BRIDGEHEALTH
BRidging Information and Data Generation for Evidence-based Health Policy and Research

Bridge Health: Concept Paper

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Executive Summary

The European Union (EU) needs a basis and infrastructure for an integrated and sustainable health information system to support health research and evidence-based policy-making in the European Union.

Over the past decade, EU health information projects have provided useful research output that has served as input for national and European decision-makers. However, these projects also demonstrated significant gaps and deficiencies that need to be overcome, such as huge diversity of health information activities in Europe, fragmentation of databases and registries, health information inequality, and lack of sustainable policy-relevant health information research and activities. There is no mechanism yet to include the data of these projects in the European Statistical System and previous major investments in data harmonisation and the development of methods and expertise may go to waste as sustainability cannot be assured.

Other health information activities are carried out by EU agencies and the European Commission, such as Eurostat, and other international organisations, such as the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation Regional Office for Europe (WHO-EUR). However, gaps and deficiencies persist. The different health information areas are not systematically covered in the EU. Large differences can be found between Member States in both the quality and availability of health data. As Member States face new common challenges, this calls for stronger cooperation and better exchange of comparable data, knowledge and expertise.

The BRIDGE Health project has been given the task of investigating different possible structures for a comprehensive, integrated and sustainable EU health information system to support research and evidence-based policy for the EU and Member States. The goal of such an EU health information system is to (i) foster a common health information strategy including aspects of good governance, (ii) develop methodologies for establishing health information priorities and reducing health information inequality, (iii) develop coherence and compatibility between national systems and finally to (iv) coordinate existing EU health information infrastructures and research activities. This concept paper presents the BRIDGE Health analysis of the current situation and the possibilities for creating an organisational entity that could take up some of the support tasks that come with the need for strengthening the EU health information system.

Using multi-criteria analysis, the advantages, disadvantages and short-term feasibility are investigated for strengthening or extending existing structures (ECDC, DG SANTE, the JRC, Eurostat, WHO or OECD) or by creating a new structure (a new agency, an ERIC, a Joint Action, or a supra-European structure).

This analysis concludes that a European Research Infrastructure Consortium on Health Information for Research and Evidence-based Policy (HIREP-ERIC) is at this time the most feasible option. This may set important steps in the right direction and fulfil some of the most important criteria for an effective organisation around the scientific underpinning of health policy by new and better evidence from more and better comparable data.

Engaging via national public health institutes or equivalent national health information authorities, within the consortium of the HIREP-ERIC can provide added value for the Member States, the citizens, the national institutes and the European Commission itself.

Some disadvantages need to be taken into account when choosing for the ERIC as it cannot respond to all of the strategic needs for better governance, more coordination and transparent priority setting of the EU health information system. Finally, the urgency for a quick start might not be compatible with the creation of an ERIC. This would make a Joint Action a feasible interim solution.

The BRIDGE Health project

BRidging Information and Data Generation for Evidence-based Health policy and research (BRIDGE Health) is working towards a European health information and data generation network covering major EU health policy areas by promoting the coordination and convergence of existing key projects in health information.

The project was launched in May 2015 and runs until October 2017. It is coordinated by the Scientific Institute of Public Health in Belgium and includes 31 partners in 16 countries. It assures a knowledge transfer from past health and research frameworks in domains of population health and health system monitoring, indicator development, health examination surveys, environment and health, population-based injury and disease registries, maternal and child health, clinical and administrative health data collection systems and methods of health system performance assessment.

The main aim of the BRIDGE Health project is to work towards a comprehensive, integrated and sustainable EU health information system to support evidence-based health policy and research for the EU and Member States. The project reinforces and integrates expert and data provider networks to ensure optimal conditions for the implementation of this system. The BRIDGE Health project work is organised through vertical Work Packages (WP) and Horizontal Activities (HA). The first overarching outcome of BRIDGE Health is this concept paper.

This concept paper aims to provide interested Member States, candidate and EEA/EFTA countries with relevant information to make an informed decision on sustainable strengthening of the EU health information system.

For more information go to http://www.bridge-health.eu/ or contact the coordination team at bridge.coordination@wiv-isp.be.

1 The need for new evidence and information

Health and healthcare are major policy areas that draw intense political attention throughout the EU because a healthy population is a prerequisite for economic growth and national healthcare expenditures are increasing fast. In addition, the notions of equity, social justice and concerns with responding to the needs of citizens are high on political agendas.

Member States are facing common challenges. These include demographic changes: populations are ageing with concurrent multi-morbidities and disabilities (1). The number and severity of chronic disease patients is rising. This leads to growing healthcare needs, higher levels of medical attention and a need for increased preventive efforts. Simultaneously, higher patient expectations, the introduction of better, but often more expensive, technologies and pharmaceuticals have added to the healthcare costs (2). These healthcare and cost concerns have focussed attention on the effectiveness and efficiency of our health systems. In short: high-performing equitable health systems are a major policy priority throughout the EU now and this has been recognised by EU commissioner Andriukaitis (3). This requires optimally functioning national health information systems, including a well-governed EU system that allows for comparative analyses and benchmarking, where Member States can learn from each other Optimally functioning health information systems would allow policy makers to better understand the relationship between inputs, outputs and outcomes through which they can improve the efficiency of their health systems.

To address rising healthcare problems such as the increasing pressures on the sustainability of health systems, new and more effective health policies are needed. These have to be guided by the best available data, research and evidence on good practices, effectiveness and efficiency of our systems of healthcare and prevention. Up-to-date and high-quality health data are required to evaluate policies and interventions for their outcomes, costs and priority-setting, to determine public health system performances and to provide timely monitoring of trend in health and determinants (see Annex 3 for examples). Better evidence needs to be generated through more research using up-to-date and high quality data, and by making better use of data that may already be available in Member States and at EU-level.

Additionally, EU health information activities are extensive but diffuse, and without effective coordination this inhibits the effective use of data as inputs to policy development. Good health monitoring and healthcare evaluation practices need to feed into national and regional health policies. Timely reports and new research outcomes should inform and advise our citizens, medical professionals and managers as well as our local, regional, national and EU-level policymakers. Some areas, such as socioeconomic health inequalities and health system performance assessment have been identified as major focal areas for health information improvement, i.e. these areas face a special need for better data and indicators as well as reinforced research capacities in many Member States (4-6).

Comparing health data from EU-wide sets of healthcare providers, regions and countries allows health researchers to take advantage of the 'natural experiment' that is provided by the various types of interventions and practices that have been initiated throughout the EU. EU-wide availability of comparable data from all Member States makes it possible to gain valuable knowledge from these different approaches. To fully benefit from this European added value, improving the comparability and availability of the data becomes even more essential. The variability of sufficient or specialised research capacity to gather and analyse relevant data is a problem in many of our Member States.

The health information needs of EU citizens, health professionals, patient and health advocacy associations, professional societies, policymakers and politicians are growing fast. The current EU health information system, however, can hardly fulfil these changing needs. It also fails to take advantage of the existing opportunities to do so. In this context an EU health information system is defined as "*an integrated effort to collect, process, analyse, report, communicate and use comparable health information and knowledge covering all Member States to understand the dynamics of the health of EU citizens and populations in order to support policy and decision-making, programme action, individual and public health outcomes, health system functioning, outputs and research in the European Union.*" See Annex 1 for the definition of health information.

2 The current EU health information situation

In the past, EU health information research and evidence for policy has been taken forward through major investments in individual and independent EU projects and through the work of the European Commission and large international organisations.

Under the EU Health Monitoring Programme, EU Health Programme and the EU Framework Programmes, EU projects have provided useful input to research and national and European decision-makers (7-9). They harmonised and collected data, created strong EU-wide research networks, established working protocols, produced research articles, helped to pool scarce resources and reduced the burden of health reporting at both Member State and European level. The full list of EU-funded projects in health information which are associated with the BRIDGE Health project, but are only a fraction of the total number of projects, can be found in Annex 2. These projects have also demonstrated that there are significant gaps and deficiencies that need to be overcome such as

- diversity of health information structures in Europe;
- fragmentation of databases and registries;
- health information inequality within and between Member States; and
- lack of sustainability of health information activities (4-6;13-18).

There is no routine mechanism to include results of these projects in the European Statistical System, as stipulated by 'Regulation 1338/2008 on the community statistics on public health and health and safety at work'(19). Previous major investments will go to waste as sustainability cannot be assured (13). This will result in losing expertise, active data collection mechanisms and research capacity. As concluded by the European

Community Health Indicators (ECHI) and consecutive activities, "further efforts at DG SANCO and Eurostat are needed towards a permanent health monitoring system" (18).

Under the lead of Eurostat, the European Statistical System provides a solid working basis for gathering and providing health data. This health data is complemented by the work of WHO and OECD. The European Commission, WHO and OECD now coordinate a selection of statistical data collections and have increased their collaboration over the years. Eurostat, for example, as defined in the regulation 1338/2008, covers the following five areas of health information: health status and health determinants, healthcare, causes of death, accidents at work and occupational diseases and other work-related health problems and illnesses (20-22). In the eyes of some stakeholders in the health information area, international organisations do not yet collaborate most efficiently (23). Gaps and deficiencies persist, there is no common health information strategy or reporting agenda and we find several different but overlapping indicator sets.

Additionally, the different health information areas are not systematically or consistently covered in the EU. Activities in drug control, infectious disease control, medicines, cancer and rare diseases are respectively covered by the European Monitoring Centre for Drugs and Drug Addiction, the European Centre for Disease Prevention and Control, the European Medicine Agency and the Joint Research Centre (JRC). This does, however, not by far cover the integral area of public health and healthcare. There is still a huge area in which no health data gathering or indicator sets of comparable quality exist, which makes adequate comparative research impossible (2,6,13,18,24). A good example is the limited coverage of non-communicable diseases, even though chronic diseases are the main cause of death and poor quality of life in Europe (2).

Besides not covering all the different health information areas, the current health information activities, as observed by BRIDGE Health, also nearly always focus on vertical approaches. This approach does not foster the development of a holistic public health approach including both the areas of population health and health systems. The fragmentation leads to internal competition between public health domains, a lack of coherence and balance, and a less efficient use of the existing health data for analyses and research that support evidence-based policy. This reflects the need for an overarching coordinating and support structure that will improve comparative health research in specific areas.

3 Stakeholders have defined necessary changes

Over the years various stakeholders[1] have pointed out necessary improvements in the European health information system (1,2,6,13,24). Researchers have pointed out the need for improving:

[1]BRIDGE Health has not only found this in the literature, but also through multiple formal and informal consultations with stakeholders such as Member States representatives, former and current EU project leaders, National Public Health Institutes, consultative bodies at the European Commission.

- coordination,
- quality, availability and comparability of data,
- coverage of health information areas, and
- sustainability of health information infrastructures (2,6,13,24).

The Commission itself has already in 2004 indicated various needs to improve the operation and governance of a European Union Public Health Information and Knowledge System in a document presented to MS representatives in the area of health information (25).

In 2011, the EU parliament resolution asked the EC to "consider and assess the possibility of extending the remit of ECDC to encompass non-communicable diseases and using it as a centre for data collection" (26). The Council Conclusions of 2011, on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours, called on the EC to "consider the need for the better deployment of existing data and additional comparative data and information on unhealthy lifestyle behaviours, social health determinants and non-communicable chronic disease" (27). The conclusions indicate this should be obtained through sustainable health monitoring systems that are already in place or that might be established at EU level. These concerns were reiterated in the 2013 Council of the EU conclusions, on the reflection process on modern, responsive and sustainable systems, which invited the EC and Member States "to cooperate with a view to establishing a sustainable and integrated EU health information system ... built on what has already been achieved through different groups and projects … exploring in particular the potential of a comprehensive health information European Research Infrastructure Consortium (ERIC) as a tool" (28).

The directors of public health institutes of the EU Member States sent a joint letter to Commissioner Dalli in 2012 asking to develop a sustainable mechanism for health monitoring and reporting (23). They expressed their concern of losing expertise capable of doing coordination, development and standardisation at the European level. A second letter was sent in 2016 urging for more coordination between international organisations and to work towards a sustainable European health information system.

The Communication of the EC of 2014 on "effective, accessible and resilient health systems" calls for closer cooperation of Member States in the context of increasing interdependence and common challenges. The Communication focusses on strengthening the effectiveness of health systems, increasing the accessibility of healthcare and improving the resilience of health systems. In relation to this last point, the Communication refers to the establishment of a sustainable and integrated EU health information system. It also encourages cooperation between Member States on eHealth to improve health systems.

Besides these statements of a need for change in the past, BRIDGE Health has undertaken a stakeholder consultation meeting with EU national public health institutes in March 2016 to further investigate the issues. The consultations aimed to identify the national public health institutes' needs to strengthen the current EU health information system and their vision of an integrated and comprehensive EU health information system. All 28 Member

States' national public health institutes or corresponding institutes were invited to attend the meeting. A questionnaire was circulated before the meeting where participants were asked: what and if there is a need for an EU health information system, what could be the added value of such a system, and where improvements can be made in health information at EU level. During the meeting, the topics were further discussed in focus groups. The discussions were guided by moderators through a semi-structured interview. The consultation meeting was attended by 17 participants from 13 European countries. Ten responses to the questionnaires were received and the focus groups were composed of 14 participants in total.

The BRIDGE Health project organised a consultation meeting with the national public health institutes in the EU, since they are:

- the health information knowledge centres in the Member States, which make them potential key players in an EU health information system,
- policy supporting health researchers and the translators of research to policymakers, and
- contact points for national and international stakeholders allowing reflection of Member States' research and information needs.

The need to optimise the existing EU health information system again became obvious. Several core issues for improvement were identified in the consultation meeting with national public health institutes:

1. **International cooperation and coherence in EU actions of public health and public health research**

Currently, a variety of EU institutions and projects perform activities on health information without a holistic approach or transparent co-ordination. There is no coherent EU health information strategy or health data governance. This gives rise to issues such as the many overlaps concurrent with enormous gaps, the chasm between projects' agendas and EU health priorities and the scarce uptake of research results into public (health) practice and policy. An overarching EU health information strategy can guide and co-ordinate the necessary activities in the areas of research, monitoring and knowledge translation, and provide a link between institutions and projects. There is an additional need for a discussion forum and it is essential to overcome silo mentalities (i.e. fragmentation by health information domain).

2. **Better data quality, availability and comparability for research and evaluating policies**

Standardised methodological approaches are needed in many areas which can be adapted to the national infrastructures and culture, and together with quality control activities enhance the availability and comparability of data. An EU health information system strategy can provide the framework for this and involve key stakeholders at the Member State and EU levels such as national public health institutes or other data authorities, and health and healthcare authorities. It can prioritise the exchange of data, support the sustainability of data collection, improve the availability of data, and the usage of collected data for evidence-based policy-making and high level research. There is a need

to build trust on data and data use and look into privacy issues and how to deal with big data.

3. **Comparison and benchmarking among Member States and for the EU**

Working with an EU-wide health information strategy can support the sharing of information on population health and health systems across the EU. This would allow the Member States to have a more precise picture of the situation in their country and compare their outcomes to other Member States and regions. At the EU level, a more complete unified general picture of the public health situation can be generated. Comparing health information among EU-wide sets of health care providers, regions and countries allows health researchers to take advantage of the 'natural experiment' that is provided by the various types of interventions and practices that have been initiated throughout the EU. The availability and comparability of the data becomes even more essential then.

4. **Knowledge sharing and capacity building**

Fostering EU-wide cooperation also enables the exchange of expertise and capacity building through strong health information and research networks as the Member States can learn from each other. This also means easier access to high quality data for researchers. Simultaneously, such an approach can address health information inequalities in Member States and the EU. International collaboration toward common best practices is essential to enable all countries to benefit from health and to support the production of multi-country statistics, research and other uses of data that serve the public interest. A lack of policy-oriented health research capacity is a problem in many of the Member States.

5. **Transfer of health information into evidence-based policy-making**

Having the appropriate data, tools and knowledge allows policymakers to respond effectively to population health and health systems' challenges and to evaluate policy measures. Resources available to Member States' health systems and EU institutions are diminishing. A strong governance and framework for health information would allow efficient resource allocation through better prioritisation and reduced duplication of activities, e.g. evaluation of aspects of cross-border care.

4 Summary of health information governance needs

According to the evaluation of BRIDGE Health, the problem is that ongoing activities in the area of health information were developed to work on specific health domains using multiple disciplinary and methodological approaches. Therefore, taken as a group, they:

- are not coordinated transparently,
- lack a comprehensive priority setting methodology,
- have no systematic structural translation to policy,
- miss a focus on tackling health inequalities, and
- are often lagging behind in fulfilling current policy needs.

Various Member States have taken up national activities in assessing system performance, policy evaluation and data collection in many different ways. Throughout the EU, however, the Member States face large differences in the availability and quality of relevant health data, variable availability of expertise and capacity for analysing these data. Moreover, there is a lack of ability to use comparative health research data that allows a better assessment of the national or regional health situation.

This situational analysis calls out for improved identification and prioritisation of data needs, for more Member States involvement, better and more transparent coordination and some forms of central governance by setting up an organisational entity. This should improve harmonisation and collection of health data and indicators, better access to comparable health data, capacity for health system research and for public health analysis and research, evidence synthesis and knowledge translation and support for more and stronger health research networks and communities, for instance by focussed capacity building and a better exchange of expertise and knowledge. This requires the design and implementation of an integrated and sustainable EU health information system, which includes a clear mapping and problem definition, and a vision on a longer term. Possible added valued for stakeholders

The added value for setting up an organisational entity that could take up the tasks that come with the need for strengthening the EU health information system can be felt at different levels. Together with representatives from national public health institutes, BRIDGE Health has made an inventory and analysis of the possible types of added value which could be provided to various stakeholders.

The benefits for the health research field and public health institutes in particular are related to improving data and collaborations an EU health information system would generate (Table 1). Improvements can be made on data availability, comparability, quality and scale. Manuals and guidelines can be developed to work towards this endeavour. The research capacity can be strengthened through a structured platform of collaborative scientific exchange with knowledge exchange and capacity building. This also allows enhanced data flows, larger study populations and quicker results. By enhancing collaboration between research and public health institutes in the Member States, coordination can be improved and synergies can be created between projects and health information activities.

Table 1. Added value for research and national public health institutes

1) EU-comparative data	2) Collaboration between research and public health institutes
- Data quality - Continuous availability - Enhanced research capacity - Larger study populations and cohorts - Enhanced data access flow - Structured scientific exchange - Quicker results	- Organise and coordinate public health expertise and systems - Create synergies between projects and health information activities - Better access to existing knowledge and expertise

For the Member States, the added value would be felt by different stakeholders; including decision-makers, financiers, administrators, data providers, healthcare providers and most importantly the citizens (Table 2). An integrated and sustainable EU health information system can provide a forum for research and public health priority setting, and propose actions to address priorities. Reliable and high quality data will be available for better evidence-based decisions, better preparedness and programme evaluation. Additionally, as the Member States are facing common challenges, interaction and collaboration leads to stronger approaches to better address these challenges. Better research and enhanced monitoring will lead to improved health outcomes for citizens, where health inequalities can be addressed. Healthcare providers will have the necessary tools to perform evidence-based care and report on their performance. For administrators and data providers, the improved EU health information system can assist in international data provision. Finally, by providing an overview of activities in health information in the EU, better value for money can be generated as overlapping activities will be prevented.

Table 2. Added value for the Member States

Decision-makers	Citizens
- Quality information for evidence-based decisions - Better preparedness - International comparison: evaluate and discuss how to tackle similar challenges - Programme evaluation - Priority setting	- Improved health and wellbeing by enhanced monitoring of health risks, health status, health determinants, and the safety and quality of healthcare services - Patient reported outcomes and experiences (PROMS and PREMS) - Reduced health inequalities

Administrators/data providers	Financers	Healthcare providers
- Reduce burden by increasing harmonisation of international data collection to reduce duplication - Assist in obligation to provide data to international sources	- Better value for money in international health information activities and health research - Optimise funds allocation	- Data to set standards and protocols for evidence-based care and to evaluate their policies - Benchmarking i.e. learning from best practices

From an EU perspective, an integrated EU health information system could provide new insights into the health situation in the EU. This will include the potential to examine the causes of changes and evolutions of population health and its determinants, the distribution of health and health inequalities, and health systems. The effectiveness and efficiency of public health interventions can be evaluated. Comparison and benchmarking against other regions in the world will be facilitated. An EU health information strategy can be strengthened with alignment of activities and strategies, where investments made in the past will not be lost and future research spending will therefore be more efficient. Also clear communication of public health developments and threats will be facilitated with better support of EU initiatives in all EU departments where health information is needed.

5 A comprehensive, integrated and sustainable EU health information system

Based on the above findings, BRIDGE Health has identified the necessary key features to establish a basis and infrastructure for an integrated, sustainable EU health information system that supports health research and policy-making. This section reflects what the mission, vision, scope, goals and tasks of such a system should ideally be. These features are independent of the chosen structure.

5.1 Mission

The EU health information system improves people's health and health system performance in the EU by data integration and analytics, research, knowledge generation and dissemination that support multi-level actions.

5.2 Vision

Through research, the EU health information system provides the best available knowledge to improve the well-being and health of EU citizens and populations.

5.3 Scope

The scope of an EU health information system should be comprehensive, addressing health systems and population health including health status and determinants of health. Health information at individual and population level should be considered with equity and looking at societal values and policy (Figure 1). Data are used through research to understand the health level of the EU citizens, to understand the health gaps between EU populations and to identify the factors (health system and health determinants) affecting the level of health and the health gap between populations.

In order for the EU health information system to become operational, the main constraint is not the scope of data coverage, but rather the activities the EU health information system can carry out and how it deals with the information needs and existing data gaps. Therefore, information needs and data gaps should be identified and prioritised at a very early stage through a defined and transparent methodology and in a continuous manner.

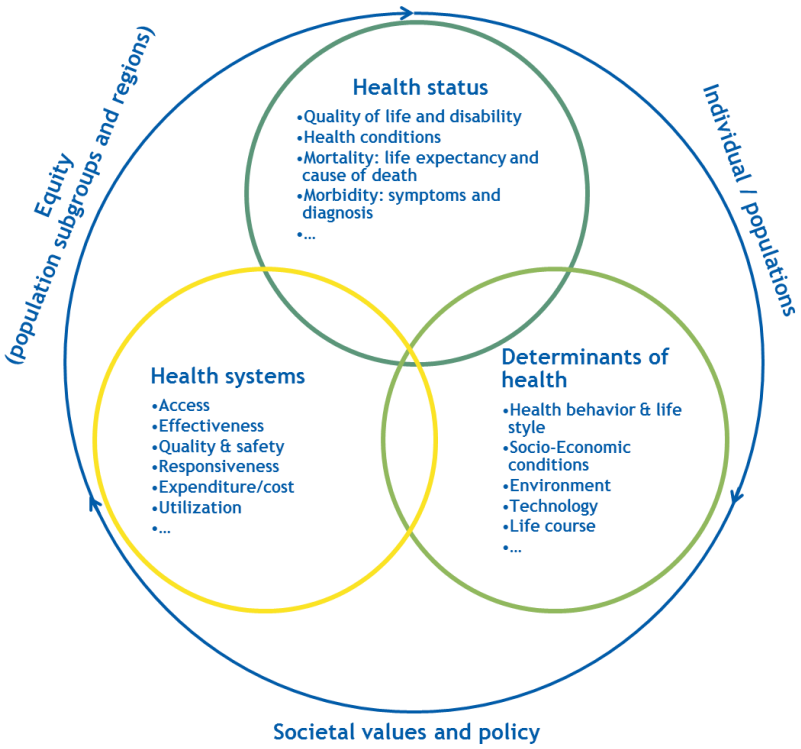

Figure 1: Scope of EU health information system

5.4 Goal

Through research, the goal of the EU health information system is to support health and non-health policy-making in the EU and all Member States by ensuring the integration, collection, analysis, and exchange of health information

1. with comparable data (harmonisation and standardisation);
2. of high relevance and usefulness (priority setting method);
3. of high quality (timeliness, internal and external validity);
4. by reducing knowledge gaps and addressing information needs; and
5. by resolving ethical and legal issues;
6. covering the whole of the European Union in a structured way.

5.5 Tasks

The tasks of an EU health information system should be broad and cover a wide range of activities. It should make use of existing data sources for research in Europe and take into account the experiences of similar undertakings by building on experience of existing projects, institutions and structures. In the start-up phase of the EU health information system, essential tasks should be integrated into a core 'work plan' that can be further broadened as the EU health information system develops.

The BRIDGE Health project made an initial selection of 10 tasks:

1. Foster coherence in activities in health information between the Member States and EU institutions to contribute to a common EU health information strategy;

2. Identify health information needs and priorities in a methodological and systematic way;
3. Map data sources and identify data gaps;
4. Set up an EU data/indicator repository;
    a. Collection (standardised tools)
    b. Compilation (access and/or transfer)
    c. Integration (data extraction)
    d. Transformation (harmonisation and loading processes)
    e. Analysis (data quality and production of outputs)
    f. Research (study data) and
    g. Inference (conclusion reached on the basis of evidence and reasoning)
5. Identify legal and ethical issues related to data ownership, sharing, access, transfer, storage, processing and reporting, and contribute to the development of common standards and best practices;
6. Link and exchange with stakeholders: support research-to-policy interaction, transferability of health information and data for policy and outline the information dissemination strategy and tools;
7. Ensure outputs are datasets for research, surveillance and monitoring purposes, public reporting of health and healthcare performance indicators; manuals/guideline/methods for data quality, for data analysis, for data interpretation and communication;
8. Create guidelines for training and capacity building for the Member States to reduce health information inequalities;
9. Ensure sustainable funding for the EU health information system;
10. Ensure regular evaluation of the EU health information system.

Figure 3. Potential branches of activities carried out by an EU health information system

To frame essential functions of the EU health information system, diverse health information domains[2] are bridged by horizontal activities within BRIDGE Health. The horizontal activities are based on the above tasks and aim at developing common methods to:

(1) enhance the transferability of health information and data for policy and improve the utility and use of data and indicators for stakeholders in policy-making, public health surveillance and healthcare;
(2) reduce health information inequality within the EU and within Member States;
(3) enhance information at regional level and specific population groups;
(4) standardise health information gathering and exchange of population health and health systems information within and between the Member States;
(5) standardise data quality assurance systems;
(6) identify relevant health information priority setting methods; and
(7) identify ethical-legal issues. The proposed methods will form the basis of a future comprehensive, integrated and sustainable EU health information system.

5.6 Structural options

BRIDGE Health has analysed the current (2016) situation and investigated the possibilities to create an organisational entity that could take up the tasks that come with the need for strengthening the EU health information system.

The following elements are essential in the evaluation of different structures:

1. Acceptability and support of the Member States and the European Commission. Consideration also of the needs to be given to the appropriate governance of the structure, so that all relevant stakeholders are engaged without inhibiting progress.
2. Feasibility in short term and in the current legal, economic and political framework.
3. Financial sustainability with resources from both EU programmes and the Member States.
4. Ability to carry out research and public health surveillance and monitoring in population health and health system performance.

A full list of potential factors that need to be taken into account when evaluating different options can be found in Annex 4.

Using multi-criteria analysis, the advantages and disadvantages are investigated of either strengthening existing structures or creating a new one. The different options were discussed in focus groups with National Public Health Institutes and BRIDGE Health work package leaders by using SWOT analyses and the criteria in Annex 4.

[2] The BRIDGE Health project coordinates and converges the best of EU projects in domains of population and health system monitoring, indicator development, health examination surveys, environment and health, population injury and disease registries, clinical and administrative health data collection systems and methods of health systems monitoring and evaluation.

5.6.1 Strengthen existing structures

At European level, various institutions and agencies carry out activities related to health information such as different Directorate Generals (DG) of the European Commission, decentralised agencies and international organisations. The advantage of working with an existing structure or a combination of existing structures is that, in general, the infrastructure and administration are already in place. There is a basic legal mandate and framework, and the political setting with existing networks is set up. Rather than creating something new, one can build on existing knowledge and expertise. However, current activities of existing structures can diverge from the role envisaged for the proposed EU health information system, as new domains are tackled, and strong political support would be needed to allocate resources and/or change activities. Various options can be considered; separately or combined. Table 3 provides an overview of strengths and weaknesses of various options.

- Expanding tasks of Eurostat

Eurostat already has long-standing experience with data and statistics. Its task to provide the EU with statistics at European level that enable comparisons between countries and regions, corresponds with the gaps of the current EU health information system and indicators could be included in the European Statistical System. Eurostat also has a legal mandate for the collection of health data as defined in the regulation 1338/2008 covering health status and health determinants, healthcare, causes of death, accidents at work and occupational diseases and other work-related health problems and illnesses. The weaknesses of selecting Eurostat are linked to the fact that Eurostat focusses on data and statistics which are to a majority not linked to public health. Eurostat provides strong governance on the statistical system, but does not provide this from a public health point of view which is needed in this context. Additionally, Eurostat has a wide range of activities, but as a statistical office it does not focus its work on translating data into knowledge for evidence-based policy-making.

- Extension of the scope of the European Centre for Disease Prevention and Control (ECDC)

The major strengths of extending the ECDC are its focus on health and the fact that one can build on existing knowledge and expertise acquired through the work on infectious diseases. The ECDC has experience in managing large networks and carrying out capacity building. This centre is also mostly linked to public health functions and has existing links with the Member States. However, infectious diseases are the main focus of the ECDC and there is no wider mandate for health information in other domains. The visibility of the ECDC is linked to infectious diseases and there is no experience in non-communicable diseases. The name of the centre does refer to disease prevention and control which could fit within the need for strengthening the EU health information system. Adding one or more units within the ECDC focusing on wider activities than infectious diseases could tackle some of the issues. Finding the necessary political will and resources for this could be very challenging.

- Reorganisation of DG Health and Food Safety (SANTE)

The strength of DG SANTE is their existing knowledge and expertise in public health, in addition to their mandate of the health programme. However, the activities of DG SANTE orient towards policy rather than towards research. The operational capacity is also low and long-term continuity cannot be assured.

- Extending work plan of DG Joint Research Centre (JRC)

The JRC has developed expertise and experience in certain aspects of health such as cancer and rare diseases. It translates health information for policymakers and can adjust its work plan according to the needs of DG SANTE. This, however, may limit the sustainability of its activities as they may change over time. The main focus of the JRC is not public health but research, and the institution has limited interaction with the Member States.

- Outsource to the World Health Organization (WHO) Europe or the Organisation for Economic Co-operation and Development (OECD)

To avoid duplication of activities, outsourcing activities to the WHO or the OECD may be considered, similarly to what is currently done for the report "Health at a Glance". Both international organisations have expertise and experience in public health and core data set work. The weakness of working with such an organisation is that they are not solely EU-focussed and may therefore have their own agenda, different mandates and policy aims.

5.6.2 Create a new structure

A new structure allows more flexibility in terms of activities and scope. It can tailor its activities to current needs and demands. It can cover the gaps of existing structures and provide an overview of existing initiatives in health information. A new structure can also have a voice of its own for better advocacy and visibility. It can build on the knowledge and experience of previous EU projects using health information or health data. However, similar to existing structures, political support is needed and financing (mechanisms) need to be found. The strengths and weaknesses of chosen various options are described in Table 4.

- Creating an independent new EU agency

Creating a new EU agency would, besides the strengths discussed above, also operate within the EU framework. It would have a strong legal basis and it is questionable why such an agency does not exist yet. In the current economic climate it is however not realistic to set up a new EU agency, but it could be a long-term goal. A strong political will would be needed. BRIDGE Health also found out during discussions that current institutions may also perceive a new EU agency as threatening.

- European Research Infrastructure Consortium (ERIC)

The strength of an ERIC is the relatively short term needed for its setup following a known procedure and the fact that an ERIC has a legal framework. It is a practical solution with a flexible format and financial framework. An ERIC can receive funding from e.g. the EU Health Programme. Research and development are part of the solution and international

collaboration can be assured. An ERIC can grow and be built up. Moreover, good examples exist and can be learned from. As many other structures, sustainability cannot be assured. An ERIC is Member State-driven and therefore depends on the willingness of the Member States. In relation to the governance, a major drawback is that the European Commission cannot be a member of the ERIC and not all Member States need to be part of the ERIC, which means its success depends almost entirely on the willingness of the Member States. Additional weaknesses include its lack of mandate to steer health information in the EU.

- Joint Action

A Joint Action is easy to be set up and can provide a transition between the BRIDGE Health project and any structure that may be created. This may be necessary as most other options (even setting up an ERIC, which is a rather medium-term solution) may take several years. The weakness of a Joint Action is that not all Member States need to participate, there is a lack of mandate and it is only a temporary solution.

- Supra-European structure

Creating a supra-European structure such as a Codex Alimentarius Commission may be prestigious and has high credibility and visibility, but it will not be EU-focussed. There is also no legal status and a high administrative burden.

5.6.3 Combination of new and existing structures

Using the strengths of an existing structure, a new structure could be built to take up the activities that remain. The strength of this format is that existing institutions are not overridden, the role of coordination and governance could be taken up by an EU institution and a long-term way of working together could be established. One of the challenges would be the coordination between those structures. Many different options can be considered combining the options described above e.g. a health information division in ECDC where the policy thinking would happen, in addition to an ERIC which could incorporate research and data infrastructure.

Table 3: Strengths and weaknesses of using an existing structure

Strengthen existing structure	**Strengths**	**Weaknesses**

Expanding Eurostat's tasks	- Existing infrastructure
	- Existing expertise and experience
	  o Works with Member States
	  o Does data collection in health with EU regulation
	  o Has a baseline on indicators
	  o Has good knowledge of data
	- Deals with cross-cutting themes (other directorates outside of health)
		- Focuses on data and statistics
		- Majority activities not related to public health
		- Does not provide any governance involving Public Health structures in Member States
		- Has no focus and knowledge translation
		- Misses a link with Ministries of health since the main link of Eurostat is with statistical institutions

Extension of the scope of the European Centre for Disease Prevention and Control (ECDC)	- Existing infrastructure
	- Existing experience and success
	  o Managing large networks
	  o Capacity building in countries
	- Provides a link between existing work on infectious diseases and EU health information system
	- Is linked to public health function
		- Focusses on infectious diseases
		- Has no mandate for wider health information
		- Visibility only connected to infectious diseases
		- Has no experience on non-communicable diseases

Reorganisation of DG SANTE	- Existing infrastructure - Existing expertise and experience - Has mandate of health programme	- Politically oriented - Misses scientific dependence - Operational capacity - Long-term continuity
Extending the work plan of the Joint Research Centre (JRC)	- Existing infrastructure - Expertise and experience in cancer and rare diseases - Translates data into policy - Flexibility	- No public health focus - Research-oriented - Sustainability - Limited interaction with MS
Outsource: WHO, OECD	- Expertise and experience in public health - Core data set work - Avoid duplication - Expertise and knowledge on international comparison of health care systems	- Not EU-focussed - Own agenda, different mandate and policy aims - Little influence on EU - Sustainability

Table 4. Strengths and weaknesses of creating a new structure

Create new structure	**Strengths**	**Weaknesses**
Independent new EU agency	- Tailored to specific needs and demands - Visibility for public health - Have a voice of its own - Strong basis - Clear vision and goals - Operate within EU frame	- Not realistic in current financial climate due to high constraints - May be perceived as threatening to existing programmes - Needs to start from scratch - Needs strong political will - Long time to be set up - High governance/administrative costs
European Research Infrastructure Consortium (ERIC)	- Practical solution due to the availability of legal framework - Can be set up in relatively short term - Is flexible in format and financial contributions - Research and development are part of the solution - Collaborate with international agencies - Can grow and be built up - Can receive EU funding from e.g. EU Health Programme - Examples of ERICs are available from which experience can be used	- Is mainly research- and science-driven - Sustainability depends on funding provided by MS - Does not require involvement of all Member States - Depends on willingness of Member States - European Commission cannot be a full member - Lack mandate to steer health information in the EU
Joint Action	- Easy to set up - May be an interim solution	- Short-term solution - Not sustainable - Limited funding - Not all MS need to participate - Lacks mandate to steer health information in the EU
Supra-European Structure (e.g. Codex Alimentarius Commission)	- Prestigious, credible and visible	- No legal status - Administrative burden and coordination - Not EU-focussed

5.6.4 An ERIC and the way forward

Compared to the other options, the strongest argument to support the setup of an ERIC is its feasibility in the relatively short term. An ERIC application takes about 9-12 months to process at the Commission (29). An ERIC is a legal entity created by a decision of the European Commission. It has legal personality and a full legal capacity recognised in all EU Member States. In the current framework, reorganising, expanding or creating a structure dependent of the European Commission is not feasible. The Commission has adopted a communication to implement a 5% staff cut in EU institutions by 2018 (30).

In terms of financial sustainability, an ERIC is eligible as a sole beneficiary for several EU funding mechanisms including Horizon 2020. The SHARE-ERIC has for example received grants by the EU commission (7th Framework Programme) and the US National Institute on Aging, which it spends on central services (31). This alleviates the fact that an EU institution cannot be a member of an ERIC. In addition, Members of the ERIC provide in cash or in kind contributions as determined in the statutes of the ERIC. These contributions vary greatly among existing ERICs and need to be discussed when drafting the statutes of the ERIC. For example, the BBMRI-ERIC Membership contribution model is stratified in groups according to the number of inhabitants: 20,000 € base contribution for Members whose number of inhabitants is below 3 million and 25,000 € whose number of inhabitants equals or exceeds 3 million (32). Also, according to the ERIC regulation, an ERIC must carry out its principal task on a non-economic basis. However, it may carry out limited economic activities, provided they are closely related to its principal task. These activities can support the sustainability of the ERIC.

An ERIC is a tool with high usability for the Member States and EU institutions. The basic internal structure of an ERIC is flexible and can be tailored to current needs and demands. As defined by its Members, an ERIC can set clear targets and objectives to focus efforts on priority research questions and make better usage of existing health information sources. An ERIC can ensure linkage with its stakeholders, including the scientific community, national infrastructures and international organisations. Through research, it can provide relevant information for decision-makers, the necessary tools for research and has the capacity to bring different actors in health information together to strengthen health information in the EU. The willingness of institutes within the Member States, i.e. national public health institutes, to contribute to the setup of an ERIC is an important added value as in general these institutions are bridging research and policy.

An ERIC is a potential tool to support the goal of working towards more and better coordination in activities related to health information in the EU, as well as for facilitating the involvement of international organisations such as the OECD and the WHO. DG SANTE has indicated its preference for this option. The Member States have indicated that alternatives should be further investigated, but when evaluating each of the options based on different criteria including the short-term feasibility, it is clear that the ERIC is maybe not the preferred but the only feasible option. Ownership at Member State level will have to be taken in order to build an ERIC, since an ERIC is 100% Member State-driven and relies on the willingness of Member States.

Some other disadvantages need to be taken into account when choosing for the ERIC as it cannot respond to several important needs for better governance, coordination and priority setting for the EU health information system. Also, the urgency of a quick start and the possibility that creating an ERIC may not meet this deadline would make a Joint Action a feasible interim solution. In the long run, the ERIC can form a template for future arrangements once it established 'proof of concept'. The structure could then evolve to one of the other more ideal options such as a new EU agency or extending the remit of Eurostat or ECDC.

Taking this together, the BRIDGE Health project recommends the creation of an ERIC in health information as a tool to strengthen research and evidence-based policy. Aiming for the ERIC seems at this time the most feasible option to set important steps in the right direction and fulfilling some of the major criteria for an effective organisation. However, the urgency of a quick start and the possibility that creating an ERIC may not accommodate this urgency, would make a Joint Action a feasible interim solution.

6 ERIC on Health Information for Research and Evidence-based Policy

BRIDGE Health has taken the lead in this document to set out an initial vision of how such an ERIC on health information could look like. These will be further developed within BRIDGE Health and the drafting group of the Expert Group on Health Information at the European Commission in collaboration with stakeholders. More details will be provided in the Technical and Scientific Description of the ERIC which is being developed.

The ERIC is called the "Health Information for Research and Evidence-based Policy - European Research Infrastructure Consortium", abbreviated as the "HIREP-ERIC".

The HIREP-ERIC will establish a basis and infrastructure for an integrated, sustainable EU health information system. The ERIC will collect and analyse data, and provide scientific and technical services. The knowledge generated by the HIREP-ERIC provides harmonised and comparable health data allowing comparison within and between Member States for informed decision-making at national and EU level. Furthermore, it will support health research, provide a sustainable structure for best practice exchange between Member States and support mutual learning.

The HIREP-ERIC will function as a network of networks, linking national experts and research facilities allowing research collaboration across Europe with strong ties to existing research projects and national and international institutions and organisations. The national public health institutes or equivalent national health information authorities can have an active role in the HIREP-ERIC and be its driving force.

6.1 The ambitions of an ERIC on health information

In accordance with the LOGIC model for the identification and assessment of impacts of EC-supported Public Health R&D projects (33), an ERIC on health information should provide a backbone and sustainable infrastructure to support the research fields of population health monitoring and health system performance assessment, by:

- Advancing scientific knowledge
- Building capacity and targeting research
- Informing decision-making, practice, and policy
- Generating health and health sector benefits
- Dissemination and transferring knowledge

When worked out in some more detail this will involve:

1] Strengthening research and research input by expanding knowledge and disseminating existing knowledge and enhancing research capacity in the EU and partner countries. The HIREP-ERIC will enable its participants to better partake in EU-funded research projects, such as the Horizon 2020 programme and the public health action programmes.

2] Supporting new or existing research project activities and networks. This involves training and capacity building for research, support actions and coordination of projects and networks as well as dissemination of outcomes (reporting, scientific publications, websites, congresses) and assisting with elements of overarching project management.

3] Contributing to relevant research outputs such as new research tools, databases for detailed analysis, harmonisation of data collection (guidelines, standards, protocols). It will also generate scientific publications, enhance investigator careers, deliver experts and expertise to policy advisory work and expert committees. An important task for the HIREP-ERIC is the strengthening of research networks towards more sustainable data collection and regular assessment and analysis.

4] Through the creation of research opportunities, the HIREP-ERIC would thus contribute to having more and better evidence and knowledge for health policy-making by harnessing a larger and more relevant health research capacity. The ERIC thus contributes to new or improved institutional and national policies, new or better regulations, more and better research and research methodologies, and more efficient resource allocation and intervention programmes. The HIREP-ERIC also contributes to better informing health professionals and citizens about possible improvements in health and healthcare and in living and working conditions and personal health behaviour.

In this way, the HIREP-ERIC contributes to improvements in health and well-being and economic and social prosperity in Europe by enhancing the output, capacity, quality, dissemination and efficacy and efficiency of European health information-related research.

6.2 Services provided by the HIREP-ERIC

The HIREP-ERIC will have specialised 'country hubs' that focus on developing specific health information areas. The country hubs will harmonise and, if needed, collect data. Through research, they will generate new insights and understanding in the dynamics of population health and healthcare systems, and new evidence for supporting policy development and evaluation. The overall task of the HIREP-ERIC will therefore be to facilitate and support network building and coordinated research project development, in particular in new or underdeveloped health policy areas in the EU.

A variety of services that will support research are to be provided by the ERIC. The core activities of the HIREP-ERIC will revolve around (1) indicators, (2) repository platforms and (3) capacity building.

1] The HIREP-ERIC will provide technical and expert support for comparable, standardised and accessible indicators for health and health determinants, health services and health systems. This includes updating indicators, developing new indicators and improving existing ones. The country hubs will facilitate this work by providing national ECHI indicators, enhancing quality and standardisation in Member States.

2] The HIREP-ERIC will facilitate and support the development and hosting of repository platforms for:

- health data;
- metadata;
- data collection protocols, including guidelines and handbooks for implementing surveys and developing and maintaining registries;
- tools and methods for pre- and post-harmonisation;
- tools and methods for data collection, quality assessment, analysis, reporting and knowledge translation; and
- tools to facilitate the access and use of data for research.

3] The HIREP-ERIC will carry out capacity building activities in the Member States in areas needed with training programmes enhancing researchers' mobility.

The three core activities above are aided by a number of other activities and services, such as:

- Support for research methodology development including the development of new and more efficient methods and tools for data collection, quality assessment, use, analysis and reporting as well as knowledge translation.
- Support for the dissemination of research outcomes via a health information methods portal. This will help individual researchers in accessing and using specific data sets and metadata, as well as tools and guidelines.

As health and healthcare cover an enormous subject area, the HIREP-ERIC activities will also include looking to create 'meta-access' to data sources suited for international comparisons, aiming at knowing where national and international data sources and repositories are located and how to access and use them. The ERIC will not do, what other stakeholders are already doing, but liaise and guide researchers to available and comparable data.

A final major area of activity of the HIREP-ERIC concerns advocacy, communication, knowledge transfer and data protection. This includes:

- Research to improve the knowledge translation of health research outcomes from the ERIC activities to the general public and to policymakers as a central activity in the HIREP-ERIC strategy. The ERIC will collect and disseminate best practices that

will enable researchers to optimise their research output to better suit policymakers and citizens.

- Dissemination of new policy-relevant articles and reports from the area of comparative population health research and from comparative research in the area of health system performance assessment as an optional service, as is developing and maintaining a library of policy-relevant reports and articles.
- Methods for and setting of research priority assessments based on population health needs and variation between Member States.
- Publication of newsletters and organisation of meetings and workshops as well as expert exchanges.
- Development of state-of-the-art distributed privacy protecting analytical platform and tools for data protection and privacy issues including ethical and legal aspects.

6.3 Governance structure of the HIREP-ERIC

The HIREP-ERIC is a distributed research infrastructure located in ERIC member countries, as well as in other countries where the ERIC has made agreements. The HIREP-ERIC operates through country hubs and their networks. It will work with and advise DG SANTE's Expert Group on Health Information (EGHI), the Member States and the European Commission.

The BRIDGE Health project investigated existing ERICs and suggests a governance structure based on this analysis. The governance structure of the HIREP-ERIC is shown in Figure 4 and is composed of an Assembly of Members, a Scientific Advisory Board, a Central Executive Management Office and a Network Committee. The strategic decisions are taken by the Assembly of Members with support from the Scientific Advisory Board. The executive activities are carried out by the Central Executive Management Office, which includes the Director General and the Core Team. The operative activities are carried out by the Network Committee.

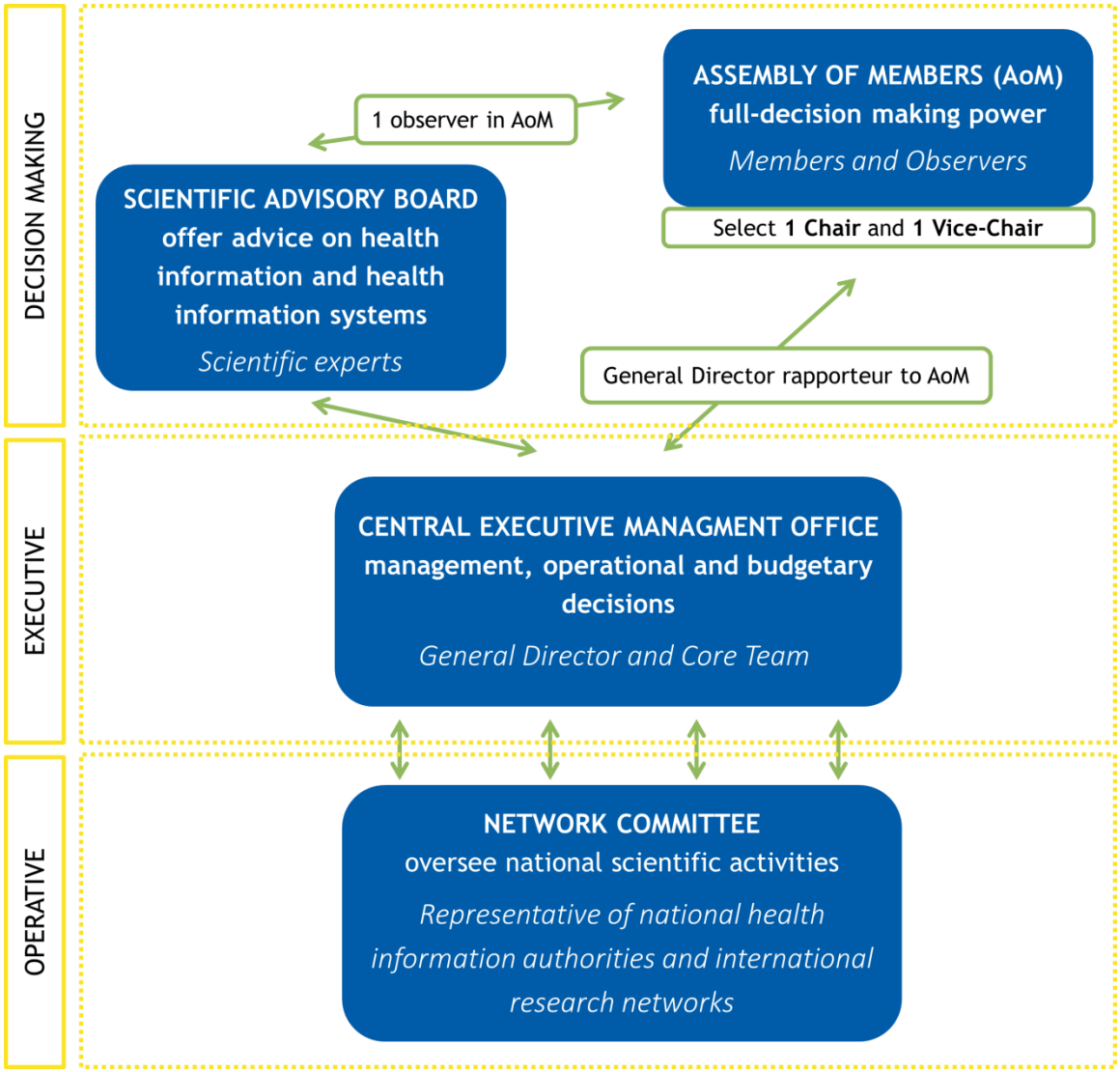

Figure 4. Governance structure of HIREP-ERIC.

6.3.1 Decision making

A. The Assembly of Members

The Assembly of Members is the governing body of the ERIC and is composed of representatives of the members of the ERIC. Members may decide to accept observers. BRIDGE Health suggests the observers to have no voting rights. The Assembly of Members is the highest and ultimate governing body of the HIREP-ERIC with full decision-making power. Each member and observer nominates an official representative. The Assembly of Members elects amongst its members a Chairperson and a Vice-Chairperson to chair the meetings. One representative of the Scientific Advisory Board is invited as an observer in the Assembly of Members. The Director General is the rapporteur of the Central Executive Management Office to the Assembly of Members.

This Assembly of Members will be responsible for the following activities:

- appoint the Director General,
- note and approve minutes from the past meeting,
- discuss, amend and adopt changes in the strategic plan, governance structure, annual or pluri-annual work plan,
- adopt the annual budget and pluri-annual budget,
- approve the annual activity report,
- approve the audited accounts and budget of HIREP-ERIC,
- adopt decisions on contributions of members and observers and the annual budget proposed by the Director General,
- evaluate the management plan of the Director General and the translation of the management plan into the strategic plan and operational objectives,
- evaluate the Director General against the realisation of the management plan,
- approve the admission of new members,
- evaluate and approve the admission of observers,
- adopt the implementing rules and approve the Internal Rules of Procedures, and
- decide on proposals for amendments to the Statutes of HIREP-ERIC and notify the EC for approval.

B. The Scientific Advisory Board

The Scientific Advisory Board consists of independent and internationally recognised scientists involved in population health research or health system performance assessment acting on their personal title and strategic experience.

The Board will offer advice on request of the Assembly of Members and may be consulted by the Central Executive Management Office on al scientifically and technologically relevant matters including questions regarding the research agenda, scientific strategies, ethical issues and the annual work programme. The Scientific Advisory Board is also tasked to evaluate the activities and products of HIREP-ERIC.

The Scientific Advisory Board can select an observer to participate in the Assembly of Members.

6.3.2 Executive

A. The Central Executive Management Office: Director General and Core Team

The Central Executive Management Office is composed of the Director General and a Core Team. The Central Executive Management Office is the executive body of the HIREP-ERIC. It is responsible for the management, operational and budgetary day-to-day decisions. The Central Executive Management Office executes the decisions taken by the Assembly of Members. There is a clear frontier between the strategic decisions taken by the Assembly of Members and the executive part carried out by the Central Executive Management Office in order to avoid any conflict of interest within the HIREP-ERIC.

The Director General is appointed by the Assembly of Members and is assisted by the Core Team. The Core Team is in charge of the coordination and support office of the HIREP-ERIC. The Core Team acts as health information domain coordinators, drives the networks, is responsible for daily operations (such as preparations of meetings), carries out prioritisation and defines objectives.

6.3.3 Operative

B. The Network Committee

The Network Committee consists of a representative of national health information authorities and international research networks in the domains covered by the ERIC. The Network Committee shall be responsible for all national scientific activities related to HIREP-ERIC and shall maintain coherence and consistency across HIREP-ERIC and collaboration between the members. The Network Committee shall be under the responsibility of the Central Executive Management Office. Specific working groups shall be created within the Network Committee following the request of the Network Committee or the Director General.

7 Recommendation

BRIDGE Health recommends that:

1. The HIREP-ERIC is created keeping in mind its strengths and weaknesses.
2. A Joint Action is set up as an interim solution between the BRIDGE Health project and the HIREP-ERIC if continuity cannot be ensured.
3. Member States play a central role in the HIREP-ERIC.
4. All Member States are optimally involved in the HIREP-ERIC.
5. National public health institutes or corresponding institutions in Member States are drivers of the HIREP-ERIC.
6. A core central structure is created with minimum overhead.
7. The HIREP-ERIC guarantees the focus on research through building on existing knowledge and experience from EU research projects represented as country hubs.
8. A work plan for HIREP-ERIC is developed with a stepwise approach, detailing essential tasks to be carried out in its initial phase. Suggested tasks are described in section 5.5.
9. The involvement of international organisations is limited to the role of observers.

8 Annexes

Annex 1 Glossary of terms

Health information

Based on the definition of the World Health Organization and discussions held between the partners of BRIDGE Health, the concept of health information is defined as (34):

Health information *is all data, evidence and knowledge that determines health and health service performance at individual or population level to facilitate research, promotion, prevention, care and support policy-making.*

EU health information system

The second key term to define is a European Union health information system. The World Health Organization defines a health information system as "an integrated effort to collect, process, analyse, report, communicate and use health information and knowledge to influence policy and decision-making, programme action, individual and public health outcomes, and research" (35). The BRIDGE Health partners adapted the definition for an EU HIS.

An EU health information system *is an integrated effort to collect, process, analyse, report, communicate and use comparable health information and knowledge covering all Member States to understand the dynamics of the health of EU citizens and populations in order to support policy and decision-making, programme action, individual and public health outcomes, health system functioning, outputs and research in the European Union.*

An EU health information system is meant to translate data on health, determinants of health and healthcare, from different sources, into actionable knowledge. It includes activities aiming at the maintenance of the system at the different levels of governance in Europe (regional, MS, EU-level), such as sustained data updates, data infrastructure upgrades and capacity building.

An international (EU) health information system needs to link and overarch (sub)national health information systems for instance by harmonising standards, tools and methods, linking national experts and their networks, identify and exchange good practices, as well as collect, analyse, store, transmit, display, disseminate and integrate harmonised and comparable national data and support the integration of the analyses and outcomes.

Annex 2 European projects associated to BRIDGE Health

- Child health research strategy (RICHE)
- Consortium to Perform Human Biomonitoring on a European Scale (COPHES)
- Developing a Child Cohort Research Strategy for Europe (CHICOS)
- Environmental Health Risk in European Birth Cohorts (ENRIECO)
- European Health Care Outcomes, Performance and Efficiency (EuroHOPE)
- European Best Information through Regional Outcomes in Diabetes (EUBIROD)
- European Collaborative for Healthcare Optimization (ECHO)
- European Cardiovascular Indicators Surveillance Set (EUROCISS)
- European Community Health Indicators Monitoring (ECHIM)
- European Health Examination Survey (EHES)
- European Life and Health Expectancy Information System (EHLEIS)
- Euro-peristat Better statistics for better health for pregnant women and their babies
- EuroREACH A Handbook to Access Health Care Data for Cross-country Comparisons of Efficiency and Quality (EUROREACH)
- European Injury Data Base (IDB)

Annex 3 The impact of health information

Example from EU project Euro-Peristat

Data from Euro-Peristat have generated multiple debates in Europe about care provision to mothers and children. Some themes that have been addressed are: (1) High rates of perinatal mortality in some countries, (2) Appropriate levels of interventions during pregnancy and in particular on the use of caesarean section (3) Organisation of perinatal care and the effect of small maternity units on health outcomes.

European countries increasing rely on reference list of indicators to evaluate their policy initiatives and benchmark their performance. In France, the Euro-Peristat indicators are the reference for evaluating perinatal networks. All networks in the country now have to evaluate their outcomes with reference to this list.

In the Netherlands, where the country's poor perinatal mortality ranking in 2004 attracted wide media attention, the 2010 report of Euro-Peristat showed major improvements in fetal and neonatal mortality over the past 5 years. A perinatal audit was set up to review perinatal deaths at term (ie, 37+ weeks), and mortality at term declined by 39% from 2004 to 2010.

Another example comes from Germany where, since publication of international comparisons of caesarean section rates, there has been a growing concern over their continued increase. The Federal Office for Quality Assurance in Health Care (AQUA-Institut) is currently proposing to extend their performance indicators (for benchmarking obstetric departments) to include caesarean rates. Similarly, debates about obstetric unit size and quality of care resulted in legislation mandating a minimum number of 14 annual admissions of neonates under 1250 g in order to operate as a level III perinatal centre. In

the light of higher minima outside Germany, there have been further calls for raising this threshold.

In Slovenia, Euro-Peristat has served to justify continued reports on perinatal health and updating of the national perinatal information system. This new system went into effect on January 1, 2013.

Data from Euro-Peristat are also used for international initiatives to improve health and health reporting. For instance, the European Foundation for Care for Newborn Infants produced a white paper to lobby for better standards for neonatal care based on statistics from our first report. Data from Euro-Peristat led the OECD to take on a study with its members to evaluate how neonatal and infant mortality data should be collected. This process will promote better perinatal health reporting worldwide.

Annex 4 Criteria

The following elements should be considered when deciding upon an EU health information system structure: stakeholder interaction and support, sustainability, legal aspects and aspects related to the content such as the potential to take up the selected activities. Overall feasibility in the current framework is particularly important to maximise its probability of success.

In relation to the content, the EU health information system governance structure should:

- focus on public health.
- have a clear mandate, coordination and vision in EU health information.
    - set clear targets and objectives to focus efforts on priority aspects.
- have the capacity to have an overarching role, which
    - brings together overlapping activities and other research projects to avoid duplication,
    - has the potential to be recognised to have EU public health leadership (including political),
    - ensures efficient decision-making procedures, consensus building and coordinated communication.
- provide information for decision-making and reliable data for research.
    - use pooled and harmonised data collected for research, as sources of information for population health and public health.
    - set up mechanisms to secure trustworthy scientific guidance.
    - allow open, coordinated and transparent access to data for researchers.
- ensure flexibility to adapt to legal and technical progress (the use of modern information and communication technologies e.g. eHealth, big data), economic constraints and to allow for reduction and expansion of scope as appropriate.
- build on experience of existing agencies and structures. The decision about a governance structure should take into account the experiences of similar undertakings (e.g. ECDC evaluation).
- establish transparent regular review and evaluation procedures to ensure continued efficiency.

In relation to stakeholder interaction and support, the EU health information system governance structure should:

- establish a forum for regular knowledge exchange and consultation with the scientific community including researchers and health professionals, with relevant national governmental departments, with international organisations (e.g. OECD and WHO) as well as with civil society groups and patient associations.
- have high acceptability and support by the Member States, the European Commission, other EU institutions, the research community and, in case it is built on an existing institution, the institution itself.
- ensure high usability for Member States and EU institutions.
- strive for equitable participation and maximal coverage of Member States.
- establish multidisciplinary networks of excellence and mechanisms to mobilise the necessary human resources and competencies at national and European level.

In relation to sustainability, the EU health information system governance structure should have long-term and short-term sustainability. The time necessary for the EU health information system implementation and sustainability of infrastructure, of resources (human and financial resources) and of content should be considered.

The EU health information system should have a clear legal basis and clear data ownership and intellectual property agreements based on common competition, ethical and data protection rules.

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