (in particular an amendment to the grant agreement that became necessary to change the project acronym, as a private company claimed the original acronym "Salus" as theirs). One interviewee also noted that, in comparison with FP7, the (financial) **administrative aspects** of running a project under the HP seemed relatively **burdensome**, and that there was fewer information available online to help resolve questions and doubts.

Overall, it seems fair to say the project was **implemented broadly in line with the work plan**, and in most cases partners did what they could to overcome the challenges and produce the required deliverables. However, there were certain challenges that could not be fully overcome, and had an impact on the eventual results of the project. Most importantly, the strong reliance on SMEs to provide input, and the latters' inability / reluctance to provide much information on their experiences with reformulation, including costs and benefits, caused certain **problems and shortcomings** in what the project was eventually able to achieve (and also affected dissemination, see below). This in itself may represent a useful learning point, but at the same time, some of the problems could have perhaps been avoided with a clearer direction and more realistic objectives from the outset (see above).

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	1.5
Effectiveness of tools and channels used	1.5
Sustainability of dissemination activities (incl. use of multipliers)	1

Significant efforts were made by the leader of WP2 and other project partners to ensure wide dissemination of the project and its results. A substantial list of stakeholders (containing more than 1,000 entries from all participating as well as some non-participating countries) was developed during the early stages of the project, and used mainly for sending periodic newsletters about the latest project developments, upcoming events, etc. The project also organised a final conference in

[123] SALUX Deliverable D7 - Cost-Effectiveness Analysis (CEA) of the major reformulations identified

Turin in June 2014, had a presence at numerous other events, workshops and seminars (including a presentation to the European Platform for Action on Diet, Physical Activity and Health in February 2015), and developed posters, flyers, brochures etc. for distribution.

The main vehicle for dissemination, however, is the **project website**,[124] which includes a section for the so-called clearing house (developed by WP8), which is a repository of documents (242 at the time of writing) on reformulation and related issues. On the positive side, the website and most of the content is available in 11 languages (those of all project partners). However, the website is structured in a way that is not necessarily intuitive and somewhat difficult to navigate; the navigation relies on two sets of links at the top and bottom of the site (with some content only accessible via the menu at the bottom), and a concise and punchy summary description of the project is missing.[125] The number of visits to the website has remained low (only slightly over 6,000 users between January 2013 and November 2014), with the only significant spike in visitor numbers coming after the final conference in the summer of 2014.

It also seems likely that the dissemination efforts were hampered by **the way the deliverables are presented** (for more details see the section on results / impacts below). The layout, structure, language used and length of most deliverables is unsuitable for wider dissemination. The project produced a relatively long report per WP, written in a way that often seems more focused on justifying the work undertaken towards funders, rather than to appeal to external audiences (including SMEs). As a consequence of this, for example, at the time of writing, the Short Guidebook on Reformulation and the Cost Evaluation Tool are only available from the website as annexes to the final deliverable of WP7 – where they are unlikely to be found by SMEs (and the Cost Evaluation Tool is only available in a non-editable version, meaning it cannot be used as such). Some of these arrangements may yet change as the project is being wound up, but the current presentation of the results seems unlikely to be conducive to their widespread dissemination and use.

These shortcomings may be partly mitigated by the production of a **layman's report** summarising key features and results in an easily understandable way, and a SALUX "**manifesto**" with five key messages from the work.[126] However, even these are not particularly prominent (and hence easy to find) on the website. What's more, the five 'key findings' hardly seem ground-breaking or of much practical use, and (as evaluators) we suspect the interest they draw from any of the intended target audiences (whether SMEs themselves or other stakeholders) is relatively limited.

The various problems and shortcomings with the deliverables and their presentation suggests that the **lack of clarity around the main target groups** and the actual key objectives of the project did represent an obstacle to more effective dissemination of the results. As noted before, the target audiences defined at the outset were rather broad and not particularly well-structured, and SMEs were not explicitly included as a target group in the proposal (although 'food manufacturers' in general were) or in the dissemination plan, possibly because these documents did not fully reflect the late change of focus following the addition of WP7. Nonetheless, parts of the project were clearly aimed at providing practical guidance for SMEs, including good practices. The

[124] http://www.salux-project.eu

[125] The text under "About SALUX" can hardly be described as particularly accessible and concise: http://www.salux-project.eu/en/web/about-salux-16

[126] Salux layman's report: http://www.salux-project.eu/upload/deliverables/SALUX_Layman_report.pdf. Manifesto: http://www.salux-project.eu/upload/deliverables/SALUX_Manifesto.pdf

interviews conducted suggest that this caused some confusion when it came to prioritising dissemination efforts, i.e. that it was not always fully clear exactly who specific deliverables should be written for and disseminated to.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	1.5
Impact on policy	1
Robustness of evaluation strategy and reporting	1.5

As noted above, the project produced a series of reports (one per work package) and a short summary "layman's report" and "manifesto. In principle, these results have a wide applicability, in terms of providing relevant information and evidence for policy makers and other stakeholders, and support for SMEs themselves. However, both because of the actual content, and because of the way it is presented (see above), the deliverables are **unlikely to be directly applicable / useful** for most audiences, and the impact both on policy across Europe and on SMEs' capacity to reformulate may well remain limited.

In terms of **content**, the research (in particular under WPs 4 and 6) was thorough and produced interesting results which have the potential to add to the evidence base and understanding of relevant issues, opportunities and barriers to food reformulation in different contexts, and thereby contribute to future policy-making. On the other hand, the good practice examples (WP 5) represent only an inventory, briefly outlining a number of initiatives by food manufacturers and public authorities, but without providing much detail or a critical assessment of success factors. The related conclusions and recommendations are very general, and the report is arguably not much use in terms of providing practical guidance as to if and how these practices could be replicated. As noted above, the cost evaluation tool and short guidebook on reformulation (WP 7)[127], while potentially relevant, seem unlikely to be received enthusiastically by SMEs, partly because of the content itself, partly because of the way it is presented.[128] Finally, the clearing house (WP 8) seems to have been very little used to date (the number of downloads of the vast majority of the 242 documents contained in the clearing house ranges from zero to 100).

For these reasons, it appears **unlikely that the project results will have a significant impact**, either on the ability of European SMEs to reformulate food products, or on national or European policy. This is because, although the topic

[127] To illustrate this point, the Salux manifesto summarises the recommendations from the good practice review as follows: "To have a significant effect, the reformulated products should be intended for daily consumption. Reformulated product should be competitive to similar non-reformulated products on the market as regards price and organoleptic properties. Activities at the national level are recommended as an important tool raising awareness and encouraging manufacture and consumption of reformulated food and should preferably involve food manufacturers. Repeated activities promoting food reformulation and combination of different measures taking into account target population, promotion of food reformulation which is related to all foods and also includes other elements of healthy behaviour are recommended."

[128] We invite anyone who disagrees with this assessment to take the time to read the deliverable of WP 7 and form their own view: http://www.salux-project.eu/upload/deliverables/WP7_FINAL_REPORT.pdf

(reformulation in SMEs) is highly relevant, and the project partners have gone to considerable length to collect and analyse relevant data, the project deliverables and the concrete results contained therein only provide a limited amount of practical information on good practices that could be applied directly by either SMEs themselves, or by policy makers. The overall conclusions and recommendations of the project remained vague, and it would appear contain relatively little that could be considered a genuine step forward in terms of identifying and removing barriers to reformulation.

As regards **evaluation**, SALUX conducted both internal and external evaluation activities. Internally, all project partners were invited to provide feedback and score each meeting, as well as their satisfaction and involvement in the project overall, using a survey tool. Externally, a panel of five external experts were invited to project meetings, and asked to provide feedback afterwards. In addition, a survey of website visitors was conducted. While this multi-pronged approach is commendable, and the involvement of the experts and their comments and suggestions reportedly also added value during the project implementation, it focused almost exclusively on the process and quality of individual meetings and deliverables. The result is a somewhat useful process evaluation, but to date there do not seem to have been any attempts to assess the actual impact of the project, or the extent to which the objectives set at the outset were achieved.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	**2.0**
Economies of scale	1.5
Promotion of best practice	**2.5**
Benchmarking for decision making	**2.0**
Cross border threats	0.3
Free movement of persons	0.0
Networking	1.3
Unlocking the potential of innovation	1.8

Criteria 1: Promotion of best practice

The project did produce a report on good practices identified "in manufacture or encouragement for manufacture or consumption of reformulated food", which includes 27 examples of reformulation of a specific product (or product category) by manufacturers, and 21 good practice "campaigns" (including joint initiatives by public authorities and the industry, as well as legislation). However, the lack of a critical discussion, the very general recommendations stemming from this, and the lack of targeted dissemination activities (see above), raises some doubts over the extent to which these practices have been, will be or can be promoted across the EU.

Criteria 2: Benchmarking for decision making

In the sense that it provides new information on the context for reformulation in 12 Member States, an inventory of good practices, feedback from SMEs themselves, and an online repository of relevant documentation, the project does add to the evidence base in this important area. However, as argued at length above, because of the way this information is presented, its use may well remain limited.

Criteria 3: Implementing EU legislation

It is important to note there is no directly relevant EU legislation in this area that the project might contribute to implementing. Instead, the project follows a call for action in a relevant White Paper (the Strategy for Europe on Nutrition, Overweight and Obesity related health issues) for the food industry to step up its efforts on reformulation. As such, the project addresses a highly relevant topic (especially due to its focus on SMEs), but its EU added value lies in areas other than implementing legislation.

Conclusions and lessons learned

This is an interesting and instructive example of a project that, in spite of the efforts of all those involved, is unlikely to achieve a significant impact, or fully generate its *potential* EU added value. As described above, SALUX addressed a highly important and relevant topic (to better understand the extent to which SMEs have engaged with food reformulation, the barriers they face and support they need), and was implemented by a broad partnership involving private and academic partners from a wide variety of countries. The applied research conducted (on national contexts, good practices and the views and experiences of SMEs themselves) produced a range of potentially interesting results.

However, the conclusion of this case study (based on a series of interviews as well as the evaluators' own review and assessment of the project documentation) is that overall, the project results fell some way short of being as useful as originally hoped. Although the project does contribute to consolidating the evidence base as regards the context of and barriers to reformulation by SMEs, the extent to which it was able to produce practically applicable best practices, guidance or tools remained limited. For this reason, we conclude that the outputs and results are likely to be of limited use for policy makers, researchers, and SMEs alike.

The likely reasons for this include the lack of sufficiently specific (or rather, the overabundance of relatively unspecific) objectives and target audiences, and a methodology that was probably over-ambitious in light of the previous experience and capabilities of the consortium (especially regarding WP7, the cost-effectiveness analysis that was not foreseen in the original proposal). On balance, the project partners seem to have expended a very significant (and commendable) amount of time and effort on what could be termed 'background research' (including attempts to engage with and collect feedback from SMEs), but were less clear on how this information could be put to the best possible use in terms of maximising its impact. As a result, most of the policy conclusions and recommendations that emerged are far from ground-breaking. Furthermore, perhaps partly due to the lack of clarity as to the envisaged use of the deliverables and the respective target audiences, the presentation of the results is not well adapted to potential users.

A key learning point is the importance of insisting on clear and achievable specific objectives for projects in order to maximise the chance of success. In this particular case, more scoping work might have highlighted some of the challenges the project was likely to face, and resulted in a more focused call for proposals and/or proposal,

as well as more clarity as to the desired results and their use (e.g. concrete guidance for SMEs, and/or policy recommendations). As it stands, the formulation in the HP annual work plan (including the vague terms "follow-up") seems to have left the project in 'no man's land' to some extent: it did not leave much room for partners to put forward their own ideas on how to address the topic in question (as is the case with most open calls for project proposals), but neither did it provide a very clear indication of what was expected from the project. In future, it is recommended that DG SANTE either define in more concrete terms what it expects from projects (and if this is very specific, consider whether a service contract might be more appropriate for achieving the envisaged results); or leaves sufficient leeway for partners to develop their own ideas. Furthermore, the experience of the project highlights the need to insist on a sufficiently detailed and systematic analysis of stakeholders and target audiences, which should inform both the content and presentation of deliverables, and the dissemination strategy.

9.7.Euroneostat II project

Summary

The EURONEOSTAT II project led to important advances in the field of neonatology, particularly in terms of developing indicators to monitor and assess care, and sharing best practice relating to patient safety and hospital-acquired infection. However, below, the project's impact was lower than anticipated, and a number of issues were faced during design, implementation and dissemination.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

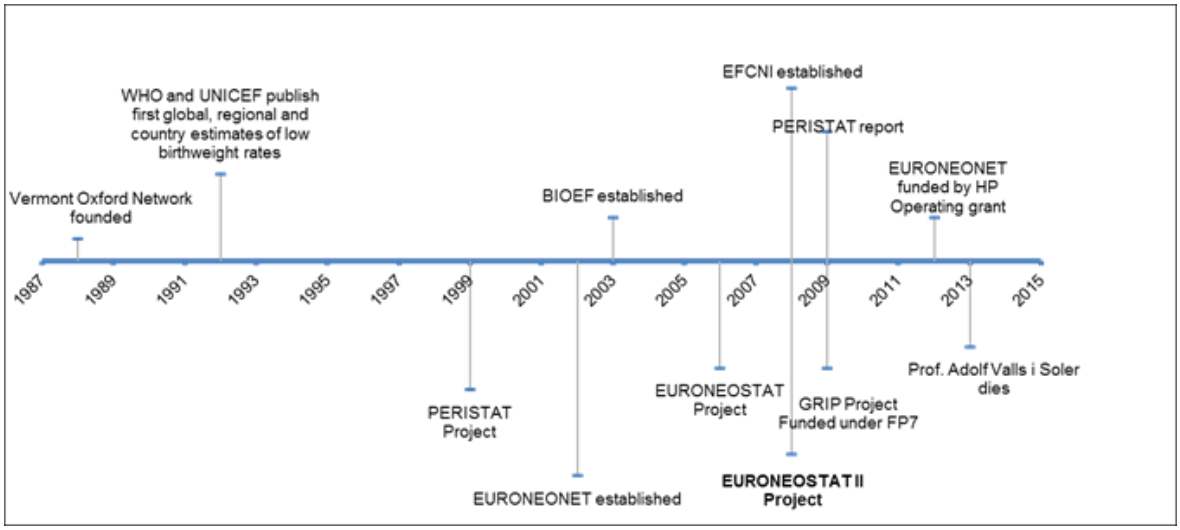
Evaluation area	Average score (1-3)	Explanation
Design	1.7	Built on the previous project and benefitted from the expertise of BIOEF and the other leading partners, but assumed that data collection would be more straight-forward than it was, and was not guided by sufficient policy steer.
Implementation / outputs	2	Good management and coordination on the part of the lead agency, but a number of challenges in data collection, meaning that several of the deliverables were not fully achieved.
Dissemination	1.7	Strong dissemination among clinicians and practitioners (through conferences, publications and the project website), but limited engagement of policy-makers, patients and NICUs outside of the networks.
Results / impacts	1.7	Led to the development of several sets of indicators and important progress being made in patient safety and hospital-acquired infection. However, the overall scope of work was not fully achieved, due to challenges with data collection.

Introduction

The EURONEOSTAT II project was established in 2009, in follow up to the previous EURONEOSTAT project (2006-2009), which sought to develop an Information System to assess the quality of health care delivered to Very Low Birth Weight Infants (VLBWI - birth weight <1.500 g) and Very Low Gestation Age infants (VLGA - gestational age<32 wks) across different units, regions and countries in Europe.

Although interest in the perinatal, neonatal and long-term care of Very Low Birth Weight Infants (VLBWI) had taken a relatively long time to materialise in Europe relative to North America (with the Vermont Oxford network set up in the United States in 1986 to facilitate information exchange on perinatal and pre-natal care), during the lifetime of EURONEOSTAT it gained considerable ground. Key initiatives, such as the establishment of the European Foundation for the Care of Newborn Infants (EFCNI) in 2008, and the commissioning of the Global Research in Paediatrics (GRIP) project in 2009 (through the FP7 framework), were undertaken during this time, pushing perinatal and neonatal care up the European policy agenda.

Table 45: Timeline for development of EURONEOSTAT II



The continuation of EURONEOSTAT II was therefore seen as a "natural next step". Given the momentum built through the first action, the continually high costs of neonatal care, and the diversity of care provided across Europe, it was recognised that further analysis, data collection and knowledge exchange was important in improving and standardising the quality of care in this area.

Further details of EURONEOSTAT II, including the main work packages (WPs) and partners, are detailed in the tables below.

Table 46: Overview of EURONEOSTAT II

Full name	Expanded European Information System to Monitor Short and Long Term Outcomes and Improve Quality of Care and Safety for Very-Low-Birth-Weight Infants
Acronym	EURONEOSTAT II
Funding instrument	Project
Action number	20081311
HP strand	3 - Health information
Priority	3.2 Collect, analyse and disseminate health information
Sub-priority	N/A
Maximum EC contribution	€ 649,969
Actual start date	November 2009
Duration (in months)	36
Status	Finalised
Lead partner	Fundación Vasca de Innovación e Investigación Sanitarias (BIOEF), Spain
No. of associated partners	11
No. of collaborating partners	15

Table 47: Work packages and partners

WP	Work Package Description	Lead institution
1	Coordination	BIOEF, Spain
2	Dissemination	University of Ulm - University Children's

		Hospital, Germany
3	Evaluation	BIOEF, Spain
4	Socio-economic indicators for health inequalities	Ospedale Pediatrico Bambino Gesù (OPBG), Italy
5	Standardised comparison of morbidity outcomes	BIOEF, Spain
6	Minimal dataset of follow-up indicators at 4 years of age	Fundación para la investigación biomédica Hospital Universitario 12 de Octubre (FIBH12o), Spain
7	Specific dataset to study causes of hospital-acquired infection (nosocomial infections)	BIOEF, Spain
8	EuroNeoSafe II: Patient Safety Initiative: incidents and near-misses.	University of Liverpool, UK
9	Building and assessing evidence-based actions to increase the quality of care and outcomes of VLWB/VLGA infants	BIOEF, this changed from the original proposal focused on utilising Software and Website for data entry and retrieval.

This case study explores the delivery of EURONEOSTAT II, its impact, EU Added Value and the dissemination activities undertaken, drawing on the following sources to do so:

- Four telephone interviews – with representatives from BIOEF, the University of Ulm and Chafea
- Review of key documentation – including the Proposal, Grant Agreement, Communications Strategy, Evaluation Report, and Interim and Final Reports
- Review of EURONEOSTAT II website and wider dissemination materials.

Design

Design	Score (1-3)
Fit within programme and policy context	1
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	2

By its nature, EURONEOSTAT II was designed to expand on the work undertaken through the first project, with the **ultimate goal** of ensuring that *"all Very Low Gestation (VLGA, gestation < 32 weeks) and Very Low Birth Weight (VLBW, birth weight < 1501 g) infants born in Europe, receive the best possible health care no matter where born by preventing existing inequalities, and that all Neonatal Units use the indicators developed, to assess the quality of care provided and implement strategies to improve outcome."* [129]

The ambitious nature of the project was also reflected in the **geographical coverage** that it was expected to reach. Outside of Europe, there was an expectation that the

[129] Final Report for Joint Actions and Projects: EURONEOSTAT II p. 13

Information System developed through EURONEOSTAT II (and its predecessor) could be rolled out to countries such as India, and regions such as West Asia and North Africa. In order to achieve these goals, the following **objectives** were set:

- To enlarge the sample size (e.g. babies in the cohorts) – by expanding the number of neonatal intensive care units (NICUs) involved and the amount of data collected
- To increase the range of data collection – in particular through:
- Collection of socio-economic indicators, in order to measure the impact of maternal socio-economic inequalities on the short and long-term outcome of VLGA/VLBW infants
- Development of a specific dataset to study the causes of hospital-acquired infection (nosocomial infections), in order to gain understanding of relevant risk factors, and inform a structured educational package of preventative measures for NICUs
- Collection of data on patient safety, via a voluntary reporting system of incidents and near-misses, to register, grade and prevent the new occurrence of so-called clinical errors
- To increase the age at neurodevelopmental follow-up - with the collection of follow-up indicators at 4 years of age, to enable the assessment of health and developmental status at 4 years
- To provide technical support in other areas – namely through research on intraventricular haemorrhage among VLGA/VLBW Infants.

Importantly, the aims of EURONEOSTAT II therefore combined **both health information and health security** strands. Through the collection of data on hospital-inquired infection, it was hoped that a *"tested on-line educational package for the prevention of nosocomial infection and software to report incidents and near-missed will be made available to the interested stakeholders"* [130] – thereby enabling practitioners and clinicians to assess, compare and improve their practice.

The **design of the initiative** was led by the late Dr Adolf Valls i Soler, coordinator of BIOEF and a leading neonatologist. Described by those interviewed as very much being "his vision", Dr Valls i Soler worked closely with the other key partners (including the University of Ulm, the University of Liverpool and EFCNI) to design the project, drawing on existing practice and ongoing priorities. In this respect, the project was **very scientist-led** (indeed, neo-natal care was not listed as a priority area in the 2008 Call for Proposals).

The design of EURONEOSTAT II undoubtedly benefitted from the **expertise and networks of BIOEF**, and the close-knit nature of the neonatal scientific community, developed around a number of national (e.g. Belgium, Ireland, Portugal and Spain), as well as regional (e.g. the Basque Country and Navarre, Lazio) networks. The project was expected to serve as an "umbrella" network, enabling comparisons of outcomes and knowledge sharing across the different countries, regions and units.

In terms of the WP themselves, the aims, objectives and specific activities, were detailed carefully in the proposal and subsequent Terms of Reference. They were felt to be well understood by the organisations involved in delivery, and structured around a series of clear milestones and actions. Where clarity was felt to be lacking, however, was in the overall **policy expectations** of the project. Was the expectation that all NICUs in Europe would contribute to the data collection, and thereby collect

[130] Ibid., p. 5

the standardised indicators? This was identified as a goal in the proposal, but was not carried through during implementation.

In addition, the **degree to which policy makers were involved** in the design process was quite minimal. Whilst the action leader trying to establish contact with national policy makers during the design stage, the response was muted, leading to the majority of design inputs coming from the scientific community. This was, as detailed below, to have important implications on the effectiveness of dissemination and impact on policy-making – and may have been impacted by the lack of a clear steer on the long-term policy objective for the initiative.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2
Fostering of collaboration and partnerships	2
Engagement with other actors (incl. DG SANTE / CHAFEA)	2

Overall, the effectiveness of implementation was reported to be quite a mixed picture. At a **strategic level**, the action leader was seen to have done a good job, enabling good linkages to be made with other initiatives and organisations (including patient organisations), and providing a clear vision for the project. BIOEF's strong reputation also facilitated delivery, as did the management infrastructure put in place by BIOEF. This included regular project review meetings (at least twice a year) and regular email/ teleconferences. The relationship with DG SANTE and CHAFEA was also seen as effective, with good communication and engagement from those involved.

Issues were also reported in **meeting milestones**, on time and to the specification required. Certainly, the start-up of the project was delayed due to the fact that it was felt that the proposal had not duly accounted for the comments provided on the final report of the first project. In addition, a number of milestones were not met during implementation, as detailed in the table below.

Table 48: Progress in delivering individual Work Packages

WP	Work Package	Feedback on implementation
1	Coordination	Implemented to plan, although concern raised that internal communication could have been better at times
2	Dissemination	Generally implemented well – good level of knowledge sharing between the NICUs involved in EURONEONET, though more limited engagement among policy-makers, parents/ families and the NICUs outside of the network.
3	Evaluation	Seen to have been implemented effectively
4	Socio-economic indicators for health inequalities	Mixed feedback – important information and led to the development of an agreed set of socio-economic indicators, but challenges in gathering data on socio-economic indicators, due to diversity of data captured and local definitions used. Only 5 NICUs were able to collect data for no more than 250 registers.
5	Standardised comparison of morbidity outcomes	Issues with delivery, due to data collection being time consuming, and hence not being submitted in a timely fashion. Measures were put in place to address this however (e.g. submission of data through the website), which meant that some analysis could be undertaken.

6	Minimal dataset of follow-up indicators at 4 years of age	Mixed feedback – a set of indicators for routine data collection at 4 years of age were collaboratively developed, but there were again issues with the data collection, as it required resources that were available in very few centres.
7	Specific dataset to study causes of hospital-acquired infection (nosocomial infections)	Mixed feedback - again challenges in data collection and cleaning (reported as extremely time-consuming). However, progress made in selecting a surveillance system to monitor hospital-acquired infection rates. The NEOKISS system was selected, which was already being used in Germany, and was piloted in some countries (e.g. Spain).
8	EuroNeoSafe II: Patient Safety Initiative: incidents and near-misses.	Implemented relatively effectively - a minimum dataset of key items was developed, as well as a list of patient safety incident 'triggers' and a risk-rating classification specific for VLGA/VLBW infants. An online data collection form was also developed, and an education and training package delivered (in Manchester in 2012), although only two units attended. In addition, the report on characteristics of reported neonatal patient safety incidents was not completed.
9	Building and assessing evidence-based actions to increase the quality of care and outcomes of VLWB/VLGA infants	Generally implemented well – involved a study on severe intraventricular haemorrhage (IVH) which led to the development of protocols for prenatal treatment and resuscitation. These were piloted through the project and were found to have an impact on reducing IVH rates, although the results needed to be tested further through a larger study.

As the table illustrates, a common issue that was faced through the project was essentially that the NICUs **struggled to capture data** on the required indicators. This was in spite of the fact that quite significant research and piloting work went on to develop the indicators, for example:

- Socio-economic indicators – evaluation of the influence of socio-economic aspects on morbidity of VLBW infants through a pilot study. The medical literature was reviewed, and indicators to be collected were decided and piloted in few units (with feasibility of assessment being one of the main selection criteria)
- Indicators at 4 years of age – developed through a literature review, two Delphi rounds of web-based questionnaires and a nominal group.

As a result of the data being unavailable or incomplete, the **level of analysis** that the project was able to undertake was greatly diminished. As cases in point, it was not possible to assess the effect of socioeconomic status on health inequality, nor model the predictive value of perinatal and "2 year" data on health status at 4 years of age. In addition, challenges were faced in sharing the data. For example, the significant work that went into developing patient safety data by the University of Liverpool was not widely shared, due at least in one case to concerns about data confidentiality, and particularly public access to the information.

Consequently, it was concluded in the interviews that the 'predetermined' approach had created challenges, and that going forward a **revised approach was required** – one that built on what was already being captured by countries, and was based on a strong understanding of what support was required to further improve data collection (moving beyond data collection to providing more technical support), and what could realistically be made available.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	1
Effectiveness of tools and channels used	2
Sustainability of dissemination activities (incl. use of multipliers)	2

Whilst key **target groups** were not particularly well-defined in the proposal and corresponding Terms of Reference, feedback gathered during the interviews suggested that the main groups were:

- Clinicians and health practitioners – including neonatologists, obstetricians, and paediatrics specialists, as well as nurses and other personnel involved in neonatal and child care. In particular, the importance of EURONEOSTAT II was seen to lie in the collection and collation of benchmarking data, and information on socio-economic issues and nosocomial infection, which could inform their practice;
- European societies of perinatal medicines;
- Parents and families.

A dissemination plan was included in the Interim Report (submitted after Year One), and contained a number of **tacit and explicit communications methods**, notably:

- Abstracts and communications sent to different neonatal, perinatal and paediatrics medical scientific meetings;
- Scientific papers submitted to international journals[131];
- Presentations at forums, symposiums, seminars and conferences – this included national (e.g. Portuguese Congress of Neonatology), European (e.g. XII European Congress of Prenatal Medicine), and international (e.g. International Congress of Paediatrics and the Global Congress of Prenatal medicine) events;
- Sharing of results on the action website (EURONEONET), which is still online – http://www.euroneonet.eu/paginas/publicas/euroneo/euroNeoStat/index.html;
- Sharing of information through relevant websites (of societies and official bodies);
- Knowledge sharing through word-of-mouth at key meetings.

When assessed against the three target groups, the **main focus was therefore clearly on clinicians and health practitioners**. Approximately 150 NICUs were estimated to have been targeted through the project, either directly or through the European reference networks. Assuming that each NICU represents approximately 100 staff, this meant that about 15,000 individuals were being targeted, with the network reported to be growing "steadily" over the project lifetime.

That said, the degree to which **practitioners outside of the "core" NICUs** were targeted was raised as a concern. The **geographical spread** of the dissemination activity was also quite limited to a few countries (e.g. Spain, Sweden, Belgium,

[131] Examples included: A Valls-i-Soler†, M Madrid, Á Azpeitia, E Santesteban, C Arránz. "Prevention of Hospital-acquired Infection in VLBW Infants. The EuroNeoKiss Trial" Acta Medica Port 2012; 25(S2):1-4; and A Valls-i-Soler†, E Santesteban, M Madrid. "EuroNeoNet. A platform for Neonatal Clinical Trials" Acta Medica Port 2012;25(S2): 5-7

Switzerland), and indeed much of the dissemination activity was reliant upon the input of the action leader, who authored 90% of the written outputs (e.g. book chapters, academic articles) produced, as detailed on the EURONEONET website.

In regard to **parents and families**, although identified as key target beneficiaries, the degree to which the project engaged with them was limited. Information and findings were presented on the website, but were done so in a way that was not particularly accessible to patients and families, and indeed the data captured through the initiative was not publicly available.

Likewise, the degree to which **politicians and policy makers** had been engaged through the project was limited. There were a few exceptions (e.g. the governments of Spain and Sweden were encouraged to establish quality improvement programmes in neonatology), and policy makers were targeted towards the later stages of the project, but these efforts were largely ineffective. The communication tools were largely the same as those used for clinicians – medical conferences and scientific publications – and whilst a conference was proposed to bring together health authorities to discuss the findings of the project, funding was not secured, with the general feeling that this work was too late in the day.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2
Impact on policy	1
Robustness of evaluation strategy and reporting	2

When reviewing the results and impacts of EURONEOSTAT II, it is important to return to what it was set up to address. Broadly speaking, the **project was aimed at**:

- Improving the collection of a range of standardised data on VBLW Infants (health information) – through the development of several sets of indicators and their adoption by NICUs;
- Improving the care provided to VLBW Infants and their families (health security) – focused specifically on nosocomial infections and patient safety.

Taking the first point, the project delivered **important results** – namely, the development of a new set of indicators relating to socio-economic status and neurodevelopmental follow-up at 4 years. However, due to challenges with data collection only a few NICUs were able to adopt these indicators, preventing any analysis of the findings from being undertaken. Certainly, some progress was still made due to the work undertaken. For example, the project succeeded in persuading the European Society of Paediatric Research/ European Society for Neonatology to set up a working group and consensus-process to standardise the neurodevelopmental follow-up of high-risk infants. In addition, it was reported that the benchmarking information made available through the project had enabled NICUs to see how they were performing relative to other units, which was accredited by one interviewee as driving up standards of care in some units (e.g. University of Ulm). However, the **inability to undertake in-depth analysis of the data** reduced the opportunity to improve the quality of care more widely.

In regards to the health security elements, **mixed feedback** was again gathered on the results. In particular:

- Nosocomial infections (WP 7) – the surveillance system selected through the project (NEOKISS) was piloted in some countries. In addition, the work led to the Spanish government establishing a policy framework in this area;

- Patient safety (WP 8) – a number of outcomes were developed through this WP (e.g. list of patient safety 'triggers', risk-rating classification for VLGA/VLW infants), but there was limited uptake of the training element, and lack of a final report.

Going forward, it would seem that the management and reporting activity was effective, including the evaluation strategy, which was deemed appropriate. Evaluation reports were seen as quite comprehensive, and useful in terms of informing project delivery. Appropriate clinical expertise was also seen to be in place, although **the 'approach' taken to data collection was not quite right**. The issues with data collection stemmed from a number of sources, including lack of in-country capacity and resources, IT issues (in sharing the data) and variability in how data was already being collected and at what frequency. Taking a more bottom-up approach, whereby the project worked with the various networks (and independent NICUs where required) to work through what they were already collecting, identify commonalities with other areas, and provide more technical support in collecting the standardised information required, may have been more appropriate.

A greater policy steer may have also been useful for this project. With **no firm policy goal** in place (e.g. the expectation that all NICUs would be collecting standardised information by a certain data), the project had limited leverage, other than to draw on the benefits that data sharing could bring. However, given the resources required for the data collection, this leverage was quite weak. Having a clearer goal in place may also have helped to gain buy-in from policy-makers, who were largely disengaged in the project, other than in the countries where the main partners were based (e.g. Spain, Germany).

When it comes to impact, it is also important to discuss the issue of **sustainability**. The drive for EURONEOSTAT II largely came from the work of the action leader, and the view was expressed that his death in 2013 meant that the work delivered through the project may eventually "vanish". In reality, it seems that momentum has been maintained (100 NICUs are still providing data), and that there is interest in further developing the project (within BIOEF and other partners). Nevertheless, the costs of maintaining a patient registry are high, and whilst EURONEONET has been supported by two operating grants since 2012, it must be questioned whether this is sustainable – it would seem that the benefits of this type of activity will really be felt when more NICUs are collecting data, but doing so will require more substantial funding than is provided through an operating grant.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	1
Economies of scale	1
Promotion of best practice	**2**
Benchmarking for decision making	0.5
Cross border threats	0.5
Free movement of persons	0

Networking	**3**
Unlocking the potential of innovation	N/A

The two areas assigned the highest *potential* EU added value score (above 1.5) were *networking* and the *promotion of best practice*. In this section, a summary is provided of the extent to which these scores materialised, based on the findings of the case study research.

Networking

The project undoubtedly leveraged the existence of the regional and national networking in neonatal care, and promoted communication and networking through attendance at the major conferences, the organisations of workshops and events, scientific publications and other communication channels. The project also worked to engage the participation of non-MS countries through, for example, some of the piloting work undertaken as part of the nosocomial infections being undertaken in Eastern European countries.

However, the project struggled to bring together representatives from different disciplines (e.g. policy makers) and to engage with patients on the work, thereby reducing the added value it was able to generate through networking. The score assigned through the IDR analysis (3) was therefore probably too high, relative to what was achieved.

Promotion of best practice

The pan-European nature of EURONEOSTAT II, and the fact that it brought together many of the leading experts in the area, meant that its ability to share ideas, knowledge and best practice was quite high. Interviewees reported that it had been helpful to work at the European level, as it had allowed gaps in practice/ knowledge to be identified, thereby justifying the score assigned.

In a number of areas, the project helped to promote best practice – for example, in terms of raising awareness of the importance of accounting for maternal socio-economic status when delivering care, of encouraging the collection of neuro-developmental indicators, and of monitoring and managing patient safety. The work undertaken as part of WP 8, which focused on how improved hospital protocols could be used to reduce IVH rates, was also innovative, and though small in scale contributed to best practice.

However, as mentioned in the networking section above, the promotion of best practice failed to engage a number of key target audiences – notably policy makers, who ultimately could have assisted in embedding best practice more widely. In addition, whilst new NICUs were involved in the project (relative to its precursor), the project was not successful at promoting best practice among non-European countries, which it had set out in its proposal to achieve.

Conclusions and lessons learned

EURONEOSTAT II provided an important contribution to the perinatal and neonatal agenda. It built upon the expertise of a number of leadings NICUs and organisations, who had a track record of working together, and a history of promoting best practice in this area. The project also enabled a number of advanced to be made, namely around the design of several sets of indicators, the development of protocols and training in the areas of patient safety and nosocomial infection, and the undertaking of pioneering research (related to intraventricular haemorrhage). During the case study,

a number of lessons learned were identified, which may be helpful in informing the EU's work in this area going forward:

- Importance of having strong clinical leadership – the vision, expertise and networks of the action leader were significant in shaping the delivery of EURONEOSTAT II;
- The need to have a clear policy direction –greater impact may have been generated with a clearer policy in place (namely around the extent to which NICUs were expected to adopt the recommendations developed through the project);
- The need to have the strong backing of policy-makers – the ability of this project to generate outcomes was limited by the fact that engagement with policy-makers was quite limited (largely to 1-2 countries). Where it was in place, the results were positive, but they were few and far between. Greater policy-backing would have greatly strengthened the incentive for MS to participate, thereby enabling the project to create greater EU added value on benchmarking for policy-making;
- The importance of recognising the diversity of the MS – the wide differences between European countries made standardisation of the data (and hence neonatal care) difficult. Exploring local data systems early on (including the differences/ gaps), and having sufficient resource to support data collection was required;
- The need to not underestimate the challenge of data collection – when assessing the data issues faced during the project, the initial aims and objectives seem somewhat ambitious. Taking a more realistic approach would have been more appropriate;
- The importance of tailoring communication channels to different audiences – the project made good use of academic articles and conferences, but largely failed to engage appropriately with policy makers and lay audiences.

9.8.EUROHEART II - European Heart Health Strategy II

Summary

The project addressed a highly relevant topic for the EU (cardiovascular disease - CVD) and was successfully delivered by a broad and varied group of organisations which disseminated the results of the project extensively. The project served to stimulate debate on CVD prevention policies at EU and national level and provided valuable information for policy-making. However, as it was not linked to any concrete Community policy or initiative, but to a wide range of interests and desires from the European Commission (EC) and the organisations involved in the partnership, it produced tons of information that, even if valuable and useful, may find it difficult to feed in the policy cycle.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Avg. score (1-3)	Explanation
Design	2.3	The project addressed a highly relevant topic, was well designed and planned, and proposed some ambitious approaches and major undertakings; however, it was weakly linked to the policy level and this may have affected the project's potential impact on policy.
Implementation / outputs	2.2	The project was implemented well and delivered as planned, with a highly-professional management by the project coordinator and good collaboration between the partners. The relationship with CHAFEA was sometimes problematic.
Dissemination	2.5	The project had a very good basis for dissemination (including the broad partnership and the coordinator's extensive experience in communication) and significant achievements were made; however it did not look into policy-makers specific information needs and failed to produce a set of concrete messages.
Results / impacts	1.8	The project was very productive and produced valuable information for policy-making. It also had a significant impact on the project's partners as it strengthened and expanded their research/advocacy work. However, the nature of the policy process and the lack of dissemination products specifically targeted at policy-makers make it difficult for the project to have a real impact on policy.

Introduction

According to the European Heart Network (EHN)[132], CVD is one of the main causes of death and a major cause of disability in Europe. However, it is estimated that 80% of

[132] http://www.ehnheart.org/

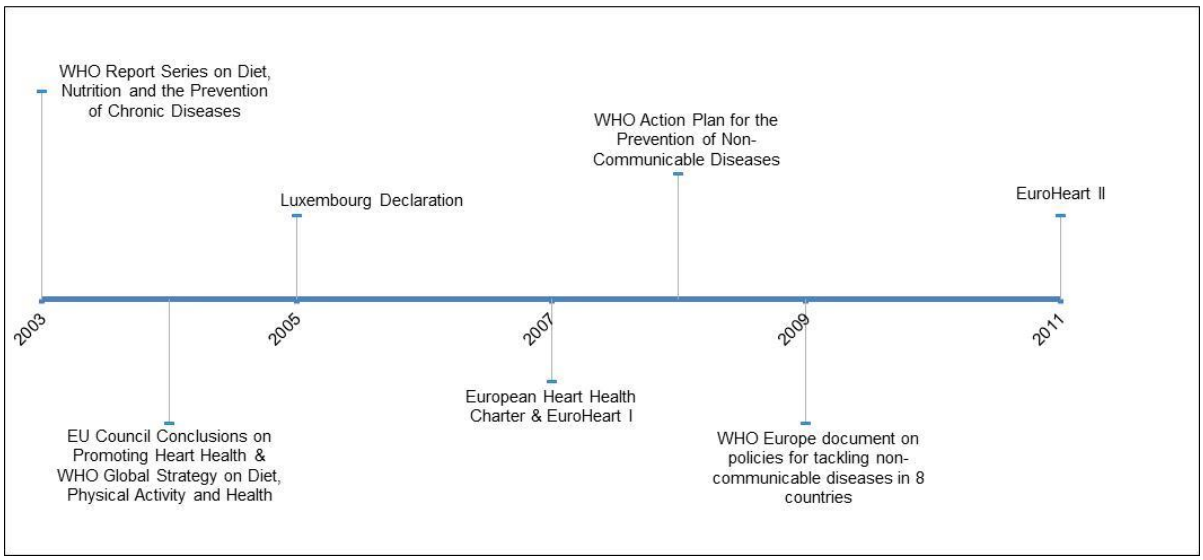
premature coronary heart disease and stroke can be prevented, leading to considerably high health gains and reduction of health care costs.

EuroHeart II was built upon various EU policy initiatives calling upon the EC and Member States (MS) to ensure that appropriate action is taken to address diseases of the heart and circulatory system, including the 2004 Council Conclusions on Promoting Heart Health and the 2005 Luxembourg Declaration[133]. The latter established the development of a consensus document, the Heart Health Charter, which should highlight the main prevention principles and evidence based intervention areas.

The European Heart Health Charter[134] was developed by the EHN and the European Society of Cardiology (ESC)[135], in cooperation with the EC and the WHO European Regional Office in 2007. Supporting this work, the EC funded the project EuroHeart I[136], led by the EHN and ESC, which was aimed at mapping national policies for CVD prevention while, at the same time, establishing a strong partnership between health care professionals, NGOs, governments and public health authorities.

These actions went in line with other important initiatives promoted by the WHO worldwide addressing different risk factors of CVD. For example, the WHO Technical Report Series on Diet, Nutrition and the Prevention of Chronic Diseases (2003), the WHO Global Strategy on Diet, Physical Activity and Health endorsed by the World Health Assembly in 2004, and the WHO Action Plan for the Prevention of Non-Communicable Diseases in 2008.

Figure 41: Key milestones on addressing cardivascular disease in Europe



The HP's 2010 Work Plan[137] called specifically for a project that would develop "European approaches and guidelines to identify strategic good practice approaches across society to address non-communicable diseases, in particular diseases of the heart and circulatory system". This should include reporting on and analysing of the current situation with regard to CVDs in the EU with the aim of using the results for developing Community initiatives on cardiovascular health. EuroHeart II was framed under this broad objective, following-up on the outputs of the prior project and

[133] Both documents can be consulted here: http://ec.europa.eu/health/major_chronic_diseases/diseases/cardiovascular/index_en.htm
[134] http://www.heartcharter.org/
[135] http://www.escardio.org/Pages/index.aspx
[136] http://www.ehnheart.org/projects/euroheart/about.html
[137] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:340:0001:0046:EN:PDF

building on the 2009 WHO Europe document 'Gaining health - Analysis of policy development in European countries for tackling non-communicable diseases' which described non-communicable disease policy developments in eight European countries.[138]

The project was co-managed by the EHN and ESC and was based on a consortium of 30 organisations including academic and research centres, NGOs and health professionals. For a summary of the project's key parameters and work packages, see the tables below.

Table 49: Key features of the project

Full name	European Heart Health Strategy II
Acronym	EuroHeart II
Funding instrument	Project
Action number	20101204
HP strand	2 - Health promotion
Priority	2.2 Reduce major diseases and injuries by tackling health determinants
Sub-priority	2.2.2 Prevent major diseases of particular significance, and rare diseases
Maximum EC contribution	€ 1,149,364
Actual start date	March 2011
Duration (in months)	36
Status	Finalised
Lead partner	European Heart Network
No. of associated partners	30
No. of collaborating partners	None

Table 50: Work packages and partners

WP	Work Package Description	Lead institution
1	Coordination	European Heart Network (EHN), Belgium
2	Dissemination	European Heart Network (EHN), Belgium
3	Evaluation	(HMP)
4	Reporting and analysing of data on CVD	The Chancellor, Masters and Scholars of the University of Oxford (UOXF.BX), United Kingdom
5	Identifying the most effective and cost-effective CVD prevention polices	University of Liverpool (UoL), United Kingdom
6	Predicting future CVD trends under different policy scenarios in the EU: Impact CVD 2020	Saint Georges Hospital Medical School (SGUL), United Kingdom

[138] Albania, Finland, France, Greece, Hungary, Ireland, Kyrgyzstan and Lithuania (http://www.euro.who.int/__data/assets/pdf_file/0018/105318/e92828.pdf)

WP	Work Package Description	Lead institution
7	Sharing knowledge on nutrition and physical activity and the prevention of CVD in Europe	European Heart Network (EHN), Belgium
8	Seminars for the cardiovascular patients' community	European Heart Network (EHN), Belgium
9	Evaluation of the ESC-EASD guideline on prevention of cardiovascular disease in diabetic patients	European Society of Cardiology (ESC), France

This case study is based on a review of relevant project documentation (proposal, grant agreement, and deliverables) and a series of interviews conducted in December 2012 with the project's coordinator, the lead partner of WP 2, and the project official at CHAFEA.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	2

EuroHeart II addressed a **highly relevant topic** to the EU. The logic under the project indicated that by providing updated data, analysis and scientific impact models, as well as by empowering various stakeholders groups to assess and address the situation with regard to CVD in their countries, EuroHeart II would contribute to developing cost-effective prevention policies. Ultimately, this would impact positively on the population's heart health.

As per the proposal's evaluation panel and our own examination of it, the project's design was **adequate to this logic**. The specific objectives were described comprehensively and where consistent with the project's general aims and expected outcomes. More concretely, EuroHeart II would contribute to policy-making in various ways, namely by: (i) providing scientific data in an easily accessible format; (ii) making innovative tools available that can support choice of most cost-effective CVD prevention policies; (iii) allowing knowledge-sharing; (iv) building capacity in the NGO sector involved in CVD prevention; and (v) evaluating the impact of guidelines related to diabetes and CVDs. These specific objectives were turned into six WPs, some linked to each other and/or to previous research studies. For example, WP5 (Identifying the most cost-effective CVD prevention polices) would incorporate data generated within WP7 (Sharing knowledge on nutrition and physical activity and the prevention of CVD in Europe) and EuroHeart I. Moreover, WP6 (Predicting future CVD trends under different policy scenarios in the EU) would build on and validate existing tools such as the IMPACT policy model, which was developed in the UK by the WP's leader.[139]

The methods and means planned were generally **applicable and feasible.** The project would basically consist of a broad and diverse partnership of 30 organisations (including academic and research centres, NGOs and health professionals) that would conduct research, collect clinical data, interview relevant stakeholders/decision-makers, and deliver EU conferences, regional workshops, and national meetings to

[139] Prof Julia Critchley and Prof Simon Capewell from the Saint Georges Hospital Medical School (SGUL) in the United Kingdom.

disseminate and discuss the outputs of the project. Research results would also be made available in reports (in print and on relevant websites) and at meetings with partners and stakeholders.

The planning and organisational capacity of the project was assessed very positively by the panel of external experts that examined the proposal. In effect, they considered it met all pre-requisites to produce the expected outputs (e.g. appropriate timetable, milestones and deliverables, a suitable distribution of tasks among partners, and a good assessment of possible risks and mitigation strategies)[140]. However, as the partnership was very extensive, one could expect that, apart from the substantial workload that the project would bring to the organisations involved, it would be quite **challenging to coordinate the work** of such number of partners. According to the evaluation panel, there was also the possibility that some WPs would entail more work than reflected in the proposal, especially considering that some of the project's deliverables would need that all partners provided updated statistics for their countries on timely manner, and that the data obtained was comparable.

As EuroHeart II was the continuation of EuroHeart I, there was also a risk that it would be limited to resuming and finishing work done under the prior project. From the proposal, it is evident that the project did continue some work carried out previously, for example, it updated the CVD statistics published in 2008. But it also proposed some **ambitious approaches** and major undertakings such as testing an hypothesis (i.e. that the countries with the largest number of established, effective CVD prevention policies have achieved the biggest reductions in population smoking, blood pressure and cholesterol levels) and projecting the retrospective IMPACT model into the future (which involved the collation of substantial data in each of the countries involved). The project also incorporated the views and needs of groups that had not been elicited in previous projects (e.g. cardiovascular patients organisations), and addressed country-specific issues in several WPs.

However, it is possible to argue that the project suffered from a **limited involvement of or link to the policy level** as it did not take policy-makers views or needs into account, especially in terms of what information they needed, and how and when it should be presented to them. The project did include a survey to assess policy-makers baseline awareness on the project and on CVD prevention statistics more generally, but it did not include any mechanisms to ensure that the results of the project were delivered to policy-makers at the right time, in the right format and with a concrete and action-oriented message. In addition, it is worth noting that the Work Plan under which this project was funded, stated that the information generated should serve to develop Community initiatives on cardiovascular health; however, it did not mention any specific initiative or policy to which to link the project. This initial lack of connection with the policy level may have affected the project's potential impact on policy (see section on results).

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2.5
Fostering of collaboration and partnerships	2.5
Engagement with other actors (incl. DG SANTE / CHAFEA)	1.5

[140] A point raised by the evaluators was that the staff costs were very high. During the negotiation process, the project coordinators were asked to reduce these and they did so.

In general terms, the project was **implemented well and delivered as planned**. There were no issues with the reporting and no unexpected outcomes. There were some delays though, in the implementation of some WPs (e.g. the timing of the first payment by the EC caused a delay in contracting the scientific researchers needed for WP6), but the coordinators managed to put the project on track quickly and finalised it within the expected timeframe. The project's deliverables were considered to be of a high-quality by the CHAFEA officer, particularly in terms of their presentation and strong visual identity.

The main **outputs** of the project were, namely: (i) three publications providing updated CVD statistics, cost-effective nutrition policy options for CVD prevention, and CHD mortality projections to 2020; (ii) an EU conference (November 2011), three regional workshops (Germany, Italy and Slovakia), and seven national meetings (UK, Ireland, Belgium, Spain, Iceland, Slovenia and The Netherlands) on diet, physical activity and CVD prevention; (iii) four seminars for patient organisations (Belgium) on national advocacy plans for cardiac and stroke rehabilitation programmes and the rights of CVD patients; and (iv) an evaluation of existing guidelines on the prevention of CVD in diabetic patients.

The overall evaluation of the project by CHAFEA concluded that the project was **managed very professionally** and that there were no major problems to flag. There were just a few number of management issues that occurred throughout the project such as staff changes, budget negotiations and contractual changes. There were also two countries (Hungary and Portugal) which did not manage to run the planned national meetings because of the partners' limited capacity and a reported lack of interest among local stakeholders to participate in the meetings. The meeting planned for France was not possible either because the French partner left the project.[141] But, overall, these issues appear to have had minimal impact on the project's deliverables and outcomes.

The EuroHeart II partnership was relatively **extensive and diverse** as it included research centres, NGOs, and governmental organisations from 17 MS (12 EU-15 MS and five EU-13 MS). The partnership also covered the views of different stakeholders such as researchers, health professionals, and practitioners. The geographical coverage was broad; however it is possible to argue that the EU-13 MS were slightly under-represented, especially South-East and Baltic countries[142]. This did not have an impact on the results of the project though, as (to the extent possible) they covered the whole Europe during the collection of data for the research studies and the organisation of regional workshops.

The partners participated in the project with their own strengths, with academic and research organisations leading the WPs with a strong research component (i.e. WP4, 5, and 6) and NGOs working mainly on WPs related to the dissemination of information, exchange of knowledge, capacity building, and networking (WP7, 8 and 9). The project coordinator explained that the tasks and responsibilities of each partner where discussed and agreed with them prior to the project application. The project's steering committee, which consisted of representatives from EHN, ESC and the WP leaders then ensured that the different activities were implemented as planned and consistently with the project's general objectives. The project's internal communication worked well, and was based on bilateral contacts between the coordinator and the WP leaders through teleconferences and meetings. All this,

[141] The French Federation of Cardiology's decision to leave the project was not related to the project itself but to a high-level decision to stop its work with EHN.

[142] According to the project's coordinator, this was because EHN did not have member organisations in those countries. Some partners tried to identify and involve organisations from these countries in the project, but there were no counter-parts interested.

together with EHN's strong familiarity with the partners, helped to ensure a **good collaboration**. Interviewees have confirmed that, despite the natural challenges arising from coordinating the work of such a large number of organisations, the project run smoothly. It was also noted that contacts were established with other EU projects/networks[143], which further added value.

The relationship between the project's partners and CHAFEA was sometimes **difficult**, which may be due to a bad or insufficient communication between the two. For example, the project's coordinators claimed that CHAFEA raised some "unfounded questions" over the policy recommendations of an EHN report[144] that had been developed prior to EuroHeart II, but – as per the grant agreement - it would be disseminated within the project (at the EU conference on diet, physical activity and CVD prevention - WP7). For CHAFEA, the EHN report contained policy recommendations which were not evidence based and was discontent that the project used a conference co-founded by the EC to launch a report that had not been previously approved. Compliance with these requirements was not viewed as "unfounded" by Chafea since it was part of the professionalism expected by any project beneficiary (NB: the report was not ready at the time of signature of the grant agreement). However, as the conference only dedicated 30 minutes to the report, CHAFEA did not reject costs of the conference.

The partners also mentioned that they would have liked to see CHAFEA participating in more of the project's steering committee meetings, but CHAFEA had no contractual obligations to attend project meetings and was committed to maintaining its independence concerning the project implementation. In addition to this, the partners claimed that CHAFEA did not respect the agreed deadlines for approving reports and issuing the project's payments. For CHAFEA this was due to the absence of mandatory supporting documents needed for the assessment of the project's costs.

With all this in view, it is possible to say that engaging in an on-going dialogue that goes beyond the formal presentation of reports can help to avoid the type of discrepancies and frustrations described above. This could improve the flow of projects implementation and relationship between CHAFEA and projects partners.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	3
Effectiveness of tools and channels used	2
Sustainability of dissemination activities (incl. use of multipliers)	2.5

Dissemination was at the core of this project. Several dissemination activities were planned for each of the WPs and all major partners played a role on external communication. The large network of partners, as well as the experience of the coordinator in communication and advocacy, provided a **very good basis** for the project's dissemination.

The list of target groups identified was quite extensive and **included all relevant actors** involved in the prevention of CVD across Europe. This included health policy-makers, pertinent advocacy groups, EC officials, MEPs, CVD patients' organisations,

[143] EConDA project[143] (where EHN and other EuroHeart II partners are members), some diabetes research networks such as EUROPREV, DePlan and EuroAspire.

[144] Diet, Physical Activity and Cardiovascular Disease Prevention in Europe, EHN, November 2011.

signatories to the European Heart Health Charter, physicians, general practitioners, and cardiologists. Specific deliverables and/or activities were planned for reaching each of these groups. For example, the reports and research outcomes were extensively disseminated to EU policy makers by mailing and in conferences/meetings. Also, presentations of research findings were delivered to practitioners in dedicated sessions at medical congresses (organised at both EU and national level). In addition, the project organised an EU conference, three regional workshops and seven national meetings on nutrition, physical activity and CVD prevention which involved a wide range of stakeholders of old and new MS (including major chronic disease organisations, food industry, agriculture sector, health sector, physical activity experts etc.). In addition to this, policy-makers and other key informants at national level were involved via interviews conducted in the framework of some of the project's research studies (e.g. for identifying the most cost-effective nutrition policy options for CVD prevention).

To disseminate EuroHeart II more broadly, WP2 leaders (EHN and ESC) created special sections in their institutional websites to provide information on the progress, activities and results of the project. The partners' existing communication channels were also used for a more extensive and diverse dissemination. In general, the project's sites and deliverables were produced with good quality, respecting a common visual and contributing to building a **strong project identity**.

In terms of the effectiveness of the tools and channels used, the final project report and the interviews conducted showed that the dissemination strategy was very productive and delivered some **important achievements.** Overall, references to the project's reports and findings appeared in several national and international publications and were also consulted regularly on the websites of the EHN and ESC. In addition, the reports' authors were invited to write articles on some well-known scientific journals. Moreover, the EU conference attracted high-level speakers including the EC, WHO and OECD officials as well as renowned scientists. The regional workshops and national meetings had over 300 participants and were particularly useful for involving national stakeholders, including representatives from national ministries and the local press. These provided a wide dissemination of the project's findings at national level and increased the likeliness of the project having an impact on policy in the future.[145] The activities under WP8 in particular (seminars for CVD patient organisations) reported high benefits to participants in terms of the exchange of information, networking and collaborations they generated. As reported by the project coordinators, it mainly served to strengthen the patients community voice on matters dealt at EU level (e.g. CVD patients' rights).

The sustainability of the dissemination activities is very likely, particularly because it is in the nature of a number of the organisations involved in EuroHeart II. Disseminating evidence to support policy-making and advocating for an EU strategy for CVD are central tasks for the EHN, ESC and many of the major NGOs involved in the project. Representatives of these organisations explained that the information generated within the project is **used and disseminated on a regular basis**, for example, when they are invited to speak at EU conferences/summits, when they speak to MEPs, and for advocacy work in general.

Considering the wide dissemination of the project's outputs so far and the many contacts established during and after the project, it is possible that EuroHeart II will eventually inform policy-making at EU/MS level. However, at least within the project, the communication means used were relatively standard and, although the

[145] For example, in Ireland and the UK, the discussion on food taxation that occurred in the framework of the EU conference led to further discussion with relevant ministries on the pros and cons of food taxation in these countries.

information was disseminated as planned and with good results, it was insufficient to ensure its uptake by policy-makers. The evidence collected in this case study indicates that the main weakness of the dissemination strategy was that it did not look into **policy-makers specific information needs** in order to provide them with concrete and ready to use policy recommendations. There are research findings from the project that could be extremely useful for policy-makers (e.g. that the interventions that address the whole population are the most cost effective and cost saving). However, the findings are scattered across the different reports produced and it is difficult to extract one or two concrete ideas and/or political messages of what is needed at policy level.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2
Impact on policy	1.5
Robustness of evaluation strategy and reporting	2

EuroHeart II was **very productive** in terms of the number of outputs produced and the activities organised to disseminate them. All of the outputs were delivered as envisaged and were of a very high quality in terms of content and presentation.[146]

Most of the project's results have a wide applicability as they provide **valuable information for policy-making,** in particular the report on "Coronary heart disease (CHD) mortality projections to 2020, comparing different policy scenarios" in 9 European countries[147]; the report "Identifying the most effective and cost-effective public health nutrition policy options for CVD prevention"[148], and the European CVD Statistics 2012, which includes a section that estimates the economic cost of CVD for the EU.[149]

The project also addressed a wide range of aspects of heart health from **different stakeholder perspectives**, including policy-makers, patients, and practitioners, and could potentially empower these groups to assess and address the situation in their countries. For example, as it was indicated by the project's partners, the results of the study predicting future CVD trends (WP6) alerted policy-makers and researchers in some countries not covered in the study about the existence of the IMPACT model and how they could use it to predict the impact of their policies on CVD.

But, as it is usually the case for projects aimed at generating and disseminating knowledge, the extent to which the information is actually used for policy-making is very difficult to assess and anticipate. In the case of EuroHeart II, one can say that it had a **significant impact on the project's partners** as it allowed them to continue with work started under the prior project (i.e. EuroHeart I), carry out some innovative research studies, and it also provided them with loads of (updated) information that will strengthen their advocacy work in the short and medium term.

146 http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications.html and http://www.escardio.org/about/what/advocacy/EuroHeart/Pages/EHII.aspx

147 http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications/publication/787-chd-mortality-projections-to-2020-comparing-different-policy-scenarios.html.

148 http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications/publication/786-identifying-the-most-effective-and-cost-effective-public-health-nutrition-policy-options-for-cvd-prevention.html

149 http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications/publication/673-european-cardiovascular-disease-statistics-2012.html

However, it is relatively unlikely that the project also had a **significant impact on policy**, at least in the short or medium term. This is not because of the type, content or quality of the project's outputs, but because of how they were presented and disseminated to policy-makers. The project could have aimed, for example, to compile a short policy document (or slides) with concrete policy recommendations and political messages, based and backed-up by the findings of the different project's WPs. These could have been distributed by the project partners to key national/EU authorities. A press release with EuroHeart II's final findings was produced at the end of the project and sent to health journalists in Europe.[150] But this consisted mainly of general messages about the project, research findings and statements emphasising the continued need of policies to reduce CVD; however it did not contain any policy propositions or recommendations.

There are some frustrations around the **difficulties** of having an effect at policy level, both among the project partners and CHAFEA. They both agree that the limited evident impact of this type of projects is due to the nature of the policy process, which makes it difficult to base policy on scientific evidence. Decisions taken at policy level are usually the result of a negotiation and the actors involved are not necessarily influenced by the information produced by NGOs/research centres in the field. Organisations as EHN and ESC may be very good in producing information, doing advocacy and empowering stakeholders at grass-root level, but they are not the key actors in policy-making and they may not even have access to these actors.

On the positive side of things, the idea of the project of providing sound analysis of CVD statistics across Europe and assessing the optimal approaches to CVD prevention is still valid and **has a potential value for policy-making**. This is more likely to realise if the project partners continue to act on the information produced so far, disseminate it in an easily and accessible format for policy-makers, build concrete political messages around it, and gain access to the relevant decision-makers.

A final remark on the evaluation strategy and reporting is that it consisted mainly of a process evaluation with adequate indicators and methods (i.e. email-based survey, telephone and face-to-face interviews with WP leaders, review of key project documents, and monitoring of press reports and journal articles). More important is the attempt made to **measure the reach and (potential) impact** of the project via the implementation of surveys with attendees to events and an online survey with representatives of the project's target audiences. The former served to assess the impact of the events on participants' level of knowledge about the topic of the events, as well as the intention of attendees to share the information with colleagues. In addition, 174 representatives from the project's target audiences were invited to participate in an online survey twice. The first survey was aimed at assessing the baseline knowledge of key stakeholders on CVD prevention related statistics and strategy in Europe. The second was implemented at the end of the project for collecting evidence on stakeholders' level of awareness of the project and specific outputs, as well as of the usage of those outputs. Even though these exercises did not provide the expected evidence of impact, mainly because of the low number of responses obtained, it is still valuable that the partners included these exercises in the project and made an effort to learn as much as possible about the impact of the project within the time and budgetary constraints available.

[150] http://www.ehnheart.org/media/news/875-euroheart-ii-sheds-light-on-cardiovascular-diseases.html

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	0.5
Economies of scale	1.5
Promotion of best practice	**1.6**
Benchmarking for decision making	**2.6**
Cross border threats	0.0
Free movement of persons	0.0
Networking	**1.6**
Unlocking the potential of innovation	0.5

Criteria 1: Promotion of best practice

The project produced a report with an overview of public health nutrition policy for 30 European countries (EU 27 plus Iceland, Norway and Switzerland) and an assessment of the most (cost) effective policies for CVD prevention in 14 of those countries (WP 5).[151] The analysis provided potential useful information that could be applied by policy-makers and/or organisations advocating for CVD prevention across the EU. The report is very well presented, it is straightforward and easy to read, and was extensively disseminated among academics, policy makers and practitioners through presentation and conferences, networking and publication in journals. However, the report itself recognises that the analysis presented has its limitations and that further research work is needed to identify and evaluate the most cost-effective health nutrition policies in the European region. As it stands now, the policy actions in the report are the evidence base "on which to develop, pilot and validate a nutrition policy assessment tool" for formulating CVD prevention strategies.

Criteria 2: Benchmarking for decision making

The project produced two reports that provide scientific information and updated data for comparison that can potentially impact on decision making at a high policy level. One is the European CVD Statistics 2012, which includes a cost of disease study on CVD in Europe[152] (WP4) and the other is the report on "Coronary heart disease (CHD) mortality projections to 2020, comparing different policy scenarios" in 9 European countries[153] (WP5). The first in particular, was an important attempt to address the lack of data and, particularly, of comparable data on CVD in Europe. The need for this data is confirmed by the high level of downloads and requests for the document

[151] http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications/publication/786-identifying-the-most-effective-and-cost-effective-public-health-nutrition-policy-options-for-cvd-prevention.html

[152] http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications/publication/673-european-cardiovascular-disease-statistics-2012.html

[153] http://www.ehnheart.org/euroheart-ii/euroheart-ii-publications/publication/787-chd-mortality-projections-to-2020-comparing-different-policy-scenarios.html.

received by the partners during the project's execution.[154] The report was also sent directly to targeted individuals after publication, made available on a number of websites (including those of the EHN, ESC and the British Heart Foundation (BHF), and presented at a number of conferences and events (including at the European Parliament).

The second report provides estimates of the effects of possible policy interventions on CHD mortality in 2020 in each of the countries covered in the study, including lessons learned about likely impact and generalizability. The results presented in the report were also submitted to/published in scientific journals and presented in relevant meetings and conferences. There is evidence also of some potential policy implications that this report may have in some of the countries studied. For example, the Finnish national expert group for CVD and Type 2 Diabetes Mellitus (T2DM) was engaged in the consultation process for the study. As reported in the project's final report, the group is now considering the EuroHeart II modelled policies and expert recommendations for their own work.

Criteria 3: Networking

The project was successful in helping build some new collaborations, particularly at the national level. As mentioned in the interviews, the meetings carried out at regional and national level in the framework of WP7 (Sharing knowledge on nutrition and physical activity and the prevention of CVD in Europe) served to strengthen some national alliances of partners and other NGOs/research centres in their countries. As it was evidenced in the interviews, some of these collaborations are likely to work together on research projects funded under Horizon 2020.

In addition, the patient meetings of WP8 have helped to establish a strong network among the patient organisations that are members of the EHN. They also led to EHN's active involvement in the European Medicines Agency (EMEA) working groups.

As was mentioned before, due to the nature of many of the organisations involved in the partnership, which are experts in advocacy work, it is highly likely that the networking will continue outside the time frame of the EuroHeart II project.

Conclusions and lessons learned

EuroHeart II did provide valuable data and analysis that could potentially inform policy-making. It also helped to stimulate discussion on CVD prevention policy, particularly in the framework of the EU conference, regional workshops and national meetings organised under WP 7. The project also led to further networking and advocacy work, in particular at the national level.

However, overall, EuroHeart II was more of a collection of different research and dissemination activities that, although they can be considered valuable individually, they were not necessarily linked to each other in order to deliver a set of concrete policy recommendations on which to base Community initiatives on cardiovascular health. The important findings and policy implications of the project are scattered among the project deliverables and, in some cases, can be considered not very specific and not innovative at all (e.g. arguing in favour of legislative measures that improve dietary standards, reduce smoking and promote physical activity and also to

[154] Only in the EHN website, the CVD statistics report was downloaded 9,000 times (to 31 January 2014). Moreover, the questionnaire to evaluate the target audiences' level of awareness of the project outputs showed that there was good awareness of the statistics report in particular, as explained in the project's final technical report.

invest in data collection systems to monitor trends in CVD risk factors, mortality rates and incidence).

In the interviews, it was noted that the project was perhaps over-ambitious and that it aimed to achieve too much based on partners strong capacity and desire to participate in the project. Thus, it could be argued that the project had something to offer to an extensive number of organisations and, as such, succeeded in covering a wide range of aspects related to CVD (e.g. food, nutrition, physical activity, diabetes, etc.) from different stakeholder perspectives (policy-makers, NGOs, patients, practitioners, etc.). However, at least in the short-term, it is not clear that it had an evident effect on groups not covered in the partnership.

One could also question the extent to which this type of projects aimed at generating data and analysis to inform policy-making have a real chance to impact policy on a 3 year-time frame when they have to collect, analyse, report on and disseminate the data, and more importantly, when - from the outset - are not linked to any specific Community initiative or need. In this respect, it would be recommended that the Work Plans under which these projects are funded were more specific about the policies these projects should inform and/or the groups they should be useful to.

Providing policy-makers with data and analysis, sharing knowledge and building capacity at grass root level is valuable and a broad range of stakeholders agree that this is needed and may actually benefit from it. However, in order to ensure better policy implications and a more effective use of resources, it could be considered that part of the project's activities could be funded under other mechanisms. For example, some of the actions carried out under EuroHeart II can be considered 'natural' tasks of the organisations involved (e.g. producing and disseminating scientific data, organising events to disseminate and exchange this information, giving voice to specific groups/needs etc.). These may be better addressed via other funding mechanisms such as operating grants, which are used to support European organisations and their activities. Or even via other EC initiatives such as the Research Framework Programmes.

9.9.EUMUSC.NET - The European Musculoskeletal Conditions Surveillance and Information Network (project)

Summary

The project EUMUSC.NET addresses a highly relevant subject, meeting an urgent health care need among the Member States. It was well implemented albeit with some delays by a varied group of project partners. The results were of high quality and the tools and outputs provided will enable representatives of patients, health care professionals and policy makers to work for more equitable access to musculoskeletal care. The network developed during the project lifespan also provides a platform for a future advocacy in the field of musculoskeletal conditions and is continued through EULAR[155], Europe's leading stakeholder organisation in rheumatology. A key success factor was the strong and deliberate policy impact focus and evidence based policy recommendations for a Community strategy in the area of musculoskeletal conditions.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2.7	The project addresses a highly relevant topic that meets a pressing health care need and prioritised are under the Health Programme. The project had a well-articulated vision following a clear logic with the steps and actions to be taken all supporting the principal objective of policy impact.
Implementation / outputs	2.2	Implementation and outputs was largely successful and of high quality though with considerable delays, in part due to not identifying risks during the design stage. While transnational collaboration was extensive, work package leaders were concentrated in the EU 15. The close collaboration and use of the professional and patient network of EULAR contributed strongly to the success of the implementation.
Dissemination	2.3	The dissemination was largely successful and managed to inform a large number of stakeholders, particularly through the effective leveraging of partner networks. Particularly patient organisations were effective multipliers since they have a clear interest in using the results in their advocacy efforts.
Results / impacts	2	The results have the potential for wide application across Member States with tools that, if implemented, would enable Member States to benchmark their position and identify areas of improvement. Furthermore, the evidence based recommendations developed are highly relevant for decision makers and other MSC stakeholders. The relatively low score on this evaluation area is primarily a result of the low score of the robustness of the evaluation.

[155] European League Against Rheumatism

Introduction

EUMUSC.NET (The European Musculoskeletal Conditions Surveillance and Information Network) was a project funded under the Health Information strand. Its primary objective was establishing and raising quality of care and enable equitable access to musculoskeletal health care across Member States. Musculoskeletal Conditions (MSCs) comprise over 150 diseases and syndromes, which are usually progressive and associated with pain. They can broadly be categorised as joint diseases, physical disability, spinal disorders, and conditions resulting from trauma.

MSCs are common across the world, as the Global Burden of Diseases study[156] shows, MSCs comprise the largest cause of disability. The prevalence of MSCs advances with age, obesity and lack of physical activity, all of which are growing across Member States. The current EU Research Framework Programme "Horizon 2020" explicitly recognises the burden of MSCs, which reflects the increasing awareness of the quality of life implications.

Especially for Europe, with an increasingly older population, the growing problem of MSCs will have a significant impact on the financial burden of health services in the future. The project was co-funded by the EU in the framework of the 2008 Public Health Call for Proposals. It addresses priority area 3: Generate and disseminate health information and knowledge of the annual work programme. Recognising MSCs importance for healthy aging and European competiveness is also a prioritised area under the Third Health Programme (2014-2020).

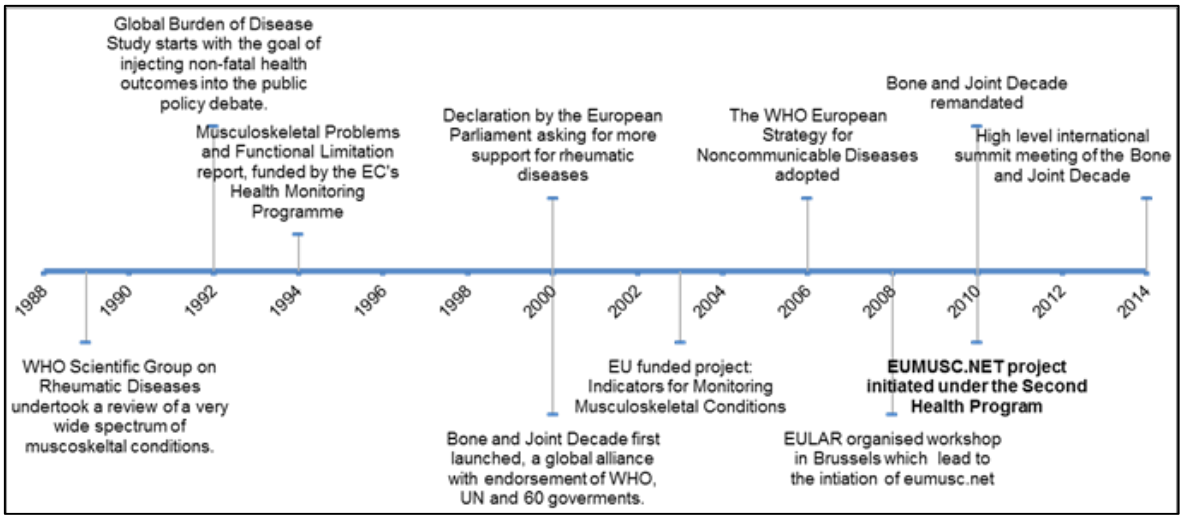
Although there is a growing interest in the issue there are not many EU related actions directly funded under the framework of the Health Programme (HP). The EU project *Indicators for Monitoring Musculoskeletal Condition* (2003) is the closest relevant example. Financed under the EC Health Monitoring Programme it contributed to identify and develop appropriate indicators to monitor musculoskeletal conditions in the population. Several of the associate members of EUMUSC.NET were also part of this project, among them key members of the lead organisation.

There has however been an array of policy initiatives aimed at raising the status of MCSs on the political agenda. Networks such as the Bone and Joint Decade and EULAR have been working with policy makers but with limited success. Shifting the focus from the emphasis on high mortality diseases to including those with high morbidity has been a difficult challenge. As a result of MSCs being the most common cause for work loss, previous EC funding related to MSCs have also been channelled through other EU institutions such as the European Agency for Safety at Work.

EUMUSC.NET was originally launched as a EULAR advocacy project during a workshop of invited experts in Brussels. The idea was at first that EULAR would lead the project but since its headquarters is located in a non-EU country (Switzerland) this was not possible. Instead they agreed to co-fund the project and became part of the steering group. A project team, led by Professor Anthony Woolf from Royal Cornwall Hospital Trust, took over the management and wrote the proposal.

[156] Global Burden of Disease 2010, Lancet. Url: http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(12)62133-3.pdf

Figure 42: Key milestones on MSC development in Europe



Full name	EUMUSC.NET
Acronym	EUMUSC.NET
Funding instrument	Project
Action number	20081301
HP strand	3 – Health information
Priority	3.4 Generate and disseminate health information and knowledge
Sub-priority	3.4.1 Development of a sustainable health monitoring system with mechanisms for collection of comparable data and information, with appropriate indicators
Maximum EC contribution	€ 987,712
Actual start date	2010
Duration (in months)	41
Status	Finalised
Lead partner	Royal Cornwall Hospital Trust (RCHT)
No. of associated partners	21
No. of collaborating partners	13

Work packages and partners

WP #	Work Package Description	Lead institution
1	Coordination	Royal Cornwall Hospital Trust
2	Dissemination of the project	Reumapatiëntenbond, Netherlands
3	Evaluation of the project	Mentor Training SA., Greece. In October 2011 the Coordinator lost contact with Mentor Training SA. A Change Request was raised to transfer the budget and responsibilities of Mentor Training

		SA to the Royal Cornwall Hospital Trust
4	Musculoskeletal health status in Europe	Royal Cornwall Hospital Trust, United Kingdom
5	Standards of care	Medizinische Universität Wien, Austria
6	MSC Health Care Quality Indicators	Lund University, Sweden
7	Barriers and facilitators to better musculoskeletal health	Diakonhjemmet sykehus AS, Norway
8	European Musculoskeletal surveillance and information network (EUMUSC.NET)	Royal Cornwall Hospital Trust, United Kingdom

Design

This section discusses the relevance of the project and its objectives, the design of the intervention logic and how feasible it is to succeed given the proposed implementation plan.

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	3
Feasibility of implementation plan	2

The project aimed to address health inequalities by ensuring the implementation of best practices in treating MSCs across the EU. This was a good and plausible fit with the Health Programme and its specific priorities as well with the broader policy context.

The **topic is highly relevant as MCSs are a major health care problem** that impacts quality of life for over 100 million Europeans[157]. This is also reflected in the call to action in the Annual Work Plan of 2008 as well as in the Decision[158] establishing the second Health Programme, identifying MSCs as one of the leading causes of morbidity. In addition, MCSs have received increased emphasis in health policies on both national and international levels in recent years. The project was well positioned within the HP to address these objectives, particularly the strategic priority of the Annual Work Plan of 2008 of reducing health inequalities in and between EU countries. In addition, it fits with the objective under the Health Information strand (i.e. priority 3.4.1 'Development of a sustainable health monitoring system with mechanisms for collection of comparable data and information, with appropriate indicator'). The relevance of the project is further reflected in that it received significant financial support from EULAR, the leading advocacy organisation for rheumatology who also agreed to sustain the project activities after its completion.

[157] European musculoskeletal health and mobility in Horizon 2020. Lidgren et al. 2014. The British Editorial Society of Bone & Joint Surgery. URL: http://www.bjr.boneandjoint.org.uk/content/3/3/48.short?rss=1

[158] Decision No 1350/2007/EC of the European Parliament and the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) Url: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF

While there is a robust body of evidence in how to treat MSCs there are wide disparities in treatment across EU, and existing best practices are not implemented. This fact was clearly reflected in the rationale of the project and its ambition to impact policy and raise awareness of MSCs impact on health and wellbeing across the EU. The overall aim for EUMUSC.NET was to "*improve musculoskeletal health through evidence based policy recommendations for the implementation of a Community strategy* [...]". This was not only done on a more aggregate level, but each country had its own national assessment providing a benchmark as well as supporting evidence for policy makers. Highlighting and identifying inequalities and inequity of access to care was also useful in embedding it in the national policy context and impacting national decision makers.

Although the project can also be seen as building on the work of previous EU projects such as the 2003 *Indicators for Monitoring Musculoskeletal Conditions* there are not many similar actions funded under the HP.

The project had a well-articulated vision following a clear logic with the steps and actions to be taken all supporting the principal objective of policy impact. This intervention logic followed from clear objectives that were aligned with each other; developing a baseline of the situation of MSC across member states, continuing with indicators to track progress, identifying barriers and best practice and finally proposing policy recommendations and operationalizing a network to build support and continue advocacy. Given its clear objectives suggests that it was well placed to deliver EU added value.

This is reflected in the content of the work packages which emphasised disseminating existing knowledge and seeing it put into practice rather than developing new knowledge. This further strengthened the prospects of success since this allowed more efforts to be put into activities intended to impact policy. This strong focus on dissemination and implementation of existing knowledge was considered relatively unusual by project interviewees. One interviewee explaining how it was a result of it being hard to convince pure researchers (which often are tasked with these types of projects) to mainly focus on *disseminating* knowledge rather than on *creating* knowledge. This focus on policy impact was an articulated vision of the project articulated by several of the partners interviewed.

The proposed implementation plan was for the most part clearly formulated and achievable, with clear links to deliverables and deadlines. The project also benefitted from being delivered by an experienced consortium with key work package leaders having proven track-records in delivery and having a shared history of collaboration with the lead organisation. There was however some minor delays in relation to some key deliverables partly due to timing issues of WPs which could have been avoided with better planning. Having the support of EULAR and distinguished associate partners, many being involved in advisory and expert bodies gave the project access to a good overview of the MSC situation in Europe, international research and policy developments that impact MSCs.

The recruitment of key WP leaders was emphasised by the project lead as especially important for the success of the project; being able to rely on key partners to deliver was an important lesson from previous EU projects. Several of the core partners had over 20 years' experience of working in international projects (including projects with EULAR). There was however awareness of the need of balance between "*being effective and being open*", which was solved by having an open policy in inviting partners for use on the "*content side*".

In terms of implementation weaknesses, managing a high number of associated partners increased the difficulties of the project and had the potential to reduce oversight and cause difficulties in coordination. There is however a strong argument for including many partners to increase the potential uptake and implementation of

the projects results among Member States. There was also little evidence of a proper risk assessment having been conducted of the implementation plan, especially planning for transition of key project personnel and the dependency of WPs on other WP results (further discussed under 1.4).

Interestingly, **parts of the proposal writing was outsourced by the lead organisation to an experienced proposal 'writer'**. The, mainly public research professionals involved, described how they not necessarily had the experience suitable for the task. This also helped in concentrating their efforts on the conceptual task of problem definition and designing the activities, rather than developing a budget or understanding how to structure a proposal. The end result was a clear problem definition and intervention logic that was well defined in terms of *what* objectives to achieve and *how* the objectives were to be achieved.

Another issue that almost caused the lead organisation to withdraw from the project was currency exchange risk. Interviewees from the lead organisation explained that not being a member of the Eurozone created hesitation among senior hospital management, since signing might result in the organisation losing money on the project if there were significant currency fluctuations.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2
Fostering of collaboration and partnerships	3
Engagement with other actors (incl. DG SANTE / CHAFEA)	1.5

The project delivered a series of high quality outputs though some deliverables were considerably delayed; the project was however extended by amendment and delivered on time. The delay of deliverables was in part a result of the work order of deliverables. WP2 - Standards of Care was dependent on WP3 - Health Care Quality Indicators but they were started in parallel rather than in a sequential work order. Also, work package 4 included a focus group which underestimated the time it took to find the right composition of interviewees. The most avoidable issue which resulted in delays was however the late recruitment of the coordinator's project manager. Not until three months after the project start was there a person in place. Contributing to the delay was the drive to present at EULAR annual European congress on rheumatology which took place after the estimated project end.

There were several factors that could have resulted in even further delays but were mitigated effectively. For example, the organisation in charge of Work Package 10 (Evaluation of the project), Mentor Training SA, stopped trading and stopped all contact with the coordinators by month twelve. It took a further six months and the use of the British Embassy in Athens to get confirmation of what had happened. The evaluation was then taken over by the lead partner from month 12 and progressed well from then on. In addition, Reumapatiëntenbond, in charge of the key dissemination WP stopped trading on the last day of the project with key personnel transitioning during the lifespan of the project. The project management team were however in frequent contact and were well placed to carry any dissemination activities forward.

The project fostered a deep collaboration among a number of partners from 17 member states, five of which were EU 12. While the transnational collaboration was extensive, work package leaders were concentrated in the EU 15, with the only exception being Norway. Key to achieving successful collaboration was the support of EULAR which developed the website and also helped with dissemination. The project

also delivered a sustainable network integrated with the professional and patient network of EULAR, which also functions as a platform for carrying the work forward after the project end. As a result of the variety of organisations and professionals represented[159], EULAR can continue to give access to project results to a range of stakeholders. Though the, interviews with the coordinators noted that some of the collaborating partners input were very variable, partly because there was not much ownership by them in the project as well as some language barriers.

Most of the work package leaders were recruited from the professional network of the lead organisation, with around a quarter of all partners having in some way collaborated or interacted previously with the lead organisation. This was in part explained by the management team being hesitant in using unknown partners for key project delivery roles since it was considered to introduce risk. This also turned out to be true when Mentor Training in charge of project evaluation ceased trading.

Also emphasised in interviews was the mutual benefit partners had from engaging with the project. The annular EULAR congress provided a platform for exposure and the project resulted in academic outputs as a result of partner's investment in the project.

Another factor contributing to effective collaboration was the strong project management from the coordinators. The management team had a part time financial officer and project manager specifically hired for the project, both with relevant experience of EC projects. Regular teleconferences were held among the core WP leaders for progress updates and encouragement, aligning work packages, and fostering shared ownership of the project.

There was widespread collaboration through partner networks with several national, international and European stakeholder organisations[160]. The extensive professional networks among project partners was leveraged effectively and helped in increasing the reach and impact of the project. Though CHAFEA's and DG SANTE's role in the project was satisfactory, interviewees felt there were some concerns about the practical issues such as financial allocation and reporting requirements.

Project partners perceived that CHAFEA were too narrowly focused on the "bureaucratic" delivery of the project - making sure that the documentation and "formal" requirements were met. On this point Chafea did not agree, the necessary documentation and formal requirements that are in place are to safe guard tax payer's money and to ensure quality project outcomes. The question of **equity versus cost-effectiveness** was intensely discussed by the project partners and CHAFEA. Principally, this was a difference in how the project management team were *allowed to manage* and *wanted to manage* the project. Especially, the question of centralising the financial management was contentious. From the coordinators view point it was more cost effective and purposeful organising meetings and booking hotels centrally. That would however appear as one country would be receiving more funding than appropriate. From a CHAFEA point of view, they were perceived as insisting on disseminating the budget among the partners. Presumably this was to spread the funding more equitable between all Member States, not only to old Member States.

[159] 44 scientific societies, 31 national social leagues, 4 allied health professionals associations and corporate members.

[160] Rand Europe, Royal Statistical Society, British Association of Sports Medicine, European Community Health Indicators Monitoring Project, Eurostat -EHIS/EHES project, ENEPRI, EFORT, Fit for Work, International Osteoporosis Foundation, European Athroplasty Register, World Federation of Physiotherapists, Council Occcupational Therapists for the European Countries, National Rheumatology societies, National Orthopaedic societies, Global Burden of Disease Project, The Bone and Joint Decade, ARMA UK

This meant that the limited budget was used equitable but not as cost-effective as possible.

Another point that came up during interviews with partners was that long after the completion of the project there were request for clarification of the financial reporting. From CHAFEA's perspective this was not perceived as an accurate description since request of payment was received in September 2013 and paid in Jan 2014 (only four months delay). This does however not take into account any ex-post audit requests which are regulated in the grant agreement. The information requests were however reported to have taken place significant time after the project was finalised, with all administrative project staff having moved on. For the project coordinator to be sole responsible for these post-project related tasks was experienced as difficult, and it was suggested that a small post-project funding could be kept in reserve to deal with these types of queries.

All in all, members of the project management team were happy with the interaction with CHAFEA and DG SANTE. However they noted that the expectations from the agency were not entirely clear from the onset which led to some confusion. For example, there was a useful workshop on financial reporting conducted in the later stages of the project which was very appreciated by the project management team. Interviewees noted that it would have been more useful to schedule it early on since the project management team discovered reporting requirements not previously known about (NB: CHAFEA noted that there was a complete introduction to financial reporting during the kick-off meeting, and CHAFEA was also available to provide clarifications during the life time of the project).

There were also several contacts initiated with other actors such as European Parliament Interest Group on Rheumatic and Musculoskeletal Diseases and a long list of organisations. Furthermore, through Standards of Care (WP5) over 45 national administrations were contacted and several organisations involved in developing the guidelines.

Dissemination

Overall the dissemination strategy was implemented well, effectively targeting key policy makers and making good use of multipliers such as the existing EULAR network and patient organisations to increase support and increase awareness for MSC. There was however an overreliance on channels that targeted health professionals with many of the dissemination activities taking place through conferences.

Dissemination	Score (1-3)
Identification of clear target groups	2
Effectiveness of tools and channels used	2
Sustainability of dissemination activities (incl. use of multipliers)	3

The dissemination strategy clearly identified a set of target groups, proposed channels and specific messages to be communicated. The main target groups included health professionals, patient associations, public health institutions, universities, policy makers, health equity advocates and NGOs. Furthermore, a mapping of the stakeholders was completed at an early stage which identified over 140 specific dissemination targets, which continued as on-going collaborative effort among the partners.

One of the key successes of this project was the focus on targeting policy makers and leveraging patient organisation support, part of this included the identification and mapping of these target groups. It is however not clear if the largely successful

dissemination was a result of clear target groups or opportunities and access created through the partnering with EULAR.

The project was largely successful in its use of tools and channels, reaching a broad audience with the relatively small means available. Part of the rationale of the project was the lack of awareness and knowledge of the impact of MSCs across Member States. This was reflected in the project strategic use of tools and channels for dissemination.

Partners played an important role in disseminating the result in the national context. Furthermore, EULAR played a significant role as a multiplier, significantly increasing the reach and effectiveness of the dissemination activities, hosting the project website and giving access to its large network of members.

There were several tools and activities employed in publicising the results of the project, such as electronic newsletters, press releases, partner websites and various publications. Particularly a number of major musculoskeletal related conferences were identified in the inception phase of the project and were targeted to inform about the results and progress of the project. Key among these being was the annual EULAR conference that gathers most of the MSC stakeholders in Europe and gave the project access to 14,000 delegates where a stand was made available and opportunity to hold briefings of the project were provided.

Though many of the deliverables were technical in their nature there was an effort to translate these into easy understandable language. Especially the patient-oriented Standards of Care and Policy Recommendations were effective in explaining in straight forward terms what those affected by MSCs can expect in terms of treatment and what needs to be done to improve MSC health across Europe. Several of the tools including the policy recommendations and case studies were also translated into all major EU languages to increase dissemination among local stakeholders.

One weakness indicated in interviews of the dissemination plan was that the patient oriented messages were missing. The use of channels could also been more diverse, mostly relying on the website, newsletters and the use of conferences as channels. However, the use of patient organisations as message multipliers through the international network of EULAR was crucial in getting the message across to these target groups. Especially considering that there is a clear interest among these stakeholders to use the results in their lobby and advocacy efforts.

All in all, around ten publications were reported to have been accepted by highly reputable a peer-reviewed journal which is an impressive result, and also speaks to the projects advancement of knowledge in the field of MSCs.

The documentation available, interviews with stakeholders and overall visibility of the project suggests that there was considerable effort put into the distributing and disseminating the results of the project. The dissemination activities were also successful in receiving outside recognition; John Dalli, EU Commissioner for Health and Consumer Policy who cited it as a key initiative of the EU Health Strategy (2009-2013).

In large part the sustainability of the project was secured by EULAR agreeing to continue future dissemination and advocacy of the EUMUSC.NET network. Collaborating partners also had fundamental role in the dissemination at country level through their own channels, such as websites, newsletters, publications, etc. EULAR especially played a strategic role in the dissemination of all the project outputs and deliverables. It hosted and developed the project website and the surveillance network that was implemented during the project. It also featured the international workshops at its annual congresses (three during the lifetime of the project) and provided exposure for the project in its newsletter and conference material. In addition, having

access to EULAR's vast network of members[161] was instrumental in reaching a broad audience.

The work that EUMUSC.NET started is also continued through a working group allowing the efforts of the project to be sustained. This speaks to the continued relevancy and sustainability of the project. The study group can in turn define specific projects to expand and continue the work of EUMUSC.NET and submit these to EULAR for potential funding. It is not entirely clear from judging the EULAR website how active the working group is at the moment but interviewees described how the work is on-going.

Results / impacts

This section will take forward the discussion in the design section and assess to which extent EUMUSC.NET realised its potential as well as examining the policy impact, wider applicability and evaluation of the project.

Results / impacts	Score (1-3)
Wider applicability of results	3
Impact on policy	2
Robustness of evaluation strategy and reporting	1

The results have the potential for wide application across Member States with tools that, if implemented, would enable Member States to benchmark their position relative to other countries and identify areas of improvement. Furthermore, the evidence based recommendations developed are highly relevant for decision makers and other MSC stakeholders. Especially being able to audit the achievement of these standards and indicators will provide comparative data has the potential to drive forward patient outcome and increasing equity across Europe.

This was not only noted by interviewees but also reflected in the outputs, which were often focused on developing tools with wide applicability. Each country also had its own national assessment providing a benchmark as well as providing evidence for policy makers in the national context with the outputs translated into all major EU languages.

The project has been particularly effective in communicating its results to key decision makers, presenting for the European Parliament Interest Groups, two EU Presidency Conferences and leveraging its EULAR network. It's difficult however to assess the direct policy impact, though the results will offer policymakers direct support for informed policy in the field of musculoskeletal diseases at all levels.

All stakeholders interviewed agreed that with the budget and resources available, the project has produced high quality results that are directly useful and would benefit a high number of stakeholders. Reinforcing this is the growing understanding and acknowledgement from both the Commission and other stakeholders of the burden MSCs places on Member State healthcare budgets and public health.

Particularly the development of patient-centred Standards of care (SOC) for the major musculoskeletal conditions of Osteoarthritis and Rheumatoid Arthritis has made best practice and evidence based standards available to all Member States. Interviewees

[161] EULAR consists of 44 scientific member societies, 31 organisations of people with arthritis/rheumatism and 4 allied health professionals associations as well as over 30 corporate members across Europe.

noted that if recommendations would be followed it would have far reaching consequences why it was difficult to see short term impacts.

The policy impact has particular potential in countries that were not yet capturing and measuring MSC data through their health care systems. In addition, employing the EULAR network of patient organisation can help put pressure and create awareness of what standards of care citizens can expect. Interviewees from EULAR described how the results are used 'again and again' in their advocacy group, especially since many of the recommendations relate to patient interests. Interviewees also described how parallel to EUMUSC.NET, the Swedish National Board of Health and Welfare developed their standards of care for osteoporosis which included results and methodologies of the project. Connecting to national structures was seen as crucial for increased policy impact. This was however described as difficult at times, where access to data and decision makers in older MSs (e.g. France and Germany) actually proved more difficult.

With these actions, EUMUSC.NET, has obtained good visibility and have provided valuable tools to assist Member States in evaluating their systems of care, implement best practice and improve equity.

The internal evaluation strategy and reporting requirements were well described and completed in time, there are however **serious questions about the value of the evaluation given that it reads more like a progress report**. The evaluation reports stated purpose was not only to report on progress but also disseminate innovative characteristics, lessons learnt and information on the main impact of the project. There is little evidence of this in the evaluation reports produced (three in total). Rather, the main function of the evaluation report appears to have been to monitor overall progress on how deliverables were following the implementation plan.

In the final report a systematic indicator matrix is presented that measures how objectives were accomplished as well as listing the type of indicator used (process, output and outcome). It did however not always list or comment on the actual indicator's level of achievement. For example the outcome indicator for objective seven (develop evidence based policy recommendations) was "*Impact of the recommendations on policy makers and other relevant stakeholders*". Granted that impact will be difficult to measure at the end of the project, the actual indicator results (e.g. what the impacts of the recommendations were) were not outlined. They were merely described in vague terms as increasing from the end of the project.

In essence, the evaluation was conducted by requiring work package leaders to fill in a series of forms and questionnaires which were returned to the evaluator for analysis who also took into account relevant documentation. The evaluation tools themselves were however not flawed by design; rather it appears the evaluation was treated as a requirement rather than an actual useful tool to improve future projects. For example, in the evaluation reports, deliverables completed on time are listed as conclusions with no substantial information about the content or the activities.

As evaluation reports are a reporting requirement for actions under the HP, there is a definite need to have stronger guidance in how to conduct evaluations as well as *why*, to avoid it merely being an bureaucratic exercise.

EU added value

This section explores EUMUSC.NET achievements in relation to EU-added value. During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is

likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	0.3
Economies of scale	1
Promotion of best practice	**2.3**
Benchmarking for decision making	**2.2**
Cross border threats	0.0
Free movement of persons	0.0
Networking	**2.7**
Unlocking the potential of innovation	0.8

Criteria 1: Promotion of best practice

One of the major achievements of the project was the development of Standards of Care for the major MSCs based on available evidence and best practice. This was recognised by both the Commission and the involved stakeholders interviewed as a major accomplishment. This was further supported by the projects access to a large network with especially patient organisations being a key driver in the promotion of the results which contributed to the likelihood of best practice uptake among member states.

Criteria 2: Benchmarking for decision making

As part of the design, several of the project outputs were aimed at benchmarking and base lining the current MSC health status across Member States. Especially WP4 - Musculoskeletal Health Status in Europe, addressed this issue. By developing harmonised information on health, social and economic impact of MSCs across all member states the project made a valuable contribution to this body of evidence. Furthermore, providing a comprehensive report and summary of Member States current status in meeting health care quality indicators generated a useful argument for patient organisation to lobby national administrations.

Criteria 3: Networking

At the heart of EUMUSC.NET was **effective partnership and networking.** By involving the influential MSC network, EULAR, which covers Member States - the project ensured effective cooperation with a range of stakeholders. Also, the surveillance and information network created through the project is likely to be sustained if not expanded by these efforts.

One of the key success factors in the delivery of the project was building on existing networks by assigning key project delivery roles to trusted partners who shared a history of collaboration with each other. This will only reinforce the cross-border collaboration among partners and establish more opportunities for future partnerships and develop a more coherent approach towards MSCs.

There was also evidence that EUMUSC.NET through their extensive network were able to link with related projects and national administrations. This was especially true for Standards of Care (WP5) were over 45 national administrations were contacted and several organisations involved in developing guidelines were contacted. Also there was extensive coordination with European, National and International advocacy organisations that represent interest of both health care professionals and patients to avoid duplication of results.

Conclusions and lessons learned

Overall, the project was well implemented with strong project management and succeeded to leverage the resources available to generate significant added value for Member States. The project addressed a highly relevant and important topic that affects up to 100 million Europeans every year and has serious implications for the wellbeing and burden on healthcare systems across Europe.

The project managed a broad partnership involving leading organisations and professionals in their field with a clear goal to impact policy. One of the key success factors was having a clear vision from the onset of what to achieve and using a pragmatic approach on how to best affect policy change. This intervention logic, with its strong focus on creating awareness of MSCs and impacting policy, was evident in both project design and implementation. This was further helped by having leading practitioners in the field of MSC developing policy recommendations and tools that were grounded in their own clinical experience. This bottom-up approach speaks to the legitimacy and practical application of the project outputs and tools developed.

Another key lesson is that having a platform to continue the work after the project ends is crucial for the project sustainability. The EULAR network and the subsequent working group have continued the policy advocacy started by the project. The involvement of a strong partner such as EULAR, with a large network of professionals and patient organisations that spans all of Europe, was a key to reaching a broad audience and increasing potential policy impact.

Overall, the project managed to achieve its objectives and produced high quality deliverables that continues to add value to a broad range of stakeholders on a highly relevant topic.

9.10. EFRETOS (Project) - European Framework for Evaluation of Organ Transplants

Summary

The project addresses a highly relevant issue of a registry for post-transplant outcomes. Evaluation of post-transplant results is important to enable Competent Authorities to make good organ allocation decisions with a limited supply of available organs and ensure optimal improvement of health of recipients. The project directly addressed Article 11 "Reporting system and management concerning serious adverse events and reactions" of Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation, which requires Member States to ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities. The intervention logic was aimed at assisting Member States in this process by developing a common definition of terms and methodology to evaluate the results of transplantation, in addition to promoting a register of registries to follow-up on organ recipients. Furthermore, the project addressed the Action Plan on Organ Donations and Transplantation.

The project was implemented well with high quality outcomes with a core group of seven partners from old Member States[162] and collaborating partners from ten member states (including four EU12 countries). The dissemination plan was focused towards the Member State Competent Authorities, for which the project results were relevant. In the end an EU wide registry itself was not feasible to set up during this project and during the Second Health Programme, but, as intended, EFRETOS has created the ground work by defining terms and methodology to evaluate the results of transplantation in a cross-Member State comparable manner. A future registry of registers in this respect depends on the agreement among the Competent Authorities of the Member States in this field.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2.3	The project is highly relevant and had a very clear policy fit within the second Health Programme (HP), directly addressing specific provision of the Action Plan on Organ Donations and Transplantation as well as DIRECTIVE 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. The intervention logic

[162] Stichting Eurotransplant International Foundation (Netherlands), European Society for Organ Transplantation (Netherlands), Agence de la Biomédecine (France), NHS Blood and Transplant (UK), Organización Nacional de Trasplantes (Spain), Istituto Superiore di Sanità (Italy), Scandiatransplant (Denmark).

		was clear but relied on a future implementation of a pan-European Registry that depended on future funding..
Implementation / outputs	2.3	EFRETOS managed to deliver the project timely and produced high quality outputs The high quality of the findings is a result of a consortium compromised by leading organisations in the field of organ transplantation. An important success factor was the extensive working experience and background in international organ donation and transplantation projects among core partners. The project was implemented with a core group of seven partners as well as collaborating partners.
Dissemination	2.2	The dissemination plan was focused towards the Member State Competent Authorities, for which the project results were relevant, and in which those are still discussed. There is however not much evidence of sustained dissemination activities towards other identified target groups after the project was completed.
Results / impacts	2	There is scope in the long term for significant impact in terms of applicability. In the short term the findings from EFRETOS have functioned as a basis for national authorities to develop their organ vigilance systems and monitoring systems of transplantation outcomes. EFRETOS supported the implementation of existing knowledge. It provided the technical tools and blue print for a future pan-European registry, though not feasible in the short-term. The evaluation strategy that had an unclear added value since it did not include a robust explanation of the evaluation results.

Introduction

In 2013 there were more than 60 000 patients waiting for an organ transplant in the European Union[163]. **With demand outstripping supply, more than 4000 patients died in the EU in 2012, while on the waiting list.** Reducing or in some cases curbing the growth in demand of organs for transplantation is a challenging area of modern medicine. In light of this, several actions to increase organ availability, quality and safety, and accessibility have been initiated. Based on the specific mandate, which the Treaty for the European Union gives in Article 168(4) on setting high standards of quality and safety of organ transplantation, the European Commission has implemented two strategic actions in the field of organ transplantation. Firstly, an Action Plan[164] on Organ Donation and Transplantation enhancing active coordination and cooperation between Member States complemented by a Directive[165] on standards of quality and safety of human organs intended for transplantation

[163] Source: Council of Europe Transplant Newsletter 2013

[164] "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States" Url: http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf

[165] DIRECTIVE 2010/45/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 July 2010 on standards of quality and safety of human organs intended for transplantation Url: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32010L0053&from=EN

containing the basic quality and safety principles as well as an implementing Directive[166] laying down the information procedures for the exchange between Members States, of human organs intended for transplantation. Further Directives have been implemented in the close by fields of tissues and cell transplantation and blood transfusion, such as Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components as well as Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Existing management of organ donation registries and waiting lists is under the domain of national competent authorities. Furthermore, European organisations are active in the field of cross-border organ such as Scanditransplant, Eurotransplant and the recent South Alliance for Transplants[167]. Several Member States also have bi-lateral agreements with neighbouring states such as Spain-Portugal and Italy-Malta. There are also several Member States that rely on small and heterogeneous registries with little linkage to other national registries. The delegation of responsibility to European Organ Exchange organisations (OEOs) is mainly the case for countries with already established organ donation practices and registries. The European Commission acknowledged the need for European collaboration to improve post-transplant results for more efficient and safe use of organ donors. The action plan[168] created for the cooperation between countries included as one of the key concepts a European registry of national registries in order to monitor and evaluate post-transplant outcomes.

Following an expert conference in Venice 2003, the emergence of a project which aimed to develop a framework for pan-European Registry on post-Transplant data was born, called European Framework for Evaluation of Organ Transplants (EFRETOS). In addition, EFRETOS was also conceived with provisions to **complement the Priority Action 9 -'Evaluation of post-transplant results' of the Action Plan on Organ Donation and Transplantation** as well as the suggested development of a vigilance system for organ donation and transplantation. The project also addresses article 11 of the Directive (2010/45/EU), which sets minimum standards to ensure quality and safety of human organs for transplantation.

Recent years have also seen several policy initiatives aimed at furthering international collaboration on the issue of organ donations and transplantations. Since EFRETOS completion there have been three joint actions funded by the EU Health Programme: (1) MODE (Mutual Organ Donation and transplantation Exchanges) (2) ACCORD (Achieving Comprehensive Coordination in Organ Donation) and FOEDUS (Facilitating exchange of organs donated in EU Member States). The European Commission also hosts a high level bi-annual meeting on organ donations and transplantations with Member States' Competent Authorities.

The EFRETOS project was completed in 2011 and implemented by a consortium led by EUROTRANSPLANT. It had as a primary goal to develop a blue print and prepare the specifications, common definitions of terms and the methodology to evaluate results of transplantation that are needed at Member State level as well as for a European

[166] Commission implementing directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation

[167] Signatory countries consist of France, Spain and Germany, later members include Czech Republic, Switzerland and Portugal. Url:

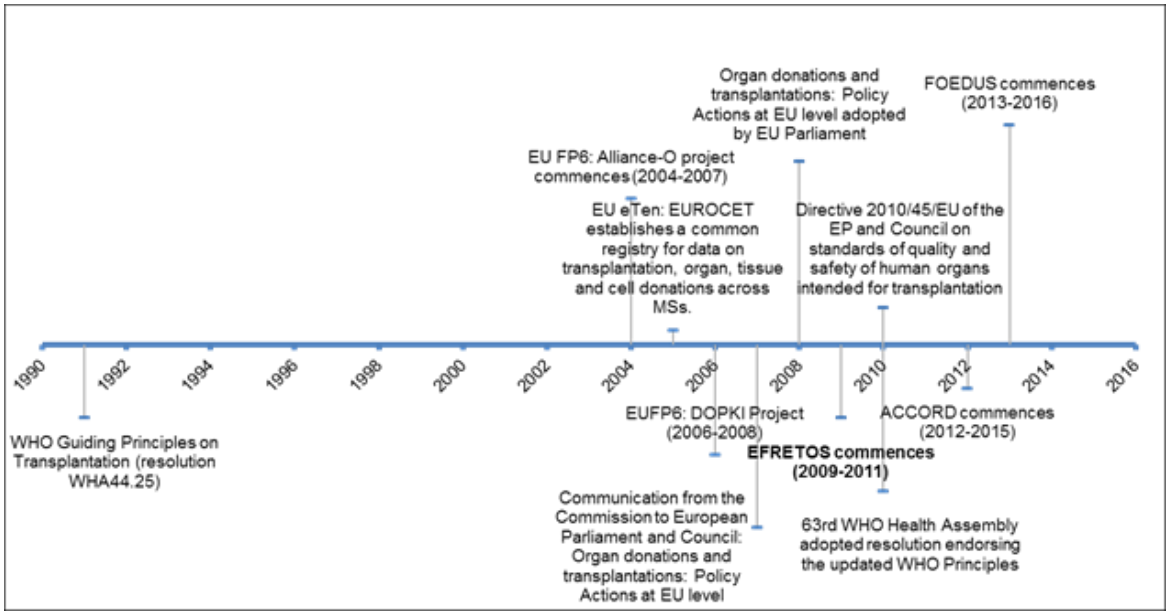
[168] European Parliament resolution of April 22, 2008. Report on organ donation and transplantation: Policy actions at EU level (2007/2210(INI)) by the Committee on the Environment, Public Health and Food Safety.

follow-up registry of patients who have had an organ transplant (referred to as "register of registries"). Furthermore it aimed to describe a feasible technical approach and functional framework as well as the legal and organisational prerequisites for realising this EU wide registry.

EFRETOS builds on previous projects with the aim to improve the progress in transplant medicine in the framework of the European Health Programme (HP). Between 2004 and 2008, the HP funded several projects that sought to increase the capacity and information sharing of organ donation and transplantation across Member States (see timeline below). These are summarised in the publication "Transplantation and Transfusion: Projects and Actions for saving and improving the quality of life of citizens by facilitating transplantation and blood transfusion in the European Union". Most relevant in the case of EFRETOS were the Alliance-0 project and DOPKI (DevelOPing and improving Knowledge In organ donation). Alliance-0 was aimed at developing strategies to improve coordination between several European countries and organisations, including research programmes for improving organ transplant efficiency. The DOPKI project aimed at improving the knowledge for recognizing potential donors for post-mortem organ donation. Several of the organisations who took part in these projects are also part of the EFRETOS consortium.

In the preceding mid-term report of the Second Health Programme, EFRETOS was part of the sample.

Figure 43: Key milestones in organ transplantation in Europe



For a summary of the project's key parameters and work packages, see below:

Full name	European Framework for Evaluation of Organ Transplants
Acronym	EFRETOS
Funding instrument	Project
Action number	
HP strand	1 - Health security
Priority	1.2 Improve citizens' safety
Sub-priority	
Maximum EC contribution	€700,000 (56%)
Actual start date	01/2009

Duration (in months)	24
Status	Finalised
Lead partner	Stichting Eurotransplant International Foundation
No. of associated partners	6
No. of collaborating partners	10

Work packages and partners

WP #	Work Package Description	Lead institution
1	Coordination of the project	Eurotransplant International Foundation (Netherlands)
2	Dissemination of the project	Instituto Superiore di Sanità (Italy)
3	Evaluation of the project	Eurotransplant International Foundation (Netherlands)
4	Development of data dictionary	European Society for Organ Transplantation (Netherlands)
5	Methods, legal and technical requirements	NHS Blood and Transplant (United Kingdom) initially later coordinated by Eurotransplant and work distributed among partners
6	Safety management	Organización Nacional de Trasplantes (Spain)
7	Quality assurance	Instituto Superiore di Sanità (Italy)

This case study is based on a review of relevant documentation on the Project (including the proposal, grant agreement, and project presentations) and a series of interviews with the coordinator, the lead partners of work packages, and officials of Chafea.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	2

The EFRETOS objectives **were clearly aligned** with the wider objectives of the HP and the specific priorities of the 2008 Annual Work Plan (AWP). More specifically the project responds directly to the specific priority action 3.2.2.2 in the AWP, Safety of Blood, Tissues, Cells and Organs. Also, EFRETOS has a supporting role in the implementation of Directive 2010/53/EU especially regarding the Directive's emphasis on quality and safety of organ transplantation and its requirement for Member States to put in place a reporting system and management concerning serious adverse events and reactions.

As the development of the Action Plan on Organ Donation and Transplantation was on-going during the inception phase of the project, most of the partner organisations had been participating in the regular meetings of Member State Competent Authorities, organised by the European Commission and were well placed to understand and

contribute to the EC prioritised areas and objectives. In some cases the project formulations almost mirrored the priorities word for word, covering most of the specific sub-priorities under Priority Action 9 – evaluation of post-transplant results.

By expanding on previous EU actions such as Alliance-O and especially DOPKI (four out of seven project partners participated in this project), EFRETOS was well positioned to further build on these results. As the shortage of organ donors is a growing problem, defining a common approach to evaluate results of transplantations has the potential to result in better patient selection and care, as well as more sophisticated risk benefit analysis. The potential EU added benefits and the rationale for such a project are in this respect clear.

Though objectives were clearly linked to the EU agenda on organ donation and transplantation the project's design relied on the future creation of a pan-European registry. Especially in the development of the intervention logic for the long-term aims of the project, the project underestimated the barriers to setting up an EU-wide "register of registers". Some of the assumptions by core partners about the viability of the registry of registries did not seem feasible. The legal obstacles were also considerable; a minority of European countries have legislation that regulates the registration of outcome after solid organ transplantation,[169] which came to the attention of project partners after project implementation. Furthermore, a majority of countries did not have a national registry for all types of transplants.

Project partners noted that the design was influenced by the implicit assumption that there would be a continuation of project funding for the implementation. In the consultation processes leading to the Directive 2010/53/EU and the Action Plan on Organ Donation and Transplantation (2009-2014) references were to the need of an EU wide registry. This led to the belief among interviewees that there would be an EU wide registry established. Implementing this registry of registries was however not actually covered by the project scope and budget but was listed as a long term aim. It was however noted by interviewees that if project partners had been more aware of the possibility of the lack of future funding the design could have been different. Investigating other governance options might have been useful in this regard and not taking for granted further future EU-funding. Particularly, in light of Member States not managing to agree to make follow-up of transplanted patients mandatory in the Directive on standards of quality and safety of human organs intended for transplantation, the complex issue of governance might have required additional budget allocation.

The implementation plan relied on a core group of experienced partners from old Members States, all experts in their fields that contributed to the work packages (WPs). The seven partners directly involved in EFRETOS WPs were all experienced in working with EU projects and shared a history of collaboration. The project also managed to include all the major European organ exchange organisations (OEOs) at the time[170]; Eurotransplant (8 EU countries[171]) and Scandiatransplant (3 EU and 2 non-EU countries[172]). The consortium also included the leading network of transplant experts, the European Society for Organ Transplantation (ESOT), which contributed to the potential for an impact through the project. In terms of collaborating partners, four of the ten associated partners were from EU12 countries[173] with no representation

[169] The making of a pan-European registry. Smiths, Niesing, Breidenbach and Collet. Transplant International. Volume 26, Issue 3, pages 307–314, March 2013

[170] In 2012 a new European organ exchange organisation was created, South Alliance for Transplants, which covers France, Italy, Portugal and Spain

[171] Covering Belgium, The Netherlands, Germany, Croatia, Austria, Luxembourg, Slovenia

[172] Covering Denmark, Sweden, Norway, Finland, Iceland

[173] Czech Republic, Poland, Slovakia and Slovenia.

in the management board or project board. Further discussed under implementation, project partners interviewed perceived that this served to limit the involvement by EU12 countries, this was also evidenced in the evaluation of action results. It was however explained by project partners that the logical partners were naturally the countries that had best practice in the field of organ transplantation and already established registries. The rationale for this was to make a scientific contribution (with limited resources) that all Member States could benefit from.

There were however questions raised by interviewees of the appropriateness of Eurotransplant being in charge of the project. Interviewees explained that there might be a risk of Eurotransplant being perceived as having vested interest in developing a framework similar to that of Eurotransplant. Nevertheless, the topic was opened in an open call for proposals under the EU Health Programme, and there were no indications that the above conflict of interest was actually the case. The future governance of a registry was in the end a difficult issue to align (see below, 1.4 Implementation / outputs) among partners.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2.5
Fostering of collaboration and partnerships	2.5
Engagement with other actors (incl. DG SANTE / Chafea)	2

EFRETOS managed to deliver the project timely and produced high quality outputs. The project was also managed professionally and there were no major problems with delivery. A couple of minor management issues occurred throughout the project, such as changes to staff, partner involvement and contractual amendments. The governance issue of the registry also took longer than expected but was in the end agreed on by project partners.

The main difficulty in regard to the project management was being able to forecast cost for different WPs. There was no financial officer available in the start of the project team nor was the financial forecasting toolkit (a spread sheet) perceived as easy to understand and use when trying different budget allocation strategies (because of changes in the work load among partners). . Nearing the end of the project, a financial officer was enlisted and the budgets were able to be recalculated, with some adjustment to the WPs as a result.

In addition, the core project partner NHS Blood and Transplant's (NHSBT) director left which meant that there was no direct involvement of NHSBT in the project for six months. Furthermore, when the new management were up to speed, they realised they would not have capacity to participate. As a result responsibility of NHSBT's WPs were transferred to Eurotransplant and redistributed among partners. This increased the workload of Eurotransplant significantly. The consortium did however in the end manage to deliver according to schedule.

There were some unexpected delays, particularly in relation to WP5, the functional, technical and legal requirements needed for a registry as the governance issues of a future registry required considerable more effort than anticipated; even though finally a high quality tool was developed.

A further reason identified by core partners was that developing an EU wide registry was a politically sensitive issue. It was explained that many MSs having their own systems for organ donations, with small MSs having relatively more transplant systems per million inhabitants than larger MSs. As a consequence, these transplant

programmes had low donation rates leading to the acceptance of higher risk organs. Project partners explained that this exposed the differences not only between countries but also between individual transplant centres, which was considered to be difficult from political standpoint. Project partners were surprised in this respect. The board of Scanditransplant as well as the then acting chairman of DSO (Deutsche Stiftung Organtransplantation) expressed their concern about the differences between the proposed registry of registries (including data requirements) and what was already in place in the Nordic countries and Germany, respectively. These issues were however mediated effectively by the coordinator. Policy officers from DG SANTE also acknowledged that the collection of and sharing of data was sensitive for the involved countries. Furthermore, overcoming other issues such as where and who should host the registry of registries were also recognised by officials and project partners. One project interviewee noted that, in hindsight, the governance issue could have merited its own WP.

There were also concerns among project partners about what approach should be taken with regard to the registry. Some consortium partners were in favour of a smaller and easier-to-comply-with registry while others wanted to have an expanded and structure (as mentioned in the internal evaluation report). These objections were however handled effectively by the project coordinator who managed to create a consensus among project partners on the way forward.

Also, countries not contributing actively to core WPs (or receiving funding), as an interviewee noted, are likely to not feel "ownership" of the project, resulting in little uptake of the results in those countries. This is particularly problematic, since the less established countries have the greatest scope to benefit from the project's results. While partnership was an award criterion, it is hard to see how a more qualified consortium could have secured the grant, since all the European OEOs and ESOT were included and many of the foremost experts and Competent Authorities in the field of organ transplantation. This is an impressive consortium well suited for the task; however project interviewees admitted that some of the less established partners that did not lead a WP were not fully engaged and with contributions not reaching the desired standard. Project partners also agreed the limited engagement of some collaborating partners was partly the result of language barriers, which prompted a core group to express concern in what extent these partners were 'heard' in discussions.

Partners interviewed noted however that the project managed to maintain an atmosphere that permitted constructive criticism, outputs with a high standard and room for fundamental discussions. This indicated an effective internal communication among partners which contributed to the successful completion of the project.

The contact with DG SANTE was described by project partners as mainly through the coordinator; project partners noted that this as satisfactory but that they would have welcomed more input on the direction of the project. Especially since several project partners were under the impression that there would be a future tender for who would host the registry of registries.

The implementation of the pilot project had also been successful which implied that that the registry of registries was feasible. Several partners of EFRETOS were however representatives of national authorities and were in parallel negotiating the Directive, which is why it was surprising that there was not more awareness of the (lack of) feasibility of the registry of registries. Managing expectations would have been useful for the involved project partners in this case. At the time of the project, it was however clear that there were many meetings in relation to the upcoming Action Plan held. Here project partners regularly met with representatives of DG SANTE and Chafea. Also, regular correspondence on the implementation of the project was performed with Chafea who was perceived as highly responsive by project partners.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	2
Effectiveness of tools and channels used	2.5
Sustainability of dissemination activities (incl. use of multipliers)	2

EFRETOS defines five clear target groups in the grant agreement:

- National governments in Europe, the body that decides on organ allocation rules and donor acceptance criteria;
- Organ Exchange Organisations (OEO), whose tasks is to advise the government on allocation rules and donor acceptance criteria;
- Physicians in the field of organ transplantation, who decide on donor acceptance and patient referral;
- Patients with end-stage organ disease, who need to be informed on the risks and benefits of organ transplantation;
- European Commission and other international organisations (WHO etc.).

Of the five target groups, the inclusion of patients with end-stage organ disease is the only one that is unclear. It is true that patients are the *indirect* beneficiaries of the project results (and benefit from analysis of post-transplant results) but it is not apparent why they would be included as a direct target group for project dissemination efforts. For example, the recommendations made on vigilance systems, and on quality and safety of organ transplantations, are valuable for national vigilance systems and other target groups but the rationale for specifically targeting patients with end-stage organ disease is not apparent. EFRETOS has however indirectly played a role in dissemination to patients in for example through the Council of Europe's 6th edition Guide on Quality and Safety of Organ Transplantation (guide used by transplant coordinators and professionals at the bed side). This guide uses much of the same categories for vigilance and monitoring of outcomes that was suggested by EFRETOS. Patient groups have a clear interest in increasing uniformity in definitions and harmonising differences in national transplant practices. To this extent, the dissemination report does not refer to patients with end-stage organ disease but includes patient groups as their target group and in their list of stakeholders. There were also several meetings with patient organisations that discussed the findings of the EFRETOS results and they were also represented during the final Symposium.

The project relied on a conventional mix of dissemination tools such as a website, conferences and networks among collaborating and associated partners. The dissemination related in its design to the technical nature of the project in developing a common data dictionary, defining a methodology and delineating legal and technical requirements for the Registry. By design, it is not targeted towards a broad audience.

There was, however, a layman's brochure developed addressed towards the general public. In the dissemination report there was also mention of a short information leaflet addressed towards media as well as a more comprehensive information brochure that was to be distributed during the final symposium. It was unclear if the technical brochure was referring to the white paper produced or another document not available on the EFRETOS website. Furthermore, there was a well written executive summary available on Eurotransplant's website but surprisingly not available on the EFRETOS website. Since some of the key target groups form part of the core project partners (OEOs) extra dissemination activities were not needed to reach these audiences.

There was, however, scope to increase the quality of some of the dissemination efforts, particularly efforts towards patients. The material available on the website could have been made more accessible. The layman's brochure, for example, outlines the project a rather technical language[174] and does not explain it in concrete terms for patients. The websites is mostly concentrated on data dissemination with work package sections pasted that seem taken from project reports. There does not appear to have been periodically updated news on findings either by WP leaders, which was stated in the dissemination report, with the news section consisting of links to articles. A status update was however included in the newsletter that is available for download. As previously stated, the project covered a technical topic but if the intention was to reach patients there could have been more efforts put into tailoring the website content.

Interviewees also described how there was scope to increase awareness about what combining registries could achieve. This could plausibly have been useful in convincing Member States to commit resources and broker political support for an EU wide registry. Project partners also agreed that the dissemination plan could have been more focused on winning over smaller Member States and involving more new MS which was also suggested in the internal evaluation report. To this effect, one interviewee commented pointed to difficulties in ascertaining the extent to which information about the project had been disseminated in these contexts. Overall, the associated partners had the potential to cover a fairly large part of stakeholders across Member States among researchers, physicians and policy makers. Especially the major European OEOs at the time, as well as ESOT contributed to the potential reach of stakeholders. Partners were responsible for large part of the dissemination in their own countries by attending local, national and/or international conferences to present the project and its results to experts in the field and involved stakeholders.

In general, the dissemination activities focussed on the website, newsletters (2), the project brochure, the Executive Summary (only available through Eurotransplant website), the White Paper and presentations such as the final symposium in which European transplant professionals, institutional representatives, health care service providers and representatives of the European Commission participated. A list of stakeholders (around 400 persons) was also used to distribute the project results. There was also a summary scientific article of the project published in Transplant International, which gives a good overview of the project. Several congresses and events (12) were also used to disseminate results of the project. The participation in these events was an important channel to reach clinicians and other stakeholders in the field of organ transplantation. It would have been useful in this context to choose events that had a wider spread of host countries (a majority took place in Italy). One possible explanation for this is that dissemination activities were (according to the dissemination report) not foreseen in the work programmes. Planning the dissemination more carefully and strategically could have helped in terms of reaching more stakeholders.

EFRETOS did not list many further dissemination activities after the project end; the dissemination report does mention that the website was going to be continually updated a year after the project end but this was not evident. The last news item is a link to a news article dated a month after project completion. The project coordinator also left his position shortly after the projected was completed. There was however one presentation during a cluster meeting with journalists, on Transplantation and Blood Transfusion, which took place in Madrid, in June 2013. The collaborating OEO's as well as ESOT served as key multipliers with a potential to reach a large part of the EU population. In the proposal the dissemination strategy was highly reliant on

[174] The same conclusion can also be found in the internal Assessment of Action Result produced by DG SANTE.

collaborating partners work within their respective Member States as well as Competent Authorities to spread the results. Furthermore, a network of national competent authorities set up by Directive 2010/53/EU (that meet twice a year in Brussels) was also used as a channel to inform on the project.

The sustainability of the project does in some sense continue through projects such as NOTIFY which builds in part on findings on organ vigilance from EFRETOS and through DG SANTE's awareness of its contribution, as evidenced in the interim report of the Action Plan on Organ Donation and Transplantation. As mentioned previously, the 6th edition of the Council of Europe Guide on quality and safety of organ transplantation used EFRETOS findings. Furthermore, EFRETOS was also reported to have been helpful for the adoption of Implementing Directive 2012/25/EU on information procedures for cross-border organ exchange. The Joint Actions MODE[175], ACCORD[176] and FOEDUS[177] were also informed by the results of EFRETOS. It is however not always clear how projects build upon each other's results, over time and among actions. This is especially true if funding mechanisms are different such as the above mentioned Joint Actions.

Interviewees also reported how there was follow-up of findings taking place with France and Netherlands, mostly in the form of data exchange but interviewees were not clear in which capacity this was occurring..

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	2.5
Impact on policy	2
Robustness of evaluation strategy and reporting	1.5

There is scope in the long term for significant impact in terms of applicability. EFRETOS main focus was on laying the foundation, developing a common methodology and standard, for a registry of registries. This has the potential to be useful for MSs or other stakeholders in the organ donation and transplant community. Particularly in the case of the vigilance system and the pan-European registry applied to organ donation and transplantation, which the consortium invested considerable effort into agreeing on the specifications of the proposed functional framework. The proposed governance structures for both these frameworks were also well executed and purposeful but there could have been concrete suggestions of different governance options. The organ vigilance system is also a requirement of Directive 2010/53/EU which adds to its potential usefulness. It is primarily the vigilance system (controlling that transplanted patients do not encounter any serious adverse events or reactions after transplantation) that has been implemented by Member States. DG SANTE officials noted that many Member States (such as Poland, Spain and Eurotransplant affiliated countries) are now using categories developed by EFRETOS as a reference for their national vigilance systems. Officials did however also mention that there was difficulties in gauging the full extent of the impact since in Directive 2010/53/EU Member States have agreed not to have mandatory reporting obligations. This meant that the implementation survey on Directive 2010/53/EU (currently being analysed by DG SANTE), that questions how and what results of EFRETOS have been

[175] Mutual Organ Donation and transplantation Exchanges
[176] Achieving Comprehensive Coordination in Organ Donation
[177] Facilitating exchange of organs donated in EU Member States

implemented could not be asked. With regard to this, interviewees reported that the NOTIFY[178] project had based parts of their work on findings from EFRETOS.

The longer term prospects of an implementation of a European registry will largely be dependent on the capacity of the Competent Authorities to develop appropriate national transplant registries as well as more generally the willingness to implement the results nationally (depending on willingness of transplant professionals and available resources).DG SANTE officials described how the main legacy of EFRETOS is a good basis for Member States to develop their vigilance systems and monitor the outcomes for their transplanted patients. This contribution is acknowledged by its use (exactly the same categories) within the Council of Europe Organs' Guide.

Even though project members expressed disappointment about the decision not to implement the registry of registries, they agreed that increasing the quality and comparability of organ transplant data could have important long-term impacts for public health. Similarly, this benefit was also recognised by DG SANTE officials that noted that enhancing vigilance system and agreeing to common terminology and categories had a very practical and organisational impact on the involved countries. In the mid-term review of the Action Plan on Organ Donation and Transplantation another reasons for not funding the can be distinguished. The implementation and active involvement on hospital/local, national and EU level was considered difficult and requiring significant investment of EU resources. As a result, developing a registry was considered a 'large-scale project' and the objectives perceived to go beyond the scope of the 2009-2015 Action Plan. Other complicating issues such as data sharing and governance were also identified by project interviewees and the midterm review. EFRETOS provided the technical tools and blue print for a future pan-European registry. This leaves the door open for future actions, particularly Joint Actions that could build political interest by engaging directly with relevant Competent Authorities. In the last years, promising examples such as the Joint Actions that engage directly with competent authorities. In the last years promising examples such as the Joint Actions ACCORD and FOEDUS indicate that the European Commission together with the Member State strengthen cooperation among competent authorities in organ donation and transplantation.

The set of recommendations developed for an organ vigilance system (WP6) was reportedly used as input for the Action Plan of Directive 2010/53/EU. Since the Action Plan was developed at the same time as the project ran, it served as an important opportunity to impact policy since several project partners were taking part in these consultations. This was also reflected in the work plan since WP6 was fast-tracked to have findings ready for the working group in charge of formulating the Action Plan. Had Member States agreed to make follow-up of transplanted patients mandatory, when negotiating the above mentioned Directive, the prospects for implementing a future registry of registries would have increased. As it stands, the European Commission has urged Member States to implement the results of EFRETOS on a national level as well as strengthen the links to national / European registries.

EFRETOS had an ambitious evaluation strategy involving numerous inputs from a range of stakeholders; it presents a rating of the specific deliverables. Eurotransplant lead the evaluation (WP3) and developed the evaluation plan. Conceptually the evaluation consisted of a three tiered structure with three types of auditors compromising (i) representatives from participating partners, (ii) representatives from participating partners not directly involved in the project and (iii) representatives from patient organisations, Competent Authorities and United Network for Organ Sharing

[178] A joint venture between WHO and the Italian Transplant Centre aimed at providing a global interface for the vigilance and surveillance of substances of human origin (organs, tissues and cells for transplantation and for assisted reproduction).

and Scientific Registry of Transplant Recipients. Each group of auditors were then tasked with rating specific parts of the project on a Likert scale through a questionnaire.

The main methodological issue was the use of a Likert scale for the work packages evaluation that made it difficult to interpret the results. Standard practice is the use of a midpoint of "average" (with the other categories being very poor, poor, good and excellent). In the case of the EFRETOS evaluation, the midpoint was "good" and the other categories being poor, average, very good and excellent). By not using equidistant categories this arguably biases any result towards a positive outcome, since there is only one category that can receive a below average rating.

The internal evaluation presented the results quantitatively (over 40 pages) and included some citations to illustrate the findings. There was however no narrative to explain the quotes, or if the quotes represented widely held beliefs or were only mentioned by a minority. This makes it difficult to follow what the main conclusions and lessons learnt were. Ideally, there would also have been an attempt to summarize the results and give explanations of reasons behind some of the questionnaire results. For example, the question if there was demonstrated need for a registry of registry was rated by three type II evaluators as either poor or average (which would translate to very poor/poor if a correct Likert scale was used) and excellent by all type III evaluators which is a highly interesting result. The quotes and questionnaire results might be easier understood by someone directly involved in the project but did not give much insight the reasons why the project (as the evaluation shows) worked well.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	**3**
Economies of scale	1
Promotion of best practice	**3**
Benchmarking for decision making	**3** (2.8 in the interim evaluation case study)
Cross border threats	2
Free movement of persons	1
Networking	2
Unlocking the potential of innovation	Not used in interim case study

Criteria 1: Implementing EU legislation

As previously mentioned, there was clear alignment between the proposed the Directive 2010/53/EU and EFRETOS. The same was true for the Action Plan on organ donation and transplantation, almost mirroring the Action priorities word for word. The project outputs correspond to the Commissions call for action.

Criteria 2: Promotion of best practice

If the registry would in the future be implemented, there is significant potential for the development of best practice guidelines to improve clinical management and address safety issues related to organ donation and transplantation. Especially since the evidence from MSs demonstrates that standard operating practices can differ significantly, even within countries. WP7 was involved in developing a common European "best practice" methodology to ensure high quality transplant follow up data was possible. Part of this WP was creating a common definition of terms, which would allow promotion of best practices throughout Europe.

Criteria 3: Benchmarking for decision making

Developing a registry for organ donation and transplantation is a way of making current practices among countries more comparable. This can be seen as to serve as basis for future decisions on both the national and the European level. By building the foundation for a pan-European framework on post-transplant outcome data would make it possible to compare for example different organ replacement strategies between related countries and identify successful approaches.

Conclusions and lessons learned

There is great added value in combining registries across Europe, and linking smaller fragmented registries to get an overview of the post-transplant situation and, to enable evaluation and evidence based decision-making. EFRETOS main legacy lies in the development of important principles of good practice and standard evaluation tools to support organ vigilance. The effective set-up of a registry of registry as proposed by EFRETOS would most likely require the transplant community to urge national authorities to free funding for setting up and maintaining national registries, and to install national legislation that should ensure that transplant programs report on a mandatory and regular basis on outcome of their patients. This said, the blue print that EFRETOS has developed to organise the follow-up on organ transplants across the EU would be of significant value to the professional transplant community. Although some of the results fell short of being as useful as originally envisioned by project members, it has still made a significant contribution to consolidating the evidence base and increasing the quality and comparability of transplant data.

The project coordinator's consensus building efforts were particularly useful when building understanding and agreement among partners on sensitive issues. The inclusion of a strong consortium, all experts in their field, also contributed to the success of the project. the project mapped out a possible way of establishing a post-transplant outcome registry The practical barriers were primarily the collection of homogenous transplant data from different MSs which proved difficult and often resulting in fragmented data. On a political level, as a result of not strong enough Member State support and the large scale funding needed, the implementation of the Registry was not feasible during the Second Health Programme.

Positives	Negatives
Experienced consortium including leading organ / transplant countries and major OEOs that delivered high quality outputs.	Somewhat limited interaction with less established countries in the field of organ transplantation. These countries can however benefit from the results and implement the findings of EFRETOS.
Clear policy link and alignment with HP objectives and priorities in AWP, had a clear direction of what to accomplish.	Future implementation of an EU wide registry is dependent on a political agreement to implement the findings.
Project met a highly relevant need among EU citizens. It also produced recommendations for the reporting and	Some of the assumptions made by project members of the future of a registry of registries impacted the design of the

Positives	Negatives
management of adverse events and reactions not only at a national level, but consistently throughout the EU. The blue print and proposed governance structures for both these frameworks were very well executed and purposeful.	project. Inclusions of governance options would have been useful for accommodating different governance solutions.

9.11. Study of the Policy Mix for the Reimbursement of Medical Products (Service Contract)

Summary

This was a well-conceived and competently performed, relatively small scale study with very clear and narrow objectives. It was aimed directly at feeding into policy discussions on reimbursement and pricing policy within one of the sub-groups to the Reflection process on modern, responsive and sustainable health systems initiated by the Council in 2011. Based on a very explicit brief developed by DG SANTE in consultation with working group members, the study used Multi-Criteria Decision Analysis to frame the preferences of various relevant stakeholder groups towards key policy options and conflicting objectives. Although most results are far from ground-breaking (i.e. could have been identified a priori without the need for a complex quantitative study), they nonetheless seem to have helped to put the discussions on this controversial and very relevant topic on a firmer and more objective basis. As such, the study demonstrates both the potential of applied research that is conducted in a way that is directly oriented towards and firmly anchored within a specific policy process, and the risks of expecting evidence to solve complex political problems.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2.7	Clear and narrow objectives, very specific and realistic Terms of Reference, and a high quality proposal that covered all the relevant points
Implementation / outputs	2.5	Competent team, good mix of consultants and academia, effective interaction between contractors and DG SANTE, all led to a study that did what it set out to without major setbacks
Dissemination	1.3	Not part of the contract, but presentations at key fora, networks and events led to reasonable awareness and use among key audiences (policy makers and stakeholders)
Results / impacts	1.5	With one or two exceptions, the results are far from surprising – they merely frame well known stakeholder preferences in quantitative terms. Nonetheless, some policy usefulness for moving discussions on the topic forward

Introduction

This case study explores the Health Programme (HP) funded "Study of the policy mix for the reimbursement of medicinal products – Proposal for a best practice-based approach based on stakeholder assessment", with a focus on conclusions that can be drawn and lessons that can be learned for the HP as a whole. The case study is based on a review of relevant documentation, and a series of telephone interviews with the authors of the study, as well as representatives of DG SANTE and CHAFEA who

commissioned / managed the contract. The interviews were conducted in December 2014.

The study was procured through a request for services under a framework contract for "Support for the Health Information Strategy" signed by CHAFEA and a short list of contractors in 2010. The specific contract was awarded to the consortium led by SOGETI Luxembourg SA; the lead partner for the study was Gesundheit Österreich Forschungs- und Planungs GmbH (GÖ). The study was produced over a 12-month period, and the final report delivered in January 2014.

Table 51: Study key parameters

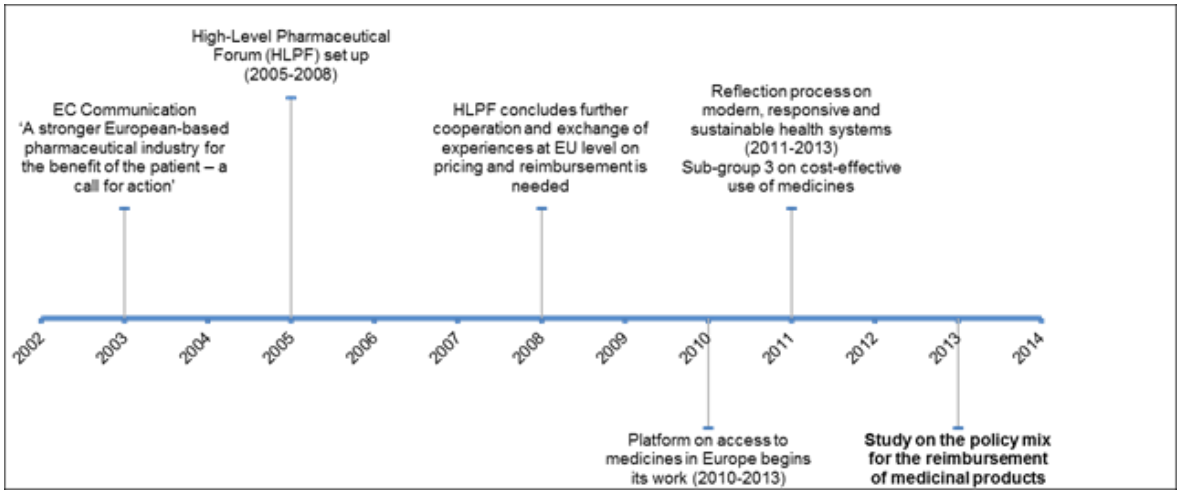
Full name	Study on the policy mix for the reimbursement of medicinal products: proposal for a best practice based approach based on stakeholder assessment.
Acronym	RFS 28 EAHC/2012/Health/18 on FWC EAHC/2010/Health/01 REIMB. MEDICINAL PROD
Funding instrument	Service contract
Action number	20126113
HP strand	3 - Health information
Priority	3.2 Collect, analyse and disseminate health information
Sub-priority	3.2.3 Analysis and TA for developing or implementing policies or legislation
Maximum EC contribution	€ 101,259
Actual start date	01/02/2013
Duration	12 months
Status	Finalised
Lead partner	Gesundheit Österreich Forschungs- und Planungs GmbH
No. of associated partners	N/A
No. of collaborating partners	N/A

The study was commissioned by DG SANTE to provide input to the discussions within the Reflection process on modern, responsive and sustainable health systems initiated by the Council in 2011. The Reflection process was under the auspices of the Working Party on Public Health at Senior Level, and aimed at identifying effective ways of investing in health. Five sub-groups were formed; one of these (sub-group 3, led by the Netherlands) was dedicated to the cost-effective use of medicines. It discussed inter alia pricing and reimbursement policies for medicines, and how to strike the right balance between various conflicting policy objectives (including access to medicines, budget control, and reward for innovation) and the interests of different stakeholder groups (including patients, pharmaceutical companies, and payers).

The work of the sub-group followed in the tradition and built on the work of other EU policy processes since around 2000, when pricing and reimbursement policies were first discussed extensively at European level within the G-10 Medicines Group (consisting of ten selected Member States and stakeholder representatives). The Group published a series of recommendations in 2002, and in July 2003 the European Commission published a Communication outlining its proposals for taking forward the G10 recommendations, including the creation of a "forum for member states to generate and share information on common relative effectiveness issues in the context of pricing and reimbursement decisions".

To follow up on these recommendations, the High Level Pharmaceutical Forum was set up in 2005. It involved EU institutions, all EU Member States, industry, health care professionals, patients and insurance funds. Three Working Groups were set up, including one on pricing and reimbursement policies, which discussed guiding principles and ideas to help Member States balance the conflicting policy objectives, including access to medicines, budget control, and reward for innovation. When the work of the Forum ended in 2008, it concluded that further cooperation at EU level was needed to address these issues. Some of the issues raised in the Forum were addressed in the Platform on Access to Medicines in Europe, which was launched in 2010 as a voluntary multi-stakeholder process to try to find non-regulatory solutions to key challenges.

Figure 44: Key milestones in the debate on pricing and reimbursement of medicinal products in Europe



Design

Design	Score (1-3)
Fit within programme and policy context	2
Robustness of objectives and intervention logic	3
Feasibility of implementation plan	3

The study pursued a **very clear, narrow objective**, which was defined by DG SANTE in consultation with the members of the sub-group on the cost-effective use of medicines. The idea reportedly originated within DG SANTE itself, which had a clear idea of what it wanted the study to achieve, namely to provide evidence that could be fed into the work of the group. The opportunity to procure the study (as well as another parallel study on a closely related topic: "External reference pricing of medicinal products: simulation-based considerations for cross-country coordination") presented itself when funds were left over at the end of 2012, leading one interviewee to describe it as a "windfall project".

The specific purpose of the study was to use **Multi-Criteria Decision Analysis (MCDA)** to systematically assess the preferences of a range of different stakeholder groups concerning a number of reimbursement policy practices (such as co-payment, managed-entry agreements, reference price systems, etc.) and policy objectives (such as timely / equitable access to medicines, reward for innovation, cost-containment, etc.), so as to score the different practices, identify trade-offs, and make recommendations to improve the mix of reimbursement policies. The idea to use MCDA to attempt to analyse and frame the different preferences arose because the discussions around reimbursement and pricing policies had reportedly been heated but

unstructured, with little progress made due to seemingly irreconcilable differences between different stakeholders and their respective interests. The hope was that MCDA techniques (which had recently drawn interest from a number of relevant actors, including the UK's National Institute for Clinical Excellence) would help structure the arguments, identify potential room for compromise, and thus put the debate on a more rational, evidence-based footing.

The Terms of Reference (ToR) for the study were drafted in a very clear and concise way that left little room for interpretation, or doubt as to what exactly was expected. SOGETI / GÖ's proposal, which was one of three proposals received in response to the request for services, was the clear winner with a score of 92%. It essentially followed the **methods and tasks** prescribed by the ToR: a literature review (Work Package 1) to help develop of a catalogue of relevant policy measures and assessment criteria (WP2); a survey to test the preferences of key stakeholders (WP3); and the application of MCDA to analyse these preferences (WP4) and based on this, develop policy recommendations (WP5).

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2.5
Fostering of collaboration and partnerships	N/A
Engagement with other actors (incl. DG SANTE / CHAFEA)	2.5

Overall, the interviews suggest that the **implementation of the study went very well**. Both sides (the contractor and DG SANTE) were very complementary of each other. The team conducting the study was described as very efficient and professional; the project stayed within the agreed timeline; the methodology was designed and applied in a meticulous and diligent way, and well documented; and the drafting was very good. GÖ was also proactive in terms of proposing additional stakeholder groups, policy measures, and assessment criteria beyond those suggested in the ToR.

A key success factor was the fact that the study team represented **a good mix of academia and consultants**; the latter tend to be very responsive, and the former ensured that things were done in a rigorous, scientific, evidence-based and unbiased way. Reportedly, many projects sway one way or the other, while this one was a very good blend. The only problem according to DG SANTE was with one specific deliverable and the formulae used therein; this took time to resolve, but in the end did not detract from the overall success of the project.

The contractor described the role of the main **DG SANTE official** as **very helpful** overall: engaged, diligent, challenging, and remarkably competent in terms of understanding and questioning the technical details of the methodology. It was noted that the presence of DG ENTR at project meetings was also positive in terms of fostering buy-in and acceptance. The role of CHAFEA was restricted to administrative aspects.

Two **key challenges** arose during the implementation of the study. The first of these was that there are several slightly different MCDA methodologies, and it took considerable time and effort to decide on the most appropriate one. The other – arguably more significant – challenge was the fact that the MCDA method required the use of a very complex questionnaire. This made it difficult and time-consuming for stakeholders to respond – especially those with fewer resources, and those that have less direct exposure to the issues at stake, namely patients and consumers, and healthcare professionals. In the end, the study team contacted 266 institutions and managed to obtain 81 responses to the survey (well short of the target of one

respondent per Member State and stakeholder group – of which there were four). It required a significant effort to motivate stakeholders to participate, and obtain an acceptable response rate while achieving a balance between different groups. This was in spite of the fact that the contractors had the advantage of having previous experience and established contacts among the key stakeholder groups.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	2
Effectiveness of tools and channels used	1
Sustainability of dissemination activities (incl. use of multipliers)	1

The primary **target audiences** of the study were policy makers and stakeholders. A possible secondary target audience are researchers, who may be more interested in the MCDA method than in reimbursement and pricing policies. Interviewees noted that the main purpose was to feed into policy discussions; as such, it was not intended (and is arguably too technical) for a wider target audience. It should be noted that the contract for the study did not foresee any dissemination activities to be undertaken by the contractors.

Thus, the main **dissemination channels** were through presentations and discussions (by DG SANTE and/or the contractor) in relevant fora, groups and meetings (including the sub-group itself and the Network of Competent Authorities on Pricing and Reimbursement). The study was also made public on the DG SANTE website. The contractor was invited to present at various congresses, seminars and networks, including invitations from stakeholder groups that had participated in the study. At the time of writing, GÖ was also considering whether to write an article on the study and submitting it to a scientific journal for publication, but no final decision had been taken.

Overall, it seems that the study was fairly widely noted and well received among its main target audiences, and is being referred to in discussions with some frequency. Wider dissemination was never intended.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	1
Impact on policy	2
Robustness of evaluation strategy and reporting	N/A

Upon reading the final report, one cannot help but wonder whether the results justified the effort and (admittedly not very large) expense that went into the study. Most of the results seem to merely **confirm the initial assumptions** regarding stakeholder preferences, as illustrated by the following quotes from the executive summary:

- 'Reward for innovation' was of high priority for pharmaceutical industry but less so for consumers/patients and authorities/payers;
- 'Timely access to medicines' was a priority for consumers/patients and industry but to a lesser extent for health professionals and authorities/payers;
- 'Cost-containment' was the policy objective to which authorities/payers gave particular priority;

- Within the group of pharmaceutical industry, the research-based pharmaceutical industry gave high priority to '[…] 'reward for innovation', whereas 'increased competition' [was] highly ranked [by] the generic medicines industry.

The **recommendations** stemming from the study (which, according to the ToR, were meant to "aim to improve the mix of reimbursement policies, whilst explicitly highlighting trade-offs at play and stakeholder considerations applying") also remained **somewhat general and elusive**. For example:

- The design of the best practice-based mix of reimbursement policies is likely to require a different approach depending on the policy goals which a country aims to give highest priority to;
- A policy mix considered as 'ideal' should take into account the different approaches to the different groups of medicines (particularly the two groups of new, high-cost medicines and generics).

Interviewees acknowledged that most of the results were hardly surprising; they mainly framed well known subjective preferences in quantitative terms. Nonetheless, they saw significant **added value** in the study results, for three main reasons:

- The one genuinely interesting (and somewhat unexpected) result relates to external price referencing, and the fact that it is rejected not only by the pharmaceutical industry, but by all stakeholders (although payers feel even more negatively towards the main alternative approach, namely differential pricing);
- The study was also said to provide a better basis for future discussions, because it established a widely accepted terminology and definitions of different measures that have the potential to reduce confusion, and also because it forced all stakeholders to state their preferences (as opposed to only their dislikes), which in itself represents an (albeit modest) improvement over the previous state of affairs;
- Finally, from a methodological point of view, the study represents a test case for the application of MCDA to a concrete problem, and may lead to more relevant work in this area in the future.

Thus, it would be **difficult to describe the outcomes of the study as "ground-breaking"**, but it does seem to have the potential to put future discussions on reimbursement and pricing policies on a more solid footing by clarifying key issues and preferences, and thereby improving the dialogue between key stakeholders and policy makers. According to interviewees, this effect is already noticeable to some extent. The study has been discussed and used already, but the expectation is that it will prove even more useful in the future, by providing a **framework to explore if compromise is possible**. This is particularly important since the issue of pricing of medicines, and possible reforms to the current systems, is likely to become more pressing due to recent innovations such as a new drug for hepatitis C, and other significant innovations that are likely to come on the market soon.

That the issue remains relevant is confirmed by the Council conclusions on the reflection process on modern, responsive and sustainable health systems of 10 December 2013, which invited the Commission and Member States to "continue reflection, on a voluntary basis, on aspects that may have an impact on availability, accessibility, prices, costs, patient safety and innovation of pharmaceuticals and medical devices and, where relevant, on systems that facilitate access, while fully respecting areas of Member States' competence".

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	0.5
Economies of scale	**1.5**
Promotion of best practice	1.3
Benchmarking for decision making	**2.0**
Cross border threats	0
Free movement of persons	0
Networking	0.2
Unlocking the potential of innovation	0.5

Criteria 1: Benchmarking for decision making

As discussed above, the study does contribute to the ongoing discussions between different stakeholders and interests seeking to formulate the ideal policy mix for medicine reimbursement and pricing policies. While it does not necessarily provide genuinely new evidence in the same way that scientific research might, it clarifies and frames stakeholder preferences in a novel way, and may thereby contribute to more informed discussions and possible compromise solutions in future.

Criteria 2: Economies of scale

While the topic area might lead observers to believe the study may indirectly lead to economies of scale, a deeper analysis of the study, its context and (intended) use makes it seem unlikely, except in the sense that it might enable certain Member States to use the results as a starting point and not have to invest resources in conducting similar research at national level.

Conclusions and lessons learned

This study, funded via a **relatively small service contract**, produced results that seem to be somewhat useful as **evidence for policy making** in the area of medicine pricing and reimbursement policies. They systematically assess and compare the preferences of different stakeholder groups concerning different policy measures and (often conflicting) policy objectives in a systematic and quantitative way by applying MCDA techniques. While the results are mostly less than surprising, they still seem to **have added (and be adding) value** to the ongoing discussions in this area by clarifying options and positions, and thereby providing a more objective foundation for the debates. In addition, the study provides a pilot case for the application of MCDA to complex policy dilemmas, which may lead to further methodological development and/or more widespread use of the method in future.

As such, the study represents an example of how service contracts funded from the HP provide DG SANTE with the opportunity to produce specific inputs to attempt to move forward policy discussions. The study was well-planned by DG SANTE, and well implemented by the contractors. The **main success factors** in this respect were very clear, unambiguous ToR; a very engaged policy lead from DG SANTE; and a well

qualified and competent team providing a good mix of the qualities typically associated with consultants on the one hand (responsiveness and project management) and academia on the other (methodological rigour and meticulousness).

In spite of the less than ground-breaking results, the study was relatively widely taken note of and discussed, which shows the advantages of the direct link with policy makers (via sub-group 3 of the reflection process), and with stakeholders (who were asked to input into the study). As such, it shows how important it is to attempt to **anchor applied research such as this within a policy process**.

9.12. Regional training seminars

Summary

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2.7	The regional seminars were politically relevant and based on an appropriate intervention logic, with clear objectives
Implementation / outputs	2.8	The seminars generated appropriate outputs, measured as participant satisfaction, collaboration and partnerships
Dissemination	2.2	The target groups were clearly defined and the project activities were adequately implemented.
Results / impacts	1.2	However, the seminars will, most likely, have a limited effect on national policy-making, since it seeks to influence a complex social process (the implementation of a new legislation), through a relatively simple action, characterised by a limited scope and intervention dosage (a 2-day seminar).

This report concerns the organisation of two regional seminars relating to a new Decision on cross-border health threats. In the table above, which provides an overview of the case study at hand, we argue that the contractor has carried out a successful project - in terms of design, implementation and immediate outputs, but that the seminars are unlikely to have a substantial impact on long-term policy processes.

The key parameters of the study is summarised in the table below.

Table 52: Study key parameters

Full name	Organisation of two regional training seminars with Member States public health authorities relating to the implementation of the new decision on serious cross-border threats to health.
Acronym	RFS2
Funding instrument	Service contract
Action number	201261112
HP strand	Health security
Priority	Protect citizens against health threats
Sub-priority	Risk management, preparedness and planning for health emergencies
Maximum EC contribution	€ 249,599
Actual start date	October 2013
Duration	7 months
Status	Finalised

Lead partner	Public Health England
No. of associated partners	2
No. of collaborating partners	N/A

Introduction

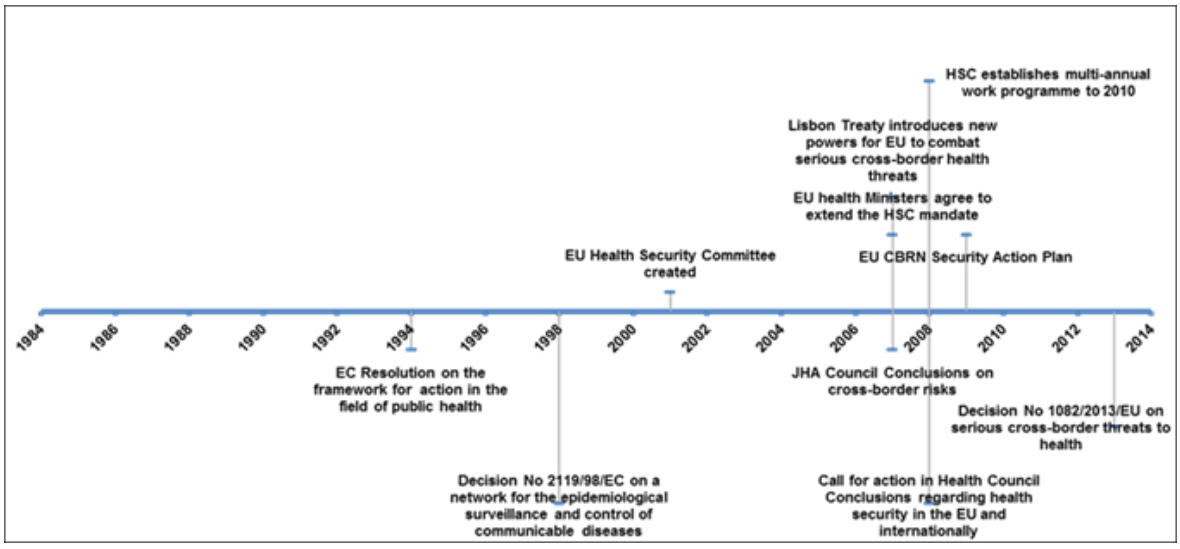
In October 2013, Decision No 1082/2013/EU was adopted by the European Parliament. The purpose of the Decision is to strengthen security measures, in order to improve the protection of EU citizens from cross-border threats to public health. At a more detailed level, the Decision has the following objectives:

- **Preparedness and response planning**: To develop a common approach to preparedness planning at EU level for all serious cross-border threats to health, ensuring coherence and interoperability among sectors and between Member States, including equitable access to medical countermeasures;
- **Risk monitoring and assessment**: To create conditions to ensure a coherent and comprehensive identification and notification of health threats, especially in crises with a multidisciplinary dimension;
- **Risk management and crisis communication**: To strengthen the coordination between Member States, the international level and the Commission, in order to ensure a coherent policy approach, thereby enabling effective responses to cross-border health threats across the European Union.

To increase the awareness of Decision No 1082/2013/EU, the Executive Agency for Health and Consumers (EAHC) commissioned four regional seminars, arranged in Luxembourg, Rome, Vilnius and Dubrovnik. In this case study, we focus solely on the Vilnius and Dubrovnik sessions.

Decision No 1082/2013/EU, as well as the related training events, needs to be analysed in a wider context of Community measures towards cross-border threats to public health. Our understanding of this context is illustrated in the figure below and briefly described in the ensuing paragraphs.

Figure 45: Key milestones in the establishment of Community measures relating to cross-border health threats



As early as 1994, the European Union sought to address the challenges raised by trans boundary health issues, which could affect citizens across the territory of several Member States. In its Resolution of 2 June 1994, on the framework for Community

action in the field of public health[179], the Council agreed that priority should be given to communicable diseases in particular. As the breadth of the health problems that may be the subject of cooperation and coordination between Member States required the development of an overall approach, which could be best tackled at Community level, the Council invited the Commission to bring forward proposals for action in the priority areas identified in the resolution.

To follow up on this resolution, the Parliament and the Council adopted Decision No 2119/98/EC[180] on 1998, setting up a network at Community level to promote cooperation and coordination between the Member States, with a view to improve the prevention and control of communicable diseases. However, this initial legislative effort was limited in its scope insofar it only covered a narrow range of cross-border threats to health, essentially from a bacterial or viral nature.

After the terrorist attacks and the deliberate release of anthrax toxins in the US, the EU Health Security Committee (HSC) was created. The HSC is an informal advisory group on health security at the European level, bringing together high-level representatives from the Ministries of Health of the EU Member States, Norway, Iceland and Switzerland under the Commission chairmanship. In 2007, the EU's Health Ministers agreed to extend the HSC mandate to include pandemic preparedness and response, as well as coordination of emergency planning at EU level.

Whilst the implementation of No 2119/98/EC and subsequent measures confirmed that coordinated Union action on monitoring, early warning and combating of cross-border threats adds value to the protection and improvement of human health, developments at Union and international level in the decade following its adoption made clear that a review of the existing legal framework was necessary.

In 2011, trans boundary health crises - such as the H1N1 pandemic, the outbreak of E.coli and the volcanic ash cloud - urged the Commission to respond to the repeated calls for action of the Council and set out a decision proposal, extending the notion of health threats to cover all heath threats caused by biological, chemical or environmental causes.

Providing for a coordinated wider approach to health security at Union level, Decision No 1082/2013/EU supplemented the existing legislation to address a number of other sources of danger to health, in particular related to other biological or chemical agents or environmental events, which could by reason of their scale or severity, endanger the health of citizens in the entire Union, lead to the malfunctioning of critical sectors of society and the economy or jeopardise an individual Member State's capacity to react.

Moreover, Decision No 1082/2013/EU empowered the relevant institutions to act, by extending the mandate of the Early Warning and Response System (EWRS) to cover all serious cross-border threats to health, and strengthening the role of the Health Security Committee.

Design

Design	Score (1-3)
Fit within programme and policy context	2.5
Robustness of objectives and intervention logic	3
Feasibility of implementation plan	2.5

[179] OJ C 165; 17.06. 1994, p. 1.
[180] OJ L 268/1; 03.10.1998, p.1.

We understand that the Decision is clearly aligned to the **policy context**; according to our interviewees, the legislation is important for many[181] Member States and their ability to counteract serious health threats. We also argue that the training seminars are relevant, in relation to the following, programme objectives:

- HP strand 1: Health Security;
- Priority 1.1: Protect citizens against health threats;
- Sub-priority 1.1.3: Risk management, preparedness and planning for health emergencies.

The **project rationale** is simple and straightforward: within the framework of two seminars, the different components of a new Decision will be explained to representatives from the Member States, thereby increasing their understanding of the legislation. Based on our assessment, the project logic is adequate; there is no reason to seriously question the link between training events and competence-development.

Although the project design is appropriate, its plausible impact could be challenged and disputed. The effective implementation of a new legislation, which is the long-term objective of the project at hand, is an intrinsically complex process, requiring knowledge and understanding, i.e. those mechanisms that are triggered by the seminars, but also a variety of additional ingredients, such as organisational capacity, regular training and political advocates. This argument is presented at more length in the next section.

In terms of the **implementation plan**, the initial contract length (7 months), agreed upon in the Service Contract, was perceived as relevant by the involved parties. However, due to delays at the political level, the seminars had to be carried within 5 months instead. According to the contractor, the condensed time frame put significant pressure on them, without affecting the quality of the seminars. This conclusion is supported by the findings from the participant evaluation, which are described at more length below.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2.5
Fostering of collaboration and partnerships	3
Engagement with other actors (incl. DG SANTE / CHAFEA)	3

By the end of the regional seminars, the participants were asked to answer a brief survey, concerning a range of aspects relating to the training sessions. This survey show that the participants, at a general level, were satisfied with the information provided. This conclusion is also illustrated in the table below.

[181] Although the Decision provides a significant foundation for joint action on serious health threats, it likely to have a stronger impact on the working practices in the MS-13, since many of the old Member States, prior to the Decision, followed the WHO regulation from 2007, with similar requirements.

Table 53: Results from the participant evaluation

Indicator	Vilnius	Dubrovnik	Average
% rating the seminar as excellent/good	73%	99%	86.5%
% stating that the seminar met their expectations	83%	96%	89.5%
% stating that the seminar met the seminar objectives	83%	100%	91.5%
% stating that the course materials were useful	83%	89%	86%
% stating that there were sufficient case studies, activities and discussions	69%	81%	75%
% stating that the seminar was relevant to their work	86%	100%	93%
% stating that they would use what they had learnt in their home country	86%	100%	93%
% stating that the EC should continue to organise these kinds of events	75%	78%	76.5%

Our case study demonstrates that the seminars generated appropriate **outputs**, measured as participant satisfaction. In terms of potential improvement, some respondents emphasised that the training sessions could have been more dynamic, practical and focused on the sharing of best practices. In the evaluation report, this stand-point is exemplified by feedback quotes, such as:

- I would have preferred more discussion points and interactive sessions;
- It was not very useful to go through the Decision word by word (we can read ourselves). It would have been more relevant if the seminar had focused on how the Decision is supposed to be implemented.

According to our interviewees, the regional seminars were successful in fostering **collaboration and partnerships** across the Member States, by providing a platform for networking and discussion. It should also be mentioned that the main contractor (Public Health England) is appreciative of the role played by **Chafea** throughout the project. During our data collection, the agency was described as a reliable and knowledgeable partner, who adequately supported the implementation of the project.

Dissemination

Dissemination	Score (1-3)
Identification of clear target groups	3
Effectiveness of tools and channels used	2.5
Sustainability of dissemination activities (incl. use of multipliers)	1

In this section, we focus upon the seminars as such, rather than the attempts to communicate about them. The purpose of the events was to raise awareness about a Decision, among a defined group of participants, and the contractor did not implement any specific dissemination activities in addition to that.

We argue that Public Health England were able to attract relevant **target groups** - at the organisational, as well as the hierarchical level. This means that the seminars, in general, were attended by appropriate actors, responsible for health security issues across the MS, with representatives from a relatively high level, which were able to influence the implementation of the Decision in their own countries.

In the absence of observable results, it is difficult to make any valid statements about the **effectiveness** of the seminars and the applied dissemination tools. With this said, we have previously stated that:

- …the project rationale is simple and straight-forward: there is no reason to seriously question the link between training events and competence-development (Section on "Design");
- …the project activities were adequately implemented, while generating appropriate outcomes, measured as participant satisfaction (Secion on "Implementation");
- …the seminars might have been even more effective if they, to a larger extent, would have focused on interactive sessions, practical examples and the sharing of best practices ("Implementation").

Although the seminars were based on a relevant design, and supported by adequate implementation processes, it is unlikely that the training sessions, as isolated activities, will have a significant effect on national policy-making. In other words, positive outputs do not necessarily transform into **sustainable impacts**. This conclusion is described at more length in the section below.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	1
Impact on policy	1
Robustness of evaluation strategy and reporting	1.5[182]

As mentioned previously, the purpose of the seminars was to increase the understanding of a new legislation. From a programme perspective, this objective represents an intermediate outcome, rather than a long-term impact. The training seminars have to influence the **implementation quality**, in order to affect the overall objectives of the Health Programme, since an improved understanding, without a changed practice, is unlikely to have a significant effect on the health situation across Europe.[183]

To adequately assess the wider applicability of the project results, and the potential impact on policy, three aspects should be taken into account, namely, the complexity of implementation processes, the overall policy context and the intervention design. These aspects are described at more length below.

Current research emphasise that an effective implementation of new policies is an intrinsically **complex process**, which requires knowledge and understanding about the subject matter, i.e. those mechanisms that are triggered by the project at hand, but also a variety of additional ingredients, such as:

- Political advocates;
- Positive norms regarding change;

182 The contractor, not an independent evaluator, carried out a survey among the participants, covering their general satisfaction with the training sessions. This survey was complemented by a brief summary of the seminar discussions, compiled by Chafea.

183 Having said this, a few words should be mentioned about the term "implementation quality". We are aware that Decision No 1082/2013 is a binding legislation, which means that the Member States are obliged to comply with its basic elements. However, the Decision itself is openly formulated and it leaves room for different interpretations, as well as ambitions, at the country level. Based on this assessment, it makes sense to treat the Decision as a continuous factor and to analyse the potential for a high quality process, as opposed to a dichotomous factor (focusing on whether an outcome will occur or not).

- Shared decision-making;
- Organisational capacity;
- Coordination with other actors;
- Skill proficiency;
- Administrative support;
- Regular training.[184]

From the implementation research, we also know that the **policy context** is crucial, when understanding outcomes. In the evaluation that was carried out by CHAFEA, the economic situation as well as national capacities, were identified as important factors. In their report, this conclusion was described as follows:

> "Another remark was about the increased request from the EU level (e.g. ECDC, Commission) at a time where national capacities to deal with these demands decrease. The shrinking of national resources (e.g. staff, IT and laboratory capacities) might also affect the implementation of the Decision, especially with its enhanced scope. These kinds of difficulties were raised by several countries."

Moreover, the plausible impact of the project should consider the basic elements of the **intervention design**. From our perspective, the regional seminars were characterised by two factors, which are important from an implementation perspective. First of all, their **scope** was limited and confined to basic training measures, as well as an exchange of good practices. Secondly, the intervention **dosage** was restricted and structured around a one-off event, lasting for two days. The low level of "treatment" was also recognised by the Project Manager, who made the following statement in one of our interviews:

> "The seminars focused on awareness-raising, but it was obvious to me that the countries needed further assistance within certain areas, especially in terms of implementation support at the national level."

To summarise, our argument regarding potential policy impacts can be expressed as follows:

- The effective implementation of a new legislation is an intrinsically complex process;
- Implementation processes can be explained by a wide range of inter-related factors, such as norms, political advocacy, coordination between different actors, skill proficiency and administrative support;
- The implementation of a new legislation is also influenced by the wider, socio-economic context, which still is affected by the financial crisis, austerity measures and a perceived lack of resources;
- With this in mind, it is unlikely that a two-day seminar, focusing on basic competence-development and awareness-raising, will have a significant and independent effect on national policy processes.

184 See also Durlak, Joseph & DuPre, Emily (2008). Implementation Matters: A Review of Research on the Influence of Implementation on Programme Outcomes and the Factors Affecting Implementation. Am J Community Psychol, p.327-350 (Vol 41).

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

Criteria	Average score
Implementing EU legislation	**1.8**
Economies of scale	1
Promotion of best practice	**2.3**
Benchmarking for decision making	1
Cross-border threats	**3**
Free movement of persons	0
Networking	**1.7**
Unlocking the potential of innovation	0.7

As part of this evaluation, our experts made an assessment of the EU added value provided by the project, based on a brief desk research. In this section, we explore the extent to which an added value is likely to materialise in practice. The discussion below takes the expert scores into account, but it also considers the additional data collection that has been carried out during the case study. In the ensuing paragraphs, we focus upon those criteria that received a score of 1.5 or more by the experts, namely:

- Cross-border threats;
- Implementing EU legislation;
- Networking;
- Promotion of best practice.

As mentioned above, Decision No 1082/2013/EU is important for many Member States and their ability to safeguard public health, which indicates a strong link between the project at hand and the added value criteria relating to **cross-border threats**. However, the actual prevention of serious health threats requires behavioural change at top levels within national administrations, and in this regard, we have questioned the relationship between general training seminars, leading to an increased awareness and long-term impacts. In short, we argue that relevant knowledge about a Decision is a necessary, but not sufficient condition, when understanding the effective **implementation of a new legislation.**

Our case study illustrates that the regional seminars were successful in fostering collaboration and partnerships across the Member States, by providing a platform for **networking** and discussion. Moreover, we argue that the training sessions generated appropriate outputs, measured as participant satisfaction, although some respondents emphasised that the training sessions could have been more interactive, practical and focused upon the **promotion of best practices**.

In sum, the additional data collection, carried out during the case study, shows that the initial scoring made by the experts could be described as too positive. The project is well-aligned to many of the added value criteria, but it is questionable whether it will lead to any strong and observable effects in practice.

Conclusions and lessons learned

The somewhat contradictory conclusion of this case study is that the contractor has been able to carry out a successful project - in terms of intervention design and implementation delivery - which is unlikely to have a strong effect on long-term policy processes. This conclusion can be understood as follows:

- The project actions (training seminars) only addressed one out of several mechanisms, essential for generating an effective implementation processes (an increased knowledge about the legislation);
- The project actions were structured around a relatively small budget (€ 249,599) and they were implemented as one-off events, lasting for a short period of time (2 days).

In other words, the lesson learned from this case study is that complex social processes, such as a high quality implementation of a new legislation, requires multifaceted actions, with a relevant intervention dosage, which focuses on several areas of the policy cycle, at different moments in time.

At a general level, such actions can be promoted through two programme management principles. One option is to **reduce the total number of projects**, thereby increasing the potential scope, length and "treatment intensity" of those actions that are funded.

Another option is to emphasise **flexible and structured selection strategies**, closely tied to a smaller number of pre-defined themes within the programme. In this scenario, a variety of relatively small projects, focusing on common objectives, at different levels, are funded at the same time within the HP.

In the case of Decision No 1082/2013/EU, a flexible and structured strategy would imply that the training seminars could have been complemented by a range of additional actions, simultaneously addressing those implementation factors that were listed under "implementation", for example: political advocacy; positive norms regarding change; shared decision-making; organisational capacity and administrative support.[185]

[185] With this said, it should be mentioned that the training seminars have been followed by a so-called Quicksilver event, which was held in September 2014. This event provided extra training and administrative support to the Member States. In other words, the Quicksilver event, together with the regional seminars, constitute a small-scale example of the flexible and structured selection strategy, although it would be possible to extend this thinking even further, by covering even more mechanisms, factors and levels involved in the implementation of Decision No 1082/2013.EU.

9.13. Action to prevent and reduce harm from alcohol - Study on the state of play in the use of alcoholic beverage labels to inform consumers about health aspects (service contract)

Summary

The study entailed an impressive effort in data collection and analysis, leading to a sizable body of evidence on the (limited) extent to which health warnings are used in different alcohol labels and the variation in their visibility. In addition to this huge mass of evidence collected, the success of the study is that it describes the state-of-the-art in alcohol labelling in European countries and thus provides examples of best practice. It was well implemented and achieved what it set out to achieve. If any criticism is levied it would mean taking a step back and questioning the ToRs and their scope.

While the study was obviously clearly rooted in EU policy, and the context clearly outlined in the Terms of Reference (ToR) (under section 2), we note that from the ToR it was not *explicit* regarding how or if the results of the scoping exercise undertaken through this study would feed directly into policy / action. The aim was to assess the situation regarding the use of labels, not recommendations for policy formation. To be better anchored in policy would require stating how the results of the study would be used and / or require recommendations – we emphasise that this is a limitation of the scope of the ToR, rather than the study itself.

The table below contains a summary of the scores allocated to this action. As explained in the introduction to Annex 9, the scores should be viewed in light of the purpose and limitations of the case study methodology, and not as substitutes for comprehensive evaluations of individual action performance. They are intended to facilitate comparison and help identify key success factors and barriers that applied beyond the level of single actions.

Evaluation area	Average score (1-3)	Explanation
Design	2.3	Study had inherent limitations in terms of the budget (and time) available but fitted well with the broader EU alcohol policy and was designed to meet narrow, clear ToR
Implementation / outputs	2	Good consortium, combining market research skills and policy knowledge, interaction between contractors and DG SANTE was unremarkable, setback in timing
Dissemination	2.6	Not part of the contract, but presentations at key fora, networks and events led to awareness among key audiences (policy makers and stakeholders)
Results / impacts	1.4	There is discussion surrounding what action should be taken however there is no evidence of (imminent) change / policy although this is in large part due to the wider policy environment and vested interests (of the alcohol industry) which are opposed to change

Introduction

The study is rooted in EU policies on alcohol and food labelling. The consumption of alcohol is an important health determinant in the European Union. It is a cause of

around 60 diseases and conditions, the third leading risk factor after high blood pressure and tobacco, and a cause of over a quarter of male deaths for 15-29 year olds (Anderson & Baumberg 2006). Harmful levels of alcohol consumption are responsible for 7% of all ill-health and premature death in the European Union.[186]

The EU published an alcohol strategy in 2006 to "help national governments and other stakeholders coordinate their action to reduce alcohol related harm in the EU".[187] One of the themes for action was to "Inform, educate and raise awareness on the impact of harmful and hazardous alcohol consumption"[188]. One year later, as part of executing the strategy two groups were set up: the Committee on National Alcohol Policy and Action to strengthen coordination and policy development and the European Alcohol and Health Forum to stimulate concrete stakeholder-driven action to reduce alcohol related harm[189].

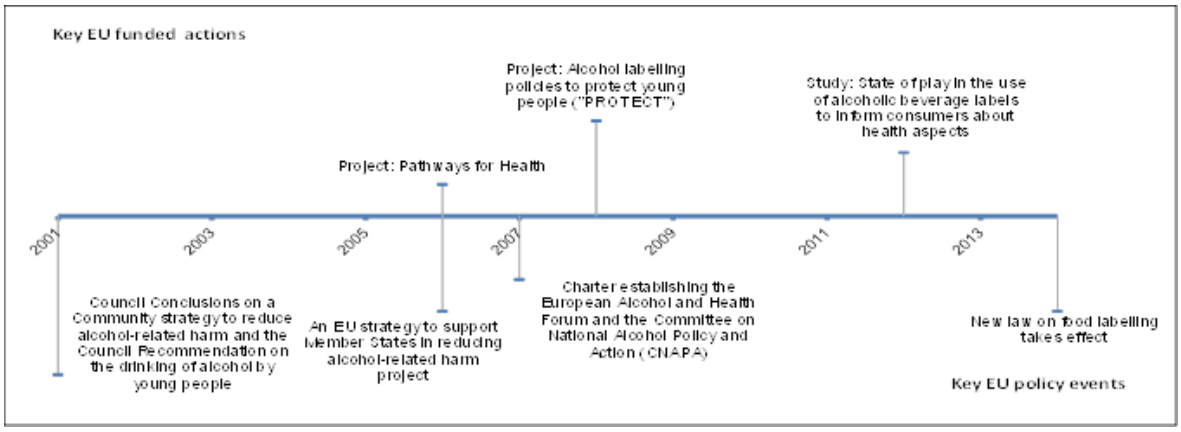
Nevertheless, EU policy on food labelling currently excludes alcoholic beverages. The EU regulates information on food labels, with new legislation passed in 2011 and in 2014 setting out requirements to take effect end 2014 and 2016 respectively.[190] The rules specify what information must be provided on labels, including a list of ingredients and mandatory allergen information, etc.[191]. Alcoholic beverages are exempt from these requirements and there are no EU regulations requiring health warnings to be provided either.[192] The 2011 legislation on food labelling included the stipulation that information requirements for alcoholic beverages are investigated and a report produced, so that, if appropriate, an accompanying legislative proposal would be produced by December 2014. (This report has been delayed and the contents of the report was not known at this stage, although according to DG SANTE, the results of the study would likely feature in the report but it will focus more on the ingredients and alcohol content).

Previous to this legislation, and following it a number of actions have been funded by the EU as part of efforts to better understand and educate consumers on the harmful effects of alcohol. Concerning labelling in particular, a project called "Pathways for Health"[193] focused – among others, on labelling of alcoholic drinks. The work included a Delphi Survey on alcohol labelling, looking at perceptions of consumer information, for example.[194] The project resulted in recommendations and conclusions including that: "Effective legislative, executive, administrative and other measures necessary to ensure appropriate packaging and labelling, should be implemented, with precise and consistent, but culturally sensitive health messages and warnings across the European Union." In 2008, a project looking specifically at "Alcohol labelling policies to protect young children" was funded and reported that only a few national governments implemented mandatory regulations, with most governments opting for voluntary rules but that it was doubtful "that the industry is really interested in implementing voluntary effective visible and legible labels with messages which aims at really

186 http://ec.europa.eu/health/alcohol/policy/index_en.htm
187 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006DC0625
188 Ibid.
189 http://ec.europa.eu/health/alcohol/forum/index_en.htm and http://ec.europa.eu/health/alcohol/committee/index_en.htm
190 http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm
191 For more information on the latest rules see: http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/docs/infographic_food_labelling_rules_2014_en.pdf
192 However, the law did require a study be undertaken looking at the case for nutritional information on alcoholic beverage labels "produce a report within 3years of the entry into force of this Regulation concerning the application of the requirements to provide information on ingredients and nutrition information to alcoholic beverages"
193 http://eurocare.org/resources/projects_database/pathways_for_health
194 http://www.dhs.de/fileadmin/user_upload/pdf/Pathways_for_Health-Project/delphisurvey_alcohol_labelling_crioc.pdf

reducing the alcohol consumption"[195]. Then, in 2012, the study on the "State of play in the use of alcoholic beverage labels to inform consumers about health aspects" was tendered and funded. This 2012 study is the subject of this case study.

Figure 46: Key milestones in relation to alcohol labelling



The annual work plan for 2012[196] made reference to the need for a "comprehensive picture" making use of "fieldwork to gather a representative sample of alcoholic beverage packages from retail outlets across the Member States to assess the effectiveness of health-related information". The ToR for this study used the same wording. The study was conducted by a market research specialist GfK, which has the capacity and expertise to conduct large scale market, with RAND, a not-for-profit research institute with expertise in health policy and a reputation for delivering objective reports as a consortium partner. The specifics of the contract are provided below.

Full name	Action to prevent and reduce harm from alcohol – Lot 2: State of play in the use of alcoholic beverage labels to inform consumers about health aspects
Acronym	EAHC/2012/Health/06 Lot 2
Funding instrument	Service Contract
Action number	20126202
HP strand	2 - Health promotion
Priority	2.2 Reduce major diseases and injuries by tackling health determinants
Sub-priority	2.2.1 Address health determinants and promote healthy lifestyles
EC contribution	€ 98,010
Actual start date	2012
Duration (in months)	Originally 7 months but extended to 9
Status	Finalised
Lead contractor	GfK Belgium, Public Services
Consortium partner	RAND

This case study is based on a review of relevant service contract documentation (including the ToR, the evaluation of the response to the ToR, the service contract,

[195] http://ec.europa.eu/chafea/projects/database.html?prjno=20081205
[196] Commission Implementing Decision (2011/C 358/06)

and service deliverables) and a series of interviews with team members of the lead company, the project officer from CHAFEA and a representative from DG SANTE.

Design

Design	Score (1-3)
Fit within programme and policy context	3
Robustness of objectives and intervention logic	2
Feasibility of implementation plan	2

The study **clearly fits within the broader EU alcohol strategy** which has at its heart to reduce the harmful effects of alcohol, including the aim to raise awareness. Specifically, the strategy states:

> "Citizens have the right to obtain relevant information on the health impact, and in particular on the risks and consequences related to harmful and hazardous consumption of alcohol, and to obtain more detailed information on added ingredients that may be harmful to the health of certain groups of consumers." [197]

In addition, as mentioned in the introduction, the 2011 legislation on food labelling- which does not include alcohol labels - included the stipulation that information requirements for alcoholic beverages are investigated and a report produced, so that, if appropriate, an accompanying legislative proposal would be produced by December 2014. As also already noted, conversations with DG SANTE revealed this report to be delayed (to be clear, the report required by this legislation is different from the study on alcohol labelling which is the subject of this case study). In addition to fitting clearly into the policy context, the study was also in line with the Health Programme objectives, specifically the objectives relating to promoting health and also distributing health information to support informed decisions.

The study set out to address a specific objective which was determined by DG SANTE and the Programme Committee, specified in the AWP for 2012 and repeated in the ToR: "The objective of the services described here is to contribute to a comprehensive picture through fieldwork to gather representative samples of alcoholic beverage packages from retail outlets across the Member States to assess the effectiveness of health information on them". The study aimed to (begin to) **fill a gap in the evidence base detailing if and how health warnings are communicated to consumers on alcohol labels in the EU**. Although surveys had been commissioned in the past[198], fieldwork of the scale and rigorousness seen under this service contract had not. In particular, the study proposed a 'mystery shopper' approach to visit retailers and collect information (photographs) to illustrate the real (rather than claimed) visibility of health warnings on alcohol labels in 15 Member States. An analysis of the results in cases where warnings were found looked at a variety of different factors, including where the health warnings were placed on the vessel; the form and size of the warning (text, logo, both); the market share of the products and packages with health information, etc. The ToR state that the study should feed into European policy. However, we note that how this will be achieved is not stipulated in the ToR nor in the offer, which although not required under the service, does present a contributing factor to the limited impact on policy realised by the study (see below section on impact).

[197] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006DC0625

[198] For example: http://ec.europa.eu/chafea/projects/database/fileref/20081205_oth-03_en_ps_health_warnings_and_responsibility_messages_on_alcoholic_beverages.pdf

In terms of the **feasibility of the implementation plans**: The ToR were clear. They left sampling considerations to the contractor, such as which countries (although a minimum of 15 was required) and retailers (the ToR asked for a 'representative' sample) would be covered. A discussion with GfK illustrated that in proposing the sample of countries, there were two primary objectives: the geographical spread across the EU in terms of cultural diversity but also a combination of the newer and older Member States. In the end, 15 out of the 27 EU Member States were covered, representing 89% of the EU population. With the benefit of hindsight, the demands of work to be conducted was highly ambitious for the time given, indeed following a decision to adjust the assessment sheets used for the fieldwork (where 25,000 labels were reviewed), an extension of the contract was required.

Implementation / outputs

Implementation / outputs	Score (1-3)
Delivery of outputs as envisaged	2
Fostering of collaboration and partnerships	2
Engagement with other actors (incl. DG SANTE / CHAFEA)	2

Both Chafea and GfK seemed to be satisfied **with how the contract was implemented** and the delivery of the outputs. The scale of the work involved, and the main finding as per the executive summary of the final deliverable is summarised below:

> "This study reports on an audit of 60 retailers across 15 European countries regarding the health-related messages that inform and educate the consumer on labels of alcoholic beverages….
>
> To conclude, only a minority of alcohol labels include health-related messages. When beverages do carry messages, there is wide divergence in their form and formatting."[199]

Ultimately, Chafea felt the final study was "well done given the budget and timeframe". DG SANTE was also satisfied with the research conducted. Although not explicitly required by the ToR, the contractors were asked to provide recommendations based on the study.

Some concerns – prompted by the critical reception of the report's conclusions at the European Alcohol and Health Forum in which key representatives include those from the alcohol industry and who have vested interests in the results of the study– that the recommendations were not sufficiently grounded in the evidence base (see also impact/results and conclusion) were mentioned. Discussions between the contractor and DG SANTE about the validity of the external criticism that was received from the alcohol industry, as well as whether the recommendations are within the scope of the service (since they are not required by the ToR), are on-going at the time of writing.

These issues point two inherent difficulties faced by the study at the outset:

- The difficultly of conducting a study in a sensitive field and with a powerful industry which is largely opposed to changes which might reduce (or risk reducing) the sale of alcohol (discussed in greater detail under results / impact)

[199] http://ec.europa.eu/health/alcohol/docs/alcohol_beverage_labels_full_report_en.pdf

- The problem with designing a study which naturally leads to recommendations but which does not explicitly require or delineate the scope of these recommendations in the ToR.

There were also **logistical challenges** worth highlighting. Firstly, the contractor was operating to a tight timetable. Chafea reported that the timeframe of 7 month was ambitious given the huge effort required to collect data and analyse a sizable quantity of data and that ultimately, and particularly in light of a change in the fieldwork (specifically changes to the assessment sheet used to assess the labels on alcoholic beverage vessels), the contract was extended by 2 months. Indeed, the contractors noted that with a study of this size, reliant on fieldwork in 15 countries, there are necessarily some logistical and management challenges. However the contractor reported that their experience enabled them to handle problems as they arose. Finally, we note that the final report details there were issues in gaining full cooperation with retailers (for example, retailers refused to cooperate) such that access was not granted in every case in some countries.[200]

In terms of partnerships, the study was the result of collaboration between GfK and RAND and drew on their separate strengths. This **collaboration reportedly worked well**. In order to carry out the field work effectively, there was a need to engage the support of shop assistants and owners. This also worked well in most (but not all) cases. In addition to the routine communication and collaboration with Chafea and DG SANTE, GfK have partaken in presentations for the European Alcohol and Health Forum involving a lot of different stakeholders such as members from the alcohol industry (this is also mentioned under "dissemination" below).[201] The study has also been presented to the 12th meeting of the Committee on National Alcohol Policy and Action.[202]

Dissemination

Dissemination activities were not foreseen in the ToR, nevertheless there were important activities in this field.

Dissemination	Score (1-3)
Identification of clear target groups	3
Effectiveness of tools and channels used	2.5
Sustainability of dissemination activities (incl. use of multipliers)	2.5

The primary **target audiences** of the study were policy makers via the Committee on National Alcohol Policy and Actions (CNAPA). A secondary target group were stakeholders (including industry representatives), for example via the European Alcohol and Health Forum. Interviewees perceived the main purpose of the study was to feed into policy discussions via these two channels. The contract for the study did not stipulate that dissemination activities would be undertaken by the contractors; rather DG SANTE would publish and share the study with relevant stakeholders.

The main **dissemination channel** was the publication of the study as a European Commission publication through the EU Bookshop, according to the European

[200] For example "Auditors were denied access based on the fact that the stores needed an authorization letter from the retailers' headquarters." See pages 29 - 32

[201] http://ec.europa.eu/health/alcohol/docs/ev_20140409_mi_en.pdf

[202] http://ec.europa.eu/health/alcohol/events/ev_20131022_en.htm

Commission's procedure[203]. Furthermore, the study was presented and discussed (by DG SANTE as well as the contractor) in relevant fora, groups and meetings (including –most recently a presentation given by the contractor at the European Alcohol and Health Forum[204]). The study was also made public on the DG SANTE website[205] and the online bookshop.

The contractor reported that they suspected the data collected were used a lot by DG SANTE. They attributed (some of) the reason for a decrease in interest *over time* to be due to the fact that the original driver commissioning the study left the unit and that this may have hampered how the study was used. DG SANTE – however – emphasised that the results of the study were being discussed and that the dissemination had proceeded according to plan.

Results / impacts

Results / impacts	Score (1-3)
Wider applicability of results	1.5
Impact on policy	1
Robustness of evaluation strategy and reporting	2

The final report provides a set of baseline findings from a sizable sample (over 25,000 labels were assessed and photographed), regarding the extent to which health warnings are used on alcohol labels. The study finds that in the majority of cases where there is no legal requirement, the industry does not present health warnings on their products. Where health warning labels do exist the type of message (i.e. whether it is about drinking during pregnancy, drinking and driving, etc,) varies, as does the visibility, the placement and clarity of the information. However, the study was designed as a "**very early starting point**" in the process of investigating alcohol labelling policy. According to DG SANTE, the study was designed to be relatively narrow in scope (i.e. did not attempt to determine what might be effective in terms of health warnings on alcohol labelling) due to the limited resources available and the complexity of the issue of how to determine the impact of information on labels (for example, the need to assess how consumers make decisions).

As noted in the minutes from the European Alcohol and Health Forum, the methodology has been criticised by the alcohol industry. Their criticism hinged on **the representativeness of the sample**: "The study was challenged by one Forum Member arguing that the study is not providing an accurate picture on the volume of the use of alcoholic beverage labels in the EU and the methodology chosen was not suitable to draw policy recommendations"[206]. The response of the contractor to this criticism was that the results should be seen in the appropriate context, as a qualitative study which presents initial conclusion as a first step for suggesting areas for further research and study[207]. Indeed, as discussed elsewhere, the criticism from the alcohol industry has to be taken in context: this body has a vested interest in

[203] http://bookshop.europa.eu/en/state-of-play-in-the-use-of-alcoholic-beverage-labels-to-inform-consumers-about-health-aspects-pbND0214432/
[204] http://ec.europa.eu/health/alcohol/events/ev_20131022_en.htm
[205] http://ec.europa.eu/health/alcohol/policy/index_en.htm under "highlights"
[206] Meeting minutes (see http://ec.europa.eu/health/alcohol/docs/ev_20141106_mi_en.pdf)
[207] "This report is not the result from weak research, but from a well-outlined and qualitatively conducted study. Furthermore, the conclusions within the report should not be seen as questionable, as they are formulated in a nuanced and tentative way. As the title of the report suggests, conclusions form a starting point for discussions and further research". Response from contractor.

downplaying the results from this study which show clearly that little information on the health impact of alcohol is routinely provided on alcohol labels.

Through our conversations with the contractors we heard that they would have seen the value in including more retailers, however given the budget and timeframe, *tough decisions on what to leave out have to be made*. Indeed, they maintained that **the study made use of a very broad sample** – across 15 Member States (accounting for 9 out of 10 consumers in the EU), with large, small/medium retailers covered, and a selection of alcohol (beer, wine, spirits and other). Nevertheless, the sample selected was not the only available option, and whether alternatives (for example based on the gross sales of different alcohol brands across the EU or in different countries) might have been even better and less open to criticism, is an important and valid question to pose.

An important measure of impact is whether policy changed as a result of the study, especially given the importance of this research in providing the groundwork and moving the discussion on alcohol labelling forward. To put this into context, DG SANTE explained that there have been delays in drawing up the report on alcohol labelling (as per 2011 legislation on food labelling) and the standstill on the direction of the broader alcohol strategy has meant that very little progress has been made in general, not just in relation to this study. Having said this, the study has generated recent discussion among stakeholders and policy makers and has meant the topic has remained relevant. While the process is on-going, it has to be said that no impact is discernible at present and that there was no indication from the information reviewed that decisive action /policy / legislation is imminent.

We emphasise again that the link between the study and policy impact was not explicitly required in the ToR and thus does not feature in the proposal or the methodology. There are clearly important external reasons why having an impact in this policy area is a significant challenge, making it all the more important that the study provides an objective and rigorously formed evidence base. Namely:

- There is a powerful industry, largely opposed to regulation in this field;
- Competency for policy dispersed over various decision-making levels; and
- Competency for policy dispersed over various domains (internal market, consumer protection, communication, health).[208]

In addition, the study was perceived by both DG SANTE and the contractors as a first step mapping the present situation, making it unrealistic to expect a large scale research study such as this to lead directly to legislation or a call for legislation.

What might – however – be reasonable to expect would be ideas or avenues for future research. Indeed, although the ToR did not require this, the contractor was asked to provide some conclusions and recommendations, sections of which are presented below:

> "It is recommended that the **development of guidelines should be informed by consumer behaviour research**, such as behavioural experiments and consumer surveys...
>
> In addition, further supply-side research could use the audit data provided by this research to explore questions relating to suppliers and producers of alcoholic beverages

[208] See Delphi study: http://ec.europa.eu/chafea/projects/database/fileref/20081205_oth-01_en_ps_delphi_study_on_labelling_from_previous_project_php.pdf

> Continued research could also **examine remaining questions in relation to alcohol labelling policy** i.e. what is the most effective policy mechanism for implementing alcohol labelling? Regulation or public-private partnership? What impacts would the presence of any labelling requirements have on Member State policy?"[209]

These conclusions and recommendations have come in for criticism from both the European Alcohol and Health Forum and DG SANTE. Both parties are concerned that there too much of a gap between the evidence and the conclusions / recommendations. This reaction (given the nuance in the recommendations, the multiple caveats and their tentative formulation) only serves to underline just how difficult it is to push for change in the area of alcohol labelling. Nevertheless, DG SANTE is presently discussing with the contractor whether or not to adjust the recommendations.

EU added value

During the review of the action outline, a panel of experts assessed the potential EU added value of the action against eight pre-defined criteria as shown in the table below. In what follows, we briefly discuss those areas with the highest potential added value, and explore to what extent this potential EU added value materialised (or is likely to materialise) in practice. A detailed explanation of the methodology for determining the scores is contained in the introduction to Annex 9.

This action did not score very highly in most areas, as would be expected given its nature: a service contract with a specific research brief. Certain EU added value areas were not applicable at all (e.g. cross border threats and free movement of persons). There are two which stood out as having a substantial potential for EU added value: implementing EU legislation and promotion of best practice.

Criteria	Average score
Implementing EU legislation	**1.7**
Economies of scale	0.5
Promotion of best practice	**2.0**
Benchmarking for decision making	1.3
Cross border threats	0.0
Free movement of persons	0.0
Networking	0.7
Unlocking the potential of innovation	0.3

Criteria 1: Implementing EU legislation

The study is a response to the call for further research into the information requirements for alcohol labelling as per the 2011 legislation on food labelling. The action supports the implementation of the Commission Communication (COM(2006) 625 final) on *An EU strategy to support Member States in reducing alcohol-related harm*. It also responds to Council conclusions of December 2009 on *Alcohol and health* (2009/C 302/07) which invites the Commission to consider further steps to protect children, adolescents and young people from alcohol-related harm. The study is clearly

[209] See final report: http://ec.europa.eu/health/alcohol/docs/alcohol_beverage_labels_full_report_en.pdf

seen as an initial step in determining the evidence of health warnings on alcohol labels and it is too early to see any concrete policy impact.

Criteria 2: Promotion of best practice

The study provides (photos of) examples, which can feed discussions on Best Practices of health warning labels on alcoholic beverages; however we note that interviewees from the Commission believed that this was not the strongest aspect of the report. Accordingly the authors of the study conclude that: "This research highlights the wide divergence in alcohol labelling in Europe. Thus, there appears to be a need for the development of guidelines or standardisation for industry in alcoholic beverage labelling and a European-wide regulation. Guidelines are needed which set out best practice in terms of the message to be conveyed, the method of communication (using text or logos), the language to be used and the presentation of the message in terms of size, position and other factors affecting clarity".

Conclusions and lessons learned

The study achieved what it set out to achieve and the contractors produced what was asked of them (and indeed more). If any criticism is levied it would mean taking a step back and questioning the ToRs and their scope. Indeed, a study aimed at providing explicit recommendations for standardised alcohol labelling could have been more beneficial but would have required significantly more resources. The more purposeful integration of the outcomes of the study in the political decision making process could have further supported the use of data gathered and their implication for European policies in this field. This is especially true given that the study conducted involves an industry with a strong lobby and which is (in general) opposed to regulation in this area. Our analysis of the situation is that to be reviewing the conclusions at this late stage – indeed after the publication of the report – implies that the Commission should have a) been clearer about what they wanted to achieve and, b) identified and flagged any concerns sooner.

10. REVIEW AND ANALYSIS OF RELEVANT MONITORING EXAMPLES IN OTHER EU AND INTERNATIONAL PROGRAMMES

In order to identify best practices and innovative monitoring methods that could be tailored to and/or applied to the HP, we conducted a systematic review of monitoring systems of comparable programmes. More concretely, we examined publicly available documentation and conducted a set of interviews[210] with individuals responsible for managing the following programmes/initiatives:

- **7th Framework Programme[211]** – EC's main instrument for funding research in Europe (now replaced by Horizon 2020)
- **European Social Fund**[212] – EC's key instrument for supporting local, regional and national employment-related projects
- **Collaborations for Leadership in Applied Health and Research and Care (CLAHRCs)**[213] –Partnerships between higher education institutions and local health services which undertake high-quality applied health research projects in the UK. It is an initiative of the National Institute for Health Research (NIHR)
- **Researchfish**[214] - Online facility that enables research funders to track the impacts of their investments, and researchers to easily log the outcomes of their work

Good practices in terms of monitoring project outputs

Based on the data gathered, we suggest exploring the applicability of the good practices identified in the comparator programmes / initiatives in order to address the following areas for potential improvements to the monitoring system of the HP:

Indicators at both programme and action-level. As has been stated in other sections of the final report, assessing the overall impact of the HP would be extremely challenging. However, the experience of FP7, ESF and CLAHRCs suggests it is still possible to agree on a common set of indicators to capture relevant outputs at programme and action level that can be used for continuous programme/action improvement. Thus, DG SANTE/Chafea should consider following the example of these other similar initiatives.

- Select and define a set of **programme-level indicators** that serve to measure important aspects of the HP's performance, like budget, funding mechanism, strand, (sub) priority, beneficiaries, geographical and organisational representativeness. The data could then be aggregated and used to keep abreast of performance and ensure alignment with priorities and objectives. The FP7's performance indicators are a good example, as they serve to measure a broad range of matters ranging from countries participation to gender equality. The example of the list of FP7 indicators is provided at the end of this document.

[210] We interviewed Researchfish's Spokesperson and Sales Director (10 February 2015), the Deputy Head of Unit A3 (Impact Assessment, Evaluation) of DG EMPL to gather data on the ESF's monitoring system (16 February 2015), and the Assistant Director of Policy at Universities UK to gather data on the CLAHRC programme (16 February 2015).
[211] http://ec.europa.eu/research/fp7/index_en.cfm
[212] http://ec.europa.eu/esf/home.jsp
[213] http://www.clahrcpp.co.uk/#!about/cgem
[214] https://www.researchfish.com/

- The periodicity of reporting against these indicators would also have to be explored. There are merits to the idea that the data on the programme-level indicators is submitted throughout the year (e.g. on a quarterly basis) by the partners/Chafea and not only at the end of the reporting year. This would allow Chafea to detect and quantify any deviation from initial plans and targets in advance and take the necessary corrective measures.

- Select and define a number of **action-level indicators** that would serve as example to partners of what types of outputs/outcomes are expected from their actions. Given that the HP funds a wide and varied range of actions, not all of the indicators would suit every action. However, partners could still be provided with a list of desired output/outcomes (for example, for each financing mechanism) from which they could select the ones that are most appropriate to their specific actions. If this is taken forward, it is important that DG SANTE/Chafea also provide definitions for each indicator, as well as an explanation of how it should be measured (e.g. how to count event participants) in order to ensure that the data can be aggregated and is comparable.

- **Develop/adopt an electronic monitoring system.** The current multiplicity of data sources and formats in which the HP's monitoring data is collected, as well as the fact that certain information is stored by DG SANTE and not Chafea, limits the ability of these organisations to use the information consistently. This inhibits them from capturing well the outputs/outcomes of the HP and from communicating effectively on results. From our knowledge, the EC does not have an electronic monitoring system that could be used by the HP to compile and analyse its monitoring data.[215] Thus, DG SANTE/Chafea could consider using an existing (but external) system such as Researchfish, which is a simple to use permissions-based interface with a comprehensive reporting capability replacing lengthy and expensive data cleaning, organising and analysis. Further details on this system are provided below.

- **Establish quality checks for the information submitted by partners**. Currently, there seem to be no specific rules or processes aimed at reviewing or validating the data reported by partners. This is particularly important if the data is to be used for communication and dissemination purposes either internally or externally. Both the interviewees from the ESF and Researchfish mentioned that one of the key strengths of electronic monitoring systems is that they include processes for automatically validating the data and avoiding partners/beneficiaries from entering wrong or misleading information.

- **Provide partners with resources for effective monitoring and reporting.** This could include monitoring guidelines with definitions of programme and action-level indicators, reporting requirements and guidelines, examples of effective monitoring reports, ad hoc support for data collection and validation, among others. The ESF, for example, provides MS (which are the ones responsible for submitting Annual Implementation Reports) with a guidance

[215] The type of systems used by the FP7 (i.e. CORDIS) and the ESF (i.e. SFC - System for Fund Management in the European Union) are not suited to the HP. In fact, CORDIS and SFC are not *monitoring systems* strictly speaking. These are mainly *information systems*. CORDIS is the EC's primary public repository and portal to disseminate information on all EU-funded research projects and their results in the broadest sense. The SFC's main function is the electronic exchange of information concerning shared fund management between MS and the EC and currently applies to the European Regional Development Fund, European Social Fund, Cohesion Fund, European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund, among others.

document for the monitoring and evaluation of projects[216], a list of ex ante conditionalities regarding statistical systems and result indicators that the MS should fulfil in order to apply for funding[217], and a data support centre data assists MS with data collection, recording, storage, and transmission of structured data to the EC.

- **Request partners to continue reporting on results even after the end of the funding period**. This would allow the HP to collect information on outcomes and impact that may only be realised long after the end of the funding cycle. We learned from Researchfish that the UK Medical Research Council (MRC) asks researchers to report on results of the funded projects (using Researchfish) during the next 5 years after the end of the funding period. If they fail to do this, they are not allowed to get further funding from the MRC. DG SANTE/Chafea could consider implementing a similar scheme.

Good practices with a view to improving dissemination

In order to facilitate the take-up and use of the actions' results, it is important that the partners themselves identify and engage with the relevant actors for mobilising the knowledge or tools that they have generated. This is more important than the dissemination that can be done at programme level. *"The actual change happens at the local level"* said the CLAHRC's representative and explained that it is the 13 CLAHRCs themselves who are the engines for securing the implementation of their research results and for mobilising that knowledge broadly. It seems appropriate for most dissemination activity to continue to take place within the framework of individual actions. However, based on the experience of the organisations reviewed during this exercise, there are a number of options for ensuring that this happens as effectively as possible:

- **Link the monitoring and dissemination systems**. It is important that both the EC and partners, as well as any other actor involved in dissemination of the HP-funded activities and results (e.g. NFPs, organisations that co-fund the actions and the new communication framework contract holder) are able to use the reported data for developing information products that can be disseminated more broadly. Implementing an electronic monitoring system such as Researchfish would allow having a single entry point for all interested parties for viewing, analysing, and building on monitoring data. Further details on the system are provided below.

- **Include a geographical dimension to the dissemination of information**. It would be important that relevant stakeholders at national level (e.g. policy-makers, health professionals, researcher organisations, etc.) can access information on actions being implemented in each country. This could be complemented with other information (coming from the monitoring system) such as key topics in each country, key researchers/organisations, etc. The ESF, for example, has a database of projects on its website which can be accessed in the form of a map or list of projects grouped under different themes.[218]

[216] http://ec.europa.eu/social/main.jsp?catId=325&langId=en&moreDocuments=yes

[217] If a MS cannot fulfil the specified ex ante conditionalities, they have to develop an action plan that would allow them to meet all requirements by 2016, year when the first Annual Implementation Report is due.

[218] http://ec.europa.eu/esf/main.jsp?catId=46&langId=en

- **Keep encouraging partners to disseminate key results of the funded actions in a targeted way.** DG SANTE/CHAFEA should continue asking partners for a dissemination plan that clearly identifies the main target audiences, as well as the tools/channels for reaching them. The CLAHRC experience shows that, in terms of take-up and actual use of research results, it is central that researchers/partners involve and engage with: public health service providers, practitioners (i.e. health and social care professionals), and patients, in addition to national/local policy-makers. An effective dissemination strategy for these groups implies having a good understanding of their interests and information needs.

- **Help partners to develop simple messages and information products** such as the CLAHRCs' BITEs (Brokering Innovation Through Evidence) or the CORDIS's Results in Brief.[219] These are 'need to know' summaries of research findings or project outcomes aimed at supporting the exploitation of results. They are a useful way of disseminating 'bite-sized' evidence to non-specialised audiences.[220] DG SANTE/Chafea could either ask all partners to produce such information products by the end of the funding cycle or identify topics which may generate a broader interest (e.g. cardiovascular disease, diabetes, drug use, end of life care, etc.) and ask the relevant partners to work on such information products on an ad hoc basis. The new communication framework contract holder could be in charge of this and provide partners with a template, guidelines and ad hoc support. It could also help to translate it to various languages. NFPs could also assist in the dissemination of this product.

- **Improve the HP's project database by including information on progress made and results**. DG SANTE/CHAFEA could populate the database easily with information coming from the monitoring system regularly (e.g. quarterly). If all partners where required to develop and submit an information product on the funded action as the one described above, this could also be uploaded in the database.

- **Consider a broader use of tools such as press kit, newsletters, key data and figures, success stories and social media**. These are dissemination tools found in all the programmes and initiatives reviewed.

- **Provide support/guidelines/templates to partners in relation to how to disseminate and present results**. This could be requested to the new communication framework contract holder.

[219] BITEs can be accessed here: http://www.clahrcpp.co.uk/#!bites/c19df. Examples of the Results in Brief can be found here: http://cordis.europa.eu/result/rcn/155968_en.html

[220] CORDIS is the EC's primary public repository and portal to disseminate information on all EU-funded research projects (funded via the different Research Framework Programmes and, now, Horizon 2020) and their results in the broadest sense. *Results in Brief* are written by CORDIS's science editors based on each Report Summary (these are summaries of the periodic and final reports submitted by the project participants and approved by the EC's projects). In the case of the *BITEs*, these are produced by the CLAHRCs themselves.

What is Researchfish?

It is the system used by the UK's Medical Research Council (MRC) to collect information on the outputs, outcomes and impact of MRC-funded research. MRC-funded researchers are asked to record these data all year-round and, once a year, to formally submit this information to the MRC. A federated version of the system was created in 2012, allowing it to be used by multiple funders to collect comparable research outputs. There are currently over 100 funders and 50,000 researchers using Researchfish in the UK, Denmark and Canada.

The advantages of using a system like Researchfish:

It would allow DG SANTE/CHAFEA to…

- ✓ Implement a **harmonised approach** to collecting output information suitable for all HP-funded actions across all health fields. This would help DG SANTE/CHAFEA to obtain a common qualitative and quantitative view of the progress, productivity, quality and impact of the actions they support. A system like this one would replace the HP's annual/interim/final reporting process with a simple online experience accessible to partners (and any other interested parties) on an on-going basis.

- ✓ Have **a single entry point** for collecting and analysing monitoring data. The system could be accessed by DG SANTE, CHAFEA project officers, and partners (as well as by any other relevant actor such as NFPs, organisations that co-fund the actions or the new communication framework contract holder). The system works with various types of permissions in order to grant complete or restricted access to the different organisations.

- ✓ Use a set of **pre-defined output and outcome indicators**, and complement these with an additional set of specific questions/indicators that can be easily added to the monitoring dashboard. Researchfisch's pre-defined output and outcome indicators for projects were developed and validated by researchers currently using Researchfish.

- ✓ Reduce the **reporting burden** by providing partners with a system where they can upload consistently and quickly the information on their actions. The system also has automatic mechanisms for validating the data and minimising the effects of misleading information or misreporting. If the actions' co-funders are also given access to the system, partners would be able to report once. In addition, reports/summaries of progress could be downloaded from the system by CHAFEA or partners themselves and be used for developing information products to disseminate more broadly (or to populate CHAFEA's database of project).

- ✓ Regularly **monitor/scrutinise** aspects that have been pointed out as relevant in this evaluation. For example, participation of institutions from different MS, dissemination activities developed by project partners, collaborations generated with organisations beyond the consortium, if partners have explicitly mentioned the HP co-funding in any publications[221], if the action is linked (or is a continuation) of a prior action funded by the HP or any other EU funding programme, if it has attracted further funding (from the EC or any other funder), among others. This would help to identify gaps and areas for improvement on an on-going basis.

[221] A bibliometric analysis on the reported HP-funded journal articles and reviews could then provide information on the citation rate of these publications.

- ✓ Produce **monitoring reports** that can range from simple graphs, to detailed analysis of an output and impact indicators (e.g. influence on policy), without the arduous task of collating outputs manually from partners' individual reports.

- ✓ Track **results** even after the end of the funding period (if partners were requested to continue entering the information for, for example, the next 5 years)

- ✓ Use the data collected through Researchfish to produce **information products** (e.g. project reports, programme/project brochures, key data and figures, newsletters, press releases) that could be disseminated on the HP's website, as well as on Cordis (in the case of health-related research projects)

Cost of the system: It works by subscription. Pricing is based on a % of grant funding available. For a programme with a budget of 1 million pounds a year, the price would be around 600 pounds a year. On a budget of 10 million pounds the price would increase to 6,000 pounds a year.

Researchfish brochure: http://rf-downloads.s3.amazonaws.com/Researchfish-Brochure-v2_6_1.pdf

Example of a report generated with information and data provided by Researchfish: http://www.mrc.ac.uk/documents/pdf/Introduction/

FP7 Programme Level Indicators

INDICATOR / ISSUE	SUB-INDICATOR	MAIN DATA SOURCE
Promotion of FP7	1.1 Nr of information days	Annual NCP Survey
	1.2 Nr of attendees at information days	Annual NCP Survey
	1.3 Commission organised meetings of NCPs	DG RTD
Perfomance of the calls	2.1 Success rates overall and by Specific Programme	CORDA
	2.2 Success rates in terms of proposals, applicants, project costs, EU contribution by Specific Programme	CORDA
	2.3 Success rate per country	CORDA
Performance of the proposal evaluation and redress procedure	3.1 Overall quality assessment of the proposal evaluators on the FP proposal evaluation process	Annual Evaluators' Survey
	3.2 Assessment of quality by the evaluators between the FP evaluation process and other equivalent systems	Annual Evaluators' Survey
	3.3 Time-to-grant	CORDA
	3.4 Redress cases upheld (i.e. leading to a re-evaluation) – numbers and percentages	DG RTD
Quality of on-going research projects	4.1 Average results of independent project review process	SESAM
	4.2 Percentage of projects covered by reviews	SESAM
Project performance by outputs	5.1 Average number of publications per project	SESAM
	5.2 Average number of open access publications per project	SESAM
	5.3 Average number of new patent applications per project	SESAM
FP activity	6.1 Total number of active projects by Specific Programme	CORDA
	6.2 Average financial size of projects by Specific Programme	CORDA
	6.3 Participation by types of organisation by Specific Programme	CORDA
	6.4 Participation totals per country	CORDA

INDICATOR / ISSUE	SUB-INDICATOR	MAIN DATA SOURCE
Achieving gender equality	7.1 Number of male and female coordinators in proposals	CORDA
	7.2 Number of male and female coordinators in projects	CORDA
	7.3 Gender breakdown (by seniority) of project participants	CORDA
	7.4 Percentage of male and female members in Advisory Groups and Programme Committees	DG RTD
Observing sound ethical principles in FP research	8.1 Number of projects going through the ethics review process by Specific Programme and theme	DG RTD
	8.2 Number of ethics reviews where the result showed insufficient attention had been given in proposal	DG RTD
	8.3 Number of projects stopped as a results of the ethics review	DG RTD
	8.4 Number of ethics screenings	DG RTD
Performance of international cooperation activities	9.1 Total numbers of participations of Third Countries by priority area and funding scheme	CORDA
	9.2 Success rates of Third Countries	CORDA
	9.3 EU contribution to Third Countries	CORDA
Simplification	10.1 Do stakeholders perceive that the FP is getting simpler to use in terms of financial and administrative procedures?	Annual NCP Survey
	10.2 How do stakeholders find the ease of use of the FP, compared to similar international research actions and large national schemes?	Annual NCP Survey
	10.3 Are there any aspects of FP procedures which are adversely affecting to a significant extent the quality of research carried out and the quality of participation in the FP?	Annual NCP Survey

Source: Sixth FP7 Monitoring Report, 7 August 2013, Annex A

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