
# Study on cost-benefit analysis of reference laboratories for human pathogens

CIVIC CONSULTING

Public Health

*June 2016*

**EUROPEAN COMMISSION**

Consumers, Health, Agriculture and Food Executive Agency
Health Unit

*Contact:* Cinthia Menel Lemos

*E-mail: cinthia.menel-lemos@ec.europa.eu*

*European Commission*
*B-1049 Brussels*

EUROPEAN COMMISSION

# Study on cost-benefit analysis of reference laboratories for human pathogens

Consumers, Health, Agriculture and Food Executive Agency
Health Programme 2008-2013, WP 2014 priority 3.2.2. Study on cost-benefit of reference laboratories for human pathogens under the Health security strand

2016 EUR 4862 EN

***Europe Direct is a service to help you find answers to your questions about the European Union.***

**Freephone number** (*)**:**

**00 800 6 7 8 9 10 11**

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).



More information on the European Union is available on the Internet (http://europa.eu).

Luxembourg: Publications Office of the European Union, 2016

| | | | |
|---|---|---|---|
| PDF | ISBN 978-92-9200-721-8 | doi:10.2818/959846 | EB-02-16-620-EN-N |



*PRINTED IN*

PRINTED ON ELEMENTAL CHLORINE-FREE BLEACHED PAPER (ECF)

PRINTED ON TOTALLY CHLORINE-FREE BLEACHED PAPER (TCF)

PRINTED ON RECYCLED PAPER

PRINTED ON PROCESS CHLORINE-FREE RECYCLED PAPER (PCF)

# Table of Contents

# List of abbreviations

| | |
|---|---|
| AST | Antimicrobial Susceptibility Testing |
| BSL-3 | Biosafety level 3 |
| BSL-4 | Biosafety level 4 |
| CCHF | Crimean-Congo haemorrhagic fever |
| CHAFEA | Consumers, Health, Agriculture and Food Executive Agency |
| CNRL | Community Network of Reference Laboratories for Human Influenza in Europe |
| COMPARE | Collaborative Management Platform for detection and Analyses of (Re-) emerging and foodborne outbreaks in Europe |
| DG SANTE | Directorate General for Health and Food Safety |
| DNA | Deoxyribonucleic Acid |
| EC | European Commission |
| ECDC | European Centre for Disease Prevention and Control |
| EEA | European Economic Area |
| EFSA | European Food Safety Authority |
| EISN | European Influenza Surveillance Network |
| EISS | European Influenza Surveillance Scheme |
| EMERGE | Efficient response to Highly Dangerous and Emerging Pathogens at EU Level (follow-up to QUANDHIP) |
| EMLab | European Mobile Laboratory Project |
| ENIVD | European Network for Diagnostics of "Imported" Viral Diseases |
| EPIS | Epidemic Intelligence Information System |
| EQA | External Quality Assessment |
| EQuATox | Establishment of Quality Assurances for the Detection of Biological Toxins of Potential Bioterrorism Risk |
| ERINHA | European Research Infrastructure on Highly Pathogenic Agents |
| ERLI-Net | European Reference Laboratory Network for Human Influenza |
| ERLTB-Net | European Reference Laboratory Network for TB |
| EU | European Union |
| EUCAST | European Committee on Antimicrobial Susceptibility Testing |
| EUR | Euro |
| EU-RL | European Reference Laboratory |
| EURLOP | EU Human Pathogen Reference Laboratories Options Report |
| EU-RL VTEC | European Union Reference Laboratory VTEC |
| FP7 | EU 7$^{th}$ Framework Programme for Research |
| FWD-Net | Food and Waterborne Disease Zoonoses Network |
| FZB | Research Center Borstel |
| GISRS | Global Influenza Surveillance and Response System |
| HHTK | Hand-Held Test Kits |
| HIP | Highly Infectious Pathogens |
| HP | EU Health Programme |
| I-MOVE | Influenza-Monitoring Vaccine Effectiveness Network |
| INMI | L. Spallanzani National Institute for Infectious Diseases |
| INSA | Instituto Nacionald e Saúde Doutor Ricardo Jorge |

| | |
|---|---|
| INSERM | Institut National de la Santé et de la Recherche Médicale |
| ISCIII | Instituto de Salud Carlos III |
| ISS | Istituto Superiore di Sanità |
| MALDI-TOF | Matrix Assisted Laser Desorption Ionization Coupled to Time of Flight |
| MERS-CoV | Middle East Respiratory Syndrome Coronavirus |
| MS | EU Member State |
| MTA | Material Transfer Agreement |
| NCE | National Center for Epidemiology, Hungary |
| NIB | Network on Highly Pathogenic Bacteria |
| NIHP | Norwegian Institute of Public Health, Norway |
| NIV | Network on Highly Pathogenic Viruses |
| NIZP | National Institute of Public Health – National Institute of Hygiene, Poland |
| NRL | National Reference Laboratory |
| NTM | Non-Tuberculous Mycobacteria |
| PCR | Polymerase-Chain-Reaction |
| PFGE | Pulsed-Field Gel Electrophoresis |
| PHAS | Public Health Agency of Sweden |
| PHE | Public Health England |
| PM | Person-Months |
| PREPARE | Platform for European Preparedness Against (Re-)emerging Epidemics |
| PUM | Philipps Universität Marburg, Germany |
| QUANDHIP | Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens |
| RIVM | National Institute for Public Health and the Environment, the Netherlands |
| RKI | Robert-Koch Institut |
| RM | Reference Materials |
| SarsCoV | Severe Acute Respiratory Syndrome Coronavirus |
| SOP | Standard Operational Procedures |
| SSI | Statens Serum Institut |
| STEC | Shiga Toxin-Producing E. *coli* |
| TB | Tuberculosis |
| TESSy | The European Surveillance System |
| TFEU | Treaty on the Functioning of the European Union |
| VTEC | Verotoxigenic E.coli |
| WHO | World Health Organisation |
| WHO-NIC | National Influenza Centres of the WHO |
| WP | Work Package |

## Abstract

*At present, there is no EU-wide system for reference laboratory networks for human pathogens that would consolidate operating standards of microbiological reference laboratories or provide resilience when significant cross-border outbreaks occur. The purpose of this study is to provide a cost-benefit analysis and analysis of regulatory options to strengthen the existing coordination of reference microbiology provision in the EU in order to support the European response coordination to outbreaks of pathogenic infectious agents. The scope for the analysis was set inter alia by identifying and characterising in detail the functions and activities of EU reference laboratory networks relevant for consideration. A set of key types of costs and benefits specific to EU reference laboratory networks was developed to guide the data collection, which was based on a set of case studies corresponding to existing reference laboratory networks or projects. The results of this study indicate that the benefits (monetary and non-monetary) of maintaining a formally-defined overarching system of EU reference laboratory networks are likely to outweigh costs, both in a Member State and in an EU perspective. The study also identified several issues that will need to be addressed in the further process of creating such a system, including the need for adequate reference laboratory infrastructure at national level; the need to provide sustainable funding, including for emergency situations; the need to consolidate the focus of the existing networks, e.g. by grouping diseases or networks with similar areas of expertise; the need to harness relevant technological improvements; and the need to choose the coordination options most suitable in specific cases*.

# 1. Introduction

*This report is the final deliverable of the study on cost-benefit analysis of reference laboratories for human pathogens.*

## 1.1 Objectives of the study

As per the Terms of Reference (TOR), the purpose of the study is to provide a cost-benefit analysis and analysis of regulatory options to strengthen the existing coordination of reference microbiology provision in the EU in order to support the European response coordination to outbreaks of highly pathogenic infectious agents.

The study will complement the findings of the European system of reference laboratories for human pathogens (EURLOP) project.

Specifically, the cost-benefit analysis will provide evidence based information aiming to support a regulatory proposal for options to establish and implement arrangements to reinforce the coordination of the existing networks of laboratories for human pathogens, including dangerous bio-toxins in the EU.

## 1.2 Scope of the study

As per the TOR, the cost-benefit analysis will cover the laboratory coordination activities of EU-RLs and include emerging and novel pathogens which might cause serious threats to health, potentially with cross-border relevance.

The cost-benefit analysis will cover the coordination options identified in the EURLOP study. Adaptation of these options is possible as well as development of new options on the basis of new lessons learned from recent events and a nuanced model applied to the four options proposed by the EURLOP study.

## 1.3 Structure of the report

The report is structured as follows:

- Section 2 presents the an overview of microbiology reference laboratories in the EU;
- Section 3 presents the methodology of the study;
- Section 4 presents the case study reports;
- Section 5 presents the analysis of costs;
- Section 6 presents the analysis of benefits; and
- Section 7 presents the conclusions.

# 2. Microbiology reference laboratories in the EU

*This section presents an updated overview of existing reference laboratories for human pathogens in the EU, including a detailed mapping of key reference laboratory networks.*

## 2.1 Existing networks of European reference laboratories

Since 1999, Decision 2119/98/EC[1] and its implementing measures connect public health authorities in the EU Member States and the Commission in order to coordinate EU-wide surveillance and early warning and response (Commission Decision 2000/57/EC)[2] to health threats caused by communicable diseases. Specifically, early warning and response coordination at EU level is ensured through the use of the Early Warning and Response System (EWRS), a confidential computer system allowing Member States to send alerts about events with a potential impact on the EU, share information, and coordinate their response.[3] In October 2013, the existing framework for preparedness and response to health emergencies in the EU was strengthened by the adoption of Decision 1082/2013/EU, which expanded its coverage to preparedness planning, risk assessment, risk management and risk communication aspects of all serious cross-border threats to health caused by communicable diseases, antimicrobial resistance and healthcare-associated infections, as well as other harmful biological agents and chemical and environmental events.

European epidemiological surveillance is conducted through disease networks that report data to the European Centre for Disease Prevention and Control (ECDC) on a regular basis.[4] Surveillance data is gathered from Member States by the ECDC using the European Surveillance System (TESSy), a metadata-driven system for collection, validation, cleaning, analysis and dissemination of data.[5] Some 47 communicable diseases and two special health issues are currently covered by EU legislation (see table below).[6]

[1] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.
[2] Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council.
[3] http://ec.europa.eu/health/communicable_diseases/early_warning/index_en.htm.
[4] http://www.ecdc.europa.eu/en/activities/surveillance/Pages/index.aspx.
[5] http://www.ecdc.europa.eu/en/activities/surveillance/TESSy/Pages/TESSy.aspx.
[6] Annex I of Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, as amended by Decisions 2003/534/EC, 2003/542/EC, 2007/875/EC, 2009/312/EC, 2009/539/EC and 2012/492/EU; see http://ec.europa.eu/health/communicable_diseases/early_warning/comm_legislation_en.htm and http://ecdc.europa.eu/en/publications/Publications/1111_SUR_Annual_Epidemiological_Report_on_Communicable_Diseases_in_Europe.pdf.

**Table 2. List of communicable diseases and special health issues for EU surveillance**

| Disease category | Diseases |
|---|---|
| Diseases preventable by vaccination | Diphtheria, Infections with haemophilus influenza group B, Influenza – including influenza A(H1N1), Measles, Mumps, Pertussis, Poliomyelitis, Rubella, Smallpox, Tetanus |
| Sexually transmitted diseases | *Chlamydia* infections, Gonococcal infections, HIV infection, Syphilis |
| Viral hepatitis | Hepatitis A, Hepatitis B, Hepatitis C |
| Food- and waterborne diseases and diseases of environmental origin | Anthrax, Botulism, Campylobacteriosis, Cryptosporidiosis, Giardiasis, Infection with enterohaemorrhagic *E.coli*, Leptospirosis, Listeriosis, Salmonellosis, Shigellosis, Toxoplasmosis, Trichinosis, Yersinosis |
| Diseases transmitted by non-conventional agents | Transmissible spongiform encephalopathies (Variant Creutzfeldt–Jakob's disease) |
| Airborne diseases | Legionellosis, Meningococcal disease, Pneumococcal infections, Tuberculosis, Severe Acute Respiratory Syndrome (SARS) |
| Zoonoses | Brucellosis, Echinococcosis, Rabies, Q fever, Tularaemia , Avian influenza in humans, West Nile virus infection |
| Serious imported diseases | Cholera, Malaria, Plague, Viral haemorrhagic fevers |
| Special health issues | Nosocomial infections, antimicrobial resistance |

*Source: Annex I of Commission Decision 2000/96/EC.*

While EU epidemiological surveillance is conducted through disease networks coordinated by the ECDC and reporting requirements are laid down in the International Health Regulations (IHR),[7] to which all Member States are signatories, there is, at present, no EU-wide system for harmonising operating standards of microbiological reference laboratories so as to ensure, for example, the inter-comparability of laboratory results (through quality control, certification, accreditation, etc.) or to provide resilience when significant cross-border outbreaks occur.[8]

The absence of a formal EU-wide network system for public health reference laboratories is closely related to the existing legal framework. While Article 168 of the Treaty on the Functioning of the European Union (TFEU) provides the basis for Union to encourage cooperation between Member States in the sphere of public health, it specifically excludes any interference in the definition of health policy by the Member States and in their organisation and delivery of health services and medical care. Although Member States are obliged to report cases of the 47 diseases (and two special health issues) covered by EU legislation, the EU is not mandated to define the means by which this surveillance and reporting takes place.
In this respect, the legal situation in the field of public health differs greatly from that for food/ feed safety and animal health, where the TFEU grants the EU a strong

[7] The International Health Regulations (IHR) are an international legal instrument that is binding on 196 countries across the globe, including all the Member States of WHO. The IHR, which entered into force on 15 June 2007, require countries to report certain disease outbreaks and public health events to WHO. Building on the experience of WHO in global disease surveillance, alert and response, the IHR define the rights and obligations of countries to report public health events, and establish a number of procedures that WHO must follow in its work to uphold global public health security (see: http://www.who.int/topics/international_health_regulations/en/).
[8] http://www.ehfg.org/fileadmin/ehfg/Website/Archiv/2011/Presentations/W1/w1_11_parry.pdf.

mandate to act.[9] In both of these areas, an EU-wide reference laboratory network system has been enshrined in Regulation 882/2004, which requires Member States to nominate one or more reference laboratories for a number of food/feed safety and animal health issues. For each of these issues one of the national reference laboratories (NRLs) is contracted to function as an EU reference laboratory (EU-RL), whose tasks include providing the other NRLs with staff training and information on analytical methods, organising proficiency tests and assisting the Commission in technical and scientific questions. The EU-RLs submit a work programme each year demonstrating their performance of these functions, with funding provided on this basis.[10]

For human pathogens, by contrast, the situation in the EU is currently characterised by NRLs working without formally agreed EU-wide capability or mechanism for rapidly responding in a coordinated manner to new and emerging infectious threats.[11] Notably, the "European system of reference laboratories for human pathogens" (EURLOP) project found that EU coordination of reference laboratories for human pathogens is insufficiently robust for some communicable diseases.[12] It noted that although a large number of microbiology networks or projects exist – according to the EURLOP project there are more than 70 microbiology networks, consortia and research groups in place across the EU – these suffer from a lack of funding and are highly diverse in terms of scope, organisation and membership. It also identified the lack of an EU-wide accreditation policy for reference microbiology laboratories as a key weakness.

For the most part, existing networks and consortia of reference laboratories are overseen and/or organised by DG SANTE, the ECDC, the EFSA and the WHO, as well as non-governmental bodies such as the European Society of Clinical Microbiology and Infectious Diseases (ECSMID). In 2013, the ECDC was responsible for coordinating 14 microbiology networks or projects.[13] These were in place for antimicrobial resistance surveillance, Carbapenemase-producing Enterobacteriaceae, Clostridium difficile infection surveillance, "imported" viral diseases, food- and waterborne diseases and zoonoses, Creutzfeldt-Jakob disease surveillance, Legionnaires' disease, influenza, gonococcal antimicrobial surveillance, diphtheria surveillance, invasive bacterial diseases surveillance, pertussis, tuberculosis and antimicrobial susceptibility testing. Two particularly well-established EU-wide laboratory networks coordinated by the ECDC are the European Reference Laboratory Network for Human Influenza (ERLI-Net) and European Reference Laboratory Network for Tuberculosis (ERLTB-Net).

The coordination/governance structure of the above-mentioned networks is diverse. Only in three cases is the ECDC directly responsible for coordination activities (antimicrobial resistance, food- and waterborne diseases, diphtheria), while in other cases responsibility for coordination is outsourced. Furthermore, even where networks are directly coordinated by the ECDC, reference laboratory functions (such as external quality assessments (EQAs)) are subcontracted. EQA services for verocytotoxin-producing Escherichia coli (VTEC), for example, are outsourced by the Food- and Waterborne Disease Network (FWD-Net) to the Statens Serum Institut (SSI) in Denmark. Reference functions may be taken over by a single contractor or split between different laboratories, with the structure that is deemed necessary for a particular network dependent on a number of factors relating to the disease in

[9] According to Articles 38, 114 and 168 (4)(b).
[10] http://ec.europa.eu/food/safety/official_controls/legislation/ref-labs/index_en.htm.
[11] http://www.ehfg.org/fileadmin/ehfg/Website/Archiv/2011/Presentations/W1/w1_11_parry.pdf.
[12] Health Protection Agency *et. al.*, *EU Human Pathogens Reference Laboratories Options Project – EURLOP: Final Report*,
[13] ECDC, ECDC Microbiology Activity Report 2013, 2015.

question, such as pathogenicity and frequency of occurrence.[14] This is an issue that has also been noted by the EURLOP project, which has not argued for a single model for all communicable diseases, but instead stressed the need for various options.[15]

There is also significant variation in the focus of and activities carried out by the various networks and projects coordinated by the ECDC. Some of these are responsible only for a small number of activities, such as the European Antimicrobial Resistance Surveillance Network (EARS-Net), whose activities are limited to the provision of EQA and advice/technical guidance (in addition to network coordination). However, the majority carry out several other activities, such as training, strain collection, supranational reference services, laboratory support to outbreak response, molecular typing, laboratory capacity/capability assessment and microbiology technology assessment.[16] Several EU laboratory networks with a focus on emerging pathogens are currently in operation, including the European Network for Diagnostics of "Imported" Viral Diseases (ENIVD). In addition, the “Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens” project (QUANDHIP), was launched in 2011, although it has now come to an end.

An overview of key reference laboratory networks in the EU is provided in the following table, summarising the results of the mapping exercise conducted in the framework of this study. It is based on a review of relevant reports and other documentation (including those published on networks’ websites), as well as interviews with the coordinators of several of the networks and other relevant stakeholders, and provides a detailed overview of existing coordination structures of reference laboratories in Europe.

[14] Based on information retrieved from exploratory interview with ECDC.
[15] Health Protection Agency *et al.*, *EU Human Pathogens Reference Laboratories Options Project – EURLOP: Final Report*, 2011.
[16] ECDC, ECDC Microbiology Activity Report 2013, 2015.

**Table 1. Key reference laboratory networks or projects in the field of public health**

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| European Network for Diagnostics of "Imported" Viral Diseases (ENIVD)(a)(b)(c) | 67 network members, covering all EU Member States, Norway, Switzerland, Serbia, Albania, Kosovo, Bosnia and Herzegovina, Macedonia | 1995 | "Imported" Viral Diseases (e.g. Yellow Fever, West Nile, Chikungunya) | ▪ Network coordination activities<br>▪ External quality assessment<br>▪ Training<br>▪ Supranational reference services<br>▪ Laboratory support to outbreak response<br>▪ Molecular typing<br>▪ Advice and technical guidance<br>▪ Laboratory capacity/capability assessment<br>▪ Microbiology technology assessment | In 2013, laboratory network coordination activities were outsourced to the Robert Koch Institut (RKI). These activities included organising the annual meeting, the website and the directory of laboratory contacts. The RKI also provided the 2013 EQA. | ECDC |
| European Influenza Surveillance Network (EISN)(d)(e) | Consists of experts from laboratories in all 28 EU Member States plus Norway and Iceland | 2008, although its predecessor (the European Influenza Surveillance Scheme, EISS) was founded in 1996 | Influenza-like illnesses (ILI) and acute respiratory infections (ARI) | Epidemiological and virological influenza surveillance, with the following objectives:<br>▪ Strengthen and support national surveillance systems<br>▪ Standardise EU-wide surveillance activities<br>▪ Improve comparability of data<br>▪ Reduce the complexity of surveillance systems<br>▪ Enhance insight into communicable disease epidemiology in Europe | The EISN consists of operational contact points for influenza epidemiology and virology. These are nominated by the national public health authority in each participating country. In communicating with Member States, the EISN utilises National Focal Points, which are responsible for overseeing interactions between the ECDC and individual Member States regarding activities related to the disease. Virological surveillance is coordinated through the European Reference Laboratory Network for Human Influenza (ERLI-Net). | ECDC |

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| European Reference Laboratory Network for Human Influenza (ERLI-Net)(c)(d)(f) | 38 laboratories covering all 28 EU Member States plus Norway and Iceland | 2003 (as CNRL, renamed ERLI-Net in 2013) | Influenza-like illnesses (ILI) and acute respiratory infections (ARI) | ▪ Network coordination activities<br>▪ External quality assessment<br>▪ Strain collection<br>▪ Supranational reference services<br>▪ Laboratory support to outbreak response<br>▪ Molecular typing<br>▪ Advice and technical guidance<br>▪ Laboratory capacity / capability assessment | In 2013, laboratory network coordination activities were outsourced to a coordination group, a consortium consisting of the following institutions: Public Health England (PHE, UK), the National Institute of Public Health and the Environment (RIVM, NL) and the MRC National Institute for Medical Research (NIMR, UK). These activities included organising the website and updating the repository of tests in use (FluLabCap). The 2013 EQA was provided by PHE. | ECDC |
| European Tuberculosis Surveillance Network(d)(f)17 | Experts from all 53 countries that make up the WHO European Region, among these 30 EU/EEA Member States | EuroTB was set up in 1996 , Health Programme (DG-SANCO) | Tuberculosis | ▪ Collects, validates, analyses and disseminates European TB surveillance data to describe the epidemiology of TB and monitor progress towards its elimination<br>▪ Key findings from surveillance and monitoring activities are published in annual reports<br>▪ Aims to improve data collection methods | European TB surveillance network members from EU/EEA countries electronically submit their national data to the European Surveillance System (TESSy) database hosted by the ECDC. Network members from the remaining countries in the region report to the WHO Tuberculosis Monitoring and Evaluation (TME) database. Network meetings take place once a year. | ECDC |

[17] http://opac.invs.sante.fr/doc_num.php?explnum_id=5166

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| European Reference Laboratory Network for TB (ERLTB-Net)(g)(h) | 33 laboratories covering EU/EEA countries | 2010 | Tuberculosis and selected other nontuberculous mycobacteria | ▪ Network coordination activities<br>▪ External quality assessment<br>▪ Training<br>▪ Strain collection<br>▪ Supranational reference services<br>▪ Laboratory support to outbreak response<br>▪ Typing<br>▪ Advice and technical guidance<br>▪ Laboratory capacity/capability assessment | In 2013, laboratory network coordination activities were outsourced, with Public Health England (PHE) as the lead coordinating partner. These coordination activities related primarily to organising the annual meeting. Two other coordinating centres complement the PHE by assuming responsibility for other functions: EQAs by the Research Centre Borstel (Germany), and training by the San Raffaele Scientific Institute (Italy). The 2013 EQA was provided by PHE and INSTAND Borstel. | ECDC |
| EUVAC-Net(d)18 | All 28 EU Member States plus Iceland, Liechtenstein and Norway | Founded in 2004, and in 2011 incorpora-ted into the ECDC. | Selected vaccine-preventable diseases (including measles, rubella, mumps) | ▪ Surveillance of measles with a view towards eliminating it from Europe<br>▪ Surveillance of other childhood vaccine-preventable diseases namely pertussis, rubella (and congenital rubella syndrome), mumps and varicella<br>▪ Mapping of laboratory performance for pertussis, measles and rubella | The epidemiological activities were carried out by the ECDC through the European Surveillance System (TESSy) in collaboration with Member States. The development and strengthening of laboratory-based activities for surveillance of pertussis were contracted to the EUpertstrain network of the National Institute for Health and Welfare based in Turku, Finland. Activities relating to laboratory diagnostic performance for measles and rubella were carried out in close collaboration with the Virus reference Department at the Centre for Infections, Health Protection Agency in London, UK. | ECDC |

[18] http://ecdc.europa.eu/en/healthtopics/vaccine-preventable-diseases/euvac/Pages/index.aspx

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| European Diphtheria Surveillance Network (EDSN)(d)19 | 32 institutions across all 28 EU Member States plus Norway, Iceland and Liechtenstein | 2005 by the Health Programme | Diphtheria diseases caused by toxigenic C. diphtheriae and C. ulcerans | ▪ Network coordination activities<br>▪ External quality assessment<br>▪ Training<br>▪ Supranational reference services<br>▪ Advice and technical guidance | In 2013, laboratory network coordination activities were outsourced to Public Health England (PHE). These activities included organising the annual meeting and hosting the database (outside of ECDC). The 2013 EQA was organised by PHE. | ECDC, although it is unclear if there are any other sources of funding. |
| EU Reference Laboratories for food and feed safety, and animal health and live animals(i)(j)(k) | One national reference laboratory (NRL) from each Member State.[20] *(the entry in the row below is provided as an example).* | The general tasks and require-ments of EU-RLs for food and feed and for animal health are laid down in Regulation 882/2004. | Varies according to network | ▪ Provide NRLs with analytical methods and diagnostic techniques, and coordinate their application<br>▪ Train NRL staff and experts from developing countries<br>▪ Assist the Commission scientifically and technically e.g. when EU countries contest results of analysis<br>▪ Collaborate with the competent laboratories in non-EU countries<br>▪ Assist actively in the diagnosis of animal disease outbreaks in the EU | The networks of NRLs are co-ordinated by selected EU-RLs, which are responsible for setting EU-wide standards. | EU-RLs receive annual EU funding to fulfil their tasks and functions and cover their operational costs (Decision 2009/470/EC) |

[19] http://www.dipnet.org/

[20] The following EU-RLs were identified as relevant for the 47+2 diseases/special health issues: EU-RL for Avian Influenza, EU-RL for monitoring bacteriological and viral contamination of bivalve molluscs, EU-RL for Campylobacter, EU-RL for Parasites, EU-RL for E. Coli, EU-RL for Listeria, EU-RL for Salmonella, EU-RL for transmissible spongiform encephalopathies, EU-RL for Bovine Tuberculosis, EU-RL for Brucellosis, EU-RL for equine disease other than African Horse Sickness, EU-RL for Rabies, EU-RL for Antimicrobial resistance

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| EU-RL network in the field of food and feed for Escherichia coli, including Verotoxigenic E. Coli, (Istituto Superiore di Sanità)(l)(m) | 42 (41 NRLs and one EU-RL), covering all EU Member States, Iceland, Norway, Republic of Macedonia, Turkey, Switzerland, Serbia | The Istituto Superiore di Sanità was designated as Reference Laboratory for VTEC starting from 2006. | Escherichia coli, including Verotoxigenic E. coli (VTEC) | ▪ Co-operation with international organisations and NRLs<br>▪ Development of diagnostic methods<br>▪ Production and collection of reference materials and methods<br>▪ Organisation of proficiency tests and ring trials<br>▪ Collaboration with laboratories responsible for E. coli infections in third countries<br>▪ Technical and scientific support to the Commission | The network consists of 41 NRLs coordinated by one EU-RL (the Istituto Superiore di Sanità). The EU-RL was selected on the basis of a tendering process by the European Commission.<br>NRLs are appointed by their competent national authority. | EU-RLs receive annual EU funding to fulfil their tasks and functions and cover their operational costs (Decision 2009/470/EC) |
| Food- and Waterborne Diseases and Zoonoses Network (FWD-Net)(c) | 91 nominated experts for Salmonella, 26 laboratories conducting activities for Salmonella[21] | 2007 | Salmonella, Shiga toxin-producing E. coli, Listeria monocytogenes | ▪ EQA<br>▪ Training<br>▪ Strain collection<br>▪ Supranational reference services<br>▪ Laboratory support to outbreak response<br>▪ Molecular typing<br>▪ Advice and technical guidance | The FWD-Net is coordinated directly by the ECDC, although specific functions such as EQAs are outsourced through open calls for tender. | ECDC |

[21] Only network members whose activities relate to Salmonella are indicated here.

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| Statens Serum Institut (SSI) – effective EU-RL for VTEC in the field of public health(w)(x) 22 | 28 countries took part in the fourth ECDC EQA exercise for typing of verocytotoxin- producing E. coli (VTEC) | Current contract covers the period 2012-2016 | Escherichia coli, including Verotoxigenic E. coli (VTEC), and others | ▪ Organisation of an EQA exercise for PFGE<br>▪ O:H serotyping<br>▪ Virulence gene detection<br>▪ Subtyping of vtx genes and common phenotypic traits of VTEC, including ESBL production | In 2012, the SSI was subcontracted by the ECDC's Food- and Waterborne Diseases Network (FWD-Net) to provide microbiological characterisation services in regard to Salmonella, Shiga toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) and Listeria monocytogenes | ECDC |
| European Research Infrastructure on Highly Pathogenic Agents (ERINHA)(n) 23 | 20 partners and 13 associated partners from 15 countries across Europe | The preparatory phase began in 2010. | Highly infectious pathogens (Risk Group 4) | ▪ Provision of open access to state-of-the-art BSL-4 facilities for the European scientific community<br>▪ Supporting participating national BSL-4 facilities in the event of surge requirements<br>▪ Promoting harmonization of biosafety & biosecurity procedures<br>▪ Developing standards for diagnosis, training and the management of biological resources<br>▪ Assisting Member States with the design, construction, operation and maintenance of BSL-4 capacity<br>▪ Provision of guidance on the safe movement of infectious and non-infectious biological materials | It was foreseen that ERINHA would be established as an integrated European research infrastructure coordinated and operated by a Central Co-ordinating Unit, and based on contributions of autonomous BSL-4 laboratories in Member States. Each existing or newly built participating BSL-4 facility would ensure that part of its capacity and capability is available to ERINHA, allowing the infrastructure to respond to all potential BSL-4 activities that may not be covered by one single site. Access to the ERINHA infrastructure would be organised through the Central Co-ordinating Unit. | Horizon 2020 |

[22] While this entry does not relate to a network, the SII is subcontracted by the ECDC's Food- and Waterborne Diseases Network (FWD-Net) to perform a number of reference laboratory functions. It is included here for reference purposes, as one of the case studies assesses the costs and benefits of EU-wide microbiology reference provision for VTEC (see Section 4.1).
[23] http://www.erinha.eu/

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| Quality Assurance Exercises and Networking on Detection of Highly Infectious Pathogens (QUANDHIP) (o) (p)(q)(z) | 37 laboratories from 21 EU Member States, Norway, and Switzerland | Founded in 2010. It ended in 2015 and its activities have been largely taken on by the EMERGE Joint Action network[24]. | High threat bacteria (Risk Group 3) and high threat viruses (Risk Group 4) | ▪ Aimed to create a permanent consortium that links up and unites highly specialised and advanced laboratories across Europe<br>▪ This was meant to enhance exchange of diagnostic strategies to support a joint European response to outbreaks of highly pathogenic infectious agents<br>▪ The project provided a supportive European infrastructure and strategy for external quality assurance exercises (EQA), training, and biosafety/biosecurity quality management | The project aimed to link two pre-existing networks, the European Network for Highly Pathogenic Bacteria (ENHPB) and European Network of P4 Laboratories (ENP4Lab). It was co-ordinated by the Robert Koch Institut (RKI) and the Lazzaro Spallanzani National Institute for Infectious Diseases (INMI). Activities were organised through meetings, audio-conferences and working groups for specific topics. | QUANDHIP was co-funded by the Health Programme (HP) of the European Union |
| Euro-GASP(c)(r) | In 2012, nominated contact points for STI surveillance from twenty EU/EEA countries. | Unclear | Neisseria gonorrhoeae | ▪ Network coordination activities<br>▪ External quality assessment<br>▪ Training<br>▪ Strain collection<br>▪ Supranational reference services<br>▪ Laboratory support to outbreak response<br>▪ Molecular typing<br>▪ Advice and technical guidance<br>▪ Laboratory capacity / capability assessment | In 2013, laboratory network coordination activities were outsourced to Public Health England (PHE) and Örebro University Hospital. These related primarily to organisation of the annual meeting. The 2013 EQA was organised by UK-NEQAS. | ECDC, although it is unclear if there are any other sources of funding. |

[24] Joint Action EMERGE: http://www.emerge.rki.eu/Emerge/EN/Home/Homepage_node.html

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| EpiSouth plus(s)(t) | Institutes of Public Health and/or the Ministries of Health of 27 Countries (11 EU, 16 non-EU) | Started in 2009, terminated in 2013 | No specific pathogens named | ▪ Establishment of a Mediterranean Regional Laboratories Network<br>▪ Promotion of common procedures in interoperable Generic Preparedness and Risk management<br>▪ Enhancing Mediterranean Early Warning functions allowing alerts and Epidemic intelligence information sharing among EpiSouth countries<br>▪ Production of a strategic document, with guidelines based on assessments and surveys, aimed at facilitating IHR implementation | National focal points were appointed in each country and were expected to actively participate in the project. In addition, the project was organised into various work packages, which each had a work package leader and steering committee. An overall Steering Committee (constituted by all WP leaders) and the Project General Assembly (constituted by all participants) were responsible for the general strategic decisions. Finally, an Advisory Board, constituted by representatives of the collaborating institutions and external experts, provided support for the preparation of relevant documents and recommendations. | Health Programme funding DG SANCO – now DG SANTE – , EuropeAid, the ECDC and various national institutions (in particular the Italian Ministry of Health). |

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| Medilab-secure(v) | 19 participating non-EU countries, plus 4 EU partners | 2014 | Emerging human and animal pathogens | ▪ Create a framework for collaboration to improve surveillance and monitoring of emerging vector borne viral diseases (arboviruses)<br>▪ Provide training for public health experts in participating countries to increase the communicable disease control in the Mediterranean and Black Sea region<br>▪ Promote knowledge development and transfer of biosafety best laboratory practices | The project is led by the Institut Pasteur and will be counselled by an Advisory Board composed of international experts. The project is divided into five work packages: coordination, communication and dissemination; animal virology; human virology; medical entomology; public health. There is a steering team and an advisory board. | EuropeAid / DEVCO |
| EMLab - European Mobile Laboratory Project(u)25 | 12 partners or associated partners in 9 EU and non-EU countries. | 2011 | Epidemic-prone infectious diseases | The project makes available three deployable mobile laboratory units for the detection and diagnosis of infectious pathogens up to the highest risk group 4 to respond to outbreaks in Europe and Africa. Specific activities include:<br>▪ Preparing equipment<br>▪ Compiling test assays<br>▪ Training and workshops<br>▪ Simulation exercises and mock deployments<br>▪ Outbreak missions<br>▪ Collaboration and meetings | The project is coordinated by the Bernhard-Nocht-Institute for Tropical Medicine (BNITM) in Hamburg, Germany. Laboratory units will be hosted by partners, two in Africa and one in Europe. Scientists from the two African institutions will be hosted in European research facilities for extensive training. | EuropeAid / DEVCO |

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

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| European Network of BSL-4 Laboratories (Euronet-P4)(y) | Six partner institutions from five EU countries, plus three other laboratories that participate as observers. | 2005. It has been merged into QUANDHIP, NIV. | Risk group 4 infectious agents | ▪ Establish a coordinated and accessible BSL-4 infrastructure<br>▪ Review current laboratory capability for RG-4 agents and disseminate best practice<br>▪ Facilitate the development of new hazard-free diagnostic tests e to be transferred to other non-BSL-4 laboratories in all Member States<br>▪ Establish communication channels for information exchange<br>▪ Standardize policies/procedures of biosafety and biosecurity | The network involved six partner institutions, with the addition of three other laboratories which were not funded by the grant, but were involved in the planning or construction of new European BSL-4 facilities, and participated in network activities as observers. Project results were presented and discussed in meetings that were held twice yearly, bringing together partners and observers. | Health Programme from the DGSANTE, European Commi-ssion |
| United Kingdom National External Quality Assessment Service (UK NEQAS)(1) | 390 schemes operating from 26 centres based at major hospitals, research institutions and universities throughout the UK | 1969 | Various | ▪ Responsible for External Quality Assessment schemes in a large number of laboratories throughout the UK | All UK NEQAS designated schemes are members of the UK NEQAS Consortium – a not-for-profit company limited by guarantee and a UK Registered Charity. This organisation, served by its elected Executive Committee and the UK NEQAS Office, fulfils central co-ordinating and administrative functions. EQA schemes are awarded the UK NEQAS designation and become UK NEQAS members through compliance with the UK NEQAS Code of Practice. This Code lays down requirements for scheme design and management, and sets out the applicable obligations and responsibilities. | Unclear |

| Name | Members | Founded | Pathogens | Main activities | Coordination / operation structure | Funding |
|---|---|---|---|---|---|---|
| Quality Control for Molecular Diagnostics (QCMD)(2) | Over 2000 participants in over 100 countries | 2001 | Various | ▪ Provides a wide-ranging quality assessment service primarily focused on molecular infectious disease | The QCMD Executive is responsible for the overall strategic aspects and management of the QCMD organisation. It is committed to the vision of providing a unified approach to molecular external quality assessment. In addition, there is a Central Office that is responsible for the overall operations and management of the organisation. Where required, QCMD collaborates closely with external contractors. | Unclear |

*Please consult the Chafea project database for the identification of the early phases of the current ECDC networks, which have been funded initially by the Health Programme, before 2005 creation of ECDC.*

*Sources: Civic Consulting taking into account*

*(a) http://www.enivd.de/index.htm;*

*(b) http://www.edenext.eu/related-activities/networks;*

*(c) ECDC, Microbiology Activities Report 2013, 2015.*

*(d)http://www.ecdc.europa.eu/en/activities/surveillance/european_surveillance_networks/Pages/european_surveillance_networks.aspx;*

*(e) http://ecdc.europa.eu/en/publications/Publications/101108_SPR_pandemic_experience.pdf;*

*(f) Interview with ERLI-Net;*

*(g) Interview with ERLTB-Net;*

*(h) http://ecdc.europa.eu/en/activities/diseaseprogrammes/programme_tuberculosis/Pages/tlaboratory_networks.aspx;*

*(i) http://ec.europa.eu/food/food/controls/reference_laboratories/eu_rls_for_feed_and_food_en.htm;*

*(j) http://ec.europa.eu/food/animal/-diseases/laboratories/index_en.htm;*

*(k) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;*

*(l) Interview with ISS;*

*(m) http://www.iss.it/vtec/?lang=2&id=146&tipo=1;*

*(n) http://www.erinha.eu/;*

*(o) http://www.quandhip.info/Quandhip/EN/Home/Homepage_node.html;*

*(p) http://www.rki.de/EN/Content/Prevention/QUANDHIP/QUANDHIP_node.html;*

*(q) http://ec.europa.eu/chafea/documents/health/health-security-1314112014-roland-grunow_en.pdf;*

*(r) ECDC, Gonococcal antimicrobial susceptibility surveillance in Europe 2012, 2014;*

*(s) http://www.episouthnetwork.org/;*

*(t) http://ec.europa.eu/chafea/documents/health/leaflet/episouth-plus-leaflet.pdf;*

*(u) http://www.emlab.eu/;*

*(v) http://www.medilabsecure.com/;*

*(w) ECDC, Technical Report: Fourth external quality assessment scheme for typing of verocytotoxin-producing E.coli (VTEC), 2014;*

*(x) ECDC, Technical Report: External quality assurance scheme for typing of verocytotoxin-producing E.coli (VTEC), 2012;*

*(y). http://www.euronetp4.eu/;*

*(z) Base d on information from interview with DG RTD;*

*(1) http://www.ukneqas.org.uk/content/PageServer.asp?S=939508409&C=1252&Type=G&ID=62;*

*(2) http://www.qcmd.org/index.php?pageId=2&pageVersion=EN.*

## 2.2 National reference laboratory systems in the EU: current situation

European networks of reference laboratories need to be underpinned by adequate and sustainable national reference laboratory infrastructure at the national level. In the following we provide an overview of the current situation in the EU.

On the one hand, the EURLOP study identified a number of strengths of current microbiology reference laboratories. In particular, the project found that more than 50% of countries had capability for the 47 communicable diseases and the two special health issues covered by the project, more than 90% of countries had BSL-3 capacity and six had BSL-4 facilities,[26] and that 22 countries had strain transfer agreements.

However, it also identified a number of weaknesses in national reference laboratory systems in EU Member States, such as competition for funds between diagnostic and reference laboratories in some countries, imbalance in distribution of operational BSL-4 facilities across the EU, imbalance in microbiological expertise between Member States and lack of collaboration between different sectors (human, veterinary, food and water). In regard to surge capacity/response capability, it noted that there were only twelve countries in the EU with formal policies in place either between government laboratories or within individual institutes. In nine countries only non-formalised ad hoc arrangements were in place, while in eight countries there appeared to be neither a formal nor an informal deployment policy.[27]

The table below provides an overview of key strengths and weaknesses of existing microbiological capacity across the EU identified by the EURLOP study (in the table, strengths/ weaknesses of national reference laboratory systems are not distinguished from those of European reference laboratory networks).

[26] The EURLOP study uses the terms “CL3” and “CL4” in this context. However, for the purposes of consistency, the terms “BSL-3” and “BSL-4” will be used throughout this report.
[27] Health Protection Agency *et al.*, *EU Human Pathogens Reference Laboratories Options Project – EURLOP: Final Report*, 2011.

**Table 4. Analytical overview of key strengths and weaknesses of existing microbiological capacity across the EU, including financial and legal enablers**

| | Overview |
|---|---|
| Key strengths | ▪ Over 50% of countries with capability for all 47 diseases and two special health issues highlighted by ECDC<br>▪ [BSL-]4 facilities in six countries; 22 countries with agreements for transfer of strains in place<br>▪ [BSL-]3 facilities in 93% of countries<br>▪ Considerable exchange of scientists between countries for training<br>▪ Extensive collaboration through networks<br>▪ Highly motivated staff in all countries<br>▪ State-of-the-art equipment and techniques in use in over 50% of countries |
| Key weaknesses | ▪ Perception that coordination of some RM (reference microbiology) activities at an EU level was insufficiently robust for certain pathogens, and also that network activities were inadequately funded<br>▪ Lack of an EU-wide accreditation policy for reference microbiology<br>▪ Imbalance in distribution of operational [BSL-]4 facilities across the EU<br>▪ Imbalance in microbiological expertise between MS<br>▪ Competition for funds between diagnostic and reference laboratories in some countries<br>▪ Overall lack of funding for RM activities<br>▪ Lack of collaboration between different sectors – human, veterinary, food and water, in several MS<br>▪ Differences between MS in arrangements for funding RM<br>▪ Considerable variance between MS in how RLs are appointed and funded within the EU<br>▪ Issues of liability; national restrictions on the transfer of data; national restrictions on the transfer of human tissue; regulations concerning the shipment of samples; notification of the public health authorities in the receiving country |

*Source: EURLOP study.*

Moreover, the ECDC recently conducted an assessment of key capabilities and capacities of public health microbiology systems as well as their robustness and functionalities with regard to infectious disease surveillance and threat detection/assessment in the EU, using a set of indicators.[28] The results indicated that the EU as a whole has a strong public health microbiology system capability and substantial capacity to fulfil its surveillance and response requirements. However, it identified substantial inter-country variation across all system targets,[29] and the average EU/EEA scores were also divergent across targets, indicating that there were common challenge areas for which many countries showed more limited provision of critical capabilities and/or low capacity. The areas where low capacity/capabilities were identified were provision and regulation of clinical microbiology services; diagnostic testing utilisation; diagnostic testing guidelines and national reference laboratory services relating to molecular typing for surveillance and national outbreak response support. The areas of best practice with consistently high levels of performance across countries, largely meeting policy targets and standards, included primary antimicrobial drug susceptibility testing and antimicrobial resistance monitoring; capability scope of the national reference laboratory services; and active laboratory collaboration within national and EU surveillance networks.

The ECDC considers it critical that Member States have access to the testing capacity that they need for effective disease control, either in their country or another Member

[28] ECDC, EU Laboratory Capability Monitoring System (EULabCap) Report on 2013 survey of EU/EEA country capabilities and capacities, 2015.
[29] A total of 12 system targets were assessed, with each system target based on 5 performance indicators.

State, supported by adequate quality standards for such tests.[30] Moreover, in accordance with the EU Health Strategy stating that "the Charter of Fundamental Rights recognises citizens' right of access to preventive healthcare and the right to benefit from medical treatment", every Member State should have access to routine and emergency diagnostic and reference laboratory services to detect, identify, characterise and subtype human pathogens of public health significance, either in their country or in another Member State through cooperative agreement.[31]

## 2.3 The potential for an EU reference laboratory system

The above-mentioned issues bring to the fore the potential for a formal EU reference laboratory system to improve coordination of laboratory activities in case of response to serious cross-border threats to health as defined under Decision 1082/2013/EU of the European Parliament and of the Council. Such a system should have the appropriate flexibility, capacity and resilience for advanced reference materials and resources to be diverted in an effective and timely manner for the study of novel pathogens or identification of significant changes in the incidence or severity of known diseases, as well as for the support of outbreak response by providing the required diagnostic capabilities. In addition, as outlined in the EURLOP study, an overarching EU reference laboratory system must be underpinned by an efficient and co-ordinated system of primary laboratories at the individual Member State level.

The need for reference laboratories for human pathogens has been recognised in the EU Health Programme 2008-2013 endorsed by the Council of Ministers which called for the establishment of a system of Community reference laboratories.[32] In 2010, the ECDC Management Board adopted a position statement in this respect, "EU Reference Laboratory Networks: a Vision to Strengthen Member State Capacity in Public Health Microbiology". This statement called for enhancing collaboration and sharing between Member States, to optimise the use of limited resources and fill existing gaps or significant differences in the quality and timeliness of reference laboratory service provision.[33] Specifically, it indicated the need to "consider the options and feasibility of creating EU reference laboratories or EU reference functions to cover specific issues which are so far partially or not covered at EU level, and for which potential risk of vulnerability has been identified."

Recent developments in diagnostic and typing techniques are also opening a new field of data generation and connection, revolutionising pathogen detection and typing in human health, and creating additional needs for coordination and reference services. Specifically, Next Generation Sequencing (NGS) used for Whole Genome Sequencing (WGS) or Whole Community Sequencing (WCS or metagenomics) are rapidly dropping in cost and starting to become in reach of routine clinical and public health laboratories. Rapid advances in these technologies are expected to contribute significantly to improving identification and mitigation of emerging infectious diseases, although it may take years before such technology becomes widely available in EU Member States.

[30] Minutes of the Twentieth Meeting of the ECDC Management Board; Stockholm, 9-10 November 2010.
[31] Update of the position statement of the Commission and ECDC on human pathogen laboratories: A joint vision and strategy for the future. ECDC Management Board Twenty-third Meeting Stockholm, 09-10 November 2011.
[32] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF.
[33] Update of the position statement of the Commission and ECDC on human pathogen laboratories: A joint vision and strategy for the future. ECDC Management Board Twenty-third Meeting Stockholm, 09-10 November 2011.

While it is important to bear in mind the effects of these new technologies when considering the policy options for reference laboratories for human pathogens, the use of NGS is considered by the EURLOP study to be entirely compatible with the creation of an EU-RL system for human pathogens. Although such technology may lead to the transfer of certain microbiology reference activities from national or supranational laboratories to the regional or primary diagnostic level, there will remain a need for expert analysis of the resulting data. Moreover, the use of genomic methods to recognise outbreaks will require the maintenance of an EU-wide database. Indeed, rather than reducing the need for reference laboratories, the use of genomic tools in the sphere of virology (where they have already been available for several years) has, according to the EURLOP study, in fact *increased* the need for them, in order to consolidate technical approaches and assure quality

# 3. Methodology

*In this section we present the key elements of the methodological approach, including the definition of the options for which the costs and benefits are analysed, a detailed overview of relevant functions and activities of EU-RL networks, the cost and benefit types reviewed in the study, and the approaches applied for data collection and data analysis.*

## 3.1 Options for European reference laboratories for human pathogens

### 3.1.1 Options for an EU reference laboratory systems as defined by EURLOP

The EU Human Pathogen Reference Laboratories Options Project study had the primary goal of developing possible options for an EU-wide reference laboratory system for human pathogens. In order to inform this analysis, data was gathered on the current level of reference microbiology (RM) provision and related funding mechanisms and legal arrangements in the EU (with 24 of 27 Member States at the time covered by the information gathering exercise, as well as three Candidate Countries, Norway and Switzerland). The study then assessed the strengths and weaknesses of the current situation and the added value that could be attained by an EU-wide reference laboratory system.

Three possible initial models for reference microbiology provision were identified by the study, namely maintenance of the status quo, the adoption of a uni-dimensional model (a single structure and/or functional model for all RM provision in the EU) and the adoption of a multi-dimensional model (various co-existing structural and functional models for different diseases/public health issues) based on a system of pan-European, supranational and national-level tiers. Arguing that a multi-dimensional model was the most appropriate for an EU-wide reference laboratory system, the study proposed four different options of RM provision under the multi-dimensional model, with varying degrees of centralisation. A weighted scale was then used to assess which option was most appropriate for each of the 47 communicable diseases and two special health issues listed in Commission Decision 2000/96/EC.

Furthermore, the study proposed a number of funding models and assessed their respective advantages and drawbacks. It also addressed the legal considerations that must be borne in mind, for example with regard to intellectual property rights, issues of liability and national restrictions on the transfer of data. Additionally, it stressed the need to take recent developments in diagnostic and typing techniques into account when discussing the future of RM provision in the EU.

### 3.1.2 Definition of coordination options for the study on cost-benefit analysis

As indicated above, the EURLOP study, proposed a ‘tier-based’ system of reference laboratories as a basis for a European reference laboratory (EU-RL) system: the pan-European, ‘supra-national’ and national level reference laboratories. The following table presents the definition of these tiers as presented by the EURLOP study and adapted for the present study.

**Table 5. Adapted definition of tiers for EU-wide reference laboratories for human pathogens according to EURLOP study**

| Tier | Level | Activities commissioned by | Main role |
|---|---|---|---|
| Tier 1 | *Pan-European (EU-RL)* | EU | Coordinate activities and provide advanced reference services to the entire EU; provide expert advice to EU |
| Tier 2 | *Supra-national (SNRL)* | EU | Coordinate activities and provide advanced reference services to a cluster of Member States. |
| Tier 3 | *National (NRL)* | Governance remains with the existing MS management and arrangements, without substantial involvement of the EU-RL. | Provide reference services nationally |

*Source: Based on EU Human Pathogen Reference Laboratories Options Project (EURLOP), adapted by Civic Consulting.*

As noted in the table above, the 'supra-national' reference laboratory as defined by the EURLOP study is commissioned by the EU and coordinates activities/provides reference services to a cluster of Member States.

In addition, as indicated in the table above, the EURLOP study assumes EU-commissioned/funded activities only for the first two tiers, i.e. not at the national level. The study underlined that an overarching EU-RL system must be underpinned by an efficient and co-ordinated system of primary laboratories at the individual MS level. It further clarified that at the foundation of the tier-based model are the assumptions (1) that each MS has in place a an efficient and co-ordinated system of primary laboratories / regional specialist laboratories for the initial isolation and identification of the organisms; (2) the initial level of reference provision in the system, Tier 3, is the NRL for the particular micro-organism or disease which, of itself, will generally involve a high standard of RM.

On the basis of these three tiers, the EURLOP study defined four options for European reference laboratory networks. The options differ according to the following characteristics:

- Whether a three-tiered or two-tiered approach is chosen;
- Whether the provision of Tier 1 functions is "physically centralised" (one laboratory) or "virtually centralised" (several laboratories sharing Tier 1 functions).

The following table presents the four options put forward in the EURLOP study in detail.

**Table 2. Options of the EURLOP study for EU-wide reference laboratories for human pathogens**

| Options | Summary | Tier 1 - Pan-European level | Tier 2 - Supra-national level | Tier 3 - National level |
|---|---|---|---|---|
| A | All three tiers needed, pan-European provision of reference laboratory functions is physically centralised | Tier 1 functions in general provided by "physically centralised" EU-RL, a specified NRL appointed based on specific expertise, capacity and capability[(a)] | Tier 2 functions provided by specified NRLs appointed based on specific expertise, capacity and capability[(a)] | Tier 3 functions provided by MS NRLs for the particular micro-organism or disease |
| B | All three tiers needed, pan-European provision of reference laboratory functions is "virtually centralised" | Tier 1 functions provided by a "virtually centralised" EU-RL, consisting of specified NRLs appointed based on specific expertise, capacity and capability[(a)] | Tier 2 functions provided by the specified NRLs | Tier 3 functions provided by MS NRLs |
| C | No Tier 2 needed, pan-European provision of reference laboratory functions is physically centralised | Tier 1 functions in general provided by "physically centralised" EU-RL, a specified NRL appointed based on specific expertise, capacity and capability[(a)] | - | Tier 3 functions provided by MS NRLs |
| D | No Tier 1, a substantive pan-European role is not anticipated | - | Tier 2 functions provided by specified NRLs appointed based on specific expertise, capacity and capability[(a)] | Tier 3 functions provided by MS NRLs |

*Source: EURLOP study. Notes: (a) Functions could also be provided by a different laboratory than the NRL (depending on tendering procedure applied).*

Following research conducted and discussion at the first expert workshop that took place in the framework of this study,[34] it was concluded that Options A, B and C should be considered in this study as they were originally defined, and that Option D should be replaced with a new option: a two-tiered approach with a virtually centralised EU-RL at the pan-European level.

Following discussions with stakeholders in exploratory interviews, the relevance of this option for consideration was confirmed. Indeed, such a structure is currently applied in

[34] The first workshop took place on Friday 24 April 2015 at the Commission premises in Luxembourg. Its main focus was the validation of the methodology, which we presented in the Work Package 1 report (i.e. deliverable 2) of this study. Reviewers were asked to provide general feedback on the report, point to additional aspects and data sources that may not have been covered completely, and validate the methodological approach of the study.

a variety of human pathogen-specific laboratory networks (e.g. the ERLI-Net or the ERLTB-Net networks) and was considered by interviewees to be a viable arrangement. Adding this option also contributed to ensuring the completeness in the range of options for consideration in the study.

Furthermore, in the first expert workshop the feasibility of all options presented by EURLOP as well as the new option described above came under scrutiny. In the discussion, Option D of the EURLOP study was not considered feasible for implementation due to its lack of centralisation, which was emphasised by experts at the workshop as crucial for building a viable EU-RL network. Moreover, it was argued that the new option is very similar to Option D but better reflects the aforementioned centralised coordination needs of a network. It was therefore concluded that the new option would be considered in place of Option D of the EURLOP study. The table below summarises the structure of the new option.

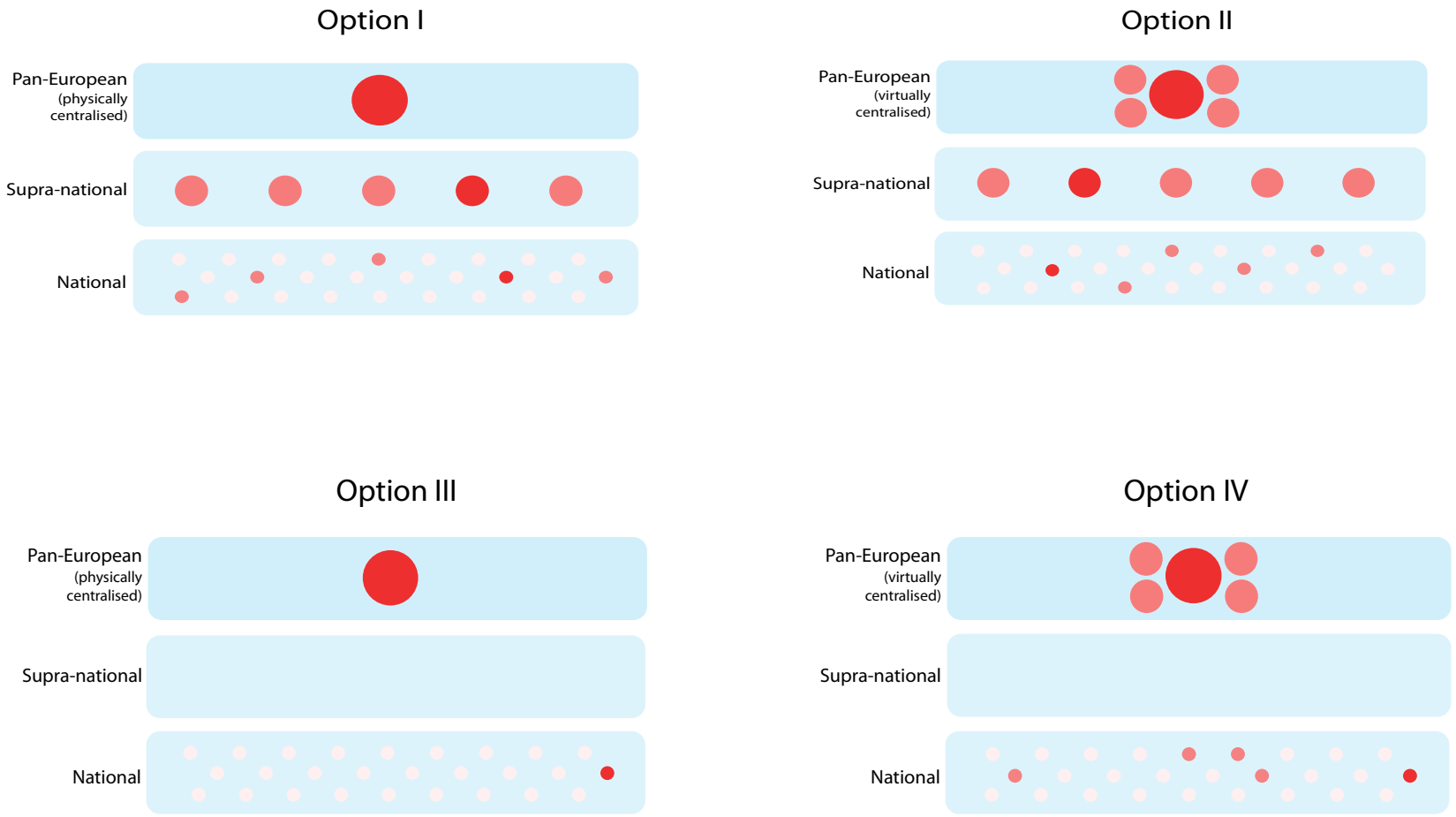
**Table 3. Definition of a new option: A two-tiered approach with a virtually centralised EU-RL at the pan-European level**

| Options | Summary | Tier 1 - Pan-European level | Tier 2 - Supra-national level | Tier 3 - National level |
|---|---|---|---|---|
| New option | No Tier 2 needed, pan-European provision of reference laboratory functions is "virtually centralised". | Tier 1 functions provided by a "virtually centralised" EU-RL, consisting of specified NRLs appointed based on specific expertise, capacity and capability[(a)] | - | Tier 3 functions provided by MS NRLs. |

*Source: Civic Consulting.*

To summarise, the following page graphically depicts all options that are considered in the study. The options have been renamed as Option I, II, III, and IV for consistency.

**Figure 1. Options for European reference laboratories for human pathogens**




*Source: Civic Consulting, partly based on the EU Human Pathogen Reference Laboratories Options Project.*

### 3.1.3 Key assumptions concerning tiers of an EU-RL network

In order to clearly distinguish between the different options and allow for a clear delineation of costs and benefits in the analysis, further characterisation of the three tiers as the foundation of the organisational structure of the EU-RL network was deemed necessary. The specific assumptions that the team developed accordingly concerning each of the tiers are outlined in the following.

*Assumptions concerning Tier 1 - Pan-European level*

- 'EU-RL' refers to one reference laboratory (as in a "physically centralised" network) or a consortium of reference laboratories (as in a "virtually centralised" network) at the pan-European level. They are selected by the EU funding entity (e.g. typically DG SANTE, CHAFEA or ECDC) for a given EU-RL network.
- Prior to its selection, the relevant laboratory(ies) have acted at the national level as reference laboratories in their field and are therefore well equipped with all infrastructure and capacity needed to fulfil the role of the EU-RL.
- As the lead contractor and the coordinator of the EU-RL network, the EU-RL directly undertakes or subcontracts EU-wide activities which require centralised implementation and coordinate(s) activities designated to be undertaken by other laboratories of the network.
- The EU-RL is the contact point for the contracting authority for the network. This role includes the responsibility to negotiate the work programme with the contracting authority and to administer all funds received in relation to these activities.
- If the EU-RL network is virtually centralised, i.e. a consortium of laboratories acts as EU-RL, work within the consortium is mainly split according to different centralised tasks (e.g. EU-wide training or EQAs), not according to geographical regions. In any case, one laboratory of the consortium is appointed as the lead contractor of the network, including with respect to the contracting authority.

*Assumptions concerning Tier 2 - Supranational level*

- Tier 2, if relevant for the Option (i.e. Option I or II), is composed of a number of 'supranational' reference laboratories which are selected and appointed by the EU contracting authority to coordinate activities for distinct country clusters of national level reference laboratories.
- Similar to the EU-RL, it is assumed that prior to their selection, supranational reference laboratories have already acted at the national level as reference laboratories and are well equipped in terms of infrastructure and capacity.
- Supranational reference laboratories are appointed by the contracting authority based on country clusters, not based on activity portfolios. Hence, all supranational reference laboratories have the same responsibilities in terms of coordination activities, but each for a different cluster of Member States. Supranational reference laboratories coordinate those activities of an EU-RL network which pertain only to their country cluster, and do not require centralised coordination.
- While their action is coordinated by the EU-RL overall, supranational reference laboratories also closely cooperate amongst each other.
- Activities undertaken in the capacity of a supranational reference laboratory are included in the work programme and hence covered by the budget of the EU-RL network. Funds are disbursed to supranational reference laboratories by the EU-RL as lead contractor.

- As supranational reference laboratories are defined as being both appointed by the contracting authority and funded by the budget of the EU-RL network, other forms of cross-border arrangements for the provision of reference laboratory services between Member States that do not fall within this scope are not considered part of Tier 2.

*Assumptions concerning Tier 3 - National level*

- Tier 3 laboratories, referred to as national reference laboratories (NRLs) for the purposes of this study, play two main roles: provision of national reference laboratory services to their country and participation in activities of the EU-RL network.
- The NRL's provision of national reference laboratory services to their country and the related funding to do so is the responsibility of the respective Member State. Whether national reference laboratory services are provided through NRLs in each country or through Member States' pooling of resources for national reference laboratory services based on bilateral agreements is therefore the responsibility of the Member State(s) in question, not of the EU-RL network.
- As for the EU-RL network, NRLs participate in a variety of network activities, including external quality assessments, workshops, and training sessions. Depending on the budgetary resources of the EU-RL network, NRLs are compensated for some of these activities (e.g. participating in workshops), while for others they are expected to participate at their own cost. Both compensated and non-compensated costs of participation in activities of the EU-RL network are relevant for establishing overall network costs.
- In close coordination with the EU-RL, NRLs can take the lead in selected activities included in the work programme of the EU-RL network to which they are particularly suited for, such as drafting a handbook or research paper. Subject to agreement with the EU-RL, such activities may be covered by the EU-RL network budget.

With this characterisation of the three tiers, we established a broad framework for the organisational structure of an EU-RL network applicable to all of the options presented above.

To assess the additional costs and benefits generated specifically by EU-RL networks, we identified the key functions and related activities that they typically undertake (see next section).

## 3.2 Scope of analysis and core functions of European reference laboratories

### 3.2.1 Scope of analysis

A crucial step in setting the scope for the analysis was to identify the functions and activities of EU-RL networks that are relevant for consideration in the analysis. This firstly meant determining those functions and activities that can be considered to be those that an EU-RL network generally conducts as part of its role. Moreover, only those activities that generate *additional* costs and benefits relative to a situation in which no EU-RL network exists have to be considered, in order to focus specifically on those costs and benefits generated by EU-RL networks (as indicated above). Taking

these points into account, we determined that the activities to be considered in the analysis need to satisfy two key requirements, namely to:

a) Fall within the scope of those functions identified as *core functions* of an EU-RL network; and

b) Feature in the *work programme* of the network for the reference year (2014 or 2013, depending on for which year the most data is available).

This ensured that the analysis of costs and benefits of options focused on only those costs or benefits that could be considered to relate to activities that the EU-RL network is expected to conduct as part of its role, as well as those activities it planned to conduct or had conducted within the reference year. Importantly, these conditions also imply that costs and benefits of the provision of reference laboratory services at the national level are not considered in the analysis, as these are not activities that fall within the responsibility of an EU-RL network (as indicated above). In conclusion, only *activities that are both included in an EU-RL network's work programme and fall within the scope of its core functions are considered* in the analysis.

In the following we set out the framework applied for identifying all relevant activities. We characterise all activities that could potentially be included in an EU-RL network's work programme, even if some activities are not undertaken by specific EU-RL networks.

### 3.2.2 Overview of core functions and activities of European reference laboratories

The ECDC's 2010 report on "Core functions of microbiology reference laboratories" [35] was used as a point of reference to develop the set of activities undertaken by an EU-RL network. In its report, the ECDC defined five core functions of microbiology reference laboratories:

- Reference diagnostics (Function 1);
- Reference material resources (Function 2);
- Scientific advice (Function 3);
- Collaboration and research (Function 4); and
- Monitoring, alert and response (Function 5).

Under each of these core functions a set of activities is described which are to be undertaken by the reference laboratory as part of the defined function. The following table displays these activities.

[35] See technical report: ECDC, Core functions of microbiology reference laboratories for communicable diseases, 2010.

**Table 8. Core functions and activities of reference laboratories**

| Function | Activities |
|---|---|
| 1. Reference diagnostics | 1a. Have up-to-date reference methods in operation for specific pathogen/disease characterisation |
| | 1b. For selected pathogens: offer diagnostic confirmation services (i.e. validate diagnostic test results, provide advice and support) |
| | 1c. Investigate atypical samples |
| 2. Reference material resources | 2a. Develop, maintain and/or have access to relevant source reference materials |
| | 2b. Provide and/or facilitate access to reference material for relevant laboratories and organisations |
| 3. Scientific advice | 3a. Provide scientific advice and recommendations to public health authorities |
| | 3b. Provide technical support for policy development, e.g. vaccine issues, outbreak response management and preparedness planning |
| | 3c. Provide advice and support to laboratories (i.e. including conducting workshops and other training activities) |
| 4.Collabo-ration and research | 4a. Participation in regional/international public health microbiology lab. networks |
| | 4b. Participation in other regionally or internationally relevant projects and initiatives, including research and development activities to underpin the quality, scope and development of core reference laboratory activities; participation in, and contribution to, international surveillance |
| 5. Monitoring, alert and response | 5a. Provide data to national surveillance institutes or, if part of a national surveillance institute, to other appropriate bodies |
| | 5b. Provide surge capacity as part of a national preparedness plans |
| | 5c. Provide advice and technical support in outbreak investigations |
| | 5d. Provide early warnings in case of unusual occurrences |

*Source: ECDC (2010).*

Considering that the functions and activities proposed by the ECDC are tailored towards provision of reference laboratory services at the national level as opposed to an EU-wide laboratory network, we adapted the list for the purposes of this study, with the addition of three core functions:

- The function of external quality assessments (EQA) was identified in discussions with interviewees as particularly important for EU-RL networks, since EQAs are an important tool to increase quality, harmonise procedures across laboratories, and detect knowledge gaps and training needs, and thus increase the comparability of results produced across the EU.
- Partly related to the EQAs but taking a broader perspective is the core function of training in an EU-RL network. As part of this function a variety of activities can be undertaken which are indispensable for the harmonisation, improvement and standardisation of methods within a network.
- Furthermore, the coordination of the network is an important core function that needs to be added to the list. The implementation and maintenance of a network require administrative and other efforts which should not be underestimated when assessing the costs of the EU-RL network.

With the addition of these three core functions and their respective activities, the following table displays the full set of activities which feature (to varying extents) in the work programme of EU-RL networks.

**Table 9. Refined core functions and activities of an EU-RL network**

| Function | Activities |
|---|---|
| 1. Reference diagnostics | 1a. Have up-to-date reference methods in operation |
| | 1b. Offer diagnostic confirmation services for laboratories in the network |
| | 1c. Typing, sub-typing, and detailed characterisation of pathogens, including investigating atypical samples |
| 2. Reference material resources | 2a. Develop, maintain and/or have access to relevant source reference materials |
| | 2b. Provide and/or facilitate access to reference material for laboratories in the network |
| 3. Scientific advice for public health authorities | 3a. Provide scientific advice and recommendations to public health authorities, e.g. contributing to risk assessment (i.e. Commission and ECDC, as well as public health authorities of MS affected by outbreak) |
| | 3b. Provide technical support for policy development related to reference microbiology, e.g. vaccine issues, outbreak response management and preparedness planning |
| 4. External Quality Assessments (EQA) | 4a. Organise proficiency tests (inter-laboratory comparison) for laboratories in the network |
| 5. Training | 5a. Undertake training activities for laboratories in the network |
| | 5b. Provide scientific advice to sub-level laboratories |
| 6.Collabo-ration and research | 6a. Participate in regional/international public health microbiology laboratory networks |
| | 6b. Participate in other regionally or internationally relevant projects and initiatives, including research and development activities |
| 7. Monitoring, alert and response | 7a. Supporting Member States in providing data to EU bodies that conduct surveillance tasks or other appropriate bodies |
| | 7b. Provide advice and technical support in outbreak investigations / surge capacity |
| 8. Governance of the network | 8a. Administration and coordination of the network |
| | 8b. Provision of IT-tools, if any |

*Source: Civic Consulting developed on basis of ECDC (2010), the analysis of existing European laboratory networks and the results of the first expert workshop held in the framework of the study.*

The scope of each EU-RL network determines which of the activities presented above is undertaken. While not all activities are applicable for all EU-RL networks, the broad scope of potentially relevant activities within an EU-RL network allowed for a sufficient basis for the in-depth research in the case studies.

### 3.2.3 Activities of European reference laboratories

In order to fully understand the implications of the activities for costs and benefits, we clarified the scope of each activity as well as the tier at which the activity would generally be undertaken, where relevant.

#### Function 1. Reference diagnostics

*Activity 1a. Have up-to-date reference methods in operation*

Efficient and accurate detection of human pathogens is of primary importance for public health. A variety of methods is available and employed throughout laboratories in the EU for the detection of a given pathogen. Furthermore, analytical methods are constantly evolving. In order to increase the laboratory capacity in the EU-RL network, it is important to follow all developments in reference diagnostic methods within the field of the network and to regularly undertake health technology assessments. The primary aim of this activity is to keep reference diagnostics up-to-date by continuously evaluating and evolving the methods in use. Tasks to fulfil this activity include:

(i) To closely follow developments in laboratory methods and testing;

(ii) To assess relevant reference methods which have been developed or modified and optimized either by members of the network or by other laboratories regarding their effectiveness, reliability and feasibility;

(iii) To implement the use of all those methods which have been identified as state-of-the-art. This implementation of new or modified methods may require investments in additional equipment, the development of new standardised laboratory procedures and protocols as well as training of staff.

Reference laboratories on all three tiers should have up-to-date reference methods in operation. However, it is specifically the responsibility of the EU-RL to evaluate relevant methods and to provide guidance whether these should be applied throughout the network. While laboratories generally should share their knowledge on reference methods and developments in their use within the network, the coordination of this activity is undertaken by the EU-RL.

*Activity 1b. Offer diagnostic confirmation services for laboratories in the network*

It is assumed that Member States ensure appropriate laboratory capacity at the national level to fully provide all reference diagnostics needed. If there are nonetheless doubts about diagnostic results, for example due to lack of the appropriate technical expertise and laboratory capacities or because the pathogen strains analysed are particularly rare, laboratories participating in the network have the opportunity to send their samples for diagnostic confirmation to a designated laboratory within the network. The designated laboratory then provides diagnostic confirmation services on behalf of the network. Services are provided by (i) undertaking a laboratory analysis of the sample that has been sent and (ii) communicating their results to the laboratory sending the sample.

Within the EU-RL network, diagnostic confirmation services for a given laboratory are undertaken by the reference laboratory at the Tier above in the system. Hence in a three tiered EU-RL network (e.g. as in Options I and II), NRLs would first send their samples to their respective SNRL. If the SNRL also needs assistance, the sample

would be sent to the EU-RL. In a two-tiered approach (which is the case for Options III and IV), NRLs would send their samples directly to the EU-RL.

*Activity 1c. Typing, sub-typing, and detailed characterisation of pathogens, including investigating atypical samples*

Typing, sub-typing, and detailed characterisation of pathogens generates important data on strains currently circulating in Europe (their relevance, frequency etc.) and provides for faster detection of newly emerging pathogens, pathogen mutations or the resistance of pathogens to medical treatment. Constant horizon scanning also includes the investigation of atypical samples and is indispensable for the establishment and maintenance of a broad overview and in-depth knowledge in the field of the network. It significantly contributes to monitoring and surveillance, preparedness planning, and outbreak investigation and is therefore an important activity for public health.

As this activity requires a high level of expertise and specialisation as well as solid consolidation of results in order to allow for relevant conclusions to be drawn, this activity should be centralised at the pan-European level. An EU-RL has the specialized capacity to investigate samples submitted by sub-level laboratories in the network and to gather results in terms of cross-border and EU-wide public health implications. Activities to obtain relevant results include the laboratory investigation of samples by applying state-of-the-art analytical methods and the evaluation and interpretation of results in terms of cross-border and EU-wide public health implications.

### Function 2. Reference material resources

*Activity 2a. Develop, maintain and/or have access to relevant source reference materials*

Reference materials (RM) are an essential part of quality assurance in microbiological laboratories. RM are used for validating methods, verifying their correct use, calibration, and internal and external quality control. They can be produced in-house or bought on the market. The main steps for the preparation of RM include the collection and synthesis of material, sample preparation, homogeneity testing, stability assessment, inactivation, and the value assignment, quantification and characterisation of the RM. The preparation of RM for non-specialised laboratories can be costly, and for this reason this activity can often be sub-contracted. With the increasing detection and characterisation of pathogens based on nucleic acid methods, this activity also includes the development, maintenance and/or access to a well-stocked biobank in the field of the network. The EU-RL as a highly specialised laboratory should have the capacity to develop and maintain all reference materials needed in the field of the network in-house. In cases where such in-house preparation is not efficient or too costly, the EU-RL should have access to relevant sources providing the RM more efficiently. If the supranational tier exists in a network, SNRLs should also develop, maintain and/or have access to relevant source reference materials. However, in very specialised cases reliance on the EU-RL may be possible.

*Activity 2b. Provide and/or facilitate access to reference material for laboratories in the network*

While it can be assumed that all laboratories in the network have access to commonly used reference materials (RM), certain RMs which are less commonly used or more complex or costly to produce may be more difficult to access, particularly for laboratories which are less well equipped. In such cases the EU-RL as a central European laboratory should facilitate access to these RM. The EU-RL has different

options at hand to undertake this activity: it can either produce and ship the requested RM itself or facilitate access to the material by sharing information on providers of the requested RM. These providers can be both commercial providers or other laboratories participating in the network.

Should Tier 2 exist in the network, SNRLs would facilitate such access to the NRLs within their clusters and would rely on the EU-RL in highly specialised cases.

### Function 3. Scientific advice for public health authorities

*Activity 3a. Provide scientific advice and recommendations to public health authorities, e.g. contributing to risk assessment (i.e. Commission and ECDC, as well as public health authorities of MS affected by outbreak and where appropriate to clinicians)*

The EU-RL as the central coordination point of the network acts within the specific field of the network as a resource of expertise for public health authorities, particularly at EU level. Upon request, the EU-RL shares its technical and scientific expertise with public health authorities (including where appropriate clinicians) on all issues of cross-border or EU-wide relevance in its field, including for the purposes of contributing to risk assessment. Such advice can include for example the interpretation and assessment of relevance of laboratory findings or the occurrence of an outbreak. Scientific advice is mainly provided on an ad-hoc basis by phone or email. In exceptional cases it may involve travel by EU-RL staff. If necessary, the EU-RL can coordinate with sub-level laboratories to provide input.

*Activity 3b. Provide technical support for policy development related to reference microbiology, e.g. vaccine issues, outbreak response management and preparedness planning*

Technical support for policy development is provided by the EU-RL to EU competent authorities, for example in relation to the evaluation of newly available standards, methods, vaccines etc. The provision of technical support for policy development is undertaken only for public health issues with cross-border or EU-wide relevance. Options to provide such support can include the preparation of technical reports or the participation in and organisation of meetings with respective authorities, for example. Again if relevant, the EU-RL coordinates contributions of sub-level laboratories.

### Function 4. External Quality Assessments (EQA)

*Activity 4a. Organise proficiency tests (inter-laboratory comparison) for laboratories in the network*

Proficiency tests are used to monitor and improve the quality and performance of laboratories. When undertaken as an inter-laboratory comparison study, samples are sent by an organising laboratory to all participating laboratories. Participating laboratories have to analyse the samples according to a given set of instructions and report their results back to the organising laboratory. The organising laboratory, adhering to the general requirements for proficiency testing specified in ISO/IEC 17043:2010, compares the results of each participating laboratory with the reference values of the sample provided and evaluates the performance of each laboratory. In an EU-RL network, inter-laboratory studies have to be undertaken in a centralised manner. Hence, they are typically organised by the EU-RL. Inter-laboratory comparison tests in the context of an EU-RL network are specialized and target at stimulating the application of particular analytical methods, obtaining information on the quality and performance level of laboratories within the network and detecting

training needs amongst participating laboratories. In order to organise a network-wide proficiency test, the EU-RL has to undertake the following activities:

- Prepare the samples;
- Test the samples for quality and stability;
- Organise the shipping of samples;
- Collect and analyse the results from participating laboratories; and
- Draw relevant conclusions, develop recommendations and discuss results with participants.

### Function 5. Training

*Activity 5a. Undertake training activities for laboratories in the network*

In an EU-RL network, training needs can arise from the request to standardise or harmonise analytical methods across the network, or individual laboratories may raise training requests, or training needs are detected in the evaluation of a proficiency test. According to the detected needs, different training activities can be undertaken, including:

Organising and conducting a workshop for the participation of all laboratories of the network;

- Developing, conducting and facilitating a set of training programmes which can be completed by experts from one laboratory at the facilities of another laboratory;
- Sending support experts to a laboratory to provide training on site.

Overall, it is expected that the EU-RL as central coordinator of the network assesses training needs and coordinates accordingly. Activities such as workshops, which are undertaken network-wide, are likely to be organised by the EU-RL itself or a suitable network partner. For more targeted training activities such as sending support experts, the EU-RL can coordinate with other laboratories in the network to undertake these tasks. For example if Tier 2 exists in the network, support experts sent to laboratories are likely to be staff members of SNRLs of the respective country cluster.

*Activity 5b. Provide scientific advice to laboratories in the network*

Providing scientific advice includes all those activities which are not covered by training activities or reference diagnostic services but are targeted at supporting a laboratory in undertaking activities as part of its functions. Advice can be provided by email or by phone. If needed, a sample can be sent or a support expert can be deployed to the facilities of the sub-level laboratory.

In a two-tiered approach the EU-RL would provide scientific advice to NRLs. In a three-tiered approach SNRLs are the first contact point for respective NRLs, and the EU-RL would provide advice if the designated SNRL is not able to fulfil this task.

### Function 6. Collaboration and research

*Activity 6a. Participate in regional/international public health microbiology laboratory networks*

As the main coordinator of laboratory work within the network, the EU-RL is well-positioned to facilitate laboratory contributions of the EU-RL network to other regional or international public health microbiology laboratory networks e.g. of the WHO. Laboratory contributions are reconciled with all efforts undertaken by contracting authorities in this regard.

*Activity 6b. Participate in other regionally or internationally relevant projects and initiatives, including research and development activities*

An EU-RL should be cognizant of the main technological and scientific developments in its field and hence has a good overview over relevant projects and initiatives. To further the knowledge and capacities of the network, the EU-RL as the main coordinator of the network is well-positioned to facilitate the participation and contribution of the EU-RL network in other initiatives and projects which relate to the scientific context. Such contributions can include:

- Participating in relevant regional and international conferences and workshops;
- Reaching out to and keeping in contact with relevant reference microbiology institutions outside of Europe;
- Initiating and/or coordinating research proposals and projects; or
- Initiating other sorts of collaboration.

The EU-RL coordinates contributions with all laboratories in the network. Contributions which relate to the strategic alignment of the network from the political/ bureaucratic perspective e.g. with international surveillance initiatives may also be conducted together with the project officer in contracting authorities.

### Function 7. Monitoring, alert and response

*Activity 7a. Supporting Member States in providing data to EU bodies that conduct surveillance tasks or other appropriate bodies*

According to the WHO public health surveillance is "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice". Data generated during the provision of diagnostic confirmation services for example or the investigation of atypical samples helps to characterise and build an understanding of pathogen strains circulating in the EU. While, it is the primary responsibility of Member States to provide all relevant data to EU competent authorities, the EU-RL through the EU-RL network can support Member States in this activity by for example developing and encouraging the use of harmonized reporting templates or by reporting information which is generated through the set-up of the EU-RL network going beyond the reporting duty of the Member States.

*Activity 7b. Provide advice and technical support in outbreak investigation/surge capacity*[36]

An outbreak can be characterised as a situation where more cases of a disease occur than expected in a certain time or place. Upon request, the EU-RL as the central laboratory can provide technical support in an outbreak situation to laboratories in the network and competent authorities dealing with the outbreak, for example in relation to verification of the diagnosis and the confirmation of the outbreak, the case definition of the outbreak, or the development and evaluation of the hypothesis as to the cause of the outbreak. Activities of an outbreak investigation could include:

- Investigation of samples sent to the EU-RL;
- Meta-level analysis and interpretation of results provided by laboratories and authorities dealing with the outbreak;
- Provision of on-site technical support.

Also relevant for this activity is the potential for provision of surge capacity for reference laboratory services following a large outbreak. Provision of surge capacity mainly falls under the responsibility of contingency planning of national authorities. Nonetheless, upon request an EU-RL as central laboratory could potentially provide relevant services for dealing with the emergency, including in terms of developing and adapting analytical methods to the specificity of the pathogen causing the outbreak or providing assistance in the analysis of additional samples.

Yet, the provision of technical/scientific expertise in the event of an emergency (due to its ad hoc nature) is generally not planned for in the work programmes of EU-RL networks from a budgetary perspective. Therefore in the event that it is required (e.g. upon request of competent authorities), resources would need to be transferred from those originally allocated to other activities in the work programme. As a result, it is possible that bottlenecks in larger outbreaks occur. Nonetheless, if an EU-RL network conducts activities that contribute to preparedness planning such as the development and adaptation of protocols and harmonised approaches for handling outbreaks, these would then be included in the work programme and hence budgeted.

In a three tiered approach the SNRL would likely undertake such activities for outbreaks which are localised in its own respective country cluster.

### Function 8. Governance of the network

*Activity 8a. Administration and coordination of the network*

The EU-RL is the main contact point for laboratories in the network as well as for the contracting authority in terms of substantive and administrative coordination of the network. As the lead coordinator from the laboratory side the EU-RL undertakes tasks such as drafting and negotiating the work programme with the contracting authority, managing the implementation of the work programme in the network and administering and distributing funds. The EU-RL may be supported by a steering group

[36] While this activity can be covered in the budget allocated to EU-RL networks, it is generally not envisaged in the work programmes of EU-RL networks due its ad hoc nature, and therefore in the event that advice and technical support is required during an outbreak (e.g. upon request of competent authorities), resources would need to be transferred from those originally allocated to other activities in the work programme. As a result, in this study, the collection of data on costs relating to provision of advice and technical support in outbreak investigations is limited to the extent to which this activity actually took place in the reference year.

or management committee to undertake these tasks. However, one dedicated contact point towards the contracting authority is appointed.

Project officers in the contracting authority act as the counterpart of the EU-RL in the coordination activities and are similarly involved in the substantive and administrative coordination of the network. Tasks include the facilitation of the selection of an EU-RL and if applicable SNRLs, the technical approval of the work programme and the budget, the administrative coordination of funds, and the facilitation of coordination with other relevant initiatives and networks.

*Activity 8b. Provision of IT-tools, if any*

In order to facilitate coordination and communication between all laboratories of the network and with the wider public, IT-tools such as a website with a restricted access area can be developed and maintained by the EU-RL or by the contracting authority.
If relevant, more elaborate IT-tools such as software to process epidemiological data and to establish microbiological data banks can be implemented and maintained within the EU-RL network. It is expected that the EU-RL would coordinate such activities.

## 3.3 Cost and benefit types for European reference laboratories

### 3.3.1 Identification of cost types

As indicated in Section 3.2, the scope of the analysis is such that only costs relating to the implementation of activities included in the work programme of an EU-RL network are considered. In order to determine the specific costs by activity, we identified a set of key cost types, which follows the structure of cost types currently eligible for EU funding in EU-RL networks in the food safety and animal health sectors.[37] Cost types considered for the analysis are:

- Staff costs. Staff costs include wages, social contributions and non-wage income of employees, such as in-kind payment. In the budget of an EU-RL network, staff time is included for all activities which are undertaken by EU-RL staff or SNRL staff in the capacity of the network. Furthermore, staff costs of NRLs participating in EU-RL network activities as well as staff costs of the contracting authority to coordinate the network also need to be considered.
- Capital equipment costs. The reduction in the value of fixed assets (laboratory equipment) due to the additional activities undertaken for the EU-RL network is considered.
- Costs of consumable materials. Consumable materials are items that get used up as a good or service is provided. In an EU-RL network, consumable materials are in particular used in laboratory processes, and include items such as chemicals, petri dishes, tubes and plates etc. This category also includes stationary consumables e.g. for printing reports.
- Travel and accommodation costs. Travel and accommodation costs include expenses (e.g. hotel and flight) as well as a daily allowances for each person travelling on behalf of the network. Costs are generally largely covered in the EU-RL network budget for meetings, training, and workshop participation. However, there may be other travel costs not included in the budget e.g. of Commission officers.

[37] Commission Implementing Regulation (EU) No 135/2013.

- Shipping costs. Shipping costs include all those fees for shipping which result from activities of the EU-RL network work programme.
- Subcontracting and costs of services. All costs and fees arising from subcontracting a certain activity or parts of a certain activity of the network are considered to be attributable to private companies or laboratories outside of the network. Furthermore, costs for services purchased externally which do not relate to laboratory competences are covered under this cost item, including catering and facility costs of workshops, the designing of a website etc.

The cost items described above were applied to categorise all costs arising from the implementation of each function/activities included in the work programme. In the case studies, costs are considered separately by function (see Section 3.4.1. for details). Costs do not only include those specified in the budget for an EU-RL network but also include in-kind contributions, for example from NRLs participating in EU-RL network activities, or costs incurred by EU authorities to coordinate the network.

### 3.3.2 Identification of benefit types

As with the cost types, we have developed a set of benefit types to categorise the benefits associated with the activities of EU-RL networks. Benefits can be categorised in two ways: a) by the monetary or non-monetary nature of the benefit and b) by the perspective applied: members of the laboratory network or society overall.

The benefits of EU-RLs networks are largely of a non-monetary nature. And in those cases in which they are monetary in nature, these financial gains are typically not separately accounted for. This means that their quantification was only be possible in a limited number of cases. As a result, the data that we obtained in the case studies relevant for the assessment of benefits is a mix of qualitative and quantitative data (where the latter is available).

Furthermore, the benefits of a given perspective (members of the laboratory network or society overall) are largely of a similar nature. In particular, monetary benefits largely relate to savings for members of the laboratory network and society overall obtained from the activities within the EU-RL networks from costs that would otherwise be incurred. Specifically, the main types of monetary benefits consist of:

- Costs savings for members of laboratory networks that would otherwise have incurred (e.g. costs saved because participation in a commercial EQA is not needed anymore);
- Receipt of any grants or in-kind benefits from institutions outside of the network for laboratory as a result of membership of the network;
- Additional income from increased demand for services provided by the laboratory as a result of membership of the network; and
- Potential cost savings for EU institutions as a result of the implementation of the laboratory network activities.

Similarly, non-monetary benefits for individual members of the laboratory network generally relate to improvements in the methods in use the laboratory and staff expertise, the quality of data, the image or reputation of the laboratory network, or its access to information and communication with other members of the laboratory network. Non-monetary benefits for society overall generally relate to improvements

in outbreak response (in particular as regards diseases prone to outbreaks such as emerging pathogens) or reductions in disease burden/costs of disease (in particular as regards diseases with a relatively stable number of cases per year, such as tuberculosis). Taking this into account, we developed key categories of benefit types for each of the perspectives to be assessed in the case studies and survey.

The key categories of benefits for members of laboratory networks assessed in the case studies/survey are:

- Improvements in methods employed by laboratories in the network;
- Improvements in staff expertise of laboratories in the network;
- Improvements in the quality and accuracy of data/results produced in laboratories in the network;
- Improvements in the image and reputation of laboratories in the network;
- Improvements in access to information, communication and/or collaboration among laboratories in the network.

The key categories benefits for society overall assessed in the case studies/survey are:

- Improvements in timely and accurate detection of pathogens in the EU;
- Reduction in the disease burden and related costs in the EU;
- Improvements in public health surveillance in the EU;
- Increase in laboratory preparedness and the capacity of coordinated response to outbreaks in the EU.

The key categories listed here were also confirmed in discussion at the first expert workshop.

## 3.4 Approach to data collection on costs and benefits of European reference laboratories

### 3.4.1 Overview

The basis for the overall analysis of costs and benefits of European reference laboratories for human pathogens and related coordination options is case studies focusing on specific EU-RL networks. The use of case studies has the advantage of allowing for the costs and benefits of EU reference laboratory networks to be analysed in specific, concrete contexts, while the diversity in their selection allows for a balanced assessment of the costs and benefits of networks across different types of networks, pathogens, and options as outlined below.

The final selection of the six networks to be covered by the case studies was made at the first expert workshop held in the framework of the study, and consists of:

- European Reference Laboratory Network for Human Influenza (ERLI-Net);
- European Network for Diagnostics of "Imported" Viral Diseases (ENIVD);
- European Union Reference Laboratory VTEC (EU-RL VTEC);

- European Reference Laboratory Network for TB ( ERLTB-Net);
- Food and Waterborne Disease Zoonoses Network (FWD-Net); and
- Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens (QUANDHIP).

The case studies aimed at gathering both:

(i) Relevant cost data concerning EU-RL networks at various levels (i.e. EU, supra-national, national levels), considering the defined cost types
(ii) Relevant data on monetary and non-monetary benefits at various levels, considering the defined benefit types

Data collection was based on interviews with key stakeholders in the framework of the case studies, a survey of laboratory network members, and complementary research and literature review. On the basis of the data collected, we compiled a report for each case study network. The case study reports are presented in Section 4 below.

The following sub-sections present the methodology of the case studies and related data collection activities in detail. Data collection activities that preceded the case studies – including exploratory interviews, an extensive literature review and a comprehensive mapping of existing European laboratory networks – are not included, as they have been described in detail in the work package 1 report.

### 3.4.2 Case study interviews

We developed separate questionnaires for the three main types of stakeholders relevant for data collection in the case studies:

a) The coordinators of the laboratory networks;
b) Members of the laboratory networks; and
c) The entity funding the networks.

Based on these questionnaires, interviews were conducted by phone and/or interviewees provided information in writing. The following table presents the interviews conducted.

**Table 10. Interviews conducted for case studies**

| Interviewees/entity | Role in the network | Date of interview | Topic of interview [a)] |
|---|---|---|---|
| **ERLI-Net** | | | |
| Maria Zambon and Ian Harrison (PHE) | Lead coordinators | 18 June 2015 | Costs and benefits of the network, additional costs and benefits of coordinators |
| John McCauley (WHO-CC, London) | Coordinator | 8 June 2015 | Additional costs and benefits of coordinator |
| Adam Meijer (RIVM) | Coordinator | 16 June 2015 | Additional costs and benefits of coordinator |
| Eeva Broberg (ECDC) | Funding entity | 7 July 2015 | Additional costs and benefits of funding entity |
| Caroline Brown (WHO) | Complementary research | 16 June 2015 | Relationship of ERLI-Net and WHO GISRIS |
| **ENIVD** | | | |
| Heinz Ellerbrok (RKI) | Coordinator | 30 July 2015 | Costs and benefits of the network, additional costs and benefits of coordinators |
| Matthias Niedrig (RKI) | Former coordinator | 28 September 2015 | Costs and benefits of the network |
| Herve Zeller (ECDC) | Funding entity | 4 August 2015 | Additional costs and benefits of funding entity |
| **VTEC** | | | |
| Alfredo Caprioli (ISS) | Coordinator | 3 June 2015 | Costs and benefits of the network, additional costs and benefits of coordinators |
| Kris de Smet (DG SANTE) | Funding entity | 2 June 2015 | Additional costs and benefits of funding entity |
| **ERLTB-Net** | | | |
| Vladyslav Nikolayevsky (PHE) | Lead coordinator | 3 August 2015 | Costs and benefits of the network, additional costs and benefits of coordinators |
| Marieke van der Werf (ECDC) | Funding entity | 23 June 2015 | Additional costs and benefits of funding entity |
| Daniela Cirillo (San Rafaelle Scientific Institute) | Coordinator | 16 July 2015 | Additional costs and benefits of coordinators |
| Doris Hillemann (Borstel FZ) | Coordinator | 31 July 2015 | Additional costs and benefits of coordinators |
| Vera Katalinic-Jankovic (Croatian National Institute of Public Health) | Member | 30 June | Additional costs and benefits of members |
| **FWD-Net** | | | |

| | | | |
|---|---|---|---|
| Johanna Takkinen (ECDC) | Coordinator and funding entity | 8 June 2015 | Costs and benefits of the network, additional costs and benefits of coordinators, additional costs and benefits of funding entity |
| **QUANDHIP[b)]** | | | |
| Roland Grunow (RKI) | Lead coordinator | *n.a.* | Costs and benefits of the network, additional costs and benefits of coordinators |
| Antonino Di Caro (INMI) | Co-coordinator | *n.a.* | Costs and benefits of the network, additional costs and benefits of coordinators |
| Markus Eickmann (PUM) | Member | *n.a.* | Additional costs and benefits of members |
| Dr Mária Herpay, Kis Zoltán PhD, Bernadett Pályi (NCE) | Member | *n.a.* | Additional costs and benefits of members |
| Hervé Raoul (INSERM) | Member | *n.a.* | Additional costs and benefits of members |
| Per Sandven (NIHP) | Member | *n.a.* | Additional costs and benefits of members |
| Aleksandra Zasada (NIZP) | Member | *n.a.* | Additional costs and benefits of members |
| Maria Sofia Núncio Soares (INSA) | Member | *n.a.* | Additional costs and benefits of members |
| Pedro Anda (ISCIII) | Member | *n.a.* | Additional costs and benefits of members |
| Andreas Bråve (PHAS) | Member | *n.a.* | Additional costs and benefits of members |

*Source: Civic Consulting. Notes: a) Additional costs are costs incurred by network members that were not provided for in the budget and for which members were not compensated by the network.*
*b) For QUANDHIP data was collected by the network coordinator RKI in collaboration with Civic Consulting. Dates of interviews are not provided.*

Interviews with network coordinators focused on the following main elements:

- Key characteristics of the laboratory network;
- Functions/activities implemented by the laboratory network;
- Specifics concerning the funding of the laboratory network;
- Costs of the laboratory network by function, in terms of staff time, consumables, equipment, travel, etc.;
- Benefits of the laboratory network, for the members of the network and for society overall in the EU; and
- Changes to costs and benefits under different coordination structures.

Interviews with members of the laboratory network focused on the following elements:

- The laboratory's role in the laboratory network;
- Additional costs incurred by the laboratory for participating in network activities;
- Monetary benefits for the laboratory for participating in the laboratory network; and

- Non-monetary benefits resulting from participating in the network, both for the laboratory and for the country in which the laboratory is located.

Finally, interviews with the entities funding the laboratory networks focused on the following elements:

- Characteristics of laboratory network;
- Process for identifying the network coordinators;
- Funding of the laboratory network;
- Costs to manage the network for the funding entity;
- Potential cost savings for EU institutions in general as a result of the implementation of the laboratory network activities; and
- Benefits of the laboratory network for society overall in the EU.

The three types of interview questionnaires used for the network coordinator, network members and the funding entity are presented in Annex I.

### 3.4.3 Survey of NRLs / laboratory network members

In order to further consider the perspective of NRLs/laboratory network members in the networks the study team conducted an online survey of NRLs/laboratory network members subject to case studies.[38]

The survey had the purpose of providing in-depth information on costs and benefits at the member level. The study team developed a structured questionnaire, including multiple-choice (closed format) and free-text (open-format) fields. The questionnaire covered two main parts: one relating to cost data and monetary benefits and another relating to data on non-monetary benefits. The reference period for assessment of costs and benefits was adapted for each network according to the information provided by laboratory coordinators.

The questionnaire was implemented in a dedicated online platform, *Qualtrics*, which allowed the questions to be adapted to respondents from different networks. In collaboration with network coordinators we invited members of the network by email to contribute to the survey.[39] Follow-up emails to remind network members of the survey were sent twice. The survey was launched on 5 August 2015 and remained open until 5 October 2015. A total of 61 completed responses to the survey were received. The following table provides an overview of the number of responses received by network.

[38] A survey of NRLs/laboratory network members was not originally envisaged as part of the offer. However, as it was found highly beneficial for the inclusion of Member States' perspectives to collect data on costs and benefits at the level of the NRLs (in addition to the data collected at the level of the EU-RL), it was agreed to implement this additional data collection tool.

[39] A specific invitation process was set up in the case of ERLI-Net. In agreement with the network coordinator, the funding entity, and CHAFEA a smaller sample of ERLI-Net network members was invited to participate in the survey. The sample was selected by network coordinators according to the following criteria: laboratories which provide training/resources to other laboratories within ERLI-Net; laboratories that utilise training/resources offered by ERLI-Net; and laboratories which either do not engage much with ERLI-Net or find it hard to implement the training/resources they get through ERLI-Net.

**Table 11. Number of survey responses by case study network**

| Case study network | ERLI-Net | ENIVD | EU-RL VTEC | ERLTB-Net | FWD-Net | QUANDHIP |
|---|---|---|---|---|---|---|
| Number of survey responses | 6 | 7 | 18 | 2 | 15 | 13 |

*Source: Civic Consulting.*

Similarly to the interviews with members of the laboratory network, the survey questionnaire focused on the following elements:

- Selection criteria for membership in the network;
- Participation of the laboratory in activities related to the core functions of networks;
- Cost savings as a result of participation in the activities;
- Costs incurred as a result of participation in the activities;
- Receipt of any grants or in-kind benefits from institutions outside of the network as a result of membership of the network;
- Additional income from increased demand for services provided by the laboratory as a result of membership of the network;
- Non-monetary benefits resulting from participation in the network, both for the laboratory and for society overall; and
- General assessment of whether the benefits of participating in the network outweigh the costs.

Annex II present an example of the survey questionnaire for members of the ERLI-Net network.

### 3.4.4 Complementary research for case studies

In addition to the interviews conducted for the case studies, and the survey of NRLs/laboratory network members, where relevant the study team conducted complementary research. In particular, documents suggested by interviewees were reviewed and additional data (e.g. staff cost data) from centralised EU-level or international data sources (in particular Eurostat) were researched. Furthermore, follow-up interviews were conducted for the cost benefit analysis.

## 3.5 Approach to data analysis

### 3.5.1 Creating a database with cost and benefit data

Throughout the course of the study a database was compiled with data on costs and benefits for each case study. The database differentiates between the different cost types (staff costs, capital equipment costs, costs of consumable materials, travel and accommodation costs, shipping costs, and subcontracting) and the different benefit types (monetary and non-monetary benefits).
Relevant sources for the database were:

- Case study interviews;
- Survey of laboratory network members;
- Additional research including complementary and follow-up interviews; and
- Centralised EU-level or international data sources.

The following sub-sections describe in further detail how the database for costs and benefits was established.

*Compiling the cost database*

The cost data was compiled individually for each case study as a matrix of two dimensions: the costs per function and the costs per tier. The costs of each core function were collected by cost item (i.e. separate cost data was collected for staff costs, equipment, consumables, travel, shipping, subcontracting/services, and overhead/administration). Cost data was provided mostly in monetary (Euro) terms. However, some participants reported data related to staff costs in terms of staff time rather than in monetary terms. If staff time was reported, staff costs were estimated using Eurostat data on labour costs in the reference year of the case studies.[40]

Cost data was collected through network coordinators, network members, and the funding entity. Coordinators and funding entities provided their costs in a predefined Excel sheet, following a detailed phone interview. Network members provided their costs by means of a survey (see Annex I and II for data collection tools).

Network coordinators provided data on the *budgeted costs* and on *additional costs*. Budgeted costs relate to those costs covered by the network budget. Coordinators provided a breakdown of the network budget by cost item as well as estimations (in percentage terms) of the share of total costs allocated to core functions. The budgeted costs per core function and cost item were calculated on this basis. Furthermore, coordinators provided data on their additional costs, i.e. the costs they incurred in the reference period for coordinating network activities and for which they were not compensated by the network budget. Additional costs were allocated evenly between those functions a coordinator had indicated to be responsible for.

Network members provided data on their additional costs (i.e. the costs they incurred in the reference period as a result of their participation in network activities and for which they were not compensated by the network budget, such as staff costs for participation in an EQA) by means of a survey. Based on the responses, the total additional costs of all network members for a case study network were extrapolated.
The funding entity provided data on additional costs, i.e. those costs relating to their management and administration of the network, by means of a questionnaire. Additional costs mainly related to Function 8 (Governance), unless the funding entity had conducted specific other tasks such as organising the annual workshop. Additional costs related to these additional tasks were allocated to the respective function of the network.

[40] The two staff categories used to collect staff cost data (i.e. *professionals* and *technicians and associate professionals*) refer to the International Standard Classification of Occupations (ISCO) of the International Labour Organisation (ILO). ISCO staff cost data was available for all EU Member States for the year of 2006. Labour costs for the reference period of case studies were then extrapolated on the basis of the yearly labour cost development in EU Member States. For the calculation of staff costs of coordinators, labour costs were calculated using the labour costs of the country the coordinator was located in. Staff costs of network members were calculated on the basis of the European average of labour costs.

Once the cost data was compiled per case study network as described above, it was annualised and the annual costs of all case study networks were included in our data base for the subsequent analysis.

*Compiling the data for monetary benefits*

Reported monetary benefits were annualised, extrapolated to all network members of a case study network, and included in the data base for the subsequent analysis.

*Compiling the data for non-monetary benefits*

Data on non-monetary benefits was collected by means of a *Likert scale*. Network coordinators, network members and the funding entity were presented with statements concerning non-monetary benefits. They then rated these statements on a scale from 1 (not at all) to 5 (very much). For each case study, an average rating was calculated separately for coordinators, network members and the funding entity.
In line with the benefit types identified, two types of non-monetary benefits were assessed (each consisting of several dimensions, see Section 3.3 above): benefits for network members and benefits for society as a whole. The funding entity only assessed the benefits for society as a whole.

*Completing the database*

Using the data on costs, monetary benefits and non-monetary benefits collected and analysed as described above, a complete database of cost data and benefit data was created. It provides cost data and monetary benefit data per case study network in the reference period and on an annual basis. Furthermore, it includes the assessments of non-monetary benefits per case study network.

### 3.5.2 Validating data collected

The data collected from interviewees and survey participants was validated. We checked for accuracy, consistency and completeness by comparing the data collected across the different data collection tools and across case studies. In cases where we found inconsistencies we conducted a number of follow-up interviews with network coordinators and funding entities and revised the database according to the newly provided information. In the few cases where missing data remained, we extrapolated from the available data.

### 3.5.3 Establishing the costs of EU-RL networks

Throughout the study, data was collected for six case study networks. After scrutinising the data sets for these case study networks, four of the six data sets were considered appropriate for the calculation of median costs, namely:

- EU-RL VTEC network;
- ENIVD;
- ERLI-Net; and
- QUANDHIP.

The dataset relating to the ERLTB-Net network was excluded from the calculation of median costs due to incompleteness of the data. Coordinators had not been able to provide a breakdown of the network budget by core function. Furthermore, only two network members participated in the survey. This response rate could not be considered representative for the whole network. The data collected for the ERLTB-Net is presented in the case study section of this report (Section 4) but was not considered in the cost analysis section (Section 5).

In addition, the data set from FWD-Net could also not be used in the calculation of median costs, as data of costs related to some functions was incomplete and no extrapolations could be undertaken. Therefore, we excluded the dataset as a basis for the calculation of median costs. Nonetheless, since the data on the most relevant functions was complete, it is still presented and discussed in the section on the analysis of costs (Section 5).

Using the data sets of the four case study networks mentioned above, annual median costs were calculated. This was done at a granular level, i.e. at the level of the cost item and for each tier and function separately. Overall annual median costs were then calculated as the sum of individual median values.

The following table illustrates the establishment of median costs.

**Table 12. Approach for establishing annual median costs**

| Core function | Cost item | Median costs Tier 1 | Median costs Tier 3 | Median costs funding entity | *Total* |
|---|---|---|---|---|---|
| Function 1 - Reference diagnostics | Staff costs | *Median* | *Median* | *Median* | *Sum* |
| | Equipment | *Median* | *Median* | *Median* | *Sum* |
| | Consumables | *Median* | *Median* | *Median* | *Sum* |
| | Travel | *Median* | *Median* | *Median* | *Sum* |
| | Shipping | *Median* | *Median* | *Median* | *Sum* |
| | Subcontracting/ services | *Median* | *Median* | *Median* | *Sum* |
| | Overhead/ administration | *Median* | *Median* | *Median* | *Sum* |
| | *Total of function* | *Sum* | *Sum* | *Sum* | *Sum* |
| Function 2 - Reference material resources | Staff costs | *Median* | *Median* | *Median* | *Sum* |
| | Equipment | *Median* | *Median* | *Median* | *Sum* |
| | … | … | … | … | … |
| | … | … | … | … | … |
| … | … | … | … | … | … |
| | … | … | … | … | … |
| … | … | … | … | … | … |
| Total | | *Sum* | *Sum* | *Sum* | *Sum* |

*Source: Civic Consulting. Note: 'Median' indicates the calculation of the median values of individual cost items on the basis of reported data from four case study networks. 'Sum' indicates the addition of relevant median values.*

The annual median costs established above were used in the subsequent analysis to assess the costs and benefits of EU-RL networks options.

### 3.5.4 Establishing the benefits of EU-RL networks

For the establishment of the benefits of an EU-RL network, monetary benefits and non-monetary benefits were considered separately.

*Establishing monetary benefits of EU-RL networks*

For the establishment of annual median monetary benefits, the same approach was taken as for the establishment of its median costs, i.e. they were calculated as the median of reported benefits of the four case study networks considered above.
Reported monetary benefits were calculated at the level of functions for network members responding to our survey and extrapolated to all members of the network. Coordinators of case study networks did not report receiving any monetary benefits deriving from their role as network coordinators. The funding entities of case study networks indicated having received monetary benefits in terms of saved costs, however, they were generally unable to quantify these cost savings. Estimates of monetary benefits provided in this study are therefore conservative in nature (see discussion of benefits in Section 6).

*Establishing non-monetary benefits of EU-RL networks*

As described above, non-monetary benefits were assessed on the basis of a *Likert scale*. Considering that all case study networks assessed the same non-monetary benefits on the same scale (from 1 to 5), we calculated the average non-monetary benefits of an EU-RL network using the average value of the reported assessments of case study networks. Average values could be calculated at the level of network coordinators, network members, funding entities and for the whole network.

These figures were then used in the subsequent analysis of costs and benefits of options.

### 3.5.5 Analysis of costs and benefits of options

Following the creation of the database of costs and benefits of case study networks and the establishment of annual median costs and benefits, we analysed the costs and benefits of different coordination options, based on the assumption that under all options an identical work programme in terms of activities conducted would be implemented.

First, we assessed the cost implications of different network coordination structures by core functions. We examined the cost implications of different coordination structures at the pan-European level (i.e. whether a network is virtually or physically centralised) and at the supranational level (i.e. whether a network has an additional supranational coordination level). Based on the comparison of case study networks, expert assessment of interviewees, and survey responses, we assessed how the implementation of core functions would change under different coordination structures, drawing conclusions for the related costs. We thereby established an assessment of differential costs between a virtually and a physically centralised network and between a network with and a network without an additional supranational level (see Section 3.1).

Second, we assessed the implications of different coordination structures for the benefits of a network. Again, we assessed the impact of different coordination

structures at the pan-European and at the supranational level on the implementation of different core functions. As for the costs, we established an assessment of differential benefits between a virtually and a physically centralised network and between networks with and without an additional supranational level (see Section 3.1).

In a final step, we used both the assessment of differential costs and of differential benefits to draw conclusions for the costs and benefits of the different coordination options presented in Section 3.1. All possible combinations of different coordination structures at the pan-European and at the supranational level were assessed. Results are presented in Sections 5 and 6.

### 3.5.6 Limitations

*Focus on additional costs and benefits of EU-RL networks*

As indicated in Section 3.1.3 concerning the assumptions of the tiers of an EU-RL network, Tier 3 laboratories, referred to as national reference laboratories (NRLs) for the purposes of this study, play two main roles: provision of national reference laboratory services to their country and participation in activities of the EU-RL network. The NRL's provision of national reference laboratory services to their country and the related funding to do so is the responsibility of the respective Member State, not of the EU-RL network. The provision of national reference laboratory services between Member States (e.g. the pooling of resources for national reference laboratory services based on bilateral agreements) is similarly the responsibility of the Member States in question.

As this study focuses specifically on the *additional* costs and benefits generated by an EU-RL network, the provision of national reference laboratory services is not considered in the analysis in this study. We have therefore not considered the overall costs and benefits of the provision of reference laboratory services, and not discussed options that Member States could implement to replace the national reference laboratory functions through other arrangements, such as sharing of laboratory infrastructure or other pooling of resources among Member States.

*Selection of case study EU-RL networks as evidence base*

The evidence base for the assessment of costs and benefits of EU-RL networks in this study is a limited number of case study laboratory networks. As shown in Section 4, these networks present substantial diversity in terms of the budget allocated, the additional costs incurred (by network members, the coordinator(s) or the funding entity), the coordination structure, the pathogens covered, the number of network members and the geographical coverage. In this regard, this selection of networks can be considered broadly representative of the diversity of existing EU-RL networks. Nonetheless, it is possible that other EU-RL networks have characteristics or features that are not shared by the case study networks assessed in this study. Accordingly, while the data collected from the case study networks as the evidence base is representative, it is not derived from a comprehensive account of all EU-RL networks.

*Precision of estimates concerning budgeted costs*

In this study, as described in Section 3.3.1 we developed a comprehensive framework of cost items (i.e. staff costs, equipment, consumables, travel, shipping, subcontracting/services, and overhead/administration). Cost data was then collected

separately for each function according to these cost items, at the level of the network coordinators, network members and the funding entity, in terms of both budgeted costs and additional (non-budgeted) costs. While data on additional costs was collected for each function in absolute monetary terms (or person-months, for staff costs), data on budgeted costs is based on network coordinators' estimations of the share of the total budget attributed to each function in percentage terms. These break-downs of budget costs were established on the basis of several rounds of consultation and follow-up with network coordinators, and hence can be considered accurate; however, they remain estimations of shares of total costs as opposed to absolute figures.

*Self-reported assessment of benefits for society overall*

The assessment of the benefits of EU-RL networks for society overall was collected from the coordinators, funding entities and members of these networks. We do not expect network members to have overestimated the benefits of EU-RL networks for society overall; indeed many network coordinators and members interviewed were hesitant to draw a connection between their activities and the long-term impacts on e.g. reduction in disease burden (for details, see Section 6). Nonetheless, it should be noted that an evaluation by external stakeholders of the networks' impacts in terms of societal benefits, including by other beneficiaries of the societal benefits beyond the funding entities themselves such as the wider public, e.g. doctors, patients and their associations, was not part of the scope of this study. The reported societal benefits are therefore limited to the consulted networks and can be expected to be more extensive for the wider public.

*Focus on costs and benefits of predefined options for network coordination*

As indicated in Section 3.1, we defined four options for network coordination to be considered in terms of costs and benefits in this study, which are based on those options originally proposed in the EU Human Pathogen Reference Laboratories Options Project (EURLOP) study. The analysis of costs and benefits of coordination structures of EU-RL networks therefore did not consider other potential options for network coordination or attempt to develop a blueprint for the coordination of future EU-RL networks. Nonetheless, conclusions from this study that may be of relevance for the future development of EU-RL networks in general are provided in Section 7.

# 4. Case studies

*The following sections present the six case studies conducted for this study. Each case study report first describes the main laboratory network characteristics, activities conducted and the coordination structures in place. Second, the reports present the funding structure of the networks, followed by the costs and benefits for network members and society.*

## 4.1 Case study: EU-RL VTEC network

This section presents the case study on the European Union Reference Laboratory on *E. coli*, including verocytotoxin-producing E.coli (VTEC) (EU-RL VTEC).

### 4.1.1 EU-RL VTEC network characteristics

The EU-RL VTEC is one of the EU reference laboratories for food and feed. It was established with the objective to "contribute to a high quality and uniformity of analytical results"[41] to support effective official controls that verify compliance with feed and food law, animal health and animal welfare rules throughout the EU. In accordance with Directive 2003/99/EC, which identifies VTEC as a zoonosis posing a significant risk to public health, the EU-RL VTEC covers all public health-related issues of food and feed of Escherichia coli, including verotoxigenic E.coli. It was established in 2006 on the basis of Regulation (EC) 882/2004 at the Istituto Superiore di Sanità (ISS) in Rome, Italy.

The EU-RL VTEC coordinates a network of 35 VTEC national reference laboratories (NRLs) from all EU Member States and the NRLs of Iceland, Norway, the Republic of Macedonia, Turkey, Switzerland, and Serbia. It was selected on the basis of a tendering process by the European Commission. All NRLs of the EU-RL VTEC network have been appointed by the national authorities of their Member States.

The EU-RL VTEC network is the only network among our case studies that has a legal basis for its establishment, namely Regulation (EC) 882/2004. Furthermore, the network focuses on VTEC from the food and animal health perspective, not from the clinical perspective.

The following table summarises the characteristics of the EU-RL VTEC network.

[41] Regulation (EC) 882/2004, recitals.

**Table 4. Network characteristics of the EU-RL VTEC network**

| Characteristic | Description |
|---|---|
| Pathogens covered | Escherichia coli, with particular focus on verotoxigenic E.coli (VTEC) |
| Founding year | 2006 |
| Establishment of network | The EU-RL VTEC was established in accordance with:<br>- Directive 2003/99/EC, which identifies VTEC as a zoonosis needing to receive priority in monitoring schemes.<br>- Regulation (EC) 882/2004, which in Article 32 and 33 defines all tasks and responsibilities of EU-RLs and related NRLs for food and feed.<br>- Regulation (EC) 776/2006, which amends Annex VII of Regulation (EC) 882/2004, listing all EU-RLs appointed by the European Commission. |
| Network coordinator | Istituto Superiore di Sanità (ISS) in Rome, Italy |
| Number of network members | 42 (41 NRLs and one EU-RL) |
| Geographical coverage | All EU Member States, Iceland, Norway, Republic of Macedonia, Turkey, Switzerland, Serbia |
| Type of network members | Government institutions including food safety institutes, veterinary institutes, and public health institutes as well as laboratories of university faculties. |
| Requirements for membership | The EU-RL was selected on the basis of a tendering process by the European Commission.<br>NRLs are appointed by their competent national authority. |
| Reference period for the case study | January 2014 - December 2014 |

*Source: Civic Consulting based on document review and information provided by network coordinator.*

### 4.1.2 Activities of the EU-RL VTEC network

Article 32 of Regulation (EC) 882/2004 outlines general tasks and responsibilities of EU-RLs. It specifies that an EU-RL is responsible for:

> *"(a) providing national reference laboratories with details of analytical methods, including reference methods;*
>
> *(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;*
>
> *(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;*
>
> *(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;*
>
> *(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;*
>
> *(f) collaborating with laboratories responsible for analysing feed and food in third countries."* [42]

[42] Regulation (EC) 882/2004, Article 32.

An annual work plan specifies activities which are implemented by the EU-RL ('network activities') in the fulfilment of these obligations. The work plan is developed in close cooperation between the EU-RL and the Commission. Activities implemented by the EU-RL VTEC in 2014 on the basis of this annual work plan are summarised in the table below.

**Table 14. EU-RL VTEC network activities implemented in the reference period (2014)**

| Core function | Scope of implementation |
|---|---|
| 1. Reference diagnostics | - Development, evaluation, and validation of analytical methods and facilitation of the transfer of these methods to NRLs, for example through training and EQAs. (In the budget, respective activities are subsumed under Function 4 and 5.) |
| 2. Reference material resources | - Maintenance of E.coli reference strains and plasmids by the EU-RL.<br>- Provision of theses reference strains and plasmids to NRLs as well as to other laboratories. |
| 3. Scientific advice to public authorities | - Provision of scientific advice to DG SANTE, EFSA, and ECDC on various topics.<br>- Provision of technical support for policy development on food safety issues to DG SANTE. |
| 4. External Quality Assessments (EQA) | - Organisation of three proficiency tests by the EU-RL for the NRLs in the network. Proficiency tests focused on the detection of VTEC in food samples (1) and on strain typing (2). |
| 5. Training | - Organisation of two types of training programmes by the EU-RL. 10 trainees from NRLs participated in one-week laboratory training courses at the EU-RL premises. 10 trainees from NRLs participated in a two-day training course at the EU-RL premises specifically on molecular typing. Furthermore, a workshop is organised annually.<br>- Provision of scientific advice by the EU-RL to NRLs mainly on analytical issues. |
| 6.Collaboration and research | Participation of the EU-RL in the EFSA programme for molecular typing of VTEC from food and animals. |
| 7. Monitoring, alert and response | In order to prepare NRLs for their obligation to submit VTEC pulsed field gel electrophoresis (PFGE) profiles to the upcoming EFSA database for molecular typing data from food and animal isolates of food-borne pathogens, training courses and a network-wide proficiency test on PFGE were organised for the participation of NRLs in the network. (In the budget, respective activities are subsumed under Function 4 and 5.) |
| 8. Governance of the network | - Administration and coordination of the network (for details see Section 1.3 on coordination structure)<br>-Provision of a website with a restricted area for NRLs to upload results of the proficiency tests. |

*Source: Civic Consulting based on information provided by network coordinator.*

### 4.1.3 Coordination structure of the EU-RL VTEC network

The EU-RL VTEC network has a physically centralised coordination structure, i.e. one coordinator (the EU-RL) at the pan-European level. The funding entity is the European Commission (DG SANTE/Unit G4).

In line with the tasks and responsibilities of EU-RLs as provided in Regulation (EC) 882/2004, the EU-RL VTEC coordinates the network of NRLs. It is responsible for proposing, implementing and reporting on all activities of the annual work plan. The EU-RL VTEC is the recipient of EU funding and spends it according to the agreed work programme/budget. While in principle coordination of specific activities of the work plan could be sub-contracted to network members or service providers, in practice this is not done and all laboratory activities are coordinated by the EU-RL VTEC.

The funding entity and counterpart of the EU-RL VTEC at the Commission is DG SANTE/Unit G4. Its main tasks are to closely collaborate with the EU-RL VTEC on the development of the annual work plan, to review and approve the proposed annual work plan, and to monitor its implementation. It is also in charge of facilitating administrative funding procedures and ensuring coherence between the EU-RL's activities and the work of other initiatives and programmes of relevant EU institutions.

The following table summarises the coordination structure of the EU-RL VTEC network.

**Table 15. Coordination of the EU-RL VTEC network**

| **Coordination structure** | |
|---|---|
| Characteristics | Physically centralised network |
| **Network coordinator** | |
| Istituto Superiore di Sanità (EU-RL VTEC) | European Union Reference Laboratory and coordinator of the network of NRLs for VTEC in the EU. Main tasks include:<br>- *Development of the work programme:* To coordinate with DG SANTE concerning priority areas of the work plan and to develop a proposal accordingly.<br>- *Implementation of the work programme and coordination with NRLs*: To facilitate the implementation of all activities of the work plan (see Section 1.2) and to coordinate all activities with NRLs.<br>- *Administrative coordination*: To facilitate all administrative procedures within the network and to coordinate with the European Commission accordingly, including in terms of reporting. |
| **Funding entity** | |
| European Commission (DG SANTE) | Administrator of the network for EU institutions, responsible for allocation of funds to the EU-RL. Main tasks include:<br>- W*ork programme*: To coordinate with the EU-RL regarding priority areas prior to the development of the work plan, to evaluate the annual work plan proposed by the EU-RL, and to monitor the implementation of all activities included in the work plan.<br>- *Funding*: To coordinate with the financial unit regarding all administrative funding procedures, to take decisions on budget shifts if needed.<br>- *Internal coordination*: To ensure coherence with the work of other units in DG SANTE and if relevant with other EU institutions. |

*Source: Civic Consulting based on information provided by network coordinator and funding entity.*

### 4.1.4 Funding received by the EU-RL VTEC network

According to Article 32 of Regulation (EC) 882/2004 *"Community reference laboratories may be granted a Community financial contribution".*[43] For the EU-RL VTEC network, all activities foreseen in the work plan are fully funded by the Commission. The provision of funds is not conditional to co-financing contributions by the EU-RL or NRLs as members of the EU-RL VTEC network.

As the following table shows, in the reference period of 2014 the total budget for implementing the annual work plan amounted to EUR 334 000, and was fully funded by the EU.

**Table 16. Funding of the EU-RL VTEC network for the reference period (2014)**

| Funding provided by | Amount of funding (in Euro) |
|---|---|
| European Commission DG SANTE | 334 000 |
| Co-financing by network members | Not required |
| *Total funding* | *334 000* |

*Source: Civic Consulting based on information provided by network coordinator and funding entity.*

### 4.1.5 Costs of the EU-RL VTEC network

The total costs of implementing the EU-RL VTEC network are the operating expenditure of the network as funded by the European Commission and the additional costs incurred by network members for activities included in the annual work programme of the network. In this section both components of the network costs are described.

*Operating expenditure of the network*

The operating expenditure of the network is the sum of the costs specified in the annual budget for the implementation of all network activities as funded by the European Commission. The following table provides an overview of the operating expenditure of the EU-RL VTEC network broken down by cost item. As the table below shows, the largest share of costs for the implementation of the network's work plan in 2014 was attributable to staff costs: 61% of the network budget was used to cover staff costs. The second and third biggest shares related to costs of consumables and travel costs (each 12%).

[43] Regulation (EC) 882/2004, Article 32.

**Table 17. Operating expenditure of the EU-RL VTEC network according to budget for the reference period (2014)**

| Cost item | Total network budget (in Euro) | Share of total network budget (as percent) |
|---|---|---|
| Staff | 204 000 | 61% |
| Capital equipment | 19 000 | 6% |
| Consumables | 40 000 | 12% |
| Travel | 39 000 | 12% |
| Shipping | 11 000 | 3% |
| Subcontracting and services | 0 | 0% |
| Overhead | 21 000 | 6% |
| *Total* | *334 000* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator.*

As the following table shows, staff time amounting to 53 person-months was financed by the European Commission in 2014 for the implementation of activities of the EU-RL VTEC network. All staff were located at the EU-RL VTEC in Rome. 29 person-months related to professionals. 24 person-months related to the category of technicians and associate professionals.

**Table 18. Person months funded for the EU-RL VTEC network in the reference period (2014)**

| Staff category | Person-months (EU funded) |
|---|---|
| Professionals | 29 |
| Technicians/associate professionals | 24 |
| *Total* | *53* |

*Source: Civic Consulting based on information provided by network coordinator.*

The table below breaks down operating expenditure by core function. It shows that the biggest share of the budget (26%) was allocated to the implementation of network-wide EQAs. Furthermore, almost one fifth of the budget (19%) was allocated to cover governance costs, while 22% of the budget was used to facilitate training activities of network members.

**Table 5. Operating expenditure of the EU-RL VTEC network by core function in the reference period (2014)**

| Core function | Expenditure (in Euro) | Expenditure as percentage of total budget |
|---|---|---|
| 1. Reference diagnostics | 0 | 0% |
| 2. Reference material resources | 36 409 | 11% |
| 3. Scientific advice to public authorities | 19 489 | 5% |
| 4. External Quality Assessments (EQA) | 87 374 | 26% |
| 5. Training | 85 555 | 26% |
| 6.Collaboration and research | 41 414 | 12% |
| 7. Monitoring, alert and response | 0 | 0% |
| 8. Governance of the network | 63 759 | 19% |
| *Total* | *334 000* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator.*

*Additional costs incurred by network members*

In the reference period, additional costs that were not compensated for by the network budget were incurred at various levels by members of the EU-RL VTEC network. The following table provides an overview of additional costs broken down by network member and cost item.

**Table 6. Additional costs incurred by EU-RL VTEC network members in the reference period (2014)**

| Cost item | Additional costs of funding entity | Additional costs of coordinator | Additional costs of all laboratory members* | Total additional costs |
|---|---|---|---|---|
| Staff costs (in Euro) | 15 514 | 141 000 | 111 817 | 268 331 |
| Consumables (in Euro) | 0 | 10 000 | 64 862 | 74 862 |
| Travel (in Euro) | 1 400 | 0 | 2 152 | 3 552 |
| Shipping (in Euro) | 0 | 0 | 810 | 810 |
| Other costs(in Euro) | 0 | 6 000 | 26 282 | 32 282 |
| *Total* | *16 914* | *157 000* | *205 923* | *379 844* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members. Note: *Extrapolation for all network members based on survey results (N=18).*

The table illustrates that additional costs were incurred in particular at the level of the EU-RL. The hosting institution of the EU-RL VTEC contributed a considerable amount of additional staff time for the coordination of the network during the reference period (in total EUR 141 000). Furthermore, it contributes costs of consumables (EUR 10 000) and equipment costs (EUR 6 000, see other costs). For NRLs, additional costs related mainly to staff time and consumables costs relating to their participation in EQAs and

training activities. Additional costs incurred by the Commission related to the facilitation of administrative procedures. Staff time and travel expenses of policy officers of the Commission were also provided as in-kind contributions.

Overall, as with the operating expenditure, staff time was the biggest additional cost item for network members.

*Total costs of the network*

The total costs of implementation of the EU-RL network, i.e. the sum of operating expenditure and additional costs, amounted to EUR 713 843 in 2014. The following table provides an overview of these costs.

**Table 7. Total costs of the EU-RL VTEC network**

| Cost item | Operating expenditure according to budget (in Euro) | Total additional costs (in Euro) | Total network costs (in Euro) |
|---|---|---|---|
| Staff | 204 000 | 268 331 | 472 331 |
| Capital equipment | 19 000 | 0 | 25 000 |
| Consumables | 40 000 | 74 862 | 114 862 |
| Travel | 39 000 | 3 552 | 42 552 |
| Shipping | 11 000 | 810 | 11 810 |
| Subcontracting and services | 0 | 0 | 0 |
| Overhead/ other costs | 21 000 | 32 282 | 47 282 |
| *Total* | *334 000* | *379 844* | *713 843* |

*Source: Civic Consulting based on information provided by network coordinator and funding entity.*

### 4.1.6 Benefits of the EU-RL VTEC network

The EU-RL VTEC network has induced benefits for network members as well as for society as a whole. They have been assessed by the network coordinator and network members, as follows.

*Benefits for network members*

Benefits for network members are of both a monetary and non-monetary nature. The following table describes the reported monetary benefits, which relate to cost savings of NRLs. NRLs of the EU-RL VTEC network save on fees that they would otherwise have incurred thanks to services provided free of charge through the network, such as EQAs, trainings or the distribution of reference materials.

**Table 8. Monetary benefits for members of the EU-RL VTEC network**

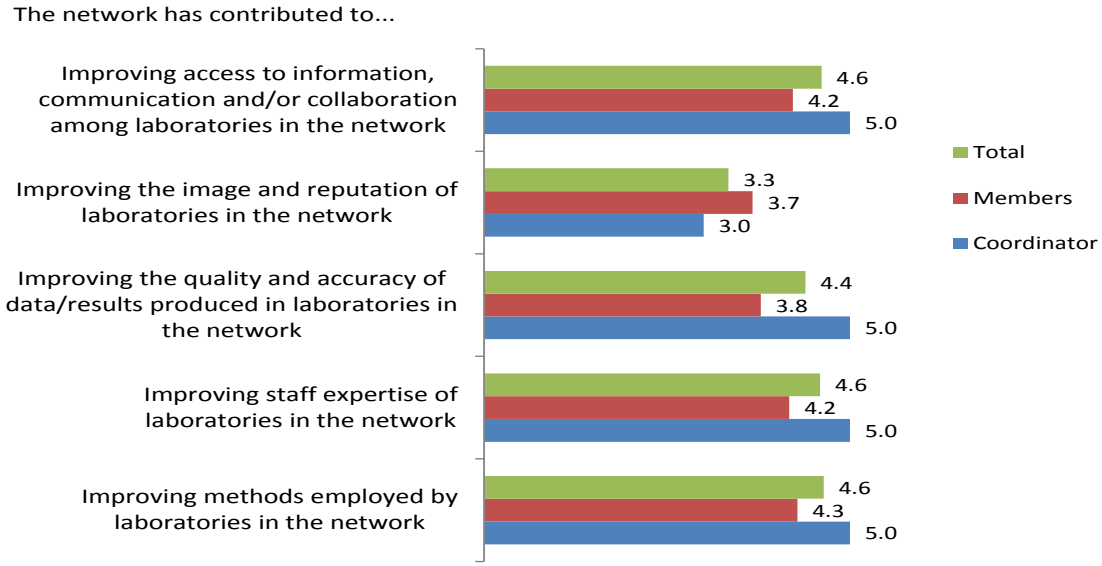
| Benefit results from | Estimated amount saved by network members (in Euro)* |
|---|---|
| Cost savings related to molecular typing of isolates | 8 213 |
| Cost saved related to reference material received through the network | 6 185 |
| Fees saved for participating in commercial EQA | 14 684 |
| Fees saved on training costs | 14 173 |
| *Total* | *43 256* |

*Source: Civic Consulting based on survey results. Note: *Extrapolation for all network members based on survey results (N=18).*

Non-monetary benefits of the EU-RL VTEC network for members include the improvement of laboratory methods, staff expertise, quality and accuracy of data and results, and the access to information, communication and collaboration.

The following figure provides a qualitative assessment of these benefits. Network members were asked to assess the statements on a scale from 1 ('not at all') to 5 ('very much').

**Figure 2. Average rating of non-monetary benefits for members of the EU-RL VTEC network**




*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=18). Note: Rating on a scale from 1 (not at all) to 5 (very much). The funding entity was not asked this question.*

As the figure above shows, except for potential improvements in the image and reputation of laboratories, all listed benefits were assessed with very high scores of at least 4.4 out of 5 points on average. The coordinator consistently ranked the benefits higher than the network members. Beyond the benefits listed in the table, an interviewee of the funding entity also emphasised that EU institutions benefit in

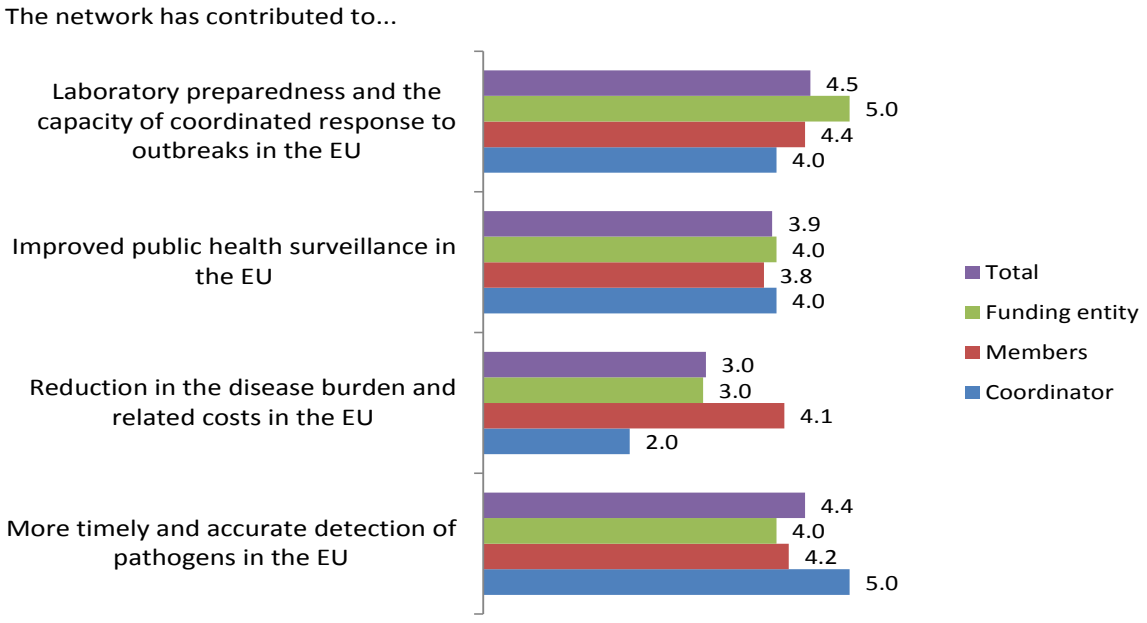
particular from receiving scientific input quickly and efficiently via the network, for example on technical issues such as methods referred to in the legislation.

*Benefits of the network for society*

Monetary benefits of the EU-RL VTEC network were also highlighted for society as a whole by interviewees, although they had difficulties estimating them. Interviewees emphasised that tasks currently coordinated by the EU-RL VTEC network are priority tasks for public health in the EU and would need to be implemented under any circumstances. In absence of the network, the tasks would instead be tendered out separately, leading to a duplication of the administrative costs related to the tendering process as well as the fixed costs of individual projects.

In terms of non-monetary benefits, interviewees positively assessed the contribution of the EU-RL VTEC network to more timely and accurate detection of pathogens, improved public health surveillance, increased laboratory preparedness and coordinated response in the EU. As the following figure shows, all of these benefits scored on average 3.9 or above out of 5 points. Only the contribution to a reduction in the disease burden received a low average assessment of 3.0. The coordinator reasoned that a direct link between the disease burden and the network is difficult to establish. Hence, while the network can be considered to contribute somewhat to its reduction, the network coordinator and authorities did not perceive it as the most relevant benefit of the network. Network members rated the contribution of the network to the reduction of the disease burden more positively with an average rating of 4.1 out of 5 points.

**Figure 3. Average rating of non-monetary benefits for society as a whole of the EU-RL VTEC network**




*Source: Civic Consulting based on information provided by network coordinator, funding entity and survey participants (N=18). Note: Rating on a scale from 1(not at all) to 5 (very much).*

## 4.2 Case study: ENIVD

This section presents the case study on the European Network for Diagnostics of "Imported" Viral Diseases (ENIVD).

### 4.2.1 ENIVD network characteristics

The European Network for Diagnostics of "Imported" Viral Diseases (ENIVD) was founded in 1995. Following several WHO expert meetings on emerging infectious diseases, scientists across Europe recognised the need for stronger collaboration in the diagnostics of these diseases. In a memorandum of understanding they declared their support for building a network on the matter and defined the following objectives for the initiative:[44]

- "Maintain a network of European laboratories working on diagnostics of "imported", rare and emerging viral infections of European Interest. Provide mutual help in the exchange of diagnostic samples, i.e. sera, viruses, methods, and information in order to improve diagnostics.
- Identify those viral infections more likely to be imported and co-ordinate the objectives and identify laboratories, capable and willing to perform the rapid diagnostics (<24h) of an acute case, suspected to be infected with a viral haemorrhagic fever.
- Work out recommendations for standardisation, biosafety requirements and quality control in diagnostics laboratories involved in the diagnostics of such diseases.
- Identify and operate standard assays according to defined quality control criteria.
- Optimise limited resources by exchanging reagents, methodologies, and expertise.
- Encourage regular contact within the network through meetings, exchange and training of personnel in biosafety and new laboratory techniques.
- Open the network for members of other European laboratories.
- Organise and co-ordinate international activities with the national or international organisations like ECDC, WHO, and CDC."

Notably, ENIVD is a network that was established by scientists and not by the EU. Nonetheless, the network received funding from the Health Programme through DG SANCO early on. Since 2008, it is funded by ECDC. Today, ENIVD has 67 members covering all EU Member States (MS) as well as Norway, Switzerland, Serbia, Albania, Kosovo, Bosnia and Herzegovina, and Macedonia. Members – mostly national reference laboratories – are invited to participate in the network on the basis of their interest, previous work related to imported viral diseases and their reputation as reference laboratory in their respective countries. Since its establishment, the network has been coordinated by the Robert-Koch Institut (RKI) in Germany.

[44] Memorandum of Understanding of the ENIVD, http://www.enivd.de/manifest.htm

**Table 9. Network characteristics of ENIVD**

| Characteristic | Description |
|---|---|
| Pathogens covered | Emerging viral diseases |
| Founding year | 1995 |
| Establishment of network | ENIVD was established upon the initiative of scientists working in the field of "imported" viral disease diagnostics in Europe. Following several expert meetings of the WHO, they recognised the need for closer collaboration and founded the network for the diagnostics of "imported" viral diseases. Since 2008 the network receives funding from ECDC. |
| Network coordinator | Robert-Koch-Institut, Berlin, Germany |
| Number of network members | 67 |
| Geographical coverage | All EU Member States, Norway, Switzerland, Serbia, Albania, Kosovo, Bosnia and Herzegovina, Macedonia |
| Type of network members | National reference laboratories |
| Requirements for membership | Membership upon invitation |
| Reference period for the case study | June 2014 - June 2015 |

*Source: Civic Consulting based on document review and information provided by network coordinator.*

### 4.2.2 Activities of ENIVD

According to ECDC, most EU Member States are well prepared for dealing with common communicable disease agents. However, gaps exist in the diagnostic capacity and preparedness of MS to respond to outbreak-prone diseases, imported agents, rare agents, unknown agents, or outbreaks related to intentional release. As an expert network for those types of agents, ENIVD addresses existing gaps by organising a number of activities. They focus on the following topics:

- Quality assessments;
- Outbreak support;
- Laboratory preparedness; and
- Training.

The following table provides further details on the activities implemented by ENIVD.

**Table 10. ENIVD network activities implemented in the reference period (06/2014-06/2015)**

| Core function | Scope of implementation |
|---|---|
| 1. Reference diagnostics | ENIVD undertakes diagnostic confirmation testing and updates standard operating procedures, where possible. |
| 2. Reference material resources | New and unusual strains are collected within the network and made available to network members. |
| 3. Scientific advice to public authorities | ENIVD provides scientific advice to ECDC and other European institutions. Activities in the reference period included:<br>– Conducting surveys for ECDC;<br>– Developing fact sheets e.g. for Viral Hemorrhagic fever viruses (general), Hantavirus Pulmonary Syndrome, Chikungunya virus, Ebola VHF; and<br>– Ensuring round-the-clock availability of experts to ECDC for all viruses covered in ENIVD. |
| 4. External Quality Assessments (EQA) | Two EQAs are conducted per reporting period, focusing on agents or groups of agents prioritised according to the needs of the network. |
| 5. Training | Short training courses are prepared and facilitated with the purpose of strengthening the laboratory and outbreak response capacity on imported viral diseases within the EU. Topics are selected according to the needs of the network. For example, in the reference period, a workshop on Ebola diagnostics for institutions without access to BSL4 or BSL3 facilities was conducted. Furthermore, all laboratories in the network can request scientific advice from experts for all viruses covered by ENIVD round-the-clock. |
| 6.Collaboration and research | ENIVD collaborates closely with other projects and networks, particularly QUANDHIP, MediLabSecure, the Global Virus Network and PREPARE. |
| 7. Monitoring, alert and response | ENIVD focuses particularly on laboratory preparedness and outbreak support. Activities in the reporting period included:<br>– The establishment of a checklist for situation assessment and for laboratory preparedness;<br>– An inventory of laboratory capacity for Ebola virus diagnostics among ENIVD laboratories and an outbreak support directory of experts in the network;<br>– Deployment of ENIVD experts for outbreak assistance; and<br>– Laboratory confirmation testing through ENIVD members in outbreak situations. |
| 8. Governance of the network | Governance of the networks includes the overall administration, the organisation of steering committee meetings, the maintenance of the directory of members and expertise, and the maintenance of the website with a public domain and restricted access for members. Furthermore, ENIVD runs an electronic mailing list programme to provide for round-the-clock information exchange and availability of experts. |

*Source: Civic Consulting based on document review and information provided by network coordinator.*

### 4.2.3 Coordination structure of ENIVD

ENIVD has a physically centralised coordination structure. One laboratory, the RKI, is responsible for implementing all network activities clustered into five work packages:

- WP1 - Network coordination;
- WP2 - External quality assessments;
- WP 3 - Outbreak support;
- WP 4 - Laboratory preparedness; and
- WP5 - Training course.

RKI serves both as host to the ENIVD secretariat as well as leader of work package 1, work package 2 and work package 5. RKI has subcontracted, however, the implementation of work package 3 and 4. The Instituto de Salud Carlos III is the leader of work package 3. Erasmus MC is responsible for implementing work package 4. Together with the "Outbreak Assisting and Response Working Group" the three laboratories form a steering committee, which supports RKI in the overall implementation of ENIVD. In relation to the network management, RKI has to conduct the following tasks:

- Overall administration;
- Directory of members and expertise;
- Organisation and delivery of Steering Committee meetings;
- Organisation and delivery of an annual Network meeting; and
- Information management and ECDC/Network website.

The main tasks of ECDC, the funding entity, relate to project management including the tendering process, administrative coordination within ECDC, the participation in network meetings, and the discussion with laboratory coordinators on the strategic and technical focus of the network.

The following table summarises the coordination structure of ENIVD.

**Table 11. Coordination of ENIVD**

| **Coordination structure** | |
|---|---|
| Characteristics | Physically centralised network. |
| **Network coordinator** | |
| Robert-Koch Institut (RKI), Germany | Lead coordinator of ENIVD, hosting the network secretariat.<br>Work package (WP) leader for:<br>- WP1 - Network coordination<br>- WP2 - External quality assessments<br>- WP5 - Training course |
| **Funding entity** | |
| European Centre for Disease Prevention and Control (ECDC) | Project management and administrative coordination. Tasks include:<br>– Implementing the tendering process;<br>– Administrative coordination within ECDC;<br>– Participation in network meetings; and<br>– Discussion with laboratory coordinators on the strategic and technical focus of the network. |

*Source: Civic Consulting based on information provided by network coordinator and funding agency.*

### 4.2.4 Funding received by ENIVD

Since 2008, ENIVD receives funding from ECDC. As the following table shows, in the reference period (June 2014 to July 2015), the total budget for implementing ENIVD amounted to EUR 313 813, and was fully funded by the EU.

**Table 12. Funding of ENIVD**

| Funding provided by | Amount of funding for the reference period (in Euro) |
|---|---|
| ECDC | 313 813 |
| Co-financing by network members | Not required |
| *Total funding* | *313 813* |

*Source: Civic Consulting based on information provided by network coordinator and funding entity.*

### 4.2.5 Costs of ENIVD

The total costs of implementing ENIVD are the sum of the operating expenditure of the network as funded by ECDC and the additional costs incurred by network members for participating in network activities, which they are not compensated for. In this section both components of the network costs are described.

*Operating expenditure of the network*

The following table provides an overview of the operating expenditure of ENIVD broken down by cost item. This operating expenditure is covered by ECDC. As the table below shows, the largest shares of costs for implementing the network activities in the reference period were: staff (39%), subcontracting and services (25%) and travel (17%).

**Table 13. Operating expenditure of ENIVD by cost item**

| Cost item | Total network budget (in Euro) | Share of total network budget (as percent) |
|---|---|---|
| Staff | 123 638 | 39% |
| Capital equipment | 0 | 0% |
| Consumables | 17 000 | 5% |
| Travel | 51 950 | 17% |
| Shipping | 0 | 0% |
| Subcontracting and services | 78 000 | 25% |
| Overhead | 43 225 | 14% |
| *Total* | *313 813* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator.*

In terms of staff, a total of 24 person-months were financed by ECDC in the reference period. Twelve person-months were allocated to professionals and technicians/associate professionals respectively. The staff time of the latter category was mainly used to run the ENIVD secretariat. The following table summarises these results.

**Table 14. Person months funded for ENIVD by ECDC**

| Staff category | Person-months (EU funded) |
|---|---|
| Professionals | 12 |
| Technicians/associate professionals | 12 |
| *Total* | *24* |

*Source: Civic Consulting based on information provided by network coordinator.*

The following table breaks down operating expenditure by core function. It shows that the biggest shares of the budget were allocated to implementing training and activities related to governance (23% and 25%, respectively). Furthermore, 17% of the budget was used for providing scientific advice, 14% were allocated to conducting network-wide EQAs and a further 14% for monitoring, alert and response.

**Table 15. Operating expenditure of ENVID according to budget by core function in the reference period (June 2014 - June 2015)**

| Core function | Expenditure (in Euro) | Expenditure as percentage of total budget |
|---|---|---|
| 1. Reference diagnostics | 14 339 | 5% |
| 2. Reference material resources | 7 170 | 2% |
| 3. Scientific advice to public authorities | 52 400 | 17% |
| 4. External Quality Assessments (EQA) | 43 016 | 14% |
| 5. Training | 72 493 | 23% |
| 6.Collaboration and research | 0 | 0% |
| 7. Monitoring, alert and response | 45 230 | 14% |
| 8. Governance of the network | 79 165 | 25% |
| *Total* | *313 813* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator.*

*Additional costs incurred by network members*

Members at various levels had to cover additional costs for the implementation of ENIVD activities. These costs were not covered by the network budget. The following table provides an overview of additional costs broken down by network member and cost item.

**Table 16. Additional costs incurred by ENIVD members in the reference period**

| Cost item | Additional costs of funding entity | Additional costs of coordinator | Additional costs of all laboratory members* | Total additional costs |
|---|---|---|---|---|
| Staff costs (in Euro) | 28 753 | 37856 | 208 882 | 275 491 |
| Consumables (in Euro) | 0 | 0 | 159 412 | 159 412 |
| Travel (in Euro) | 2 000 | 0 | 16 590 | 18 590 |
| Shipping (in Euro) | 0 | 0 | 2 792 | 2 792 |
| Other costs(in Euro) | 0 | 0 | 0 | 0 |
| *Total* | *30 753* | *37 856* | *387 677* | *456 286* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members. Note: *Extrapolation for all network members based on survey results (N=7).*

The table illustrates that additional costs amounted to a total of EUR 456 286 in the reference period. These costs were incurred in particular at the level of the network members, who contributed to staff costs (EUR 208 882), consumable costs (EUR 159 412), travel costs (EUR 16 590) and shipping costs (EUR 2 792). The funding entity contributed to staff costs and travel costs and the coordinator contributed only to staff costs. Overall, as with the operating expenditure, staff costs made up the largest share of additional costs borne by network members.

*Total costs of the network*

The total costs of implementing ENIVD amounted to EUR 770 099 in the reference period. The following table provides an overview of these costs.

**Table 17. Total costs of ENIVD**

| Cost item | Operating expenditure according to budget (in Euro) | Total additional costs (in Euro) | Total network costs (in Euro) |
|---|---|---|---|
| Staff | 123 638 | 275 491 | 399 129 |
| Capital equipment | 0 | 0 | 0 |
| Consumables | 17 000 | 159 412 | 176 412 |
| Travel | 51 950 | 18 590 | 70 540 |
| Shipping | 0 | 2 792 | 2 792 |
| Subcontracting and services | 78 000 | 0 | 78 000 |
| Overhead/ other costs | 43 225 | 0 | 43 225 |
| *Total* | *313 813* | *456 286* | *770 099* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members.*

### 4.2.6 Benefits of ENIVD

The implementation of ENIVD leads to a number of benefits for network members as well as for society as a whole. The following sub-sections present the assessment of these benefits.

*Benefits for network members*

Network members enjoy both monetary and non-monetary benefits. The following table presents the monetary benefits reported by network members. As shown below, these benefits amounted to EUR 441 897 in the reference period. They resulted from cost savings of individual laboratory members on reference diagnostics, reference material, participation fees for EQAs and participation fees for training.

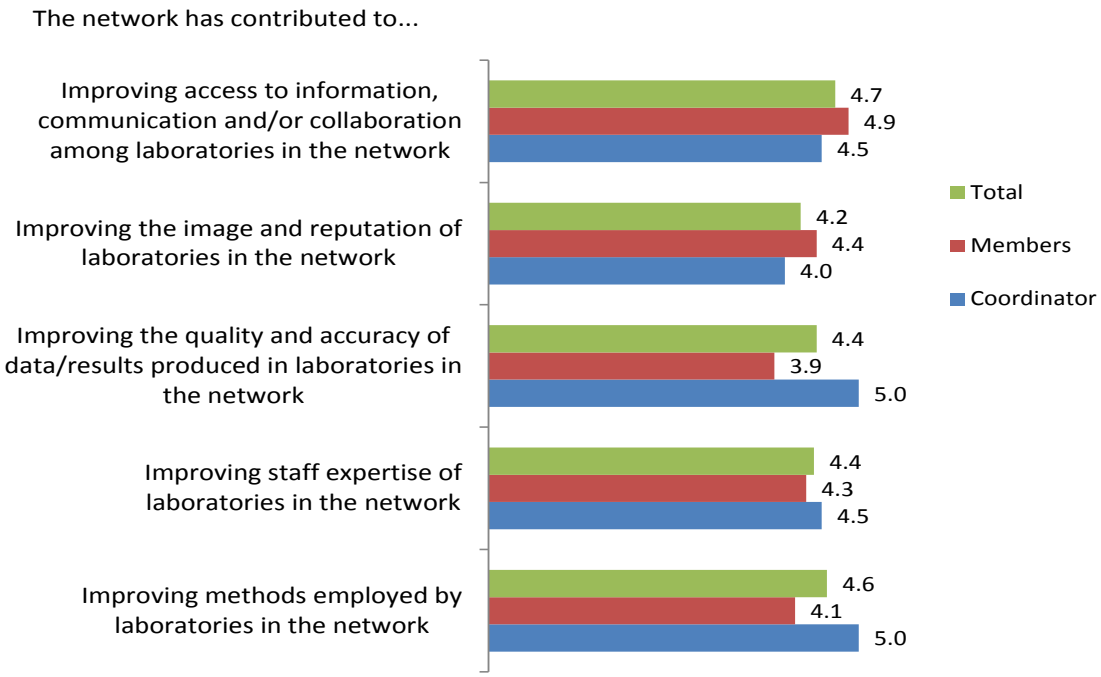
**Table 18. Monetary benefits for members of ENIVD in the reference period**

| Benefit results from | Estimated amount saved by network members (in Euro)* |
|---|---|
| Cost savings related to reference diagnostics | 67 000 |
| Costs savings related to reference material | 227 800 |
| Fees saved for the participation of EQAs | 139 121 |
| Fees saved for the participation in external training courses | 7 976 |
| *Total* | *441 897* |

*Source: Civic Consulting based on survey results. Note: *Extrapolation for all network members based on survey results (N=7).*

Non-monetary benefits for members deriving from ENIVD were assessed on a scale from 1 ('not at all') to 5 ('very much'). The following figure illustrates the results.

**Figure 4. Average rating of non-monetary benefits for members of ENIVD**




*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=7). Note: Rating on a scale from 1(not at all) to 5 (very much).*

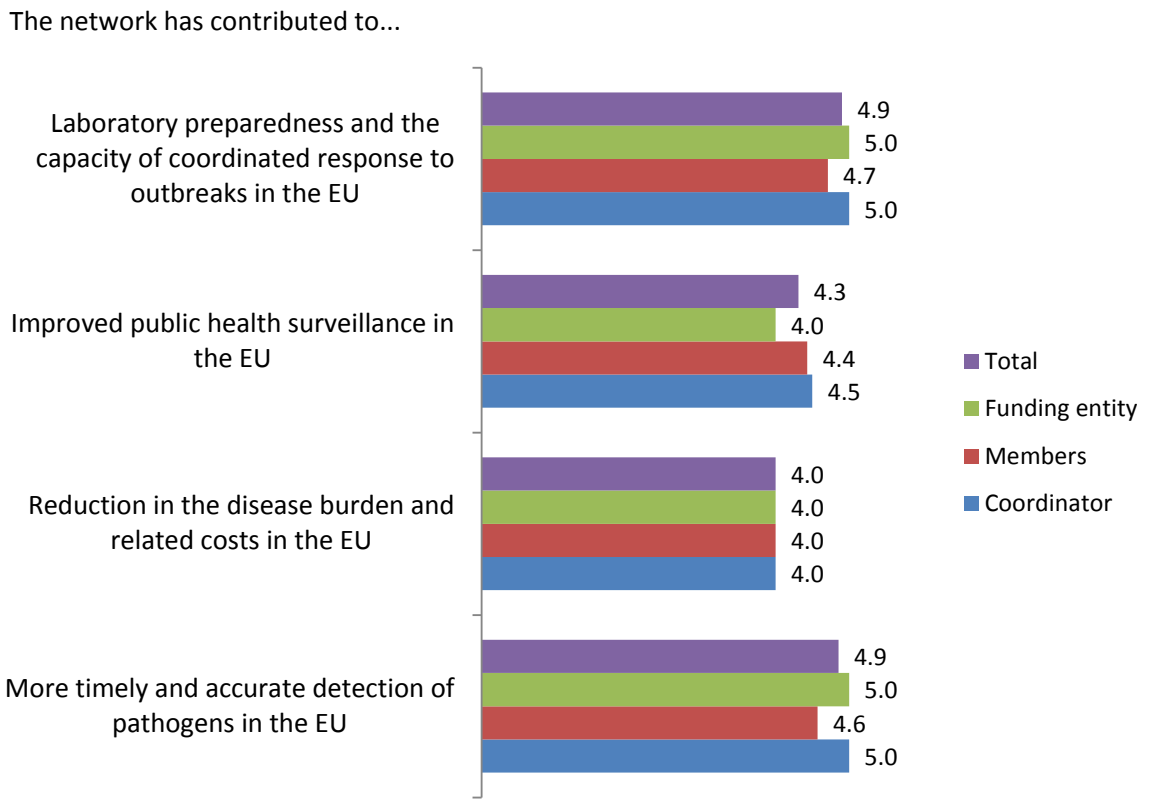
As the figure above shows, all benefits were assessed very positively with an average rating between 4.2 and 4.7 points. The contribution of ENIVD to improving access to information, communication and collaboration was assessed most positively (4.7), followed by the improvement of methods employed by laboratories in the network (4.6). The contribution of the network to improving the quality and accuracy of data and results and to improving staff expertise both received ratings of 4.4. Benefits of the network related to improving the image and reputation of individual members was rated the lowest (4.2) but were nonetheless viewed very positively.

*Benefits of the network for society*

In terms of non-monetary benefits for society as a whole, the contribution of ENIVD to increased laboratory preparedness and outbreak response and more timely and accurate detection of pathogens in the EU were evaluated most positively by ENIVD members, receiving a rating close to the maximum score of 5. ENIVD was also considered to contribute to improved public health surveillance and to the reduction of the disease burden with these benefits receiving average scores of 4.3 and 4.0 respectively. Overall, benefits of ENIVD for society as a whole were rated very positively, with all non-monetary benefits receiving a rating of 4.0 points and higher on a scale from 1 to 5.

The following figure illustrates the assessment of benefits deriving from ENIVD for society as a whole.

**Figure 5. Average rating of non-monetary benefits for society as a whole of ENIVD**




*Source: Civic Consulting based on information provided by network coordinator, funding entity and survey participants (N=7). Note: Rating on a scale from 1(not at all) to 5 (very much).*

## 4.3 Case study: FWD-Net

This section presents the case study on the Food and Waterborne Diseases and Zoonoses Network (FWD-Net).

### 4.3.1 FWD-Net characteristics

The Food- and Waterborne Diseases and Zoonoses Network (FWD-Net) is one of the three European-wide disease networks under ECDC's Food and Waterborne Diseases and Zoonoses Programme. In contrast to the remaining case studies, the implementation of FWD-Net's activities is coordinated by ECDC, and not by a laboratory member of the network. As such, ECDC defines the focus of activities and chooses the means of implementation, with selected activities outsourced through public or closed tendering processes. The objective of the network is to ensure appropriate national capabilities in support of surveillance, detection and response to food- and water-borne outbreaks in the EU.

The FWD-Net was established in 2007 as a continuation of the DG SANCO funded Human Enteric Pathogen Surveillance Network. The FWD-Net covers a total of 21 food and waterborne diseases but has identified six priority diseases: *salmonellosis, Shiga Toxin –producing E. coli (STEC) infection, listeriosis, campylobacteriosis, shigellosis, and yersiniosis*. For the purposes of this case study, the calculation of costs and

benefits will focus on activities related to *Salmonella*. 91 nominated experts for Salmonella participate in the FWD-Net (52 microbiologists and 39 epidemiologists). 26 laboratories took part in activities conducted by FWD-Net for Salmonella. The network covers all 28 EU Member States as well as two EEA countries (Iceland and Norway). Additionally, some enlargement countries participate.

The following table summarises the main characteristics of the FWD-Net.

**Table 19. Network characteristics of the FWD-Net**

| Characteristic | Description |
|---|---|
| Pathogens covered | 21 food and waterborne diseases, specific priorities lie on Salmonella, Shiga Toxin-producing E. Coli (STEC), Listeria, Campylobacter, Yersinia, and Shigella. . |
| Founding year | 2007 |
| Establishment of network | The FWD-Net is a continuation of the EU Health Programme / DG SANCO funded Human Enteric Pathogen Surveillance Network (Enter-Net). It is now coordinated by ECDC. |
| Network coordinator | European Centre for Disease Prevention and Control (ECDC) |
| Number of network members | 91 nominated experts for Salmonella, 26 laboratories conducting activities for Salmonella |
| Geographical coverage | All EU Member States as well as two EEA countries (Iceland and Norway) and some enlargement countries |
| Type of network members | Microbiologists and epidemiologists mainly employed by national public health reference laboratories and institutes |
| Requirements for membership | By national appointment |
| Reference period for the case study | January 2013 - December 2014 |

*Source: Civic Consulting based on document review and information provided by network coordinator.*

### 4.3.2 Activities of FWD-Net

To ensure appropriate national capabilities for supporting surveillance and the detection and response to food- and water-borne outbreaks in the EU, ECDC identifies key standard methods for typing for selected food and waterborne diseases. The use of standard methods throughout the EU produces comparable results, which can be collected and analysed centrally. ECDC assesses the EU level need for support in national reference laboratories and public health institutes to produce such results and defines activities for the FWD-Net in the annual work plan accordingly.

The following table summarises the key activities of FWD-Net carried out in the reference period.

**Table 20. FWD network activities implemented in the reference period (2013/14)**

| Core function | Scope of implementation |
|---|---|
| 1. Reference diagnostics | One of the main activities of the FWD-Net is to identify and update key standard methods for molecular typing. Methods are disseminated and implemented in the network through EQAs. Additional molecular typing services are provided through an outsourced service contract. |
| 2. Reference material resources | Based on direct service contracts, Statens Serum Institut (SSI) provide reference strains to Member States. Orders exceeding the EU-wide offer are managed on a voluntary basis directly between Member States. |
| 3. Scientific advice to public authorities | ECDC coordinates a number of specific expert groups within the network and beyond, which aim to support ECDC by providing scientific advice. Furthermore, ECDC has outsourced (through an open call for tender) activities related to quality checks of molecular typing data and the interpretation of analysed results. Finally, Member States have extensive experience and expertise in investigating foodborne outbreaks. Much of the scientific support to ECDC and other EU institutions occurs through the collaboration of epidemiologists and microbiologists within the network. |
| 4. External Quality Assessments (EQA) | ECDC has outsourced the conduct of EQAs through an open call for tenders. The framework contract is executed through the implementation of several specific contracts, which further specify the focus of the EQAs according to the needs of the network. EQA schemes for *Salmonella* (and also for STEC, *Listeria* and *Campylobacter*) are conducted annually. |
| 5. Training | FWD-specific training activities for the network consisted of specific multi-disciplinary workshops. The training was organised and conducted by ECDC. Issues relating to *Salmonella* were mostly covered in the two annual meetings conducted in the reference period. |
| 6.Collaboration and research | ECDC has close contacts with PulseNet US and PulseNet International to ensure that developments in Europe are globally compatible and comparable. In addition, ECDC closely follows developments in the research communities relevant for the FWD-Net. Furthermore, ECDC is part of and/or funds other research projects related to FWD-Net, e.g. COMPARE. |
| 7. Monitoring, alert and response | As the coordinator of FWD-Net, ECDC provides an information exchange platform (EPIS) that facilitates the early detection and assessment of multi-country/multinational molecular typing clusters and outbreaks of food and waterborne diseases. The platform connects epidemiologists and microbiologists across countries. Finally, ECDC has procedures in place to send experts to the field in case of expressed need for support. |
| 8. Governance of the network | In addition to all administrative tasks within ECDC and the implementation of calls for tenders, ECDC also supports Member States to upgrade their molecular typing software by providing reporting plug-ins for easy and smooth reporting of data. ECDC hosts a molecular typing database in the European Surveillance System (TESSy) which is available for MS and provides the Epidemic Intelligence Information System (EPIS) to FWD-Net members. |

*Source: Civic Consulting based on information provided by network coordinator.*

### 4.3.3 Coordination structure of FWD-Net

The FWD-Net has a physically centralised coordination structure. The implementation of all network activities is coordinated by ECDC, which at the same time is also the funding entity for the network. Compared to other case studies, ECDC as an EU

agency is more actively involved in the day-to-day work of the network. Selected activities requiring laboratory expertise are outsourced through a tendering process. In such cases, the tenderer coordinates the activity. ECDC organises expert groups to receive advice and support for setting priorities in the network.

The following table summarises the coordination structure of the FWD network.

**Table 21. Coordination of the FWD-Net network**

| **Coordination structure** | |
|---|---|
| Characteristics | Physically centralised network |
| **Network coordinator / funding entity** | |
| European Centre for Disease Prevention and Control (ECDC) | ECDC is the network coordinator and the funding entity of the FWD-Net. Main tasks include:<br>- *Development of the work programme:* Identification of priority issues for the network and development of an appropriate work programme for FWD-Net.<br>- *Implementation of the work programme and coordination with members*: Coordination of a number of activities of the work programme including e.g. the organisation of network meetings and working groups and implementation of a tendering process to outsource selected activities, where relevant.<br>- *Administrative coordination*: Facilitation of all administrative procedures within ECDC and with network members as well as supervision of administrative procedures of outsourced activities. |

*Source: Civic Consulting based on information provided by network coordinator and funding agency.*

### 4.3.4 Funding received by FWD-Net

Since FWD-Net is coordinated by ECDC, the funding received directly by the network is limited to the activities which are outsourced in a tendering process. In the reference period, two contracts related to *Salmonella* (amongst other pathogens). One contract covered EQAs, the provision of reference material and molecular typing services. The other contract related to the curation of PFGE of *Salmonella* strains and the provision of expert advice. Both activities were contracted to the Statens Serum Institut (SSI) in Copenhagen. The funding for *Salmonella* amounted to EUR 279 492.45

The following table presents the budget provided to SSI by ECDC.

[45] Contracts with SSI covered *Salmonella*, STEC, and *Listeria*. The cost reported here are only for *Salmonella*.

**Table 22. Funding of the FWD-Net activities (Salmonella outsourced)**

| Funding provided by | Amount of funding in the reference period (in Euro) |
|---|---|
| ECDC | 279 492 |
| Co-financing by network members | Not required |
| *Total funding* | *279 492* |

*Source: Civic Consulting based on information provided by network coordinator/funding entity.*

### 4.3.5 Costs of FWD-Net

The total costs of implementing the FWD-Net are composed of the operating expenditure for the activities outsourced by ECDC to SSI and the additional costs incurred by network members for participation in the network and ECDC as the coordinator/funding entity.

*Operating expenditure of the network*

The following table presents the operating expenditure by cost item for the activities outsourced by ECDC. The bulk of the expenditure (92%) is allocated to subcontracting and services. Contracts tendered out to Statens Serum Institut (SSI) only specified three cost types:

- Travel;
- Project management costs; and
- Service costs.

In our framework of analysis project management costs relate to the cost item overhead and administration. Service costs, however, relates to a lump sum composed of staff costs, consumables and equipment. For the purpose of this case study, these categories have been reported as subcontracting and services based on the argument that SSI is a subcontractor to ECDC.

The following table illustrates the operating expenditure of FWD-Net.

**Table 23. Operating expenditure by cost item of activities outsourced by FWD-Net**

| Cost item | Total network budget in the reference period (in Euro) | Mean budget per year (in Euro) | Share of total network budget (in percent) |
|---|---|---|---|
| Staff | 0 | 0 | 0 |
| Capital equipment | 0 | 0 | 0 |
| Consumables | 0 | 0 | 0 |
| Travel | 4 000 | 2 000 | 1% |
| Shipping | 0 | 0 | 0% |
| Subcontracting and services | 259 493 | 129 746 | 93% |
| Overhead | 16 000 | 8 000 | 6% |
| *Total* | 279 492 | *139 746* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator/funding entity.*

The table below breaks down operating expenditure of FWD-Net's outsourced activities according to their core functions. It shows that the biggest share of the budget was allocated to the implementation of network-wide EQAs (33%), followed by reference diagnostics (30%) and training (16%). Scientific advice and reference material resource made up 13% and 8% of the operating expenditure respectively.

**Table 24. Operating expenditure of outsourced activities of the FWD-Net by core function**

| Core function | Expenditure in reference period (in Euro) | Expenditure per year (in Euro) | Expenditure as percentage of total budget |
|---|---|---|---|
| 1. Reference diagnostics | 83 879 | 41 939 | 30% |
| 2. Reference material resources | 21 667 | 10 833 | 8% |
| 3. Scientific advice to public authorities | 37 000 | 18 500 | 13% |
| 4. External Quality Assessments (EQA) | 92 667 | 46 334 | 33% |
| 5. Training | 44 280 | 22 140 | 16% |
| 6. Collaboration and research | 0 | 0 | 0% |
| 7. Monitoring, alert and response | 0 | 0 | 0% |
| 8. Governance of the network | 0 | 0 | 0% |
| *Total* | 279 492 | *139 746* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator/funding entity.*

*Additional costs incurred by network members*

In the FWD-Net, additional costs were incurred by laboratory network members and by ECDC in its dual role as a funding entity and network coordinator. It is important to note that any activities that ECDC does not outsource through tendering processes are

reflected in these additional costs. Moreover, as network members also conduct activities that do not specifically concern Salmonella, it is possible that the reported costs also reflect these activities. The following table presents an overview of additional costs of the FWD-Net in the reference period.

**Table 25. Additional costs incurred to FWD-Net members in the reference period (two years)**

| Cost item | Additional costs of funding entity / coordinator | Additional costs of all laboratory members* | Total additional costs |
|---|---|---|---|
| Staff costs (in Euro) | 141 151 | 365 290 | 506 441 |
| Consumables (in Euro) | 0 | 195 735 | 195 735 |
| Travel (in Euro) | 0 | 0 | 0 |
| Shipping (in Euro) | 0 | 3 300 | 3 300 |
| Other costs(in Euro) | 0 | 0 | 0 |
| *Total* | *141 151* | *564 325* | *705 476* |

*Source: Civic Consulting based on information provided by network coordinator/funding entity and network members. Note: *Extrapolation for all network members based on survey results (N=15).*

As shown in the table, staff costs make up the largest share of additional costs, amounting to EUR 506 441. This cost item is followed by costs of consumables (EUR 195 735) which are only incurred by network members. Additional shipping costs amounted to EUR 3 300.

*Total costs of the network*

The total costs for the implementation of the FWD-Net, i.e. the sum of operating expenditure of outsourced activities and of the additional costs, amounted to EUR 984 950 in the reference period. The following table provides an overview of these costs.

**Table 26. Total costs of the FWD-Net in the reference period (two years)**

| Cost item | Operating expenditure according to budget (in Euro) | Total additional costs (in Euro) | Total network costs (in Euro) |
|---|---|---|---|
| Staff | 0 | 506 441 | 506 441 |
| Capital equipment | 0 | 0 | 0 |
| Consumables | 0 | 195 735 | 195 735 |
| Travel | 4 000 | 0 | 4 000 |
| Shipping | 0 | 3 300 | 3 300 |
| Subcontracting and services | 259 493 | 0 | 259 493 |
| Overhead/ other costs | 16 000 | 0 | 16 000 |
| *Total* | 279 492 | *705 476* | *984 950* |

*Source: Civic Consulting based on information provided by network coordinator/funding entity and network members.*

### 4.3.6 Benefits of FWD-Net

The implementation of the FWD-Net leads to benefits for network members and for society as a whole. They have been assessed by the network coordinator/funding entity and by network members, as follows.

*Benefits for network members*

The following table describes the reported monetary benefits for FWD-Net members. These benefits are cost savings of individual laboratories related to reference material, participation in EQAs, and participation in network trainings. They amounted to approximately EUR 26 434 in the reference period. As funding entity/coordinator, ECDC also reported receiving monetary benefits. It found, however, that they were too difficult to estimate.

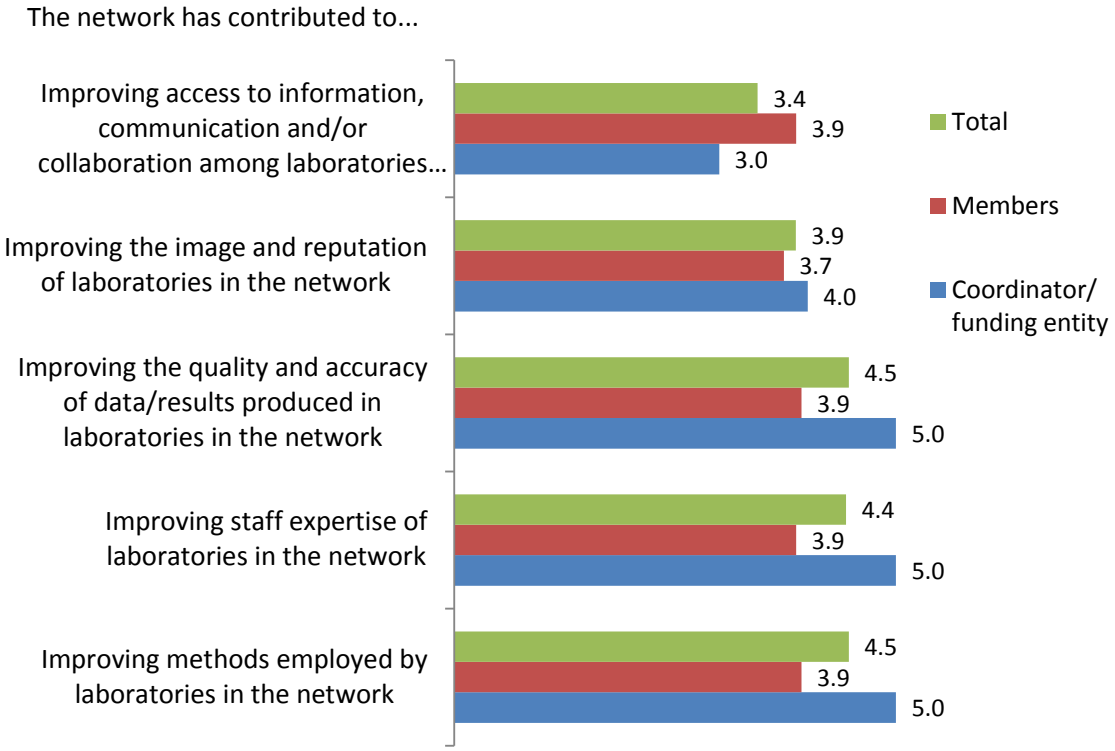
**Table 27. Monetary benefits for members of the FWD-Net**

| Benefit related to | Estimated amount saved by network members (in Euro)* |
|---|---|
| Cost savings related to reference material | 5 200 |
| Fees saved for participating in commercial EQA | 19 500 |
| Fees saved on training courses | 1 734 |
| *Total* | *26 434* |

*Source: Civic Consulting based on survey results. Note: *Extrapolation for all network members based on survey results (N=15).*

In addition to the monetary benefits estimated above, the implementation of FWD-Net also provides non-monetary benefits to ECDC and network members. Non-monetary benefits of FWD-Net were assessed on a scale from 1 ('not at all') to 5 ('very much') by ECDC and network members.

**Figure 6. Average rating of non-monetary benefits for members of the FWD-net**



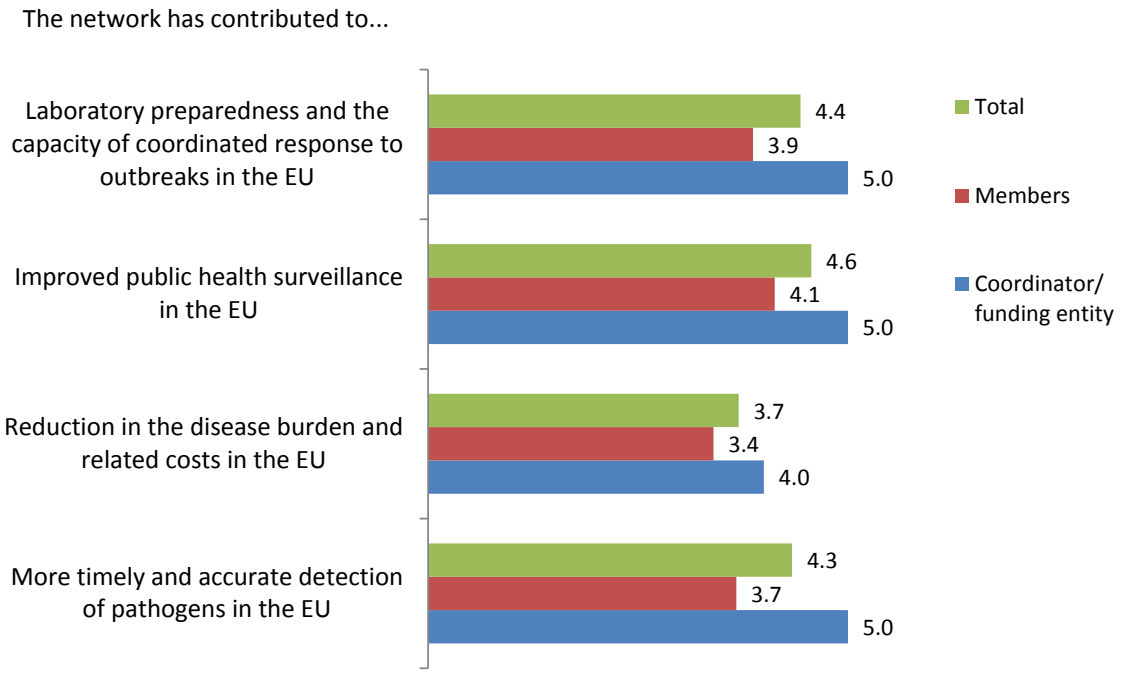

*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=15). Note: Rating on a scale from 1 (not at all) to 5 (very much).*

The figure above illustrates that all non-monetary benefits for network members were assessed positively, i.e. each benefit received a rating of above 3.0 or higher. In particular, members considered that they benefited from the FWD-Net in terms of improved laboratory methods, quality and accuracy of data/results they produced and staff expertise. These benefits received scores of 4.5, 4.5, and 4.4 respectively. The contribution of the network to an improved image and reputation of laboratories was assessed with a score of 3.9. Its contribution to improved access to information, communication, and collaboration received the lowest rating (3.4), but was still viewed positively by respondents.

*Benefits of the network for society as a whole*

Non-monetary benefits deriving from FWD-Net for society as a whole were also assessed very positively, with average ratings of at least 3.7 out of 5 points. Improved public health surveillance was rated highest with a score of 4.6 points, followed by increased laboratory preparedness (4.4) and a more timely and accurate detection of pathogens (4.3). Only the contribution of FWD-Net to the reduction of the disease burden in the EU received a rating below 4 points (i.e. 3.7).

**Figure 7. Average rating of non-monetary benefits of FWD-Net for society as a whole**




*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=15). Note: Rating on a scale from 1 (not at all) to 5 (very much).*

## 4.4 Case study: ERLI-Net

This section presents the case study on the European Reference Laboratory Network for Human Influenza (ERLI-Net).

### 4.4.1 ERLI-Net characteristics

The European Reference Laboratory Network for Human Influenza (ERLI-Net) emerged from a long history of virological surveillance of human influenza in Europe. In 1952 the World Health Organisation (WHO) recognized laboratories throughout Europe as national influenza centres of the WHO (WHO-NICs). For a long time this network of WHO-NICs remained the primary scheme for influenza surveillance in Europe. In 1995, the European Commission established the European Influenza Surveillance Scheme (EISS), which links epidemiological and virological data collection. To formalise the network of national influenza reference laboratories participating in EISS, the Community Network of Reference Laboratories for Human Influenza in Europe (CNRL) was established in 2003 as a sub-network of EISS. Since 2008 the European Centre for Disease Prevention and Control (ECDC) coordinates this network, which in 2013 was renamed ERLI-Net.

Today, ERLI-Net is a network of 38 laboratories covering 30 countries (all EU Member States plus Iceland and Norway). Members are mostly WHO-NICs, with a few exceptions. Hence, they mostly participate in both the ECDC-coordinated ERLI-Net and the WHO-coordinated Global Influenza Surveillance and Response System (GISRS).

NIC laboratories are usually (but not always) embedded in national public health structures. The purpose of ERLI-Net is also to align the NIC virology laboratory activities with national public health clinical surveillance and link it to disease monitoring and health intervention policy.

The main objectives of ERLI-Net are to carry out virological surveillance and to ensure the timely reporting of accurate data to the European Influenza Surveillance Network (EISN, formerly EISS). In order to fulfil these objectives, ERLI-Net members must be able to perform a number of key tasks relating to influenza diagnostics, such as direct detection, culture, typing, subtyping and strain characterisation of influenza viruses, diagnostic serology and the creation of archives for clinical specimens and virus isolates. The capacities of each of the ERLI-Net members vary in this regard, however.

The following table summarises the characteristics of ERLI-Net.

**Table 28. Network characteristics of ERLI-Net**

| Characteristic | Description |
|---|---|
| Pathogens covered | Influenza virus (to an extent other respiratory viruses such as MERS-CoV are also relevant) |
| Founding year | 2003 (as CNRL, renamed ERLI-Net in 2013) |
| Establishment of network | ERLI-Net was established as a sub-network of the EISS (now EISN) with the purpose of formalising the network of national influenza reference laboratories collaborating in EISS. It was first funded by the EU Health Programme, through the DG SANCO. In 2008 ECDC took over the coordination of the network. |
| Network coordinators | - Public Health England (PHE)<br>- The Worldwide Influenza Centre, The Francis Crick Institute<br>- National Institute for Public Health and the Environment (RIVM) |
| Number of network members | 38 |
| Geographical coverage | All EU Member States, Iceland, Norway |
| Type of network members | National influenza centres, national reference laboratories |
| Requirements for membership | While it is not an official requirement, most laboratories became members as they were already a recognised WHO-NIC. |

*Source: Civic Consulting based on document review and information provided by interviewees.*

### 4.4.2 Activities of ERLI-Net

ERLI-Net performs a variety of activities aimed at improving virological surveillance of influenza in Europe. Key tasks of the network relate to daily and weekly surveillance of influenza viruses, external quality assessments of the laboratories and laboratory training courses, antiviral resistance analysis and surveillance support, for example through reagent supplies and direct advice to the laboratories.

The following table provides an overview of the activities conducted by ERLI-Net in the reference period as part of the work plan. Activities conducted in the framework of WHO's GISRS are excluded from the analysis and are therefore not included in the table.

**Table 29. ERLI-Net network activities implemented in the reference period (2/2013-2/2015)**

| Core function | Scope of implementation |
|---|---|
| 1. Reference diagnostics | - Detailed characterisation and further typing and subtyping of samples sent by network members.<br>- Diagnostic confirmation of atypical samples.<br>- Protocol sharing, advice and training on standards and methods to ensure that laboratories are up to date. |
| 2. Reference material resources | - Reference material (reference viruses, antisera etc.) is routinely provided to network members. Special distributions are organised when there are newly circulating viruses. |
| 3. Scientific advice to public authorities | - Scientific advice is provided to European authorities, in particular in relation to newly emerging threats from influenza, such as newly emerged zoonotic viruses and new human antigenic drift variants and influenza antiviral susceptibility monitoring. Based, in part, on detailed analyses of the samples sent from NICs, advice is disseminated as rapid risk assessments and preparedness planning. |
| 4. External Quality Assessments (EQA) | - Members of ERLI-Net participate as WHO-NICs in EQAs organised by the WHO (every year) and EQAs organised by ERLI-Net (one EQA every second year). This EQA complements WHO EQAs by assessing different capabilities; including virus isolation, antigenic characterisation and antiviral characterisation by genetic and phenotypic methods. These techniques are not covered as comprehensively by other international EQA programmes. |
| 5. Training | Training within ERLI-Net was conducted on a number of topics and included activities such as:<br>- Training courses<br>- Twinning arrangements<br>- Web-laboratory courses<br>- Webinars<br>- Written guidance and training documentation (available through ECDC extranet)<br>- An annual workshop. |
| 6.Collaboration and research | - As a result of its emergence from WHO-NIC networks, ERLI-Net very closely collaborates with the Global Influenza Surveillance and Response System (GISRS) through the WHO Regional office of Europe. Since 2015 a shared weekly surveillance report is being prepared between the WHO regional office and ECDC.<br>- Network data are used in research projects and collaborations. Furthermore, members of ERLI-Net participate in EC-funded projects such as PREPARE and I-MOVE, linking virological and epidemiological data for estimating vaccine effectiveness.. |
| 7. Monitoring, alert and response | - Contribution through working groups to the harmonisation of surveillance data reporting standards.<br>- Provision of technical support and advice in outbreak situations. |
| 8. Governance of the network | - Provide technical updates, administrative coordination of the network, and where relevant updating the website. |

*Source: Civic Consulting based on information provided by network coordinators.*

### 4.4.3 Coordination structure of ERLI-Net

ERLI-Net has a virtually centralised coordination structure. A consortium of three laboratories shares the coordination for implementing all network activities. Furthermore, ECDC, as the funding entity, is highly involved in the coordination of the network and implements activities outside of the work plan.

Public Health England (PHE), The Francis Crick Institute, and the National Institute for Public Health and the Environment of the Netherlands (RIVM) constitute the consortium of ERLI-Net coordinators. PHE takes the lead in the consortium. The institute is the main contracting partner of and contact point for ECDC. It conducts all administrative tasks for the consortium including the reporting to ECDC, the administration of funds, etc. The coordination of all other activities is split between the consortium partners. For each network activity, one laboratory takes the lead in its implementation, while the other two coordinators contribute to the work. For example, PHE is the lead coordinator of the EQAs. The institute prepares and disseminates the samples and collects and analyses the results. The Francis Crick Institute contributes to implementing EQAs by advising on the composition of the panel and validating the panel of viruses for PHE, while RIVM is involved in the design and analysis of the EQA.

In contrast to other case studies, ECDC plays a significant role in the coordination of ERLI-Net. Besides preparing and processing all contractual and administrative issues as the funding entity and discussing and defining the work focus of ERLI-Net, ECDC is involved in two other important activities. First, it analyses the weekly influenza surveillance data, prepares reports and other publication material and maintains all online tools. Second, it prepares and organises the annual network meetings and meetings of task groups.

The following table summarises the coordination structure of ERLI-Net.

**Table 30. Coordination of ERLI-Net**

| | |
|---|---|
| **Coordination structure** | |
| Characteristics | Virtually centralised network i.e. a consortium of three laboratories share the coordination of all laboratory activities. |
| **Network coordinators** | |
| Public Health England | Lead coordinator of the laboratory consortium. Main tasks include:<br>- All administrative tasks relating to contractual issues, including reporting requirements, the administration of funds etc.<br>- Lead coordination of EQAs, training activities, collaboration and research<br>- Provision of scientific advice[46]<br>- Support coordination of activities led by other coordinators. |
| The Worldwide Influenza Centre, The Francis Crick Institute | Member of the coordinating consortium. Main tasks include:<br>- Lead coordination of pathogen characterisation and analysis of samples provided by ERLI-Net members, of provision of reference materials, and of selected training activities.<br>- Provision of scientific advice<br>- Support coordination of activities led by other coordinators. |
| National Institute for Public Health and the Environment (RIVM) | Member of the coordinating consortium. Main tasks include:<br>- Lead coordination in particular on issues of antiviral susceptibility, of a number of training activities, and of the provision of advice and analytical expertise to network members etc.<br>- Support coordination of activities led by other coordinators.<br>- Assists ECDC in development of TESSy for capturing and validating complex influenza virus strain-based data. Curating strain-based data and contacts with ERLI-Net members on issues.<br>- Provision of scientific advice |
| **Funding entity** | |
| European Centre for Disease Prevention and Control (ECDC) | Administrator of the network for the EU institutions, responsible for the allocation of funds to ERLI-Net. Main tasks include:<br>- Capture and integrate information from multiple diverse sources<br>- The analysis of the weekly virological and clinical surveillance data and the publication of a weekly surveillance overview as well as development and maintenance of tools and online reports for analysis of the data.<br>- Organisation and preparation of network meetings, in particular the agenda.<br>- Preparation of the framework and yearly specific contracts for support of the laboratory functions of the network. |

*Source: Civic Consulting based on information provided by network coordinator and funding entity.*

### 4.4.4 Funding received by ERLI-Net

To implement its activities, ERLI-Net receives funding from ECDC. For the two-year reference period (02/2013-02/2015) covering the distribution of one EQA panel, ECDC provided a total of EUR 657 947, which on an annual basis signifies EUR 326 474 per year. The following summarises the funding structure of ERLI-Net.

[46] PHE is the source of specific medical and public health advice on influenza and other respiratory infections within the consortium.

**Table 31. Funding of ERLI-Net**

| Funding provided by | Amount of funding for the reference period (in Euro) | Amount of funding as annual average (in Euro) |
|---|---|---|
| ECDC | 652 947 | 326 474 |
| Co-financing by network members | Not required | Not required |
| *Total funding* | *652 947* | *326 474* |

*Source: Civic Consulting based on information provided by network coordinator and funding entity.*

### 4.4.5 Costs of ERLI-Net

The total costs of implementing ERLI-Net are composed of the operating expenditure funded by the ECDC and additional costs incurred by network members for participating in network activities. The following section describes both components of the network costs.

*Operating expenditure of the network*

The operating expenditure of the network is the sum of the costs specified in the budget funded by ECDC for the implementation of all network activities. The following table provides an overview of the operating expenditure of ERLI-Net broken down by cost item. It again presents the total amount for the reference period and an annual average.

As the table below shows, the largest share of costs for the implementation of the network's work plan was attributable to staff costs, with 57% of the network's budget. The second and third biggest shares related to consumables (23%) and overhead/administrative costs (12%).

**Table 32. Operating expenditure of ERLI-Net by cost item**

| Cost item | Total network budget (in Euro) - reference period | Total network budget (in Euro) - annual | Share of total network budget (as percent) |
|---|---|---|---|
| Staff | 370 360 | 185 180 | 57% |
| Capital equipment | 0 | 0 | 0% |
| Consumables | 149 276 | 74 638 | 23% |
| Travel | 50 832 | 25 416 | 8% |
| Shipping | 0 | 0 | 0% |
| Subcontracting and services | 4 490 | 2 245 | 1% |
| Overhead | 77 992 | 38 996 | 12% |
| *Total* | *652 952* | *326 476* | *100%* |

*Source: Civic Consulting based on information provided by network coordinator.*

ECDC funded staff time amounting to 80 person-months in the reference period for ERLI-Net. 30 person-months related to the category of technicians and associate professionals. 50 person-months related to professionals. The following table illustrates these findings and provides the figures on an annual basis.

**Table 33. Person-months funded for ERLI-Net**

| Staff category | ECDC funded person-months - reference period | ECDC funded person-months - annual basis |
|---|---|---|
| Professionals | 50 | 25 |
| Technicians/associate professionals | 30 | 15 |
| *Total* | *80* | *40* |

*Source: Civic Consulting based on information provided by network coordinator.*

The table below breaks down operating expenditure by core function. It illustrates that the biggest share of the budget (33%) was allocated to reference diagnostics. Furthermore, one fifth of the budget (20%) was used for training, while 17% of the budget covered costs related to the function of reference material resources.

**Table 34. Operating expenditure of ERLI-Net by core function**

| Core function | Expenditure (in Euro) - reference period | Expenditure (in Euro) - annual basis | Expenditure as percentage of total budget |
|---|---|---|---|
| 1. Reference diagnostics | 214 574 | 107 287 | 33% |
| 2. Reference material resources | 112 807 | 56 404 | 17% |
| 3. Scientific advice to public authorities | 4 740 | 2 370 | 1% |
| 4. External Quality Assessments (EQA) | 68 817 | 34 409 | 11% |
| 5. Training | 127 449 | 63 725 | 20% |
| 6.Collaboration and research | 0 | 0 | 0% |
| 7. Monitoring, alert and response | 29 556 | 14 778 | 5% |
| 8. Governance of the network | 95 004 | 47 502 | 15% |
| Total | 652 947 | 326 474 | 100% |

*Source: Civic Consulting based on information provided by network coordinator.*

*Additional costs incurred by network members*

In the reference period, additional costs that were not compensated for by the network budget were incurred at various levels. The following table provides an overview of additional costs broken down by network member and cost item.

**Table 35. Additional costs incurred by ERLI-Net members in the two-year reference period**

| Cost item | Additional costs of funding entity | Additional costs of coordinator | Additional costs of all laboratory members* | Total additional costs |
|---|---|---|---|---|
| Staff costs (in Euro) | 486 091 | 105 352 | 277 915 | 869 358 |
| Consumables (in Euro) | 0 | 30 000 | 238 767 | 268 767 |
| Travel (in Euro) | 10 000 | 0 | 28 500 | 38 500 |
| Shipping (in Euro) | 0 | 25 000 | 22 800 | 47 800 |
| Other costs(in Euro) | 128 081 | 0 | 0 | 128 081 |
| *Total* | *624 172* | *160 352* | *567 982* | *1 352 506* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members. Note:*Extrapolation for all network members based on survey results (N=6).*

The table illustrates that ECDC, as the funding entity for ERLI-Net, had to cover a substantial amount of additional costs (EUR 624 172). Furthermore, additional costs also accrued to network members and the coordinator (EUR 567 982 and EUR 160 352 in the reference period respectively). Overall, staff costs represent the largest share of the additional costs for all stakeholders. Additionally, laboratory coordinators and members have to cover a considerable share of the costs.

*Total costs of the network*

The total costs of implementation of ERLI-Net, i.e. the sum of operating expenditure and additional costs, amounted to EUR 2 005 458 in the reference period. The following table provides an overview of these costs.

**Table 36. Total costs of ERLI-Net in the two-year reference period**

| Cost item | Operating expenditure according to budget (in Euro) | Total additional costs (in Euro) | Total network costs (in Euro) |
|---|---|---|---|
| Staff | 370 360 | 869 358 | 1 239 718 |
| Capital equipment | 0 | 0 | 0 |
| Consumables | 149 276 | 268 767 | 418 043 |
| Travel | 50 832 | 38 500 | 89 332 |
| Shipping | 0 | 47 800 | 47 800 |
| Subcontracting and services | 4 490 | 0 | 4 490 |
| Overhead/ other costs | 77 992 | 128 081 | 206 073 |
| *Total* | *652 952* | *1 352 506* | *2 005 458* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members.*

### 4.4.6 Benefits of ERLI-Net

Benefits resulting from ERLI-Net can be clustered according to the levels at which they accrue, i.e. at the level of network members and for society as a whole. They have been assessed by network members and coordinators as follows.

*Benefits for network members*

Benefits for network members are of both a monetary and non-monetary nature. The following table describes the reported monetary benefits. Laboratory members of ERLI-Net in particular received benefits, relating to fees saved for EQAs, reference material and training, which were provided free of charge to network members. Coordinators did not report any savings from the network. The funding entity, while confirming that monetary benefits existed, was not able to provide estimates. The following table provides an overview of monetary benefits for network members in the two-year reference period.

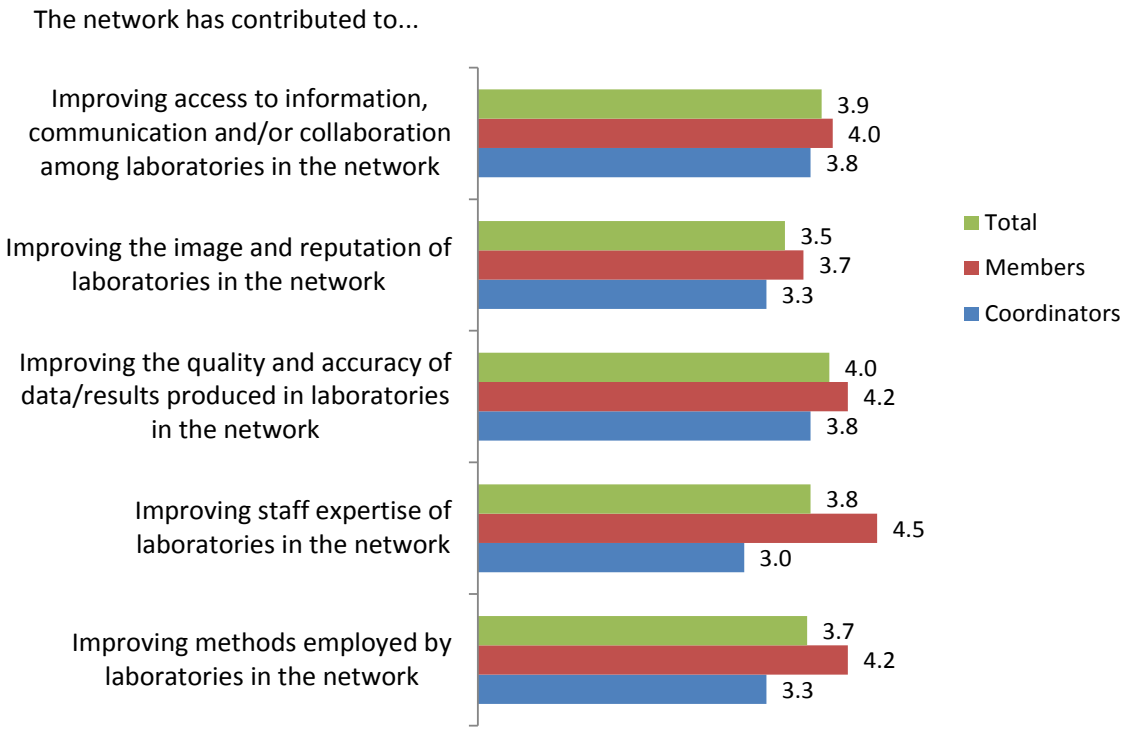
**Table 37. Monetary benefits for members of ERLI-Net in reference period**

| Benefit results from | Estimated amount saved by network members (in Euro)* |
|---|---|
| Cost savings related to diagnostics | 1 900 |
| Cost savings related to reference material | 19 000 |
| Fees saved for participating in commercial EQA | 10 450 |
| Fees saved on training costs | 12 667 |
| *Total* | *44 017* |

*Source: Civic Consulting based on survey results. Note:*Extrapolation for all network members based on survey results (N=6).*

Non-monetary benefits of ERLI-Net for network members were assessed on a scale from 1 ('not at all') to 5 ('very much'). The following figure illustrates the results.

**Figure 8. Average rating of non-monetary benefits for members of ERLI-Net**



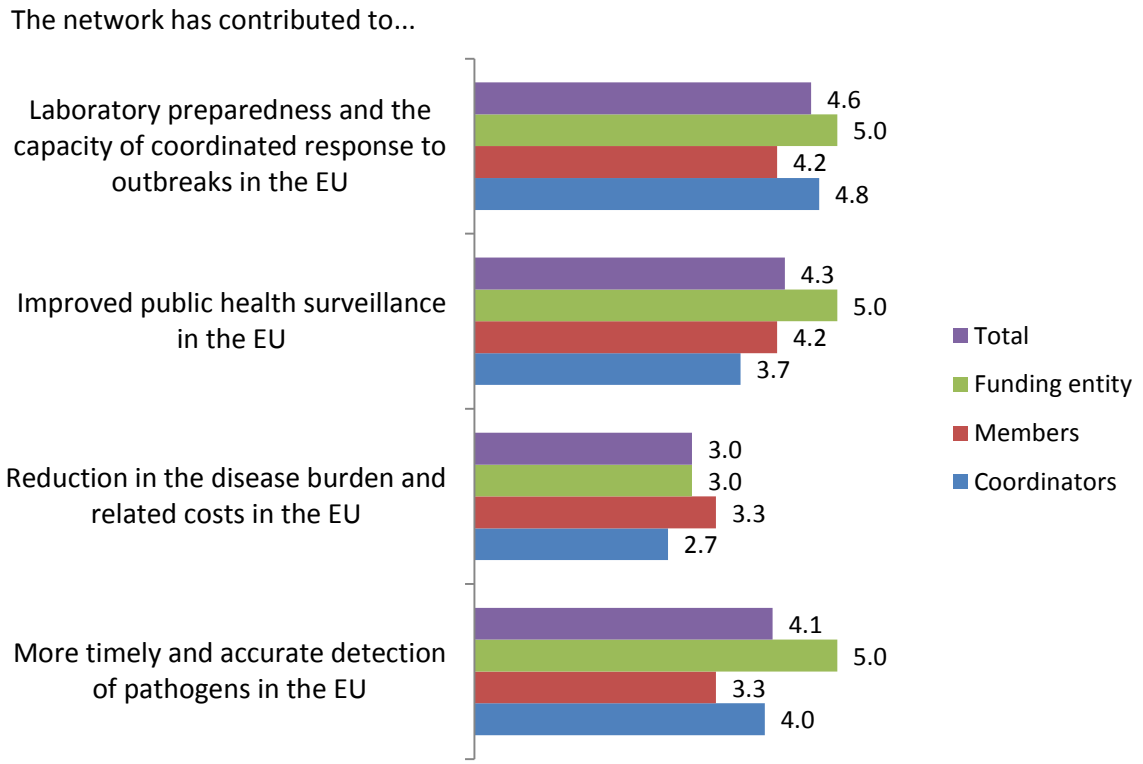

*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=6). Note: Rating on a scale from 1(not at all) to 5 (very much).*

As the figure above shows, the image and reputation of laboratories received the lowest score overall (3.5 out of 5 points). The contribution of the network to improved quality and accuracy of data and results produced was rated highest (4.0 out of 5 points), followed by the improved access to communication and information (3.9) and the improvements in staff expertise (3.8). Overall, members of the network consistently rated all benefits higher than their laboratory coordinators.

*Benefits of the network for society as a whole*

Study participants assessed increased laboratory preparedness and the capacity of coordinated response highest amongst non-monetary benefits for society as a whole (i.e. 4.6 out of 5 points). This was followed by improved public health surveillance and more timely and accurate response, which were assessed on average with 4.3 and 4.1 out of 5 points respectively. The contribution of the reduction of the disease burden was assessed with 3.0. Ratings were very mixed across different stakeholder groups. However, ECDC as funding entity stood out by rating three out of four benefits with 5 out of 5 points.

**Figure 9. Average rating of non-monetary benefits for society as a whole of ERLI-Net**




*Source: Civic Consulting based on information provided by network coordinator, funding entity and survey participants (N=6). Note: Rating on a scale from 1(not at all) to 5 (very much).*

## 4.5 Case study: QUANDHIP

This section presents the case study on the European joint action "Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens" (QUANDHIP).[47]

### 4.5.1 QUANDHIP network characteristics

The "Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens" (QUANDHIP) was established in 2011 as a European joint action. It was funded for 42 months by the European Commission Health Programme (DG SANTE), and came to an end in 2015. QUANDHIP linked and consolidated two existing EU-funded networks, namely the "European Network for Highly Pathogenic Bacteria" coordinated by the Robert Koch-Institut (RKI), Germany and the "European Network of P4 Laboratories" coordinated by L. Spallanzani National Institute for Infectious Diseases (INMI), Italy.[48]

In support of a European response strategy for outbreaks of highly pathogenic infectious agents (e.g. the Ebola virus), the primary objective of QUANDHIP was to

[47] This case study was conducted by RKI, the coordinator of QUANDHIP. Civic Consulting summarised the results.

[48] In QUANDHIP they are referred to as the network on highly pathogenic bacteria (NIB) and the network on highly pathogenic viruses (NIV).

create a stable consortium of 37 highly specialised and advanced partner laboratories dealing with highly pathogenic bacteria and/or viruses. Network members of QUANDHIP (i.e. partners) were government institutions including public health, veterinary, and military laboratories as well as laboratories of university faculties. Laboratories were appointed by their competent national authority on the basis of one of the following criteria:

- Specialisation in the handling of highly pathogenic bacteria (BSL3 containment) or viruses (BSL4 containment);
- In the process of specialisation for the handling of highly pathogenic bacteria (BSL3 containment) or viruses (BSL4 containment); or
- Focus on diagnostics, with subsequent collaboration for further characterisation of the agents under high containment conditions.

Network members of QUANDHIP covered 23 European countries. The following table summarises the characteristics of the QUANDHIP network.

### Table 38. Characteristics of the QUANDHIP network

| Characteristic | Description |
|---|---|
| Pathogens covered | – Highly pathogenic bacteria of risk group 3 such as *B. anthracis*, *Y. pestis*, *F. tularensis*, *C. burnetii*, *B. pseudomallei*, *B. mallei*, and *B. melitensis*-group.<br>– Highly pathogenic viruses of risk group 4/3 such as Filo-, New World Arena-, Hendra/Nipah-, Pox-, CCHF-, SarsCo- and MersCo-Viruses, and other new viruses. |
| Founding year | 2011 – 2015 (42 months) |
| Establishment of network | QUANDHIP was established as a European joint action, funded by DG SANTE/CHAFEA. The network brought together two existing EU funded networks: the "European Network for Highly Pathogenic Bacteria" coordinated by the Robert Koch-Institut (RKI), Germany and the "European Network of P4 Laboratories", coordinated by L. Spallanzani National Institute for Infectious Diseases (INMI), Italy. |
| Network coordinator | Robert Koch-Institut, Berlin, Germany |
| Number of network members | 37 highly specialised diagnostic laboratories (33 funded) |
| Geographical coverage | 21 EU Member States, Norway, and Switzerland |
| Type of network members | Government institutions including public health, veterinary, and military laboratories as well as laboratories of university faculties. |
| Requirements for membership | The partners were appointed by their competent national authority. Partners had to:<br>– Be specialized in the handling of highly pathogenic bacteria (BSL3 containment) or viruses (BSL4 containment);<br>– Be in the process of specialization for the handling of highly pathogenic bacteria (BSL3 containment) or viruses (BSL4 containment); or<br>– Focus on diagnostics, with subsequent collaboration for further characterisation of the agents under high containment conditions. |
| Reference period | 2011-2015 (42 months) |

*Source: Grant Agreement CHAFEA, extracted by network coordinator.*

### 4.5.2 Activities of QUANDHIP

QUANDHIP conducted activities separately and across both networks (i.e. the network on highly pathogenic bacteria (NIB) and the network on highly pathogenic viruses (NIV)). Activities focused on the following issues:

- External Quality Assessments (EQAs);
- Reference material resources/repository;
- Training;
- Biosafety and biosecurity; and
- Support to coordination of laboratory response to cross-border events.

The following table provides an overview of QUANDHIP activities clustered according to network functions.

### Table 53. QUANDHIP network activities implemented in the reference period

| Core function | Scope of implementation |
|---|---|
| 1. Reference diagnostics | The network ensures that appropriate reference methods are in operation between partners. It focuses in particular on molecular, virological diagnostic approaches and bacteriological diagnostic approaches. QUANDHIP also offers diagnostic confirmation services to members in cases of request and emergency. However, this task is not the main focus of the work programme. |
| 2. Reference material resources | QUANDHIP is built on the existing repositories developed by the NIB and the NIV. To strengthening theses repositories, internal databases have been set up, which provide data on the characteristics of the samples. In this regard, the following activities were undertaken:<br>– Extension of the available bacterial and viral isolates.<br>– Validation of the characterisation of these isolates.<br>– Development and extension of the database and linking with existing databases on viruses and bacteria.<br>– Establishment of antimicrobial susceptibility data on bacteria.<br>Furthermore, a material transfer agreement (MTA) was designed and agreed upon between partners of QUANDHIP. This MTA facilitates the transfer of material between all partners. It is intended to be used also for rapid exchange of material in outbreak situations. |
| 3. Scientific advice to public authorities | Scientific advice to authorities related in particular to recommendations for bio-risk management and outbreak response management. In addition the network supported the Commission and the Health Security Committee in emergency situations and outbreak response, for example in the latest Ebola crisis. |
| 4. External Quality Assessments (EQA) | The aim of the EQAs was to ensure a high quality of laboratory diagnostic methodologies as well as conformity participating laboratories' methods to best practices. Both networks, NIB and NIV, performed three External Quality Assessments (EQAs) in the reference period. At face-to-face meetings, the results and best practices obtained in the EQAs were exchanged and discussed. Participating laboratories agreed that quantitative standards should be developed for better comparison of the sensitivity of both established and new methods. |
| 5. Training | Partners of the network offered practical laboratory-based training to other partners. These related to bringing laboratory diagnostic response strategies for the preparation and analysis of samples within BSL-3 and/or BSL-4 facilities in line with best practices. 12 training courses were provided by selected partners at their institutions. A workshop was conducted on training and handling in relation to BSL-4 containments, which generated ideas for future training programmes. Furthermore, QUANDHIP updated previously developed infrastructure checklists for biosafety and biosecurity concerning the handling of risk group 3 and 4 agents and provided a practically applicable integrated check list for bio-risk management for BSL-3 and BSL-4 laboratories. |
| 6. Collaboration and research | QUANDHIP collaborates with other networks including for example ENIVD, ERINHA, etc. |
| 7. Monitoring, alert and response | A working group was established to develop proposals for the coordination of laboratory activities in case of outbreak response. Standard operational procedures (SOPs) for the coordination of laboratory activities during outbreaks were developed. A detailed description of capabilities of QUANDHIP laboratories was produced and is available. The document addresses the following areas:<br>– Activation and role of QUANDHIP network in case of highly infectious pathogens (HIP) events;<br>– Essential actions for QUANDHIP laboratories during at-distance or on-the-field assistance to local laboratories in case of HIP outbreaks; |

| | |
|---|---|
| | – Essential information to be exchanged among the QUANDHIP laboratories and other actors involved in outbreak response.<br>Moreover, the document includes a toolkit for local laboratories involved in the outbreak response and an updated inventory of diagnostic capabilities and logistic resources and procedures of all QUANDHIP laboratories. |
| 8. Governance of the network | The project was managed by RKI. The management included the organisation of all meetings, reporting to the EC and the maintenance of a public website with a restricted access area for members. |

*Source: Grant Agreement CHAFEA, extracted by network coordinator.*

### 4.5.3 Coordination structure of QUANDHIP

QUANDHIP had a virtually centralised coordination structure, i.e. responsibilities for implementing the project were shared by a lead coordinator and a co-coordinator. The lead coordinator was the RKI, Germany which was responsible for the overall management of the project as well as for coordinating the NIB. INMI, the co-coordinator of QUANDHIP, supported RKI in its tasks and coordinated the NIV. The QUANDHIP consortium selected a steering committee to support coordinators in the implementation of the network. CHAFEA, DG SANTE/Unit C3 as well as an independent international advisory board supervised the implementation of QUANDHIP from the institutional side.

QUANDHIP carried out common and separate activities for the NIV and NIB networks. Activities were clustered into five core work packages led by designated QUANDHIP partners including the coordinators. The work packages were allocated to different coordinators as follows:

- WP1 Coordination: RKI
- WP2 Dissemination: INMI
- WP3 Evaluation: PUM (Philipps Universität Marburg, Germany)
- WP4 External Quality Assessments (EQA): RKI
- WP5 Repository for reference materials: RKI
- WP6 Training: NIPH (Norwegian Institute of Public Health, Norway)
- WP7 Biosafety and Biosecurity: RKI
- WP8 Support to coordination of laboratory response to cross-border events: INMI

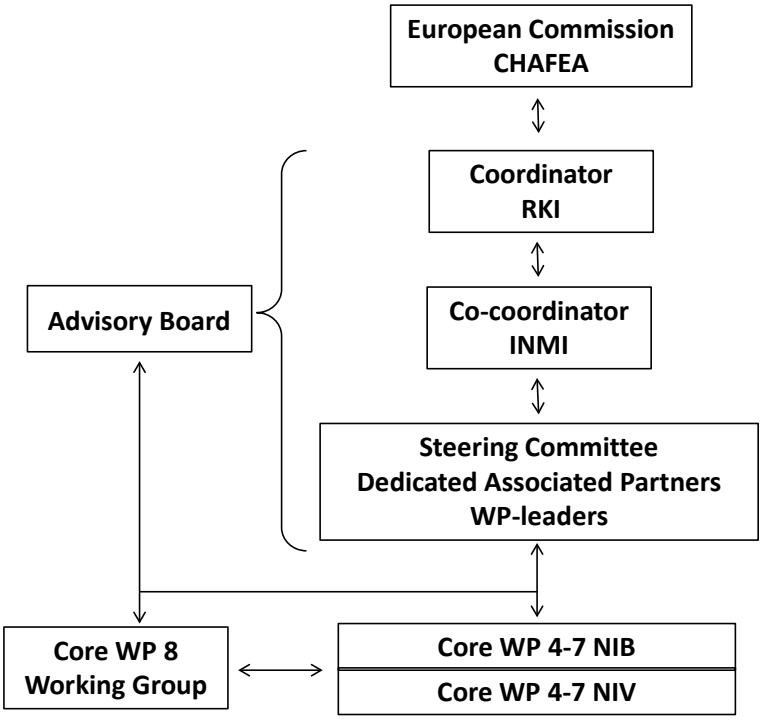
Due to the combination of two networks with a different pathogen focus within QUANDHIP, the core work package 4 on EQAs was shared between RKI (providing EQAs on bacteria) and PUM (providing EQAs on viruses). All other work packages, while having a designated leader, were implemented through close collaboration of several partners.

The two coordinators organised the exchange of information on all activities between partners. Each network performed 6 meetings within the framework of QUANDHIP. Three meetings brought together all participants of both the NIB and NIV. The final meeting reviewed the outcomes of QUANDHIP and presented laboratory strategies and capabilities to respond to biological threats in the EU.

The principal management structure of QUANDHIP is illustrated in the following figure.

The principal management structure of QUANDHIP is illustrated in the following figure.

**Figure 10. Management structure of the QUANDHIP network**




*Source: Network coordinator (RKI). Note: NIB – Network on highly infectious bacteria. NIV – Network on highly infectious viruses.*

The following table summarises the coordination structure of the QUANDHIP network.

### Table 39. Coordination of the QUANDHIP network

| **Coordination structure** | |
|---|---|
| Characteristics | Virtually centralised coordination structure. |
| **Network coordinators** | |
| Robert Koch-Institut (Lead coordinator) | Main tasks included:<br>- *Development of the work programme:* Coordinate with CHAFEA and DG SANTE concerning priority areas of the work plan and develop a proposal accordingly.<br>- *Implementation of the work programme and coordination with partners*: Facilitate the implementation of all activities of the work plan (see Section 1.2) and coordinate all activities with partners.<br>- *Development of specific activities for the network on bacteria*: Provide EQAs.<br>- *Administrative coordination*: Facilitate all administrative procedures within the network and coordinate with the European Commission accordingly, including in terms of reporting on activities and finances. Provide technical and financial reports. |
| L. Spallanzani National Institute for Infectious Diseases (co-coordinator) | Main tasks included:<br>- *Development of the work programme*: Develop a proposal specific for the network on viruses.<br>- *Support of the coordinator in implementation of the work programme and coordination with partners*: Facilitate the implementation of all activities of the work plan and co-coordinate all activities with partners.<br>- *Development of specific activities for the network on viruses*: Coordinate provision of EQAEs.<br>- *Administrative co-coordination*: Facilitate all administrative procedures within the network, especially concerning viruses, and co-coordinate with the European Commission accordingly, including in terms of reporting on activities and finances. |
| **Coordination of work packages** | |
| WP4 External Quality Assurance Exercises (EQA- bacteria): RKI | - Organisation and provision of EQAs including sample preparation and shipping. |
| WP4 External Quality Assurance Exercises (EQA- viruses): co-leader PUM | - Organisation and provision of EQAs including coordination of sample preparation from risk group 4 viruses and shipping (inactivated material). |
| WP5 Repository for reference materials: RKI/ co-lead PUM | - Establishment of centralised repository of highly pathogenic bacteria.<br>- Coordination of a decentralised repository of highly pathogenic viruses.<br>- Development of well-characterised reference material. |
| WP6 Training: NIPH | - Design training programmes and exchange experience between the network partners. Partners implemented and provided practical laboratory-based training to relevant participants for the preparation and analysis of samples in BSL-3, and/or BSL-4 facilities. |
| WP7 Biosafety and Biosecurity: RKI | - Previously developed check-lists for laboratory biosafety and biosecurity concerning the handling of risk group 3 and 4 agents were further developed and promoted as an international tool for (self-) evaluation of relevant laboratories. |
| WP8 Support to coordination of | - Development of recommendations for support to coordination of operational response to health threats events caused by highly |

| | |
|---|---|
| laboratory response to cross-border events: INMI | infectious pathogens, provision of an overview of laboratory capacities and capabilities. |
| **Network Partners** | |
| 32 Associated partners<br>3 Collaborating partners (no funding) | - Participation in all practical activities of the work programme: EQAs, training etc.<br>- Participation in meetings and provision of results, participation in planning of activities.<br>- Contributing to dissemination by presentations and publications.<br>- Contributing to evaluation by completing questionnaires.<br>- Financial administration of received funds and reports. |
| **Funding entity** | |
| European Commission (DG SANTE/ CHAFEA) | Administrator of the QUANDHIP network, responsible for allocation of funds to the network. Main tasks include:<br>- *Work programme*: Coordinate with the QUANDHIP network/coordinators priority areas prior to the development of the work plan; agree on the objectives and work plan; evaluate interim and final reports; and monitor the implementation of all activities included in the work plan.<br>- *Funding*: Coordinate with the financial unit regarding all administrative funding procedures; take decisions on budget shifts if needed.<br>- *Internal coordination*: Ensure coherence with the work of other units in DG SANTE and if relevant with other EU institutions. |

*Source: Grant Agreement CHAFEA, extracted by network coordinator.*

### 4.5.4 Funding of QUANDHIP

QUANDHIP was co-funded by the Health Programme of the European Union under the priority area 3.2 'Improve Citizen's Health Security' and by QUANDHIP consortium members themselves. The duration of co-funding was 42 months. QUANDHIP consortium members contributed 50% of the funding.

The following table provides an overview of the budget. Numbers refer to the whole funding period (42 month) and the mean budget per year.

**Table 40. Funding of the QUANDHIP network**

| Funding provided by | Amount of funding (in Euro) | Mean amount per year (in Euro) |
|---|---|---|
| European Commission (DG SANTE/CHAFEA) | 2 831 488 (50%) | 808 997 |
| Co-financing by network members | 2 962 691 (50%) | 846 483 |
| *Total funding* | *5 794 179 (100%)* | *1 655 480* |

*Source: Network coordinator (RKI)*

### 4.5.5 Costs of QUANDHIP

The total costs of implementing the QUANDHIP network are comprised of the operating expenditure of the network plus additional costs.

*Operating expenditure of QUANDHIP*

The operating expenditure of the network is the sum of the costs specified in the QUANDHIP budget as co-funded by the European Commission and contributed by the network partners. The following table provides an overview of the operating expenditure of the network broken down by cost item. It shows that the largest share of costs for the implementation of the network's work plan was attributable to staff costs, with 69% of the network budget. The second largest share related to consumables (16%).

**Table 41. Operating expenditure of the QUANDHIP network by cost item**

| Cost item | Total network budget (in Euro) | Mean budget per year (in Euro) | Share of total network budget (as percent) |
|---|---|---|---|
| Staff | 4 004 768 | 1 144 219 | 69% |
| Capital equipment | 68 135 | 19 467 | 1% |
| Consumables | 914 321 | 261 235 | 16% |
| Travel | 230 884 | 65 967 | 4% |
| Shipping | 135 545 | 38 727 | 2% |
| Subcontracting and services | 61 468 | 17 562 | 1% |
| Overhead | 379 058 | 108 302 | 7% |
| *Total* | *5 794 179* | *1 655 480* | *100%* |

*Source: Network coordinator (RKI).*

As the following table shows, staff time amounting to 104 person-months per year was co-funded by the European Commission. 235 person-months per year were financed by the partners for the implementation of activities of the QUANDHIP network.

**Table 42. Person-months funded for the QUANDHIP network**

| Staff category | Person-months per year/total funding period | Person-months (EU co-funded) per year/total funding period | Person-months (own contribution) Per year/total funding period |
|---|---|---|---|
| Professionals | 215/751 | 47/164 | 168/587 |
| Technicians/associate professionals | 123/431 | 57/199 | 67/233 |
| *Total* | *338/1182* | *104/363* | *235/820* |

*Source: Network coordinator (RKI).*

The table below breaks down operating expenditure by core function. It shows that the biggest share of the budget (32%) was allocated to the implementation of network-wide EQAs. Furthermore, almost one fifth of the budget (19%) was allocated to cover costs for reference materials and repositories, while 15% of the budget was used to facilitate training activities of network members.

**Table 43. Operating expenditure of the QUANDHIP network by core function**

| Core function | Expenditure total (in Euro) | Expenditure per year (in Euro) | Expenditure as percentage of total core function budget |
|---|---|---|---|
| 1. Reference diagnostics | 645 516 | 184 433 | 11% |
| 2. Reference material resources | 1 124 596 | 321 313 | 19% |
| 3. Scientific advice to public authorities | 234 431 | 66 980 | 4% |
| 4. External Quality Assessments (EQA) | 1 833 702 | 523 915 | 32% |
| 5. Training | 846 182 | 241 766 | 15% |
| 6. Collaboration and research | 278 801 | 79 657 | 5% |
| 7. Monitoring, alert and response | 278 801 | 79 657 | 5% |
| 8. Governance of the network | 552 150 | 157 757 | 10% |
| *Total* | *5 794 179* | *1 655 480* | *100%* |

*Source: Grant Agreement CHAFEA extracted by network coordinator (RKI).*

*Additional costs incurred by QUANDHIP members*

In the reference period, additional costs that were not compensated for by the network budget were only incurred by DG SANTE/CHAFEA, as the funding entity of QUANDHIP. Laboratory network members mainly contributed through their official co-financing requirements included as part of the operating expenditure in the budget.

**Table 44. Additional costs incurred to QUANDHIP in the reference period (42 months)**

| Cost item | Additional costs of funding entity | Additional costs of coordinator | Additional costs of all laboratory members* | Total additional costs |
|---|---|---|---|---|
| Staff costs (in Euro) | 26 800 | 19 331 | 802 920 | 849 051 |
| Consumables (in Euro) | 0 | 0 | 40 656 | 40 656 |
| Travel (in Euro) | 4 826 | 0 | 1 423 | 6 249 |
| Shipping (in Euro) | 0 | 0 | 0 | 0 |
| Other costs(in Euro) | 0 | 0 | 5 082 | 5 082 |
| *Total* | *31 626* | *19 331* | *850 081* | *901 039* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members. Note: *Extrapolation for all network members based on survey results (N=13).*

*Total costs of QUANDHIP*

The total costs of implementation of the QUANDHIP network, i.e. the sum of operating expenditure and additional costs, amounted to EUR 6 695 218 in the reference period. The following table provides an overview of these costs.

**Table 45. Total costs of the QUANDHIP network in the reference period (42 months)**

| Cost item | Operating expenditure according to budget | Total additional costs | Total network costs |
|---|---|---|---|
| Staff | 4 004 768 | 849 051 | 4 853 819 |
| Capital equipment | 68 135 | 0 | 68 135 |
| Consumables | 914 321 | 40 656 | 954 977 |
| Travel | 230 884 | 6 249 | 237 133 |
| Shipping | 135 545 | 0 | 135 545 |
| Subcontracting and services | 61 468 | 0 | 61 468 |
| Overhead/ other costs | 379 058 | 5 082 | 384 140 |
| *Total* | *5 794 179* | *901 039* | *6 695 218* |

*Source: Civic Consulting based on information provided by network coordinator, the funding entity and network members.*

### 4.5.6 Benefits of QUANDHIP

The QUANDHIP network induced benefits for network members as well as for society as a whole. These were identified by representative network partners, including work package leaders and members.

*Benefits for network members*

Benefits for network members are of both monetary and non-monetary nature. The following table describes the reported monetary benefits, which relate particularly to cost savings of individual partners. The partners of the network save on fees that they would otherwise have incurred thanks to services provided free of charge through the network, such as EQAs and training courses or the distribution of strains and DNA/RNA as reference material.

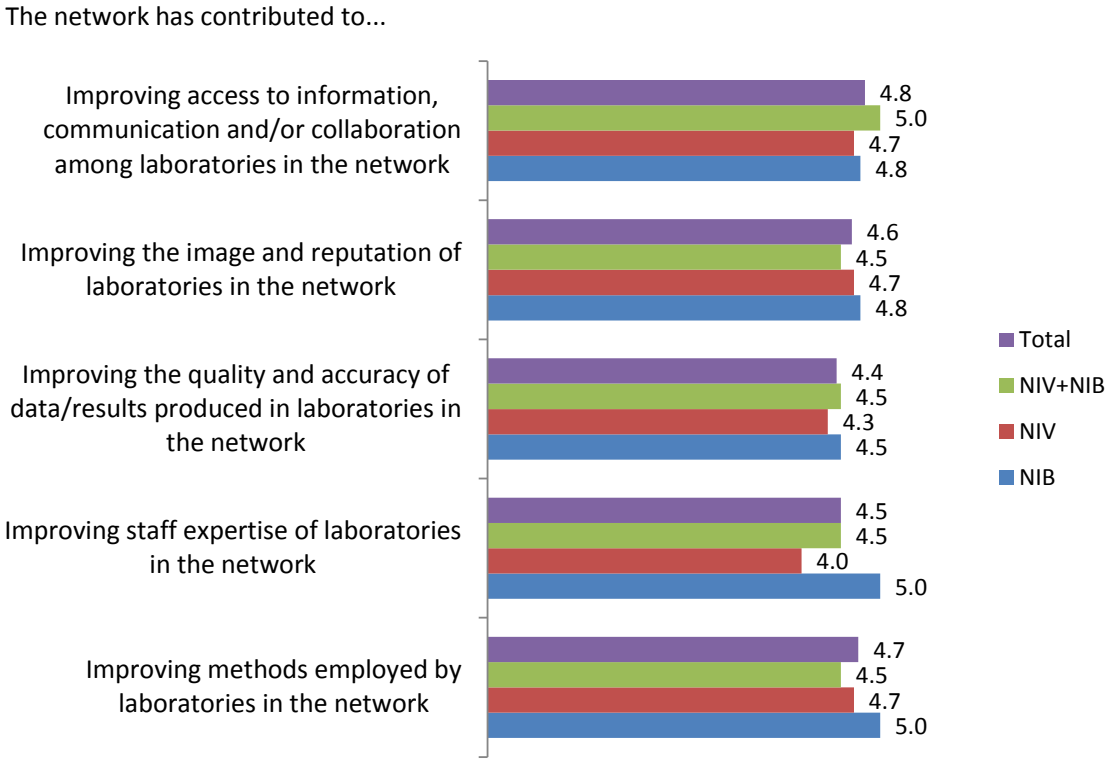
**Table 46. Monetary benefits for QUANDHIP network members**

| Benefit results from | Average amount saved (in Euro)* |
|---|---|
| Reference material resources | 3 917 |
| Reference diagnostics | 3 125 |
| Training | 6 400 |
| EQA | 11 667 |
| Scientific advice | 2 500 |
| Collaboration and research | 10 000 |
| Total | 37 609 |

*Source: Network coordinator based on information provided by network members. *Nine exemplarily partners were selected randomly, of which 6 provided information for monetary benefits.*

Non-monetary benefits of the QUANDHIP network for members include the improvement of laboratory methods, staff expertise, quality and accuracy of data and results, and the access to information, communication and collaboration. The following figure provides a qualitative assessment of these benefits. It ranks the average assessment of benefits by network members on a scale from 1 ('not at all') to 5 ('very much').

**Figure 11. Average rating of non-monetary benefits for QUANDHIP members**




*Source: Network coordinator based on information provided by network members. Data were collected from 9 randomly selected partners. Note: Rating on a scale from 1 (not at all) to 5 (very much).*

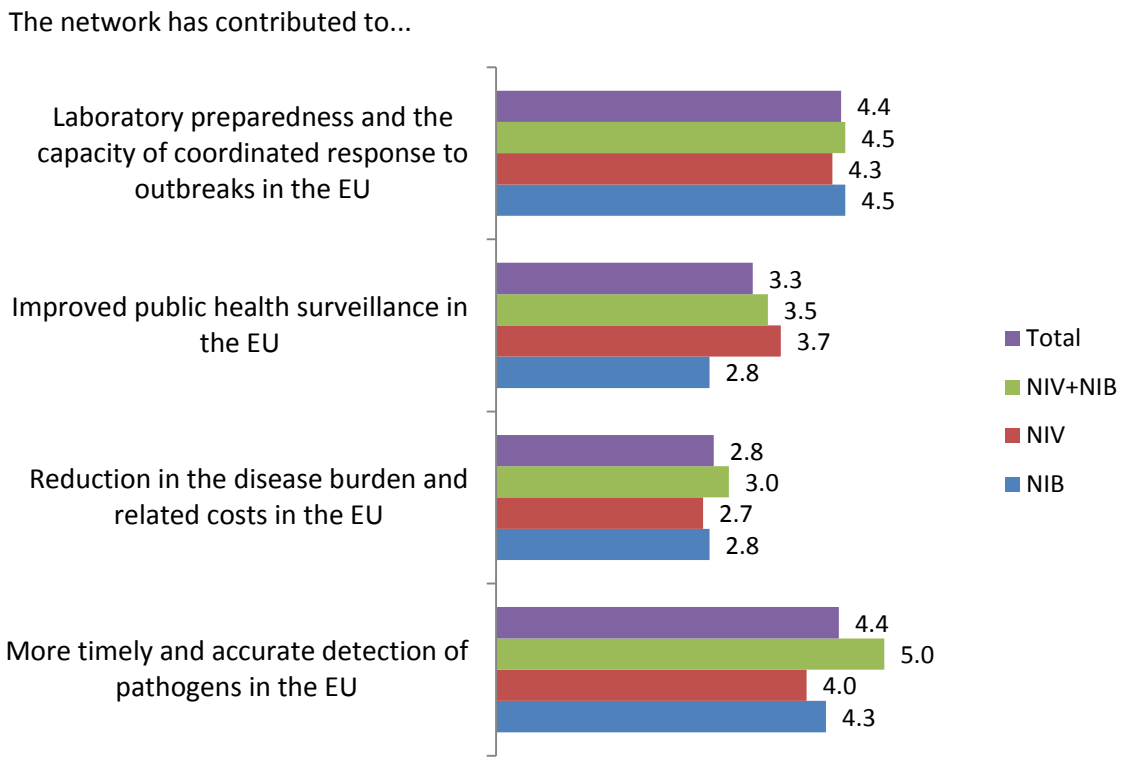
As the figure above shows, QUANDHIP network members assess all listed benefits with very high scores of at least 4.0 out of 5 points on average.

On the basis of discussion between coordinators and network members, it was concluded that the EQAs, training, the provision of reference materials, the exchange of knowledge and the collaboration of partners in the network are priority tasks for the partners themselves and for public health in the EU. They would need to be implemented under any circumstances. In absence of the network, the tasks would instead be carried out, if at all, on a smaller and less effective scale. In addition, it would lead to uncoordinated duplications of activities and elevated costs. Thus, the networking of laboratories achieved through QUANDHIP was highly appreciated by all network partners.

*Benefits for society as a whole*

In terms of non-monetary benefits for society as a whole, respondents positively assessed the contribution of the QUANDHIP network to more timely and accurate detection of pathogens as well as to increased laboratory preparedness and coordinated response to outbreaks of infectious diseases in the EU (scoring between 4 and 5, see the following figure). On the other hand, the network was not seen as having a significant effect on the existing disease burden and related costs, which scored between 2.7 - 3.0 points (overall 2.8 points). This may relate to the fact that surveillance of infectious diseases was not a topical issue of the network. A somewhat higher score was attributed to improved surveillance (scoring between 2.8 and 3.7; overall 3.3).

**Figure 12. Average rating of non-monetary benefits for society as a whole for QUANDHIP.**




*Source: Network coordinator based on information provided by network members. Data were collected from 9 randomly selected partners. Note: Rating on a scale from 1 (not at all) to 5 (very much).*

## 4.6 Case study: ERLTB-Net

This section presents the case study on the European Reference Laboratory Network for Tuberculosis (ERLTB-Net).

### 4.6.1 ERLTB-Net network characteristics

The European Centre for Disease Prevention and Control (ECDC) launched the European Reference Laboratory Network for Tuberculosis (ERLTB-Net, formerly ERLN-TB) in January 2010. This network focuses on the causative agents of tuberculosis (TB), i.e. on Mycobacterium tuberculosis complex and on other non-tuberculous mycobacteria (NTM), excluding M. leprae.

The ERLTB-Net network was originally created following the results of a situational analysis of EU-wide TB reference laboratory services that demonstrated the added value of establishing an EU network of reference laboratories. The expected added value related especially to strengthening diagnostic method services in the EU.49 The three main goals of the network are therefore to support methods harmonisation within the EU/EEA, to develop External Quality Assurance (EQA) schemes and to

[49] ECDC Tuberculosis programme, 2009. http://ecdc.europa.eu/en/press/news/Documents/100125_ERLN_TB_information_flyer.pdf

provide training activities within the network to ensure EU-wide standard capacity building.

ERLTB-Net consists of 33 national reference laboratories from EU/EEA Member States that were nominated by their respective national bodies and endorsed by ECDC. These laboratories form a consortium with three designated network coordinators among the consortium laboratories.

The following table summarises the characteristics of the ERLTB-Net network.

**Table 47. Characteristics of the ERLTB-Net network**

| Characteristic | Description |
|---|---|
| Pathogens covered | - Mycobacterium tuberculosis complex<br>- Other nontuberculous mycobacteria (NTM), except M. *leprae* |
| Founding year | 2010 |
| Establishment of network | The ERLTB-Net network was created following the results of a situational analysis of EU-wide TB reference laboratory services performed in 2008. The results indicated that establishing an EU network of reference laboratories would bring added value, especially with regards to strengthening diagnostic method services. Under the overall responsibility of ECDC, the ERLTB-Net network was launched in 2010. |
| Network coordinators | - Public Health England (PHE), UK<br>- Research Centre Borstel (FZB), Germany<br>- San Raffaele Scientific Institute, Italy |
| Number of network members | 33 |
| Geographical coverage | EU/EEA Member States |
| Type of network members | National reference laboratories |
| Requirements for membership | The network laboratories were nominated by their competent national authority and endorsed by ECDC. All partners formed a consortium of laboratories and the consortium was selected by means of a tendering process. |
| Reference period for the case study | Reporting period 2014 – 2015 (1 year) |

*Source: Civic Consulting based on information provided by network coordinators.*

### 4.6.2 Activities of ERLTB-Net

ERLTB-Net implemented various activities during the reference period. The main scope of practice of the network relates to the following activities:

- Having up-to-date and harmonised methods in operation;
- Developing and providing reference material resources;
- Providing expert advice and scientific support;
- Organising External Quality Assessments (EQAs);
- Training.

The following table provides an overview of the activities undertaken by ERLTB-Net in the reference period as part of the work plan.

**Table 48. ERLTB-Net network activities implemented in the reference period (2014-2015)**

| Core function | Scope of implementation |
|---|---|
| 1. Reference diagnostics | The TB network had developed a handbook of reference methods in order to provide information on up-to-date reference methods in operation. A second version of the handbook was prepared in the reference period which includes significant updates. The network develops a list of reference services available in the network on a yearly basis. Practical help such as diagnostic confirmation is only provided occasionally to laboratories. |
| 2. Reference material resources | The network has developed a reference strain collection that was validated using a range of methods. Reference strains are distributed to network members. |
| 3. Scientific advice to public authorities | Scientific advice is provided to public health authorities. In the reference period the network developed a systematic review on the role of whole genome sequencing (WGS) in TB epidemiology and surveillance. The network issued a technical report on the diagnostic value and added value of rapid molecular tools in TB diagnosis. |
| 4. External Quality Assessments (EQA) | Two EQA rounds were organised for network members in the reference period: one on conventional TB diagnosis laboratory methods and another on genotyping. |
| 5. Training | The network developed an extensive training program including the concept of support experts training as well as staff exchanges and task force visits. Training needs are identified through EQAs and task force visits or staff exchanges are organised accordingly. In practice, two large-scale training workshops and three to five smaller and more practical workshops were organised for network members. |
| 6. Collaboration and research | Network members participated in joint annual meetings with other networks, coordinated by the ECDC and WHO Europe. Network members also participate in joint initiatives, e.g. with EUCAST and WHO. These initiatives include training sessions, operational research and other research projects funded under FP7. |
| 7. Monitoring, alert and response | ERLTB-Net contributes to the disease surveillance platform hosted by ECDC (The European Surveillance System TESSy) by providing data on TB genotypes circulating in the EU and data on drug resistance. The network puts continuity and emergency arrangements in place in order to distribute the workload among network members in case of overload. |
| 8. Governance of the network | Administrative coordination of the network and communication activities are mainly undertaken by PHE. Network members upload material to the Extranet, while the website of the network is maintained by ECDC. |

*Source: Civic consulting based on information provided by network coordinators.*

### 4.6.3 Coordination structure of ERLTB-Net

ERLTB-Net has a virtually centralised coordination structure. The network is coordinated by three partners who share tasks related to the general coordination and implementation of network activities.

The network coordination is distributed according to the functions and activities carried out in the network. The consortium, composed of all network laboratories, has designated Public Health England (PHE) as lead coordinating partner of ERLTB-Net. PHE takes on the largest share of the coordinating activities for the network and is the main contact point for ECDC. In particular, PHE is responsible for the redistribution of funds provided by ECDC to the work package leaders or other network members who undertake specific activities on behalf of the consortium. Two other laboratories complement the work of PHE by taking the lead on certain work packages. The

Research Center Borstel coordinates the external quality assurance activities, with the input from PHE on specimen preparation and data analysis. The San Raffaele Scientific Institute in Milan is the work package leader for training activities, but is supported by the other two coordinators in conducting related tasks.

For general decision-making, a management committee consisting of representatives of the three coordinating laboratories and other consortium partners was established. Funds are allocated based on decisions made by the management committee regarding the activities to be undertaken by the network. As the funding entity of the network, ECDC is also involved in the coordination of ERLTB-Net, taking on activities related to collaboration and research.

The following table provides an overview of the coordination structure of ERLTB-Net.

**Table 49. Coordination of the ERLTB-Net network**

| **Coordination structure** | |
|---|---|
| Characteristics | Virtually centralised coordination structure. The coordination of network activities is shared by three coordinating laboratories. |
| **Network coordinators** | |
| Public Health England (Lead coordinator) | Lead coordinator of the laboratory consortium. Main tasks include:<br>- All administrative tasks including the administration of funds;<br>- Supporting the coordination of activities led by other coordinators. |
| Research Center Borstel (co-coordinator) | Co-coordinator. Main tasks include:<br>- Coordination of the EQAs;<br>- Supporting the coordination of activities led by other coordinators. |
| San Raffaele Scientific Institute (co-coordinator) | Co-coordinator. Main tasks include:<br>- Coordination of the training activities;<br>- Supporting the coordination of activities led by other coordinators. |
| **Funding entity** | |
| ECDC | Main tasks include:<br>- Decision-making on the strategic direction of the network;<br>- Allocating funding for activities;<br>- Coordinating and organising activities related to collaboration and research;<br>- Providing support for external communication and publication. |

*Source: Civic consulting based on information provided by network coordinators and funding entity.*

### 4.6.4 Funding of ERLTB-Net

To implement its activities, ERLTB-Net receives funding from ECDC. For the reference period of one year, ECDC provided a total of EUR 177 271. During the reference period, the lead coordinator Public Health England also contributed 10% of the total funding.

The following table provides an overview of the budget. Numbers refer to the whole funding period (one year 2014-2015).

**Table 50. Funding of the ERLTB-Net network**

| Funding provided by | Amount of funding (in Euro) |
|---|---|
| ECDC | 177 271(90%) |
| Co-financing by network members | 19 697 (10%) |
| *Total funding* | *196 968 (100%)* |

*Source: Civic Consulting based on information provided by network lead coordinator (PHE).*

### 4.6.5 Costs of ERLTB-Net

The total costs of implementing the ERLTB-Net network include the operating expenditure of the network mostly funded by the ECDC, and the additional costs incurred by network members for participating in network activities. The following section describes both components of the network costs.

*Operating expenditure of ERLTB-Net*

The operating expenditure of the network is the sum of the costs specified in the budget funded by ECDC for the implementation of all network activities. The following table provides an overview of the operating expenditure of ERLTB-Net broken down by cost item for the one-year reference period.

As shown in the table below, staff costs represented the largest share of the total costs related to the implementation for the network's work plan, accounting for 50% of the network's operating expenditure. The second and third largest shares of the network's operating expenditure related to travel costs (23%) and subcontracting and services (15%).

**Table 51. Operating expenditure of the ERLTB-Net network by cost item in the reference period (1 year)**

| Cost item | Total network budget (in Euro) | Share of total network budget (as percent) |
|---|---|---|
| Staff | 99 013 | 50% |
| Capital equipment | 1 379 | 1% |
| Consumables | 9 552 | 5% |
| Travel | 44 473 | 23% |
| Shipping | 0 | 0% |
| Subcontracting and services | 29 665 | 15% |
| Overhead | 12 886 | 7% |
| *Total* | *196 968* | *100%* |

*Source: Civic Consulting based on information provided by network lead coordinator (PHE).*

As indicated in the table below, 14.85 person-months were allocated for ERLTB-Net over the reference period of one year. All funded staff time related to the staff category professionals.

**Table 52. Person-months funded for the ERLTB-Net network.**

| Staff category | Person-months (one year) |
|---|---|
| Professionals | 14.85 |
| Technicians/associate professionals | 0 |
| *Total* | *14.85* |

*Source: Network coordinator (PHE).*

No data were provided regarding the distribution of the ERLTB-Net operating expenditure by function thus a breakdown cannot be shown for this case study.

*Additional costs incurred by ERLTB-Net members*

Additional costs that were not compensated by the network budget were incurred by ECDC, the network coordinators, and the network members in the course of the reference period. The following table shows the nature and distribution of these additional costs. Staff costs represent by far the largest share of additional costs. For example, while the core costs of EQAs are covered by the network budget, the consumables used by network members to analyse the samples and the related staff time are not accounted for. The total additional costs incurred by all network members should be interpreted with care, as the final figure is based on an extrapolation of survey data provided by 2 of the 33 network members only.[50]

[50] According to the network coordinator, additional costs of members are largely overestimated as a result of the low survey response rate.

**Table 53. Additional costs incurred to ERLTB-Net in the reference period (1 year)**

| Cost item | Additional costs of funding entity | Additional costs of coordinators | Additional costs of all laboratory members* | Total additional costs |
|---|---|---|---|---|
| Staff costs (in Euro) | 47 415 | 26 759 | 124 971 | 199 146 |
| Capital equipment | 0 | 0 | 20 076 | 20 076 |
| Consumables (in Euro) | 0 | 600 | 33 000 | 33 600 |
| Travel (in Euro) | 0 | 0 | 33 000 | 33 000 |
| Shipping (in Euro) | 0 | 500 | 3 300 | 3 800 |
| Other costs(in Euro) | 0 | 0 | 0 | 0 |
| *Total* | *47 415* | *27 859* | *214 348* | *289 622* |

*Source: Civic Consulting based on information provided by network coordinators, the funding entity and network members. Note: *Extrapolation for all network members based on survey results (N=2).*

*Total costs of ERLTB-Net*

The total costs related to the implementation of the ERLTB-Net network, i.e. the sum of operating expenditure and additional costs, amounted to EUR 486 591 in the reference period. The following table provides an overview of these costs.

**Table 54. Total costs of the ERLTB-Net network**

| Cost item | Operating expenditure according to budget | Total additional costs | Total network costs |
|---|---|---|---|
| Staff | 99 013 | 199 146 | 298 159 |
| Capital equipment | 1 379 | 20 076 | 21 456 |
| Consumables | 9 552 | 33 600 | 43 152 |
| Travel | 44 473 | 33 000 | 77 473 |
| Shipping | 0 | 3 800 | 3 800 |
| Subcontracting and services | 29 665 | 0 | 26 665 |
| Overhead/ other costs | 12 886 | 0 | 12 886 |
| *Total* | *196 968* | *289 622* | *486 591* |

*Source: Civic Consulting based on information provided by network coordinators, the funding entity and network members.*

### 4.6.6 Benefits of ERLTB-Net

The ERLTB-Net network provides benefits for network members as well as for society as a whole. These were identified by representative network partners, including work package leaders and members.

*Benefits for network members*

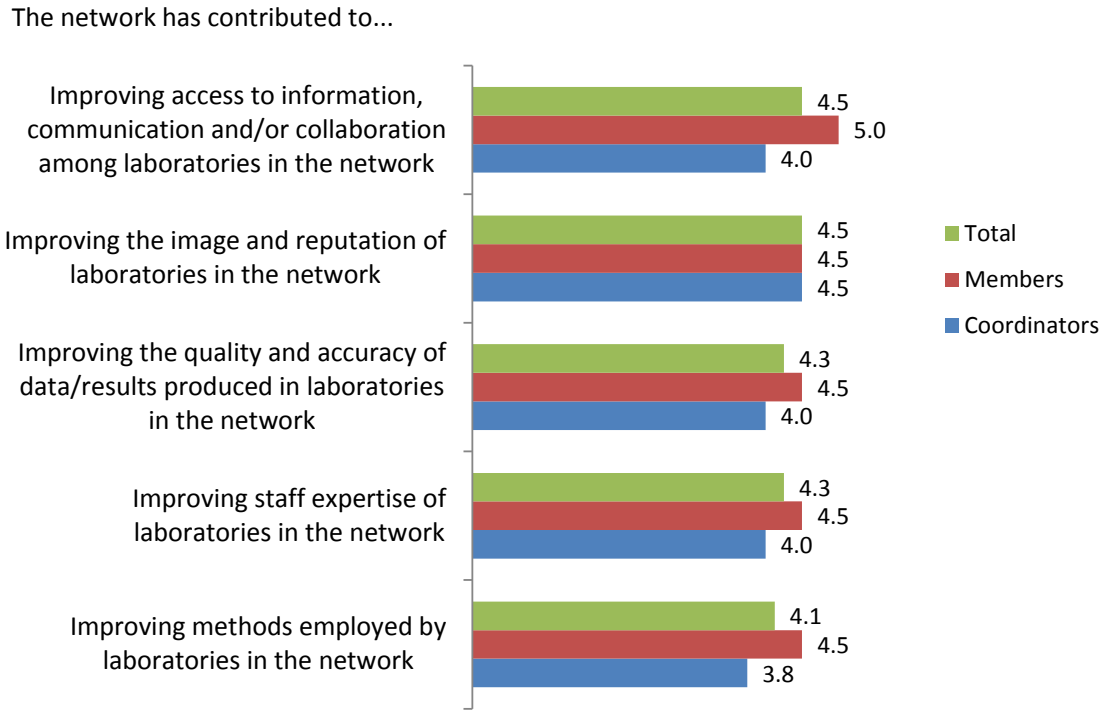
Benefits enjoyed by network members are of both monetary and non-monetary nature. The network coordinators did not report any savings related to coordination activities. The monetary benefits identified relate to cost savings of individual network members, particularly in relation to reference diagnostics. The following table provides an overview of the monetary benefits by function in the one-year reference period. The average benefits presented below are based on data provided by network members participating in related activities.

### Table 55. Monetary benefits for ERLTB-Net network members in the reference period

| Benefit results from | Estimated amount saved by network members (in Euro)* |
|---|---|
| Cost savings related to Reference material resources | 5 000 |
| Cost savings related to Reference diagnostics | 82 500 |
| Fees saved on training costs | 2 000 |
| Fees saved for EQAs | 5 500 |
| *Total* | *95 000* |

*Source: Civic Consulting based on survey results. Note:*Extrapolation for all network members based on survey results (N=2).*

### Figure 13. Average rating of non-monetary benefits for ERLTB-Net members




*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=2). Note: Rating on a scale from 1 (not at all) to 5 (very much).*

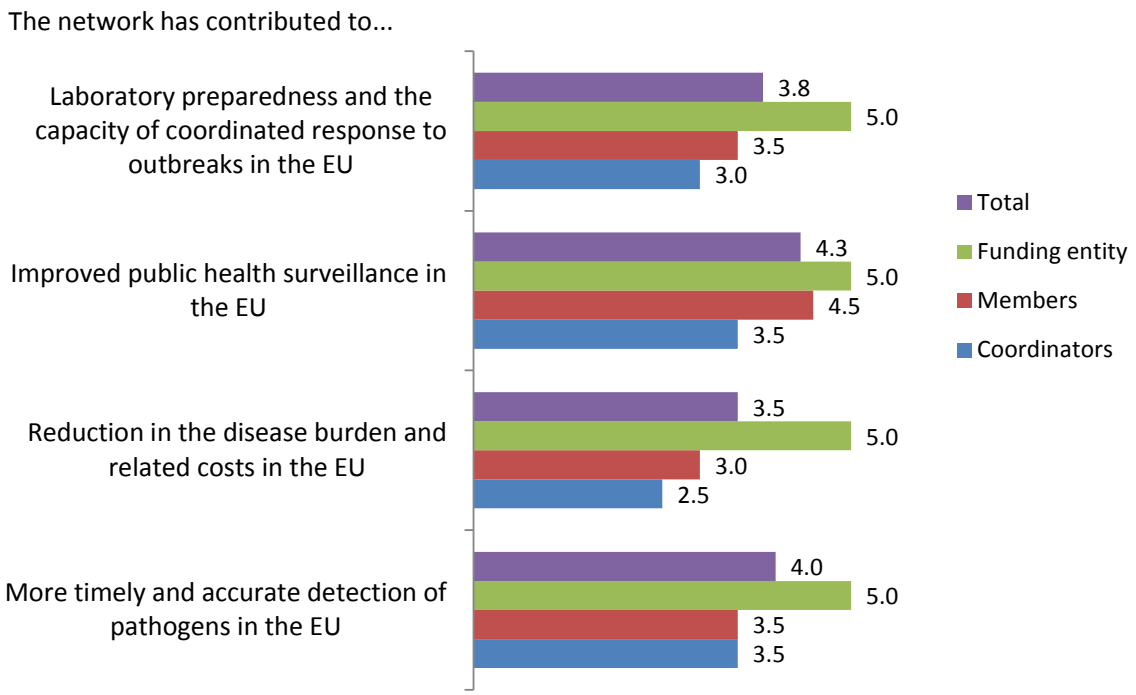
As the figure above shows, ERLTB-Net network members assessed all non-monetary benefits very positively, with all average scores above 4.0. On average, the contribution of the network to improving the image and reputation of laboratories in the network and to improving access to information, communication and/or collaboration among laboratories in the network both received the highest rating of 4.5.

*Benefits for society as a whole*

Furthermore, the ECDC and network coordinators and members assessed the non-monetary benefits of the ERLTB-Net network for society as a whole.

Respondents provided a positive assessment concerning the contribution of the ERLTB-Net network from a societal perspective. The highest scores were attributed to the network's contribution to improved public health surveillance in the EU (average score of 4.3) and to more timely and accurate detection of pathogens in the EU (average score of 4.0). The assessment concerning the network's contribution to laboratory preparedness and coordinated response to outbreaks of infectious diseases in the EU was slightly lower (average score of 3.8); this is also true of the assessment concerning the network's contribution to the reduction in the disease burden and related costs in the EU (average score of 3.5).

**Figure 14. Average rating of non-monetary benefits for society as a whole for ERLTB-Net**




*Source: Civic Consulting based on information provided by network coordinator and survey participants (N=2). Note: Rating on a scale from 1 (not at all) to 5 (very much).*

# 5. Analysis of costs

*This section presents the analysis of costs. Costs are assessed individually for each core function of an EU reference laboratory network. On the basis of the case study data, median costs are derived and the implications of different coordination options are discussed.*

## 5.1 Function 1 – Reference diagnostics

### 5.1.1 Costs of reference diagnostics

The total costs of the case study networks related to the reference diagnostics function range from EUR 61 595 (EU-RL VTEC network) to EUR 288 092 (QUANDHIP) in the reference year 2014.[51] This includes costs for the provision of information on up-to-date reference methods (activity 1a), diagnostic confirmation services (activity 1b), and network-wide typing, sub-typing and characterisation of samples, including atypical samples (activity 1c).

The following table presents the total costs of reference diagnostics by cost item for each case study network. The term 'total costs' in this and the following sub-sections refers to the total of budgeted costs for the function plus any additional costs that network members – including coordinator(s) – and funding entity may have incurred in relation to the implementation of the work programme in the reference year.

[51] Data was collected for the reference year of 2014. The last reporting period of the network was used. If important activities were not conducted in 2014 (e.g. EQAs in ERLI-Net are conducted biannually, with the last EQA conducted in 2013) the reference period was extended such that all relevant activities of the case study network were covered. An annual average was calculated which is presented in this and the following sections.

**Table 56. Annual network costs related to Function 1 - Reference diagnostics (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| Coordination structure of the network | Physically centralised | Physically centralised | Physically centralised | Virtually centralised | Virtually centralised |
| Staff costs | 27 352 | 143 862 | 125 632 | 169 168 | 241 828 |
| Equipment | 0 | 0 | 0 | 0 | 3 893 |
| Consumables | 15 925 | 92 125 | 41 054 | 65 755 | 55 093 |
| Travel | 0 | 7 258 | 333 | 485 | 0 |
| Shipping | 810 | 2 792 | 442 | 6 967 | 1 936 |
| Subcontracting/services | 0 | 0 | 39 606 | 0 | 0 |
| Overhead/administration | 17 501 | 1975 | 2 000 | 0[b)] | 12 341 |
| Total | *61 595* | *248 012* | *209 068* | *242 374* | *288 092* |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

As the table above shows, staff costs and costs of consumables represent the two largest cost items for reference diagnostics across all case study networks. They amount to between EUR 27 352 and EUR 241 828 for staff costs and between EUR 15 925 and EUR 92 125 for costs of consumables. In contrast, costs related to equipment and subcontracting appear less relevant: for each of these items only one network reported costs. Shipping costs are relevant across all case study networks. However, compared to the total costs of reference diagnostics, they represent a very small amount. Depending on the network, only one to two percent of the costs for reference diagnostics relate to shipping costs. Travel costs also make up only a small share of the costs of reference diagnostics. Two case study networks do not report any travel cost. Overhead and administration costs differ from case study network to case study network.

When analysing the costs of reference diagnostics across case study networks, the scope of the activities implemented by each network has to be scrutinised. While all case study networks aim to ensure the use of up-to-date reference methods amongst network members (activity 1a), e.g. by providing up-to-date standard operating procedures, only some networks undertake diagnostic confirmation services (activity 1b) and the typing, subtyping and characterisation of samples (activity 1c) as a network activity.

For example, the work plan of the EU-RL VTEC network does not include diagnostic confirmation or the continuous characterisation of samples. The tasks reported relating to reference diagnostics focus on the transfer of reference methods to network members. Since the transfer of methods is mainly ensured through the implementation of EQAs and training courses, no separate funds are allocated in the network budget for reference diagnostics (see detailed table in case study, Section 4.1). The costs reported in the table above refer to the additional costs incurred by network members for adapting their reference methods in response to network activities. This explains the comparatively small amount of costs (EUR 61 595) of the EU-RL VTEC network for reference diagnostics.

In contrast, costs for reference diagnostics in other case study networks are significantly higher – from three to seven times as high – compared to those of the EU-RL VTEC network. FWD-Net reported costs of a total amount of EUR 209 068. ENIVD and ERLI-Net reported almost the same amount of costs (around EUR 245 000) while for QUANDHIP costs amounted to EUR 288 092. The difference in costs among these networks is likely to result from the varying scope of the activities implemented. For example, FWD-Net, ENIVD and QUANDHIP undertake diagnostic confirmation testing in addition to the provision of updated standard operating procedures. The amount of diagnostic confirmation testing conducted differs, however. In ERLI-Net the continuous characterisation, typing and sub-typing of pathogens is an important task of the network.

Establishing the costs of reference diagnostics as the share of overall network costs provides the following picture: for the EU-RL VTEC network only 9% of the total costs result from reference diagnostics, while for QUANDHIP and ERLI-Net these costs amount to 15% and 24% respectively. For ENIVD, 32% of the costs are associated with reference diagnostics. For FWD-Net these related costs amount to 43%.

The following table summarises these results.

**Table 57. Costs of reference diagnostics as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 9% | 32% | 43% | 24% | 15% |

*Source: Civic Consulting.*

The large share of reference diagnostics costs for ENIVD can be attributed both to the objectives and scope of the network as well as to the high number of pathogens covered. As already discussed in Section 4.2, ENIVD has a strong focus on diagnostics. Furthermore, ENIVD covers a large number of different and sometimes rare viruses. Therefore, contrary to other networks such as ERLI-Net, where all network members can perform basic reference diagnostics for the pathogens covered in the network, laboratories in ENIVD are specialised in different viruses. Network members act as a resource to continuously seek and provide scientific advice to each other, including diagnostic confirmation. Costs relating to this continuous availability are mainly incurred by network members and make up the largest share of the overall network costs. Similarly, in FWD-Net in particular, members of the network cover the costs for reference diagnostics. If the amount of diagnostic confirmation services exceeds the services foreseen in the work plan, network members provide diagnostic confirmation for each other at their own cost.

As indicated above (see Section 3.5), annual median costs of reference diagnostics have been calculated for the purposes of this study across the four case study networks that provided comparable data (i.e. EU-RL VTEC, ENIVD, ERLI-Net and QUANDHIP) for the reference year, as a measure of the costs incurred for this function. The median costs for reference diagnostics are presented in the following table, which also lists their share in total network costs (i.e. in the sum of the median costs for all EU-RL functions). Activities underlying these costs relate not only to keeping reference methods up-to-date but also to conducting diagnostic confirmation testing and the characterisation of samples.

**Table 58. Annual median costs for reference diagnostics (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 128 943 | 16.5% |
| Equipment | 0 | 0.0% |
| Consumables | 40 840 | 5.2% |
| Travel | | 0.0% |
| Shipping | 1 801 | 0.2% |
| Subcontracting/services | | 0.0% |
| Overhead/administration | 1 191 | 0.2% |
| Total | *172 775* | *22.1%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

Reflecting the way median costs are calculated, their structure resembles the cost structure of case study networks: Staff costs and consumables are the two largest cost items (EUR 128 943 and EUR 40 840). Equipment, travel and subcontracting costs are not incurred. The total amount of costs for reference diagnostics amounts to EUR 172 775. The share of costs for reference diagnostics in total network costs is 22.1%.[52]

### 5.1.2 Implications of different coordination options for costs of reference diagnostics

In this step, we analyse the extent to which median costs can be expected to change depending on different coordination options, first by considering a physically centralised vs. a virtually centralised network coordination (Options III and IV; see Section 3.1), and second by considering an additional supranational level (Options I and II).

*Physically vs. virtually centralised coordination*

Table 56 above indicates whether coordination in each case study network is physically or virtually centralised. When reviewing the cost data regarding reference diagnostics presented in this table, there does not appear to be a clear relationship between the type of coordination structure and the costs for this function. For both physically centrally and virtually centralised case study networks, the share in total network costs for reference diagnostics can either be higher or lower than the median costs (which, as described above, are derived from all case studies for which complete data was available, including both centrally and virtually centralised networks). It therefore appears that the type of coordination structure of the network is less relevant than other factors, such as the scope of activities. A closer look at the implementation of reference diagnostics activities within each case study network supports this observation. It also shows that in practice the overall coordination structure of the network is not always reflected in the way a particular function is implemented.

[52] A detailed overview of the range of total costs per network for each cost item is provided in Table 56 'Annual network costs related to Function 1 - Reference diagnostics (in Euro)' (see above).

For example, the EU-RL VTEC network is a physically centralised network in which the lead coordinator (the EU-RL) takes full responsibilities for all activities related to reference diagnostics. The EU-RL provides information on methods and standards to network members, who are legally obliged to adapt their methods. On the contrary in ENIVD, which is also a physically centralised network, the lead coordinator of the network is not responsible for the implementation of as many reference diagnostics activities. Specifically, since ENIVD covers a large number of viruses and members of the network rely on each other's capabilities, different network members take the lead in reference diagnostics activities for different viruses. Hence, besides the overall physically centralised coordination structure, the implementation of activities in ENIVD is much less centralised than in the EU-RL VTEC network.

For ERLI-Net, a virtually centralised network, only one of the three coordinators, namely the Francis Crick Institute, takes the lead in characterising, typing and subtyping samples sent by network members. RIVM, as one of the other coordinators, focuses in particular on the harmonisation of antiviral-susceptibility testing methods. Therefore, despite the overall virtually centralised coordination structure of ERLI-Net, individual activities tend to be conducted in a physically centralised manner, i.e. one coordinator takes the lead. In QUANDHIP, responsibilities for implementing reference diagnostics activities are mostly shared between coordinators and other network members, in particular because both virological and bacteriological expertise is needed. Hence, more than one coordinator takes the lead.

To summarise, the coordination of reference diagnostics activities in the case study networks does not necessarily resemble the overall coordination structure of a network. A physically centralised network, such as ENIVD, can implement activities in a virtually centralised manner, while vice versa a virtually centralised network, such as ERLI-Net, implements activities in a physically centralised manner. Overall, the differences in the costs of reference diagnostics between case study networks therefore relate rather to the:

(i) Scope of the activities implemented; and

(ii) Objectives of the network.

Costs are less impacted by the overall coordination structure. Thus, for the implementation of Function 1 - reference diagnostics, we conclude that differential costs between options related to a virtually centralised and a physically centralised reference laboratory network (in terms of overall coordination) are not expected.[53] The following table summarises these results.

[53] As indicated in Section 3.5, for the assessment of differential costs we have assumed that the work programme of a network does not change under the different options. Cost differences that could arise from variations in labour costs between different laboratory locations are not considered.

**Table 59. Differential costs between a virtually and a physically centralised network for reference diagnostics**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *n.a.* | Cost type not relevant for this function |
| Consumables | *None* | No change expected |
| Travel | *None* | No change expected |
| Shipping | *None* | No change expected |
| Subcontracting/services | *n.a.* | Cost type not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

*Additional supranational level*

None of the case study networks currently has a coordination structure that involves a supranational level, i.e. second tier laboratories that would act as coordinators of country clusters at the supranational level, taking the lead in implementing activities only for their cluster of laboratory members. Therefore, we have discussed with the case study networks how the implementation of network activities would change if a supranational coordination level were to be introduced, and analyse related cost differentials on this basis.

The first activity (1a) relating to keeping reference methods up-to-date is unlikely to be coordinated from the supranational level. The activity concerns the harmonisation of reference methods throughout the whole network, which requires that the same information be provided to all network members. The most likely scenario is therefore that one coordinator from the pan-European level implements this task in a centralised manner. Since the supranational level is not involved in implementing the activity, no differential costs can arise.

The supranational level may, however, be involved in implementing the second activity (1b) related to diagnostic confirmation services. It seems reasonable that supranational coordinators conduct diagnostic confirmation testing for the members of their cluster under the condition that they have the capabilities to do so.[54] Network members would send the samples to their coordinator at the supranational level instead of the pan-European coordinator. By definition, the scope of the activity, i.e. the amount of diagnostic confirmation testing, would not change. The activity would only be undertaken at a different location. Accordingly, no differential costs relating to staff time, consumables and overhead costs would be incurred. Travel costs are not expected to be relevant for this activity. However, the change in location could impact shipping costs. Yet, considering that shipping costs only make up 1% of the median costs of reference diagnostics, we do not expect significant differential costs arising from the coordination at the supranational level.

[54] In networks such as ENIVD, where a large number of viruses are covered, the supranational coordinator may not have the capabilities to conduct diagnostic confirmation for all viruses. Therefore, it is likely that in such networks the supranational level would not be involved in the activity. Instead, they would adhere to their current implementation approach and thus no differential costs would be incurred.

For the coordination of the third activity related to reference diagnostics (1c), the typing, sub-typing, and detailed characterisation of pathogens, it is again unlikely that the supranational level would become involved. This activity concerns the establishment of a database of characterised pathogens. The information would be managed centrally in one database at the pan-European level, irrespective of the location of the laboratory work. Different databases coordinated each by supranational coordinators would thus appear to be an unlikely scenario. The addition of the supranational level to a network coordination structure is therefore unlikely to change the approach of implementing activity 1c, and hence is not likely to lead to differential costs.

In conclusion, supranational coordination would only become relevant in one of the three activities relevant for reference diagnostics. And differential costs related to this activity could only arise from shipping samples to different locations, which are likely to be minor. Considering, furthermore, that shipping costs make up only 1% of the costs for reference diagnostics, respective total differential costs for this function will be marginal, i.e. differential costs for reference diagnostics between a coordination structure with and a coordination structure without a supranational level are expected to be very minor, if any. The following table summarises these findings.

**Table 60. Differential costs of a supranational level for reference diagnostics**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None to very minor* | No significant change expected |
| Equipment | *n.a* | Not relevant for this function |
| Consumables | *None to very minor* | No significant change expected |
| Travel | *None* | No change expected |
| Shipping | *None to minor* | Depending on the new location of the laboratory performing diagnostic confirmation testing, shipping costs may change. |
| Subcontracting/services | *n.a.* | Not relevant for this function |
| Overhead/administration | *None* | No change expected |
| *Total* | *None to very minor* | Considering that the share of shipping costs is very low (1% of median costs for reference diagnostics), the differential cost changes are likely to be not relevant or very minor in terms of total costs. |

*Source: Civic Consulting*

## 5.2 Function 2 – Reference material resources

### 5.2.1 Costs of reference material resources

The total annual costs related to reference material resources range from EUR 33 113 (ENIVD) to EUR 405 873 (QUANDHIP). This relates to two activities in particular: the development and maintenance of relevant source reference materials (activity 2a) and the provision and/or facilitation of access to this reference material for all laboratories in the network (activity 2b).

The following table presents the total costs of reference material resources by cost item for each case study network.

**Table 61. Annual network costs related to Function 2 - Reference material resources (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Neta) | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Staff costs | 41 803 | 21 357 | 13 416 | 10 414 | 312 358 |
| Equipment | 3 000 | 0 | 0 | 0 | 3 893 |
| Consumables | 10 764 | 7 179 | 17 613 | 50 143 | 52 247 |
| Travel | 0 | 3 589 | 833 | 0 | 0 |
| Shipping | 2 200 | 0 | 0 | 633 | 15 491 |
| Subcontracting/services | 0 | 0 | 7 000 | 0 | 0 |
| Overhead/administration | 2 339 | 988 | 3 000 | 0b) | 21 884 |
| Total | 60 106 | 33 113 | 41 862 | 61 190 | 405 873 |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

The table above illustrates that staff costs and consumables costs represent the two biggest cost items for reference material resources. They range from EUR 10 414 to EUR 312 358 and from EUR 7179 to EUR 52 247 respectively. Equipment costs and travel costs are reported by two case study networks each, while shipping costs are incurred by three networks. All three cost items each make up no more than one tenth of the total costs of reference material resources of a case study network. Subcontracting is only reported by FWD-Net, reflecting the unique coordination structure of this network. FWD-Net is coordinated by ECDC. Since ECDC does not have laboratory capacities, the maintenance and provision of reference material was included in a project which ECDC outsourced in a tendering process to a laboratory member of the FWD-Net.

Scrutinising the activities implemented by case study network shows that all case study networks implement both activities subsumed under reference material resources, i.e. maintaining reference material resources and ensuring the access to these materials for all network members:

- In the EU-RL VTEC network, the coordinator maintains and makes available reference materials to network members and other laboratories upon request.
- In ENIVD, new and unusual strains are collected within the network and made available to network members.
- In FWD-Net, a direct services contract with a laboratory member ensures the maintenance and provision of reference materials to laboratories in the network.
- ERLI-Net provides reference materials every flu season to network members in order to ensure that reference materials used by network members are appropriate to detect the rapidly mutating influenza viruses. The network is sharing this task with the WHO GISRIS network.
- The QUANDHIP network strengthened existing reference material repositories for both viruses and bacteria and established an internal database describing the characteristics of samples. Furthermore, the network designed a material transfer agreement which facilitates the transfer of materials between all network members. The agreement is intended to be used for rapid exchange of materials in future outbreak situations.

Overall, activities implemented in relation to reference material resources appear to be very similar across all case study networks. Only in the QUANDHIP network were additional activities implemented. Nonetheless, the total costs relating to these similar activities vary. The EU-RL VTEC network and ERLI-Net each spend around EUR 60 000 on reference material resources, which suggest a very similar scope of the activities across the two networks. The total costs for ENIVD amount only to about half those for the EU-RL VTEC network, FWD-Net, and ENIVD (i.e. EUR 33 113). One reason for this difference may be the distinct set up of ENIVD. ENIVD network members each have different expertise in terms of the viruses covered by the network. They therefore rely on each other's capabilities in terms of reference diagnostics. It is expected that instead of providing reference material resources through the network, network members directly provide the diagnostic confirmation services to each other. Costs related to reference material resources therefore may be lower. QUANDHIP incurs significantly higher costs related to reference material resources than any other network. Part of these costs may result from the fact that QUANDHIP deals with highly infectious pathogens. Furthermore, the network conducts additional activities which may have cost implications. In addition to the maintenance and provision of reference materials to network members, QUANDHIP also established a database of sample characteristics and developed a materials transfer agreement. Finally, it seems likely

that while building on existing reference materials repositories, the maintenance of two repositories, one for viruses and one for bacteria, is also reflected in the high costs.

Looking at the costs of reference material resources as a share of the overall network costs supports these observations. The following table presents these shares for each case study network.

**Table 62. Costs of reference material resources as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 8% | 4% | 9% | 0.2% | 21% |

*Source: Civic Consulting.*

As the table above illustrates, in all listed case study networks except QUANDHIP, 9% or less of the overall network costs relate to reference material resources. In QUANDHIP, 21% of the costs relate to this function, which reflects the additional activities QUANDHIP conducts in relation to this function. The considerably low share of ERLI-Net in comparison to the EU-RL VTEC network and FWD-Net (which were comparable in absolute costs) may reflect the fact that a large share of the costs related to reference material resources in ERLI-Net is actually covered by the WHO GISRIS network. The low share of ENIVD, as discussed above, is likely to stem from the unique set-up of the network, which is more suited to the conduct of reference diagnostics than to the provision of reference materials through the network.

The costs of case study networks in relation to reference material resources were again used for calculating the annual median costs of this function, as presented in the following table. The underlying activities include the development and maintenance of reference materials as well as their provision to network members.

**Table 63. Annual median costs for reference material resources (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 31 580 | 4.1% |
| Equipment | 1 500 | 0.2% |
| Consumables | 30 453 | 3.9% |
| Travel | | 0.0% |
| Shipping | 1 417 | 0.1% |
| Subcontracting/services | | 0.0% |
| Overhead/administration | 1 664 | 0.2% |
| Total | *66 614* | *8.6%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

The table above illustrates that staff costs and consumable costs are the two biggest cost items, representing an equal proportion of total costs (EUR 31 580 and EUR 30 453). The maintenance and provision of reference material resources is a concrete service of the network to its members. It primarily requires the preparation and provision of consumable material, i.e. the use of staff time and consumable material. Furthermore, it involves the use of equipment and the shipping of the reference materials, which is reflected in the equipment and shipping costs. Finally, as for every function, overhead and administration costs are incurred.[55]

### 5.2.2 Implications of different coordination options for costs of reference material resources

*Physically vs. virtually centralised coordination*

In order to understand the implications of physically and virtually centralised coordination structures on the costs of reference material resources, we take a closer look at the implementation of the activities in the different case study networks. Similarly to reference diagnostics activities, the implementation approaches related to reference material resources in case study networks do not always reflect their overall coordination structure.

For example, the EU-RL VTEC network, a physically centralised network, takes a centralised approach for the implementation of reference material resources. The EU-RL as the pan-European coordinator develops, maintains and distributes reference materials throughout the network. ENIVD on the other hand, the second physically centralised network, is different: as a result of the divided expertise amongst network members (i.e. different network members focus on different pathogens), different types of reference strains are maintained and distributed by different network members. Hence, while ENIVD is physically centralised overall, multiple laboratories share the implementation of reference material resources activities.

[55] A detailed overview of the range of total costs per network for each cost item is provided in Table 61 'Annual network costs related to Function 2 - Reference material resources (in Euro)' (see above).

In ERLI-Net, a virtually centralised network, the provision of reference materials to network members is undertaken centrally by one laboratory, namely the Francis Crick Institute in London. As a result of its continuous typing, subtyping and characterisation of samples provided by network members, the Francis Crick Institute is likely to have the most complete overview of the specific influenza viruses circulating in the EU during a flu season. On this basis the coordinator can provide the appropriate reference materials to network members. In QUANDHIP, the second virtually centralised network, the work package relating to the development of a repository for reference materials is centrally coordinated, namely by RKI. However, the task requires maintaining and enhancing two repositories, one for bacterial and one for viral reference strain. Hence, a certain degree of decentralisation in the activity can be established.

To summarise, the main coordination structure at the pan-European level does not always reflect the structure of the implementation approach of activities related to reference material resources. Virtually centralised networks, e.g. ERLI-Net, can have activities implemented by one coordinating laboratory (i.e. in a physically centralised manner), while physically centralised networks such as ENIVD can share implementation of activities between multiple coordinating laboratories (i.e. in a virtually centralised manner). A further assessment of the implementation approaches of case study networks suggests that the choice of implementation approach is likely to depend on the pathogens covered in a network.

For example, ERLI-Net (virtually centralised) and the EU-RL VTEC network (physically centralised) each cover one disease (influenza and E.coli) and distribute reference materials centrally through one coordinator. ENIVD (physically centralised) and QUANDHIP (virtually centralised) on the other hand cover multiple pathogens and share the distribution of reference materials between multiple coordinators. Therefore, rather than the pan-European coordination structure, it appears that the number of pathogens covered by a network is most relevant in determining whether the maintenance and development of reference materials should be undertaken by one or multiple coordinating laboratories: for each pathogen covered, the implementation of related activities seems to resemble a physically centralised approach. If a network covers multiple pathogens, it is more likely that multiple coordinators get involved.

To conclude, the pan-European coordination structure of a network does not seem to have considerable implications for the implementation of activities related to reference material resources, as this seems to depend on the pathogens covered by a network. Hence, it appears unlikely that the pan-European coordination structure impacts implementation costs considerably. Therefore, differential costs between a physically centralised and a virtually centralised network for reference material resources are not expected.

The following table summarises this result.

**Table 64. Differential costs between a virtually and a physically centralised network for reference material resources**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *None* | No change expected |
| Consumables | *None* | No change expected |
| Travel | *n.a.* | Cost type not relevant for this function |
| Shipping | *None* | No change expected |
| Subcontracting/services | *n.a.* | Cost type not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

*Additional supranational level*

As discussed in previous sections, none of the case study networks has an additional supranational level. In order to assess cost implications of this additional element to the coordination structure, we need to understand how it would change the implementation of the activities related to reference material resources. A closer look at the two activities subsumed under this function reveals that it is unlikely for the supranational level to change the implementation approach significantly.

Activity 2a pertains to the development and maintenance of reference material. In order to ensure the consistent quality and appropriate variety of the reference materials it seems likely that one laboratory conducts this task. The involvement of supranational coordinators would mean that multiple laboratories (i.e. the supranational coordinators) would produce the same types of reference materials but only for a selected cluster of countries. Such an approach could potentially compromise the consistent quality of the reference materials in the network and is likely to lead to a duplication of work. Furthermore, in networks such as ENIVD, where network members each have different expertise, it would be difficult to identify laboratories that would have the capacities to produce all types of reference materials needed for their country cluster. To conclude, a scenario in which the supranational level gets involved in the coordination of Activity 2a is unlikely. Hence, an additional supranational level in the overall coordination structure is unlikely to have any impact on the development and maintenance of reference materials.

Activity 2b relates to the provision of reference materials to network members. Deriving from the centralised pan-European implementation approach of Activity 2a, it seems unlikely that the supranational level would get involved in Activity 2b. It appears reasonable to assume that reference materials are provided to network members by those laboratories that developed and maintained them (i.e. the laboratories conducting activity 2a). A scenario in which supranational coordinators receive reference materials from pan-European coordinators and redistribute the materials to laboratories in their clusters appears unlikely. Such a scenario could compromise the quality of reference materials and would furthermore be a duplication of work. Supranational coordinators could act as an intermediary, communicating to

laboratories in their cluster on how they can request reference materials through the network. The staff time involved in such an intermediary role, however, can be considered to be very minor. Once laboratories in the cluster have understood the process, they would not need to consult supranational coordinators any more. To conclude, the implementation of Activity 2b is unlikely to be materially affected by an additional supranational level.

Overall, we conclude that a supranational level in the overall coordination structure is unlikely to be involved in the implementation of activities subsumed under reference material resources. Therefore, the differential costs between a network with and a network without an additional supranational coordination level are expected to be none to very minor. The following table summarises these results.

**Table 65. Differential costs of a supranational level for reference material resources**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None to very minor* | No significant change expected |
| Equipment | *None* | No change expected |
| Consumables | *None* | No change expected |
| Travel | *n.a* | Not relevant for this function |
| Shipping | *None* | No change expected |
| Subcontracting/services | *n.a.* | Not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None to very minor* | - |

*Source: Civic Consulting.*

## 5.3 Function 3 – Scientific advice to public authorities

### 5.3.1 Costs of scientific advice to public authorities

The total annual cost related to scientific advice to public authorities in case study networks range from EUR 2 370 (ERLI-Net) to EUR 66 980 (QUANDHIP). These costs relate to two types of activities: the provision of scientific advice and recommendations to public health authorities (Activity 3a) and technical support for policy development (Activity 3b). Scientific advice to public authorities is mainly provided to authorities at the EU level.

The following table presents the total costs of scientific advice by cost item for each case study network in the reference year of 2014.

**Table 66. Annual network costs related to Function 3 - Scientific advice to public authorities (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Staff costs | 20 700 | 6 182 | 6 950 | 2 370 | 57 211 |
| Equipment | 1 500 | 0 | 0 | 0 | 0 |
| Consumables | 0 | 0 | 0 | 0 | 0 |
| Travel | 4 191 | 0 | 500 | 0 | 0 |
| Shipping | 0 | 0 | 0 | 0 | 0 |
| Subcontracting/services | 0 | 39 000 | 17 000 | 0 | 5 269 |
| Overhead/administration | 1 918 | 7 218 | 1 000 | 0[b)] | 4 501 |
| Total (in Euro) | *28 309* | *52 400* | *25 450* | *2 370* | *66 980* |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

The table above illustrates that the costs of scientific advice mainly relate to staff costs. Staff costs are the biggest cost item across all case study networks, ranging from EUR 2 370 to EUR 57 211. Consumables and shipping costs, two important cost items for other core functions, are not relevant for scientific advice: none of the case study networks reported costs in relation to these costs items. Travel costs arose from the participation of network coordinators in meetings with EU institutions. Two case study networks incurred these costs. Subcontracting costs were specified by three case study networks. The coordinator of ENIVD subcontracted the work package on scientific advice for EUR 39 000 to another network member. In QUANDHIP, the preparation of a biosafety check list was partially outsourced to a subcontractor. The related costs amounted to EUR 5 269. ECDC, the coordinator of FWD-Net, outsourced scientific advice in a tendered project to a laboratory network member and incurred costs of EUR 17 000.

The costs presented above derived from activities related to provision of scientific advice to public authorities which differed among the case study networks:

- The EU-RL VTEC participated in a number of meetings at EU institutions to provide scientific expertise in different policy processes. Furthermore, it was involved in an EFSA project on PFGE typing data collection at EU level from food, feed and animal isolates.[56]
- ENIVD conducted surveys for ECDC amongst network members, developed fact sheets on a number of issues related to 'imported' viral diseases and ensured round-the-clock availability of experts for ad hoc scientific advice on all viruses covered in the network.
- ERLI-Net provided scientific expertise to EU institutions in particular in relation to influenza antiviral susceptibility monitoring, rapid risk assessments and preparedness planning.
- QUANDHIP provided scientific advice mainly in relation to recommendations for bio-risk management and outbreak response management. The network furthermore supported the European Commission and the Health Security Committee in emergency situations and outbreak response, for example in the recent Ebola crisis.
- In FWD-Net, expert advice related to the quality check of molecular typing data and the interpretation of analysed results.

To summarise, all case study networks provided scientific advice to public authorities, both as short term advice in response to ad hoc public health developments and in terms of expertise for long term policy development. The scope of this advice mainly depended on the needs of EU institutions in the different fields. The costs for the function varied across case study networks and mainly related to staff time. Hence, staff time appeared to be the most important resource for implementing this function.

The shares of activities related to scientific advice in overall network costs appear to be comparable across case study networks. The following table presents these shares.

[56] The project covered three pathogens: Salmonella, Listeria and VTEC. It was conducted in collaboration with EU-RLs for these pathogens.

**Table 67. Costs of scientific advice to public authorities as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 4% | 7% | 5% | 0.2% | 4% |

*Source: Civic Consulting.*

The EU-RL VTEC network, FWD-Net and QUANDHIP each incurred 4% to 6% of their overall network costs from scientific advice. The EU-RL VTEC network and QUANDHIP planned for longer projects related to scientific advice in their respective work programmes, the former on data collection and the latter on bio-risk and outbreak response management. Scientific advice in FWD-Net mainly related to the interpretation of data and analysis of results, which was particularly important considering that the network's main coordinator is an EU institution (i.e. ECDC) not a laboratory.

In ERLI-Net costs related to scientific advice amounted only to 0.2% of the network's overall costs. As described above, ERLI-Net contributed predominantly to the monitoring and surveillance tasks of ECDC. Projects similar to those conducted by QUANDHIP and the EU-RL VTEC network were not envisaged. In ENIVD, on the other hand, a total of 7% of the overall costs incurred related to scientific advice. These slightly higher costs (compared to the EU-RL VTEC network, FWD-Net and QUANDHIP) might result from the focus of the network. It is the only network that established a work package on scientific advice and did not subsume this task under other activities. ENIVD maintains round-the-clock availability of expert advice as a major task of its work programme; costs in this regard can potentially become significant.

Annual median costs of scientific advice were calculated across the case study networks for the reference year, as a measure of the costs incurred for this function. The following table summarises this. Activities underlying these costs would include both longer term projects for policy development and ad-hoc scientific advice to EU institutions.

The largest cost item is staff costs (EUR 13 441), followed by subcontracting/services (EUR 2 634) and by overhead/administration (EUR 3 209). All other cost items (i.e. equipment, consumables, travel, and shipping) are not relevant for providing scientific advice.

**Table 68. Annual median costs for scientific advice to public authorities (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| *Staff costs* | 13 441 | 1.7% |
| *Equipment* | 0 | 0.0% |
| *Consumables* | 0 | 0.0% |
| *Travel* | 0 | 0.0% |
| *Shipping* | 0 | 0.0% |
| *Subcontracting/services* | 2 634 | 0.3% |
| *Overhead/administration* | 3 209 | 0.4% |
| *Total* | *19 285* | *2.5%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

The cost implications of the coordination structure for these activities are discussed in the following.[57]

### 5.3.2 Implications of different coordination options for costs of scientific advice

*Physically vs. virtually centralised coordination*

To assess the differential costs of scientific advice between a virtually centralised and a physically centralised network we assess the implementation of related activities in case study networks. This assessment provides the following picture.

In the EU-RL VTEC network, a physically centralised network, the coordinator of the network (i.e. the EU-RL) is fully responsible for conducting all activities related to scientific advice. EU-RL staff members participated in the reference period in meetings to provide expertise to EU institutions and contributed to the EFSA project on PFGE typing data collection at EU level. Hence, the activities are implemented in a centralised manner. In ENIVD, also a physically centralised network, scientific advice is conducted under work package 3. This work package concerns the establishment of an 'Outbreak Assisting and Response Working Group' which is appointed to work collaboratively in providing scientific advice in particular to ECDC. Through this working group, multiple coordinators share the implementation of activities related to scientific advice. Hence, the network implements scientific advice in a virtually centralised manner.

QUANDHIP, a virtually centralised network, provided scientific advice also in a rather virtually centralised manner. Depending on whether viral or bacterial expertise was requested, different coordinators responded. Furthermore, projects such as the development of bio-risk management and outbreak response management were implemented collaboratively by network members. For ERLI-Net, also a virtually centralised network, scientific advice is not a major network task. However,

[57] A detailed overview of the range of total costs per network for each cost item is provided in Table 66 'Annual network costs related to Function 3 – Scientific advice to public authorities (in Euro)' (see above).

coordinators of the network contribute according to their expertise. For example, PHE provided input on rapid risk assessments and preparedness planning, while RIVM mainly responded to issues on influenza antiviral susceptibility monitoring. On the one hand, the advice provided by ERLI-Net can be characterised as virtually centralised since multiple coordinators are involved. On the other hand, coordinators seem to have differentiated fields of expertise. If a request falls within their expertise, they respond to this request in a physically centralised manner i.e. individually.

To conclude, only in the EU-RL VTEC network can scientific advice be considered to be implemented in a physically centralised manner. ENIVD, QUANDHIP and ERLI-Net all take virtually centralised approaches. However, these approaches are not uniform. They differ in their degree of involvement of different network members and the collaboration between the laboratories involved.

For example, in ERLI-Net, a network which provides scientific advice on specific issues, different network coordinators are involved depending on the field of expertise required. The response to request from EU institutions appears to be provided mainly on an individual basis. In QUANDHIP and ENIVD on the other hand, the approach appears much more collaborative. Multiple network members are involved and collaborate with each other, for example in ENIVD's 'Outbreak Assisting and Response Working Group'. In both networks scientific advice appear to also be a particular focus in terms of long term projects. QUNADHIP's project on outbreak management for example was envisaged as part of the work programme, as opposed to being conducted in response to a short-term particular request.

This suggests that the approach to providing scientific advice depends on the type of activity rather than on the overall coordination structure of a network. Hence, assuming that a physically centralised and a virtually centralised network were requested to implement the same activity, both networks are likely to take a similar approach in terms of the number of network members involved and the degree of collaboration between these network members. The amount of staff time involved is expected to be comparable. Considering, furthermore, that staff costs are the main cost item when providing scientific advice it is likely that differential costs between a physically centralised and a virtually centralised network would be very minor, if any.

The following table summarises this result.

**Table 69. Differential costs between a virtually and a physically centralised network for scientific advice to public authorities**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None to very minor* | No significant change expected |
| Equipment | *n.a.* | Cost type not relevant for this function |
| Consumables | *n.a.* | Cost type not relevant for this function |
| Travel | *None* | No change expected |
| Shipping | *n.a.* | Cost type not relevant for this function |
| Subcontracting/services | *n.a.* | Cost type not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None to very minor* | - |

*Source: Civic Consulting.*

*Additional supranational level*

To assess differential costs of an additional supranational level in a coordination structure, we discuss in the following how the implementation of scientific advice would change in case study networks.

In the EU-RL VTEC network, the EU-RL as the contract holder is the first contact point for the European Commission to request scientific advice. Due to its legal status it seems unlikely that another network member than the EU-RL would respond to these requests or participate in meetings with EU institutions. Therefore, if they play any role at all, supranational coordinators are therefore more likely to support the EU-RL in its tasks. However, owing to a potential duplication of work and an increase in costs, it seems unlikely that a supranational coordinator would e.g. join the meetings with EU institutions. Hence, the role of supranational coordinators is likely to be limited to providing input on request for scientific advice to the EU-RL. The EU-RL would then have to consolidate this input before it provides its response to EU institutions. Such an approach is likely to lead to an increase in staff time spent by supranational coordinators to provide scientific advice and by the EU-RL to coordinate it.

ENIVD already takes a very collaborative approach to the implementation of scientific advice by establishing the 'Outbreak Assisting and Response Working Group'. If supranational coordinators were added to the network coordination structure, it seems likely that these coordinators would automatically become members of the working group. In order to keep the working group at a manageable size however, it does not appear likely that the number of working group members would increase. Supranational coordinators would instead substitute selected working group members. Therefore, the overall approach to the conduct of scientific advice is unlikely to change.

Also for ERLI-Net and QUANDHIP, a change in the implementation approach of scientific advice appears unlikely. Coordinators at the pan-European level are usually the first point of contact for EU institutions. If these coordinators can respond to the request, it seems unlikely that additional expertise form the supranational level is

needed. If coordinators cannot respond to the request they may seek assistance. However, it is likely that the assistance will be provided by a network member with the respective expertise. This network member can be a supranational coordinator but it does not have to be one.

In conclusion, it seems very likely that coordinators at the pan-European level will remain the focal point for scientific advice in the case study networks. While pan-European coordinators could potentially reach out for support in the network if needed, it seems unlikely that supranational coordinators would provide this support based on their role as sub-level coordinators. It is more likely that support is provided on the basis of expertise.

To summarise, across all case study networks it seems rather unlikely that the supranational level gets involved as such in the coordination of scientific advice. The current implementation approaches seem to be adaptable to the requirements of the tasks. A specific role for supranational coordinators could not be identified. Therefore, we conclude that an additional supranational level would not change the current implementation approach to scientific advice in case study networks. Consequently, differential costs of an additional supranational level are unlikely to arise.

The following table summarises these results.

**Table 70. Differential costs of a supranational level for scientific advice to public authorities**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *n.a* | Not relevant for this function |
| Consumables | *n.a* | Not relevant for this function |
| Travel | *None* | No change expected |
| Shipping | *n.a* | Not relevant for this function |
| Subcontracting/services | *n.a.* | Not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

## 5.4 Function 4 – External quality assessments

Function 4 - *external quality assessments* (EQAs) consist only of one activity. The costs of this function and respective cost implications of different coordination structures are discussed in the following subsections.

### 5.4.1 Costs of external quality assessments

EQAs are conducted in all case study networks. The total annual costs related to EQAs range from EUR 103 649 (FWD-Net) to EUR 569 754 (QUANDHIP). These costs cover

only one activity (Activity 4a): the organisation, conduct and analysis of network wide proficiency tests (i.e. inter-laboratory comparison studies).

The following table presents total annual costs of EQAs for case study networks by cost item.

**Table 71. Annual network costs related to Function 4 - External quality assessments (EQAs) (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Neta) | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Staff costs | 158 119 | 86 455 | 38 536 | 91 490 | 384 669 |
| Equipment | 9 000 | 0 | 0 | 0 | 7 787 |
| Consumables | 57 137 | 57 716 | 18 320 | 39 030 | 108 929 |
| Travel | 0 | 0 | 333 | 0 | 0 |
| Shipping | 8 800 | 0 | 459 | 12 500 | 21 300 |
| Subcontracting/services | 0 | 0 | 44 000 | 2 245 | 12 294 |
| Overhead/administration | 12 704 | 5925 | 2 000 | 0b) | 34 775 |
| Total | 245 760 | 150 096 | 103 649 | 145 265 | 569 754 |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

The table above illustrates that except for travel costs, which are only reported by one network, all cost items are relevant for conducting network wide EQAs. Staff costs and consumable costs are the two biggest cost items, ranging from EUR 38 536 to EUR 384 669 and from EUR 18 320 to EUR 108 929, respectively. Furthermore, the shipping of samples is a considerable cost factor. Four out of five case study networks reported shipping costs. Three networks reporting outsourcing of selected tasks of the EQA implementation through sub-contracting. Equipment costs were specified by two networks. Overhead costs differed across case studies. Overall, the table above illustrates that total costs of EQAs vary across case study networks. Whether these differences relate to the scope of implementation of EQAs will be assessed in the following.

Case study networks implemented EQAs as follows:

- The EU-RL VTEC network conducted three EQAs in the reference period (one year in this case).
- ENIVD conducted two EQAs in one year.
- ERLI-Net conducts EQAs on a biannual basis since the WHO GISRIS network is the main provider of EQAs to ERLI-Net members. Costs presented in the table above are annualised, i.e. the costs of ERLI-Net represent the costs of 50% of an EQA.
- QUANDHIP conducted six EQAs during its duration (3.5 years), three bacterial and three viral EQAs. Hence, annual costs presented in the table above cover 1.7 EQAs.
- The costs of FWD-Net stem from two EQAs covered by the network.

To an extent the difference in the number of EQAs conducted seems to correlate with cost differences across case study networks, although other factors are also relevant.

For example, the costs for three EQAs in the EU-RL VTEC network amount to approximately half of the costs of 1.7 EQAs of QUANDHIP. One factor that explains these cost differences may be the pathogens covered in a network. For example, part of the costs of EQAs conducted in the QUANDHIP network may stem from the safety requirements of BSL-3 and BSL-4 pathogens. Furthermore, the complexity of an EQA can increase costs considerably. According to the QUANDHIP coordinator, the EQA panels were prepared with a high degree of complexity, which was costly in its development and is costly in the analyses. Hence, the cost difference between QUANDHIP and the EU-RL VTEC network may relate more to the pathogens covered than to the number of EQAs conducted. ERLI-Net coordinators confirmed this conclusion in stating that the biannual EQAs conducted by ERLI-Net have a high complexity and are therefore quite costly for the network.

To conclude, total costs of EQAs vary considerably across case study networks. Looking at the scope of the EQAs conducted suggests that cost differences relate to a number of factors, including the pathogens covered, the complexity of an EQA and the number of samples distributed.

Looking at the share of costs for EQAs of the overall network costs illustrates that in relative terms costs across case study networks seem to be comparable. The following table presents these shares.

### Table 72. Costs of EQAs as share of overall network costs

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 34% | 19% | 21% | 14% | 30% |

*Source: Civic Consulting.*

With 34% of its overall network costs relating to EQAs, the EU-RL VTEC network represents the upper bound of the sample. In QUANDHIP 30% of the overall costs stem from EQAs. For ENIVD and FWD-Net, these costs amount to around 20%. The comparably small share realised by ERLI-Net (i.e. 14%) may result from ERLI-Net's overlap with the WHO GISRIS network. ERLI-Net members participate in GISRIS EQAs on an annual basis. This provides ERLI-Net with the discretion to allocate a larger share of resources to other core functions.

The annual median costs of EQAs were calculated for the reference year, as a measure of the costs incurred for this function. These are presented in the following table.

### Table 73. Annual median costs for EQAs (in Euro)

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 122 832 | 15.7% |
| Equipment | 3 893 | 0.5% |
| Consumables | 48 083 | 6.2% |
| Travel | - | 0.0% |
| Shipping | 10 650 | 1.4% |
| Subcontracting/services | 1 123 | 0.1% |
| Overhead/administration | 5 710 | 0.7% |
| Total | *192 291* | *24.6%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

The median costs reflect the main cost components of the EQA function. Staff costs needed for the development, distribution and the analysis are the biggest cost item (EUR 122 832), followed by consumables (EUR 48 083). With costs of around EUR 10 650, shipping costs are also of significant relevance. All other cost items are of a comparatively minor size. As discussed above, travel is not relevant for implementing EQAs.[58]

[58] A detailed overview of the range of total costs per network for each cost item is provided in Table 71 'Annual network costs related to Function 4 – External quality assessments (in Euro)' (see above).

### 5.4.2 Implications of different coordination options for costs of external quality assessments

*Physically vs. virtually centralised coordination*

Table 71 shows that costs for the implementation of EQAs differ widely across case study networks. As discussed above, to an extent these differences relate to the pathogens and the scope of the EQAs implemented by case study networks. Whether the coordination structure of networks at the pan-European level also has implications on these costs appears, however, questionable. Comparing the annual median costs for EQAs (see Table 73) with those of case study network costs for this function (see Table 71), reveals that total costs of both physically and of virtually centralised case study networks can either be higher or lower than the median costs. To further assess whether the pan-European coordination structure has implications for the costs of EQAs, we discuss how EQAs are implemented across case study networks.

All case study networks, regardless of their coordination structure at the pan-European level, appear to follow a similar, physically centralised approach for the implementation of EQAs. One laboratory coordinates the development and distribution of EQA samples and analyses the results sent by participating laboratories: In the EU-RL VTEC network, the EU-RL centrally coordinates the preparation and distribution of EQA panels (i.e. sets of samples) and analyses the results submitted by network members. In ENIVD, RKI takes the lead in the quality assessment work package and conducts the EQAs of the network. While RKI may ask for the support of other laboratories, for example in terms of reference strains, they keep the overall coordination in-house. For ERLI-Net, PHE is the main coordinator of EQAs. It is supported by the other two coordinators. For example, the Francis Crick Institute contributes to implementing EQAs by advising on the panel composition and validating the panel for PHE, while RIVM is involved in the design and analysis of the EQA. Overall, however, PHE conducts the main tasks. In QUANDHIP the coordination of EQAs is shared between two laboratories: one laboratory coordinates the viral EQA, while the other laboratory coordinates the bacterial EQA. Hence, while the coordination of the function is shared, the implementation of individual EQAs is done by only one laboratory.

To summarise, besides the support in some issues, such as decisions regarding the panel composition or the validation of samples, case study networks appear to conduct EQAs in a physically centralised manner, i.e. one laboratory takes the lead in organising EQAs, regardless of the coordination structure at the pan-European level. We therefore conclude that the pan-European coordination structure of a network does not influence the implementation approach of EQAs. Consequently, this suggests that for EQAs, differential costs between a physically centralised and a virtually centralised network are likely to be very minor, if any.

The following table summarises these results.

**Table 74. Differential costs between a virtually and a physically centralised network for EQAs**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None to very minor* | No significant change expected |
| Equipment | *None* | No change expected |
| Consumables | *None* | No change expected |
| Travel | *n.a.* | Cost type not relevant for this function |
| Shipping | *None* | No change expected |
| Subcontracting/services | *None* | No change expected |
| Overhead/administration | *None* | No change expected |
| Total | *None to very minor* | - |

*Source: Civic Consulting.*

*Additional supranational level*

In order to assess the cost implications of an additional supranational coordination level we analyse how this change in the coordination structure could potentially impact the implementation of EQAs.

As discussed in Section 3.1, laboratories acting as coordinators at the supranational level would take the lead in implementing activities, but only for a cluster of laboratory members. Considering, however, that EQAs are conducted network-wide it seems unlikely that a supranational coordination level would be involved in the organisation and implementation of this function.

The first task for an EQA coordinator is to prepare the EQA panels. In order to ensure that the quality and characteristics of each sample are the same, this task has to be conducted centrally. The subsequent distribution of samples to participating laboratories is then likely to be organised by the same coordinator who prepared the samples. If the coordinator sent the samples to supranational coordinators who then distributed these samples to their members in their clusters, this could increase the time needed, reduce the quality of samples and duplicate work. Therefore, it does not seem efficient to involve the supranational coordinators as an intermediary in the distribution of samples. Finally, the collection and analysis of results from participating laboratories is likely to be conducted in a centralised approach level as well. The purpose of a network wide EQA is, inter alia, to assess and compare the capabilities of network members. Such an assessment needs to be coordinated centrally, i.e. at the pan-European.

If a supranational coordination level exists in a network, it is likely that supranational coordinators receive the results for their cluster from the main EQA coordinator. Supranational coordinators could then further analyse results and detect specific gaps and patterns of laboratories in their cluster. Such an activity would only involve staff time. Compared to the staff time used by the main coordinator to organise the EQA and by network members to participate, differential costs related to staff time are likely to be very minor.

Overall, we therefore conclude that as a result of the very limited involvement of supranational coordinators in the conduct of EQAs the differential costs between a network with and a network without a supranational level are minor, if any. The following table summarises these results.

**Table 75. Differential costs of a supranational level for EQAs**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None to minor* | A supranational coordinator may analyse the results of EQAs in further detail for its cluster. Compared to the overall staff time required for implementing EQAs, differential costs are likely to be minor. |
| Equipment | *n.a* | Not relevant for this function |
| Consumables | *None* | No change expected |
| Travel | *n.a* | Not relevant for this function |
| Shipping | *None* | No change expected |
| Subcontracting/services | *None* | No change expected |
| Overhead/administration | *None* | No change expected |
| Total | *None to minor* | Considering that the differential costs only relate to a limited additional task (the analysis of results by supranational coordinators for their cluster), it seems reasonable that differential costs are minor, if this task is conducted by supranational coordinators at all. |

*Source: Civic Consulting.*

## 5.5 Function 5 – Training

### 5.5.1 Costs of training

In case study networks, the total costs for training range from EUR 24 634 (FWD-Net) to EUR 246 116 (QUANDHIP) per year. Two types of activities are covered by these costs. The first activity (5a) relates to all types of training measures for laboratories in the network such as network-wide workshops, training courses for a selected number of experts, or twinning arrangements. The second activity (5b) focuses on ad hoc scientific advice for laboratory network members. The following table presents the total costs for training for each case study network by cost item.

### Table 76. Annual network costs related to Function 5 - Training (in Euro)

| Cost item | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| **Staff costs** | 90 428 | 49 782 | 1 832 | 60 131 | 175 714 |
| **Equipment** | 5 250 | 0 | 0 | 0 | 1 947 |
| **Consumables** | 11 935 | 17 000 | 0 | 7 391 | 26 392 |
| **Travel** | 23 311 | 26 523 | 0 | 34 338 | 26 387 |
| **Shipping** | 0 | 0 | 662 | 2 533 | 0 |
| **Subcontracting / services** | 0 | 0 | 22 140 | 64 041 | 0 |
| **Overhead / administration** | 5 755 | 9 985 | 0 | 0[b)] | 15 677 |
| **Total** | *136 678* | *103 290* | *24 634* | *168 433* | *246 116* |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

As the table above illustrates, the biggest cost item for training activities across all case study networks is staff costs, ranging from EUR 1 832 to EUR 175 714. Other relevant costs relate to consumables and travel costs. The amount of costs differs from case study network to case study network. For example, for ENIVD consumables amount to EUR 17 000, while travel costs amount to EUR 26 523. In ERLI-Net, the network incurs EUR 7 391 for consumables and EUR 34 338 for travel. For the QUANDHIP network consumables and travel costs are almost of the same size, amounting to around EUR 26 390. In FWD-Net neither travel nor consumable costs have been reported. Overall, equipment costs, shipping costs, and subcontracting/services costs are less relevant. These cost items are each reported only by two case study networks each. Overhead/administration costs vary from case study network to case study network.

To further analyse the costs of training across case study networks, the scope of the activities implemented by each network has to be scrutinised. All case study networks conduct both types of training activities subsumed under function 5, i.e. laboratory training and scientific advice to member laboratories. However, the scope of the activities entailed the costs described above differs across case study networks:

- The EU-RL VTEC network conducted two training programmes in the one-year reference period – a one-week laboratory training course and a two-day training course specifically on molecular typing – which were each attended by 10 trainees. Scientific advice was provided to laboratory network members mainly on analytical issues.
- ENIVD conducted short training courses on topics selected according to the needs of the network. For example, in the reference period, a workshop on Ebola diagnostics was conducted for institutions without access to BSL-4 or BSL-3 facilities. ENIVD members provided scientific advice to each other according to their needs and expertise.
- Training within ERLI-Net included activities such as: training courses, twinning arrangements, web-laboratory courses/webinars, and written guidance/training documentation.
- QUANDHIP conducted 12 training courses in its 3.5-year project duration, hosted by different network members. Furthermore, one workshop on training and handling of BSL-4 containments was conducted.
- FWD-Net conducted an annual workshop in the reference period, which covered Salmonella-related issues, inter alia. Furthermore, expert advice for laboratories was provided as part of a tendered project.

All case study networks held an annual workshop or network meeting, which at least in parts was directed towards the exchange of best practices or similar training sessions.

To conclude, all case study networks conduct training activities which were adapted to the needs of network members. The amount and the type of training differed from case study network to case study network. Overall, it therefore seems difficult to compare the scope of the training between different case study networks. However, it seems likely that the scope of the activities conducted at least to some extent relates to the costs incurred. The low costs of FWD-Net, for example, seem to result from the fact that the network limits its training to expert advice. Besides the sessions on Salmonella in the annual workshop, no other training courses were conducted. All

other case study networks, however, conducted training courses in one way or another.

Looking at the training costs of cases study networks in terms of shares of overall network costs illustrates that in relative terms training costs of case study networks seem to be comparable. The following table presents these shares.

**Table 77. Costs of training as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| **19%** | 13% | 5% | 17% | 13% |

*Source: Civic Consulting.*

At 18%, 17%, 13% and 13% respectively, the proportion of costs attributable to training for the EU-RL VTEC, ERLI-Net, ENIVD and QUANDHIP are very similar. In FWD-Net, 5% of the costs relate to training. As discussed above this low share reflects the fact that FWD-Net did not conduct any training courses on Salmonella in the reference period. We nonetheless conclude that training costs and the scope of training activities are comparable across case study networks.

Annual median costs were calculated using the reported case study costs for the reference year, as a measure of the costs incurred for this function. The cost item with the largest share of the median costs is staff costs (EUR 71 664), followed by travel costs (EUR 24 381) and consumables cost (EUR 14 134). Equipment costs only amount to EUR 973 while overhead and administration costs still add up to EUR 7 336. Shipping and subcontracting are not relevant for the median costs of training in the reference year.

The following table summarises this.[59]

[59] A detailed overview of the range of total costs per network for each cost item is provided in Table 76 'Annual network costs related to Function 5 – Training (in Euro)' (see above).

**Table 78. Annual median costs for training (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 71 664 | 9.2% |
| Equipment | 973 | 0.1% |
| Consumables | 14 134 | 1.8% |
| Travel | 24 917 | 3.2% |
| Shipping | 0 | 0.0% |
| Subcontracting/services | 0 | 0.0% |
| Overhead/administration | 7 336 | 1.0% |
| Total | *119 024* | *15.2%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

### 5.5.2 Implications of different coordination options for costs of training

*Physically vs. virtually centralised coordination*

To scrutinise the implications of the pan-European coordination structure for the costs of training, we take a closer look at the implementation of training activities in case study networks. Comparing the share of median training costs in total network costs (

Table ***78***) with those of case study networks (Table 76) shows that the share of case study network costs both for virtually centralised and physically centralised networks can be either higher or lower than median costs. Hence, a relationship between the pan-European coordination structure and a network's training costs cannot be established. An assessment of training activities of the case study networks furthermore illustrates that the approach to implementing the activities may follow the overall network coordination structure, but is not necessarily bound by it.

ENIVD, a physically centralised network, relies on the expertise of its network members for the implementation of training activities. While the annual workshop is centrally organised by the ENIVD coordinator, other training activities, in particular provision of scientific advice to network members, are provided by different network members based on their expertise in the handling of certain pathogens. Hence, this physically centralised network takes a virtually centralised approach to training. The EU-RL VTEC network, which is also physically centralised, also follows this network coordination structure for the implementation of training activities. The EU-RL centrally organises the different training courses and provides scientific advice to network members.

In ERLI-Net, a virtually centralised network, training activities are coordinated by its different coordinators. RIVM for example provided webinars, written guidance and training documentation on antiviral susceptibility monitoring, while the Francis Crick Institute provided in-house training for staff from network members. PHE furthermore coordinated several training courses and twinning arrangements for ERLI-Net. Hence, the network followed a virtually centralised implementation approach for training activities. In QUANDHIP, similarly to ERLI-Net, different network members hosted a variety of training courses. Again, a virtually centralised case study network uses a virtually centralised implementation approach for training.

To conclude, except for the EU-RL VTEC network, training appears to be implemented in a virtually centralised manner across case study networks. Different coordinators are involved according to their expertise. Looking at individual activities provides, however, the impression of a physically centralised implementation approach. An individual training activity is implemented only by one coordinator. From this perspective, the virtually centralised and the physically centralised case study networks are similar in their implementation of training activities. Individual activities are implemented by individual coordinators. It therefore seems likely that the total costs of training activities will be of a similar size in a virtually centralised and in a physically centralised network. It can be argued that if individual training activities are conducted by different coordinators, a certain amount of staff time will be required to ensure that the overall training approach is coherent and no duplication of work arises. However, as case study networks have shown, such coordination may be required in both physically centralised and in a virtually centralised network.

To conclude, differences in training costs can arise if additional coordination efforts are needed to ensure a coherent training approach in a network where multiple coordinators each implement activities individually. However, these cost differences are less likely to be linked to the overall coordination structure of a network but more likely linked to the allocation of expertise amongst network members. Different network members are more likely to be involved in the coordination of training activities if their difference in expertise requires them to do so. For example in ENIVD (a physically centralised network) multiple laboratories are involved in training activities, since network members each focus on different pathogens. Overall, it is therefore expected that differential costs between a virtually and a physically

centralised network for training are very minor, if any, assuming that all else remains constant. The following table summarises these results.

**Table 79. Differential costs between a virtually and a physically centralised network for training**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | None to very minor | No significant change expected |
| Equipment | None to very minor | No significant change expected |
| Consumables | None to very minor | No significant change expected |
| Travel | None to very minor | No significant change expected |
| Shipping | n.a. | Cost type not relevant for this function |
| Subcontracting/services | n.a. | Cost type not relevant for this function |
| Overhead/administration | None to very minor | No significant change expected |
| Total | None to very minor | - |

*Source: Civic Consulting.*

*Additional supranational level*

For the assessment of differential costs between networks with and without a supranational level, we need to understand how the additional coordination level would be involved in the coordination of training activities. For this purpose the various training activities have to be differentiated.

For training related to Activity 5a (training courses, twinning arrangements etc.) the involvement of the additional supranational level is likely to depend on the type of activity conducted. For example, the organisation of a network-wide workshop seems likely to be conducted at the pan-European level, as it requires centralised coordination. Supranational coordinators could provide their input to the workshop agenda. Considering, however, that the topics of the network wide workshops in most case study networks are already developed collaboratively, it seems unlikely that an additional supranational level would change the implementation approach for a network-wide workshop. Hence, the costs of the conduct of a network wide workshop are expected to remain the same.

In training courses for only a selected group of laboratories, e.g. the ENIVD workshop for Ebola diagnostics for institutions without access to BSL-4 or BSL-3 facilities, it seems more likely that supranational coordinators become involved. Instead of the coordination from the pan-European level, supranational coordinators could organise the training courses. However, they would only do so if the topic of the training course would only pertain to laboratories in their cluster. If a training course was targeted to a selected group of laboratories which were however not members of the same cluster it seems likely that the training course would be coordinated from the pan-European level. Overall, considering that the involvement of the supranational level (if at all) would only shift the responsibility to a different laboratory the costs of the implementation should remain constant.

Similarly, supranational coordinators could become involved in the coordination of twinning arrangements within their cluster. Again, it seems, however, unlikely that this would change the costs of implementation. Which laboratory deploys the support expert should not have any cost implication for the conduct of the activity.[60]

For scientific advice to member laboratories in relation to activity 5b, the supranational level furthermore could potentially be involved as follows: Network members could request scientific advice first from their supranational coordinators. If the supranational coordinator receives a request it cannot respond to, the request has to be passed on to a laboratory that has the expertise to respond to the request. Depending on the expertise of supranational coordinators, this scenario may lead to a duplication of work and hence of costs. In practice, it seems unlikely that such an approach would be used. Scientific advice to laboratories in case study networks seems to be organised in a less hierarchical approach. For example in ENIVD and QUANDHIP, network members provide scientific advice to each other on the basis of their expertise. Rather than approaching a laboratory with a coordinating role, members seek advice from laboratories with appropriate expertise. In ENIVD, such an approach is even institutionalised by maintaining a directory of network members and their expertise.

To conclude, supranational coordinators could potentially become involved in training activities pertaining to the laboratories in their cluster. Such an involvement, however, mainly entails the reallocation of responsibilities to a different laboratory. The amount of resources used to implement the activity implemented is likely to remain constant. Therefore, differential costs between a network with and one without a supranational level seem in most cases unlikely. Only in relation to the provision of scientific advice could minor differential costs arise, if a supranational level coordinator received a request it could not answer. The involvement of an additional coordinator to respond to the request may lead to the duplication of work and hence of costs. These costs most likely would relate only to staff time. However, as discussed above, such a scenario in practice seems to be rather unlikely. Therefore, overall, we expect that differential costs related to training arising from an additional supranational level in a network to be very minor. The following table summarises these results.

**Table 80. Differential costs of a supranational level for training**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *Very minor* | If a supranational coordinator cannot provide the scientific advice requested by a laboratory in its cluster, it would have to request assistance from another laboratory in the network. As a result of the duplication of work, additional staff costs may arise. |
| Equipment | *None* | No change expected |
| Consumables | *None* | No change expected |
| Travel | *None* | No change expected |
| Shipping | *n.a.* | Not relevant for this function |
| Subcontracting/services | *n.a.* | Not relevant for this function |

[60] As described in Section 3.5, cost differences arising from different labour costs due to the location of the support experts are not considered.

| | | |
|---|---|---|
| Overhead/administration | *None* | No change expected |
| Total | *None to very minor* | Considering that scientific advice is in practice most likely to be requested from laboratories with appropriate capabilities, considerable differential costs are unlikely. |

*Source: Civic Consulting.*

## 5.6 Function 6 – Collaboration and research

### 5.6.1 Costs of collaboration and research

Excluding ENIVD, which did not conduct activities and did not report any costs for this function, the total costs of case study networks relating to collaboration and research range from EUR 16 102 (FWD-Net) to EUR 80 064 (QUANDHIP). These costs relate to two activities: the participation of the case study network in other regional/international public health microbiology laboratory networks (activity 6a) and the participation in other regionally or internationally relevant projects and initiatives, including research and development activities (activity 6b). The following table presents the total costs by cost item for each case study network.

**Table 81. Annual network costs related to Function 6 - Collaboration and research (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Staff costs | 32 166 | 0 | 12 722 | 15 429 | 57 211 |
| Equipment | 5 000 | 0 | 0 | 0 | 973 |
| Consumables | 19 102 | 0 | 3 293 | 50 667 | 13 062 |
| Travel | 5 850 | 0 | 0 | 0 | 3 705 |
| Shipping | 0 | 0 | 87 | 0 | 0 |
| Subcontracting/services | 0 | 0 | 0 | 0 | 0 |
| Overhead/administration | 3 054 | 0 | 0 | 0[b)] | 5 113 |
| Total | *65 172* | *0* | *16 102* | *66 096* | *80 064* |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

As the table above illustrates, the two most important cost items for collaboration and research were staff costs and costs of consumables. Both cost items were reported by all case study networks conducting the function and ranged from EUR 12 722 to EUR 57 211 and from EUR 3 293 to EUR 50 667, respectively. Two of the four case study networks that reported costs for collaboration and research indicated also having incurred equipment, overhead and travel costs. One case study network furthermore reported minor shipping costs. Subcontracting/service costs were not reported by any of the case study networks.

When assessing the costs of activities related to collaboration and research in case study networks it is important to note that only the EU-RL VTEC network and QUANDHIP had planned for these activities in their budget. For FWD-Net and ERLI-Net the costs reported in the table above only relate to additional costs covered by laboratory network members.

The total costs for collaboration and research incurred by the EU-RL VTEC network, ERLI-Net and QUANDHIP seem to be comparable. They amounted to approximately EUR 65 000 to 80 000. For the EU-RL VTEC network, costs were incurred mainly as a result of the network coordinator's participation in the EFSA research project on molecular typing of STEC from food and animals. Network members did not appear to be involved in collaboration and research projects on behalf of the EU-RL VTEC network and therefore hardly report related costs.

In ERLI-Net, on the contrary, it was the network members who mainly reported costs in relation to collaboration and research on behalf of the network. For example, ERLI-Net members formed several Virology Task groups which supported ECDC in various issues related to influenza. Furthermore, some network members conducted a considerable amount of activities related to the analysis of TESSy data.

Similarly to ERLI-Net, QUANDHIP also formed working groups to e.g. for the development of the network's proposals for support in the coordination of laboratory activities in the case of an outbreak response. Furthermore, QUANDHIP established close collaborations with other networks including ENIVD, EQuATox (Establishment of Quality Assurances for the Detection of Biological Toxins of Potential Bioterrorism Risk), and EMLab (European Mobile Laboratory Project).

In FWD-Net, costs reported in relation to collaboration and research also related mainly to network members. These costs were however considerably lower than those of the EU-RL VTEC network, ERLI-Net and QUANDHIP. Network members indicated having participated in projects such as an FWD molecular surveillance pilot project, a study to EUCAST (European Committee on Antimicrobial Susceptibility Testing) or a Salmonella Enteritidis Interlaboratory Validation Study.

ENIVD network members did not report having participated in research and collaboration activities on behalf of the network. Hence, no costs were reported.

To conclude, except for ENIVD, all case study networks participated in different activities related to collaboration and research. The scope of collaboration and research activities appears to vary. Overall, while case study networks considered the function important for furthering the knowledge in their field they did not consider it to be a main objective of their networks. This is supported by the shares of collaboration and research costs in overall network costs, as the following table presents.

**Table 82. Costs of collaboration and research as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 9% | 0% | 3% | 7% | 4% |

*Source: Civic Consulting.*

As the table above illustrates, less than 10% of the overall network costs of case study networks relates to collaboration and research.

Annual median costs for collaboration and research were calculated using the reported case study network costs for the reference year as a measure of the costs incurred for this function,, and are presented in the following table.

**Table 83. Annual median costs for collaboration and research (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 32 166 | 4.1% |
| Equipment | 973 | 0.1% |
| Consumables | 18 663 | 2.4% |
| Travel | 3 298 | 0.4% |
| Shipping | 0 | 0.0% |
| Subcontracting/services | 0 | 0.0% |
| Overhead/administration | 2 604 | 0.4% |
| Total | *57 705* | *7.4%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

For the median costs presented in the table above, staff costs and consumable costs again are the most important cost items, amounting to EUR 32 166 and EUR 18 663 respectively. All other cost items are of a considerable smaller size or not relevant at all. Activities underlying these costs are likely to relate to both research projects and collaboration with other networks.[61]

### 5.6.2 Implications of different coordination options for costs of collaboration and research

This section assesses the implications of different coordination options for costs of collaboration and research. It considers a physically centralised versus a virtually

[61] A detailed overview of the range of total costs per network for each cost item is provided in Table 81 'Annual network costs related to Function 6 – Collaboration and research (in Euro)' (see above).

centralised network coordination and examines the addition of a supranational level to the coordination structure.

*Physically vs. virtually centralised coordination*

As already discussed in Section 3.2, collaboration and research is not the main focus of case study networks. While four of the five case study networks reported costs in relation to collaboration and research (see Table 81), only two of them, namely the EU-RL VTEC network and QUANDHIP, covered related costs at least partly with their network budget. In the other two case study networks (ERLI-Net and FWD-Net), network members had to offset related costs. Covering collaboration and research costs through the network budget does not seem to be a question of the overall coordination structure of case study networks. Both a physically and a virtually centralised case study network did not cover the costs of collaboration and research by their network budget. Amongst the case study networks that did cover at least parts of these costs through the network budget, one network was physically and one was virtually centralised. Therefore, it seems difficult to link the overall coordination structure to the costs of collaboration and research.

Assessing the activities related to collaboration and research of those case study networks that did not allocate any specific budget, i.e. ERLI-Net and FWD-Net, reveals that there was no specific coordination at the pan-European level. From the evidence collected it appears that network members participated in collaboration and research activities in an individual capacity, i.e. participated in projects related to the network but were not necessarily formally appointed by the network to do so. For example, members of FWD-Net participated in an FWD molecular surveillance pilot project from ECDC on a voluntary basis. As a result of the absence of network coordination, costs related to different overall coordination structures are unlikely to arise.

In the EU-RL VTEC network and in QUANDHIP the network budget at least partly covered the costs of activities in relation to collaboration and research. Costs reported by the EU-RL VTEC network (a physically centralised network) were incurred mainly from the pilot project on molecular typing of STEC from food and animals. EFSA requested the involvement of the EU-RL VTEC on the basis of its (legal) status as a coordinator of the EU-RL VTEC network. Network-wide coordination of the activity was not reported. Besides this project other activities related to collaboration and research were not reported. Therefore, costs related to the conduct of the project rather than the coordination structure of the network.

In QUANDHIP (a virtually centralised network) costs reported on collaboration and research related to the participation of network members in working groups that were established by the network. These working groups dealt for example with antimicrobial susceptibility testing (AST group), with mass spectroscopy as an upcoming tool for rapid identification of bacteria (MALDI-TOF group), and testing of rapid hand-held test kits focusing on lateral flow assays (HHTK group). Working groups were set up on both bacterial and viral topics, indicating a virtually centralised coordination structure for these activities.

To summarise, four out of five case study networks reported costs on collaboration and research. Scrutinising the implementation approach of related activities revealed that network wide coordination of collaboration and research is formally implemented only in one case study network (i.e. QUANDHIP), in a virtually centralised manner. In all other case study networks, the implementation of activities related to collaboration and research appeared to be rather spontaneous e.g. by network members voluntarily participating in a project (e.g. the FWD-Net pilot project) or by network members

being requested to participate (e.g. the EU-RL VTEC). Therefore, we conclude that the overall coordination structure of a network at the pan-European level is unlikely to have implications for the implementation approach of activities related to collaboration and research. Hence, differential costs between a physically and a virtually centralised network are not expected.

The following table summarises these results.

**Table 84. Differential costs between a virtually and a physically centralised network for collaboration and research**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *None* | No change expected |
| Consumables | *None* | No change expected |
| Travel | *None* | No change expected |
| Shipping | *n.a.* | Cost type not relevant for this function |
| Subcontracting/services | *n.a.* | Cost type not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

*Additional supranational level*

An additional supranational level in the coordination structure of case study networks is unlikely to affect the implementation of activities in relation to collaboration and research.

As discussed above, collaboration and research, while important, is not the main focus of the case study networks. Costs for the related activities were reported by four out of five case studies. Network coordination of activities responsible for these costs appeared absent in all but one case study network. Instead of a structured approach to coordination, activities appeared to be implemented spontaneously. For example, network members participated in relevant collaboration and research projects on a voluntary basis, without being appointed by the network. The absence of an overall coordination approach also suggests that the addition of a supranational level is unlikely to imply the need for structured coordination of collaboration and research activities.

Furthermore, interviewees indirectly indicated that a structured approach is not necessarily desirable. As several interviewees stated, collaboration and research developed in the case study networks often on the basis of similar interest and repeated personal contact. It could be encouraged by external public health developments or incentives provided by funding entities. However, they emphasised that cooperation tended to occur spontaneously. Therefore, structured coordination, whether with or without a supranational coordination level, does not appear to be a critical to ensuring the participation of network members, at least in those projects mentioned as examples by interviewees.

To summarise, collaboration and research is not the main focus of case study networks. Related activities tend to occur spontaneously without requiring a structured overall coordination approach. The absence of a coordination approach suggests that a supranational level is unlikely to be involved in the coordination of activities. Hence, differential costs arising from this supranational level in relation to cooperation and research are not expected.

The following table summarises these results.

**Table 85. Differential costs of a supranational level for collaboration and research**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *None* | No change expected |
| Consumables | *None* | No change expected |
| Travel | *None* | No change expected |
| Shipping | *n.a* | Not relevant for this function |
| Subcontracting/services | *n.a.* | Not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

## 5.7 Function 7 - Monitoring, alert and response

### 5.7.1 Costs of monitoring, alert and response

Excluding the EU-RL VTEC network that did not report any costs, the total costs of case study networks related to monitoring, alert and response ranged from EUR 28 682 (ERLI-Net) to EUR 89 246 (QUANDHIP). The specific activities relate to either supporting Member States in providing data to EU bodies conducting surveillance tasks or other appropriate bodies (activity 7a) and providing technical support in outbreak investigation (activity 7b). However, as data on costs of the case study EU-RL networks covered in this study was collected for specific reference years in which outbreaks/emergencies did not occur, the cost data related to the provision of surge capacity (activity 7c) was not collected.

The following table presents the case study costs of monitoring, alert and response in further detail.

**Table 86. Annual network costs related to Function 7 - Monitoring, alert and response (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Staff costs | 0 | 13 028 | 11 359 | 27 415 | 62 734 |
| Equipment | 0 | 0 | 0 | 0 | 973 |
| Consumables | 0 | 2 393 | 17 587 | 0 | 17 128 |
| Travel | 0 | 0 | 0 | 0 | 3 298 |
| Shipping | 0 | 0 | 0 | 1 267 | 0 |
| Subcontracting/services | 0 | 39 000 | 0 | 0 | 0 |
| Overhead/administration | 0 | 6 230 | 0 | 0[b)] | 5 113 |
| Total | *0* | *60 651* | *28 946* | *28 682* | *89 246* |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

As the table above illustrates, the EU-RL VTEC network has not reported any costs in relation to monitoring, alert and response since the network does not conduct this function. Amongst most of the other case study networks, staff costs are the biggest cost item, ranging from EUR 11 359 to EUR 62 734. Only in ENIVD do subcontracting costs (at EUR 39 000) exceed staff costs. Costs related to consumables were reported by three of the four case study networks reporting costs for monitoring, alert and response. Furthermore, shipping costs, equipment costs and travel costs were each reported by one case study network. For the analysis of these costs related to monitoring, alert and response across case study networks, scrutinising the type and the scope of the activities implemented is of particular importance. As described in the following, activities differ widely across case study networks.

- The EU-RL VTEC network did not conduct any activities related to monitoring, alert and response. The network coordinator emphasised that this function would fall under the responsibilities of national reference laboratories and was not a core function of the EU-RL VTEC network. Only on one occasion has the network provided technical support in an outbreak situation. The EU-RL, as the coordinator of the EU-RL VTEC network, supported German reference laboratories in relation to the STEC outbreak in Germany in 2011. However, in the reference period the EU-RL VTEC network did not provide any such support and therefore did not report any costs.
- ENIVD focused especially on laboratory preparedness and outbreak support as its main activity relating to monitoring, alert and response. Two work packages established dedicated working groups and included in the reference period activities such as:
    - The establishment of a checklist for situation assessment and for laboratory preparedness;
    - An inventory of laboratory capacity for Ebola virus diagnostics among ENIVD laboratories and an outbreak support directory of experts in the network;
    - Deployment of ENIVD experts for outbreak assistance; and
    - Laboratory confirmation testing through ENIVD members in outbreak situations.

  The ENIVD coordinator subcontracted parts of these activities to other network members and therefore reported subcontracting costs.
- In FWD-Net costs related to monitoring, alert and response were reported only by network members; specific activities in relation to this function were not planned for in the budget of FWD-Net. ECDC as the network coordinator has procedures in place to send experts to the field in case of requests for immediate support. However, such activities were not reported for the reference period. Costs reported by network members related to activities such as providing support to each other in terms of reference diagnostics, in particular on whole genome sequencing of pathogens.
- ERLI-Net costs of monitoring, alert and response were almost equally covered by the network budget and by network members. Activities conducted in the reference period related in particular to contributing to the harmonisation of data reporting standards within working groups and to providing technical support and advice in outbreak situations, as well as to the conduct of additional PCRs and to provision of data and specimens.
- QUANDHIP established a working group to develop proposals for the coordination of laboratory activities in case of outbreak response. The working group developed standard operational procedures for the coordination of laboratory activities during

outbreaks as well as an inventory of diagnostic capabilities and logistic resources and procedures of all QUANDHIP laboratories. Moreover, the working group prepared a toolkit for local laboratories involved in outbreak response.

To conclude, barring the EU-RL VTEC network, all case study networks conducted activities related to monitoring, alert and response. While ERLI-Net and FWD-Net focused on the provision of technical support, in the form of additional PCRs and whole genome sequencing respectively, QUANDHIP and ENIVD also conducted activities in relation to the preparedness of the network for outbreak situations. For example, both networks developed and maintained an inventory of laboratory capacities and capabilities of network members and prepared operational procedures and guidelines for outbreak situations. These two different scopes of activities conducted in case study networks appear to explain at least partly the differences in the costs. While ERLI-Net and FWD-Net, the two networks with a smaller scope, reported costs of around EUR 29 000 each, QUANDHIP and ENIVD, the two networks with more extensive activities, reported costs of around EUR 60 000 and 90 000 respectively.
Looking at the case study network costs in relative terms provides the following picture: With 8% of its overall network costs, compared to other case study networks ENIVD spends most on activities relating to monitoring, alert and response. It is followed by FWD-Net (6%), QUANDHIP (5%) and ERLI-Net (3%) (as discussed above, the EU-RL VTEC network did not conduct any activities relating to monitoring, alert and response in the reference period).

The following table summarises these results.

**Table 87. Costs of monitoring, alert and response as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 0% | 8% | 6% | 3% | 5% |

*Source: Civic Consulting*

Annual median costs for activities related to monitoring, alert and response were calculated using the reported case study network data for the reference year, as a measure of the costs incurred for this function. The following table presents these median costs.

**Table 88. Annual median costs for monitoring, alert and response (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 27 415 | 3.6% |
| Equipment | 0 | 0.0% |
| Consumables | 2 393 | 0.3% |
| Travel | 0 | 0.0% |
| Shipping | 0 | 0.0% |
| Subcontracting/services | 0 | 0.0% |
| Overhead/administration | 5 113 | 0.7% |
| Total | *34 921* | *4.5%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

The biggest share of the median costs related to monitoring, alert and response is represented by staff costs, amounting to EUR 27 415. Consumable costs amount to EUR 2 393. Except for overhead, all other cost items are irrelevant for the conduct of activities related to monitoring, alert and response.[62]

### 5.7.2 Implications of different coordination options for costs of monitoring, alert and response

*Physically vs. virtually centralised coordination*

When reviewing the cost data regarding monitoring, alert and response presented in Table 86 there does not appear to be a clear relationship between the type of coordination structure and the costs for this function. The costs of physically centralised networks (i.e. EU-RL VTEC and ENIVD) as well as of virtually centralised networks (i.e. ERLI-Net and QUANDHIP) vary considerably within their category. For example, the reported costs of QUANDHIP are three times greater than those for ERLI-Net. Both networks are virtually centralised. The total for ENIVD, a physically centralised network, roughly marks the middle point between the costs of QUANDHIP and ERLI-Net. Hence, a relationship between the costs for monitoring, alert and response and a network's coordination structure is difficult to establish. To further assess this observation we take a closer look at the implementation of related activities.

Activities conducted in case study networks in relation to monitoring, alert and response can be broadly clustered into two categories. On the one hand these activities relate to technical support e.g. concerning reference diagnostic methods. On the other hand, some case study networks conduct activities in relation to the preparedness of the network e.g. the development of a directory of capabilities of network members. Technical support activities appear to be conducted in a physically centralised manner across case study networks, regardless of the overall coordination

[62] A detailed overview of the range of total costs per network for each cost item is provided in Table 86 'Annual network costs related to Function 7 – Monitoring, alert and response (in Euro)' (see above).

structure. For example, one network member provides e.g. additional PCRs (see ERLI-Net) for a number of samples. For this specific task the network member is unlikely to involve another network member.

In contrast, activities related to the preparedness of the network appear to be implemented in a collaborative manner, regardless of the overall coordination structure of the case study networks. Those case study networks conducting activities in relation to the preparedness of the network perform these tasks within working groups, in one way or another. Via dedicated working groups ERLI-Net contributes to the harmonisation of reporting standards. ENIVD established the 'Outbreak Assisting and Response Working Group' to provide for round-the-clock scientific advice and support, including in outbreak situations. QUANDHIP also established a working group, the tasks of which included the development proposals for the coordination of laboratory activities in case of outbreak response.

To summarise, activities conducted in case study networks in relation to monitoring, alert and response are not necessarily aligned in their implementation approach with the overall coordination structure of the network. It appears that the type of activity is more likely to determine the implementation approach. All case study networks conduct some activities related to monitoring, alert and response on an individual basis (i.e. physically centralised) and some case study networks conducted activities in working groups (i.e. virtually centralised). Hence, a relationship between the overall coordination structure of a network and the implementation of activities related to monitoring, alert and response cannot be established. Therefore, implications of the overall coordination structure of a network for the costs of monitoring, alert and response are not expected. The following table summarises these results.

**Table 89. Differential costs between a virtually and a physically centralised network for monitoring, alert and response**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *n.a.* | Cost type not relevant for this function |
| Consumables | *None* | No change expected |
| Travel | *n.a.* | Cost type not relevant for this function |
| Shipping | *n.a.* | Cost type not relevant for this function |
| Subcontracting/services | *n.a.* | Cost type not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

*Additional supranational level*

The case study networks assessed do not feature a supranational coordination structure. To assess implications of this additional tier, in the following we discuss

potential changes in the implementation of activities related to monitoring, alert and response.

As discussed in the previous section, activities implemented by case study networks in relation to monitoring, alert and response can be grouped into two broad clusters: those related to technical support and those related to the preparedness of the network. The discussion above showed that the former are likely to be implemented in a physically centralised manner (i.e. by individual network members). The latter appear to be implemented in a virtually centralised manner (i.e. in dedicated working groups).

The addition of a supranational level is unlikely to affect the implementation approach of activities related to technical support. Within ERLI-Net, some network members provided additional PCRs, for example. They appear to provide this service on the basis of their individual capacities, not on the basis of their specific role in the network. Furthermore, relevant network members are likely to conduct such activities on an individual basis in their own laboratories. Therefore, overall, a supranational coordinator is not expected to get involved in these individual activities.

As for activities related to the preparedness of networks, the criteria for the selection of working group members can differ in case study networks. It is expected that supranational coordinators would participate in these working groups. However, it is rather unlikely that this would change the overall implementation approach of the activities and hence the costs.

To summarise, an additional supranational level in the overall coordination of a network is unlikely to change the implementation approach of activities related to monitoring, alert and response. Activities related to technical support are likely to be conducted by individual network members without the involvement of the supranational tier. In activities related to network preparedness, the supranational level may get involved through the participation of supranational coordinators in the working groups. However, since it is expected that the size of the working group would remain constant, the implementation approach overall would not change. Since the implementation approach of activities related to monitoring, alert and response are unlikely to change if a supranational level is added to the coordination structure of a network, differential costs arising from this additional level are not expected. The following table summarises these results.

**Table 90. Differential costs of a supranational level for monitoring, alert and response**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *None* | No change expected |
| Equipment | *n.a.* | Cost type not relevant for this function |
| Consumables | *None* | No change expected |
| Travel | *n.a.* | Cost type not relevant for this function |
| Shipping | *n.a.* | Cost type not relevant for this function |
| Subcontracting/services | *n.a.* | Not relevant for this function |
| Overhead/administration | *None* | No change expected |
| Total | *None* | - |

*Source: Civic Consulting.*

## 5.8 Function 8 - Governance

### 5.8.1 Costs of governance

The total costs of case study networks related to governance range from EUR 42 764 (FWD-Net) to EUR 288 317 (ERLI-Net) and comprise costs of both funding entities and network coordinators for this purpose. Governance activities relate to the administration and coordination of the network (activity 8a) and the provision of IT-tools, if any (activity 8b).

The following table presents the governance costs of case study networks by cost items.

**Table 91. Annual network costs related to Function 8 - Governance (in Euro)**

| Cost item | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Staff costs | 101 764 | 78 463 | 42 764 | 282 437 | 122 079 |
| Equipment | 1 250 | 0 | 0 | 0 | 0 |
| Consumables | 0 | 0 | 0 | 0 | 0 |
| Travel | 9 200 | 33 170 | 0 | 5 880 | 34 362 |
| Shipping | 0 | 0 | 0 | 0 | 0 |
| Subcontracting/services | 0 | 0 | 0 | 0 | 0 |
| Overhead/administration | 4 009 | 10 904 | 0 | 0[b)] | 10 352 |
| Total | *116 223* | *122 537* | *42 764* | *288 317* | *166 793* |

*Source: Civic Consulting, based on information provided by funding entities, network coordinators and network members for the reference period. ERLTB-Net is excluded from the table as no data were provided regarding the distribution of the operating expenditure by function. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. Due to its specific structure FWD-Net is not considered in the calculation of median costs for this function (see below). b) Costs of overhead/administration for ERLI-Net are included in the specified cost items.*

As the table above presents, the two largest cost items for governance costs are staff costs and consumable costs. Costs related to staff range from EUR 42 764 to EUR 282 437, while consumables costs range from EUR 2 400 to EUR 34 362. The third cost item relevant for governance costs is overhead/administration. Costs in this regard range from EUR 4 190 to EUR 10 904. (Minor) equipment costs were reported by the EU-RL VTEC only. All other cost items do not seem to be relevant as none of the case study networks reported any related costs.

Overall, the governance costs presented above vary across case study networks. Nonetheless, the nature of the related activities appears broadly similar. All lead coordinators of case study networks carry out the financial and organisational administration of the network. This includes tasks such as administering funds, managing the contract with funding entities, reporting on the progress of activities, etc. Furthermore, coordinators generally maintain a network website. In addition to the costs of network coordinators, funding entities also incur costs for (mainly administrative) activities related to the case study networks.
In more detail, governance arrangements and related cost factors in the case study networks are as follows:

- The EU-RL as the lead coordinator of the EU-RL VTEC network conducts all administrative activities for the network and maintains a public website with a restricted access area for network members. Its main governance costs relate to staff time. DG SANTE as the funding entity of the EU-RL VTEC network incurs costs related to the management of the contract, which includes tasks such as the negotiation of the annual work programme, administration of funds, etc.
- In ENIVD, RKI as the network coordinator and contract holder with ECDC conducts all tasks related to governance. RKI is the work package leader of work package 1, the network management. Beyond the usual governance-related activities, including financial and organisational administration of the network and the maintenance of a network website, RKI carries out two additional tasks: the organisation of steering committee meetings and the maintenance of a directory of members and expertise including an electronic mailing list. ECDC conducts all administrative activities related to its role as funding entity.
- In FWD-Net, the financial and organisational administration of the network is conducted by ECDC, which in this case is both the network coordinator and the funding entity. Therefore, besides the facilitation of the tendering process for outsourced activities, costs presented in Table 91 above also relate to tasks such as the definition of a work programme and the administrative support for specific projects subject to tender procedures.
- In ERLI-Net, PHE as the lead coordinator and contract holder carries out the overall financial and organisational administration of the network, including the disbursement of funds to co-coordinators. Co-coordinators are furthermore responsible for conducting similar tasks, but for their work packages alone. ECDC's involvement as the funding entity appears more pronounced in the ERLI-Net coordination than in the coordination of other networks. It includes the maintenance of a website, but also analysing and publishing of data produced by ERLI-Net and coordinating of ERLI-Net's collaboration with the WHO GISRIS network. Considering that ERLI-Net deals with influenza, a pathogen of great variability that requires constant monitoring by the EU, ECDC conducts related tasks on a weekly basis. Therefore, costs incurred by ECDC in relation to the network coordination of ERLI-Net are considerably higher than in other networks. While in other case study networks the costs of the funding entity relating to governance make up less than

5% of the overall network costs, in ERLI-Net the costs of the funding entity amount to 24%.63

- In the QUANDHIP network, financial and organisational administration was mainly carried out by RKI, the main coordinator and contract holder. RKI was supported by its co-coordinator INMI, who coordinated the network activities related to viruses. CHAFEA carried out relevant administrative tasks related to its role as funding entity for QUANDHIP.

To summarise, the EU-RL VTEC network, ENIVD and QUANDHIP are very similar in the way activities related to governance are implemented. In ERLI-Net, ECDC as the funding entity takes on a larger role in the overall coordination of the network. FWD-Net is a special case in terms of governance, since ECDC is both the network coordinator and the funding entity.

Looking at the share of governance costs in overall network costs provides the following picture. Governance costs in the EU-RL VTEC network and ENIVD amount to very similar shares of overall network costs (i.e. 17% and 16%, respectively). FWD-Net and QUANDHIP both incurred 9% of their overall costs from governance activities. For the reasons discussed, in ERLI-Net governance costs made up a comparatively large share of overall network costs, at 29%.

The following table summarises these results.

**Table 92. Costs of governance as share of overall network costs**

| EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|
| 17% | 16% | 9% | 29% | 9% |

*Source: Civic Consulting.*

The annual median costs for governance activities were calculated using reported case study costs for the reference year, as a measure of the costs incurred for this function. They are presented in the following table. Activities underlying these costs relate to the main tasks of network coordination, including financial and organisational administration and the maintenance of the website as well as the administrative tasks of the funding entity.

[63] At the second expert workshop held within the framework of this study, it was noted that the total governance costs of coordinating ERLI-Net may be underestimated as some of the meeting costs are borne separately from the consortium service contract by the funding entity (ECDC meeting budget) when the meeting is organised within a wider influenza EU/EEA country representative network meeting, such the EISN meeting.

**Table 93. Annual median costs for governance (in Euro)**

| Cost item | Median costs | Share in total network costs |
|---|---|---|
| Staff costs | 90 113 | 11.5% |
| Equipment | 0 | 0.0% |
| Consumables | 0 | 0.0% |
| Travel | 21 185 | 2.8% |
| Shipping | 0 | 0.0% |
| Subcontracting/services | 0 | 0.0% |
| Overhead/administration | 7 180 | 0.9% |
| Total | *118 479* | *15.2%* |

*Source: Civic Consulting. Note: For each cost item, median costs are calculated as the sum of the median costs reported by the coordinator(s), funding entity and network members across case study networks, excluding FWD-Net and ERLTB-Net.*

The table above illustrates that for activities related to the governance of the network only three types of costs are relevant when considering median costs: staff costs, travel costs and overhead/administration costs. At EUR 90 113, staff costs are the biggest cost item followed by travel costs at EUR 21 185.[64]

### 5.8.2 Implications of different coordination options for costs of governance

*Physically vs. virtually centralised coordination*

As shown in the previous section, the activities conducted in relation to the governance of a network appear to be very similar across all case study networks. They include in particular the financial and organisational administration of the network and the maintenance of a network website. Table 91 above presents the costs of case study networks related to these activities and furthermore indicates the overall coordination structure of case study networks.

It appears that the EU-RL VTEC network and ENIVD, the two physically centralised networks, have very similar governance costs of EUR 110 000 to 120 000. Furthermore, at 17% and 16% respectively, the share of governance costs in overall network costs are comparable. QUANDHIP and ERLI-Net, the two virtually centralised networks, on the other hand reported considerably higher costs in relation to governance (i.e. EUR 166 793 and EUR 288 317, respectively). This observation could suggest that the coordination structure at the pan-European level may to some extent have implications for the costs related to network governance.

Looking at the implementation approach of activities related to governance, however, puts this assertion into question. All case study networks appear to mainly conduct the same activities related to the financial and organisational administration of the network and the maintenance of a network website. Most of these activities are conducted by the lead coordinator of the network, and in ERLI-Net partly also by the

[64] A detailed overview of the range of total costs per network for each cost item is provided in Table 91 'Annual network costs related to Function 8 – Governance (in Euro)' (see above).

funding entity. This suggests that the implementation approach is very similar across all case study networks. Hence, the cost differences between the physically centralised and the virtually centralised networks cannot necessarily be explained by the implementation approach of governance activities.

Further scrutinizing the costs of the virtually centralised case study networks (QUANDHIP and ERLI-Net) supports this conclusion as it reveals other reasons for the comparatively higher governance costs of these two networks. As discussed above, for ERLI-Net, ECDC conducts a considerable amount of tasks on a weekly basis (data analysis, coordination with GISRIS, etc.) which is very different from the role of the funding entities in other networks. As a result, 24% of the overall network costs incur as governance costs to ECDC while only 5% of the overall network costs incur as governance costs to PHE. This suggests that governance cost of ERLI-Net rather result from the specific involvement of ECDC than from the implementation of ERLI-Net as a virtually centralised network. QUANDHIP also has considerable governance costs. In relative terms (i.e. as share of overall network costs, see Table 92 above), however, the governance costs of QUANDHIP (a virtually centralised network) are comparable to the costs of physically centralised case study networks. This suggests that governance costs increase with the increase of overall costs rather than as a result of a virtually centralised coordination structure.

A closer look at the financial and organisational administration of a network suggests nonetheless, that the number of coordinators may have implications for the costs of governance. The overall administration of funds and the reporting on their use to the funding entity is likely to be coordinated centrally by one coordinator even in a virtually centralised network. Interviewees of virtually centralised case study networks nonetheless confirmed that co-coordinators would need to administer their parts of the funds and report on the use of these funds to the lead coordinator. In a virtually centralised network, the lead coordinator thereby has a dual role: it has to administer and report on its own funds and has to disburse funds to co-coordinators as well as collect their input for the overall reporting to the funding entity. Hence, compared to a physically centralised network with one coordinator, the financial and organisational administration required in a virtually centralised network is likely to be more significant in terms of the inputs, and hence in terms of cost.

Assessing the cost items relevant for governance costs suggests that in a virtually centralised network in particular staff costs for governance could be higher than in a physically centralised network. Staff costs increase as a result of the additional time used by co-coordinators to administer their funds and to report on related activities as well as the additional coordination efforts the lead coordinator has to undertake in order to disburse funds and consolidate the reporting. Travel cost could increase with the number of coordinators i.e. in a virtually centralised network. This however depends on the approach to collaboration of network coordinators and whether they conduct meetings in person or as phone conferences. Overhead/administration costs could increase assuming that all coordinators will request overhead. To summarise, differential costs between a virtually centralised and a physically centralised network are expected to be of minor to significant, depending on the implementation details.

The following table summarises these results.

**Table 94. Differential costs between a virtually and a physically centralised network for governance**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *Minor to significant* | Minor to significant increase from a physically centralised to a virtually centralised network expected as a result of additional staff time used by co-coordinators in a virtually centralised network for financial and organisational administration of their network activities. |
| Equipment | *n.a.* | Cost type not relevant for this function |
| Consumables | *n.a.* | Cost type not relevant for this function |
| Travel | *Minor* | Minor increase from a physically centralised to a virtually centralised network expected if physical meetings of network coordinators are conducted. |
| Shipping | *n.a.* | Cost type not relevant for this function |
| Subcontracting/services | *n.a.* | Cost type not relevant for this function |
| Overhead/administration | *Minor* | Minor changes from a physically centralised to a virtually centralised network expected due to multiple coordinators receiving overhead. |
| Total | *Minor to significant* | - |

*Source: Civic Consulting.*

*Additional supranational level*

None of the case study networks currently has a coordination structure which includes a supranational coordination level. Therefore, during our interviews we have discussed how the governance of a network would change if a supranational coordination level were to be introduced in case study networks, and have assessed related costs differences on this basis.

As discussed above, the activities conducted across all case study networks in relation to governance include primarily the financial and organisational administration of the network and the maintenance of a network website. The latter activity is likely to be conducted at the pan-European level. Supranational coordinators would only conduct activities pertaining to their laboratory cluster. The maintenance of a website is likely to be conducted by a central coordinator who may receive input from network members for the content of the website but maintains the website on its own. Hence, regardless of the coordination structure, the implementation approach and related cost will remain the same.

The approach to the financial and organisational administration of the network, however, is likely to change with an additional supranational level. As mentioned for the virtually centralised network in the previous section, additional coordinators in a

network potentially lead to an increase in governance costs. As interviewees mentioned, laboratories that will be appointed to become a supranational coordinator are likely to request funding for a (part-time) staff post conducting the tasks related to this role. Furthermore, they could also request overhead cost, depending on the administrative arrangements. Hence, the appointment of additional supranational coordinators in a network is likely to increase the costs related to network governance. Whether this pertains also to travel costs will depend on the amount of meetings conducted face-to-face.

To conclude, the addition of a supranational coordination level is likely to cause additional costs related to the network governance. Differential costs between a network with and a network without a supranational coordination level are likely to be minor to significant, depending on the implementation details.

The following table summarises these results.

**Table 95. Differential costs of a supranational level for governance**

| Cost item | Differential costs | Comments |
|---|---|---|
| Staff costs | *Minor to significant* | Minor to significant change form a network with to a network without a supranational coordination level is expected, as a result of some basic task in relation to the financial and organisational administration of the network, which will are expected to be conducted by every coordinator individually. |
| Equipment | *n.a* | Not relevant for this function |
| Consumables | *n.a* | Not relevant for this function |
| Travel | *Minor* | Minor changes are expected form a network with to a network without a supranational coordination level if coordinators conduct physical meetings. |
| Shipping | *n.a* | Not relevant for this function |
| Subcontracting/services | *n.a.* | Not relevant for this function |
| Overhead/administration | *Minor* | Minor change form a network without to a network with a supranational coordination level is expected, if each coordinator requests overhead funds. |
| Total | *Minor to significant* | - |

*Source: Civic Consulting.*

## 5.9 Summary of costs differences of case study networks

In this section we provide an overview of the total annual costs reported by the case study networks by function as well as an overview of the key characteristics of case study networks (the pathogens covered, the coordination structure, etc.). We then describe potential factors that may explain differences in costs across case study networks ('cost factors'), from the perspective of both the functions (summarising the previous sub-section) as well as of key characteristics of the case study networks.

### 5.9.1 Overview of costs of functions by case study network and potential cost factors

The table below provides an overview of total annual costs of functions by case study network

### Table 96. Overview of total annual costs of functions of case study networks

| Characteristic | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP | ERLTB-Net[b)] |
|---|---|---|---|---|---|---|
| 1. Reference diagnostics | 61 595 | 248 012 | 209 068 | 242 374 | 288 092 | n.a. |
| 2. Reference material resources | 60 106 | 33 113 | 41 862 | 61 190 | 405 873 | n.a. |
| 3. Scientific advice to public authorities | 28 309 | 52 400 | 25 450 | 2 370 | 66 980 | n.a. |
| 4. External Quality Assessments (EQA) | 245 760 | 150 096 | 103 649 | 145 265 | 569 754 | n.a. |
| 5. Training | 136 678 | 103 290 | 24 634 | 168 433 | 246 116 | n.a. |
| 6. Collaboration and research | 65 172 | 0 | 16 102 | 66 096 | 80 064 | n.a. |
| 7. Monitoring, alert and response | 0 | 60 651 | 28 946 | 28 682 | 89 246 | n.a. |
| 8. Governance of the network | 116 223 | 122 537 | 42 764 | 288 317 | 166 793 | n.a. |
| *Total annual costs* | *713 843* | *770 099* | *492 475* | *1 002 726* | *1 912 920* | *486 591* |

*Sources: Civic Consulting. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. b) No data were provided regarding the distribution of the ERLTB-Net operating expenditure by function, thus a breakdown cannot be shown for this case study. Furthermore, the additional costs reported by network members (which make up part of the total costs) should be interpreted with care, as the figures are based on an extrapolation of survey data provided by 2 of the 33 network members only.*

For reference diagnostics, differences in costs appear to result from the varying scope of the activities implemented. For example, FWD-Net, ENIVD and QUANDHIP undertake diagnostic confirmation testing in addition to the provision of updated standard operating procedures. The amount of diagnostic confirmation testing conducted differs, however. In ERLI-Net the continuous characterisation, typing and sub-typing of pathogens is an important task of the network. In contrast, the work plan of the EU-RL VTEC network does not include diagnostic confirmation or the continuous characterisation of samples.

A potential factor affecting costs of reference material resources is the set-up of the network. For example, ENIVD network members each have different expertise in terms of the viruses covered by the network. They therefore rely on each other's capabilities in terms of reference diagnostics. It is expected that instead of providing reference material resources through the network, network members directly provide the diagnostic confirmation services to each other. Costs related to reference material resources therefore may be lower. Other factors may be pathogenicity, the extent to which additional activities are conducted, and the need for special repositories. For example, QUANDHIP in particular deals with highly infectious pathogens. Furthermore, the network conducts additional activities which may have cost implications: in addition to the maintenance and provision of reference materials to network members, QUANDHIP also established a database of sample characteristics and developed a materials transfer agreement. Finally, it seems likely that while building on existing reference materials repositories, the maintenance of two repositories, one for viruses and one for bacteria, is also reflected in the costs.

Differences in costs of activities relating to scientific advice to public authorities may relate to the scope of the advice provided, which itself depends on the needs of EU institutions in the different fields. For example, ENIVD has a separate work package on scientific advice, and maintains round-the-clock availability of expert advice as a major task of its work programme. Moreover, QUANDHIP provided scientific advice mainly in relation to recommendations for bio-risk management and outbreak response management. The network furthermore supported the European Commission and the Health Security Committee in emergency situations and outbreak response, for example in the recent Ebola crisis. In contrast, ERLI-Net provided scientific expertise to EU institutions in particular in relation to influenza antiviral susceptibility monitoring, rapid risk assessments and preparedness planning.

To an extent the differences in costs external quality assessments (EQAs) may depend on the number of EQAs conducted. As shown, the EU-RL VTEC network conducted three EQAs in one year. ENIVD conducted two EQAs in one year. QUANDHIP conducted six EQAs during its duration (3.5 years), three bacterial and three viral EQAs, amounting to 1.7 EQAs per year. However, other factors may be relevant, such as the pathogens covered in the network and the complexity of an EQA. For example, part of the costs of EQAs conducted in the QUANDHIP network may stem from the safety requirements of BSL-3 and BSL-4 pathogens. According to the QUANDHIP coordinator, the EQA panels were prepared with a high degree of complexity, which was costly in its development and is costly in the analyses. ERLI-Net coordinators confirmed this conclusion in stating that the biannual EQAs conducted by ERLI-Net have a high complexity and are therefore quite costly for the network.

While it is difficult to compare the scope of the training between different case study networks, it seems likely that the scope of the activities conducted at least to some extent relates to the costs incurred. For example, the EU-RL VTEC network conducted two training programmes in the one-year reference period. ENIVD conducted short training courses on topics selected according to the needs of the network. QUANDHIP

conducted 12 training courses in its 3.5-year project duration, hosted by different network members. In contrast, FWD-Net limits its training to mainly expert advice for laboratories.

Differences in costs of collaboration and research activities appear to relate to the scope of the activities. For example, for the EU-RL VTEC network, costs were incurred mainly as a result of the network coordinator's participation in the EFSA research project on molecular typing of STEC from food and animals. ERLI-Net members formed several Virology Task groups which supported ECDC in various issues related to influenza. On the other hand, ENIVD network members did not report having participated in research and collaboration activities on behalf of the network.
Similarly, type and scope of activities relating to monitoring, alert and response appears to be a factor in explaining cost differences. For example, ERLI-Net and FWD-Net focused on the provision of technical support, in the form of additional PCRs and whole genome sequencing respectively. QUANDHIP and ENIVD also conducted activities in relation to the preparedness of the network for outbreak situations. However, the EU-RL VTEC network did not conduct any activities related to monitoring, alert and response.

Finally, across case study networks, the EU-RL VTEC network, ENIVD and QUANDHIP are very similar in the way activities related to governance are implemented. Cost differences appear to relate to the level of involvement of the funding entity in the coordination of the network. ECDC's involvement as the funding entity appears more pronounced in the ERLI-Net coordination than in the coordination of other networks. It includes the maintenance of a website, but also analysing and publishing of data produced by ERLI-Net and coordinating of ERLI-Net's collaboration with the WHO GISRIS network. Another factor may be the specific set-up of the network; for example, in FWD-Net, the financial and organisational administration of the network is conducted by ECDC, which in this case is both the network coordinator and the funding entity.

To conclude, in general it appears that the costs of functions differ across networks primarily in accordance with the scope of activities, although for specific functions other factors also appear relevant; examples include the type of pathogens covered or the specific set-up of the network.

### 5.9.2 Overview of key characteristics of case study networks and potential cost factors

The table below provides an overview of key characteristics of case study networks. It illustrates the diversity of the networks in terms of pathogens covered, the coordination structure, the number of network members, the geographical coverage, and number of annual person months spent on network activities (showing the breakdown by professionals and technicians).

**Table 97. Overview of key characteristics of case study networks**

| Characteristic | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP | ERLTB-Net[b)] |
|---|---|---|---|---|---|---|
| Pathogens covered | Escherichia coli, with particular focus on verotoxigenic E.coli (VTEC) | Emerging viral diseases | 21 food and waterborne diseases, specific priorities include *Salmonella* | Influenza virus (to an extent other respiratory viruses such as MERS-CoV) | Highly pathogenic bacteria of risk group 3 and highly pathogenic viruses of risk group 4/3. | Mycobacterium tuberculosis complex and other nontuberculous mycobacteria |
| Coordination structure | Physically centralised | Physically centralised | Physically centralised | Virtually centralised | Virtually centralised | Virtually centralised |
| Size and coverage | 42 (41 NRLs and one EU-RL) covering all EU Member States, Iceland, Norway, Republic of Macedonia, Turkey, Switzerland, Serbia | 67 laboratories covering all EU Member States, Norway, Switzerland, Serbia, Albania, Kosovo, Bosnia and Herzegovina, Macedonia | 26 laboratories focusing on Salmonella-related activities, covering all EU Member States as well as two EEA countries (Iceland and Norway) and some enlargement countries | 38 laboratories all EU Member States, Iceland, Norway | 37 highly specialised diagnostic laboratories (33 funded) covering 21 EU Member States, Norway, and Switzerland | 33 laboratories covering EU/EEA Member States |
| Annual person months (technicians) | 54.25 | 44.78 | 35.90 | 48.15 | 144.19 | 115.76 |
| Annual person months (professionals) | 53.95 | 43.47 | 21.60 | 63.87 | 260.57 | 25.21 |
| Total annual costs | *713 843* | *770 099* | *492 475* | *1 002 726* | *1 912 920* | *486 591* |

*Sources: Civic Consulting. Notes: a) Only costs relating to salmonella are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC. The costs of activities tendered out by ECDC are included as subcontracting. b) The additional costs reported by network members (which make up part of the total costs) should be interpreted with care, as the figures are based on an extrapolation of survey data provided by 2 of the 33 network members only.*

As shown in the table, differences in pathogen coverage across networks are significant. Some networks focus on a single pathogen (e.g. ERLI-Net), while others focus on a group, defined e.g. by a mode of transmission of a theme (e.g. FWD-Net, ENIVD). As discussed previously, the highly pathogenic nature of the pathogens covered by the QUANDHIP network is likely to be a factor in the total costs of the network. The conduct of EQAs and provision of reference material resources – the functions with the first and second highest level of expenditure of QUANDHIP – is likely to be substantially more costly for highly pathogenic bacteria and viruses than for other categories of pathogens. Indeed, part of the costs of EQAs conducted in the QUANDHIP network may stem from the safety requirements of BSL-3 and BSL-4 pathogens. Furthermore, considering that ERLI-Net deals with influenza, a pathogen of great variability that requires constant monitoring, ECDC analyses and publishes data produced by ERLI-Net on a weekly basis. ECDC therefore has greater involvement in the network, which may contribute to the significantly higher additional costs for ERLI-Net.

The case study networks also present differences in coordination structure at the pan-European level: three are virtually centralised and three are physically centralised. Coordination structure, however, is unlikely to play a role in substantial differences in costs between networks. As shown in the previous sub-sections, there did not appear to be a clear relationship between the types of coordination structure – whether physically or virtually centralised – and total costs for any of the functions (except for function 8 – governance). Moreover, only for some functions were minor changes in costs deemed possible to arise if a different coordination structure were implemented. For several of the functions, the fact that costs are unlikely to change is because the implementation of the activities is unlikely to be done differently if a different coordination structure were in place. For example, the implementation of EQAs and reference diagnostics activities appears to generally be coordinated by one laboratory, independently of the pan-European coordination structure.

The size and coverage similarly do not appear to bear a relationship with the total costs of the case study networks. The number of laboratory members of the network ranges from 26 (FWD-Net) to 67 (ENIVD). Yet networks such as ERLI-Net or QUANDHIP report higher annual costs for roughly half the number of laboratory members (38 and 37 respectively). This is in line with the findings of our research, for example concerning EQAs: as indicated in the previous sub-section, the number of EQAs conducted, the pathogen focus of the EQAs and their complexity play a role in the costs, but the number of laboratories participating in the EQA is of less relevance. Moreover, the geographical coverage is broadly similar across networks – nearly all networks cover all EU Member States as well as selected EEA states or enlargement countries.

Finally, the number of annual person months appears to vary to some extent with the total annual costs. This is to be expected considering that staff costs make up the majority of costs for most of the activities conducted by networks. Staff costs are also more likely to be higher when the scope of activities is larger: indeed, as shown in the case study reports in Section 4, the QUANDHIP and ERLI-Net networks appear to have had a comparatively larger scope of activities than in other networks.

In conclusion, the key characteristics that appear to be a factor that may explain differences in costs between case study networks are the type of pathogens covered and the number of person months, which itself is related to the scope of activities. In contrast, the type of coordination structure or the size and coverage of the networks do not appear to play a significant role in the overall costs of the case study networks.

# 6. Analysis of benefits

*This section presents the analysis of benefits of European reference laboratory networks and related options for coordination. It presents the monetary and non-monetary benefits for network members as well as the non-monetary benefits for society overall in the EU, based on the key types of benefits for which evidence was collected. It then describes the implications of different coordination options for the assessed benefits.*

## 6.1 Overview

As indicated in Section 3.5, in the context of this study we differentiate between monetary and non-monetary benefits of European reference laboratory networks, from the perspective of both members of the networks themselves and society as a whole. The following table presents the key benefit types for which we have collected data.

**Table 98. Key benefits relevant for the analysis**

| Perspective | Monetary benefits | Non-monetary benefits |
|---|---|---|
| Members of the EU-RL network | - Cost savings for members of the network as a result of participation in network activities.<br>- Receipt of financial contributions by members of the network as a result of participation in network activities.<br>- Additional income received by members of the network thanks to increased demand for services as a result of membership in the network. | - Improvement in laboratory methods employed by members of the network.<br>- Improvement in staff expertise of members of the network.<br>- Improvement in quality of data produced by members of the network.<br>- Improvement in image or reputation of the members of the network.<br>- Improvement in access to information and communication, communication and/or collaboration among members of the network. |
| Society overall | - Cost savings of EU institutions as a result of the implementation of network activities. | - More timely and accurate detection of pathogens in the EU.<br>- Reduction in the disease burden and related costs in the EU.<br>- Improvement of public health surveillance in the EU.<br>- Increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU. |

*Sources: Civic Consulting.*

In the following sections we present the results concerning monetary benefits, followed by non-monetary benefits for network members and those for society as a whole in the EU.

## 6.2 Monetary benefits of network members

### 6.2.1 Reported monetary benefits

The total monetary benefits resulting arising from the case study networks ranged from EUR 13 217 (FWD-Net) to EUR 220 949 (ENIVD). These amounts include only the monetary benefits of laboratories participating in the network. Coordinators of case study networks did not report receiving any monetary benefits deriving from their role as network coordinators. They did, however, report monetary benefits from their participation in network activities as network members. For example, network coordinators received monetary benefits from the receipt of reference material distributed through the network - although this did not apply for their coordination activities related to reference material resources.

The funding entities of case study networks indicated having received monetary benefits in terms of saved costs. As several interviewees indicated, if funding entities had not tendered out the network activities as a package, they would have had to implement a tendering process for each activity individually. Individual tendering processes would have been more expensive. Hence, funding entities realised monetary benefits resulting from economies of scale. However, they were generally unable to quantify these cost savings.[65] Estimates of monetary benefits provided below are therefore conservative in nature.

The following table provides an overview of reported monetary benefits of network members for each case study network on the basis of the data collected. The table presents figures for monetary benefits at the network level, which were obtained by extrapolating reported average savings of laboratory members who responded to the survey to the overall number of members of the network.

[65] While a quantification of savings was mostly not provided, ECDC indicated as an example that according to one estimation, the cost of obtaining an EQA panel through a tender procedure was approximately 7.5 times higher than the cost of an EQA obtained through a funded network.

### Table 99. Annual monetary benefits received by laboratory network members (total, in Euro)

| Type of benefit | EU-RL VTEC | ENIVD | FWD-Net[a)] | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **Coordination structure of the network** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Benefits related to reference diagnostics | 8 213 | 105 286 | 0 | 950 | 5 204 |
| Benefits related to reference material resources | 6 185 | 42 115 | 2 600 | 9 500 | 16 206 |
| Benefits related to EQAs | 14 684 | 69 561 | 9 750 | 5 225 | 40 807 |
| Benefits related to training | 14 173 | 3 988 | 867 | 6 334 | 30 230 |
| *Total* | *43 255* | *220 949* | *13 217* | *22 009* | *92 447* |

*Source: Civic Consulting, based on assessments of funding entities, network coordinators and network members for the reference period. Owing to incomplete data, the ERLTB-Net network has been excluded from the table; see Section 3.5 for more details. The table shows total monetary benefits at network level, which were obtained by extrapolating reported savings of laboratory members who responded to the survey to the overall number of members of the network. Responses received: EU-RL VTEC (N=18); ENIVD (N=7); FWD-Net (N=15), ERLI-Net (N=6); QUANDHIP (N=13). Note: a) Only monetary benefits relating to salmonella-related activities are considered for FWD-Net. In contrast to the other case study networks, FWD-Net is not coordinated by a laboratory member of the network but by ECDC.*

As the table above illustrates, network members received monetary benefits deriving in particular from four core functions:

- Reference diagnostics;
- Reference material resources;
- EQAs; and
- Training.

All functions listed above involve the provision of a direct service to members in the network. Specifically, monetary benefits derive from the fees laboratories have saved, since this service was provided by the network free of charge. No monetary benefits for members relating to other functions were reported.

The size of the monetary benefits reported varies considerably between case study networks. Particularly in the ENIVD and QUANDHIP networks, network members reported realising significant benefits of EUR 220 949 and EUR 92 447 respectively. In ENIVD monetary benefits relate especially to reference diagnostics, which amount to EUR 105 286. To an extent, these benefits reflect the specific objective and set-up of ENIVD. As already discussed in Section 4.2, ENIVD has a focus on reference diagnostics and the provision of such services amongst network members to each other. Since members of ENIVD each focus on different pathogens, they do not have the capabilities to conduct reference diagnostics for every pathogen covered by ENIVD. Therefore, network members rely to a much larger extent than in other case study networks on each other's capabilities to conduct diagnostic confirmation. In contrast, In ERLI-Net, for example, all network members have basic capacities to conduct this task. Hence, diagnostic confirmation services for individual network members appear much less relevant.

Furthermore, both ENIVD and QUANDHIP cover highly pathogenic viruses and (in the case of QUANDHIP) bacteria that require high bio-safety standards (BSL-3 or BSL-4). It is therefore expected that the provision of reference materials to network members is more costly than in other case study networks. Hence, receiving this expensive service free of charge is expected to translate to higher monetary benefits for network members.

Additionally, EQAs conducted in these two networks are also shown to lead to considerable monetary benefits. EQAs in both networks are marked by high complexity in terms of sample preparation and distribution. Again, monetary benefits derive from the fact that network members receive this service free of charge. Participating in commercial EQAs of such complexity is likely to be expensive, if commercial EQAs are available at all.[66] Moreover, as described in Section 4.1, the EU-RL VTEC network conducted three EQAs and an extensive amount of training activities in the reference period. These activities may explain that the cost savings in the EU-RL VTEC network relate to these two functions. ERLI-Net, on the other hand, conducts EQAs twice a year, but provides an extensive amount of reference materials to network members throughout each flu season. Hence, network members reported higher monetary benefits from reference material resources than from EQAs.

Finally, in FWD-Net EQAs and the curation of reference strains are tendered out by ECDC to a laboratory in the network, for which the monetary benefits are similarly

[66] The ECDC's recent survey of EU/EEA country laboratory capabilities and capacities (EULabCap) also confirmed that in many instances relevant EQAs are not available for purchase on the market, signaling the uniqueness of the provision of EQAs at EU level via EU-RL networks.

reflected in the cost savings reported by network members. No specific training activities for salmonella were conducted in the reference period. The only activity in this respect was an annual workshop, which partly covered issues related to salmonella. Accordingly, monetary benefits deriving from the training were only minor. To conclude, the reported differences in monetary benefits across case study networks appear to relate primarily to the scope of the activities implemented and to the type of pathogens covered by the network.

In addition to these monetary benefits related to network functions, some members across case study networks also reported receiving additional grants as a result of their participation in the network, for example from the laboratory's national ministry of health or other public funding institution. The size of the grants reported ranged from less than EUR 1 000 to up to EUR 1 000 000. However, most network members surveyed did not provide an answer to this question. Therefore, an estimate per case study network cannot be provided.

### 6.2.2 Median monetary benefits

As for costs, for each function we have calculated annual median monetary benefits on the basis of the reported data of case study networks (which only considers monetary benefits for network members), as a measure of the benefits conferred by each function. The following table presents these estimated median benefits.

**Table 100. Annual median monetary benefits (in Euro)**

| Monetary benefits related to … | Median benefits | Share (of total monetary benefits) |
|---|---|---|
| Reference diagnostics | 6 709 | 12% |
| Reference material resources | 12 853 | 22% |
| EQAs | 27 746 | 48% |
| Training | 10 253 | 18% |
| Total | *57 560* | *100%* |

*Source: Civic Consulting. Note: Median benefits are calculated as the median of case study data, excluding FWD-Net and ERLTB-Net. For discussion of total network benefits, see Section 7.1.*

As the table above illustrates, the estimation of median benefits is based on all four core functions providing a direct service to network members. Fees saved from the participation in EQAs represent the highest monetary benefit, amounting to EUR 27 746, or a share of 48% in total monetary benefits of network members. Training and reference material resources are each the source of approximately one fifth of the monetary benefits of network members, amounting to EUR 10 253 and EUR 12 853 respectively. Monetary median benefits resulting from reference diagnostics amount to EUR 6 709.67

[67] For an overview of the range of monetary benefits reported by case study networks used as a basis to calculate the median for each function, please refer to Table 99 above.

## 6.3 Non-monetary benefits of network members

### 6.3.1 Overview of benefits

As outlined in the description of the methodological approach in Section 3, the non-monetary benefits for network members assessed in the study are as follows:

- Improvement in methods employed by laboratories in the network;
- Improvements in staff expertise of laboratories in the network;
- Improvement in quality and accuracy of data/results produced in laboratories in the network;
- Improvement in image or reputation of the laboratories in the network;
- Improvement in access to information, communication and/or collaboration among laboratories in the network.

Overall, study participants evaluated the above-mentioned non-monetary benefits for network members very positively. On a scale from 1 (not at all) to 5 (very much), all benefits were rated above 3 points (where 3 can be considered a neutral rating). Four out of the five types of benefits were assessed very similarly, receiving average scores between 4.3 and 4.4. Only the contribution of the network to improving the image and reputation of laboratories was evaluated with a slightly lower average score (3.9).

The following table provides an overview of the average assessment of benefits by case study networks.

### Table 101. Non-monetary benefits for network members

| | EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **The laboratory network contributed to improving…** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Methods employed by laboratories in the network. | 4.6 | 4.6 | 4.5 | 3.7 | 4.7 |
| The quality and accuracy of data/results produced in laboratories in the network. | 4.4 | 4.4 | 4.5 | 4.0 | 4.6 |
| Staff expertise of laboratories in the network. | 4.6 | 4.4 | 4.4 | 3.8 | 4.6 |
| Access to information, communication and/or collaboration among laboratories in the network. | 4.6 | 4.7 | 3.4 | 3.9 | 4.8 |
| The image and reputation of laboratories in the network. | 3.3 | 4.2 | 3.9 | 3.5 | 4.0 |

*Sources: Civic Consulting, based on assessments of funding entities, network coordinators and network members. Owing to incomplete data, the ERLTB-Net network has been excluded from the table; see Section 3.5 for more details. Average ratings are shown. Note: Non-monetary benefits were rated on a scale from 1 (not at all) to 5 (very much). Colour-coding employed corresponds to ranges of ratings of 0.5 points.*

The table illustrates that contributions to improvements in methods employed by laboratories, staff expertise and the quality and accuracy of data/results were assessed particularly positively. Four out of the five case study networks shown provided an average assessment of at least 4.4 out 5 for these benefit types. Benefits related to improved access to information, communication and/or collaboration among laboratories in the network were similarly highly rated, with three of five case study networks provided a rating of 4.6 or higher on average. The contribution of the network to improving the image and reputation of laboratories in the network was rated lowest of the types of benefits assessed: none of the case study networks provided a rating higher than 4.2.[68]

### 6.3.2 Discussion of results by benefit type

#### 6.3.2.1 Improved methods employed by laboratories in the network

The improvement of methods employed by laboratories in the network can relate either to the better implementation of existing laboratory methods (such as diagnostic analytical methods or methods for typing and sub-typing of pathogens) or to the use of new methods in laboratories (e.g. next generation sequencing). As noted above, on average study participants evaluated the impact of the laboratory network on methods employed by the network very positively (4.4 of 5). According to study participants, the improvement of laboratory methods among network members is primarily the result of the implementation of reference diagnostics activities (mainly activity 1a); external quality assessments (EQAs); and training activities.

First, EQAs very significantly contribute to improving laboratory methods in the following respects:

- Verification of correct application of laboratory methods. An EQA provides the opportunity for participating laboratories to test whether they are capable of applying a specific laboratory technique. The evaluation of the results submitted by laboratories can either confirm the correct application of methods or identify random and systematic errors. This allows laboratories to revise their methods and to remedy these errors.
- Adoption of more advanced laboratory methods. If laboratories apply other methods in their daily work, an EQA could incentivise these laboratories to reconsider their approach and to adapt their methods accordingly. As an interviewee from FWD-Net stated, whole genome sequencing techniques are now implemented in several laboratories as a result of the requirement to apply this technique in related EQAs.
- Boost in funding for upgrading laboratory equipment required for employing better methods. The request for the application of a certain method in a network-wide EQA and/or the results of the participation of a laboratory could incentivise its funding entity to provide funds to upgrade laboratory equipment in order to enable its participation in and/or a better result from future EQAs.

Second, training courses contribute very significantly to improving laboratory methods in the following respects:

[68] Considering the different mandates and activities of the networks, it is not possible to draw conclusions based on comparisons of ratings between specific networks. Moreover, at the second expert workshop that took place in this study, it was highlighted that the lower ratings provide by ERLI-Net members may relate to the overlap of the GISRIS and ERLI-Net networks.

- Courses dedicated to teaching specific laboratory methods. Training courses in networks are often dedicated to the application of specific methods. Network members participating in the training course can thereby either learn to apply a specific method or verify and improve their approach. After their participation, network members can revise their methods and improve them accordingly.
- Twinning arrangements involving expert support to revise laboratory methods. Through twinning arrangements, the network provides an opportunity for network members to receive expert support in their laboratories. The expert(s) can work with laboratory staff to revise standard operating procedures and/or demonstrate the use of selected methods.
- Exchange of best practices on laboratory methods during workshops. During annual workshops in many networks, a significant amount of the time is dedicated to the exchange of best practices and experiences. Such exchanges help network members verify whether their methods are up-to-date. Based on the experience of other laboratories a network member can revise its own methods subsequent to the workshop.

Third, reference diagnostics activities also contribute significantly to improving laboratory methods, in two main respects:

- Standard operating procedures for up-to-date laboratory methods. Standard operating procedures and information on new or revised methods, which are distributed throughout the network, can be used by network members to check their methods and operating procedures in use and to update and revise their work processes accordingly. The provision of up-to-date information on reference diagnostics such as protocols ensures the dissemination of knowledge to a wide number of laboratories throughout the EU. The revision of work processes can then lead to the improvement of the methods applied.
- Verification of laboratory methods through confirmation of diagnostic results. Diagnostic confirmation services provided in the network help to either confirm diagnostic results or identify errors. Network members can use the results either to verify their methods or to revise them in order to remedy the detected errors.

Interviewees and survey participants noted that less advanced laboratories usually benefit to a higher degree from EQAs, training courses and reference diagnostic activities than more advanced laboratories. Less advanced laboratories receive direct support in implementing new methods, while laboratories with advanced techniques tend to drive the development and use of the methods at EU level. Nonetheless, as one interviewee from a comparatively more advanced laboratory stated, while advanced laboratories tend to set the standards, they can also learn a lot from the other laboratories e.g. in terms of improving their preparation of EQA samples for the network.

Finally, activities related to reference material resources and collaboration and research contribute to improving methods to a minor degree, as described below:

- Provision of materials allowing different laboratory methods to be applied. If the network provides reference material that a laboratory could not otherwise have access to, it enables the network member to apply a different method. This could potentially improve the methods of the laboratory. However, as most laboratories are likely to have access to relevant reference material from other sources, the provision the material would instead contribute to improving the quality of the

results produced rather than the methods employed (see below on improvements to quality and accuracy results).

- Research projects allowing exchange of best practices, potentially dedicated to development of laboratory methods. The exchange of best practices via collaboration with other networks could improve the methods employed by network members. Furthermore, if research projects are dedicated to the development and refinement of laboratory methods or to the assessment of whether certain methods can be employed throughout the network, such projects could also contribute to the improvement of methods used by laboratories in the network. However, it is expected that the contribution would be minor, since the process from a research project to the direct application in laboratories is assumed to be rather time-consuming.

The functions of scientific advice, monitoring, alert and response, and governance of the network are not considered relevant for the improvement of laboratory methods, as the former does not relate to services provided to members of laboratory networks and the other functions relate primarily to administrative action (in particular in response to outbreak situations) and procedures.

In conclusion, activities relating to EQAs, training and reference diagnostics contribute significantly to very significantly to improvements in methods employed by laboratories, while activities relating to reference materials and collaboration and research contribute to a minor extent.

The table below provides a summary of the assessment.

**Table 102. Contribution of core functions to improving the methods of laboratories in the network**

| Core function | Contribution | How function contributes to improving laboratory methods |
|---|---|---|
| 1. Reference diagnostics | Significant | ▪ Standard operating procedures as a benchmark for up-to-date laboratory methods.<br>▪ Verification of laboratory methods through confirmation of diagnostic results. |
| 2. Reference material resources | Minor | ▪ Provision of materials allowing different laboratory methods to be applied. |
| 3. Scientific advice to public authorities | None | *Function not directly relevant for improving laboratory methods.* |
| 4. External Quality Assessments (EQA) | Very significant | ▪ Verification of correct application of laboratory methods.<br>▪ Adoption of more advanced laboratory methods.<br>▪ Boost in funding for upgrading laboratory equipment required for employing better methods. |
| 5. Training | Very significant | ▪ Courses dedicated to teaching specific laboratory methods.<br>▪ Twinning arrangements involving expert support to revise laboratory methods.<br>▪ Exchange of best practices on laboratory methods during workshops. |
| 6. Collaboration and research | Minor | ▪ Research projects allowing exchange of best practices, potentially dedicated to development of laboratory methods. |
| 7. Monitoring, alert and response | *Not relevant* | *Function not directly relevant for improving laboratory methods.* |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for improving laboratory methods.* |

*Source: Civic Consulting.*

#### 6.3.2.2 Improved quality and accuracy of data/results produced by laboratories in the network

As noted above, on average study participants evaluated the impact of the laboratory network on methods employed by the network very positively (4.4 of 5). As with methods and staff expertise, this benefit can primarily be traced to EQAs, training activities and reference diagnostics, but also to the provision of reference materials, as described in the following.

First, provision of reference materials contributes very significantly to improved quality and accuracy of data and results produced by laboratories. The distribution of *well-characterised and high quality reference materials* distributed throughout the network can significantly contribute to the accuracy of analysis and comparability of results produced by network members. As interviewees confirmed, this is also particularly relevant for reporting data in TESSy, the European surveillance system.

Second, EQAs contribute very significantly to improving the quality and accuracy of data/results produced by laboratories:

- Detection of errors through evaluation of results submitted. The evaluation of the results submitted during the participation in an EQA can help network members to detect systematic and random errors in their results. Laboratories can trace back these errors and remedy their root cause, which is then expected to lead to an improvement in the quality and accuracy of results they produce.
- Indirect impact through better methods and expertise resulting from EQAs. As discussed above, EQAs contribute significantly to improving staff expertise and methods in use in laboratories. This is then likely to have a positive impact on quality and accuracy of results.

Third, training courses also contribute significantly to improving the quality and accuracy of data/results:

- Twinning arrangements involving expert support to detect inaccuracies in results. Network members can receive direct support in their laboratory through twinning arrangements. Visiting experts can identify the root cause of inaccuracies on the spot and can help to revise laboratory procedures in order to produce high quality results.
- Indirect impact through better methods and expertise resulting from training. As discussed above, training courses contribute significantly to improving staff expertise and methods in use in laboratories. This is then likely to have a positive impact on quality and accuracy of results.

Moreover, reference diagnostic activities also contribute significantly to improving the quality and accuracy of results:

- Detection of inaccuracies through diagnostic confirmation. The comparison of the first diagnostic results produced by a laboratory and the results provided through the diagnostic confirmation service of the network can help to identify inaccuracies. On this basis, network members can revise their operating procedures in order to remedy these inaccuracies and increase the quality of the results they produce.
- Indirect impact through better methods and expertise. As discussed above, standard operating procedures contribute to both improving methods in operation in laboratories and staff expertise. This is then likely to have a positive impact on quality and accuracy of results.

In contrast with 'improvements to methods' and 'staff expertise', activities related to the above functions are expected to contribute to the improvement of quality and accuracy of results in all laboratories regardless of their comparative capacities and capabilities.

However, collaboration and research activities are only likely to contribute in specific cases to improvements in quality and accuracy of results, e.g. research projects dedicated to improving operating procedures and the detection of systematic errors in the application of methods. Furthermore, the time gap between the production of knowledge and its translation into actionable information means that drawing a direct link between the function and the size of its impact on the quality and accuracy of data/results is difficult, even if the contribution may be significant in the long term. Overall therefore, we judge the contributions of collaboration and research activities are expected to vary in impact from minor to significant.

In addition, the functions of scientific advice to public authorities, monitoring, alert and response, and governance of the network are not considered relevant for the improvement of quality and accuracy of data/results produced by laboratories in the network.

In conclusion, activities relating to EQAs, reference material resources, training and reference diagnostics contribute significantly to very significantly to improvements in the quality and accuracy of data/results produced by laboratories, while activities relating to collaboration and research, contribute to a minor to significant extent, depending on the nature of the research.

The table below provides a summary of the assessment.

**Table 103. Contribution of core functions to improving the quality and accuracy of data / results produced by laboratories in the network**

| Core function | Contribution | How function contributes to improving quality and accuracy of data / results |
|---|---|---|
| 1. Reference diagnostics | Significant | ▪ Detection of inaccuracies through diagnostic confirmation.<br>▪ Indirect impact through better methods and expertise. |
| 2. Reference material resources | Very significant | ▪ Increased accuracy and comparability of results from better quality reference materials. |
| 3. Scientific advice to public authorities | *Not relevant* | *Function not directly relevant for improving quality and accuracy of data/results.* |
| 4. External Quality Assessments (EQA) | Very significant | ▪ Detection of errors through evaluation of results submitted.<br>▪ Indirect impact through better methods and expertise resulting from EQAs. |
| 5. Training | Significant | ▪ Twinning arrangements involving expert support to detect inaccuracies in results.<br>▪ Indirect impact through better methods and expertise resulting from training. |
| 6. Collaboration and research | Minor-significant | ▪ Research projects dedicated to improving operating procedures and the detection of systematic errors in the application of methods, if applicable. |
| 7. Monitoring, alert and response | *Not relevant* | *Function not directly relevant for improving quality and accuracy of data/results.* |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for improving quality and accuracy of data/results.* |

*Source: Civic Consulting.*

#### 6.3.2.3 Improved staff expertise of laboratories in the network

The improvement of staff expertise in the network is closely linked to the enhancement of laboratory methods. Without capable staff members, improved methods cannot be employed. As noted above, on average study participants evaluated the impact of the laboratory network on staff expertise very positively (4.3 of 5). Study participants confirmed that, as with methods, the increased level of staff

expertise is primarily attributable to network activities related to EQAs, training, and reference diagnostics, albeit potentially to differing degrees, as described in the following. Beyond dedicated training programmes, study participants also highlighted the leadership role played by EU-RL networks in fostering the development of staff competencies in national reference laboratory systems.

First, as with methods, EQAs contribute very significantly to improving staff expertise in the laboratories of a network:

- Confirmation of capabilities of laboratory staff. Laboratories participating in an EQA can test whether their staff members are capable of undertaking the required diagnostics. If laboratories detect gaps either because their staff members could not conduct the EQA or because the results submitted are incorrect, the EQA can be used as an opportunity to improve their staff expertise accordingly.
- Boost in funding for staff development. The request for the application of a certain method in a network-wide EQA could also incentivise the funding entity of a laboratory to provide funds for general staff development and training to acquire the capabilities to participate in the EQA and/or improve the results of the laboratory's participation.

Second, training courses contribute very significantly to improving staff expertise:

- Courses dedicated to staff training. Members of the network can take the opportunity to send a number of their staff to training courses at no cost (beyond the staff time involved). Participants in the courses are then expected to subsequently train the staff in their own laboratory.
- Twinning arrangements involving expert support to train staff. The deployment of external experts to laboratories in the network through twinning arrangements serves the purpose of training staff members in their own institution. Such arrangements particularly contribute to staff expertise of the hosting laboratory, since staff members are trained in their own environment and according to the capacities the hosting laboratory can provide.
- Exchange of best practices on staff training needs during workshops. The annual workshop as conducted in most networks provides a platform for exchanging best practices and experiences. Laboratories can detect gaps in their own staff expertise and can arrange for training courses and support accordingly.

Third, reference diagnostics activities could potentially also play a significant role in improving staff expertise:

- Standard operating procedures as additional guidance to staff members. As discussed above, standard operating procedures and information on new or revised methods distributed in the network can act as a benchmark for network members to revise their own operating procedures. Considering that operating procedures also provide guidance to staff in conducting their tasks, the revision of operating procedures is expected to improve staff expertise.
- Detection of gaps in expertise through diagnostic confirmation. As discussed, above, diagnostic confirmation services provided in the network help to either confirm diagnostic results or identify errors. Network members could use the results either to verify the level of their staff expertise and detect knowledge gaps and thus train their staff accordingly.

As with methods, while less advanced laboratories are likely to profit on a larger scale, more advanced laboratories may nonetheless benefit from the abovementioned activities in terms of improvement of staff expertise. As one interviewee stated, the implementation of network activities has led to the consolidation of existing expertise at the laboratory he represented. Furthermore, another interviewee acknowledged the network meetings as a unique platform for all network members, regardless of their capabilities, to exchange experiences and to take on the best practices of others.

Finally, activities related to collaboration and research and monitoring, alert and response also contribute to improving staff expertise, albeit to a minor degree, as described below:

- Research projects as a means to further staff knowledge. Research projects by definition further the knowledge of scientists conducting the project. These scientists can share their knowledge with other network members and thereby improve the staff expertise across laboratories in the network. However this knowledge may only be directly applicable in the longer term, in particular if this does not relate to the day-to-day work of the laboratories (e.g. research projects on potential new laboratory methods that will require validation and certification). Hence the overall contribution of this function to staff expertise is considered to be minor.
- Detection of gaps in staff expertise through preparedness exercises. If a gap is detected in the preparedness of staff to react quickly, this function can contribute to improving the staff expertise of network members. However, the focus of this function rather lies on clarification of procedures and responsibilities in outbreak situations. Therefore, contributions to staff expertise are expected to be minor.

In contrast, the provision of reference materials is expected to only contribute to a minor degree to improving staff expertise. If, for example, reference materials which could not otherwise be accessed by a network member is distributed, their staff expertise may improve as a result of learning to use the new reference materials. However, it appears unlikely that reference materials alone will be an incentive for staff to apply new methods. Moreover, similarly to 'improvement of methods', scientific advice,[69] and governance of the network are not considered relevant for the improvement of staff expertise.

In conclusion, activities relating to EQAs and training and reference diagnostics contribute significantly to very significantly to improvements in staff expertise by laboratories; those relating to reference diagnostics may also contribute significantly depending on the network; and activities relating to collaboration and research, monitoring, alert and response, and reference material resources contribute to a (very) minor extent.

The table below provides a summary of the assessment.

[69] However, as noted at the consultation meeting held in the framework of this study, network members may nonetheless benefit indirectly from activities relating to scientific advice to public authorities as a result of the network's interaction with the public authorities, although these benefits may not be visible to them.

**Table 104. Contribution of core functions to improving the staff expertise of laboratories in the network**

| Core function | Contribution | How function contributes to improving staff expertise |
|---|---|---|
| 1. Reference diagnostics | Minor-Significant | ▪ Standard operating procedures as additional guidance to staff.<br>▪ Detection of gaps in expertise through diagnostic confirmation. |
| 2. Reference material resources | Very minor | ▪ Distribution of new reference materials incentivising staff learning. |
| 3. Scientific advice to public authorities | *Not relevant* | *Function not directly relevant for improving staff expertise.* |
| 4. External Quality Assessments (EQA) | Very significant | ▪ Confirming capabilities of laboratory staff.<br>▪ Incentivising funding for staff development. |
| 5. Training | Very significant | ▪ Courses dedicated to staff training.<br>▪ Expert support to train staff through twinning arrangements.<br>▪ Exchange of best practices on staff training needs during workshops. |
| 6. Collaboration and research | Minor | ▪ Research projects as a means to further staff knowledge. |
| 7. Monitoring, alert and response | Minor | ▪ Detection of gaps in staff expertise through preparedness exercises. |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for improving staff expertise.* |

*Source: Civic Consulting.*

#### 6.3.2.4 Improving access to information, communication and collaboration

One of the most important benefits according to members of the case study networks is the access to information, communication, and collaboration, with an average rating of 4.3. In the network meetings and through informal communication channels members of a network exchange best practices, discuss common problems, and establish agreements to collaborate on other projects. In general, interviewees did not point to a particular network function as a basis for this significant benefit, but rather described it as a result of concentrated 'networking opportunities' (i.e. opportunities to develop relationships with people with common research or professional interests). As one interviewee stated, the network provides a platform for a selected group of people dealing with the same issues (i.e. the heads of reference laboratories) to discuss very specific problems. Accordingly, these benefits appear to be mostly related to the overall participation of laboratories in the network.

Nonetheless, training activities, via the *platform they provide for network members to meet, directly communicate and to exchange information*, can nonetheless be considered to contribute significantly to improving access to information, communication and collaboration. Other platforms such as scientific conferences would make it much more difficult to identify relevant peers and to discuss problems in such a targeted and in-depth manner.

Some links can also be drawn in terms of minor contributions to access to information, communication and collaboration for other specific functions:

- Standard operating procedures as direct provision of information to network members. The provision of standard operating procedures and other advice on new methods relating to reference diagnostics is a direct provision of information to network members. Laboratories would not have had access to such information or would have had to undertake more efforts to acquire it if they had not participated in the network. Standard operating procedures may also be developed on the basis of feedback collected from several network members, which necessarily involves a high level of communication and exchange of information between those members. However the level of collaboration among network members for the development of standard operating procedures is highly network-specific, and this activity only constitutes one of several main activities relating to reference diagnostics. Considering this uncertainty, the overall contribution of the reference diagnostics function can be considered to be vary from minor to significant.
- Provision of information regarding obtainment of reference materials. The network ensures the access to reference material or at least the information to a source where the reference material can be obtained. While it can be assumed that laboratories in the network could research this information on their own, the network reduces the burden of acquiring this information. However, the type of information provided under this function is very limited. Therefore, only a minor contribution to access to information and communication is expected.

Furthermore, collaboration between laboratories in the network in research projects as well as with other networks may stimulate increased communication between those network members participating in these activities. Considering, however, that overall this function is of minor importance compared to other core functions and that not all network members are involved, only a minor contribution to improving access to information and communication is expected. The functions of scientific advice,[70] EQAs, monitoring, alert and response and governance of the network are not considered relevant as these relate respectively to provision of information to EU institutions, assessments of the capabilities of laboratories, the handling of outbreak situations, and administrative procedures.

In conclusion, overall participation of laboratories in the network contributes significantly to improvements in access to information and communication of network members. Moreover, activities relating to training also contribute significantly, while activities relating to reference diagnostics, reference material resources and collaboration and research contribute to a minor extent.

The table below provides a summary of the assessment.

[70] Again, as noted at the consultation meeting held in the framework of this study, network members may nonetheless benefit indirectly from activities relating to scientific advice to public authorities as a result of the network's interaction with the public authorities, although these benefits may not be visible to them.

**Table 105. Contribution of core functions to improving the access to information and communication of laboratories in the network**

| Core function | Contribution | How function contributes to improving access to information and communication |
|---|---|---|
| 1. Reference diagnostics | Minor-significant | ▪ Standard operating procedures as direct provision of information to network members. |
| 2. Reference material resources | Minor | ▪ Provision of information regarding obtainment of reference materials. |
| 3. Scientific advice to public authorities | *Not relevant* | *Function not directly relevant for improving access to information and communication.* |
| 4. External Quality Assessments (EQA) | *Not relevant* | *Function not directly relevant for improving access to information and communication*. |
| 5. Training | Significant | ▪ Provision of a platform for network members to meet, directly communicate and to exchange information. |
| 6. Collaboration and research | Minor | ▪ Increased communication between network members collaborating on research projects. |
| 7. Monitoring, alert and response | *Not relevant* | *Function not directly relevant for improving access to information and communication*. |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for improving access to information and communication*. |
| Overall participation in network | Significant | ▪ Network provides platform for a members dealing with the same issues to discuss specific problems. |

*Source: Civic Consulting.*

#### 6.3.2.5 Improved image and reputation of laboratories in the network

Members across all case study networks are to some degree selected on the basis of their standing as laboratories in their country. Therefore, it appears plausible that interviewees reported only limited contributions of the network to their image, which is also reflected in the relatively lower average score that study participants evaluated the impact of the laboratory network on image and reputation (3.9 of 5).

Yet the selection of only reputable laboratories entails that membership of the network also signals a certain reputation to the outside world. Some interviewees confirmed this effect by stating that as a result of their involvement in the network, awareness of selected capabilities of their laboratory had increased. For example, one interviewee mentioned that its laboratory is now more widely known as an EQA provider. Another interviewee reported that its active participation in the network had supported the selection of its institute as a reference laboratory for other diseases. Other potential knock-on effects of increases in reputation include better access to funding, including more research grants.

None of the study participants stated that the participation in only one particular network activity was responsible for their improved image and reputation. Hence, in contrast to benefits relating to improvements in methods, staff expertise or quality of results which can be linked to specific functions, these improvements are instead relatively more linked to the overall participation of laboratories in the network.
Some links can nonetheless be drawn in terms of minor contributions to image and reputation for specific functions:

- Reputational effect of good performance in EQAs. A consistently good performance in network-wide EQAs could potentially boost the reputation of a laboratory. However, if a laboratory was already held in high regard at the time of its participation in the network-wide EQAs, consistent good performances would tend to confirm its reputation rather than improve it. Hence, in general the contribution of EQAs is likely to be minor.
- Reputational effect of favourable research project outcomes. Depending on the outcome of a research project, the image and reputation of scientists and their hosting institutions can increase significantly. Considering, however, that research projects play only a very minor role in networks, the overall contribution of this function to the image and reputation of laboratories is expected to be relatively minor.
- Reputational effect of acting as scientific partner with EU institutions. Laboratories providing scientific advice to EU institutions on a regular basis can build a reputation in these institutions as a reliable partner. However, it is expected that EU institutions will request scientific advice mainly from laboratories which have a good reputation in the first place. Therefore, it seems more likely that the regular provision of scientific advice would tend to confirm an existing reputation rather than improve it. Hence, in general the reputational effects of providing scientific advice are likely to be minor.

Finally, network training activities might have an impact on the image and reputation of a laboratory if it manages to translate its participation into improvements of its work and to signal these improvements to the outside world. However owing to the very indirect link, the contribution is expected to be very minor. Moreover, other network functions (i.e. reference diagnostics, reference material resources, monitoring, alert and response, and governance of the network) would not be relevant from the perspective of the image and reputation of laboratory members.

In conclusion, overall participation in a network may in some cases improve the image of laboratories significantly, although this is strongly dependent on the laboratory's original standing outside the network. Activities relating to EQAs, scientific advice, collaboration and research, and training, contribute to a (very) minor extent.

The table below provides a summary of the assessment.

**Table 106. Contribution of core functions to improving the image and reputation of laboratories in the network**

| Core function | Contribution | How function contributes to improving image and reputation |
|---|---|---|
| 1. Reference diagnostics | *Not relevant* | *Function not directly relevant for improving image and reputation.* |
| 2. Reference material resources | *Not relevant* | *Function not directly relevant for improving image and reputation.* |
| 3. Scientific advice to public authorities | Minor | ▪ Reputational effect of acting as scientific partner with EU institutions. |
| 4. External Quality Assessments (EQA) | Minor | ▪ Reputational effect of good performance in EQAs. |
| 5. Training | Very minor | ▪ Potential reputational effects through improvements relating to training. |
| 6. Collaboration and research | Minor | ▪ Reputational effect of favourable research project outcomes. |
| 7. Monitoring, alert and response | *Not relevant* | *Function not directly relevant for improving image and reputation.* |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for improving image and reputation.* |
| Overall participa-tion in network | Minor - Significant | ▪ Reinforcement of existing positive image through participation in network. |

*Source: Civic Consulting.*

## 6.4 Non-monetary benefits for society overall

### 6.4.1 Overview of benefits

As outlined in the description of the methodological approach in Section 3, the non-monetary benefits for society overall in the EU assessed in the study are as follows:

- Reduction in the disease burden and related costs in the EU
- Improved public health surveillance in the EU
- More timely and accurate detection of pathogens in the EU
- Improved laboratory preparedness and the capacity of coordinated response to outbreaks in the EU.

Overall, study participants evaluated non-monetary benefits for society overall in the EU very positively. On a scale from 1 (not at all) to 5 (very much), all benefits were rated above 3 (where 3 can be considered a neutral rating). Three of the four benefits are assessed fairly similarly, receiving scores between 4.2 and 4.6. Only the reduction in the disease burden and related costs in the EU was evaluated with a substantially lower average score (3.5).

The following table provides an overview of the average assessment of benefits by case study networks.

### Table 107. Non-monetary benefits of laboratory networks for society overall in the EU

| | EU-RL VTEC | ENIVD | FWD-Net | ERLI-Net | QUANDHIP |
|---|---|---|---|---|---|
| **The laboratory network has contributed to…** | **Physically centralised** | **Physically centralised** | **Physically centralised** | **Virtually centralised** | **Virtually centralised** |
| Laboratory preparedness and the capacity of coordinated response to outbreaks in the EU | 4.5 | 4.9 | 4.4 | 4.6 | 4.9 |
| More timely and accurate detection of pathogens in the EU | 4.4 | 4.9 | 4.3 | 4.1 | 4.5 |
| Improved public health surveillance in the EU | 3.9 | 4.3 | 4.6 | 4.3 | 3.7 |
| Reduction in the disease burden and related costs in the EU | 3.0 | 4.0 | 3.7 | 3.0 | 3.7 |

*Sources: Civic Consulting, based on assessments of funding entities, network coordinators and network members. Owing to incomplete data, the ERLTB-Net network has been excluded from the table; see Section 3.5 for more details. Average ratings are shown. Note: Non-monetary benefits were rated on a scale from 1 (not at all) to 5 (very much). Colour-coding employed corresponds to ranges of ratings of 0.5 points.*

The table illustrates that benefits in terms of improved laboratory preparedness and the capacity of coordinated response to outbreaks in the EU were assessed particularly positively, with all five case study networks providing an average assessment of 4.4 or higher out of 5. Benefits relating to more timely and accurate detection of pathogens were similarly highly rated, with all five case study networks providing a rating of at least 4.1. Benefits related to improved public health surveillance were assessed by members of three case study networks at 4.3 or above on average, while the highest rating provided for the impact on the disease burden and related costs in the EU was 4.0.[71]

Looking at the results by case study shows that ENIVD assessed the benefits types with the highest scores, which all received ratings above 4.0 points, although benefits relating to improvements in detection of pathogens and preparedness were rated particularly highly (4.9). Scores for QUANDHIP were the second-highest for all benefit types except for improvements in public health surveillance, with similarly very high ratings for the two abovementioned benefit types. Average assessments for the remaining three case study networks presented were somewhat lower but broadly similar across all benefit types.

Of particular note are the contrasting ratings of networks for impacts on both laboratory preparedness/capacity of coordinated response to outbreaks in the EU and detection of pathogens on the one hand and on the disease burden and related costs on the other. This may be related to the difficulty of establishing a direct link between improvements at the level of laboratories (in the short term) and impacts on disease (in the longer term), especially as disease burden can be influenced by a range of factors, many of which are unrelated to the functions and activities of laboratory networks.

### 6.4.2 Discussion of results by benefit type

#### 6.4.2.1 Increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU

The impact of the laboratory network on increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU received the highest average rating of the societal benefits assessed, at 4.6. According to study participants, these improvements are primarily the result of the implementation of activities relating to reference diagnostics, reference material resources, EQAs and training.

As discussed, reference diagnostics activities contribute significantly to the improvement of the methods, staff expertise and quality/accuracy of data and results of network members. Hence they directly contribute to the capacities of reference laboratories in the network to fulfil their public health duties. These capacities are the basis for laboratory preparedness in the EU and therefore the function can be considered to contribute significantly to laboratory preparedness. However, a direct link is more difficult to establish between reference diagnostic activities and increased capacity for a coordinated response to outbreaks in the EU, as several other factors also play a role in determining capacity for outbreak response. Owing to this uncertainty the contribution of the function to the assessed benefit as a whole can be

[71] As the ENIVD and QUANDHIP networks primarily focus on pathogens that do not currently exist in the EU, survey responses from members of these networks concerning the reduction of disease burden in the EU need to be interpreted with caution.

qualified as significant/indirect. The same reasoning for reference diagnostic activities also applies for reference material resources, EQAs and training.

Additionally, activities relating to monitoring, alert and response focus on coordinated response to outbreak situations, in particular activity 7b relating to the provision of advice/technical support in outbreak investigations/surge capacity. Within the scope of these activities, protocols and provisions are developed that can provide guidance for the network to clarify responsibilities in outbreak situations. For example in the QUANDHIP network, a clear responsibility structure was developed for the network in crisis mode. The provision of technical support in outbreak investigations also contributes to preparedness planning in the longer term. Therefore, overall, this function significantly contributes to the increased capacity of coordinated response to outbreaks.

Moreover, public authorities typically play an important role in the coordination of the response to outbreak situations. Scientific advice provided in this context, e.g. contributing to risk assessment, therefore contributes significantly to increasing the capacity of coordinated response.

As well, if collaboration and research projects are dedicated to the topic of laboratory preparedness and coordinated response, they may contribute to accelerating these capacities in the EU. Importantly, collaboration and research activities leading to the development of a framework for the identification of research priorities as well as to facilitate investment decisions (e.g. in relevant diagnostic capacities/capabilities for specific pathogens) can be important for laboratory preparedness and capacity for coordinated response as well as broader societal preparedness in general over the longer term. However, as with other types of benefits, the time gap between these research projects and activities and the application of their results in practice would only imply minor contributions of this function to the assessed benefit.

Finally, again, through synergies between laboratories and public health institutions, the overall participation of laboratories in the network contributes indirectly to increased laboratory preparedness and capacity for coordinated response to outbreaks.

In conclusion, activities relating to monitoring, alert and response and scientific advice to public authorities contribute significantly to increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU; the contribution of activities relating to reference diagnostics, reference material resources, EQAs and training vary from minor to significant; and the contribution of collaboration and research activities can be considered minor.

The table below provides a summary of the assessment.

**Table 108. Contribution of core functions to increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU**

| Core function | Contribution | How function contributes to increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU |
|---|---|---|
| 1. Reference diagnostics | Significant/ indirect | ▪ Improvements in laboratory methods, staff expertise and quality and accuracy of data/results.<br>▪ Activities thereby indirectly contribute to improving reference laboratories' capacities to fulfil their public health duties, which is a basis for laboratory preparedness. |
| 2. Reference material resources | Significant/ indirect | *See function 1.* |
| 3. Scientific advice to public authorities | Significant | ▪ Public authorities acting on scientific advice received from networks play an important role in the coordination of the response to outbreak situations. |
| 4. External Quality Assessments (EQA) | Significant/ indirect | *See function 1.* |
| 5. Training | Significant/ indirect | *See function 1.* |
| 6. Collaboration and research | Minor | ▪ Potential collaboration and research projects dedicated to the topic of laboratory preparedness and coordinated response/identification of relevant research and investment priorities |
| 7. Monitoring, alert and response | Significant | ▪ Activities specifically dedicated to increasing capacity of a coordinated response within the network and the development of protocols and provisions providing guidance, technical support and clarifying responsibilities in outbreak situations. |
| 8. Governance of the network | *Not relevant* | *Function not relevant for improving quality and accuracy of data/results.* |
| Overall participation in network | Indirect | ▪ Through synergies between laboratories and public health institutions, the overall participation of laboratories in the network contributes indirectly to increased laboratory preparedness and capacity for coordinated response to outbreaks. |

*Source: Civic Consulting.*

#### 6.4.2.2 More timely and accurate detection of pathogens

As noted above, on average funding entities, coordinators and network members assessed the impact of the laboratory network on more timely and accurate detection of pathogens in the EU very positively (4.4 of 5). According to study participants, these improvements are primarily the result of the implementation of activities relating to reference diagnostics, reference material resources, EQAs and training.

Concerning reference diagnostics activities, the circulation of standard operating procedures and other relevant information on laboratory methods (activity 1a) and the continuous typing, subtyping, and characterisation of pathogens (activity 1b)

significantly contribute to keeping reference methods up-to date and to developing and maintaining a consolidated overview of pathogens and pathogen mutations circulating in the EU. Furthermore, the provision of diagnostic confirmation services through the network (activity 1b) reinforces the accurate detection and characterisation of pathogens. All activities subsumed under this function therefore play a role in contributing to this benefit. An example provided by ERLI-Net study participants is the fast distribution and implementation of H3N2v and H7N9 detection protocols in the EU/EEA in the ERLI-Net network and subsequent take-up by network members, which was considered to shorten the time for detecting the related influenza viruses. Reference diagnostic activities can therefore be considered to significantly contribute to more timely and accurate detection of pathogens in the EU.

The provision of accurately calibrated reference materials to laboratories in the network improves the quality and accuracy of the results produced by network members. Furthermore, making reference materials rapidly available can decrease the detection time of pathogens. For example, ERLI-Net provides new reference materials in every flu season to network members. Since coordinators of ERLI-Net have an overview of which influenza viruses are currently circulating in the EU with the distribution of reference materials they ensure that relevant flu viruses can be detected quickly. Therefore, this function significantly contributes to more accurate and timely detection of pathogens in the EU.

EQAs request participating laboratories to employ specific methods in the analysis of EQA samples. These methods can generally be considered as state-of-the-art and with the request to use them in network-wide EQAs, the methods are disseminated throughout the EU. Network-wide EQAs, through their impact on keeping reference methods in the network up-to-date in the EU, therefore contribute significantly to the timely and accurate detection of pathogens in the EU.

Training activities in networks significantly contribute to improving the laboratory methods, staff expertise and quality and accuracy of data/results among network members. All three capacities are indispensable for the timely and accurate detection of pathogens in the EU. Therefore, training activities can also be considered to provide a significant contribution to more timely and accurate detection of pathogens in the EU.

Also, research projects directed towards improving laboratory capacities can contribute to more timely and accurate detection of pathogens. However, considering the time gap between the conclusion of a research project and the application of the results in practice, if these are found to be relevant, the contribution of this function to improvements in the detection of pathogens is considered to be minor.

Finally, the overall participation of laboratories in the network and the resulting synergies among laboratories and public health institutions are likely to have an indirect positive impact on detection of pathogens in the EU.

Activities related to monitoring, alert and response and scientific advice to public authorities are not considered relevant as these concern mainly supporting Member States in providing data to EU bodies as well as technical support to public authorities in outbreak investigations and in general, as opposed to direct improvements in pathogen detection. Governance of the network is similarly not considered relevant.
In conclusion, activities related to reference diagnostics, reference material resources, EQAs and training contribute significantly to more timely and accurate detection of pathogens in the EU, while specific research projects may also contribute to a minor extent.

The table below provides a summary of the assessment.

**Table 109. Contribution of core functions to more timely and accurate detection of pathogens in the EU**

| Core function | Contribution | How function contributes to more timely and accurate detection of pathogens in the EU |
|---|---|---|
| 1. Reference diagnostics | Significant | ▪ Improvements in laboratory methods, staff expertise and quality and accuracy of data/results.<br>▪ Development and maintenance of a consolidated overview of pathogens and pathogen mutations circulating in the EU.<br>▪ Provision of diagnostic confirmation services reinforcing the accurate detection and characterisation of pathogens. |
| 2. Reference material resources | Significant | ▪ Rapidly available reference materials can decrease the detection time of pathogens.<br>▪ Improvement in quality and accuracy of data/results. |
| 3. Scientific advice to public authorities | *Not relevant* | *Function not directly relevant for more timely and accurate detection of pathogens in the EU.* |
| 4. External Quality Assessments (EQA) | Significant | ▪ State-of-the-art methods disseminated throughout the EU through network-wide EQAs.<br>▪ Improvements in laboratory methods, staff expertise and quality and accuracy of data/results. |
| 5. Training | Significant | ▪ Improvements in laboratory methods, staff expertise and quality and accuracy of data/results. |
| 6. Collaboration and research | Minor | ▪ Research projects directed at improving laboratory capacities/identification of relevant research and investment priorities |
| 7. Monitoring, alert and response | *Not relevant* | *Function not directly relevant for more timely and accurate detection of pathogens in the EU, as it relates mainly to supporting Member States in providing data to EU bodies and provision of technical support in outbreak investigation.* |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for more timely and accurate detection of pathogens in the EU.* |
| Overall participation in network | Indirect | ▪ Through synergies between laboratories and public health institutions, the overall participation of laboratories in the network contributes indirectly to more timely and accurate detection of pathogens. |

*Source: Civic Consulting.*

#### 6.4.2.3 Improved public health surveillance in the EU

As noted above, on average study participants evaluated the impact of the laboratory network on improved public surveillance in the EU quite positively (4.2 of 5). According to study participants, these improvements are primarily the result of the implementation of activities relating to reference diagnostics, reference material resources, EQAs, training and scientific advice to public authorities.

As discussed in Section 6.3, reference diagnostics activities contribute significantly to the improvement of the methods, staff expertise and quality/accuracy of data and results of network members on an individual basis. It also furthers the harmonisation of methods used in the network as a whole. These outcomes increase the comparability of the results reported to public health authorities. Considering that public health surveillance relies on the provision of comparable and accurate data, improvements in this regard are expected to also improve public health surveillance. Hence, reference diagnostics can be considered to contribute significantly, although indirectly, to improved public health surveillance. The same reasoning also applies for reference material resources, EQAs and training.

Furthermore, activities related to scientific advice for public authorities include the provision of expertise on questions related to public health surveillance, for example on the type of data that can be collected or the standardisation of reporting requirements. An example is the outbreak assistance working group set up in the ENIVD network coupled with the round-the-clock availability of experts for the provision of advice for EU institutions such as ECDC, upon request. Another example provided by study participants from EU-RL VTEC network is the PFGE pilot project in which the network participates aiming to test the feasibility of collecting PFGE (pulsed-field gel electrophoresis) typing data from food and animal samples on salmonella, listeria and VTEC at EU level in view of improving public health surveillance through the provision of advice based on more comparable data. A third example is ERLI-Net's support to public health systems through the rapid sharing of viruses and RNA to serve as control materials for the designation of diagnostics during the emergence of H7N9 in 2013. We also conducted an in-silico exercise to evaluate which diagnostic assays could detect the new virus and provided information about how to modify assays that were not suitable. Activities relating to the provision of scientific advice to public authorities of networks can therefore be considered to contribute significantly to the improvement in public health surveillance in the EU.

Moreover, if research and collaboration projects are directed towards issues of public health surveillance, they can contribute to its improvement. An example from the EU-RL VTEC network is the PFGE pilot research project mentioned above, which is coordinated by EFSA. However, considering the time gap until the application of results, the contribution of this function to improved public health surveillance is considered to be minor.

Also, while most activities under the function of monitoring, alert and response relate to contributing to dealing with outbreak situations as opposed to general surveillance, networks also provide assistance to Member States in their reporting duties. An example is networks' developing and encouraging the use of harmonised reporting templates. However, as the significance of the contribution to improved public health surveillance is difficult to assess, it can only reasonably be qualified as indirect.
Finally, again, through synergies between laboratories and public health institutions, the overall participation of laboratories in the network contributes indirectly to improved public health surveillance in the EU.
In conclusion, activities related to reference diagnostics, reference material resources, EQAs, training, scientific advice to public authorities contribute significantly to improved public health surveillance in the EU, while those relating to collaboration and research and monitoring, alert and response may also contribute to a minor or extent or in an indirect manner, respectively.

The table below provides a summary of the assessment.

**Table 110. Contribution of core functions to improved public health surveillance in the EU**

| Core function | Contribution | How function contributes to improved public health surveillance in the EU |
|---|---|---|
| 1. Reference diagnostics | Significant/ indirect | ▪ Improvements in laboratory methods, staff expertise and quality and accuracy of data/results which further the harmonisation of methods used in the network as a whole.<br>▪ These outcomes increase the comparability of the results reported to public health authorities. |
| 2. Reference material resources | Significant/ indirect | *See function 1.* |
| 3. Scientific advice to public authorities | Significant | ▪ Provision of expertise on questions related to public health surveillance, e.g. on the type of data that can be collected or the standardisation of reporting requirements. |
| 4. External Quality Assessments (EQA) | Significant/ indirect | *See function 1.* |
| 5. Training | Significant/ indirect | *See function 1.* |
| 6. Collaboration and research | Minor | ▪ Research projects and collaboration directed towards issues of public health surveillance/identification of relevant research and investment priorities |
| 7. Monitoring, alert and response | Indirect | ▪ Assistance to Member States in their reporting duties, by providing complete and accurate data. |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for improving quality and accuracy of data/results.* |
| Overall participation in network | Indirect | ▪ Through synergies between laboratories and public health institutions, the overall participation of laboratories in the network contributes indirectly to improved public health surveillance in the EU. |

*Source: Civic Consulting.*

#### 6.4.2.4 Reduction in the disease burden in the EU

As noted above, on average study participants evaluated the impact of the laboratory network on the reduction in the disease burden in the EU as having a relatively lower magnitude in comparison to other assessed impacts (3.5 of 5). As suggested previously, this may be related to the difficulty of establishing a direct link between improvements at the level of laboratories (in the short term) and impacts on disease (in the longer term), especially as disease burden can be influenced by a range of factors, many of which are unrelated to the functions and activities of laboratory networks. Some links can nonetheless be drawn in terms of indirect contributions to reduction in the disease burden for specific functions as described in the following.

As discussed in Section 6.3, activities related to reference diagnostics contribute to improving the laboratory methods, staff expertise and quality/accuracy of data and results of network members. Hence, this function contributes to the maintenance of an EU-wide capacity to detect pathogens in a timely and an accurate manner. Early and accurate detection of pathogens can then contribute to the reduction of the burden of disease for which reference diagnostics activities are conducted, by allowing

appropriate treatment to be provided early on such that the spread of infectious diseases can be contained to the minimum possible. In particular, diagnostic confirmation and the continuous typing, subtyping and characterisation of pathogens accelerate these benefits. The same reasoning applies for reference material resources, EQAs and training. However, considering that the links are difficult to measure and uncertain, the significance of the contribution of these activities to reducing the disease burden cannot reasonably be assessed, and can only be qualified as indirect.

Moreover, activities related to monitoring, alert and response are aimed at increasing preparedness to handle outbreak situations. The immediate response to outbreak situations is of great importance in order to limit the economic, social, and public health impacts of an outbreak. Hence, these activities also aim to decrease the burden of disease, but again the contribution of the function to this aim is indirect in nature.

Similarly, the function of scientific advice to public authorities does not directly contribute to the diagnostic capacities of laboratories. However, the advice provided both in an outbreak situation and for the purposes of policy development in general, can be considered to contribute indirectly to a reduction in disease burden.

Collaboration and research activities contribute to the development of a framework for the identification of research priorities as well as facilitate investment decisions, e.g. in relevant diagnostic capacities/capabilities for specific pathogens. However, it is unlikely that such activities directly contribute to a reduction in the disease burden. Therefore, the contribution of this function to a reduction of the disease burden is also qualified as indirect.

Finally, the overall participation of laboratories in the network and the resulting synergies among laboratories and public health institutions are likely to have an indirect positive impact on reduction in the disease burden in the EU.

Furthermore, the governance function only relates to administrative procedures of the network coordination and is therefore not relevant for assessing impacts on the disease burden.

In conclusion, most activities can be considered to contribute in an indirect manner to a reduction of disease burden in the EU, although an assessment of the significance of the contribution is not possible. A reduction of the disease burden can be mainly linked to the other societal benefits assessed, such as better detection of pathogens and increased preparedness.

The table below provides a summary of the assessment.

**Table 111. Contribution of core functions to reduction in the disease burden in the EU**

| Core function | Contribution | How function contributes to reduction in the disease burden in the EU |
|---|---|---|
| 1. Reference diagnostics | Indirect | ▪ Improvements in laboratory methods, staff expertise and quality and accuracy of data/results leading to improvements in detection of pathogens.<br>▪ This allows for increased capacities for detection of pathogens, allowing for the appropriate treatment to be provided early on. |
| 2. Reference material resources | Indirect | *See function 1.* |
| 3. Scientific advice to public authorities | Indirect | ▪ Advice provided both in an outbreak situation and for the purposes of policy development may indirectly contribute to a reduction in disease burden. |
| 4. External Quality Assessments (EQA) | Indirect | *See function 1.* |
| 5. Training | Indirect | *See function 1.* |
| 6. Collaboration and research | Indirect | ▪ Long-term impact through relevant research projects/identification of relevant research and investment priorities |
| 7. Monitoring, alert and response | Indirect | ▪ Increase in capacities for the detection of unusual occurrences and the preparedness to handle outbreak situations. |
| 8. Governance of the network | *Not relevant* | *Function not directly relevant for reduction in disease burden in the EU.* |
| Overall participation in network | Indirect | ▪ Through synergies between laboratories and public health institutions, the overall participation of laboratories in the network contributes indirectly to reduction in disease burden in the EU. |

*Source: Civic Consulting.*

## 6.5 Implications of different coordination options for benefits

In this section we consider the implications of different overall network coordination options for the benefits assessed. We first present the implication of differences at the pan-European level, focusing on the differential impacts of a virtually centralised coordination structure over a physically centralised coordination structure. We then present the same analysis at the supranational level, considering the implications of an additional supranational level vs. no supranational coordination.

### 6.5.1 Physically vs. virtually centralised coordination

This section concerns the implications of a physically vs. virtually centralised coordination structure at the pan-European level. Options I and III of the options for European reference laboratories for human pathogens depict a physically centralised coordination structure at the pan-European level, while Options II and IV depict a virtually centralised coordination structure. See Section 3.1 for more details.

#### 6.5.1.1 Overview

The potential differences in the implementation of activities for different coordination structures at the pan-European level have already been discussed in the context of each function in Section 5 on the cost analysis. The following table provides a summary of these, which for each function indicates the expected implications of a different pan-European coordination structure on the implementation of the activities and the supporting rationale.

### Table 112. Implications of a different pan-European coordination structure

| Core function | Implications of a different pan-European coordination structure | Rationale |
|---|---|---|
| 1. Reference diagnostics | ▪ Implementation of activities is unlikely to differ. | Implementation of activities related to reference diagnostics appears to depend on the distribution of expertise for specific reference methods among network members, rather than the pan-European coordination structure. |
| 2. Reference material resources | ▪ Implementation of activities is unlikely to differ. | Implementation of activities related to reference material resources appears to depend on the number of pathogens covered by the network, rather than the pan-European coordination structure. |
| 3. Scientific advice to public authorities | ▪ Implementation of activities is unlikely to differ. | Implementation of activities related to scientific advice to public authorities appears to depend on the type of activity (e.g. short term or as part of a work package) as well as the distribution of expertise to respond to specific requests among network members, rather than the pan-European coordination structure (although communication with the public authority could always be managed by one laboratory). |
| 4. External Quality Assessments | ▪ Implementation of activities is unlikely to differ. | Implementation of EQAs appears to generally be coordinated by one laboratory, independently of the pan-European coordination structure. |
| 5. Training | ▪ Implementation of activities is unlikely to differ. | Implementation of training activities appears to depend on the distribution of expertise and training capacities among network members, rather than the pan-European coordination structure. |
| 6. Collaboration and research | ▪ Implementation of activities is unlikely to differ. | Implementation of collaboration and research activities does not appear to require any specific coordination. |
| 7. Monitoring, alert and response | ▪ Implementation of activities is unlikely to differ. | Implementation of monitoring, alert and response activities appears to depend on the type of activities conducted, rather than the pan-European coordination structure: technical support in an outbreak situation tends to be implemented by one laboratory; preparedness activities such as the development of protocols are likely to be conducted through working groups of multiple laboratories. |
| 8. Governance of the network | ▪ Implementation of activities may differ. | Implementation of specific activities related to network governance (such as financial administration) appears to depend on the pan-European coordination structure: a single pan-European coordinator is likely to conduct such activities alone; multiple pan-European coordinators are likely to split such activities between themselves (e.g. according to their share of the funding), with one coordinator consolidating all efforts. |
| Overall participation in network | ▪ Potential differences in how network members develop links. | Several pan-European coordinators may more readily facilitate the development of links and synergies among network members than one pan-European coordinator alone. |

*Source: Civic Consulting.*

The following sub-section discusses the implications of physically vs. virtually centralised coordination for the benefits assessed, first the benefits received by network members (monetary[72] and non-monetary), followed by those for society overall.

#### 6.5.1.2 Implications for benefits for network members

The analysis of monetary benefits in Section 6.2 above indicated that benefits for laboratory network members derive from the following four functions that provide a direct service to network members, namely:

- Reference diagnostics;
- Reference material resources;
- EQAs; and
- Training.

Also, as described above in Section 6.3, the improvement in laboratory methods used by network members and their staff expertise derives in particular from the implementation of activities relating to EQAs, training and reference diagnostics. Improvements in quality of data and results similarly also derive mainly from the implementation of activities relating to reference diagnostics, EQAs and training, with activities relating to reference material resources also contributing to this benefit.

As shown in the overview table above, the implementation of activities relating to reference diagnostics, reference material resources, EQAs and training is unlikely to differ depending on the pan-European coordination structure. Moreover, regardless of the overall coordination structure, activities relating to reference material resources and EQAs would generally be coordinated by one laboratory. As the approach to implementation is not likely to differ, the differential benefits derived from the activities (including monetary benefits) are expected to be very minor, if any.

Next, as discussed above, any reputational impact of a network on laboratories can essentially be attributed to their overall participation in the network as a whole. However, for entities outside of the network, the overall coordination structure is irrelevant for the purposes of judging the value of the laboratory, and therefore differences in overall coordination structures are unlikely to play a role in reputational impact of the network. Hence, whether the network is virtually or physically centralised is not expected to substantially change the scale of any reputational benefits achieved, such that any differential benefits are therefore likely to be very minor.

Finally, as mentioned above, improvements in access to information and communication for network members mainly derive from overall participation in the network, as well as training activities. As indicated in the overview table, it could be expected that several pan-European coordinators may more readily facilitate the development of links and synergies among network members than one pan-European coordinator alone, as a certain amount of communication is required for the shared management of the network. Therefore, it is expected that some differential benefits in a virtually centralised network could be achieved, if minor.

[72] For the reasons indicated above (see Section 6.2), the analysis of monetary benefits focuses on network members.

Overall, we therefore conclude that in most cases benefits for network members are unlikely to differ depending on the coordination structure chosen at the pan-European level. The net benefits of a virtually centralised network may be positive but minor, considering potential greater benefits in terms of access to information and communication for network members.

The table below summarises the findings.

**Table 113. Differential benefits of a virtually centralised coordination structure for network members**

| Benefit | Differential benefits | Main sources of benefit | Rationale |
|---|---|---|---|
| *Monetary benefits* | ▪ None to very minor | ▪ Reference diagnostics<br>▪ Reference material resources<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to reference diagnostics, reference material resources, EQAs and training is unlikely to differ depending on the pan-European coordination structure. |
| Improved methods | ▪ None to very minor | ▪ Reference diagnostics<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to reference diagnostics, EQAs and training is unlikely to differ depending on the pan-European coordination structure. |
| Improved staff expertise | ▪ None to very minor | ▪ Reference diagnostics<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to reference diagnostics, EQAs and training is unlikely to differ depending on the pan-European coordination structure. |
| Improved quality of data and results | ▪ None to very minor | ▪ Reference diagnostics<br>▪ Ref. material resources<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to reference diagnostics, EQAs and training is unlikely to differ depending on the pan-European coordination structure. |
| Improved image and reputation | ▪ None | ▪ Overall participation in network | ▪ Participation in the network and related reputational effects are irrelevant to the overall coordination structure. |
| Improved access to information and communication | ▪ Minor | ▪ Overall participation in network<br>▪ Training | ▪ Participation in the network and related communication approaches may benefit from a virtually centralised coordination structure. |

*Source: Civic Consulting.*

#### 6.5.1.3 Implications for benefits for society overall

As discussed above, the contribution of a network to more timely and accurate detection of pathogens in the EU derives from improved staff expertise, laboratory methods, and the quality and accuracy of results, and hence indirectly from the functions of reference diagnostics, reference material resource, EQAs and training. As shown in the overview table above, the implementation approach for all of these activities is unlikely to differ by the pan-European coordination structure of the network. Hence, benefits indirectly derived from these functions are even less likely to differ. It is therefore expected that the differential benefits in terms of detection of pathogens of a virtually centralised network, if any, are likely to be very minor.

Moreover, the contribution of a network to improved public health surveillance in the EU derives directly from improved quality and comparability of data as well as from network members providing scientific advice to public health authorities. The pan-European coordination structure of a network is unlikely to affect the direct benefit of improvements in quality and comparability of data, as mentioned. Moreover, the implementation of activities related to scientific advice to public authorities appears to depend on the distribution of expertise to respond to specific requests among network members, rather than the pan-European coordination structure (although communication with the public authority could always be managed by one laboratory). Therefore, differential benefits of improved public health surveillance in the EU of a virtually centralised coordination structure are likely to be very minor too, if any at all.

Furthermore, laboratory preparedness derives in particular from the direct benefits of improved staff expertise, methods and quality and accuracy of results. As already argued above, these direct benefits are likely to be the same in a physically and a virtually centralised network (if all other things are held constant). Improvements in laboratories' capacity for coordinated response can also be directly related to monitoring, alert and response activities, in particular the preparation of protocols clarifying the approach to handling outbreaks and the allocation of responsibilities in crisis situations, and to scientific advice to public authorities, in particular the collaboration of scientific expertise and public health institutions. The implementation of monitoring, alert and response activities appears to depend on the type of activities conducted, rather than the pan-European coordination structure: technical support in an outbreak situation tends to be implemented by one laboratory; preparedness activities such as the development of protocols are likely to be conducted through working groups of multiple laboratories. Moreover, as discussed above, the implementation of activities relating to provision of scientific advice is unlikely to differ. Hence, overall, the differential benefits, if any, are likely to be very minor.

In addition, also as discussed, the significance of the contribution of the network to the reduction of the disease burden can only be qualified as indirect. A reduction in disease burden is also strongly linked with the other societal benefits assessed, yet as discussed material differences in the extent of these societal benefits by coordination structure are likely to be very minor, if any.

Overall, we conclude that net benefits for society overall of virtually centralised coordination of network would only differ to a very minor extent, if at all, from those that could be achieved with physically centralised coordination.

The table below summarises these findings.

**Table 114. Differential benefits of a virtually centralised coordination structure for society overall**

| Benefit | Differential benefits | Main sources of benefit | Rationale |
|---|---|---|---|
| More timely and accurate detection of pathogens in the EU | ▪ None to very minor | ▪ Improvements in methods, staff expertise and quality of results<br>▪ Overall participation in network | ▪ Improvements in methods, staff expertise and quality of results are likely to be independent of the overall coordination structure. |
| Reduction in the disease burden and related costs in the EU | ▪ None to very minor | ▪ Other societal benefits<br>▪ Overall participation in network | ▪ Reduction of disease burden is indirect and linked to the other societal benefits assessed, yet material differences in the extent of these benefits depending on the overall coordination structure are likely to be very minor, if any. |
| Improved public health surveillance in the EU | ▪ None to very minor | ▪ Scientific advice to public authorities<br>▪ Improvements in quality of results for network members<br>▪ Overall participation in network | ▪ Improved quality of results is likely to be independent of the overall coordination structure.<br>▪ Implementation of activities related to scientific advice to public authorities is unlikely to differ depending on the pan-European coordination structure. |
| Laboratory preparedness and the capacity of coordinated response to outbreaks in the EU | ▪ None to very minor | ▪ Scientific advice to public authorities<br>▪ Monitoring, alert and response<br>▪ Improvements in methods, staff expertise and quality of results<br>▪ Overall participation in network | ▪ Implementation of activities related to scientific advice to public authorities and monitoring, alert and response is unlikely to differ depending on the pan-European coordination structure.<br>▪ Improvements in methods, staff expertise and quality of results are likely to be independent of the overall coordination structure. |

*Source: Civic Consulting.*

### 6.5.2 Additional supranational level vs. no supranational coordination

This section concerns the implications of an additional supranational level in the overall coordination structure, as opposed to no supranational coordination. This relates to the options for European reference laboratories for human pathogens as follows: Options I and II depict a network with a supranational level; Options III and IV depict one without (i.e. only coordination at the pan-European level). See Section 3.1 for more details.

#### 6.5.2.1 Overview

As with the previous section, the following table provides a summary of the relevant differences between a network with a supranational level and one without, indicating the expected implications of the different coordination structure and the supporting rationale for each function. However, while the findings concerning the implications of a virtually centralised coordination structure were based on evidence from the case study networks, the lack of a supranational coordination structure in any of the case study networks prevents a similar analysis concerning the implications of an additional supranational level. Thus, in the table below the focus is instead on whether the supranational level could, in theory, contribute to the coordination of activities relating to specific functions.

**Table 115. Implications of an additional supranational level in the overall coordination structure**

| Core function | Implications of additional supranational level | Rationale |
|---|---|---|
| 1. Reference diagnostics | ▪ Implementation of activities may differ. | Supranational coordinators could get involved in diagnostic confirmation activities. This would shift responsibilities from the pan-European level to the supranational level. |
| 2. Reference material resources | ▪ Implementation of activities is unlikely to differ. | To ensure uniform quality of reference materials across the network, reference material resources are likely to be coordinated by one laboratory for the whole network. |
| 3. Scientific advice to public authorities | ▪ Implementation of activities is unlikely to differ. | Public authorities requesting scientific advice are likely to fist contact the coordinator(s) at the pan-European level, as their main contract partners. If needed, pan-European laboratories could then consult with network members. However, this is more likely to be based upon the expertise of laboratories than their being supranational coordinators. |
| 4. External Quality Assessments (EQA) | ▪ Implementation of activities is unlikely to differ. | To ensure coherence across the network, EQAs are likely to be coordinated by one laboratory for the whole network. |
| 5. Training | ▪ Implementation of activities may differ. | Supranational coordinators could coordinate those training activities that pertain to laboratories in their cluster e.g. training courses for a smaller number of laboratories, twinning arrangements, etc. This would shift responsibilities from the pan-European level to the supranational level. |
| 6. Collaboration and research | ▪ Implementation of activities is unlikely to differ. | Implementation of collaboration and research activities does not appear to require any specific coordination. |
| 7. Monitoring, alert and response | ▪ Implementation of activities is unlikely to differ | While technical support in an outbreak situation tends to be implemented by one laboratory for the whole network, supranational coordinators may get involved in preparedness activities conducted through working groups of multiple laboratories. However, this is more likely to be based upon their expertise than their being supranational coordinators. |
| 8. Governance of the network | ▪ Implementation of activities may differ. | Supranational coordinators are likely to be involved in financial administration of the network, at least in relation to their share of the funding (e.g. reporting on the use of funds). The supranational coordinators are likely to conduct these activities for their respective clusters, with one coordinator on the pan-European level consolidating all efforts. |
| Overall participation in network | ▪ Potential differences in how laboratories develop network links. | Supranational coordinators may more readily facilitate the development of links and synergies among laboratories in their respective clusters. |

*Source: Civic Consulting.*

As with the previous section, the following sub-sections assess the implications of additional supranational level vs. no supranational coordination for the benefits assessed, first the benefits received by network members (monetary and non-monetary), followed by those for society overall.

#### 6.5.2.2 Implications for benefits for network members

The assessment of the potential differential benefits for network members of an additional supranational level follows a very similar argumentation to that for different coordination structures at the pan-European level. It is assumed that a difference in monetary benefits would derive from different outcomes of the underlying activities related to the functions of reference diagnostics, reference material resources, EQAs and training.

Yet, as shown in the overview table above, the implementation of activities relating to reference material resources and EQAs is unlikely to differ by the coordination structure at the supranational level. Moreover, regardless of the overall coordination structure, activities relating to reference material resources and EQAs would generally be coordinated by one laboratory for the whole network. Outcomes of activities relating to reference material resources and EQAs are therefore unlikely to change.

Supranational coordinators could however contribute to activities relating to both reference diagnostics and training: they could get involved in diagnostic confirmation for their cluster (i.e. the group of countries for which they are the coordinator) as well as coordinate those training activities that only pertain to laboratories in their cluster e.g. training courses for a smaller number of laboratories, twinning arrangements, etc. In both cases this would shift responsibilities from the pan-European level to the supranational level. Yet, in both cases the same level of service is being provided to other network members, meaning that the outcomes of these activities are unlikely to differ.

As a result, the differences in benefits (including monetary benefits) arising from the reference diagnostics, reference material resources, EQAs and training functions – i.e. improved methods employed by laboratories, improved staff expertise and improved quality of data and results – between a network with a supranational level and one without are expected to be very minor, if any.

Moreover, concerning improvements to image and reputation, the same argumentation as for the pan-European level can also be applied here: the overall coordination structure is irrelevant for external judgements concerning the value of the laboratory, and therefore differences in coordination structures are unlikely to play a role in reputational impact of the network. Hence, whether the network features a supranational level is not expected to change the scale of any reputational benefits achieved overall.

Finally, an additional supranational level may have implications relating to the overall participation of laboratories in the network and hence an impact on benefits relating to access to information and communication. In particular, supranational coordinators may more readily facilitate the development of links and synergies among laboratories in their respective clusters. More intensive communication between a limited number of cluster members may be possible. Furthermore, a smaller group might encourage less active network members to participate more actively. However, a smaller number of laboratories could also entail less variety in the expertise and capacities to draw from. Furthermore, the focus on clusters might lead to a less direct exchange within

the network as a whole and a decrease in the intensity of the overall communication. Interviewees generally indicated that the net benefit of an additional supranational level would be negative in this regard, since it complicates direct information exchange and communication between all network members. The resulting decrease in network-wide communication is unlikely to be outweighed by more intensive exchange within the network clusters.

Overall, we conclude that net differential benefits for network members of an additional supranational coordination are likely to be negative. However, the size of this impact is expected to be minor.

The table below summarises for non-monetary benefits by benefit type.

**Table 116. Differential benefits of an additional supranational level in the overall coordination structure for network members**

| Benefit | Differential benefits | Main sources of benefit | Rationale |
|---|---|---|---|
| *Monetary benefits* | ▪ None to very minor | ▪ Reference diagnostics<br>▪ Ref. material resources<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to EQAs and reference material resources unlikely to differ due to an additional supranational level.<br>▪ Differences in implementation of reference diagnostics and training activities unlikely to have implications for outcomes of the activities. |
| Improved methods | ▪ None to very minor | ▪ Reference diagnostics<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to EQAs unlikely to differ due to an additional supranational level.<br>▪ Differences in implementation of reference diagnostics and training activities unlikely to have implications for outcomes of the activities. |
| Improved staff expertise | ▪ None to very minor | ▪ Reference diagnostics<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to EQAs unlikely to differ due to an additional supranational level.<br>▪ Differences in implementation of reference diagnostics and training activities unlikely to have implications for outcomes of the activities. |
| Improved quality of data and results | ▪ None to very minor | ▪ Reference diagnostics<br>▪ Ref. material resources<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to EQAs and reference material resources unlikely to differ due to an additional supranational level.<br>▪ Differences in implementation of reference diagnostics and training activities unlikely to have implications for outcomes of the activities. |
| Improved image and reputation | ▪ None | ▪ Overall participation in network | ▪ Participation in the network and related reputational effects are not affected by an additional supranational level. |
| Improved access to information and communication | ▪ Minor | ▪ Overall participation in network<br>▪ Training | ▪ Differences in implementation of training activities unlikely to have implications for outcomes of activities.<br>▪ Potentially more intensive communication in country clusters. However, smaller groups also entail less variety in the expertise and capacities to draw from. The focus on clusters may also lead to a less direct exchange within the whole network. On the whole, the decrease in network-wide communication is unlikely to be outweighed by more intensive exchange within the network clusters. |

*Source: Civic Consulting.*

#### 6.5.2.3 Implications for benefits for society overall

Finally, the assessment of the potential differential benefits for society overall of an additional supranational level follows a very similar argumentation to that for different coordination structures at the pan-European level.

As indicated above, improvements in methods, staff expertise and quality of results – the main drivers of more timely and accurate detection of pathogens, improved health surveillance in the EU, and improved laboratory preparedness and coordinated outbreak response – are likely to be independent of the coordination structure, including at the supranational level.

Furthermore, as shown in the overview table above, the implementation of activities relating to scientific advice to public authorities and monitoring, alert and response are unlikely to differ: while supranational coordinators may be requested to provide advice as well as get involved in preparedness activities conducted through working groups, this is more likely to be based upon their expertise than their being supranational coordinators.

Also as discussed, the significance of the contribution of the network to the reduction of the disease burden can only be qualified as indirect. A reduction in disease burden is also strongly linked with the other societal benefits assessed, yet as discussed material differences in the extent of these societal benefits by overall coordination structure are likely to be very minor, if any.

Overall, we conclude that net benefits for society overall of an additional supranational level would only differ to a very minor extent, if at all, from those that could be achieved without supranational coordination.

The table below summarises these findings.

**Table 117. Differential benefits an additional supranational level in the overall coordination structure for society overall**

| Benefit | Differential benefits | Main sources of benefit | Rationale |
|---|---|---|---|
| More timely and accurate detection of pathogens in the EU | ▪ None to very minor | ▪ Improvements in methods, staff expertise and quality of results | ▪ Improvements in methods, staff expertise and quality of results are likely to be independent of the coordination structure. |
| Reduction in the disease burden and related costs in the EU | ▪ None to very minor | ▪ Other societal benefits<br>▪ Overall participation in network | ▪ Reduction of disease burden is indirect and linked to the other societal benefits assessed, yet material differences in the extent of these benefits depending on the overall coordination structure are likely to be very minor, if any. |
| Improved public health surveillance in the EU | ▪ None to very minor | ▪ Scientific advice to public authorities<br>▪ Improvements in quality of results for network members | ▪ Improved quality of results is likely to be independent of the coordination structure. |
| Laboratory preparedness and the capacity of coordinated response to outbreaks in the EU | ▪ None to very minor | ▪ Scientific advice to public authorities<br>▪ Monitoring, alert and response<br>▪ Improvements in methods, staff expertise and quality of results | ▪ Implementation of activities relating to scientific advice to public authorities and monitoring, alert and response is unlikely to differ due to an additional supranational level.<br>▪ Improvements in methods, staff expertise and quality of results are likely to be independent of the coordination structure. |

*Source: Civic Consulting.*

# 7. Conclusions

*This section summarises the background and objectives of the study and presents its key conclusions. It compares the overall costs and benefits of EU-RL networks as well as costs and benefits for different options for their coordination, and considers the implications for future EU reference laboratories for human pathogens.*

## 7.1 Background and objectives of the study

### 7.1.1 Reference laboratories for human pathogens in the EU

At present, there is no EU-wide system for reference laboratory networks for human pathogens that would harmonise operating standards of microbiological reference laboratories or provide resilience when significant cross-border outbreaks occur. The absence of an EU-wide network system for public health reference laboratories relates to the existing legal framework of the TFEU[73], which specifically excludes any interference in the definition of health policy by the Member States and in their organisation and delivery of health services and medical care. In this respect, the legal situation in the field of public health differs greatly from that for food/feed safety and animal health, where the TFEU grants the EU a strong mandate to act. In both of these areas, an EU-wide reference laboratory network system has been enshrined in Regulation 882/2004, which requires Member States to nominate one or more reference laboratories for a number of food/feed safety and animal health issues. For each of these issues one of the national reference laboratories (NRLs) is contracted to function as an EU reference laboratory (EU-RL), whose tasks include providing the other NRLs with staff training and information on analytical methods, organising proficiency tests and assisting the Commission in technical and scientific questions. [74]

For human pathogens, by contrast, the situation in the EU is currently characterised by NRLs working without formally agreed EU-wide capability or mechanism for rapidly responding in a coordinated manner to new and emerging infectious threats. And while at present there is a large number of microbiology networks, consortia or research groups across the EU - more than 70 according to the 'European system of reference laboratories for human pathogens' (EURLOP) project - these are considered to suffer from a lack of funding. They are also highly diverse in terms of scope, organisation, membership, coordination/governance structure, and activities carried out, as evidenced by the mapping exercise conducted in the framework of this study.

Moreover, the EURLOP project indicated that while national reference laboratory systems in the EU present a number of strengths, weaknesses include competition for funds between diagnostic and reference laboratories in some countries, imbalance in distribution of operational BSL-4 facilities across the EU, imbalance in microbiological expertise between Member States and lack of collaboration between different sectors (human, veterinary, food and water). Significantly, in nine countries only non-formalised ad hoc arrangements were in place for surge capacity/response capability, while in eight countries there appeared to be neither a formal nor an informal deployment policy. A recent assessment of key capabilities and capacities of public health microbiology systems conducted by ECDC furthermore concluded that while the

[73] TFEU – Treaty on the Functioning of the European Union, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN

[74] While some EU-RLs in the field of animal health and food safety also cover human pathogens, their mandate does not extend to the public health field.

EU as a whole has a strong public health microbiology system capability, there are a number of areas where low capacity/capabilities were identified, including provision and regulation of clinical microbiology services; diagnostic testing utilisation; diagnostic testing guidelines and national reference laboratory services relating to molecular typing for surveillance and national outbreak response support.

The Commission's report on the implementation of Decision 1082/2013/EU of the European Parliament and European Council noted that cooperation among the relevant Commission services and collaboration with the Commission agencies and Member States to implement the framework provided by the Decision has worked well since its entry into force.[75] However, it also noted that "a major conclusion from the Ebola outbreak is that there is scope for improving the implementation of provisions whereby Member States are to co-ordinate their national responses". Stronger support to Member States' coordination for preparedness and response to pandemic threats are listed as priorities for DG SANTE in 2016.

The scope for building upon the implementation of Decision 1082/2013/EU and improving the coordination of Member States' responses as well as the existing fragmentation and imbalances in reference laboratory systems in the EU highlighted above bring to the fore the potential for an overarching EU reference laboratory system for human pathogens to improve coordination of laboratory activities in case of response to serious cross-border threats to health as defined in the Decision. The ECDC noted in particular the need to consider the options and feasibility of creating EU reference laboratories or EU reference functions to cover specific issues which are so far partially or not covered at EU level, and for which potential risk of vulnerability has been identified. Such an overarching EU reference laboratory system would also need to be underpinned by adequate and sustainable national reference laboratory infrastructure at the national level, as emphasised by the EURLOP project. The present study, commissioned by the Consumers, Health, Agriculture and Food Executive Agency, explores options for an EU reference laboratory system for human pathogens.

### 7.1.2 Objectives and approach of this study

The purpose of the study is to provide a cost-benefit analysis and analysis of regulatory options to strengthen the existing coordination of reference microbiology provision in the EU in order to support the European response coordination to outbreaks of highly pathogenic infectious agents. It complements the findings of the EURLOP project.

The four coordination options this study considers are adapted from options developed by the EURLOP project, each of which was defined by an overarching 'tier-based' system of reference laboratories as a basis for a European reference laboratory (EU-RL) system: Tier 1 – the pan-European (EU) level, Tier 2 – the 'supra-national' level (i.e. an intermediate level where several selected reference laboratories coordinate activities/provide reference services to NRLs in 'their' cluster of Member States) and Tier 3 – the level of national reference laboratories. In order to clearly distinguish between the different options and allow for a clear delineation of costs and benefits in the analysis, we further characterised these three tiers with a set of consistent assumptions (see Section 3.1.3).

[75] European Commission, COM(2015)617 Final - Report on the Implementation of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on Serious Cross-Border Threats to Health and Repealing Decision No 2119/98/EC, 2015.

We further set the scope for the analysis by identifying the functions and activities of EU-RL networks that are relevant for consideration in the analysis. This meant determining those functions and activities that can be considered to be those that an EU-RL network generally conducts as part of its role. Moreover, only those activities that generate *additional* costs and benefits relative to a situation in which no EU-RL network exists were considered, in order to focus specifically on those costs and benefits generated by EU-RL networks. As part of this task, we identified and characterised eight distinct functions and their respective activities that are specific to EU-RL networks. This was in particular facilitated by a comprehensive mapping of existing reference laboratory networks in the EU, as well as the first expert review meeting.[76]

The table below summarises the functions and activities of EU-RL networks (details are in Section 3.2.3).

[76] Held on 24 April 2015.

**Table 118. Refined core functions and activities of an EU-RL network**

| Function | Activities |
|---|---|
| 1. Reference diagnostics | 1a. Have up-to-date reference methods in operation |
| | 1b. Offer diagnostic confirmation services for laboratories in the network |
| | 1c. Typing, sub-typing, and detailed characterisation of pathogens, including investigating atypical samples |
| 2. Reference material resources | 2a. Develop, maintain and/or have access to relevant source reference materials |
| | 2b. Provide and/or facilitate access to reference material for laboratories in the network |
| 3. Scientific advice for public health authorities | 3a. Provide scientific advice and recommendations to public health authorities, e.g. contributing to risk assessment (i.e. Commission and ECDC, as well as public health authorities of MS affected by outbreak) |
| | 3b. Provide technical support for policy development related to reference microbiology, e.g. vaccine issues, outbreak response management and preparedness planning |
| 4. External Quality Assessments (EQA) | 4a. Organise proficiency tests (inter-laboratory comparison) for laboratories in the network |
| 5. Training | 5a. Undertake training activities for laboratories in the network |
| | 5b. Provide scientific advice to sub-level laboratories |
| 6.Collabo-ration and research | 6a. Participate in regional/international public health microbiology laboratory networks |
| | 6b. Participate in other regionally or internationally relevant projects and initiatives, including research and development activities |
| 7. Monitoring, alert and response | 7a. Supporting Member States in providing data to EU bodies that conduct surveillance tasks or other appropriate bodies |
| | 7b. Provide advice and technical support in outbreak investigations / surge capacity |
| 8. Governance of the network | 8a. Administration and coordination of the network |
| | 8b. Provision of IT-tools, if any |

*Source: Civic Consulting developed on the basis of ECDC (2010), the analysis of existing European laboratory networks and the results of the first expert workshop held in the framework of the study.*

In order to determine the specific costs and benefits by function and activity, we identified a cost framework (a set of key types of costs) and a benefit framework (a set of potential benefits types specific to EU reference laboratory networks). The data collection then focused on these specific costs and benefit types in the context of selected case studies, which each corresponded to an existing EU reference laboratory network. The use of case studies allowed for the costs and benefits of EU reference laboratory networks to be analysed in specific, concrete contexts, while the diversity in their selection allowed for a balanced assessment of the costs and benefits of networks across different types of networks, pathogens, and coordination options. For each case study, we collected data on costs and benefits through interviews with network coordinators, the funding entity, and network members; a survey of national reference laboratories/members of each network; and other complementary research.

We compiled a database bringing together the data collected across all case studies, which we used as basis to establish the overall costs and benefits of the EU-RL networks, as well as analyse the costs and benefits of different coordination options. Finally, we established conclusions concerning overall costs and benefits based on a comparison of the overall annual median costs and benefits of EU-RL networks as well as concerning the implications of changes in coordination structure for these costs and benefits. The following sections present the results of this analysis.

## 7.2 Comparison of overall costs and benefits of reference laboratories for human pathogens

### 7.2.1 Overall costs

The overall annual costs of the case study networks ranged from EUR 486 591 (ERLN-TB) to EUR 1 912 920 (QUANDHIP). On the basis of the reported data we have calculated the overall annual median costs, which amount to EUR 781 091, including budgeted costs, co-financing contributions (where applicable) and additional costs incurred for network activities by network coordinators, funding entities and member laboratories. To analyse typical costs in more detail, the following table presents a breakdown of overall costs by core function and cost item. It is a summary of the annual median costs which were presented in Section 5.

**Table 119. Overview of annual median costs (overall network, in Euro)**

| Cost items | Function 1 - Reference diagnostics | Function 2 - Reference material resources | Function 3 - Scientific advice | Function 4 - EQAs | Function 5 - Training | Function 6 - Collaboration and research | Function 7- Monitoring, alert and response | Function 8 - Governance | Total |
|---|---|---|---|---|---|---|---|---|---|
| Staff costs | 128 943 | 31 580 | 13 441 | 122 832 | 71 664 | 32 166 | 27 415 | 90 113 | 518 153 |
| Equipment | 0 | 1 500 | 0 | 3 893 | 973 | 973 | 0 | 0 | 7 340 |
| Consumables | 40 840 | 30 453 | 0 | 48 083 | 14 134 | 18 663 | 2 393 | 0 | 154 567 |
| Travel | 0 | | 0 | 0 | 24 917 | 3 298 | 0 | 21 185 | 49 400 |
| Shipping | 1 801 | 1 417 | 0 | 10 650 | 0 | 0 | 0 | 0 | 13 868 |
| Subcontracting/services | 0 | | 2 634 | 1 123 | 0 | 0 | 0 | 0 | 3 757 |
| Overhead/administration | 1 191 | 1 664 | 3 209 | 5 710 | 7 336 | 2 604 | 5 113 | 7 180 | 34 006 |
| Total | *172 775* | *66 614* | *19 285* | *192 291* | *119 024* | *57 705* | *34 921* | *118 479* | *781 091* |

*Source: Civic Consulting. Note: Median costs are calculated as the median of case study data for the reference year, excluding FWD-Net and ERLI-TB. Median costs are calculated for each cost item at the level of each network function and tier, and then added up to obtain overall annual median costs (see Section 3 for more details). For most case study networks, the reference year was the year 2014. In other networks, a reporting period of 2 years (2013-2014, for networks ERLI-Net and FWD-Net) or 3.5 years (2011-2015, for QUANDHIP) was used as reference period, and cost estimates were annualised for comparison purposes. For an overview of costs by functions for each case study network separately, refer to Table 96 in Section 5.9.*

As the table above illustrates, the largest share of costs can be attributed to the implementation of EQAs (Function 4) in a network, followed by reference diagnostics (Function 1); the respective costs amount to EUR 192 291 and EUR 172 775 respectively. Training costs (Function 5) and governance costs (Function 8) amount to similar levels, of around EUR 119 000. Reference material resources (Function 2) and collaboration and research (Function 6) each result in costs of around EUR 60 000. The two functions that are least costly are Function 7- Monitoring, alert and response and Function 3 - Scientific advice, for which the respective costs amount to EUR 34 921 and EUR 19 285.

The table above also illustrates that staff costs represent the largest cost item across all core functions. Consumables costs are also significant; they were reported for six out of the eight core functions and constitute the second largest cost item for most functions. Equipment costs were reported for four out of the eight core functions. Both shipping costs and travel costs were reported for three of the eight core functions. Subcontracting costs were estimated only for two core functions and are of a considerably small size. Finally, overhead and administration costs of a broadly similar range were reported for all core functions.

To summarise, the table above indicates that the implementation of four core functions, namely EQAs, reference diagnostics, governance and training, each lead to costs of between approximately EUR 115 000 and EUR 190 000. In comparison, the other four core functions, (i.e. reference material resources, collaboration and research, monitoring, alert and response, and scientific advice) each result in costs of less than EUR 70 000. These cost differences are indicative of the relative importance of the core functions for a network. Indeed, interviewees of case study networks repeatedly emphasised that EQAs and training are the two most important functions of their networks. Furthermore, they indicated that the harmonisation of reference diagnostic methods, diagnostic confirmation, and the continuous characterisation, typing and subtyping of pathogens constitute core tasks of networks, in particular for those networks in which network members each focus on different pathogens. Overall, therefore, networks spend a considerable amount of resources on the provision of key services and assistance to network members.

The following table presents the costs of network functions in relative terms, i.e. as their share in overall network costs. It also reveals the allocation of costs among Tier 1 (i.e. the sum of budgeted costs and additional costs of pan-European coordinators), Tier 3 (i.e. additional costs of national member laboratories) and the funding entity (i.e. additional costs of the funding entity). None of the case study networks featured a ‘supra-national’ level (Tier 2), i.e. in none of the networks selected reference laboratories coordinated NRLs in distinct country clusters in addition to the pan-European coordination. This tier is therefore not listed in the table.

**Table 120. Overview of median costs as share of overall network costs**

| Core function | Tier 1 - Coordinators | Tier 3 - Members | Funding entity | Total |
|---|---|---|---|---|
| Function 1 - Reference diagnostics | 9.9% | 12.2% | 0.0% | 22.1% |
| Function 2 - Reference material resources | 7.2% | 1.4% | 0.0% | 8.6% |
| Function 3 - Scientific advice to public authorities | 2.5% | 0.0% | 0.0% | 2.5% |
| Function 4 - EQAs | 13.4% | 11.3% | 0.0% | 24.7% |
| Function 5 - Training | 13.2% | 2.0% | 0.0% | 15.2% |
| Function 6 - Collaboration and research | 6.5% | 0.9% | 0.0% | 7.4% |
| Function 7- Monitoring, alert and response | 2.5% | 1.9% | 0.0% | 4.4% |
| Function 8 - Governance | 12.1% | 0.0% | 3.1% | 15.2% |
| Total (in Euro) | *67.3%* | *29.7%* | *3.1%* | *100%* |

*Source: Civic Consulting. Note: Median costs are calculated as the median of case study data, excluding FWD-Net and ERLI-TB.*

The table above again illustrates that EQAs and reference diagnostics are the two functions to which the largest shares of costs are attributed, namely 24.7% and 22.1% respectively. It also shows that the costs of these functions are almost equally split between Tier 1 and Tier 3, i.e. between coordinators and network members. For EQAs, the costs for network members relate in particular to the costs of assessing the EQA samples. For reference diagnostics, network members incur costs mainly as a result of diagnostic confirmation. Particularly in those networks that cover multiple pathogens, network members rely on each other's expertise for the diagnostic confirmation of samples.

Governance and training costs respectively constitute the third and fourth largest shares of overall network costs, each amounting to about 15%. However, these are mainly covered by Tier 1, i.e. by the network budget plus any additional costs borne by coordinators. For governance, only a small share of costs is incurred by the funding entity; these mainly relate to administration and project management costs. For training, a small share of costs is incurred by network members, relating to their staff time spent in training courses, for example. Costs of reference material resources, collaboration and research, and scientific advice to public authorities are also mainly covered by Tier 1. The costs of monitoring, alert and response, which make up only 4.5% of the overall network costs, are almost equally covered by Tier 1 and Tier 3.

To summarise, the largest share of annual median costs (67.3%) is covered in the reference year by Tier 1, i.e. by the network budget plus additional costs of coordinators. Tier 3, the network members, covers 29.7% of the overall network costs. The funding entity covers the smallest share of the overall network costs, namely 3.1%.[77]

[77] The funding entity also provides the network budget. For the purposes of this study, the network budget was, however, allocated to Tier I, considering that in the case study networks this tier spends the funds on the implementation of activities (Tier II corresponding to a supranational level does not feature in any of the case study networks).

### 7.2.2 Overall benefits

In the context of this study we differentiate between monetary and non-monetary benefits of European reference laboratory networks, from the perspective of both members of the networks themselves and society as a whole.

#### 7.2.2.1 Benefits for network members

*Monetary benefits*

The total monetary benefits resulting from the case study networks ranged from EUR 13 217 (FWD-Net) to EUR 220 949 (ENIVD). These amounts include only the monetary benefits of laboratories participating in the network.

For further analysis, we have calculated the annual median monetary benefits generated by function on the basis of the reported data of case study networks (which only considers monetary benefits for network members in the reference year). The following table presents these estimated median benefits.

**Table 121. Annual median monetary benefits (in Euro)**

| Monetary benefits related to … | Median benefits | Share (of total monetary benefits) |
|---|---|---|
| Reference diagnostics | 6 709 | 12% |
| Reference material resources | 12 853 | 22% |
| EQAs | 27 746 | 48% |
| Training | 10 253 | 18% |
| Total | *57 560* | *100%* |

*Source: Civic Consulting. Note: Median benefits are calculated as the median of case study data, excluding FWD-Net and ERLI-TB. For discussion of total network benefits, see Section 7.2.2*

As the table above illustrates, the estimation of median benefits is based on all four core functions providing a direct service to network members. Monetary benefits derived from participation in EQAs are the highest in the reference year, amounting to EUR 27 746, or a share of 48% in total monetary benefits of network members. This relates to the fact that network members receive this service free of charge. Indeed, participating in commercial EQAs of such complexity is likely to be expensive, if commercial EQAs are available at all. Training and reference material resources are each the source of approximately one fifth of the monetary benefits of network members, amounting to EUR 10 253 and EUR 12 853 respectively. These relate to savings made from training activities that would anyhow need to be conducted, or the reference materials received free of charge which would otherwise need to have been purchased. Finally, monetary median benefits resulting from reference diagnostics amount to EUR 6 709.

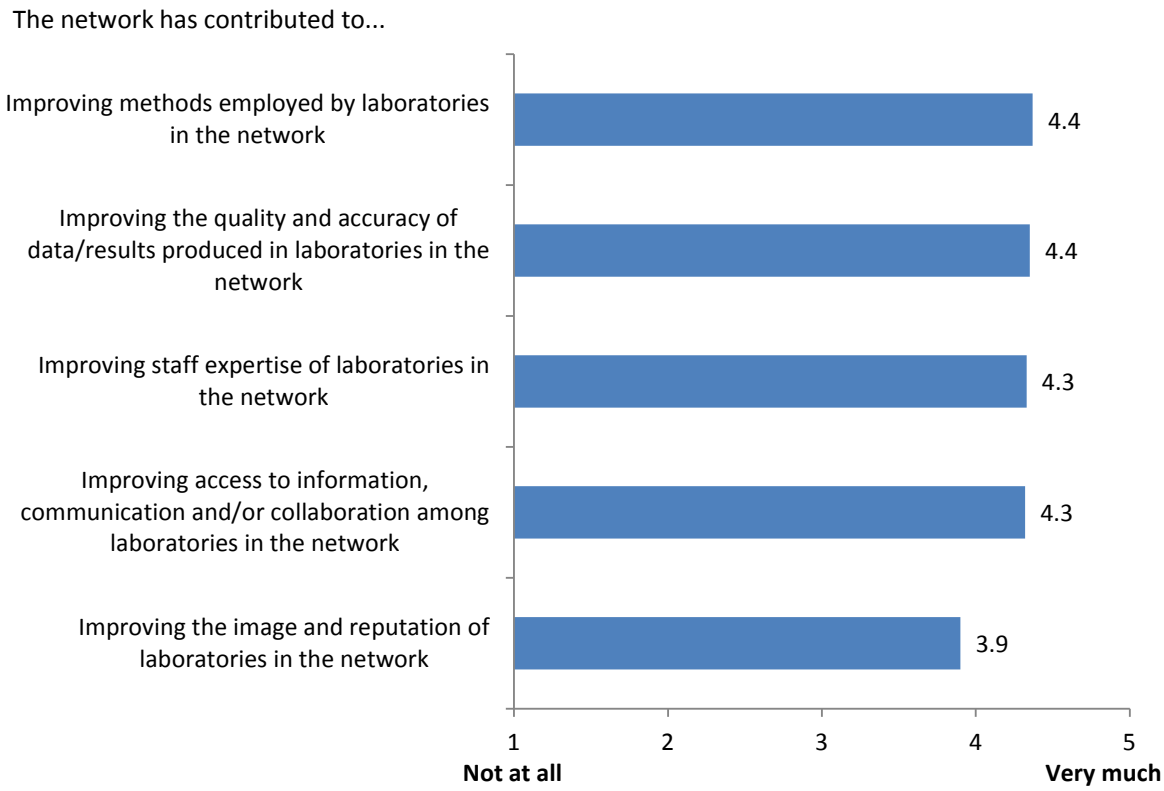
*Non-monetary benefits*

The non-monetary benefits for network members assessed in the study are as follows:

- Improvement in methods employed by laboratories in the network;
- Improvements in staff expertise of laboratories in the network;
- Improvement in quality and accuracy of data/results produced in laboratories in the network;
- Improvement in image or reputation of the laboratories in the network;
- Improvement in access to information, communication and/or collaboration among laboratories in the network.

Overall, study participants evaluated the above-mentioned non-monetary benefits for network members very positively. On a scale from 1 (not at all) to 5 (very much), all benefits were rated above 3 points (where 3 can be considered a neutral rating). The following figure presents the average rating of benefits for network members.

**Figure 15. Assessment of non-monetary benefits for network members**




*Source: Civic Consulting, based on assessments of funding entities, network coordinators and network members. Non-monetary benefits were rated on a scale from 1 (not at all) to 5 (very much). Average ratings are shown in the figure.*

As the figure above illustrates, four out of the five types of benefits are assessed very similarly, receiving scores between 4.3 and 4.4. Only the contribution of the network to improving the image and reputation of laboratories was evaluated with a slightly lower average score (3.9).

The table below provides an overview of the contributions of each of the core network functions to the non-monetary benefits assessed, in combination with the scale-based assessment of the overall contribution of the network. The final column presents a synthesis of the non-monetary benefits for each function, based on the highest assessment provided for any of the non-monetary benefits.

**Table 122. Overview of contributions of core network functions to non-monetary benefits for network members assessed**

| Core function | Contribution to… | | | | | Synthesis of non-monetary benefits for network members |
|---|---|---|---|---|---|---|
| | Improvement in methods employed by laboratories in the network | Improved quality and accuracy of data/results produced by laboratories in the network | Improved staff expertise of laboratories in the network | Improving access to information, communication and collaboration | Improved image and reputation of laboratories in the network | |
| Assessment of overall network contribution | 4.4 | 4.4 | 4.3 | 4.3 | 3.9 | 4.3* |
| 1. Reference diagnostics | Significant | Significant | Minor-significant | Minor-significant | *Not relevant* | Significant |
| 2. Reference material resources | Minor | Very significant | Very minor | Minor | *Not relevant* | Very significant |
| 3. Scientific advice to public authorities | None | *Not relevant* | *Not relevant* | *Not relevant* | Minor | Minor |
| 4. External Quality Assessments (EQA) | Very significant | Very significant | Very significant | *Not relevant* | Minor | Very significant |
| 5. Training | Very significant | Significant | Very significant | Significant | Very minor | Very significant |
| 6. Collaboration and research | Minor | Minor-significant | Minor | Minor | Minor | Minor |
| 7. Monitoring, alert and response | *Not relevant* | *Not relevant* | Minor | *Not relevant* | *Not relevant* | Minor |
| 8. Governance of the network | *Not relevant* | *Not relevant* | *Not relevant* | *Not relevant* | *Not relevant* | *Not relevant* |
| Overall network participation | *Not relevant* | *Not relevant* | *Not relevant* | Significant | Minor - significant | Significant |

*Source: Civic Consulting. * Refers to average of assessments across types of non-monetary benefits*

Looking at individual non-monetary benefit types, we see that the scale-assessments of the overall network's contribution are broadly reflected in the qualitative assessments. For each of the benefit types receiving a score above 4 – except for improving access to communication, information and collaboration – there is at least one function identified as providing a 'very significant' contribution.

Looking at individual functions, we note that the functions contribute to varying extents to the total non-monetary benefits for network members, on the basis of the synthesis. Activities related to EQAs, training, and reference material resources can be considered to benefit network members most, with assessments of 'very significant'. As indicated above, these assessments are also supported by the data on monetary benefits. Activities relating to reference diagnostics can be considered to contribute to a significant extent to non-monetary benefits, which is also mirrored by the median monetary benefits for network members for this function. In contrast, network activities relating to scientific advice to public authorities, collaboration and research, and monitoring, alert and response are considered to contribute to a minor extent to non-monetary benefits, which is again supported by the absence of reported monetary benefits for these functions. The governance function of the network is furthermore not considered to be relevant for benefits for network members.

The functions assessed as providing an overall very significant or significant contribution to benefits for network members are instrumental in relation to specific benefit types. In particular EQAs, training, reference material resources and reference diagnostics activities are of significant importance for improvements in methods employed by laboratories, improved staff expertise of laboratories, and improved quality and accuracy of data/results produced by laboratories in the network. In contrast, improvements in access to information, communication and collaboration as well as image and reputation of laboratories can instead be linked to the overall participation of laboratories in the network.

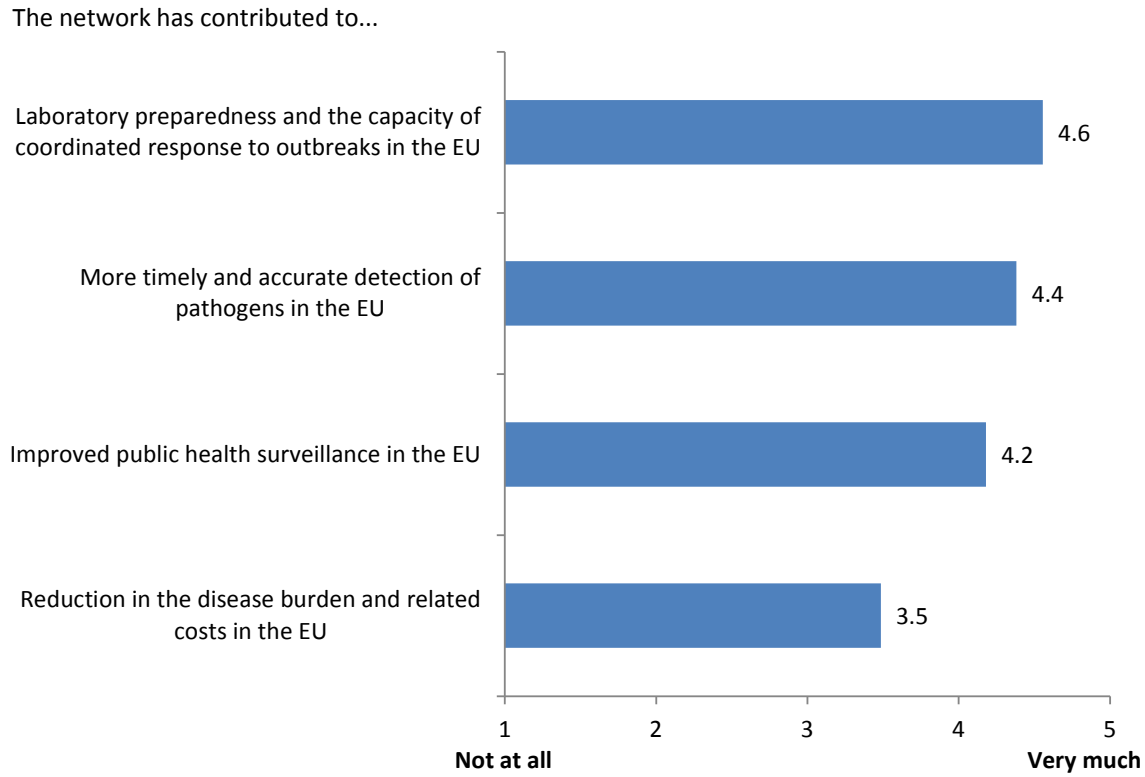
#### 7.2.2.2 Benefits for society overall

The non-monetary benefits for society overall in the EU assessed in the study are as follows:

- More timely and accurate detection of pathogens in the EU;
- Reduction in the disease burden and related costs in the EU;
- Improved public health surveillance in the EU;
- Improved laboratory preparedness and the capacity of coordinated response to outbreaks in the EU.

Overall, study participants evaluated non-monetary benefits for society overall in the EU very positively. On a scale from 1 (not at all) to 5 (very much), all benefits were rated above 3 (where 3 can be considered a neutral rating). The following figure presents the average rating of benefits for society overall.

**Figure 16. Assessment of non-monetary benefits for society overall**




*Source: Civic Consulting, based on assessments of funding entities, network coordinators and network members. Non-monetary benefits were rated on a scale from 1 (not at all) to 5 (very much). Presented are average results.*

As the figure above illustrates, three of the four benefits are assessed fairly similarly, receiving scores between 4.2 and 4.6. Only the reduction in the disease burden and related costs in the EU was evaluated with a substantially lower average score (3.5).

As with the non-monetary benefits for network members, the table below provides an overview of the contributions of each of the core network functions to the non-monetary benefits for society overall assessed, in combination with the scale-based assessment of the overall contribution of the network. The final column presents a synthesis of the non-monetary benefits for society overall for each function, based on the highest assessment provided for any of the non-monetary benefits.

**Table 123. Overview of contributions of core network functions to non-monetary benefits for society overall assessed**

| Core function | Contribution to… | | | | Synthesis of non-monetary benefits for society overall |
|---|---|---|---|---|---|
| | Increased laboratory preparedness and capacity of coordinated outbreaks response to in the EU | More timely and accurate detection of pathogens | Improved public health surveillance in the EU | Reduction in the disease burden in the EU | |
| Overall assessment of study participants | 4.6 | 4.4 | 4.2 | 3.5 | 4.2* |
| 1. Reference diagnostics | Significant/indirect | Significant | Significant/indirect | Indirect | Significant (partly indirect) |
| 2. Reference material resources | Significant/indirect | Significant | Significant/indirect | Indirect | Significant (partly indirect) |
| 3. Scientific advice to public authorities | Significant | *Not relevant* | Significant | Indirect | Significant (partly indirect) |
| 4. External Quality Assessments (EQA) | Significant/indirect | Significant | Significant/indirect | Indirect | Significant (partly indirect) |
| 5. Training | Significant/indirect | Significant | Significant/indirect | Indirect | Significant (partly indirect) |
| 6. Collaboration and research | Minor | Minor | Minor | Indirect | Minor (partly indirect) |
| 7. Monitoring, alert and response | Significant | *Not relevant* | Indirect | Indirect | Significant (partly indirect) |
| 8. Governance of the network | *Not relevant* | *Not relevant* | *Not relevant* | *Not relevant* | *Not relevant* |
| Overall network participation | Indirect | Indirect | Indirect | Indirect | Indirect |

*Source: Civic Consulting. * Refers to average of assessments across types of non-monetary benefits.*

Looking at individual benefit types, we again see that the scale-assessments of the overall network's contribution are broadly reflected in the qualitative assessments. For each of the benefit types receiving a score above 4 there is at least one function identified as providing a 'significant' contribution.

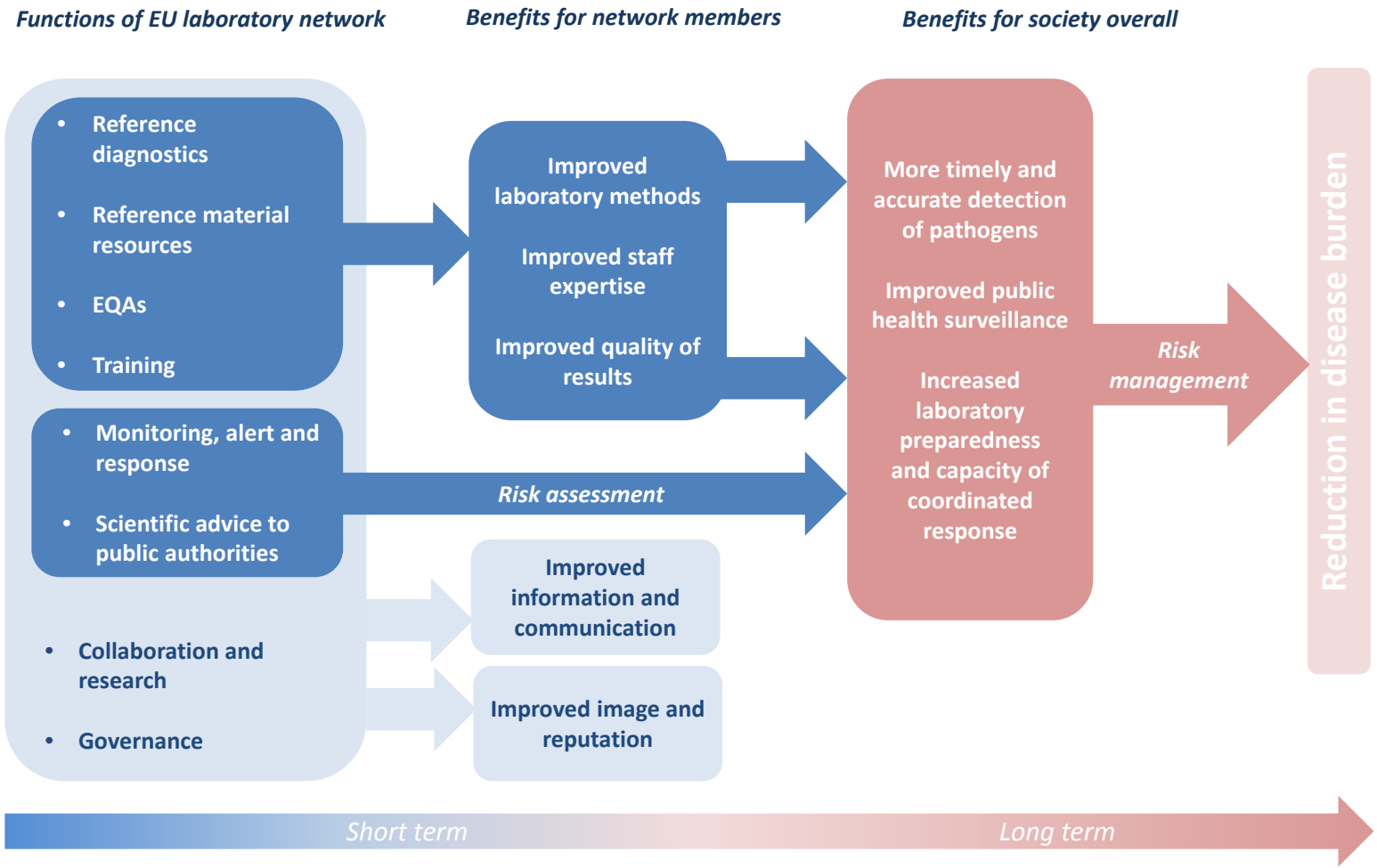
Looking at individual functions, we note that functions contribute to varying extents to non-monetary benefits for society, on the basis of the synthesis. Activities related to scientific advice to public authorities and monitoring, alert and response can be considered to benefit society to a 'significant' extent. Activities relating to reference diagnostics, reference material resources, EQAs and training also contribute to a significant extent to societal benefits, although mainly in an indirect manner. The rationale is that these functions primarily directly benefit network members themselves, as discussed above, in terms of improvements in laboratory methods, staff expertise and quality of data/results, which in turn contribute to the societal benefits assessed. In contrast, network activities relating to collaboration and research are considered to contribute to a minor extent to non-monetary societal benefits. The governance function of the network is furthermore not considered to be relevant for societal benefits. Moreover, the contribution of the overall network participation of laboratories, while potentially also important to societal benefits through relevant synergies among laboratories and public health institutions, is assessed as 'indirect'.

The functions assessed as providing a (direct) significant contribution to societal benefits – scientific advice to public authorities and monitoring, alert and response – are mainly relevant in terms of improvements to laboratory preparedness/capacity of coordinated response to outbreaks and improved public health surveillance in the EU. The functions with a relatively more direct focus on network members – reference diagnostics, reference material resources, EQAs and training – while contributing to these benefits as well indirectly, also contribute to improvements in the time and accuracy of detection of pathogens.

Finally, due to the difficulty of establishing a direct link between improvements at the level of laboratories (in the short term) and impacts on disease (in the longer term), especially as disease burden can be influenced by a range of factors, many of which are unrelated to the functions and activities of laboratory networks, the contribution of the network to a potential reduction in the disease burden is also assessed as indirect.

The following diagram specifies the main links between the core functions/overall network, the benefits for network members (short term), and those for society overall (long term). Moreover, it identifies the role of EU-RL networks in contributing to risk assessment in a societal perspective, as well as the risk management role of public authorities in contributing to a reduction in disease burden.

**Figure 17. Non-monetary benefits of EU-RL network functions for network members and society overall**




*Source: Civic Consulting.*

### 7.2.3 Comparison of overall costs and benefits

In this section, we bring together the data presented in the previous sections on overall costs and benefits for a comparison, both at the level of network members and society overall. For consistency, we keep the perspectives separate: costs for network members are compared with benefits for network members, and the remaining costs of networks – costs for the coordinator and the funding entity – are compared with benefits for society overall.

*Comparison of costs and benefits for network members*

The table below allows for annual median costs for network members (Tier 3) and the monetary benefits for network members in the same period to be compared.

**Table 124. Comparison of annual median costs and monetary benefits for network members**

| Core function | Median costs for network members | Median monetary benefits for network members | Synthesis of non-monetary benefits for network members |
|---|---|---|---|
| Function 1 - Reference diagnostics | 95 309 | 6 709 | Significant |
| Function 2 - Reference material resources | 15 805 | 12 853 | Very significant |
| Function 3 - Scientific advice to public authorities | n.a. | n.a. | Minor |
| Function 4 - EQAs | 94 064 | 27 746 | Very significant |
| Function 5 - Training | 16 706 | 10 253 | Very significant |
| Function 6 - Collaboration and research | 3 787 | 0 | Minor |
| Function 7- Monitoring, alert and response | 8 985 | 0 | Minor |
| Function 8 - Governance | n.a. | n.a. | *Not relevant* |
| Overall participation in network | n.a. | n.a. | Significant |
| Total (in Euro) | *234 656* | *57 560* | n.a. |

*Source: Civic Consulting. Note: Median costs and monetary benefits are calculated as the sum of the median costs and benefits for the coordinators, funding entity and network members of case study networks, excluding FWD-Net and ERLTB-Net.*

The first point of comparison is the median costs of each function against their respective reported monetary benefits. As shown, in all cases, the costs incurred by network members outweigh the monetary benefits. Moreover, the total costs for network members outweigh the monetary benefits by EUR 177 096. However, in some cases the relative difference is small: the monetary benefits of training activities for

network members cover approximately two thirds of the costs, while those for reference material resources cover over 80% of the costs.

Another observation is that for some functions, the median costs tend to mirror the amounts/significance of the monetary and non-monetary benefits for network members. EQAs and reference diagnostics are by far the most costly functions for network members; this is mirrored by significant or very significant contributions to non-monetary benefits for network members, and, particularly in the case of EQAs, substantial monetary benefits. On the other hand, scientific advice to public authorities, collaboration and research and monitoring, alert and response entail much lower (or zero) costs for network members; and their contributions to benefits for network members are assessed as minor.

However, other functions do not bear the same relationship. Training activities and activities relating to reference material resources implemented by the network lead to significantly lower costs than EQAs and reference diagnostics activities for network members, yet can be considered to induce very significant benefits and sizeable monetary benefits. And overall participation in the network involves no material costs for network members, yet leads to significant non-monetary benefits.

Accordingly, functions entailing comparatively more significant costs are matched with significant benefits for network members, while those that are comparatively less costly are matched with *either* minor *or* very significant benefits for network members (i.e. in the case of reference material resources and training). This finding therefore supports the notion that the significance of the non-monetary benefits for network members tends to in principle at least be in line with the costs involved.

Some further insights can be yielded by looking at the laboratory/Member State level. Based on the case study networks, we can consider that a typical network might comprise about 30 laboratories. Dividing the total amount of costs for network members by this number, we arrive at a cost of EUR 7 822 per laboratory. The same calculation leads to EUR 1 919 in monetary benefits per laboratory. As a result, each laboratory bears a net monetary cost of EUR 5 903.

By their very nature, it is not possible to quantitatively value the non-monetary benefits. However, considering that the significance of the non-monetary benefits for network members tends to be at least in line with the costs involved for each function, it is likely that they make up for the remaining EUR 5 903 net costs involved to a large extent. On top of this, as mentioned above, a significant non-monetary benefit is achieved through the laboratory's overall participation in the network.

Additional evidence from the survey also supports this assertion. Network members participating in the survey were asked to assess the extent to which 'the benefits of the laboratory network outweigh the costs of implementing network activities' on a scale of 1 (not at all) to 5 (very much). The average assessment provided was 4.6, which would indicate that benefits are considered to outweigh the costs to a large extent.

We therefore conclude that on balance, benefits induced for network member laboratories are likely to outweigh the costs they incur for the implementation of the network activities.

*Comparison of costs and benefits for society overall*

The table below presents an overview of annual median costs for coordinators and the funding entity of a network in the reference year combined, compared with the overall contribution of network functions to benefits for society overall, by function.

**Table 125. Comparison of annual median costs for coordinators and funding entity and benefits for society overall**

| Core function | Median costs for coordinators and funding entity | Synthesis of non-monetary benefits for society overall |
|---|---|---|
| Function 1 - Reference diagnostics | 77 466 | Significant/indirect |
| Function 2 - Reference material resources | 55 421 | Significant/indirect |
| Function 3 - Scientific advice to public authorities | 40 354 | Significant |
| Function 4 - EQAs | 92 564 | Significant/indirect |
| Function 5 - Training | 103 278 | Significant/indirect |
| Function 6 - Collaboration and research | 29 002 | Minor |
| Function 7- Monitoring, alert and response | 30 004 | Significant |
| Function 8 - Governance | 95 546 | *Not relevant* |
| Overall participation in network | n.a. | Indirect |
| Total (in Euro) | *523 635* | n.a. |

*Source: Civic Consulting. Note: Median costs are calculated as the median of case study data, excluding FWD-Net and ERLI-TB.*

As with benefits for network members, the costs of the relatively more expensive functions tend to mirror the assessments for the societal benefits. Specifically, reference diagnostics, reference material resources, EQAs and training are each considered to contribute significantly, in an indirect manner, to societal benefits. Collaboration and research, a less costly function, is similarly matched by a minor assessment for its beneficial societal impacts.

In contrast, activities relating to monitoring, alert and response, and scientific advice to public authorities have median costs within the range of those for collaboration and research, but confer significant benefits from a societal perspective.

In this respect, a similar picture from the comparison of costs with benefits for network members appears: functions entailing comparatively more significant costs are matched with significant benefits for society (be they in an indirect manner), while those that are comparatively less costly are matched with *either* minor *or* significant benefits for society. This finding therefore supports the notion that the significance of the non-monetary benefits for society overall tends to at least be in line with the costs involved for coordinators and funding entities.

As with the non-monetary benefits for network members, by their very nature it is not possible to quantitatively value the non-monetary benefits for society. Nonetheless,

the nature of those non-monetary benefits which were very positively assessed by study participants provides some indications of their potential value. As indicated above, these included first and foremost improvements in the preparedness of network laboratories and the capacity of coordinated response to outbreaks in the EU. To a potentially lesser but nonetheless significant extent, the case study networks were also found to contribute to improvements in the detection of pathogens and public health surveillance overall in the EU.

As mentioned above, it is difficult to establish a direct link between the networks' activities and a reduction in the burden of disease and related costs, as these are influenced by a range of factors, many of which are unrelated to the functions and activities of laboratory networks. Nonetheless, improvements in preparedness, outbreak response, pathogen detection and surveillance are expected to contribute to this end at least to some extent. The occurrence and severity of outbreaks varies from one disease to another, but their impacts on society can be devastating, both in terms of human life and economic losses. And while the methodologies applied in cost-of-illness or burden-of-disease studies vary, they typically provide estimates in the range of billions of Euro per year for key pathogens.[78] Moreover, the value of a human life has been estimated to be in the order of millions of Euro,[79] with quality-adjusted life years valued in the tens of thousands of Euro.[80]

To further put the societal costs and benefits of EU-RL networks in perspective, the box below presents an overview of the results of recent studies that provide estimates of benefits of disease surveillance systems in terms of impacts on cases of diseases.

[78] E.g. Direct influenza-associated health care costs for Europe have been estimated at more than EUR 50 million per million of population per year (i.e. for the whole of Europe roughly EUR 2.5 billion per year); see COM (2009) 353 final/2.
[79] See e.g. OECD, The value of statistical life: a meta-analysis, 2012.
[80] See e.g. the FP6 research project 'European Value of a Quality Adjusted Life Year'.

**Societal benefits of diseases surveillance systems: two examples**

*An Economic Evaluation of PulseNet - A Network for Foodborne Disease Surveillance (Scharff et al., 2015)*

The PulseNet surveillance system is a molecular subtyping network of public health and food regulatory agency laboratories in the United States designed to identify and facilitate investigation of foodborne illness outbreaks. This study estimated the health and economic impacts associated with PulseNet. Conservatively, accounting for underreporting and underdiagnosis, 266,522 cases of illness from Salmonella, 9,489 cases of illness from Escherichia coli (E. coli), and 56 cases of illness due to Listeria monocytogenes were avoided annually, according to the study. This was estimated to have reduced medical and productivity costs by USD 507 million. Additionally, direct effects from improved recalls reduced cases of illness from E. coli by 2,819 and Salmonella by 16,994, were estimated to have led to USD 37 million in costs averted. Annual costs to public health agencies were USD 7.3 million. The study concluded that the health and economic benefits from PulseNet and the foodborne disease surveillance system are substantial.

*Costs and benefits of a subtype-specific surveillance system for identifying Escherichia coli O157:H7 outbreaks (Elbasha et al., 2000)*

The purpose of this study was to assess the economic feasibility (from a societal perspective) of implementing a subtype-specific surveillance system for identifying outbreak-associated Escherichia coli (E. coli) O157:H7 infections. The study carried out this assessment based on data from Colorado, where such a surveillance system was already in place. The study found that if 15 cases of illness of E. coli were averted by the recall of the 25 million pounds of potentially contaminated beef, the Colorado system would have recovered all costs for the 5 years of start-up and operation by detecting a single outbreak. As a comparison, the outbreak-related 1993 recall of 255,000 regular (0.1-lb) hamburgers in Washington State was estimated to have prevented 800 cases of illness. The study concluded that from a societal perspective, a surveillance system does not need to prevent a large number of cases to yield return on the resources invested in it.

Hence, at EUR 523 635 in the reference year, the median costs for coordinators and the funding entity (and thus the cost for EU taxpayers) of running a European reference laboratory network for human pathogens appear well within the range of what could be considered reasonable in order to achieve the abovementioned benefits for society, even if the link between improvements at the level of reference laboratories and reduction in the disease burden and related costs is indirect.

## 7.3 Comparison of costs and benefits of different coordination options

### 7.3.1 Costs of different coordination options

As described before in detail (see Section 3.1.1), the EURLOP study proposed a ‘tier-based’ system of reference laboratories as a basis for a European reference laboratory system: the pan-European, ‘supra-national’ and national level reference laboratories. The following table presents the definition of these tiers as presented by the EURLOP study and adapted for the present study.

**Table 126. Adapted definition of tiers for EU-wide reference laboratories for human pathogens according to EURLOP study**

| Tier | Level | Activities commissioned by | Main role |
|---|---|---|---|
| Tier 1 | *Pan-European (EU-RL)* | EU | Coordinate activities and provide advanced reference services to the entire EU; provide expert advice to EU |
| Tier 2 | *Supra-national (SNRL)* | EU | Coordinate activities and provide advanced reference services to a cluster of Member States. |
| Tier 3 | *National (NRL)* | Governance remains with the existing MS management and arrangements, without substantial involvement of the EU-RL. | Provide reference services nationally |

*Source: Based on EU Human Pathogen Reference Laboratories Options Project (EURLOP), adapted by Civic Consulting.*

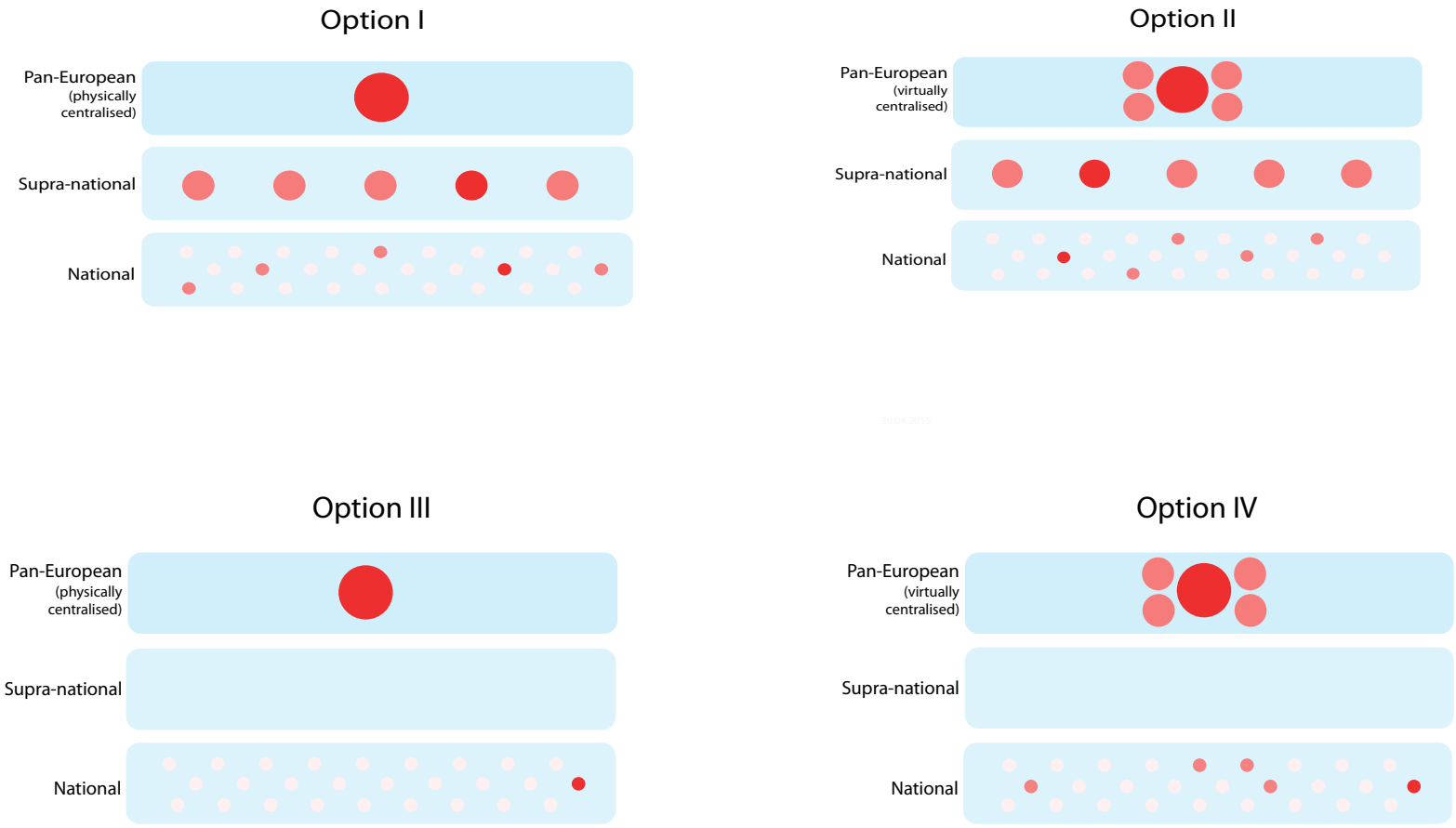
As noted in the table above, while overall coordination is done at the pan-European (EU) level, at the 'supra-national' level several selected reference laboratories would in addition coordinate activities/provide reference services to NRLs in 'their' cluster of Member States.

Based on the EURLOP study, and refined and adapted on basis of our research and the results of the first expert workshop that took place in the framework of this study, four options for network coordination were considered in this study. The options differ according to the following characteristics:

- Whether a three-tiered approach (Tiers 1, 2 and 3) or two-tiered approach (Tiers 1 and 3) is chosen;
- Whether the provision of Tier 1 functions is "physically centralised" (one laboratory) or "virtually centralised" (several laboratories sharing Tier 1 functions).

The following page repeats the graphical presentation of all four options (I to IV).

**Figure 18. Options for European reference laboratories for human pathogens**




*Source: Civic Consulting, partly based on the EU Human Pathogen Reference Laboratories Options Project.*

#### 7.3.1.1 Physically vs. virtually centralised network

Differential costs between a physically centralised and a virtually centralised network have been assessed by function on the basis of the data from the case study networks (see Section 5).

The analysis showed that notable differential costs between a physically centralised network and a virtually centralised network might only arise in the implementation of Function 8 – Governance. This is because the financial and organisational administration required in a virtually centralised network is likely to be more significant in terms of the inputs, and hence in terms of cost. Staff costs in particular could potentially see a significant increase compared to a physically centralised network, as a result of the additional time used by co-coordinators to administer their funds and to report on related activities as well as the additional coordination efforts the lead coordinator has to undertake in order to disburse funds and consolidate the reporting. Travel cost could increase with the number of coordinators i.e. in a virtually centralised network. This however depends on the approach to collaboration of network coordinators and whether they conduct meetings in person or as phone conferences. Overhead/administration costs could increase assuming that all coordinators request overhead. To summarise, differential costs between a virtually centralised and a physically centralised network are expected to be minor to significant, depending on the implementation details.

On the other hand, the differential costs relating to the implementation of the other functions are likely to be negligible. As discussed in Section 4, the overall coordination structure of a network is unlikely to have implications on the approach for implementation of these functions and hence on the costs. The analysis of case study networks showed that for some functions, a broadly similar implementation approach is used across all case study networks, regardless of their overall coordination structure (i.e. across physically and virtually centralised networks). For other functions, different implementation approaches were applied, but these did not appear to depend on the pan-European coordination structure of the network.

For example, EQAs and reference material resources are both functions which are likely to be implemented by one laboratory, regardless of the overall coordination structure of a network. As shown in the case study networks, it is likely that one laboratory would prepare and distribute the samples for an EQA and that one laboratory would develop, maintain and distribute reference material resources of the same type. This approach ensures the consistent quality of EQA panels and reference materials throughout the network. As the approach to implementation does not differ depending on the pan-European coordination structure, differential costs between these two types of networks are unlikely to arise.

The functions reference diagnostics, scientific advice to public authorities, and training were implemented differently in the case study networks. In some case study networks, all activities relating to one of these functions were implemented by one laboratory, while in other case study networks the activities were split between different laboratories. For example, in the EU-RL VTEC network all training activities are coordinated by the EU-RL, while in ERLI-Net training activities are split between the different laboratories. However, a closer look at the implementation of individual activities conducted within the scope of these functions revealed that each activity was implemented by one laboratory. Hence, the involvement of multiple laboratories simply meant dividing the responsibilities according to the function's individual activities, without affecting the approach to implementation of the activities. Therefore, differential costs are unlikely to arise for these functions.

The function collaboration and research is characterised by an absence of network wide coordination in the case study networks. For example, network members appeared to participate in the related activities on a voluntary basis or upon invitation by the funding entity. A specific approach to the coordination of activities in relation to collaboration and research could not be identified. As a result, the implementation of activities is unlikely to depend on the pan-European coordination structure, meaning that differential costs are unlikely to arise.

The implementation of the monitoring, alert and response function again appears similar across case study networks. As discussed in Section 4.7, individual activities related to technical support tend to be implemented by one laboratory. Activities related to the preparedness of the network (e.g. the development of operating procedures for the network in an outbreak situation) are likely to be implemented in working groups. The implementation of these activities therefore appears to depend on the type of activity rather than the pan-European coordination structure of the network. Hence, differential costs between a physically and a virtually centralised network are unlikely to arise.

To conclude, the differential costs of a different coordination structure at the pan-European level are only notable for Function 8 – Governance, and can vary from minor to significant. For all other functions, a different pan-European structure is likely to have only very minor implications for costs, if any at all. As governance costs make up a substantial proportion of overall network costs, the increase in overall network costs could also be considered to range from minor to significant.

The following table summarises these findings.

**Table 127. Differential costs of virtually centralised network, compared to a physically centralised network**

| Core function | Differential costs | Comments |
|---|---|---|
| Function 1 - Reference diagnostics | *None to very minor* | No significant change expected. |
| Function 2 - Reference material resources | *None to very minor* | No significant change expected. |
| Function 3 - Scientific advice | *None to very minor* | No significant change expected. |
| Function 4 - EQAs | *None to very minor* | No significant change expected. |
| Function 5 - Training | *None to very minor* | No significant change expected. |
| Function 6 - Collaboration and research | *None to very minor* | No significant change expected |
| Function 7- Monitoring, alert and response | *None to very minor* | No significant change expected |
| Function 8 - Governance | *Minor to significant* | Due to the number of coordinators, minor to significant increase of staff costs; minor increase in travel costs (if physical meetings of coordinators are conducted); minor increase in overhead/administration costs. expected |
| Total | *Minor to significant* | Relates to change in governance costs, which make up a substantial proportion of overall costs |

*Source: Civic Consulting.*

#### 7.3.1.2 Additional supranational level

As with the pan-European level (Tier 1), differential costs of an additional supranational level where several selected reference laboratories coordinate activities/provide reference services to NRLs in 'their' cluster of Member States (Tier 2) were assessed by function (see Section 5). The discussion in Section 5 showed that only the costs of Function 8 - Governance are likely to be considerably impacted by an additional supranational coordination level. Similarly to the reasoning for the pan-European level, these costs would relate to the additional number of coordinators. Supranational coordinators would need to conduct basic administrative tasks in relation to the funds they receive, which would result in additional staff costs. Furthermore, potential face-to-face meetings of supranational coordinators may lead to additional travel costs. Additional overhead costs could arise from the fact that more coordinators in the network could request overhead. Hence, an additional supranational coordination level may lead to minor to significant differential costs related to governance.

Yet, similar to the pan-European level, the costs of the other functions are unlikely to be affected by an additional supranational level. This is because either supranational coordinators are unlikely to get involved in the coordination of activities related to a specific function, or their involvement would only lead to a shift of responsibilities from

the pan-European to the supranational level, without modifying the implementation of the related activities.

Specifically, reference material resources, EQAs and scientific advice to public authorities are each likely to be coordinated from the pan-European level, without the involvement of the supranational level. Their coordination from the pan-European level ensures the uniform quality of reference strains and EQA panels throughout the network. The scenario of multiple supranational coordinators maintaining reference materials and conducting EQAs within their country clusters would result in inefficiencies and therefore appears unlikely. And while it is possible that some differential costs related to staff time would arise from an additional analysis of EQA results at the supranational level, these would most likely be very minor. Moreover, concerning scientific advice, public authorities are likely to contact the pan-European level first since it is their main contact point. Assuming that pan-European coordinators generally have the capacity to respond to the request, the involvement of supranational coordinators appears unlikely. Hence, as the implementation of activities is unlikely to differ due to the supranational level, differential costs are unlikely to arise for these functions.

As discussed in Section 6.3, supranational coordinators could get involved in selected activities related to reference diagnostics and training. For reference diagnostics, it is likely that supranational coordinators would provide diagnostic confirmation to laboratories of their cluster. Similarly, for training, supranational coordinators could coordinate those training activities that pertain to their cluster (e.g. twinning arrangements or targeted training courses). In both cases, this represents a shift of responsibilities from the pan-European to the supranational level. For reference diagnostics, a minor (but likely negligible) increase in shipping costs may occur; for training, a minor (but likely negligible) increase in staff costs may occur. As such, these potential cost differences are unlikely to substantially alter the costs of implementation. Overall therefore, the involvement of the additional supranational level is unlikely to lead to considerable differential costs.

Finally, as discussed above, collaboration and research activities appear to be implemented in a spontaneous manner without requiring any specific coordination. Therefore, it seems unlikely that the supranational level would take over the coordination of the related activities. Hence, differential costs of an additional supranational level are unlikely to arise.

To conclude, only in relation to Function 8 - Governance are notable differential costs likely to arise as a result of an additional supranational level, ranging from minor to significant. For all other functions differential costs are unlikely to arise, since either the supranational level is not involved in the coordination of the function, or its involvement only leads to a shift of responsibilities with only very minor potential impacts of the costs of specific activities. Nonetheless, considering that the governance function is relatively more costly, the overall differential costs for a network with an additional supranational level could range from minor to significant.

The following table summarises the results and presents the differential costs of an additional supranational level by function.

**Table 128. Differential costs of an additional supranational level**

| Core function | Differential costs | Comments |
|---|---|---|
| Function 1 - Reference diagnostics | *None to very minor* | Minor change in relation to shipping costs possible, but likely to be of negligible size. |
| Function 2 - Reference material resources | *None to very minor* | No significant change expected. |
| Function 3 - Scientific advice | *None to very minor* | No significant change expected. |
| Function 4 - EQAs | *None to very minor* | Minor increase of staff costs possible, but likely to be of negligible size |
| Function 5 - Training | *None to very minor* | Minor increase of staff costs possible, but likely to be of negligible size |
| Function 6 - Collaboration and research | *None to very minor* | No significant change expected |
| Function 7- Monitoring, alert and response | *None to very minor* | No significant change expected |
| Function 8 - Governance | *Minor to significant* | Due to the number of coordinators, minor to significant increase of staff costs; minor increase in travel costs (if physical meetings of coordinators are conducted); minor increase in overhead/administration costs. expected |
| Total | *Minor to significant* | Relates to change in governance costs, which make up a substantial proportion of overall costs |

*Source: Civic Consulting.*

### 7.3.2 Benefits of different coordination options

#### 7.3.2.1 Physically vs. virtually centralised network

*Differential benefits for network members*

As shown above, monetary benefits for laboratory network members derive from the following four functions that provide a direct service to network members, namely:

- Reference diagnostics;
- Reference material resources;
- EQAs; and
- Training.

As described above, the improvement in laboratory methods used by network members and their staff expertise derives in particular from the implementation of activities relating to EQAs, training and reference diagnostics. Improvements in quality of data and results similarly also derive mainly from the implementation of activities relating to reference diagnostics, EQAs and training, with activities relating to reference material resources also contributing to this benefit.

As discussed, the implementation of activities relating to reference diagnostics, reference material resources, EQAs and training is unlikely to differ depending on the pan-European coordination structure. Moreover, regardless of the overall coordination structure, activities relating to reference material resources and EQAs would generally be coordinated by one laboratory. As the approach to implementation is not likely to differ, the differential benefits derived from the activities are expected to be very minor, if any.

Next, as discussed above, any reputational impact of a network on laboratories can essentially be attributed to their overall participation in the network as a whole. However, for entities outside of the network, the overall coordination structure is irrelevant for the purposes of judging the value of the laboratory, and therefore differences in overall coordination structures are unlikely to play a role in reputational impact of the network. Hence, whether the network is virtually or physically centralised is not expected to substantially change the scale of any reputational benefits achieved, such that any differential benefits are therefore likely to be very minor.

Finally, as mentioned above, improvements in access to information and communication for network members mainly derive from overall participation in the network, as well as training activities. It could be expected that several pan-European coordinators may more readily facilitate the development of links and synergies among network members than one pan-European coordinator alone, as a certain amount of communication is required for the shared management of the network. Therefore, it is expected that some differential benefits in a virtually centralised network could be achieved, if minor.

Overall, we therefore conclude that in most cases benefits for network members are unlikely to differ depending on the coordination structure chosen at the pan-European level. The net benefits of a virtually centralised network may be positive but minor, considering potential greater benefits in terms of access to information and communication for network members.

*Differential benefits for society overall*

The contribution of a network to more timely and accurate detection of pathogens in the EU derives from improved staff expertise, laboratory methods, and the quality and accuracy of results, and hence indirectly from the functions of reference diagnostics, reference material resource, EQAs and training. As discussed, the implementation approach for all of these activities is unlikely to differ by the pan-European coordination structure of the network. Hence, benefits indirectly derived from these functions are even less likely to differ. It is therefore expected that the differential

benefits in terms of detection of pathogens of a virtually centralised network, if any, are likely to be very minor.

Moreover, the contribution of a network to improved public health surveillance in the EU derives directly from improved quality and comparability of data as well as from network members providing scientific advice to public health authorities. The pan-European coordination structure of a network is unlikely to affect the direct benefit of improvements in quality and comparability of data, as mentioned. Moreover, the implementation of activities related to scientific advice to public authorities appears to depend on the distribution of expertise to respond to specific requests among network members, rather than the pan-European coordination structure (although communication with the public authority could always be managed by one laboratory). Therefore, differential benefits of improved public health surveillance in the EU of a virtually centralised coordination structure are likely to be very minor too, if any at all.

Furthermore, laboratory preparedness derives in particular from the direct benefits of improved staff expertise, methods and quality and accuracy of results. These direct benefits are likely to be the same in a physically and a virtually centralised network (if all other things are held constant). Improvements in laboratories' capacity for coordinated response can also be directly related to monitoring, alert and response activities, in particular the preparation of protocols clarifying the approach to handling outbreaks and the allocation of responsibilities in crisis situations, and to scientific advice to public authorities, in particular the collaboration of scientific expertise and public health institutions. As discussed, the implementation of monitoring, alert and response activities appears to depend on the type of activities conducted, rather than the pan-European coordination structure, while the implementation of activities relating to provision of scientific advice is unlikely to differ. Hence, overall, the differential benefits, if any, are likely to be very minor.

In addition, also as discussed, the significance of the contribution of the network to the reduction of the disease burden can only be qualified as indirect. A reduction in disease burden is also strongly linked with the other societal benefits assessed, yet as discussed material differences in the extent of these societal benefits by coordination structure are likely to be very minor, if any.

Overall, we conclude that net benefits for society overall of virtually centralised coordination of network would only differ to a very minor extent, if at all, from those that could be achieved with physically centralised coordination.

The table below summarises these findings.

**Table 129. Overview of differential benefits for network members and society overall of a virtually centralised network**

| Perspective | Benefit type | Differential benefits | Main sources of benefits | Rationale |
|---|---|---|---|---|
| Network members | *Monetary benefits* | ▪ None to very minor | ▪ Reference diagnostics<br>▪ Reference material resources<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to reference diagnostics, reference material resources, EQAs and training is unlikely to differ depending on the pan-European coordination structure. |
| | Improved methods | ▪ None to very minor | | |
| | Improved staff expertise | ▪ None to very minor | | |
| | Improved quality of data and results | ▪ None to very minor | | |
| | Improved image and reputation | ▪ None | ▪ Overall participation in network | ▪ Participation in the network and related reputational effects are irrelevant to the overall coordination structure. |
| | Improved access to information and communication | ▪ Minor | ▪ Overall participation in network<br>▪ Training | ▪ Participation in the network and related communication approaches may benefit from a virtually centralised coordination structure. |
| Society overall | Laboratory preparedness and the capacity of coordinated response to outbreaks in the EU | ▪ None to very minor | ▪ Scientific advice to public authorities<br>▪ Monitoring, alert and response<br>▪ Improvements in methods, staff expertise and quality of results<br>▪ Overall participation in network | ▪ Implementation of activities related to scientific advice to public authorities and monitoring, alert and response is unlikely to differ depending on the pan-European coordination structure.<br>▪ Improvements in methods, staff expertise and quality of results are likely to be independent of the overall coordination structure. |
| | More timely and accurate detection of pathogens in the EU | ▪ None to very minor | | |
| | Improved public health surveillance in the EU | ▪ None to very minor | | |
| | Reduction in the disease burden and related costs in the EU | ▪ None to very minor | ▪ Other societal benefits<br>▪ Overall participation in network | ▪ Reduction of disease burden is indirect and linked to the other societal benefits assessed, yet material differences in the extent of these benefits depending on the overall coordination structure are likely to be very minor, if any. |

*Source: Civic Consulting.*

#### 7.3.2.2 Additional supranational level

*Differential benefits for network members*

The assessment of the potential differential benefits for network members of an additional supranational level, where several selected reference laboratories coordinate activities/provide reference services to NRLs in 'their' cluster of Member States, follows a very similar argumentation to that for different coordination structures at the pan-European level. As discussed, the implementation of activities relating to reference material resources and EQAs is unlikely to differ by the coordination structure at the supranational level. Indeed, regardless of the overall coordination structure, activities relating to reference material resources and EQAs would generally be coordinated by one laboratory for the whole network. Outcomes of activities relating to reference material resources and EQAs are therefore unlikely to change.

As mentioned, supranational coordinators could contribute to activities relating to both reference diagnostics and training: they could get involved in diagnostic confirmation for their cluster (i.e. the group of countries for which they are the coordinator) as well as coordinate those training activities that only pertain to laboratories in their cluster e.g. training courses for a smaller number of laboratories, twinning arrangements, etc. In both cases this would shift responsibilities from the pan-European level to the supranational level. Yet, in both cases the same level of service is being provided to other network members, meaning that the outcomes of these activities are unlikely to differ.

As a result, the differences in benefits arising from the reference diagnostics, reference material resources, EQAs and training functions – i.e. improved methods employed by laboratories, improved staff expertise and improved quality of data and results – between a network with a supranational level and one without are expected to be very minor, if any.

Moreover, concerning improvements to image and reputation, the same argumentation as for the pan-European level also applies: the overall coordination structure is irrelevant for external judgements concerning the value of the laboratory, and therefore differences in coordination structures are unlikely to play a role in reputational impact of the network. Hence, whether the network features a supranational level is not expected to change the scale of any reputational benefits achieved overall.

Finally, an additional supranational level may have implications relating to the overall participation of laboratories in the network and hence an impact on benefits relating to access to information and communication. In particular, supranational coordinators may more readily facilitate the development of links and synergies among laboratories in their respective clusters. More intensive communication between a limited number of cluster members may be possible. Furthermore, a smaller group might encourage less active network members to participate more actively. However, a smaller number of laboratories could also entail less variety in the expertise and capacities to draw from. Furthermore, the focus on clusters might lead to a less direct exchange within the network as a whole and a decrease in the intensity of the overall communication. The net benefit of an additional supranational level is likely to be negative in this regard, since it complicates direct information exchange and communication between all network members. The resulting decrease in network-wide communication is unlikely to be outweighed by more intensive exchange within the network clusters.

Overall, we conclude that net differential benefits for network members of an additional supranational coordination are likely to be negative. However, the size of this impact is expected to be minor.

*Differential benefits for society overall*

Finally, the assessment of the potential differential benefits for society overall of an additional supranational level follows a very similar argumentation to that for different coordination structures at the pan-European level.

As indicated above, improvements in methods, staff expertise and quality of results – the main drivers of more timely and accurate detection of pathogens, improved health surveillance in the EU, and improved laboratory preparedness and coordinated outbreak response – are likely to be independent of the coordination structure, including at the supranational level.

Furthermore, as discussed, the implementation of activities relating to scientific advice to public authorities and monitoring, alert and response are unlikely to differ: while supranational coordinators may be requested to provide advice as well as get involved in preparedness activities conducted through working groups, this is more likely to be based upon their expertise than their being supranational coordinators.

Also as discussed, the significance of the contribution of the network to the reduction of the disease burden can only be qualified as indirect. A reduction in disease burden is also strongly linked with the other societal benefits assessed, yet as discussed material differences in the extent of these societal benefits by overall coordination structure are likely to be very minor, if any

Overall, we conclude that net benefits for society overall of an additional supranational level would only differ to a very minor extent, if at all, from those that could be achieved without supranational coordination.

The table below summarises these findings.

## Table 130. Overview of differential benefits for network members and society overall of an additional supranational level

| Perspective | Benefit | Differential benefits | Main sources of benefit | Rationale |
|---|---|---|---|---|
| Network members | *Monetary benefits* | ▪ None to very minor | ▪ Reference diagnostics<br>▪ Reference material resources<br>▪ EQAs<br>▪ Training | ▪ Implementation of activities related to EQAs and reference material resources unlikely to differ due to an additional supranational level.<br>▪ Differences in implementation of reference diagnostics and training activities unlikely to have implications for outcomes of the activities. |
| | Improved methods | ▪ None to very minor | | |
| | Improved staff expertise | ▪ None to very minor | | |
| | Improved quality of data/results | ▪ None to very minor | | |
| | Improved image and reputation | ▪ None | ▪ Overall participation in network | ▪ Participation in the network and related reputational effects are not affected by an additional supranational level. |
| | Improved access to information and communication | ▪ Minor | ▪ Overall participation in network<br>▪ Training | ▪ Differences in implementation of training activities unlikely to have implications for outcomes of the activities.<br>▪ While communication may intensify in clusters, this is unlikely to outweigh the reduction in network-wide communication. |
| Society overall | Lab. preparedness and capacity of coord. response to outbreaks in the EU | ▪ None to very minor | ▪ Scientific advice to public authorities<br>▪ Monitoring, alert and response<br>▪ Improvements in methods, staff expertise and quality of results | ▪ Implementation of activities relating to scientific advice to public authorities and monitoring, alert and response is unlikely to differ due to an additional supranational level.<br>▪ Improvements in methods, staff expertise and quality of results are likely to be independent of the coordination structure. |
| | More timely and accurate detection of pathogens in the EU | ▪ None to very minor | | |
| | Improved public health surveillance in the EU | ▪ None to very minor | | |
| | Reduction in the disease burden and related costs in the EU | ▪ None to very minor | ▪ Other societal benefits<br>▪ Overall participation in network | ▪ Reduction of disease burden is indirect and linked to the other societal benefits assessed, yet material differences in the extent of these benefits depending on the overall coordination structure are likely to be very minor, if any. |

*Source: Civic Consulting.*

### 7.3.3 Comparison of costs and benefits for different coordination options

#### 7.3.3.1 Physically vs. virtually centralised network

As shown above, the only function for which a virtually centralised coordination structure is likely to entail a material difference in costs of implementation is governance. A minor to significant increase of staff costs, as well as minor increases in travel costs and overhead/administration costs, are expected related to the number of coordinators. Concerning the benefits, the only benefit type likely to be materially affected is access to information and communication: participation in the network and related communication approaches may benefit to a minor extent from a virtually centralised coordination structure. The table below provides an overview of these findings.

**Table 131. Material differential costs and benefits of a virtually centralised network**

| Aspect | No material differences identified for | Material differences identified for | Potential impact of differences identified |
|---|---|---|---|
| **Costs** | Functions 1-7, i.e. reference diagnostics, reference material resources, scientific advice to public authorities, EQAs, training, collaboration and research; and monitoring, alert and response. | Function 8 - governance | Minor to significant increase of costs for governance function related to increase in staff costs, travel costs and overhead/administration costs expected related to the number of coordinators. |
| **Benefits** | *For network members:* Monetary benefits; Improved methods; Improved staff expertise; Improved quality of data/results; Improved image and reputation *For society overall:* Laboratory preparedness and capacity of coordinated response to outbreaks in the EU; More timely and accurate detection of pathogens in the EU; Improved public health surveillance in the EU; Reduction in the disease burden and related costs in the EU. | *For network members:* Access to information and communication | Minor increase of access to information and communication for network members, as participation in the network and related communication approaches may benefit from a virtually centralised coordination structure. |

*Source: Civic Consulting.*

As a result, whether it is most suitable for the pan-European coordination structure of a network to be virtually or physically centralised comes down to weighing the increased costs of a virtually centralised network related to governance against its

increased benefits related to access to information and communication for network members.

An initial insight can be gleaned from the rationale of the cost increase: the increase in governance costs in a virtually centralised network is related to the number of coordinators. Therefore, if a physically centralised network is compared with the extreme scenario of a virtually centralised network featuring a large number of coordinators, it is likely that the additional governance costs would outweigh any differential benefits relating to access to information and communication for network members.

However, the picture is less clear in the case of a small number of coordinators of a virtually centralised network (which is the typical situation), and in the absence of quantitative data on the potential increase in costs and benefits, a precise comparison is not possible. Nonetheless, as shown by the case study networks, both types of coordination structures appear to be viable options. Hence, whether the benefits outweigh the costs is therefore likely to be highly case-specific.[81] If the additional costs for financial administration and management required for a virtually centralised network are limited, they could well be outweighed by the added value of multiple pan-European coordinators stimulating increased participation of members in the network, the development of links and synergies among members and the related improvements in information exchange and communication. If, on the other hand, the additional coordinators show minimal engagement to encourage the network's development and have a largely administrative role, then a physically centralised network may be preferable.

#### 7.3.3.2 Additional supranational level

As with the pan-European level, the only function for which an additional supranational level structure is likely to entail a material difference in costs of implementation is governance. A minor to significant increase of staff costs, as well as minor increases in travel costs and overhead/administration costs are expected related to the number of coordinators. Concerning the benefits, the only benefit type likely to be materially affected is again access to information and communication. However, in contrast to the pan-European level, it is likely that the difference in the related beneficial impacts is negative: while a more intensive exchange within the network clusters is expected, this is unlikely to outweigh the expected decrease in network-wide communication. The table below provides an overview of these findings.

[81] This consideration is also likely to be affected by the location of laboratories with the expertise to take on coordination roles for a network, due to differences in labour costs between countries. Labour cost differences are not considered in the assessment of options, see Section 3.5.

**Table 132. Material differential costs and benefits of an additional supranational level.**

| Aspect | No material differences identified for | Material differences identified for | Potential impact |
|---|---|---|---|
| Costs | Functions 1 -7, i.e. reference diagnostics, reference material resources, scientific advice to public authorities, EQAs, training, collaboration and research; and monitoring, alert and response | Function 8 - governance | Minor to significant increase of costs for governance function related to increase in staff costs, travel costs and overhead/administration costs expected related to the number of coordinators. |
| Benefits | *For network members:* Monetary benefits; Improved methods; Improved staff expertise; Improved quality of data/results; Improved image and reputation *For society overall:* Lab. preparedness and capacity of coord. response to outbreaks in the EU; More timely and accurate detection of pathogens in the EU; Improved public health surveillance in the EU; Reduction in the disease burden and related costs in the EU | *For network members:* Access to information and communication | Minor decrease in access to information and communication for network members, as decrease in network-wide communication due to the focus on clusters is unlikely to be outweighed by more intensive exchange within the network clusters. |

*Source: Civic Consulting.*

As a result, in contrast to the pan-European level, determining whether or not to adopt an additional supranational level in the overall coordination structure in a network appears to be a straightforward decision in the European context.[82] The additional differential costs related to governance are not offset by positive differential benefits. Specifically, the likely minor decrease in communication levels among network members makes it clear that in general, a coordination structure without a supranational level is to be preferred to one that does feature supranational coordination (all other things being equal). This finding also reflects the observations in the case study networks: while differences were observed at the pan-European level, none of the case study networks featured a supranational coordination structure. In fact, as indicated previously, many experts interviewed were opposed to the suggestion and were unaware of its implementation in any existing EU-RL networks.

[82] This study has not assessed additional supranational levels in larger-scale networks (e.g. global networks of laboratories).

## 7.4 Overall conclusions and recommendations

In this study we calculated the overall annual median costs and benefits of case study networks as a means to compare the overall costs of EU-RL networks with their benefits. The overall annual median costs of the four laboratory networks examined as case studies for which detailed comparable data exists amount to EUR 781 091. These consist of the costs incurred by network coordinators, by the funding entities and by the member laboratories (which include co-financing contributions, where applicable). In all cases, costs related to network functions that may arise in addition to budgeted costs were also considered.

Of the overall network costs, the median costs incurred by member laboratories amount to EUR 234 656 in the reference year. The monetary benefits received by member laboratories as a result of their participation amount to EUR 57 560 in the same period. In a network of approximately 30 laboratories, for example, this would mean that each laboratory bears a net cost of EUR 5 903. Member laboratories also enjoy substantial non-monetary benefits as a result of their participation in the network:

- Improvement in methods employed by laboratories in the network;
- Improvement in quality and accuracy of data/results produced in laboratories in the network;
- Improvements in staff expertise of laboratories in the network;
- Improvement in access to information, communication and/or collaboration among laboratories in the network;
- Improvement in image or reputation of the laboratories in the network.

The significance of these benefits tends to in principle at least be in line with the costs involved (see analysis in Table 124 above). This result of the study is in line with the assessment of network members participating in our survey who strongly supported the notion that benefits of the laboratory network outweigh their costs of implementing network activities. We therefore conclude that on balance, benefits induced for member laboratories by a network are likely to outweigh the costs they incur for the implementation of the network activities.

Of the overall network costs, the median costs incurred by the network coordinator(s) and the funding entity amount to EUR 523 635 in the reference year, with some monetary benefits received by the funding entity.[83] While these could not be quantified, evidence indicates that society overall enjoys substantial non-monetary benefits as a result of the existence of the network. These include:

- Improved laboratory preparedness and the capacity of coordinated response to outbreaks in the EU;
- More timely and accurate detection of pathogens in the EU;
- Improved public health surveillance in the EU;
- Reduction in the disease burden and related costs in the EU.

[83] The funding entities of case study networks indicated having received monetary benefits in terms of saved costs, e.g. because of economies of scale involved in supporting networks with multiple functions rather than procuring commercial services of a similar nature from different providers. However, they were generally unable to quantify these cost savings. Coordinators of case study networks did not report receiving any monetary benefits deriving from their role as network coordinators. They did, however, report monetary benefits from their participation in network activities as network members.

This study concludes that the significance of these benefits tends to in principle at least be in line with the costs involved. Moreover, the costs for coordinator(s) and the funding entity (and thus the cost for EU taxpayers) appear well within the range of what could be considered reasonable in order to achieve these benefits. As indicated before, it is difficult to establish a direct link between the networks' activities and a reduction in the burden of disease and related costs, as these are influenced by a range of factors, many of which are unrelated to the functions and activities of laboratory networks. Nonetheless, improvements in preparedness, outbreak response, pathogen detection and surveillance are expected to contribute to this end at least to some extent. The occurrence and severity of outbreaks varies from one disease to another, but their impacts on society can be devastating, both in terms of human life and economic losses. And while the methodologies applied in cost-of-illness or burden-of-disease studies vary, they typically provide estimates in the range of billions of Euro per year for key pathogens.[84] Moreover, as shown above, previous studies assessing societal benefits of disease surveillance systems have shown that such systems do not need to prevent a large number of cases in order to yield return on the resources invested in them.

In conclusion therefore, the results of this study indicate that the benefits (monetary and non-monetary) of maintaining a formally-defined overarching system of EU reference laboratory networks are likely to outweigh costs, both in a Member State (participating member laboratory) and in an EU perspective (coordinator and funding entity). The EURLOP study already made the case for such a system from a public health perspective; the results of this study provide the economic case for such a system.

However, while these overall conclusions indicate a convergence of arguments for setting up an overarching system of EU reference laboratory networks, the study also identified several issues that will need to be addressed in the further process of creating such a system, including:

- The need for adequate reference laboratory infrastructure at national level;
- The need to provide sustainable funding, including for emergency situations;
- The need to define the focus of the networks, potentially by grouping diseases in line with existing approaches;
- The need to harness relevant technological improvements;
- The need to choose the coordination options most suitable in specific cases.

The following sub-sections describe these issues in more detail.

*The need for adequate reference laboratory infrastructure at national level*

As this study focuses specifically on the *additional* costs and benefits generated by an EU-RL network compared to a situation without such network, our analysis did not concern the provision of national reference laboratory services as such. However, evidence collected in the course of this study - expert interviews, EURLOP study and the ECDC's recent assessment of key capabilities and capacities of public health microbiology systems - indicates that there is substantial variation in the reference laboratory infrastructure across Member States. The EURLOP study already emphasised that an overarching EU-RL system must be underpinned by an efficient and co-ordinated system of primary laboratories at the individual Member State level.

[84] See Section 7.2.1 above.

Any future system of EU reference laboratory networks will require that adequate and sustainable reference laboratory services are in place at the national level.

*The need to provide sustainable funding, including for emergency situations*

Existing networks and consortia of reference laboratories are often financed on a short-term project/tender basis, are disparate and are overseen and/or organised by a diverse range of entities. The current model has implications for the extent of benefits that can be achieved by EU-RL networks. In particular, members of case study networks have indicated that significant time and administrative funds are required for tendering and contract renewal procedures, and the short-term nature of the projects may lead to gaps in the functioning of the networks (if the follow up project is not approved or tendered in time), and makes long-term planning and related investments difficult.

An alternative model enabling funding on a more sustainable longer-term basis could therefore be considered. One option to consider for the design of an alternative funding model is the recently established system of European Reference Networks (ERNs) for cross-border healthcare, which allows the funding of ERN for a period up to 5 years.[85] Moreover, in light of the success of the systems of EU reference laboratory networks in place in the food/feed safety and animal health areas, elements of these systems could be considered for a similar model in the public health field. For example, the role of oversight of the networks could be consolidated under one or a few specific entities - e.g. Commission and/or the ECDC - taking into account their respective competencies and historical role in governing existing networks.

Furthermore, typically, in the existing networks funding is based on an annual or multi-annual work programme. The provision of technical/scientific expertise in the event of an emergency or large disease outbreak to public authorities or other laboratories in the network is generally not planned for in the work programmes of the networks from a budgetary perspective. Therefore, in the event that significant resources are required for this purpose, they need to be transferred from other activities in the work programme. As a result, the surge capacity of existing laboratory networks is limited, and in the event of large outbreaks networks may not have sufficient resources available to meet needs. In this regard, a system of EU reference laboratory networks in the public health field may need to have access to a separate budget line for emergencies, through which additional resources could be mobilised.[86] In addition, considering that several EU networks also deal with diseases and related outbreaks posing cross-border health threats inside and outside Europe (e.g. members of case study networks deployed in West Africa to deal with the Ebola outbreak), funding tied to surge capacity for EU-RL networks could also be considered with a global health security (as opposed to solely EU) perspective.

[85] ERNs are to be set up on the basis of the Cross-border Healthcare Directive (Directive 2011/24/EU) and Commission Implementing Decision 2014/287/EU.

[86] Relevant mechanisms exist in other areas. For example, the Financial Framework Regulation (EU) No 652/2014 concerns food chain, animal and plant health expenditures, including related emergency measures. While there are no provisions made that explicitly concern the EU reference laboratory system, according to the related guidelines for Member States for EU funding of veterinary emergency measures, under the heading "Other essential costs" specific expenditures may exceptionally be eligible taking into account the specifics of the disease and the particularities of the situation, including the costs of laboratory tests (which include related personnel costs).

*The need to define the focus of the networks, potentially by grouping diseases in line with existing approaches*

There are also important choices to be made concerning the focus and size of EU reference laboratory networks for human pathogens in view of maximising efficiency. Significantly, it appears that consolidated networks with a unique focus on several pathogens of a similar nature could lead to efficiencies through economies of scale, which could contribute to improved service provision, especially when combined with sustainable funding.

As illustrated by the case study networks, EU-RL networks can be defined by a focus on a specific pathogen (e.g. influenza, or tuberculosis) or on a specific mode of transmission or theme (e.g. food-borne/water-borne, emerging diseases). The EURLOP study considered disease groupings a viable option for an EU-RL system. For any grouping of diseases, the experience and existing set-up of laboratory networks should be considered. Based on the mapping exercise conducted in this study, existing groups of networks based on a similar theme relate to inter alia:

- Food- and water-borne diseases;
- Emerging and vector-borne diseases;
- Highly pathogenic diseases; or
- Vaccine-preventable diseases.

ECDC's activities are also organised within seven disease group-based horizontal programmes,[87] while Annex I of Commission Decision 2000/96/EC on the communicable diseases to be progressively covered by the Community network provides a comprehensive disease categorisation;[88] both of these could be considered as a basis for disease groupings. Other factors to consider with regard to the consolidation of networks include, inter alia:

- European dimension of the pathogens covered. Networks based on pathogens with a clear European dimension, e.g. diseases which pose serious cross-border health threats to public health, appear important to maintain and strengthen in light of their EU-wide relevance and the fact that national reference laboratory systems in some Member States lack the capacities to adequately deal with such pathogens;
- Possibility to conduct the same reference laboratory activities for several pathogens. Depending on the pathogens, in a consolidated network covering multiple pathogens, the same EQA could be conducted for several pathogens of a similar nature; the focus of such EQAs could be 'syndromic', i.e. focusing on groups of symptoms;
- Relevant technological improvements. Ideally, consolidated networks should be 'future-proof', i.e. not made obsolete or ineffective by future technological changes, e.g. in terms of bioinformatics and next-generation sequencing.

As identified by the EURLOP project, there were more than 70 microbiology networks, consortia and research groups in place across the EU in 2011. In some cases more than one network exists with a focus on the same pathogen or group of pathogens - e.g. influenza or tuberculosis, for which one network has a focus on reference

[87] Antimicrobial Resistance and Healthcare-associated Infections Programme; Emerging and Vector-borne Diseases Programme; Food- and Waterborne Diseases and Zoonoses Programme; Influenza and other Respiratory Viruses Programme; HIV, Sexually Transmitted Infections and viral Hepatitis Programme; Tuberculosis Programme; and Vaccine-preventable Diseases Programme.
[88] See Table 1 for the disease categories.

laboratory activities and the other on surveillance activities – and whether these can be combined will likely depend on a case-by-base assessment. In some cases it is likely there will be a need to strike a balance between administrative efficiency of networks and their effectiveness/depth of focus, considering the risk that consolidation of networks may dilute the concentration of disease-specific expertise. Moreover, consolidation of networks should not be viewed by policymakers as an opportunity to reduce the overall level of funding for networks of reference laboratories; rather, the focus should be on creating synergies and maximising impacts.

*The need to harness relevant technological improvements*

Existing and future EU-RL networks should harness technological improvements relating to reference laboratory activities in order to maximise benefits and efficiency. Improvements in bioinformatics as well as increasing data availability, in particular with regard to next-generation sequencing,[89] have the potential to deliver substantial benefits for pathogen identification (particularly in a cross-sector perspective) and therefore the investments in the relevant skills and capabilities to employ such technology need to be considered in EU-RL networks.[90]

Additionally, relevant IT tools for training and communication could be exploited with the aim of reducing costs. Key examples include e-learning/-training and the use of online platforms including question & answer fora. Some case study networks already employ e-learning approaches for staff, which were reported to have substantially contributed to staff training. Moreover, the web-based communication platform EPIS (Epidemic Intelligence Information System) established by ECDC is an example of a platform incorporating an active and effective question and answer forum, which contributes to improving laboratory expertise at low cost and timely information exchange between public health authorities.[91] Another example is virtual meetings, which could be used as a complementary tool to face-to-face meetings in order to reduce travel costs.

*The need to choose the coordination options most suitable in the specific case*

In this study we assessed four options for European reference laboratory networks for human pathogens relating to different overall network coordination structures, based on the options originally developed in the EURLOP study. These options are distinct from each other in two respects: a) whether one coordinator ('physically centralised network') or multiple coordinators ('virtually centralised network') exist on the pan-European (EU) level; and b) whether or not an additional 'supranational' coordination level exists, i.e. an intermediate level where several selected reference laboratories coordinate activities/provide reference services to NRLs in 'their' cluster of Member States.

[89] A recent report by the UK Food Standards Agency provides a good overview of the benefits of whole-genome sequencing of foodborne pathogens: Food Standards Agency, *Chief Scientific Adviser's Science Report. Issue Three: Whole-Genome Sequencing of Foodborne Pathogens*, 2016.

[90] In this context it could also be explored how to use the platform provided by the COMPARE project for future EU reference laboratories. COMPARE is a large EU project with the intention to speed up the detection of and response to disease outbreaks among humans and animals worldwide through the use of new genome technology, see http://www.compare-europe.eu/.

[91] Evidence from Gossner, C. M., B. de Jong, C. J. Hoebe, and D. Coulombier, *Event-Based Surveillance of Food- and Waterborne Diseases in Europe: Urgent Inquiries (Outbreak Alerts) during 2008 to 2013*, *Euro Surveillance*, 2015 has shown that the introduction of the epidemic intelligence information system platform (EPIS) in 2010 has strengthened the role of the Food- and Waterborne Diseases and Zoonoses network in facilitating timely exchange of information between public health authorities of the participating countries.

The analysis showed that significant differential costs both between a physically centralised network and a virtually centralised network and between a network with and without a supranational level might only arise in relation to the governance of the network. Specifically, a virtually centralised network or a network with a supranational level may imply a relative increase in costs mainly as a result of the involvement of the additional coordinators in the financial administration of the network.

It also showed that the only network benefits likely to be materially affected are those enjoyed by member laboratories in terms of access to information and communication thanks to their participation in the network. The differential benefits in a virtually centralised network are likely to be positive, as additional coordinators are expected to stimulate information and exchange and communication among network members. In contrast, the differential benefits of an additional supranational level are likely to be negative, as overall network-wide communication may suffer as a result of a focus on clusters of countries.

Accordingly, we conclude that determining whether the differential benefits of a specific pan-European coordination approach – physically centralised or virtually centralised network – outweigh the differential costs is highly case-specific. As shown by the networks examined in this study, both types of coordination structures are currently used in practice. In these networks, the choice of a physically or virtually centralised network appears to be based on pragmatic reasons. In both cases, coordination is handled in a collaborative and flexible manner, with advisory boards, subcontractors, working groups, and work package leaders, etc. In these networks, the availability of expertise, relevant infrastructure and capacities to take on the workload and task requirements of the work programme among laboratories may therefore be the main factor that determines the selection of one or multiple laboratories as network coordinators.

In contrast, owing to the relative increase in costs and reduction in benefits, a network without an additional supranational coordination level, i.e. without an intermediate level where several selected reference laboratories coordinate activities/provide reference services to NRLs in 'their' cluster of Member States appears preferable in the EU context. Indeed, many experts interviewed did not consider this a practicable option and were unaware of its implementation in any existing EU-RL networks.

Considering the four options assessed in the study, these findings mean that, when considering the coordination structure of future EU-RL networks, Options III and IV, which depict no supranational coordination structure, are preferable to Options I and II, which both depict a supranational coordination structure. However, between Options III and IV, which respectively depict a physically and virtually centralised coordination structure at the pan-European level, the decision is highly case-specific, depending e.g. on expertise, infrastructure and capacities of potential network coordinators. Both options could therefore be considered for organising European networks of reference laboratories for human pathogens.

The table below summarises the assessment regarding each coordination option.

**Table 133. Summary of assessment of coordination options**

| Pan-European level (Tier 1) | *With* a supranational level (Tier 2) | *Without* a supranational level (Tier 2) |
|---|---|---|
| *Physically* centralised | *Option I*<br>▪ Lower governance costs at pan-European level due to a single EU coordinator.<br>▪ Additional governance costs incurred for the supranational coordinators.<br>▪ Implementation of most network activities unlikely to be affected, as most activities such as EQAs would still be coordinated by one laboratory in the network. | *Option III*<br>▪ Lower governance costs at pan-European level due to a single EU coordinator.<br>▪ No governance costs at the supranational level. |
| *Virtually* centralised | *Option II*<br>▪ Higher governance costs at pan-European level due to involvement of multiple coordinators at EU level.<br>▪ Additional governance costs incurred for the supranational coordinators.<br>▪ Supranational coordinators may facilitate the development of links and synergies among laboratories in their respective clusters. However, the focus on clusters may lead to a less direct exchange within the network as a whole. | *Option IV*<br>▪ Higher governance costs at pan-European level due to involvement of multiple coordinators at EU level.<br>▪ No governance costs at the supranational level.<br>▪ Participation in network and communication approaches may benefit from virtually centralised coordination structure, as several coordinators can more readily facilitate the development of links and synergies among network members. |

*Source: Civic Consulting.*

# Annex I - Interview questionnaire

# Case study questionnaire – EU institutions funding laboratory networks

Civic Consulting has been commissioned by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) of the European Commission to conduct a study on cost-benefit analysis of reference laboratory networks for human pathogens. The study is aimed at providing an analysis of the costs and benefits of reference laboratory networks for human pathogens, as well as an analysis of options to strengthen the existing coordination of reference microbiology provision in the EU and support European response coordination to outbreaks of highly pathogenic infectious agents. As part of the data collection process, we are conducting case studies on a selection of existing European reference laboratory networks. The case studies are aimed at collecting detailed data on costs and benefits of European reference laboratory networks across different types of networks, pathogens and coordination structures.

**Please answer this questionnaire in the capacity of your institution managing the network. The answers you provide should be based on the activities you undertake within your institution to manage the network, not the laboratory activities undertaken by the network.**

1. *Identification data*
   - 1.1. Name: …
   - 1.2. Institution: …
   - 1.3. Name of the laboratory network: …
   - 1.4. Tel: …
   - 1.5. Email: …

2. *Characteristics of laboratory network and process of identifying the network coordinator*
   - 2.1. a) What are your main tasks in managing the network for your institution?
     …
     b) Which other units/staff members are involved in the management of the network and what are their main tasks?
     …
   - 2.2. Please describe the procedure for identifying the network coordinator (e.g. procurement process, call for proposals etc.):
     …
   - 2.3. Please indicate the duration of the contract for the network:
     …
   - 2.4. Please indicate the resources typically involved in the procurement procedure (in terms of staff time and other costs, if any):
     …

3. *Reference period*

Please indicate the last period of financial reporting for the network for which financial data on expenditure is available (preferably the year 2014):

Start: MM/YY End month: MM/YY

**Please take this period as the reference period when responding to the questionnaire.**

4. *Funding of the laboratory network*

4.1. Please indicate the total funding provided by your institution for the implementation of the network's work programme in the reference period:

Amount of EU-funding: …€
Comment: …

4.2. Is co-financing by network members also required?

☐ No
☐ Yes
- Percentage of co-financing required: …%
- Co-financing contributed by: …
- Comment: …

5. *Costs to manage the network for your institution:*

5.1. In addition to the budget provided to the network, please provide an estimate of the costs incurred by your institution to manage the network in the reference period (e.g. staff time you and your colleagues spent on managing the network).

| Cost item | Description of cost item | Cost incurred | Comments |
|---|---|---|---|
| **Staff costs** | Please provide staff time in terms of **person month** and differentiate: Professionals (P) and Technicians and associate professionals (T). | P:…person-month<br>T:… person-month | … |
| **Travel costs** | Amount in Euro spent for travel, accommodation and daily allowance for staff of your institution involved in the management of the network | …€ | … |
| **Other costs (if applicable)** | Any other costs incurred by your institution in the management of the network (e.g. costs to provide a website or particular software to the network). Please specify type of costs and amount | Type of cost: …<br>…€ | … |

6. *Potential cost savings of EU institutions as a result of the implementation of the laboratory network activities*

6.1. a) In your view, did the implementation of the functions/activities of the laboratory network in the reference period lead to cost savings for EU institutions (i.e. avoided costs for activities that EU institutions otherwise would have implemented or financed such as costs of commissioning a study on a topic now covered by the network)?
Yes/No

Comment: …

b) If yes:
The following table breaks down potential activities of the laboratory network by function. Please indicate which of the network activities led to these cost savings.

*For a detailed description of the functions and related activities please see the Annex.*

| Function of the laboratory network | Costs saved? | Please describe how you saved costs | Estimate of savings you made |
|---|---|---|---|
| **1. Reference diagnostics** | Yes/No/Not applicable | … | …€ |
| **2. Reference material resources** | Yes/No/Not applicable | … | …€ |
| **3. Scientific advice** | Yes/No/Not applicable | … | …€ |
| **4. External Quality Assurance (EQA)** | Yes/No/Not applicable | … | …€ |
| **5. Training** | Yes/No/Not applicable | … | …€ |
| **6. Collaboration and research** | Yes/No/Not applicable | … | …€ |
| **7. Monitoring, alert and response** | Yes/No/Not applicable | … | …€ |
| **8. Governance of the network** | Yes/No/Not applicable | … | …€ |

7. Benefits of the laboratory network for the EU

7.1. Please assess on a scale from 1 (not at all) to 5 (very much) the benefits of the laboratory network for the EU:

| | 1 (Not at all) | 2 | 3 | 4 | 5 (Very much) | Comments |
|---|---|---|---|---|---|---|
| **The network contributed to more timely and accurate detection of pathogens in the EU** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The network contributed to a reduction in the disease burden and related costs in the EU** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The network contributed to improved public health surveillance in the EU** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The network contributed to increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The benefits the EU receives from the implementation of the network outweigh the costs of the network for EU institutions.** | ☐ | ☐ | ☐ | ☐ | ☐ | … |

7.2. Do you have estimates of the size of the benefits indicated above in quantitative terms, or are you aware of any studies that have assessed these benefits?
...

*7.3.* a) Are there other benefits which have not been listed above?
Yes/No

b) If yes, please describe these benefits*:* ...

8. Please provide any additional comments you think we should take into account for the assessments of costs and benefits in this study, including any additional data sources you think we should consult:

…

# Case study questionnaire – Members of the laboratory network

Civic Consulting has been commissioned by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) of the European Commission to conduct a study on cost-benefit analysis of reference laboratory networks for human pathogens. The study is aimed at providing an analysis of the costs and benefits of reference laboratory networks for human pathogens, as well as an analysis of options to strengthen the existing coordination of reference microbiology provision in the EU and support European response coordination to outbreaks of highly pathogenic infectious agents. As part of the data collection process, we are conducting case studies on a selection of existing European reference laboratory networks. The case studies are aimed at collecting detailed data on costs and benefits of European reference laboratory networks across different types of networks, pathogens and coordination structures.

**Please answer this questionnaire in your capacity of laboratory network member/partner. The answers you provide should be based on the activities your laboratory is undertaking within the network. Furthermore, when responding to questions, please take only those activities that are implemented as part of the network's work programme into account.**

1. *Identification*
   - 1.1. Name: …
   - 1.2. Institution: …
   - 1.3. Name of the laboratory network: …
   - 1.4. Tel: …
   - 1.5. Email: …

2. *Reference period*

Please indicate the last period of financial reporting for the network for which financial data on expenditure is available (preferably the year 2014).

Start: MM/YY End month: MM/YY

**Please take this period as the reference period when responding to the questionnaire.**

*3. Role in the laboratory network*

In the table below we provide a list of core functions of laboratory networks developed for the purposes of this study. Before answering this question, please have a look at the annex for a detailed description of their scope.

In the table, please indicate if your laboratory played a role in the activities related to each function in the reference period, and describe it. If a particular function was not part of the work programme of your laboratory network in the reference period, please specify "not applicable".

| **Core functions of the network** | **What was your role in this function? Please select 'Yes' or 'No' for a) and b) below** | | **If applicable, please briefly describe the role of your laboratory (e.g. organising training activities, participating in an EQA, receiving/providing scientific advice).** |
|---|---|---|---|
| | a) Our laboratory was the lead coordinator for selected activities related to this function | b) Our laboratory participated in selected activities relating to this function | |
| **1. Reference diagnostics** | Yes/No | Yes/No | … |
| **2. Reference material resources** | Yes/No | Yes/No | … |
| **3. Scientific advice** | Yes/No | Yes/No | … |
| **4. External Quality Assessments (EQA)** | Yes/No | Yes/No | … |
| **5. Training** | Yes/No | Yes/No | … |
| **6. Collaboration and research** | Yes/No | Yes/No | … |
| **7. Monitoring, alert and response** | Yes/No | Yes/No | … |
| **8. Governance of the network** | Yes/No | Yes/No | … |

4. *Additional contributions of your laboratory of participating in the network:*

4.1. a) Did your laboratory incur any additional costs to participate in network activities in the reference period i.e. costs that were not reimbursed by EU-funding and were also not included as your co-financing contribution in the budget (e.g. additional staff time or consumables used for your participation in an EQA, or travel costs to participate in training not reimbursed or indicated as co-financing in the budget)?

☐ Yes
☐ No

b) If yes, please provide details on your additional contributions in the Excel sheet.

5. *Benefits for your laboratory of participating in the laboratory network*

5.1. a) Did your membership in the network lead to the receipt of any grants or in-kind benefits for your laboratory from institutions outside of the network (not considering the EU funding for network activities) e.g. additional public funds, research grants, etc.?

☐ Yes
☐ No

b) If yes, please specify the type of financial grants or in-kind benefits you received in the reference period: …

c) Please provide an estimate in Euro of these benefits received as a result of your membership in the network.

☐ 1-999€
☐ 1000-4999€
☐ 5000-9999€,
☐ 10000-19999€,
☐ 20000€-49999
☐ 50000€-100000€
☐ more than 100000€

d) Comment: …

5.2. a) Did your membership in the network lead to an increased demand for services provided by your laboratory for which you were financially compensated (e.g. services for clients which approached you because you are a member of the network)?

☐ Yes
☐ No

b) If yes, please provide an estimate in Euro concerning the additional turnover in the reference year as a result of your membership in the network.

☐ 1-999€
☐ 1000-4999€
☐ 5000-9999€,
☐ 10000-19999€,
☐ 20000€-49999
☐ 50000€-100000€
☐ more than 100000€

c) Comment: …

5.3. As a result of your participation in the network did you save costs that your laboratory would have otherwise incurred (e.g. costs saved because participation in commercial EQA is not needed anymore)?

☐ Yes
☐ No

5.4. The following table breaks down activities of the laboratory network by function. For each function, please indicate if the function has led to cost savings by your laboratory. If you have not participated in a function or the function was not part of the network's work programme, please indicate "not applicable".

| *Potential core functions of a network* | Costs saved? | Please describe how you saved costs | Estimate of savings you made |
|---|---|---|---|
| **1. Reference diagnostics** | Yes/No/Not applicable | … | …€ |
| **2. Reference material resources** | Yes/No/Not applicable | … | …€ |
| **3. Scientific advice** | Yes/No/Not applicable | … | …€ |
| **4. External Quality Assessments (EQA)** | Yes/No/Not applicable | … | …€ |
| **5. Training** | Yes/No/Not applicable | … | …€ |
| **6. Collaboration and research** | Yes/No/Not applicable | … | …€ |
| **7. Monitoring, alert and response** | Yes/No/Not applicable | … | …€ |
| **8. Governance of the network** | Yes/No/Not applicable | … | …€ |

5.5. Please assess on a scale from 1 (not at all) to 5 (very much) the benefits of the network.

| | 1 (Not at all) | 2 | 3 | 4 | 5 (Very much) | Comments |
|---|---|---|---|---|---|---|
| ***As a result of our participation in the network*** | | | | | | |
| **The methods employed in our laboratory have improved** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The staff expertise in our laboratory has improved** | ☐ | ☐ | ☐ | ☐ | ☐ | |
| **The quality and accuracy of data/results we produced in our laboratory have improved** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The image and reputation of our laboratory has improved** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **The access to information, communication and/or collaboration of our laboratory with other laboratories in the network have improved** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| ***Overall, the network contributed to*** | | | | | | |
| **More timely and accurate detection of pathogens in my country** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **A reduction in the disease burden and related costs in my country** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **Improved public health surveillance in my country** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **Increased laboratory preparedness and the capacity of coordinated response to outbreaks affecting my and other countries in the EU** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| ***For my laboratory*** | | | | | | |
| **The benefits of participating in the network outweigh the costs incurred by my laboratory for participating in the network** (regardless of whether costs were specified as co-financing in the budget or additional contributions by you) | ☐ | ☐ | ☐ | ☐ | ☐ | … |

5.6. a) Are there other benefits for your laboratory or for your country that result from the laboratory network which have not been listed above?

☐ Yes

☐ No

b) If yes, please describe these other benefits: …

6. Please provide any additional comments you think we should take into account for the assessments of costs and benefits in this study, including any additional data sources you think we should consult:

…

# Case study questionnaire – Coordinators of laboratory networks

Civic Consulting has been commissioned by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) of the European Commission to conduct a study on cost-benefit analysis of reference laboratory networks for human pathogens. The study is aimed at providing an analysis of the costs and benefits of reference laboratory networks for human pathogens, as well as an analysis of options to strengthen the existing coordination of reference microbiology provision in the EU and support European response coordination to outbreaks of highly pathogenic infectious agents. As part of the data collection process, we are conducting case studies on a selection of existing European reference laboratory networks. The case studies are aimed at collecting detailed data on costs and benefits of European reference laboratory networks across different types of networks, pathogens and coordination structures.

**Please answer this questionnaire in your capacity as a laboratory network coordinator. The answers you provide should be based on activities of the network overall, not only the activities your laboratory is undertaking for the network. Furthermore, when responding to questions, please take only those activities into account that are implemented as part of the network's work programme.**

1. *Identification*
   - 1.1. Name: …
   - 1.2. Institution: …
   - 1.3. Name of the laboratory network: …
   - 1.4. Tel: …
   - 1.5. Email: …

2. *Characteristics of laboratory network*
   - 2.1. a) How many members are in the laboratory network?
     …
     b) What type of laboratories are members in the network (e.g. national reference laboratories, human medical labs, veterinary labs, military labs)?
     …
     c) How did laboratories become members of the network (e.g. nominated by Member State, self-nomination, invited to participate by the coordinator)?
     …
     c) What is the geographical coverage of the network?
     …
   - 2.2. In what year was the laboratory network founded?
     …
   - 2.3. Which pathogen(s) or disease(s) does the laboratory network focus on?
     …
   - 2.4. a) Is the network coordinated by one laboratory or by several laboratories (i.e. where different laboratories coordinate different activities)?
     …
     b) If the laboratory network has multiple coordinating laboratories, is coordination shared according to activities or according to groups of countries/country clusters?
     …

3. *Reference period*

Please indicate the last period of financial reporting for the network for which financial data on expenditure is available (preferably the year 2014):

Start: MM/YY End month: MM/YY

**Please take this period as the reference period when responding to the questionnaire.**

4. *Functions/activities implemented by the laboratory network*

In the table below we provide a list of core functions of laboratory networks developed for the purposes of this study. Before answering this question please have a look at the annex for a detailed description of their scope.

In the table, please indicate for each function and related activity whether it was implemented by your network as part of the work programme in the reference period.

| **Core functions of networks** | **Activities** | **Activities implemented in the reference period as part of work programme** | **Scope of the activity undertaken** (e.g. number of EQAs) |
|---|---|---|---|
| **1. Reference diagnostics** | 1a. Have up-to-date reference methods in operation | Yes/No | … |
| | 1b. Offer diagnostic confirmation services for laboratories in the network | Yes/No | … |
| | 1c. Typing, sub-typing, and detailed characterisation of pathogens, including investigating atypical samples | Yes/No | … |
| **2. Reference material resources** | 2a. Develop, maintain and/or have access to relevant source reference materials | Yes/No | … |
| | 2b. Provide and/or facilitate access to reference material for laboratories in the network | Yes/No | … |
| **3. Scientific advice** | 3a. Provide scientific advice and recommendations to public health authorities (i.e. Commission and ECDC, as well as public health authorities of MS affected by outbreak) | Yes/No | … |
| | 3b. Provide technical support for policy development related to reference microbiology, e.g. vaccine issues, outbreak response management and preparedness planning | Yes/No | … |
| **4. External Quality Assessments (EQA)** | 4a. Organise proficiency tests (inter-laboratory comparison) for laboratories in the network | Yes/No | … |
| **5. Training** | 5a. Undertake training activities for laboratories in the network | Yes/No | … |
| | 5b. Provide scientific advice to sub-level laboratories | Yes/No | … |
| **6. Collaboration and research** | 6a. Participate in regional/international public health microbiology laboratory networks | Yes/No | … |
| | 6b. Participate in other regionally or internationally relevant projects and initiatives, including research and development activities | Yes/No | … |
| **7. Monitoring, alert and response** | 7a. Supporting Member States in providing data to EU bodies that conduct surveillance tasks or other appropriate bodies | Yes/No | … |
| | 7b. Provide surge capacity | Yes/No | … |
| | 7c. Provide advice and technical support in outbreak investigations | Yes/No | … |
| | 7d. Inform competent authorities in case of unusual occurrences for their provision of early warnings | Yes/No | … |
| **8. Governance of the network** | 8a. Administration and coordination of the network | Yes/No | … |
| | 8b. Provision of IT-tools, if any | Yes/No | … |

*5. <u>Funding of the laboratory network</u>*

5.1. In the reference period, did the budget for implementing the network's work programme foresee any co-financing or is it fully covered by EU funding?

☐ Budget foresees only EU-funding
☐ Budget foresees EU-funding plus co-financing
- Percentage of co-financing required: …%
- Co-financing contributed by: …
- Comment: …

5.2. In addition to funds specified in the budget for implementing the network's work programme, were additional contributions used by network members in the reference period to implement the programme (e.g. additional staff time or consumables used for participation in an EQA, or travel costs to participate in training not reimbursed or indicated as co-financing in the budget)

☐ Yes
☐ No

5.3. If yes:
a) Where did these additional contributions come from? …
b) What were the additional contributions used for? …

Comment: …

*Note: You will be asked to provide details concerning additional contributions in a separate questionnaire.*

*6. <u>Costs of the laboratory network</u>*

Please fill out all sheets of the attached Excel document on expenditure of the network for the reference period, according to the instructions provided in the sheet.

7. *Benefits of the laboratory network*

7.1. Please assess in the table below the benefits resulting from implementing the work programme of the network. In the 'comments' field please provide details on how the benefit materialised (e.g. result of a specific network activity), and whether it can be quantified in monetary terms.

| | 1 (Not at all) | 2 | 3 | 4 | 5 (Very much) | Comments |
|---|---|---|---|---|---|---|
| **Benefits for members of the network** | | | | | | |
| ***The laboratory network…*** | | | | | | |
| Has contributed to improving methods employed by laboratories in the network | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has contributed to improving staff expertise of laboratories in the network | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has contributed to improving the quality and accuracy of data/results produced in laboratories in the network | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has contributed to improving the image and reputation of laboratories in the network | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has contributed to improving access to information, communication and/or collaboration among laboratories in the network | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **Benefits of the network for society overall** | | | | | | |
| ***The laboratory network…*** | | | | | | |
| Has contributed to a more timely and accurate detection of pathogens in the EU | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has contributed to a reduction in the disease burden and related costs in the EU | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has improved public health surveillance in the EU | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| Has increased laboratory preparedness and the capacity of coordinated response to outbreaks in the EU | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **Overall benefits compared to costs** | | | | | | |
| ***Overall, …*** | | | | | | |
| The benefits of the laboratory network outweigh the costs of implementing the network activities | ☐ | ☐ | ☐ | ☐ | ☐ | … |

7.2. Are there other benefits resulting from the laboratory network which have not been listed above?

☐ Yes

☐ No

7.3. If yes, please describe these other benefits: …

*8. Changes to costs and benefits under different coordination structures*

In the following we outline different scenarios for coordination structures of laboratory networks. Compared to the current coordination structure of your network, please assess how these scenarios would change:

(i) The costs of implementing the work programme of the network; and
(ii) The benefits accruing to members of the network and to society overall.

Please assume that the work programme implemented in these scenarios is the same as your current work programme. The only change is in the structure for coordinating its implementation. For each assessment, please provide details in the 'comments' field to justify your assessment.

**8.1. Scenario 1: Imagine that, instead of the current structure of one laboratory coordinating the network, the implementation of the work programme of the network is coordinated by a consortium of laboratories, with each consortium member taking the lead in a different activity of the work programme.**

a) Would you say that, as a result of a consortium coordinating the network, the total expenditures for implementing the current work programme of the network (as you specified in the Excel sheet) are likely to…

☐ Significantly increase
☐ Somewhat increase
☐ Remain unchanged
☐ Somewhat decrease
☐ Significantly decrease

Comments: …

b) If expenditures are likely to increase or decrease, which of the following cost items would change most? Please provide reasons for your assessment.

☐ Staff …
☐ Equipment …
☐ Consumables …
☐ Travel …
☐ Shipping …
☐ Subcontracting/services …
☐ Overhead/administration …

c) If expenditures are likely to increase or decrease, please provide your best estimate of the change in percentage terms: …% increase/decrease

d) Please consider again a situation in which a consortium of laboratories is coordinating the implementation of the work programme of your network, instead of one laboratory. In the table below please assess how the benefits of the network you specified above (in question 7) would change. If benefits are likely to increase/decrease, please use the 'comments' field to describe how.

| *As a result of the new coordination structure…* | Significantly increase | Somewhat increase | Remain unchanged | Somewhat decrease | Significantly decrease | Comments |
|---|---|---|---|---|---|---|
| **Benefits for members of the network as specified above would** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **Benefits for society as specified above would** | ☐ | ☐ | ☐ | ☐ | ☐ | … |

e) Would additional benefits arise from the new coordination structure?

☐ Yes
☐ No

f) If yes, please describe these other benefits: …

**8.2. Scenario 2: Imagine, that in addition to the current coordination of your network at the pan-European level a number of laboratories are appointed at the 'supranational' level, coordinating the implementation of the work programme for different country clusters.**

a) Would you say that, as a result of the introduction of the 'supranational' level, the total expenditures for implementing the current work programme of the network (as specified by you in the Excel sheet) are likely to…

☐ Significantly increase
☐ Somewhat increase
☐ Remain unchanged
☐ Somewhat decrease
☐ Significantly decrease

Comments: …

b) If total expenditures are likely to increase or decrease, which of the following cost items would change most? Please provide reasons for your assessment.

- ☐ Staff …
- ☐ Equipment …
- ☐ Consumables …
- ☐ Travel …
- ☐ Shipping …
- ☐ Subcontracting/services …
- ☐ Overhead/administration …

c) If expenditures are likely to increase or decrease, please provide your best estimate of the change in percentage terms: …% increase/decrease

d) Please consider again a situation in which a 'supranational' level is introduced to the coordination structure of your network. In the table below please assess how the benefits of the network you specified above would change. If benefits are likely to increase/decrease, please use the 'comments' field to describe how.

| *As a result of the new coordination structure…* | **Significantly increase** | **Somewhat increase** | **Remain unchanged** | **Somewhat decrease** | **Significantly decrease** | **Comments** |
|---|---|---|---|---|---|---|
| **Benefits for members of the network as specified above** | ☐ | ☐ | ☐ | ☐ | ☐ | … |
| **Benefits for society as specified above** | ☐ | ☐ | ☐ | ☐ | ☐ | … |

e) Would additional benefits arise from the new coordination structure?

- ☐ Yes
- ☐ No

f) If yes, please describe these other benefits: …

9. Please provide any additional comments you think we should take into account for the assessments of costs and benefits in this study, including any additional data sources you think we should consult:

…

# Annex II - Survey questionnaire

EB-02-16-620-EN-N

Publications Office

doi: 10.2818/959846