

17 December 2013

A potential ERIC on Health Information

Scoping paper

for considerations of EU Member States and EEA/EFTA countries
in the Expert Group on Health Information

This document was produced for information purposes to the discussion in the Expert Group on Health Information (EGHI) meeting held 22 January 2014. It does not represent an official position of the Commission on this issue, nor does it anticipate such a position.

Table of contents

1. Introduction	2
2. EU context and societal challenges	3
3. General objective of a health information ERIC	5
4. Tasks and activities of the health information ERIC	7
5. Governance	11
5.1. Organisation of an ERIC	11
5.2. Membership	11
5.3. A proposal for the governance structure of the potential health information ERIC	12

Working document

1. Introduction

The idea of the health information European Research Infrastructure Consortium (ERIC) was first presented to the Expert Group on Health Information (EGHI) on 29-30 May 2013. As a result of a brainstorming during the meeting an Ad-hoc Core working group on potential ERIC on health information was established. Since then this group has met twice¹, and once in a limited format² to facilitate a drafting of key tasks and activities for this scoping paper.

Currently the Ad hoc Core working group includes the following countries: Belgium, Germany, Finland, France, Italy, Latvia, Malta, the Netherlands, Poland, Romania, Portugal, Spain, Sweden and Norway, and experts involved in the following projects: ECHI, COPHES, EHES, EHLEIS, EuroREACH, JAMIE, EUBIROD, EURO-PERISTAT, EUROCISS, DISMEVAL, ECHO, EUprimecare, EuroHOPE and CHICOS. An ERIC is not a continuation of projects. The involvement of these experts does not a priori include or exclude any health information task or activity. Additional elements could be considered at any time of the process. The final decision on the proposed scope will be with the applicants for the ERIC, i.e. Member States.

An ERIC on health information as a sustainable and comprehensive option for the future health information and monitoring system at EU level was also presented to the Council Working Party on Public Health at Senior Level³. Moreover, **Council conclusions on the "Reflection process on modern, responsive and sustainable health systems" adopted on 10 December 2013**⁴ under the Lithuanian Presidency of the Council of the EU **invite the Commission and Member States to** *"cooperate with a view to establishing a sustainable and integrated EU health information system, built on what has been already achieved through different groups and projects, such as ECHI-ECHIM projects, **exploring in particular the potential of a comprehensive European health information research infrastructure consortium as a tool**".* The same Council conclusions welcome *"further development and consolidation, while avoiding duplication of work, of a health monitoring and information system at EU level based on the European Core Health Indicators (ECHI) and existing health monitoring and reporting systems developed as a result of a cooperation between Member States supported by the Programmes of Community Action in the field of Health"*.

The **aim of this document** is to outline the possible **scope** of the potential ERIC for discussion of Member States and EEA/EFTA countries in EGHI in January 2014. The scope excludes elements that at EU level are covered by other existing bodies and agencies, such as the European Centre

¹ 5 July and 7 November 2013

² 10 December 2013: Meeting of Subject clusters under the EGHI Ad hoc Core Working Group on the potential ERIC on health information

³ See Council document 12985/1; Available at:

<http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%2012985%202013%20INIT&r=http%3A%2F%2Fregister.consilium.europa.eu%2Fpd%2Fen%2F13%2Fst12%2Fst12985.en13.pdf>

⁴ Available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/140004.pdf

for Disease Prevention and Control (ECDC) in the area of communicable diseases, the Joint Research Centre in the area of cancer, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Finally, the establishment of an independent ERIC will support the European Statistical System and the leading role of Eurostat in the resource intensive process of data collection.

Member States and EEA/EFTA countries will be asked to give their opinion on the proposed scope and:

- identify any immediate gaps, and
- grade tasks proposed in this scoping paper⁵.

The document contains also some elements considered relevant for discussions on the structure of the potential health information ERIC. The aim of this document is not to outline financial implications.

2. EU context and societal challenges

In accordance with Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities. The Union shall complement and support national health policies, encourage the cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the national authorities for shaping their health policies and organising and delivering health services and medical care. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.

In order to respond effectively to population health and health systems' challenges, health policy must be based on the best scientific evidence derived from sound data and information, and relevant research.

Additionally, structured health information could support several policy areas even beyond the health sector. As an example of such synergies it is worth highlighting that consumer product safety regulatory policy, standardisation and market surveillance activities could receive important information from data collection related to accidents/injuries and their causes.

In the past years several EU funded projects have been working towards the development of harmonised methods that would allow for comparable evidence in the field of health. The results

⁵ See Annex 1

from these projects, although positive, have also demonstrated that there are still methodological gaps and differences in the collection and analysis of data between geographical areas, which invites for further research in the field.

Providing appropriate health information means providing different types of information responding to different objectives. A good foundation for overall monitoring of health in the EU is the system of European Core Health Indicators (ECHI). But other/additional information is relevant to adequately respond to pertinent policy needs and societal challenges. The tasks of the health information ERIC should answer to information and data needs in the five broad policy areas defined under the ECHI-framework: (1) health services and healthcare, (2) ageing of population, (3) health determinants, (4) diseases and mental health, and (5) health in all policies.

The response to these needs, i.e. health information ERIC should take into account the following criteria⁶:

- a 'knowledge management' approach with greater focus on analysing, disseminating and applying health information at EU and national levels, including customising information to specific users and issues and ensuring feedback on how useful it is in practice in bringing about improvements in health;
- setting priorities for EU health information in order to help measure progress towards improving healthy life years, focusing on the largest parts of the burden of ill-health such as chronic diseases, mental health, and accidents and injuries and their causes;
- developing further information regarding the key determinants of ill-health (in particular tobacco, alcohol, nutrition, physical activity, as well as determinants of mental health) and facilitating research on interventions to address them;
- developing better information on healthcare quality and outcomes, as well as better information on the efficient and effective use of innovations in healthcare;
- including in all above mentioned priorities key cross-cutting issues, such as better regional information, inequalities, specific population groups such as children and the elderly, and providing information not only about problems but also key elements of best practice in how to address them.
- More recently health systems performance assessment has been discussed in different EU fora. The health information ERIC can serve any "common EU health systems performance assessment framework" to be agreed at EU level with Member States, but it is not its role to replace the process of defining such a framework. Defining this framework is currently on-going as part of other processes, i.e. the Reflection process on sustainable health systems and the development of an assessment framework on health based on the Joint Assessment Framework methodology in the Social Protection Committee.

⁶ Based on: http://ec.europa.eu/health/strategy/docs/ev_20090428_rd01_en.pdf

3. General objective of a health information ERIC

The health information ERIC aims to build a sustainable research infrastructure to support the generation of evidence and methods that will support health policy development at national and at EU level.

The health information ERIC will link individual researchers and their networks in the area of public health and health systems by:

- Building a highly accessible data and information base to support research that provides better evidence for health policy preparation and evaluation.
- Coordinating and supporting work by international expert networks that perform policy relevant data collections and analyses in their countries or at EU level.

These analyses will consist of trend analyses and comparisons, as well as performance assessments of prevention and care. These aim to add explanations to observed trends and variations in important aspects of public health and health systems in the EU, its Member States and their regions. This will result in generating better evidence for policy preparation and evaluation and to enable the identification and exchange of good practices and policies.

Priority areas for data collection, analysis and reporting and for methodology development will be determined and taken up by the health information ERIC in close collaboration with Member States and with possible funding sources, including various EU programmes. The work taken up by the health information ERIC will in this way become adequately attuned to existing policy needs and priorities.

The ERIC as an open and flexible international organisation will be able to support different international actors, such as OECD, WHO and EC in the development of indicators. This will contribute to further harmonisation of health indicators and help avoiding unnecessary differences between those indicators.

For certain areas and activities to be taken up by the consortium, the health information ERIC can build on previous work from EU funded projects. Future EU-sponsored projects could work in cooperation with the ERIC in order to find synergies and ways of complementing each other's activities, to avoid unnecessary divergence in concepts and methodologies, and to avoid duplication of activities or ineffective use of resources.

The scientific and research work taken up by the health information ERIC will include the following general and horizontal aspects:

- *Indicator development and analysis to support health policy preparation and evaluation*

This means a development of indicators that allow regular comprehensive comparative research on relevant aspects of public health and health systems performance.

- *Developing expertise and capacity building for health research, and improving data quality*

By working towards common methodologies the ERIC will support the spread and development of health sciences expertise. The knowledge and expertise on data quality, comparability and methods of collection can support capacity building where needed. This will be facilitated by providing training and guidance.

- *Collecting and hosting data, metadata and information, building repositories*

European Health Indicator Repository: The ERIC will host and disseminate relevant background documentation that relates to the quality and availability of the preferred sources and definitions for the ECHI-indicators as well as other indicators in the ERIC. It will provide access to information on the progress of work on indicators by other international organisations.

European Health Data Repository: Take up and host health datasets, including archiving and disseminating the related background documentation. In these ways the ERIC will enable the international health research community to access and to control or redo previous studies and benefit from methods and quality improvements on datasets that have already been performed.

It will support and undertake the dissemination of national and international datasets at the most disaggregated level with the aim to provide research data for international comparative studies and for tentatively computing new indicators.

European Health Project Outcome Repository: Outcomes from EU funded projects in the area of population health and health systems can be stored and disseminated by the ERIC. Examples are definitions, standards and guidelines related to data collections developed in such projects. The ERIC could also act as interface to facilitate the overcoming of ethical and legal issues related to the use of these data.

- *Facilitate the building and maintenance of European expert research networks*

A central strategic element in the ERIC work will be to build on existing high quality expert networks, with proven EU added value and take up research in areas that need sustainable action and repeated assessments. Active data collections will, however, only take place in areas where such data are not collected as regular surveys or statistics. New data collected should provide added EU value such as information on specific thematic areas. Good examples are 'accidents and injuries', 'perinatal health'.

- *Reporting, Communication and Interpretation*

The ERIC will prepare reports about all relevant aspects of its work, communicate them to relevant stakeholders and assist in the interpretation of the results.

4. Tasks and activities of the health information ERIC⁷

In order to implement the general objectives described in Chapter 3 **the health information ERIC should provide infrastructure and scientific basis for the following tasks:**

1. Population health and health systems monitoring by using common validated indicators;
2. Harmonized population based health examination surveys;
3. Monitoring of impacts of environmental chemicals to health;
4. Monitoring and reporting of perinatal and child health;
5. Platform for population based registries for diseases;
6. Platform for injury surveillance;
7. Platform for Clinical and Administrative data on Health Care;
8. Establishing standards and approaches for clinical and administrative health data collection and data sharing between countries;
9. Support monitoring and evaluation of health care systems in interested countries.

Activities under individual tasks are as follow:

1. Population health and health systems monitoring by using common validated indicators

- *Activities*
 - Define work plan for indicators' development, e.g. further development and consolidation of ECHI list, update quality and availability of indicators, deficit analysis, evaluate existing indicators, identify relevant, valid, feasible and actionable indicators for all levels of care;
 - Maintain a network of national experts on health indicators;
 - Structure the core set of agreed indicators according to a common multidimensional health systems' evaluation framework.

2. Harmonized population based health examination surveys

- *Activities*
 - Produce standardized and comparable health indicators for major chronic disease risk factors (such as obesity, hypertension, high cholesterol and diabetes) at the population

⁷ The starting point for defining individual tasks and activities of health information ERIC should be the existing knowledge and tools. Besides, the activities of Eurostat in health statistics, of the Joint Research Centre in the European cancer information system, of the European Centre for Disease prevention and Control in non-communicable diseases surveillance and information, as well as other EU bodies and agencies as far as relevant should always be considered in order to avoid duplication.

level;

- Establish a system for management of standardized data;
- Prepare and develop standardized survey protocols for new measurements of interest;
- Establish laboratory quality control systems.

3. Monitoring of impacts of environmental chemicals on health

- *Activities*

- Develop prioritisation schemes for substances to be monitored;
- Coordinate biomarker and analysis methods development;
- Develop guidelines /standards for survey protocols;
- Provide Tools/Manuals/Training for field work, communication, data protection and ethical issues;
- Establish a system for management of standardized data.

4. Monitoring and reporting on perinatal and child health

- *Activities*

- Improve perinatal and child health information systems, e.g. improve data availability and comparability, manage list of indicators;
- Prepare regular Perinatal and Child Health Reports;
- Establish a system for management of standardized data.

5. Platform for population based registries for diseases

- *Activities*

- Facilitate the methodology development of population based registers on e.g. CVD, diabetes and other non-communicable diseases not yet covered;
- Scientific and technical support for data collection by these registries;
- Establish a system for standardized data management.

6. Platform for injury surveillance

- *Activities*

- Elaborate Guidelines and Manuals for setting up injury surveillance in countries;
- Develop harmonized injury data capture methodology and classification;
- Ensure regular reporting on data and trends;
- Establish a system for standardized data management.

7. Platform for Clinical and Administrative data on Health Care

- *Activities*

- Identify and classify the content and type of all data sources (statistics, administrative

data, disease registers, observational studies and surveys) at different levels (national/regional, local, provider and individual level);

- Provide a conceptual basis and information management infrastructure to support the analyses of available data;
- Integrate information contributed from all data sources.

8. Establishing standards and approaches for clinical and administrative health data collection and data sharing between countries

- *Activities*

- Defining common protocols for a harmonized construction of selected indicators;
- Work with interested countries in order to assess the impact of different data models.

9. Support monitoring and evaluation of health care systems in interested countries

- *Activities*

- Support identification, assessment and implementation of a common set of methods to be routinely applied for the evaluation of health care systems (healthcare performance, evaluation of health care policies, impact of interventions, etc.);
- Structure an effective procedure for public reporting to be translated into different user profiles;
- Aid interpretation through an objective presentation of strengths and limitations of the results obtained, working along with relevant stakeholders to identify the beneficial uses and reduce misinterpretation of health care information;
- Enable countries to apply the aforementioned methodological approaches, through a validated open-source set of tools.

Relevance of tasks for monitoring defined policy areas*

TASKS	HEALTH SERVICES AND HEALTH CARE			AGEING AND POPULATION			HEALTH DETERMINANTS		DISEASES AND MENTAL HEALTH			HIAP
	Sustainable health care system	Health system performance, Quality of care, Efficiency of care, patient safety	(Planning of) health care resources and health care cost	Health ageing, Ageing population	Maternal and perinatal health	Child health	Health inequalities (including accessibility of care)	Preventable health risks and lifestyle, health behaviour (incl young adults)	Non-communicable diseases (NCD), Chronic Diseases	(Preventable) Burden of Disease (BoD) and health threats, communicable diseases	Mental health	Health in all policies
1. Population health and health systems monitoring by using common validated indicators	X	X	X	X	X	X	X	X	X	X	X	X
2. Harmonized population based health examination surveys							X	X	X	X		X
3. Monitoring of impacts of environmental chemicals to health					X	X	X	X	X	X		X
4. Monitoring and reporting on perinatal and child health					X	X	X	X	X	X	X	X
5. Platform for population based registries for diseases	X	X	X	X	X	X			X	X		
6. Platform for injury surveillance			X	X		X	X	X			X	X
7. Platform for Clinical and Administrative data on Health Care	X	X	X		X				X			
8. Establishing standards and approaches for clinical and administrative health data collection and data sharing between countries	X	X	X		X				X			
9. Providing harmonised indicators, methods and tools to support monitoring and evaluation of health care systems in interested countries	X	X	X									

* Policy table based on: http://ec.europa.eu/health/indicators/docs/echi_shortlist_by_policy_area_en.pdf

5. Governance

This Chapter provides some information on organisation and membership of an ERIC based on the legal framework for a European Research Infrastructure Consortium. Finally it includes the initial proposal for the governance structure of the potential health information ERIC.

5.1. Organisation of an ERIC⁸

Article 12 of the Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium⁹:

*The Statutes shall provide for **at least the following bodies** having the following competencies (a) **an assembly of members** as the body having full decision-making powers, including the adoption of the budget; (b) **a director or a board of directors**, appointed by the assembly of members, as the executive body and legal representative of the ERIC. The Statutes shall specify the manner in which the members of the board of directors legally represent the ERIC.*

5.2. Membership¹⁰

Article 9 of the Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium¹¹:

1. *The following entities may become members of an ERIC:*

- (a) Member States;*
- (b) associated countries;*
- (c) third countries other than associated countries;*
- (d) intergovernmental organisations.*

2. *The membership of an ERIC must include **a Member State and two other countries that are either Member States or associated countries**. Further Member States or associated countries may join as members at any time on fair and reasonable terms specified in the Statutes and as observers without voting rights on conditions specified in those Statutes. Third countries other than associated countries as well as intergovernmental organisations may also become members of an ERIC, subject to approval by the assembly of members referred to in Article 12(a), in accordance with the conditions and procedure for changes in membership laid down in its Statutes.*

⁸ Legal framework for a European Research Infrastructure Consortium – ERIC Practical Guidelines; Available at: http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=eric1

⁹ Available at: http://ec.europa.eu/research/infrastructures/pdf/council_regulation_eric.pdf

¹⁰ Legal framework for a European Research Infrastructure Consortium – ERIC Practical Guidelines: http://ec.europa.eu/research/infrastructures/pdf/eric_en.pdf#view=fit&pagemode=none

¹¹ As amended by COUNCIL REGULATION (EU) No 1261/2013 of 2 December 2013 amending Regulation (EC) No 723/2009 concerning the Community legal framework for a European Research Infrastructures Consortium (ERIC); Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:326:0001:0002:EN:PDF>

3. Member States or associated countries shall hold jointly the majority of the voting rights in the assembly of members. For an ERIC hosted by a Member State, proposals for amending its Statutes shall require the agreement of the majority of the Member States that are members of that ERIC.

In practice, expertise on research matters is often concentrated in legal entities which are separate from the State and for example the representation of a State by a research organisation is quite common in existing international facilities. Article 9(4) allows such representation of members of an ERIC by one or more public entities (including regions) or private entities with a public service mission.

The terms of such representation depend on the specific mandate a member wishes to give to one or several such entities and should be clearly communicated to the other members of the ERIC, especially as regards eventual voting rights.

An ERIC may foresee **observers**, which may be Member States, associated countries or intergovernmental organisations.

5.3. A proposal for the governance structure of the potential health information ERIC

5.3.1. General Assembly

The General Assembly is the body having full decision-making powers where all full members are represented. Each member carries one vote.

The General Assembly shall convene at least once a year, and shall at least appoint, suspend or dismiss the Executive Director, decide on strategies for the construction and use of the ERIC, approve the annual work programme and annual budget, approve annual reports and accounts; approve each member's contribution, approve accession of new members and observers (if those will be foreseen in the ERIC); decide on termination of membership and observer status; decide on ending of the ERIC.

The General Assembly may establish subsidiary bodies if deemed necessary for the functioning of the ERIC as for example:

Scientific Board (optional)

The members of the Scientific Board shall be appointed by the General Assembly for a limited duration determined by the General Assembly. Its role shall be advisory. It shall consist of high-level researchers who are independent. The Scientific Board shall provide input to the General Assembly through solicited and unsolicited advice on strategic issues, including but not limited to vision, new initiatives, work programme(s) and quality assurance.

5.3.2. Executive director

The Executive Director is appointed by the General Assembly for a fixed duration determined by the General Assembly. The Executive Director shall act as the Chief Executive Officer and legal representative of the ERIC. The Executive Director shall be responsible for the implementation of the health information ERIC and for supporting the General Assembly to which it shall be accountable.

Among others the Executive Director will be in charge of the execution of the work programme and expenditure of the budget; set the agenda of the General Assembly meetings and prepare its deliberations; prepare a draft annual work programme, including a draft budget, provide the General Assembly with the annual report, including financial accounts.

The Executive Director will be the interface of the General Assembly with the Committee of (National) Coordinators. The Executive Director will be responsible to regularly brief the Committee on the implementation of the health information ERIC and consult it on the work programme, including as appropriate strategic issues and new initiatives.

Management Committee

The Management Committee shall be established by the Executive Director and shall consist of the coordinators of the individual hubs of the ERIC (thematic hubs and technical hubs providing common services).

The Management Committee shall be responsible for contributing to and supporting the Executive Director in the development of a draft annual work programme and a draft budget and in the execution of the work programme. It shall be responsible for supporting the ERIC and the (national) coordinators.

Support office

The Support office shall be daily operations office and shall assist the Executive director and the Management Committee.

5.3.3. Committee of (National) Coordinators

The Committee of (National) Coordinators shall act as an Advisory Committee to the Executive Director and should be the forum for consultation and advice on health information activities at EU level that are not limited only to the members of the ERIC. The Committee of (National) Coordinators shall be chaired by the Executive Director. The Support office will act as the Secretariat to the Committee of (National) Coordinators.

This Committee should help preventing inequalities in health information between countries. The Committee should help avoiding duplication of activities at national or international level and it

should contribute to implementation of the health information ERIC, including in those countries that are not full members of the ERIC.

It will meet back to back with EGHI meetings. Ideally the nominated national representatives of EGHI shall also be the nominated national coordinators, acting as the main liaison between the health information ERIC and their country.

In case of intergovernmental organisations the representatives would be called “coordinators”. The coordinator shall act as the main liaison between the ERIC and the operational unit(s) of the organisation concerned.

Working document

Annex 1

Grading table of tasks of the potential health information ERIC according to their relevance

Tasks	Should this task be included in the health information ERIC		If yes, please grade according to your priorities: 1 - Very important 2 - Important 3 - Desirable
	YES	NO	
1. Population health and health systems monitoring by common validated indicators			
2. Implementation of harmonised population based health examination surveys			
3. Monitoring and detection of impacts of environmental chemicals to health			
4. Monitoring and reporting of perinatal and child health			
5. Platform for population based registries for diseases			
6. Platform for injury surveillance			
7. Platform for Clinical and Administrative data on Health Care			
8. Establishing standards and approaches for clinical and administrative health data collection and data sharing between countries			
9. Support monitoring and evaluation of health care systems in participating countries			