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Published in:
Health Policy

DOI:
[10.1016/j.healthpol.2021.09.006](https://doi.org/10.1016/j.healthpol.2021.09.006)

Publication date:
2021

Document Version
Publisher's PDF, also known as Version of record

[Link to publication in Tilburg University Research Portal](#)

Citation for published version (APA):
Bogaert, P., Verschuuren, M., Van Oyen, H., & Van Oers, H. (2021). Identifying common enablers and barriers in European health information systems. *Health Policy*, 125(12), 1517-1526.
<https://doi.org/10.1016/j.healthpol.2021.09.006>

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Identifying common enablers and barriers in European health information systems

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ARTICLE INFO

Article history:

Received 20 March 2021

Revised 17 September 2021

Accepted 19 September 2021

ABSTRACT

European countries possess unique health information systems (HISs) and face similar health system challenges. Investigating common enablers and barriers across Europe pinpoint where HISs need improvements to address these challenges. This study aims to identify common enablers and barriers for optimal functioning of HISs across the European Union and associated countries, and to interpret what this means for the further development of HISs in Europe. A qualitative thematic analysis was carried out based on nine countries HISs assessments. Two main observations are made. Firstly, regardless of the differences between HISs, each HIS had its strengths and weaknesses and often the same barriers and enablers arose. Secondly, barriers were identified in all HIS areas. The five most important barriers are (i) fragmentation of data sources, limited accessibility, use and re-use of data, (ii) barriers in the implementation of EHR-systems, (iii) governance issues related to unclear responsibilities, discontinuous financing and weak intra- and inter-sectorial collaboration, (iv) legal gaps and General Data Protection Regulation (mis)interpretation, and (v) limited skilled staff. The enablers identified in this study lead to potential solutions to address these. Solutions can be implemented by national initiatives, but there is considerable added value in a joint European approach. Several international initiatives provide opportunities to improve HISs, but these need to be strengthened and better geared towards tackling the identified barriers.

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1. Introduction

Population-based health information systems (HISs) allowing public health monitoring and research are set-up to support evidence informed decision making at various levels ranging from healthcare facility to health authority and national government. HISs include data collection, interpretation (analysis and synthesis), reporting and knowledge translation, and the total of resources, stakeholders, activities and outputs to do so [1]. European countries possess unique but mutually different HISs, which are based on specific historical, cultural and governance contexts [2]. Previous studies have shown that despite rapid developments of HISs in Europe, countries are not progressing equally [3]. Regardless, European countries are facing similar challenges in demography,

health and health care. They are confronted with ageing populations, increasing burdens of disease, persistent inequalities and growing pressure on health systems [4]. Additionally, the digital era is pushing for the implementation of digitisation applications (e.g. electronic health records, e-prescription and cloud solutions for data storage) and the need to harness new technologies. Strong and interoperable HISs are key to address these challenges.

In order to improve HISs across Europe, more insight is needed into which factors enable and hamper the functioning of these systems. Research in European HIS has been carried out regarding the quality, value, effects and impacts of information technology and digital applications in the healthcare environment, to improve health information applications and to enable the emergence of an evidence-based health informatics clinical profession and practice [5–7]. In this context, the term HIS is used to refer to computer-based information systems used in healthcare settings. However, in this study we aim to investigate population-based HISs, which include the healthcare environment but also other areas. A population-based HIS comprehensively covers both healthy

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and non-healthy populations in areas of prevention, promotion, cure and care. For such comprehensive HISs, the research related to factors enabling or hampering performance is scarce, hence the need for this study.

As countries are facing similar challenges, investigating common enablers and barriers across Europe pinpoint where European population-based HISs need improvements to address these challenges. Countries can benefit from identified common enablers. Identified common barriers can provide insights into what inhibits European HISs from operating optimally. In that way equity between HISs across Europe can be stimulated.

The aim of this study is to identify the common enablers and barriers for optimal functioning of population-based HISs across the European Union and associated countries, and to interpret what this means for the further development of HISs in Europe.

2. Materials and methods

2.1. Study setting

This study is done within the framework of the Joint Action on Health Information (InfAct, HP-JA-2017, 801553). One of the activities of this Joint Action focuses on the status of health information systems in European countries and regions. This includes mapping and assessing HISs in nine European Union and associated countries through peer assessment.

2.2. Assessment schedule

The selection of the nine countries was based on interest raised by these countries to participate in the assessment when drafting the InfAct-proposal. Based on the United Nations geoscheme for Europe, all four regions of Europe were covered, including two countries in Eastern Europe, four countries in Northern Europe, one country in Southern Europe and two countries in Western Europe, resulting in a wide spectrum of HISs in the study [8]. The countries were split into three groups, to mix HISs from the different European regions as just described. Within each of the three groups, a rotation system was made in which health information experts from the participating countries assessed the HISs in peer review format. In each group of three countries, the HIS in one country was assessed by experts from the other two countries, and this was repeated until all three countries were assessed. The first assessment in each group took place in the period February – March 2019, the second in May – June 2019, and the third in October – November 2019. The assessments were carried out by one or two peer assessors from each assessing country, meaning a maximum of four assessors in total. All assessors were trained in a two-day course on how to perform the assessment. A contact person in the assessed country acted as the national liaison during the assessment and organised the peer assessment. An observer provided support during the assessment based on previous experience with the assessment methodology, to ensure that the assessments were performed according to professional standards and procedures.

2.3. Data collection

The assessment methodology was based on the WHO Support tool to assess HISs and develop and strengthen health information strategies [9]. The assessments were composed of a preparatory desk review, a country visit including semi-structured interviews with key HIS stakeholders, a final report and a multi-stakeholder follow-up meeting. The desk review was prepared by the assessors with documentation provided by the contact person in the assessed country. The desk review aimed to create a general

overview of existing or potential problems in the HIS under assessment and was used as a starting point for the interviews during the country visits. The desk review was composed of a rapid review of reports or documents available at national or international level such as former HIS assessments; Health Systems in Transition (HiT) series of the European Observatory on Health Systems and Policies [10]; national health information policies, strategies and legislation; State of health by European Commission [11]. The desk review was summarized in a short preparatory report used for fine-tuning the country visits assessment programme. The contact person in the assessed country developed a two day programme for the country visits, i.e. an overview of which stakeholders would be interviewed. Typical stakeholders include Ministries of Health, National Public Health Institutes, Statistical Offices and Health Insurance Funds. The assessors carried out the interviews using a HISs items list available in the appendices. It is an old version of HIS item list which has now been updated in the latest version of the WHO support tool [12]. This items list covers the following domains of HISs: resources, indicators, data sources, data management, national HISs data quality/information products, and dissemination and use. Based on the outcomes of the interviews, the assessors wrote an assessment report, which was revised by the observer and the contact person in the assessed country. This final report was then presented to the stakeholders that participated in the assessment through a virtual multi-stakeholder follow-up meeting in the assessed country. The participants jointly validated the final reports, discussed the outcomes and investigated potential next steps. The final reports included a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis, as well as recommendations for improvement.

2.4. Data analysis

A qualitative thematic analysis of the nine SWOTs in the final reports was carried out. The SWOTs were pooled and a methodology of deductive thematic analysis was used to identify themes that were common across the nine SWOTs. The methodology of Braun and Clarke [13] was used consisting of the following consecutive steps: repeated reading of the SWOTs and final reports; coding in as many as possible patterns, and themes based on an overarching framework; collating the codes in broader sub-themes; reviewing themes with extraction of sub-themes based on coherent patterns; validating the sub-themes; analyzing the sub-themes in relation to the story that is told and in relation to each other.

The overarching framework used to structure the identified themes is based on the above-described HIS domains of the assessment tool. This framework was subsequently adjusted based on the outcomes of the analyses, to better accommodate the identified themes and sub-themes.

Within each theme and sub-theme, the common enablers and barriers were identified. The coding and analysis was carried out with Nvivo 12. An external validation was carried out by cross checking the results with the assessors by written feedback. The assessors were asked if the themes reflected common barriers and enablers in the HIS in their country or in the ones they assessed, if any themes were missing and if any identified themes were not relevant. No new themes were identified and the identified themes were endorsed. Based on this feedback, it was concluded that our analysis captures the range of most important barriers and enablers across the assessed HISs.

3. Results

In the analysis 11 main themes were identified and within two of these main themes a total of seven subthemes. The themes and subthemes are presented in the first column of Table 1.

Table 1
Overview barriers and enablers in assessed European health information systems.

Themes	Enabler	Barrier
1. Data collection and sources > Data sources > Data collection > Registries > Information at various administrative levels	<ul style="list-style-type: none"> • Centralised data storage • Up to date and high quality registries • Comprehensive set of data/indicators at regional, district or municipality level • Communication and support between levels • Investments and committed governance 	<ul style="list-style-type: none"> • Fragmentation of data sources • Data gaps • Resource intensive maintenance • Overburdening
2. Data infrastructure: Electronic Health Record (EHR) system	<ul style="list-style-type: none"> • Common terminology • Transparent governance structure • Involving actors 	<ul style="list-style-type: none"> • Incompatibility of databases, • Outdated paper based data collection, • Unskilled staff, • High burden on staff, • Outdated legislation • Lack of resource
3. Data management > Data management procedures > Linkage > Sharing data and secondary use	<ul style="list-style-type: none"> • Quality and transparency in data collection and distribution • Usage by stakeholders • Formalized in legal documents • Routine linkage • Data management procedures • Unique patient and personal identifier • Trust • Strong inter-institutional connections • Support to external and end-users • Remote and free access 	<ul style="list-style-type: none"> • Lack or vague data management procedures • Ad hoc linkage • Lengthy process of linkage • Recoding and (pseudo)anonymization • Gaps in legislation • Limited knowledge of available data sources and products • Resistance between institutions or administrative levels.
4. Data analysis		<ul style="list-style-type: none"> • Restrictions due to linkage • Shortage of staff • Lack of initiative
5. Reporting tools	<ul style="list-style-type: none"> • User friendly • Easy to navigate • Public and remote access • Creative and innovative data visualization • Easy to read documents 	
6. Knowledge translation	<ul style="list-style-type: none"> • Collaboration among different types of stakeholders • Target to end-users designed products 	<ul style="list-style-type: none"> • Lack of investment • Lack of knowledge translation products • Unawareness, misunderstanding or limited use of health information at policy level • Instability, unclear roles and fragmentation of political responsibility • Misunderstanding or unawareness of products by policy makers
7. Political setting	<ul style="list-style-type: none"> • Political will and leadership • Close relations and trust between researchers and policy makers • Availability of (partial) health information strategy • Health information system's coordination mechanism • Engagement in international collaboration 	<ul style="list-style-type: none"> • Weak inter-sectorial collaboration
8. Legal framework	<ul style="list-style-type: none"> • The new realities of the digital environment led to adaptations in the law • Involve stakeholders in the legislative review processes • Good understanding of GDPR • Amendments to clarify legislation 	<ul style="list-style-type: none"> • Gaps in legislation • Lack of clear laws regulating secondary use of data • Time-consuming process of changes in legislation • Outdated laws • Narrow or mis- interpretation of GDPR • Complexity and load for data entry and collection • Lack of staff with IT competences or IT competences in combination with health competencies • Difficulties to attract and retain staff • Unequal distribution of staff within the country • Software heterogeneity and incompatibility • Outdated infrastructure • Shortage and unequal resources • Under funding and project based funding
9. Human resources	<ul style="list-style-type: none"> • Provision of continuous specialized training • Attractive employment conditions 	
10. ICT infrastructure	<ul style="list-style-type: none"> • Continuous investment 	
11. Financial resources		

3.1. Data collection and sources

Within this theme, four subthemes were identified. Under the sub-theme *data sources* the first common barrier that was identified is fragmentation of data sources between stakeholders. The SWOTs stated on the one hand that when data sources are fragmented and hosted in different institutions (e.g. primary vs hospi-

tal care) or across different administrative levels (municipal vs regional vs state level), linkage, access and continuity of care is hampered, especially when there is limited communication between these stakeholders. Additionally, fragmentation hampers getting a comprehensive picture of a person or patient because essential information is missing. Consequently, information may need to be collected again, leading to duplication of data collection. A com-

prehensive view (combining data across social care, prevention and healthcare) is needed not only for a person's health care needs, but also for statistics and research at population level. Centralised data storage on the other hand was identified as an enabler. Having the sources 'under one roof' allows for linkage opportunities.

Under the sub-theme *data collection*, data gaps emerged as a common barrier. Based on the SWOT analysis, in almost all the assessed countries data gaps exist. Gaps were reported for data on health status (e.g. prevalence of chronic diseases), for health care provision or health care use (e.g. ambulatory care, primary care, mental health care), and health care costs (e.g. costs of illness by age groups or by healthcare sector) and most commonly for data from private healthcare providers.

Under the sub-theme *registries*, up-to-date and high quality registries are reported by the assessors as an enabler for well-functioning HISs. Moreover, these registries are experienced as enablers when they are hosted 'under one roof' because such integrated registries provide excellent linkage opportunities. Limited resources (limited human and financial resources, gaps in legislation) are experienced as a barrier since this can hamper the continuity of registries. Other barriers relate to governance aspects e.g. the registry may fall under another ministry than the ministry of health.

The fourth sub-theme is *information at various administrative levels*. Several assessed countries have a comprehensive set of data/indicators at regional, district or municipal level, providing a strong asset at national level. Good communication and support between these different geographical levels is a strong enabler for well-functioning HISs. Barriers are overburdening of local authority and health professionals due to increasing complexity of data entry and handling. Especially when regions are politically independent and have certain responsibilities in health care delivery (and health data collection), the workload at regional level can be higher.

3.2. Data infrastructure: electronic health records (EHR) system

The developments across Europe regarding EHR-systems offer many opportunities to European HISs according to the assessments, including enabling data linkage within and outside the health sector, increasing patient and other stakeholders involvement, developing common terminology, simplifying administrative procedures, improving effectiveness of data processing, creating a transparent governance structure, and improving quality, comparability and coverage of health data. Many of the assessed countries are investing in their EHR-systems and governments are committed to support and strengthen them. However, it comes at a cost. Barriers related to the implementation of EHR-systems mentioned by assessors are incompatibility of electronic information systems, outdated paper based data collection which are difficult to integrate in EHR-systems, unskilled staff, high burden on staff, outdated legislation and lack of resource (financial, human and infrastructure). Furthermore, an important barrier is the common misunderstanding that the EHR-system can replace registries.

3.3. Data management

Within this theme, three subthemes are identified. The first subtheme concerns *standardised data management procedures*. Having such procedures in place is identified as strong enablers in HISs although, according to the SWOTs, many countries lack good data management procedures. Such standardised procedures contribute to quality and transparency in data collection and distribution, stated the assessors. It may also provide clarity on the procedures for usage of data by different stakeholders and therefore it closely relates to the subthemes *linkage of data* and *sharing and re-use of data*.

The second subtheme concerns *linkage of data* between data sources of different stakeholders. In the SWOTs this is stated as one of the main challenges in HISs. Problems with linkage are seen as a barrier, and may lead to many missed opportunities, especially concerning linking data in a routine way for monitoring. In many HISs data are linked on an ad hoc basis regardless if it is data from inside or outside the health sector. An additional barrier is the lengthy process of linkage, even though usually some form of linkage is possible, according to the assessors. Although most countries have a unique patient and personal identifier, linkage is still difficult due to the different recoding or anonymization systems of patient IDs by each of the data providers/sources. This barrier is common across all the assessed HISs.

The third subtheme is the lack of *sharing and re-use of data*. The legal framework to share and re-use data was a common topic in all SWOTs. Gaps in legislation can be a barrier having important consequences on data access for secondary purposes such as monitoring, research and policy-making. Some countries exchange individual level data between the HIS's actors which can be based on trust or inter-institutional connections. These are perceived as enablers. Another enabler to sharing and re-use of data is when external users can access the data remotely and free of charge, and are supported by data owners in their quest for data. Another barrier identified in the SWOTs is limited use of data. According to the assessors, this may be due to a lack of knowledge of data sources and products by the potential users. Finally, the assessors pointed out that some actors may also be resistant to sharing data with other organisations.

3.4. Data analysis

The analysis showed that more data analysis could be done with the available data in HISs, potentially leading to more relevant information to support health policy decisions. By analysing available data further, new indicators can be obtained, better assessment of the health status can be done and duplication of data collection can be avoided. Common barriers that hamper comprehensive analyses are restrictions of linkage, as explained before, shortage of staff that can allocate time to analysis or lack of initiative to analyse the data.

3.5. Dissemination and access to health information

Under this theme, user-friendliness and easy to navigate websites are identified as enablers in several countries. Additionally, allowing remote access and making data publicly available are key enablers to well-functioning HISs. Also the periodic production and publication of reports emerge as an enabler. Moreover, data visualisation (especially when represented in infographics) plays an important role in the HISs facilitating, according to the assessors, understanding and dissemination to users, such as policy-makers and the wider public. Finally, easy to read documents, and creative and innovative dissemination methods are common enablers across HISs.

3.6. Knowledge translation

In the SWOTs, overall a lack of knowledge translation was identified. This is due to three main barriers. The first, a general lack of investment in knowledge translation, is experienced in many countries. The second barrier is that knowledge translation products targeted to end-users are often not developed. The third identified barrier is unawareness of availability of health information, misunderstanding of health information or limited use of health information at policy level. In practice, according to the SWOTs, this

means that policy makers are often not aware of available products, do not understand the need for indicators or misunderstand the usability of EHR-systems.

Most commonly, strengthening interaction between scientists and policy makers or other stakeholders was seen as an enabler to knowledge translation.

3.7. Political setting

The political governance structure and political climate are important enablers or barriers in HISs. Common barriers reported in the SWOTs are instability, unclear roles and fragmentation of political responsibility within the HIS or the country, which complicate decision making. Often the main focus is on healthcare generated data, and less attention is given to public health surveillance data. Policy makers sometimes misunderstand or are unaware of health information products or outputs. For example, some SWOTs have indicated an unsatisfactory level of understanding of the need for indicators for policy making at governmental level. The underlying reasons are rapid staff turnover or lack of experience.

Political will and leadership are recurrent enablers in the SWOTs, which can bring forward change e.g. interest in e-health or health system performance analysis. Other identified enablers are close relations and trust between researchers and policy makers. Regular contacts between these stakeholders for example stimulate an exchange on needs for indicators.

Another enabler to well-functioning HISs, is the existence of a HIS strategy. In the SWOTs, it was seen as a weakness that almost all countries lack such a strategy. As a consequence, stakeholders' needs may not be considered. However, as pointed out by the assessors, some sort of health information strategy was usually in place in the form of e.g. a health statistics or e-health plan.

In the SWOTs, a central coordination mechanism for the HIS in a country is perceived as a real enabler. It is needed especially when there is no health information strategy. According to the SWOTs, it facilitates good cooperation between HISs' actors, reduces duplication, allows better (re)use of collected information and leads to better integrated health reports. Often in the SWOTs, it appeared that the network of HISs' stakeholders is large and their function in the HIS is not clear. Depending on the country, the coordination mechanism may have a different format. Examples described in the SWOTs include e.g. inter-ministerial conferences, state health commissions or statistics councils. A barrier in many HISs is weak inter-sectorial collaboration.

Finally, participation in international projects and the engagement in international collaboration can be identified as a common enabler in European countries. According to the assessors, this facilitates the strengthening of national skills, enhances comparison, supports transformation processes and allows exchange of experiences and expertise among countries.

3.8. Legal framework

The legal framework is an important tool to support the HIS in countries, according to the assessments. Many SWOTs mentioned the legal framework in the context of data management i.e. for routine collection, linkage and sharing data between stakeholders.

A common barrier in the SWOTs is gaps in legislation, e.g. legislation may not cover clear mandates and permanent data collection activities for registries, or linkage of routine data collections, which leads to ad hoc, lengthy linkage processes. Various countries also mention the lack of clear laws regulating secondary use of data. The legal basis might be there, yet the laws may be written in a way that leads to ambiguous interpretation. An additional barrier is that amending existing legislation is experienced as time-consuming.

On a positive note, as reflected in the SWOTs, institutes could build the right trust framework with the right governance in place through the establishment of a less formal inter-institutional agreement, such as a Memorandum of Understanding, which clarifies the parameters for exchange of data between them. Such arrangements are seen as an important strength by the assessors. It could also help that stakeholders e.g. the Public Health Institute is involved in writing the laws.

The General Data Protection Regulation (GDPR) has been experienced as a barrier in some countries according to the SWOTs. In some countries, the assessors reported that the national translation of the GDPR does not support the use of health data for regular routine health statistics and health monitoring. Moreover, according to the assessors, sometimes the legislation is misunderstood or misinterpreted, leading to limited data usage and data networking, even regarding activities that are permitted by the GDPR. Assessors have indicated that organisations are not inclined to share data because they are afraid not to comply with GDPR.

3.9. Human resources

Firstly, in the SWOTs the burden on data collectors for the entry, collection and management of data was mentioned as a barrier, due to e.g. increasing complexity or many to fill in forms. Secondly, computer literacy is reported as a barrier in HISs. E-developments require IT staff and health data engineers. A lack of specialists with IT competences or IT competences combined with health competences is reported in the SWOTs and can be understood as a barrier. Training is an enabler to well-functioning HISs through capacity building in e.g. continuous skills development related to collecting, reporting and analysis of public health data. Thirdly, many European countries face difficulties to attract and retain staff. There are various reasons according to the SWOTs: migration of health professionals, ageing of the staff, financial reasons, lack of incentives or lack of specialists. Some countries also reported an unequal distribution of staff within the country.

3.10. ICT infrastructure

The main barriers in this theme identified in the SWOTs are software heterogeneity and incompatibility of digital information systems, as such not taking interoperability into account within and between e.g. primary and secondary care. Further barriers include shortage of IT resources for EHR-system developments, outdated ICT infrastructure, and unequal resources between and within administrative levels.

3.11. Financial resources

In this theme lack of sustainability is an important recurrent barrier in the SWOTs, often caused by underfunding or project based approaches. The analysis showed that there is a lack of financial resources for funding HIS staff in particular.

4. Discussion

Across the nine HISs assessments, common enablers and barriers could be identified. Two main overarching observations can be made. Firstly, regardless of the differences between the assessed HIS, each HIS had its strengths and weaknesses and often the same barriers and enablers arose across the assessed HISs. Secondly, barriers were identified in all areas of the HIS: not only in the area of data collection, but also in its interpretation (analysis and synthesis), reporting, knowledge translation, in the political and legal setting, and with regards to human, technical and financial resources. This implies that the sole fact of having data is not sufficient for

guaranteeing a well-functioning HIS. In order to produce knowledge and wisdom from this data, all the areas of the HIS play an important role. Across the wide spectrum of HISs that were investigated, often high quality data sources are available, and valuable information for research and policy making was produced. A recent study by OECD stated that ‘health systems remain data rich but information poor’ [14]. Our study shows that European HISs do produce relevant information and knowledge, but clearly there is potential to achieve more with the outputs of HISs.

4.1. The main barriers in HISs

The barriers in the assessed HIS can be grouped into five main ones: (i) fragmentation of data sources, limited accessibility, use and re-use of data, (ii) barriers in the implementation of EHR-systems, (iii) governance issues related to unclear responsibilities, discontinuous financing and weak intra- and inter-sectorial collaboration, (iv) legal gaps and GDPR (mis)interpretation, and (v) limited skilled staff.

Similar barriers have been identified in the literature. Common barriers mentioned in the literature are the absence of data, non-utilization of existing data, missing possibilities to link data (e.g. by using personal identifiers), legal obstacles (e.g. lack of legislation on a national or international level) and organisational issues (e.g. discontinuous financing, lack of human resources or lack of political will) [15–21]. A study by Verschuuren et al is worth mentioning separately as it used the same WHO assessment tool and investigated common strengths and challenges across four HIS assessments with very similar results. Common barriers found in this study are: lack of a clear HIS strategy, missing or poorly functioning central multi-sectorial coordination mechanisms, limited prospect for sustainability of e-health (predominantly donor funded), limited analytical capacity, data quality issues, unclear roles and responsibilities for data exchange, and limited use of health information for decision making [2]. The OECD Health at a Glance report 2020 also highlighted the pressing need for improved data exchange to better monitor and manage public health issues and health systems. Data fragmentation and limited degree of interoperability of HIS are mentioned as barriers [4].

4.2. Addressing the main barriers

The enablers identified in this study lead to potential solutions to address these barriers. The first barrier, the fragmentation of data sources, is caused by the fact that health data are collected, registered, hosted and handled by different organisations. These organisations then often do not routinely exchange or link the data. This can be overcome by hosting the data under one roof or having a central organisation that manages or coordinates collection of and access to health data. Such an approach provides more opportunities for linkage, sharing and re-use of data. Several European HISs are already moving in that direction. There seems to be a trend towards the setup of centralised data storage and/or a centralised organisation that manages health data, e.g. France (French Health Data Hub) [22], Finland (Findata) [23], Germany (Forschungsdatenzentrum (DaTraV)) [24], Denmark (Danish Health Data) [25], and Belgium (healthdata.be) [26]. These developments are enabled by digitalisation processes in combination with political will.

The second main barrier relates to the implementation of EHR-systems. This study showed that successful implementation of the EHR-system needs to go hand in hand with clear and transparent governance structures and involvement of the key HIS stakeholders. A study of Fragidis et al. confirms this based on a study in 13 countries. The study concludes that the most significant success factor of a nationwide EHR system implementation process is the

commitment and involvement of all stakeholders [27]. As reflected in the assessments, trust, communication and support between institutions and administrative levels are key for a successful EHR implementation.

The third main barrier are governance issues such as unclear responsibilities, discontinuous financing and weak intra- and inter-sectorial collaboration. Our study shows that a HIS coordination mechanism can provide fruitful results to strengthen collaboration amongst stakeholders and support continuous investments and implementation of a long-term strategy. This is also confirmed in the literature [10,20]. Michelsen et al. point out that good coordination is important between ministries, institutions or subsystems with responsibilities for databases or the implementation of IT structures and systems. In particular, the centralization of responsibilities for registries and surveys in one place was mentioned as an advantage [15]. Other useful tools that, based on our study, can be added to this are clear data management procedures and inter-institutional agreements to address unclear responsibilities and weak intra- and inter-sectorial collaboration. These tools can clarify who can have access to data for secondary use and as such also address the first main barrier.

To address the fourth barrier, legal gaps and GDPR (mis)interpretation, legislation needs to be amended and better understood. The GDPR has health research exemptions which had to be implemented into national law [28–30]. Member States were allowed through specification clauses to adjust the application of certain aspects of the regulation to their national situation. This has led to variation between countries in how the GDPR is implemented. This fragmented approach complicates cross-border research [31]. Additionally, our study shows that the national translation of the GDPR does not support the use of health data for regular routine health statistics and health monitoring in some countries. Data holders are now more reluctant to share data in fright of infringing the GDPR. To overcome this barrier, legislation needs to be amended and better understood. This can be facilitated by involving HIS stakeholders in the drafting or revision processes.

Finally, with regards to human resources, the fifth main barrier, continuous investments in human resources is essential through the provision of continuous specialised training and attractive employment conditions. Our study shows there is a lack of specialists with IT competences or IT competences combined with health competences. Also, to stimulate the (re-)use of health information outputs, capacities need to be strengthened to produce target-to-end-user designed products that are designed to fit the needs of the reader. This includes training in the area of knowledge translation, communication and health policy.

More detailed analyses is recommended to investigate factors underlying the main barriers. That would help with the development of tailored interventions and identification of good practices.

4.3. A European approach

Since the barriers for a well-functioning HIS are common across various European countries, there are opportunities for a joint European approach to address these challenges. Several initiatives are supporting the development of European HISs through a joint approach. One of these initiatives is the Distributed Infrastructure on Population Health (DIPoH) and operationalised as a practical use case in the Population Health Information Research Infrastructure (PHIRI) with a focus on COVID-19 [32]. DIPoH and PHIRI facilitate the identification, access, assessment, and re-use of population health data and information across Europe. DIPoH and PHIRI are addressing some of the barriers that have been identified in this study through various activities. For example, they support countries in overcoming governance issues by building a national HIS

coordination mechanism (National Nodes). This is an organisational entity, often linked to a core group of national institutions or governmental units, that functions as a national liaison and brings together relevant national stakeholders in a systematic way [33,34]. Other examples of how DIPoH and PHIRI address some of the identified barriers is by providing trainings, supporting the exchange of expertise to strengthen national skilled staff [35] and strengthening the understanding of the implications of the GDPR [36]. These efforts are however not sufficient because only few of the barriers described are addressed by these initiatives, moreover these initiatives are currently project based. More needs to be done e.g. to overcome fragmentation. Furthermore, current initiatives are lacking resources to be able to implement solutions in a systematic way.

Another initiative for which the outcomes of this study provide useful insights is the European Health Data Space (EHDS). The European Commission is currently developing the legal, governance framework and the digital infrastructure for this EHDS [37]. The way national HISs are organized and how well they are performing will have a significant impact on the EHDS as the EHDS is foreseen to operate through a national single point of contact for data access. [38]. This raises to three concerns. Firstly, our study shows that the GDPR led to complication with regards to accessing, sharing and re-using health data across Europe. The question is how the new legislation will overcome this without adding additional complexity to the equation. Secondly, our study highlighted the fact that central coordination mechanism are currently lacking in various HIS. Since this central coordination in countries will be at the essence of the EHDS, the concern is if the countries with strong central coordination mechanisms will not be advantaged and how the EHDS will address inequities in this area. Thirdly, the implementation of the EHDS will put additional strain to European HISs, and human, technical and financial resources in these HISs are scarce, as shown in this study. This is an important consideration that will need to be accounted for when implementing the EHDS.

European initiatives will be able to address some of the barriers identified in this study, but not all of them will be solved at European level. National actions are essential to strengthen HISs. The fragmentation of data sources, for example, can only be solved at national level. Further national actions include clear and transparent governance structures, national HIS coordination mechanisms, continuous investments in human resources and revising legislation.

4.4. Limitations

Two limitations may be identified in this study. Firstly, the final reports of the country assessments may have been influenced by the assessors' professional background and the expertise of the interviewees. Assessors may have strong knowledge in a particular area of the HIS and therefore miss to identify strengths and weaknesses in areas they are less familiar with. The expertise of the interviewees will also influence the outcomes of the assessments. If the scope of their expertise is limited, some strengths and weaknesses may be missed. To address this potential limitation, the assessments were performed by multiple assessors to cover a wide range of knowledge and backgrounds. Moreover, assessors from two different countries were involved in each assessment. Additionally, an observer also participated in the assessments supporting the assessors throughout the exercise. Secondly, the generalisability of the results to all EU countries may be questioned. The assessments were carried out in nine countries. The generalisability of the findings however is endorsed by the fact that a wide range of HISs were included in the study to represent the diver-

sity of HISs in Europe and that similar results were found in the literature.

5. Conclusions

In conclusion, common enablers and barriers for optimal functioning of population-based HISs across the European Union and associated countries have been identified. Moreover, two main observations are made. Firstly, regardless of the differences between the assessed HIS, each HIS had its strengths and weaknesses and often the same barriers and enablers arose across the assessed HISs. Secondly, barriers were identified in all areas of the assessed HIS. The five most important barriers in the assessed HIS are (i) fragmentation of data sources, limited accessibility, use and re-use of data, (ii) barriers in the implementation of EHR-systems, (iii) governance issues related to unclear responsibilities, discontinuous financing and weak intra- and inter-sectorial collaboration, (iv) legal gaps and GDPR (mis)interpretation, and (v) limited skilled staff. The enablers identified in this study lead to potential solutions to address these barriers. As shown in this study, assessing HISs provides crucial insights on how to improve HISs and where focus efforts on. To further stimulate the development of HISs across Europe it is worth to assess the HISs in a systematic way and on a regular basis. Finally, national actions are essential to address the identified barriers. There is also considerable added value in a joint European approach to facilitate accessing, sharing and re-use of health data. Several international initiatives provide opportunities to address inequities and to improve HISs such as DIPoH and the EHDS, but these need to be strengthened and better geared towards tackling the identified barriers.

CRedit author statement

Petronille Bogaert: Conceptualization, Writing - Original Draft, Writing - Review & Editing Formal analysis. **Marieke Verschuuren:** Conceptualization, Writing - Review & Editing Validation, supervision. **Herman Van Oyen:** Conceptualization, Funding acquisition. **Hans van Oers:** Validation, Conceptualization, Writing - Review & Editing, Validation, Supervision.

Conflicts of interest

The authors declare that they have no competing interests.

Acknowledgements

The preparation of this paper has benefited from the contribution of the Joint Action on Health Information partners. We would like to express our sincere thanks to Adriana Galan, Andrea Schmidt, Ausra Zelviene, Borislav Srdic, Claudia Dima, Claudia Stein, David Novillo Ortiz, Hakon Haaheim, Heidi Lyshol, Irisa Zile, Ilze Malkevica, Janis Misins, Kim Vyncke, Linda Abboud, Maja Kristic, Mare Ruuge, Marie-Sophie Croenne, Merike Ratsep, Neville Calleja, Oleg Lozan, Rodica Gramma, Tadek Krzywania and Zilvne Naslene.

This research has been carried out in the context of the project '801553 InfAct' which has received funding from the European Union's Health Programme (2014-2020).

Appendices

Health Information System (HIS) item list

The HIS item list was used in this study. A new version has been develop in the latest version of the WHO support tool [12].

Category & nr	Item
I. Resources	
Policy & planning_1	The country has up-to-date legislation providing the legal framework for all relevant components of the national HIS: ideally, this legal framework also covers an evidence-informed policy cycle
Policy & planning_2	There is a comprehensive, written HIS strategic plan in active use and it is implemented at the national level
Policy & planning_3	The ministry of health has established a multisectoral HIS coordination mechanism with the other main HIS stakeholders in the country (e.g., a task force on health statistics); this coordination mechanism has a clear role and mandate
Policy & planning_4	There is a routine system in place for monitoring the performance of the HIS and its various subsystems
HIS institutions, human resources and financing_1	The institutions with official roles in the health information system (e.g. the ministry of health, national statistical office, national public health institute, subnational health authorities) have adequate and sustainable capacity in core health information sciences (epidemiology, demography, statistics, ICT, knowledge integration (including forecasting), health reporting, knowledge translation)
HIS institutions, human resources and financing_2	The institutions with official roles in the health information system (e.g. the ministry of health, national statistical office, national public health institute, subnational health authorities) have adequate and sustainable resources for their health information activities
HIS Infrastructure	Adequate ICT infrastructure (e.g. computers, data management software, internet access) and adequate ICT support is in place at the national level, at relevant sub-national levels and at hospital/provider level.
II. Indicators	
Indicators_1	Core indicators have been selected in a transparent way and implemented for national and relevant subnational levels, covering all categories of health indicators (e.g. determinants of health; health system inputs, outputs and outcomes (health systems performance assessment); health status; health inequalities)
Indicators_2	Reporting on the set(s) of core indicators occurs on a regular basis
Indicators_3	The usefulness and completeness of the core indicators is periodically evaluated together with policy-makers and other end users
Indicators_4	There is adequate alignment between the core indicators used at national and at sub-national levels; there is adequate alignment between the core indicators used by the different sub-national health authorities
III. Data Sources	
Census	The country has adequate capacity to: [1] implement data collection; [2] process the data; [3] analyse the data: and [4] disseminate the analyses and the (micro)data
Civil Registration and Vital Statistics (CRVS)_1	There is high coverage of deaths registered through CRVS
Civil Registration and Vital Statistics (CRVS)_2	There is high coverage of cause-of-death information recorded on the death registration form
Civil Registration and Vital Statistics (CRVS)_3	There is high quality of cause-of-death information recorded on the death registration form: there is a low proportion of all deaths coded to ill-defined causes
Civil Registration and Vital Statistics (CRVS)_4	The country has adequate capacity to: [1] implement data collection; [2] process the data; [3] analyse the data: and [4] disseminate the analyses and the (micro)data
Population-based surveys_1	The country has adequate capacity to: [1] conduct regular population based surveys (including sample design and field work); [2] process the data; [3] analyse the data: and [4] disseminate the analyses and the (micro)data.
Population-based surveys_2	The health and statistical constituencies in the country work together closely on survey design, implementation and data analysis and use
Health and disease records (including disease surveillance systems)_1	The country has adequate capacity to: [1] diagnose and record cases of notifiable infectious diseases; [2] report and transmit timely and complete data on these diseases; and [3] analyse and act upon the data for outbreak response and planning of public health interventions
Health and disease records (including disease surveillance systems)_2	There is a high level of implementation of the <i>International Statistical Classification of Diseases and Related Health Problems version 10 (ICD-10)</i> for reporting hospital discharge diagnoses
Health and disease records (including disease surveillance systems)_3	Adequate and sustainable resources for operating the national cancer registry according to international standards are available
Health service records_1	There is a comprehensive electronic health service based information system that brings together data on discharge diagnoses, procedures and other treatments and services provided and their costs from all public and private facilities
Health service records_2	The electronic health service based information system has a cadre of trained health information staff, both at the central level and at the level of facilities, and regular training to keep the staff's knowledge up to date and to guarantee a sufficient pool of trained staff is provided
Health service records_3	There is a mechanism in place for verifying the completeness and consistency of data from facilities and for feeding this information back to the facilities
Resource records_1	There is a national database of public and private-sector health facilities with complete coverage. Each health facility has been assigned a unique identifier code that permits data on facilities to be merged.
Resource records_2	There is a national human resources (HR) database that tracks the number of health professionals by major professional category working in either the public or the private sector with complete coverage
Resource records_3	There is a national database that tracks the annual numbers graduating from all health-training institutions with complete coverage
Resource records_4	Financial records are available on general government expenditure on health and its components (e.g., by ministry of health, other ministries, social security, regional and local governments, and extra budgetary entities) and on private expenditure on health and its components (e.g., household out-of-pocket expenditure, private health insurance, NGOs, firms and corporations)

(continued on next page)

Category & nr	Item
Data sources general_1	There are adequate human resources and equipment for maintaining and updating the various health services records and resource databases described above and for producing and disseminating outputs based on these databases
Data sources general_2	The periodicity and timeliness of the routine data collections as described above is adequate and meets the demands of the end user (e.g. health facility managers, health insurance companies)
Data sources general_3	Data from the electronic health service based information system is readily available for public health monitoring (i.e. policy support) and research purposes and are actually being used for such secondary purposes
Data sources general_4	Regular assessments of the completeness and quality of the routine data collections as described above take place
IV. Data management	
Data management_1	There is a written set of procedures for data management including data collection, storage, cleaning, quality control, metadata requirements, analysis and presentation for target audiences, and these are implemented throughout the country
Data management_2	There is an integrated data warehouse at central level containing data from all population-based and institution-based data sources, both at the national and relevant sub-national levels, and a user-friendly reporting utility accessible to various user audiences
Data management_3	A unique patient identifier is in place that allows for the linkage of various data sources at the subject level and such integrated data analyses are regularly performed
V. National HIS data quality/information products	
Information products_1	Policy makers, at the national as well as at the relevant sub-national levels, have access to all the information they need to support their policy decisions, i.e. there are no major information gaps. In particular, all data and information necessary for monitoring the targets of the national health strategy are available
Information products_2	The data collection method for core indicators is in line with (inter)national standards and recommendations
Information products_3	The country is able to meet all data delivery requirements from the international organizations of which it is a member/with which it is collaborating
Information products_4	The timeliness with which the data for official indicators are being collected and the timeliness with which these indicators are being computed and reported is adequate and meets the needs of policy makers
Information products_5	The periodicity with which the data for official indicators are being collected and the periodicity with which these indicators are being computed and reported is adequate and meets the needs of policy makers
Information products_6	The consistency over time of datasets from major data sources used for computing official indicators is high
Information products_7	The coverage of major data sources used for computing official indicators is high; representativeness of estimates based on these sources is good
Information products_8	Official indicators can be disaggregated by demographic characteristics (e.g. sex, age) socioeconomic status (e.g. income, occupation, education) and locality (e.g. urban/rural, major geographical or administrative region).
Information products_9	In-country adjustments use transparent, well-established methods
VI. Dissemination and use	
Dissemination and use_1	Senior managers and policy-makers demand complete, timely, accurate, relevant and validated HIS information and know how to interpret and use it
Dissemination and use_2	Integrated health reports, including information on the core indicators and their disaggregations, are publicly distributed regularly
Dissemination and use_3	Integrated health reports, including information on the core indicators and their disaggregations, are demonstrably used in (national and sub-national) health policy making processes
Dissemination and use_4	Adequate mechanisms for knowledge translation* are in place and functioning well
Dissemination and use_5	* E.g. resources, tools, networks and platforms to structurally support the uptake of health information in policy making, i.e. to structurally support evidence-informed policy-making
Dissemination and use_5	Making health information available for research and contribute to publications. Participation in (inter)national projects and networks.

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