



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Information
and Standards

Evidence for Policy: International review of approaches to registries in health and social care in six countries in the context of the European Health Data Space

November 2025

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children’s special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children’s social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children’s social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland’s health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Visit www.hiqa.ie for more information.

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This report was led by the following staff in HIQA's Health Information Quality and Assurance Team.

Name	Role
Elaine Meehan	Project Lead
David Morrissey	Research Officer

The following individuals from the Health Information and Standards Directorate of HIQA also contributed to the management, technical writing or dissemination of this review: Rachel Flynn, Barbara Foley, Suzanne Barror, Fiona Geaney, Marie Higgins, Elena Vaughan, Chloe Walsh and Anna Ring.

Conflicts of interest

None reported.

Overview of the health information function of HIQA

Good information is the foundation of a high-quality health and social care service. As part of a person's journey through the health and social care system, information is collected and shared at different stages and used to inform their care. This is known as the primary use of information. High-quality data is also important for other purposes such as planning and managing services, policy-making, research and innovation. For example, information may be used to decide where to locate a new service or to understand how practice can be changed to improve a person's experience of care. This is known as the secondary use of information.

Whether used for primary or secondary purposes, it is essential that information is managed effectively and securely and used to its full potential to promote safer better care, improved outcomes and overall wellbeing for people using health and social care services. A human rights-based approach should be of central importance and seek to balance the rights of people with the broader societal value of using health and social care information. A strategic and coordinated approach that is aligned with information standards is also essential to ensure data is captured and managed in line with best practice. A well-embedded standards-based information environment will allow all stakeholders, including the general public, patients and service users, health and social care professionals, and policy-makers to make choices or decisions based on the best available information.

Digital health, which is the use of digital technologies to improve health, is critical to ensuring that information is available when and where it is required. An effective digital health infrastructure can support the secure, effective transfer of information by ensuring information is captured in the right format so that it can be shared easily and securely across services. The necessary information should be accessible by all health or social care professionals providing care and by the person it relates to. This will lead to more efficient and effective delivery of care and ensure people do not have to provide the same information on multiple occasions.

The Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance against those standards, as set out in Section 8(1) of the Health Act 2007. Under the Act, HIQA is also charged with evaluating the quality of the information available on health and social care and making recommendations to the Minister and the Health Service Executive (HSE) in relation to improving the health information system. Through its health information function, HIQA also plays a key role in providing evidence to inform national health information policy and shape the health information landscape in Ireland. HIQA works to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services which in turn ensures safer better care for all.

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1. Executive summary

1.1 Background

Registries are an important part of modern healthcare systems. In addition to being used for epidemiological and public health purposes, they play a key role in facilitating the monitoring and evaluation of healthcare quality. However, establishing and maintaining a registry can be associated with substantial effort, and the sustainability of funding in the long term is an issue for many registries. Other common issues include the lack of availability of professional expertise to support registries, as well as challenges ensuring the long-term relevance of registries.

The digital transformation of health services in Ireland will lead to greater availability of health information and improved efficiency with regard to how data is collected, used and shared. Underpinned by national and EU legislation, including Ireland's Health Information Bill 2024 and the European Health Data Space (EHDS) Regulation, the Department of Health's Digital Health Framework and the HSE's Digital Health Strategic Implementation Roadmap (Digital for Care 2030) set out how Ireland's health service will be digitally transformed over the coming years. The framework and roadmap offer significant potential to drive improvements and increase efficiencies with regard to registries. They will also help to ensure Ireland can meet its obligations with regard to the secondary use of data under the EHDS Regulation.

Within the context of these significant ongoing legislative and health system reforms, the Health Information and Quality Authority (HIQA) has conducted this international review of approaches being taken to registries in the following jurisdictions: Belgium, Denmark, Estonia, Finland, Sweden and Wales.

Wales, although outside of the EU, was selected for inclusion in our review in light of its comprehensive system of data collection through National Health Service (NHS) Wales and its well-developed infrastructure for secondary data use.

The methodology employed in this review comprised a desktop review of available evidence from the six countries, as well as interviews with key informants from each country.

This international review is the first stage of a project to develop a set of prioritisation criteria and a roadmap for the future of Ireland's registries. The overarching aim of the international review was to produce evidence to inform national health information policy around registries. Building on the international review, the second stage is to conduct an As-is analysis describing the current

registry landscape in Ireland. This will be followed by the development of the prioritisation criteria and areas for consideration for Ireland.

1.2 Key findings

This international review found a number of similarities and differences in approaches to registries across Belgium, Denmark, Estonia, Finland, Sweden and Wales. The main findings relate to terminology, governance arrangements, the categories and types of registries in operation, the maturity of systems and approaches taken to prioritisation. Future developments, particularly within the context of the EHDS Regulation, were also explored.

Terminology

- Variation in terminology exists between countries with regard to the registries that fall into one of the three categories of registry set out in the EHDS Regulation. In general:

1) Population-based (or public health) registries are established and operate under a legislative basis, usually without the need for individual consent; these registries are often referred to as national registries, particularly in the Nordic countries.

2) Medical and mortality registries often operate at a hospital or regional level, sometimes with the requirement for individual consent. They are used to monitor and evaluate healthcare quality and outcomes for particular diseases, conditions or interventions; these registries are often referred to as quality registries. National clinical audit programmes are also generally included within this category.

3) Medicinal product and medical device registries capture data on the use, safety, and effectiveness of medicinal products and medical devices. This includes products such as prescription and over-the-counter medications and vaccines, and devices such as implantable devices and diagnostic equipment.

Categories and types of registries

- Across the six countries, Denmark has the largest number of population-based registries (referred to as national registries). The most frequently occurring population-based registries were in the areas of:
 - cancer
 - pregnancies and births
 - deaths
 - hospital utilisation (national patient registries)
 - prescribed medications
 - congenital malformations
 - abortions.

- Sweden has the largest number of medical and mortality registries (referred to as quality registries), followed by Denmark. Across the six countries, the types of morbidity most frequently covered by such registries included:
 - kidney disease
 - diabetes
 - cardiac
 - trauma
 - cystic fibrosis
 - intensive care
 - breast cancer
 - inflammatory bowel disease
 - cerebral palsy
 - HIV
 - inflammatory rheumatic diseases.
- With regard to medicinal product and implanted device registries, registries of prescribed medicines, arthroplasty (hip and knee replacement) registries, and implantable cardiac device and pacemaker registries were the most common.

Governance arrangements

- In all six countries included in this review, there was at least one organisation identified that played a key role in overseeing and managing registries at a national level.
- The Nordic countries of Denmark, Finland and Sweden have strong traditions of registries, with the routine collection of data occurring systematically across the healthcare system, and the data being managed through systems of population-based registries. In these countries, governance and oversight of all registries is the responsibility of one or two key organisations, with clear differentiation between the different types of registries managed by each organisation.
- Most notably, in Denmark, the Danish Health Data Authority plays a key role in data governance at a national level. It has direct responsibility for population-based health registries in Denmark, and also plays an oversight role for the medical and mortality registries (referred to as quality registries) that are all centralised under the newly established Danish Healthcare Quality Institute. Under the Danish Health Act and Danish data protection legislation, Denmark's systems of population-based and medical and mortality registries have a legislative basis and operate without the need for individual consent; the small number of registries that operate outside of this framework are considered to be research registries and require individual consent.

- Under Denmark's Vision for Better Use of Health Data, which is part of the government's Strategy for Life Science 2021, the Ministry of the Interior and Health and the Danish Health Data Authority will establish a national contact point for health data and a national analysis platform in the coming years.
- In Belgium, there is less coordination of registries, with multiple data holders and various organisations playing a role in the management of registries, all of which collect data from multiple health sources and providers. The differentiation between the different types of registries in Belgium is less defined than it is in the Nordic countries.
- In Estonia, all population-based registries are managed by the Ministry of Social Affairs or an agency that falls under that Ministry. The Estonian Health Information System (HIS) — the country's national repository of data — is jointly managed by the Ministry of Social Affairs, the Health and Welfare Information Systems Centre, and the Estonian Health Insurance Fund. There is currently no national-level system of registries for coordinating the assessment of health system quality.
- Wales has a comprehensive system of data collection through NHS Wales and well-developed infrastructure for secondary data use. The number of individual registries remains low. For the majority of morbidities, Wales contributes to the UK-wide registries and national programmes of clinical audit.

Total population registries and unique identifiers

- Total population registries exist in the Nordics and act as a tool for the monitoring of population statistics and demographics. They also play a key role in facilitating the use of registries in the health field. These registries are linked to the countries' systems of unique identification, whereby each resident is assigned a unique personal identity number at birth or upon immigrating to the country, and this number follows each person across their lifespan. The general purpose of these numbers is administrative and they are used in all aspects of life, including healthcare. Examples include Denmark's civil registration number, called a CPR number, which is linked to the country's Population Statistics Register. From the perspective of registries, these numbers enable easy, accurate and unambiguous individual-level data linkage and are essential for using registries to their full potential.

National patient registries

- Each of the Nordic countries reviewed also has a national patient registry in operation. While there is some variation between countries, these registries generally contain data submitted from hospitals on inpatient and outpatient

care. They primarily act as a tool for healthcare planning, but also act as the basis for statistics on several disease areas.

Prioritisation

- Standardised approaches for prioritising registries were identified in Finland and Denmark, with similarities in the criteria across both frameworks. The prioritisation criteria centre on the following:
 - societal need
 - validity
 - feasibility
 - comprehensiveness
 - professional support
 - patient involvement
 - cost effectiveness
 - alignment with legislation and policy
 - existence of data gaps.

Digital health maturity, electronic health records and the provision of data to registries

- Belgium, Estonia and Denmark feature in the top three most mature countries across the EU in terms of their eHealth capabilities. Sweden and Finland both score close to the EU average. The Welsh healthcare system has become increasingly digitalised in recent years, and the country is currently working towards the development of a single digital health and social care record.
- A country's eHealth maturity level does not always correlate with the maturity of its system of registries. Various issues and limitations with the use of electronic health records (EHRs) and EHR repositories as the primary data source for registries were identified. These included the presence of different EHR systems and vendors across healthcare providers leading to poor interoperability of systems, and the predominance of unstructured data, such as discharge summaries and diagnostic imaging reports, leading to issues with data quality in EHR repositories.

Maturity of registries

- The factors that were associated with the most mature and fit-for-purpose systems for the management and oversight of registries in Denmark, Finland and Sweden were:
 - A small number of organisations with clearly defined roles with regard to the management and coordination of the different types of registries and a clear differentiation between population-based registries and medical and mortality registries.

- Legislation to clearly outline the legal basis for different types of registries, and the roles and responsibilities of the various parties with regard to the provision and collection of data for registries.
- High levels of public trust in how data is used across the health system and an acceptance that people's data will be used to improve healthcare.
- Infrastructure to streamline and automate the collection of data for registries and reduce duplication of effort and burden on data holders.
- Total population registries, linked to systems for unique identification that facilitate the routine linkage of individuals' data from different registries.
- National patient registries that can be used as a tool for healthcare planning and also as the basis for statistics on several disease areas.
- Extensive use of registry data to drive improvements in the quality of healthcare (such as regular targeted reports for individual hospitals and clinicians in addition to annual reports).
- Tools and resources to facilitate access to the data for both members of the public (such as through web-based dashboards) and to promote the use of the data for various secondary purposes, such as research and policy-making.

EHDS preparedness

- In most countries, it was evident that the key organisations with responsibility for overseeing registries are still examining how the EHDS Regulation will impact on their functions and how they currently operate.
- However, Belgium is progressing with plans to significantly change its approach to registries:
 - In March 2025, recommendations for the development of a new vision for the future of registry policy in Belgium, within the context of the implementation of the EHDS Regulation and the establishment of the Belgian Health Data Agency, were published.
 - Under the proposed policy, for the most part, registries in their current form will be replaced by federated data sharing and processing; data will remain with data holders rather than being centralised and permanently managed in single registries.
 - It is proposed that there will be two types of registries: permanent registries, which have a legislative basis, and temporary registries, which are established on an ad hoc basis to answer specific research questions. The number of permanent registries and the variables within each will be kept low. A process of prioritisation will be undertaken to determine which registries will be designated as permanent registries, and what the variables within each will be.

- Under this proposal, Belgium's health data access body (HDAB) under the EHDS Regulation will play a key role in relation to the temporary registers.

1.3 Conclusion

This review has highlighted that different models are in place for registries across the six jurisdictions that were reviewed and that changes are planned in some countries over the coming years. This is in particular in the context of the EHDS, which is at the early stages of implementation. Based on the findings, the following themes emerged as key features of a mature system of registries:

- clear **governance structures** and well-defined roles and responsibilities for organisations with regard to both the provision and collection of data for registries
- coordinated **oversight** of registries to provide assurances with regard to how they are being managed and the quality of the data
- enabling **legislation** that sets out the legal basis for registries and the roles and responsibilities of all parties
- a structured process to identify and **prioritise data needs** of key stakeholders such as health and social care professionals, national-level decision makers and policy-makers
- adequate **infrastructure** to support the secondary use of data
- the ability to optimise the use and utility **of existing data sources** to facilitate analysis and produce health statistics
- the presence of a **unique identifier** to facilitate easy, accurate and unambiguous individual-level data linkage
- engagement with the public to build and improve **public trust** in the collection, use and sharing of data.

Additionally, a key learning from this review is that although EHRs can be a rich source of data, issues with regard to interoperability and a predominance of unstructured data can potentially limit how useful they are for the purpose of registries. This finding underscores the importance of the EHDS Regulation which aims to address these issues across the EU over the coming years.

1.4 Country summary tables

1.4.1 Belgium

Population	11.7 million
Healthcare system	Belgium has a universal healthcare system funded through mandatory health insurance and social security contributions. Relative to other EU Member States, Belgium is ranked highly in terms of its eHealth capabilities; however, there are issues with regard to the interoperability of the electronic health record (EHR) systems that are in place and there is no centralised repository of EHR data available at a national level.
Summary of approach to registries	Belgium has a long history of routinely collecting population-level health data. Prior to the establishment of the healthdata.be platform in 2015, registries were fragmented, with no centralised repository of registry data. Data was collected from multiple health sources and providers, all of which had different information systems and or EHRs. The healthdata.be platform, managed by Sciensano, was developed to centralise the data needed for the health registries, which primarily comes directly from the hospitals.
Governance and oversight	Responsibility for registries is divided between several government-funded organisations, including the National Institute for Health and Disability Insurance (NIHDI), Sciensano, the Federal Public Service (FPS) for Public Health, Statbel, the Federal Agency for Medicines and Health Products (FAMHP) and the Intermutualist Agency (IMA). The Belgian Cancer Registry is an independent organisation established in 2005 as a partnership between the federal and regional governments. Several other government and non-government funded organisations across Belgium are responsible for individual registries. Each organisation is responsible for transferring its registry data to the healthdata.be platform.
Legislation	There is a legislative basis for the majority of population-based registries, including those held by the NIHDI and IMA, with compulsory submission of hospitals' data required. This includes the Quality Electronic Registration of Medical acts, Implants, and Devices (QERMID) registries, managed by NIHDI. Sciensano has a legal mandate to operate certain registries (such as infectious disease surveillance registries) without consent from individuals. Others operate on a consent basis, with approval required from the Information Security Committee in some circumstances.
Prioritisation	No evidence was found of any recent prioritisation undertaken; in the coming years, the focus is likely to be on prioritising the development of a small number of permanent registries under a new vision for the future of registry policy in Belgium (see EHDS plans). A programme of work is underway to assess which of Belgium's current registries should be

	retained under this new registry policy. Criteria to inform this process include the legal basis for each registry, utility of registry data and registry performance.
Use of registry data	Registry data is made available in a number of open data platforms, such as the IMA Atlas which is based on the registries held by the agency and allows users to explore factors affecting the use of healthcare using interactive tools. Based on its registry data, NIHDI also makes statistics available on medical care, benefits, and medicines, as well as statistics on the monitoring of healthcare providers and the evaluation of medical practice.
EHDS plans	In March 2025, a new vision for the future of registry policy in Belgium within the context of the EHDS was published. Under the proposed policy, registries in their current form will be replaced by federated data sharing and processing. Under this system, data will remain with data holders rather than being centralised and permanently managed in single registries. Two types of registries are proposed in the policy: permanent registries which have a legislative basis, and temporary registries which are established on an ad hoc basis to answer specific research questions. One of the objectives of the policy is to keep the number of permanent registries, and the variables within each, low. Under the proposed registry policy, Belgium’s coordinating HDAB will play a key role in relation to the temporary registries in particular.

1.4.2 Denmark

Population	6.0 million
Healthcare system	Denmark has a universal healthcare system, funded through taxation, with three levels of administration: the national level (the State), the regional level (comprising five regions, reducing to four in January 2027), and the local level (comprising 98 municipalities). Relative to other EU Member States, Denmark is ranked highly in terms of its eHealth capabilities with all healthcare records, including from GPs and hospitals, fully digitalised. EHR data is stored at a regional level, in regional data warehouses.
Summary of approach to registries	Denmark has a strong tradition of registries, with data for the country's system of national registries routinely and systematically collected at every point of contact with the healthcare system. Data linkage is facilitated through the country's national civil registration system (the CPR number that serves as a unique patient identifier). The registries can be broadly categorised as national registries and clinical quality registries.
Governance and oversight	A total of 28 population-based registries are managed by the Danish Health Data Authority, which is funded by the Ministry of Health, while the country's comprehensive system of approximately 85 clinical quality registries is managed by the Danish Healthcare Quality Institute (DHQI). This institute, funded by the Danish Regions, was established in January 2025 and took over responsibility of the clinical quality registries from the Regions' Clinical Quality Development Program. The Danish Health Data Authority is responsible for approving the establishment of new clinical quality registries and oversees their operation by the DHQI. Some registries for genetic and rare diseases are managed by university hospitals and government agencies throughout the country; in regulatory terms, these registries are operated as research registries or serve as supplements to the electronic patient record.
Legislation	The national registries and clinical quality registries all operate under the provisions of the Danish Health Act, which provides a legislative basis for data to be collected for registries without the need for consent from individuals. Registries that are operated outside of the Danish Health Data Authority or DHQI are considered to be research registries, and informed consent from all participants is required.
Prioritisation	To establish a new clinical quality registry, a formal application must be made to the DHQI. Applications are assessed based on several key factors, including the level of support from professional bodies; the value and relevance of the database; the presence of clinical guidelines; the availability of valid and accurate data; the severity of the disease or condition and the proportion of the population affected by it; and the

	<p>inclusion of patient perspectives. If a clinical quality registry is prioritised for establishment, it must first be approved by the Danish Health Data Authority. As part of the approval process, the Authority assesses, among other things, whether the purpose of the registry is proportionate to the scope and amount of data to be collected.</p>
<p>Use of registry data</p>	<p>Data from the national registries is used by the Danish Health Data Authority for the publication of regular statistics and reports on the health of the population and the Danish healthcare system. With regard to the quality registries, the DHQI produces daily reports for the clinicians and health service managers to allow for quality improvement and benchmarking. The DHQI also publishes annual reports, and undertakes thematic analyses and extractions of data for specific purposes as required. Danish citizens can access information from the national registries on the sundhed.dk platform, while the National Service Platform is the infrastructure that enables the use of the national registries in patient care. Data from both the national health registries and the clinical quality registries are routinely made available for approved research projects without individual consent, as permitted under the Danish Health Act and Danish data protection law.</p>
<p>EHDS plans</p>	<p>It was acknowledged that the relevant organisations, including the Danish Health Data Authority and the DHQI, will be obligated to make data from registries available for secondary use under the EHDS Regulation. Work is also ongoing by the Ministry of Health and the Regions to establish a single access point for health data.</p>

1.4.3 Estonia

Population	1.3 million
Healthcare system	Estonia has a universal healthcare system, funded through health insurance contributions deducted from employed individuals' salaries, via the Estonian Health Insurance Fund (EHIF) which enters into agreements with healthcare providers. The health service has been fully digital for a number of years and there is a nationwide EHR system in place. A nationally agreed set of data generated in the healthcare system is transmitted and stored in a centralised database, known as the Health Information System (HIS).
Summary of approach to registries	Registries have evolved over time and today there is a combination of well-established and more recently established registries, all collecting data in different ways. The HIS is used as the basis for a minority of registries, with the majority collecting data directly from healthcare providers in various ways. At present, there is no national quality registry system that consolidates data for assessing healthcare quality and outcomes. Instead, healthcare quality and outcomes are assessed in various ways through the use of different data sources.
Governance and oversight	The HIS is jointly held by the Ministry of Social Affairs, the EHIF and the Health and Welfare Information Systems Centre. The Ministry of Social Affairs has responsibility for setting registry policy and directly manages two other population-based registries. Various agencies that sit under the Ministry of Social Affairs play key roles in the management of other registries, such as the National Institute for Health Development, the Center of Health and Welfare Information Systems, and the Estonian Health Board. The EHIF also plays an important role.
Legislation	Data for the national registries is collected under national legislation without the need for consent. Relevant legislation includes the Health Services Organisation Act, Public Health Act, Estonian Health Insurance Fund Act, Medicinal Products Act, Public Information Act, and the Establishment of Cause of Death Act.
Prioritisation	Prioritisation of registries is based on the strategic objectives of the Ministry of Social Affairs and the priorities set by the Estonian government. Strategic priorities in the health sector arise from the eHealth strategy, the latest of which was published in January 2025 and is being implemented by an eHealth steering committee, led by the Ministry of Social Affairs. Data policy priorities are being specified in the latest data strategy which is expected to be completed later in 2025. The latest registry to be prioritised for development was a donor registry to capture information on fertility treatment.

Use of registry data	As the main source of health and healthcare statistics in Estonia, the Ministry of Health's National Institute for Health Development utilises data from its national registries to publish aggregated data and statistics on morbidity and healthcare utilisation in the country. The EHIF and Estonian Health Board also publish health statistics using data from its registries.
EHDS plans	National changes are required to ensure Estonia can meet its obligations relating to the processing and issuing of research permits and establishing secure data processing environments. The long-term vision in Estonia is to develop the HIS database further so it is more suitable for secondary uses, including as the basis for more health registries. This would include the collection of more standardised and structured data and the development of systems that would reduce the need for registries to collect data from providers in different ways.

1.4.4 Finland

Population	5.6 million
Healthcare system	Finland has a universal healthcare system funded through taxation. The health system is fully digitalised, with a national electronic health record. Individuals have access to their health information via Kanta, a centralised repository for all social welfare and healthcare data.
Summary of approach to registries	Finland has a strong tradition of registries with data routinely and systematically collected at every point of contact with the healthcare system and data linkage facilitated through the personal identity code. Several national registers with population-wide coverage exist, as well as a comprehensive system of quality registers. Kanta is used as the basis for some registries, with the regions' data lakes used as another key data source. Infrastructure has been developed to facilitate the transfer of data from Kanta and the data lakes directly to the registries.
Governance and oversight	The Finnish Institute for Health and Welfare, funded by the Ministry of Social Affairs and Health, is responsible for managing 10 national registries, in addition to the Finnish Cancer Registry which is managed by the Cancer Society of Finland; however, the Institute for Health and Welfare is the data controller. Since 2022, it also has responsibility for nine clinical quality registers, with this number expected to grow. Other quality registers are managed by various hospital and government agencies. The Social Insurance Institution of Finland (Kela) maintains the Kanta services.
Legislation	The responsibilities of the National Institute for Health and Welfare with regard to the management of registries are set out in the Act on the National Institute for Health and Welfare. Under this legislation, consent is not required for the registers under the remit of the institute, including the quality registers; however, consent is generally required for the quality registers that are managed by other organisations. Other relevant legislation includes the Personal Data Act and the Act on National Personal Data Registers Kept under the Health Care System.
Prioritisation	In recent years, there has been a focus on clinical quality registries and a process was established to provide a framework for deciding which clinical quality registers would be brought under the remit of the Finnish Institute for Health and Welfare. The overarching criteria for prioritising these registries include: relevance, feasibility, validity, and cost-effectiveness.
Use of registry data	The Finnish Institute for Health and Welfare uses data from its national registries to produce statistics on various topics, such as alcohol and drug consumption, cancer, access to healthcare services, and sexual and

	<p>reproductive health. This statistical data, together with indicators of health, welfare and functioning of the health system, can be browsed on a web platform hosted by the institute. Kela also produces statistics and provides open data relating to the registries it holds, allowing users to make custom reports from its data using a dedicated online platform.</p>
EHDS plans	<p>Findata has been established as a data permit authority in Finland. The FinHITS project, which commenced in 2024, was established by FinData to strengthen Finnish health data ICT and data quality for the secondary use of health data.</p>

1.4.5 Sweden

Population	10.6 million
Healthcare system	Sweden has a universal healthcare system funded primarily through taxation and managed at regional and municipal levels; the federal government sets overall policy, and the regions and municipalities are responsible for providing services.
Summary of approach to registries	There is a strong tradition in Sweden of using registries to support the healthcare system, with data routinely and systematically collected at every point of contact with the healthcare system and data linkage facilitated through the personal identity code. Registries are broadly categorised as national registries which are population-based and operate under a legislative remit, and quality registries which are used to assess and drive improvements in healthcare.
Governance and oversight	The National Board for Health and Welfare (Socialstyrelsen), funded by the Ministry of Health and Social Affairs, is the largest health data holder in the country and manages a total of thirteen population-based registries. Sweden’s system of over 100 healthcare quality registries is coordinated and partly funded by the Swedish Association of Local Authorities and Regions (SALAR), with the remainder of funding coming from the Swedish government. Each quality registry is managed by a different registry holder but is overseen by one of thirteen central data protection authorities (CPUAs) and supported by one of six regional registry centres. Each registry also has a steering group which plays an advisory role.
Legislation	All healthcare providers are mandated to provide information to the national registries hosted by the National Board of Health and Welfare under the Health Data Register Act. Under this legislation, consent from individuals is not required. The system of quality registries is regulated under the Patient Data Act; consent is required for these registries.
Prioritisation	The National Board for Health and Welfare was instructed by the Swedish government to expand its collections of data to include outpatient data, data from primary care, and data on medicines administered in healthcare settings. Planning is underway to develop a framework to support the National Board of Health and Welfare’s ability to prioritise new datasets.
Use of registry data	Data from the national registries is used by the National Board of Health and Welfare to produce official statistics, and facilitate analysis and development of the Swedish health care and social services. For many of the registries, it makes available statistical databases on a regular basis, providing statistics on topics such as abortion, acute

	<p>myocardial infarction, cancer, and causes of death. Data from the quality registries is used extensively for monitoring and evaluating quality among healthcare providers and for assessing treatment options and clinical practice in the regions.</p>
<p>EHDS plans</p>	<p>A HDAB has not yet been designated in Sweden. While not directly linked to the EHDS, work is ongoing to automate the processes for information provision between health information systems and the quality registers in particular. Work is also ongoing to reduce the number of IT platforms used by the quality registers and the number of CPUAs in operation.</p>

1.4.6 Wales

Population	3.2 million
Healthcare system	Wales has a universal healthcare system, funded through taxation and provided by the Welsh public health service, NHS Wales.
Summary of approach to registries	In comparison to the Nordic countries in particular, Wales has fewer population-based registries, with its national public health agency, Public Health Wales, having a focus on cancer, congenital anomaly and rare disease registries. However, as a devolved nation, it does contribute data to a number of UK-wide registries. Wales does not have a system of quality registries; instead, it participates in programmes of national clinical audits and clinical outcome reviews.
Governance and oversight	Public Health Wales is part of NHS Wales, and with regard to population-based registries, it oversees the Welsh Cancer Registry and the Congenital Anomaly Register. There are some registries in operation at a local level, for example in individual hospitals and laboratories; however, it was not possible to get a full account of the number or extent of these registries. Established in 2021 as part of NHS Wales, Digital Health and Care Wales (DHCW) has been tasked with developing national digital and data services across the country. It hosts the National Data Resource (NDR) platform, which sets out to bring together and streamline data from across all health and social care services in Wales over the coming years. Wales participates in a number of national programmes of clinical audit and clinical outcome reviews, such as the programmes run by the Healthcare Quality Improvement Partnership (HQIP) and the National Institute for Cardiovascular Outcomes Research (NICOR). The Secure Anonymised Information Linkage (SAIL) Databank, funded by the Welsh government and hosted by Swansea University, acts as a national repository of de-identified datasets about the population of Wales. It provides a platform for data to be linked and used for secondary purposes.
Legislation	Public Health Wales has a statutory remit to operate the cancer and congenital anomaly registries without the need for individual consent. Other relevant legislation includes the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, which set out the requirements for controlling or processing personal data, including health data.
Prioritisation	The development of the NDR platform by DHCW will be the main priority over the coming years and plans are in place to prioritise the addition of more datasets to this platform.

<p>Use of registry data</p>	<p>Public Health Wales uses data from the registries under its remit to publish data and evidence on a range of public health topics, in particular cancer and congenital anomalies. The Cancer Reporting Tool, hosted on the Public Health Wales website, holds official statistics for cancer incidence, mortality and survival. It includes an interactive dashboard to enable the user to explore the data in different ways. Registry data is also made available to data users for secondary use purposes through the SAIL platform.</p>
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2. Introduction

2.1 Background

Internationally, registries have evolved from being used primarily for epidemiological purposes to being an important part of healthcare systems. While traditionally they set out to enable a better understanding of the natural history of diseases, other purposes include identifying risk factors for the development of diseases and evaluating the effectiveness and monitoring the safety of new treatments, products, services or procedures.^(1,2) In modern healthcare systems, registries are utilised for disease prevention, early diagnosis and screening programmes, healthcare planning, and for monitoring and evaluating healthcare quality.⁽³⁾ With regard to rare diseases in particular, registries are seen as an effective way of furthering our understanding of the incidence and natural history of a disease, as well as bringing together people with rare diseases and enabling the identification and recruitment of eligible participants for clinical trials.⁽⁴⁾ Ultimately, registries play an important role in advancing medical research, improving our understanding of diseases and improving patient care and safety.

The registry landscape in Ireland is somewhat fragmented, with several organisations involved in managing a large number of individual registries of varying sizes.⁽⁵⁾ In recent years, there have been calls for a number of new registries to be established. These include registries for multiple sclerosis, diabetes, heart failure and dementia.^(6,7,8,9) However, establishing and maintaining a registry can be associated with substantial effort and the sustainability of funding in the long term is an issue for many registries. Other common issues include the lack of availability of professional expertise to support registries, as well as challenges ensuring the long-term relevance of registries.^(10,11)

This international review follows previous HIQA reports which have outlined several issues with Ireland's current health information system, including the fact that it lacks an entity with responsibility for centralising and coordinating data collections such as registries.^(12,13) While the National Office for Clinical Audit, established in 2012, manages a total of 11 established national clinical audits and registries, there remains a significant number of registries outside its remit which are managed by organisations of varying sizes and with different governance structures.⁽¹⁴⁾ This review is also being carried out at a time when there is substantial work underway to digitally transform health services in Ireland through the Department of Health's Digital for Care: A Digital Health Framework and the HSE's Digital Health Strategic Implementation Roadmap.^(15,16) These ambitious goals for Irish health services, as set out in these key documents, are underpinned by the Health Information Bill 2024 which provides a comprehensive legislative framework to ensure Ireland has a fit-for-purpose national health information system.⁽¹⁷⁾

Within the HSE roadmap, registries are set out as one of the digital tools that will support public health programmes and improve the overall wellbeing of people and communities. As the use of technology across the health service increases, and as Ireland's digital health capability matures, there is potential for registries to leverage this technology to enable real-world data collection and build learning healthcare systems that will enable data-informed decision-making at all levels of the health service.

At an EU-level, the EHDS Regulation entered into force in March 2025 and has set out a number of requirements for Member States with regard to secondary data use.⁽¹⁸⁾ Under the regulation, holders of 17 categories of health data (three of which relate to registries) will be required to make their metadata available to a health data access body (HDAB) and following a request from a data user, will be obliged to make their data available to data users. Twelve of these categories of data (including those relating to registries) will need to be made discoverable and available by 2029 and the remaining five categories by 2031.

2.2 Aim of this review

The overall aim of this international review was to produce evidence for national policy on registries and identify areas of consideration for Ireland by exploring the approaches being taken in six countries, with a particular focus on governance arrangements for registries, the maturity of systems, approaches to prioritisation, and future developments.

3. Methodology

In order to ensure a standardised approach, to allow for transparency, to assist with project management and to mitigate risks, there were four distinct steps to this international review, as follows:

- Step 1: Defining the scope
- Step 2: Searching relevant international sources
- Step 3: Reviewing and extracting relevant information
- Step 4: Summarising the findings.

3.1 Defining the scope

For the purposes of this review, registries were defined as organised systems that collect, analyse, and disseminate data and information on a group of people defined by a particular disease, condition, exposure, or health-related service, and that serve a predetermined scientific, clinical and or public health (policy) purpose. Included within this definition were:

- 1) registries relating to specific diseases or conditions (such as cancer)
- 2) registries relating to specific products (such as drugs or devices)
- 3) registries relating to specific services or procedures (such as hospital discharge data).

The following countries were selected for inclusion:

- Belgium
- Denmark
- Estonia
- Finland
- Sweden
- Wales.

These countries were selected on the basis that they have mostly centralised models for national health and social care data collections and mature health information infrastructures, combined with other factors such as geographical proximity to Ireland, similar population size, organisation of health services, EU membership and availability of documents in English.

3.2 Searching relevant international sources

The key organisations that play a role in setting policy for and or managing and overseeing registries in the field of health in each country were identified. A search of each organisation's website was performed to identify all relevant resources,

including reports, plans, strategies and press releases. A list of all organisations included in these searches is included in Appendix A.

3.3 Reviewing and extracting relevant information

Information on the following was extracted from the resources identified from each country:

- oversight and governance arrangements for registries
- general approaches to registries
- criteria used to prioritise registries
- strategies and plans for registries
- future plans for registries, particularly in light of the EHDS Regulation.

A data extraction form was developed and piloted on one country initially to ensure the steps described above and the data extraction form itself were fit-for-purpose. See Appendix A.

Documents and websites that were published in languages other than English were translated with DeepL machine translation software.

Information gathered for each country was verified through arranging online meetings with key individuals in each of the relevant organisations. These individuals were identified by emailing the relevant unit or department of the organisation with a brief description of the project and an overview of what the meetings would entail. The relevant individuals were subsequently nominated to participate in the meetings. In some cases, during the meetings, participants suggested further contacts and where appropriate, the team made contact with these people and arranged additional meetings. A semi-structured schedule of questions was prepared for each meeting, with each schedule modified to include relevant questions for each country. See Appendix A. Following the meetings, the individuals were sent a draft of the summary table and oversight structures diagram for their country to provide them with a further opportunity to verify the information included.

3.4 Summarising the findings

Information on approaches to registries in each of the countries included in this review was documented and presented in a narrative format. Tables have been used throughout to summarise key points and findings. The countries are compared and contrasted under each of the main headings.

4. Findings

4.1 History of registries

4.1.1 The Nordic countries — Denmark, Finland, and Sweden

Of the six countries included in this review, most have a long history of using registries to support the healthcare system. In particular, the Nordic countries of Denmark, Finland and Sweden have strong traditions of registries, with some of the first registries dating back as far as the 1950s. In these countries, there are high levels of public trust and general perceptions among the public that the maintenance of registries and the collection and secondary use of health data are for the common good. Each has a system of publicly funded universal healthcare, where the routine collection of data occurs systematically at every point of contact with the healthcare system. The data is managed through systems of national health registries, and as a result, there are many rich sources of longitudinal health data with population-wide coverage.

In each country, registries of the entire population are maintained. These total population registries (Denmark's Population Statistics Register; Finland's Population Information System Register; and Sweden's Total Population Register) are primarily administrative and form the basis for monitoring population statistics and demographics.^(19,20,21) They contain personal identity data for all individuals, including date of birth and date of death (if applicable), and they are a key tool for registry-based research, facilitating complete follow-up of the population. A key feature of each country is the potential to routinely link individuals' data from all sources through their systems of unique identifiers which are linked to the total population registries: Denmark's civil registration number, called a CPR number; Sweden's personal identity number; and Finland's personal identity code.^(22,23,24) These numbers are assigned to residents at birth or upon immigrating to the country, and follow each person across their whole lifespan. The general purpose of these numbers is administrative, and they are used in all aspects of life. From the perspective of registries, these numbers are key identifiers and enable easy, accurate and unambiguous individual-level data linkage and are essential for using registries to their full potential.⁽²⁵⁾

National patient registries covering a number of decades are also in operation in Denmark, Finland and Sweden. The primary aim of the national patient registries is to monitor hospital and health service utilisation to provide a tool for healthcare planning. In Sweden and Denmark, they contain data on all hospital encounters, including data on admissions, tests, procedures and diagnostic imaging.^(26,27) In Finland, the Finnish Care Register for Health Care serves a similar purpose, containing data on inpatient, outpatient and day procedures.⁽²⁸⁾ These patient

registries are used as the basis for several other registries. In Denmark, for example, all hospital reporting to the Cancer Registry, Birth Registry, and Rehabilitation Registry is done electronically via the National Patient Registry.⁽²⁶⁾ Similarly, in Sweden, the National Patient Register forms the basis for official statistical reporting on diseases and symptoms; surgery and treatments; compulsory psychiatric care; injuries and poisoning; waiting times; and heart attacks and stroke.⁽²⁷⁾

In recent years, the healthcare systems of each country have become fully digitised, which has benefited their registries in many ways. In both Sweden and Denmark, EHR data is stored centrally at a regional-level and from here, is shared with the organisations that are responsible for the national registries.^(29,30) In Finland, EHR data is held in the regional data lakes and also at a national level through the Kanta services; both the data lakes and the Kanta system act as data sources for the registries.⁽³¹⁾

4.1.2 Belgium

In Belgium, registries have evolved over time, and today the system is characterised by a combination of well-established registries, such as the Cancer Registry, together with several more recently established registries, all managed by different organisations and collecting data in different ways. The vast number of individual registries and different managing organisations is associated with a number of problems, and the fragmentation means that the necessary registry data is often not available for data users, such as policy-makers, when required. In light of the EHDS Regulation entering into force, Belgium is reflecting on the problems with its current system and the potential to change its approach, moving to a more federated system. Belgium's vision for the future of its registries is outlined in Section 4.7.1.

4.1.3 Estonia

Estonia, widely recognised as a global leader in digital health innovation, has leveraged its nationwide EHR system to develop the Estonian Health Information System (HIS), a repository of patient data from all healthcare providers. In a similar way to the Nordic countries, data is collected at every point of contact with the health system. Estonia's comprehensive system of population-based registries is mostly managed and coordinated centrally.

All Estonians are allocated a personal identification code which is linked to the country's Population Register.⁽³²⁾ This code forms the basis for the Estonian electronic ID-card, a compulsory identity document used across various sectors of Estonian society.⁽³³⁾ This unique identifier facilitates linkage of individuals' data from various sources.

4.1.4 Wales

In Wales, there is a comprehensive system of data collection and well-developed infrastructure for secondary data use. There are a number of long-running national registries in place, as well as several registries managed at a local level. The NHS number acts as the unique patient identifier for healthcare purposes and is used across all registries to facilitate data linkage.⁽³⁴⁾ As a devolved nation, Wales contributes to several UK-wide registries. In recent years, for some diseases and conditions — such as diabetes — there has been a move from standalone registries to UK-wide healthcare quality improvement programmes, including a programme of national clinical audit and clinical outcome review programmes.⁽³⁵⁾

Note

While traditionally, some groups have differentiated between the terms 'registry' and 'register', using the term 'registry' to refer to an organisation that manages one or more individual 'registers', the two terms tend to be used interchangeably today.

For the remainder of this report, we use the term 'registry', unless referring to certain registries' official names.

4.2 Terminology, categories and types of registries

Across each of the six countries included in this review, there was variation in the terminology used in relation to the different types and purposes of registries. Other terms that are often used to refer to registries include:

- clinical registries
- clinical data registries
- disease registries
- outcomes registries
- quality registries
- clinical quality registries.⁽³⁶⁾

Of the 17 categories of data for secondary use that are set out in Chapter IV of the EHDS Regulation, three relate to registries.⁽¹⁸⁾ See **Table 1** for a description of each category.

Table 1. Categories of registries set out in Chapter IV of the EHDS Regulation

EHDS category	Description of category ⁽³⁷⁾
Category (k): Population-based health data registries (public health registries)	Systematic collections of health-related data from a defined population. These registries are typically maintained by government agencies, health organisations, or research institutions to support public health decision-making, policy development, and healthcare planning.
Category (l): data from medical registries and mortality registries	<p>Medical registries are systematic collections of data on patients with a specific disease, condition, or characteristic, such as transplantation registries containing collections of data on organ transplantation outcomes, including patient characteristics, transplant procedures, complications, and graft survival rates.</p> <p>Mortality registries are systematic collections of data on deaths, including information on cause, circumstances, and demographics, such as cause-of-death registries containing data on the underlying cause of death, including information on disease, injury, or condition.</p>
Category (o): data from registries for medicinal products and medical devices	<p>Collections of data on the use, safety, and effectiveness of medicinal products and medical devices, including two types of registries:</p> <ol style="list-style-type: none"> 1. Medicinal product registries: These registries collect data on medicinal products, including prescription and over-the-counter medications, vaccines, and biologics.

- | | |
|--|--|
| | 2. Medical device registries: These registries collect data on medical devices, including implantable devices, diagnostic equipment, and software. |
|--|--|

Findings in relation to each of these three EHDS categories of registries are outlined in the following section.

Note

For the remainder of this report, where possible, we align with the EHDS categories of registries and use the terms 'population-based registry', 'medical registry', 'mortality registry' and 'product and device registry' to differentiate between the different types of registries. Where relevant, we acknowledge where different terminology is used to describe these types of registries in each country.

4.2.1 Population-based registries

Population-based (or public health) registries are often referred to as national registries, particularly in the Nordic countries of Denmark, Finland and Sweden where they are easily distinguishable from other types of registries.^(38,39,40)

In general, they are established and operate under a legislative basis, usually without the need for individual consent. They are characterised by having population-wide coverage, and are used to facilitate monitoring and reporting on the health of the entire population and or the services of the entire healthcare system. These types of registries generally operate on the basis of being in the interest of public health as opposed to answering a specific research question.

Overall, the largest number of population-based registries are in operation in Denmark, with 28 national health registries listed on the website of the Danish Health Data Authority at the time of this review (Appendix B). This was followed by 21 population-based registries managed by agencies of the Estonian Ministry of Social Affairs (Appendix C); and 15 population-based registries managed by the Finnish Institute for Health and Welfare (Appendix D). In Sweden, 13 population-based registries are currently managed by the National Board of Health and Welfare, while the Public Health Agency of Sweden and the Swedish eHealth Agency are responsible for a further four registries (Appendix E). A total of eight population-based registries were identified for Wales (Appendix F).

In Belgium, the differentiation between the types of registries is less clear; however, it appears that many of the registries that are managed by the Belgian Cancer

Registry, Federal Public Service (FPS) for Public Health, Intermutualist Agency, Statistics Belgium, and the National Institute for Health and Disability Institute (NIHDI) fall into this category of population-based registries. A total of 14 registries in this category were identified; however this number is likely to be significantly higher as some of the registries that are listed as single registries represent multiple registries (Appendix G).

Notably, in Denmark, Finland and Sweden, population-based national patient registries covering a number of decades are maintained. The primary aim of these registries is to monitor hospital and health service utilisation to provide a tool for healthcare planning. In Sweden and Denmark, they contain data on all hospital encounters, including data on admissions, tests, procedures and diagnostic imaging.^(26,27) In Finland, the Finnish Care Register for Health Care serves a similar purpose, containing data on inpatient, outpatient and day procedures.⁽²⁸⁾ These patient registries are used as the basis for several other registries. In Denmark, for example, all hospital reporting to the Cancer Registry, Birth Registry and Rehabilitation Registry is done electronically via the National Patient Registry.⁽²⁶⁾ Similarly, in Sweden, the National Patient Register forms the basis for official statistical reporting on: diseases and symptoms; surgery and treatments; compulsory psychiatric care; injuries and poisoning; waiting times; and heart attacks and stroke.⁽²⁷⁾

Across all six countries, there were some similarities with regard to the registries in this category. For example:

- In all six countries, there is a national **cancer** registry.
- Registries of **pregnancies and births**, as well as registries of **deaths** (including causes of death), are also in operation in all six countries.
- In three of the six countries (Denmark, Finland and Sweden), there is a **national patient registry** (referred to as the Care Register for Healthcare in Finland). These are population-based registries of hospital utilisation and provide a tool for healthcare planning. While standalone registries for this information are not available in Estonia or Finland, this type of data is available from the HIS and Kanta system, respectively.
- Registries of **congenital malformations** are in operation in Finland, Sweden and Wales. In the other countries, data and statistics on congenital malformations are available from existing registries.
- Registries of **abortions** are in operation in three countries (Denmark, Estonia and Finland), while statistics on abortion are made available in Belgium, Sweden and Wales on an annual basis.

See Appendix H for a full overview and comparison of the population-based registries that were identified for each country.

4.2.2 Medical and mortality registries

Across the countries included in this review, medical and mortality registries often operate at a hospital or regional level and are used to monitor and evaluate healthcare quality and outcomes for particular diseases, conditions or interventions. These registries are often referred to as quality registries, particularly in the Nordic countries. For example, these types of registries are referred to as:

- clinical quality registries in Denmark;
- healthcare quality registers in Finland; and
- national quality registers in Sweden.^(41,42,43)

For these registries, there is variation between countries with regard to consent requirements. For example, in Sweden, individual consent is required; however, in Denmark and Finland, the relevant organisations have a legislative remit to operate and collect data for these registries without individual consent.^(44,45,46)

National clinical audit programmes also generally fall under this category. For example, in Wales, there is no national-level system of registries to monitor and evaluate healthcare quality and outcomes. Instead, Wales participates in a number of UK-wide programmes of clinical audit and clinical outcome review.^(47,48) In Estonia, there is no system of national quality registries and no programme for assessing healthcare quality at a national level.⁽⁴⁹⁾

Overall, the largest number of registries in this category were identified in Sweden, with a total of 100 national quality registries listed on the website of the National System for Knowledge Management in Health Care at the time of this review (Appendix I). This was followed by 82 clinical quality registries in Denmark, managed by the Danish Healthcare Quality Institute (DHQI) (Appendix J).

In Finland, the Finnish Institute for Health and Welfare manages nine healthcare quality registries at present (Appendix D); however, while individual registries are not maintained on a permanent basis for other diseases, conditions, or healthcare interventions, it is possible to extract data from the other registries or from the data lakes or the Kanta system on an ad hoc basis to answer specific research questions as required.

In Belgium, the differentiation between the types of registries is less clear; however, it appears that many of the registries that are managed by the National Institute for Health and Disability Institute (NIHDI), Sciensano, and other regional and local organisations fall into this category of medical and mortality registries. A total of 37 registries in this category were identified (Appendix G).

For Wales, a total of 47 registries or national clinical audit programmes in which Welsh data is included were identified. The national clinical audit programmes managed by the HQIP and NICOR accounted for the majority (Appendix F).

Across the six countries included in this review, there were some similarities with regard to morbidities covered by the medical and mortality registries that are currently in operation. For example:

- In all six countries, there are registries in operation to assess **cardiac** care and or surgery outcomes: the Belgian Association for Cardio-Thoracic Surgery Registry; the Danish Cardiac Arrest Registry; the Estonian Myocardial Infarction Registry; the Finnish Cardiac Registry; Sweden's SWEDEHEART Registry; and in Wales, the National Adult Cardiac Surgery Audit managed by NICOR.
- In five countries (Belgium, Denmark, Finland, Sweden and Wales), there is at least one registry for **diabetes** in operation: the Belgian Diabetes Register; the Danish Diabetes Database; the Finnish Diabetes Register; the Swedish National Diabetes Register; and in Wales, the National Paediatric Diabetes Audit.
- In four countries (Belgium, Finland, Sweden and Wales), there is at least one registry for **kidney disease** in operation: Belgium's Chronic Kidney Disease treatment registry; the Finnish Kidney Disease Register; the Swedish Kidney Registry; and in Wales, the UK Renal Registry.
- In four countries (Belgium, Denmark, Sweden and Wales), there is a **trauma** registry in operation.
- In three countries (Denmark, Sweden and Wales), there is quality registry for **breast cancer** in operation: the Danish Breast Cancer Quality Database; the Swedish National Quality Registry for Breast Cancer; and in Wales, the National Audit of Primary Breast Cancer managed by the Healthcare Quality Improvement Partnership (HQIP).

See Appendix K for a full overview and comparison of the medical and mortality registries that were identified for each country.

Notably, in both Denmark and Sweden there is a strong focus on cancer quality registries. In Sweden, a total of 25 cancer quality registries were identified, including registries for colorectal cancer, gynaecological cancer, lung cancer, breast cancer and kidney cancer (see Appendix I). In Denmark, 22 cancer quality registries were identified, including registries for lung cancer, pancreatic cancer, prostate cancer, breast cancer and testicular cancer (see Appendix J).

4.2.3 Medicinal products and medical device registries

Medicinal products and medical device registries capture data on the use, safety, and effectiveness of medicinal products and medical devices. This includes products such as prescription and over-the-counter medications and vaccines, and devices such as implantable devices and diagnostic equipment.

The most common types of medicinal product registries in operation across the six countries were registries of **prescribed medications**. Prescribed medication registries are in operation at a national level in Denmark, Estonia and Sweden. While standalone registries for this information are not available in Belgium, this type of data is available from the datasets held by National Institute for Health and Disability Insurance and the Intermutualist Agency, while in Finland, prescribed medications data is available from the Kanta system.

The most common types of medical implant registries in operation across the six countries included in this review were arthroplasty (hip and knee replacement) registries and cardiac (implantable cardiac defibrillator and pacemaker) registries.

- National **arthroplasty** registries are in operation in five countries (Belgium, Denmark, Finland, Sweden and Wales). In Denmark and Sweden, these registries are managed and coordinated under the countries' systems of quality registries.
- Registries of **implanted cardiac devices** are in operation in Belgium, Denmark, Sweden and Wales. In Denmark and Sweden, these registries are managed and coordinated under the countries' systems of quality registries.

See Appendix L for an overview of registries of medicinal products and implanted medical devices in operation in each country.

4.2.4 Summary

- Variation in terminology was apparent across countries. In general, the EHDS category of population-based registries are referred to as national registries, particularly in the Nordics. The EHDS category of medical and mortality registries are often referred to as quality registries; national clinical audit programmes also generally fall under this category.
- Denmark has the largest number of population-based registries, followed by Estonia, Sweden and Finland. The most frequently occurring population-based registries across countries were in the areas of cancer, pregnancies and births, deaths, and hospital utilisation (national patient registries).
- The largest number of medical and mortality registries is in operation in Sweden. Across the six countries, the types of morbidities most frequently

covered by such registries include kidney disease, diabetes, cardiac, trauma, cystic fibrosis, intensive care and trauma.

- The most frequently occurring medicinal produce and implanted device registries are for prescribed medications, arthroplasty and implantable cardiac devices.

4.3 Oversight and governance arrangements

4.3.1 Organisational governance

In all six countries included in this review, there was a single organisation identified that played a key role in overseeing and managing registries at a national level; these organisations are marked with an asterisk in Table 2. In most cases, there were also other organisations that played related roles, for example in managing a subset of registries.

Table 2. Summary of key organisations in each country

Country	Key organisations and their roles
Belgium	National Institute for Health and Disability Insurance (NIHDI) – administers the country's compulsory national schemes for health insurance and disability benefits and plays a key role in assessing the performance of the health system and the quality of services provided *
	Sciensano – Belgium's national public health institute; responsible for the healthdata.be platform
	The Federal Public Services (FPS) for Public Health, Food Chain Safety and Environment – government agency with responsibility for carrying out research and developing and implementing strategy for public health
	Intermutualist Agency/Common Sickness Funds Agency (AIM-IMA) – manages data on reimbursed healthcare services and prescription medications from Belgium's seven sickness funds
	Statistics Belgium (Statbel) – Belgium's official statistical institution
Denmark	Danish Health Data Authority – manages the country's system of national health registries and is responsible for approving and overseeing the national system of clinical quality registries *
	Danish Healthcare Quality Institute – manages the country's system of clinical quality registries
Estonia	Ministry of Social Affairs – government department with responsibility for social, health and welfare services. Under its direct remit are: <ul style="list-style-type: none"> ▪ National Institute for Health Development * ▪ Centre of Health and Welfare Information Systems ▪ State Agency of Medicines ▪ Estonian Health Board
	Estonian Health Insurance Fund – the country's public health insurance programme

Finland	Finnish Institute for Health and Welfare – a national research institute that carries out research to support the social welfare, healthcare, and social security systems, and maintains statistics and registers in the areas of health and welfare *
	Social Insurance Institution of Finland (Kela) – maintains Kanta, the centralised repository of health and social data
Sweden	National Board of Health and Welfare – maintains health data registries, social care registries and official statistics *
	Swedish Association of Local Authorities and Regions (SALAR) – represents the interests of the regions and municipalities and provides support and funding to the national quality registries
	Public Health Agency of Sweden – Sweden’s national public health institute
	Swedish eHealth Agency – coordinates the government's eHealth initiatives
Wales	Public Health Wales – the national public health agency in Wales *
	DHCW – responsible for delivering digital health services in Wales
	NHS Wales – the publicly funded healthcare system
	SAIL Databank – a repository of de-identified datasets about the population of Wales
	Welsh government’s Health and Care Research Wales – funds the SAIL Databank and provide oversight of health and social care research

*Key role in the management and oversight of registries at a national level.

4.3.1.1 *Belgium*

Belgium has a mature health information system and a long history of routinely collecting population-level health data; however, systems for data collection and registries remain quite fragmented. There are multiple data holders and various organisations with roles to play in the management of registries, all of which collect data from multiple health sources and providers, such as hospitals and GPs, that have different information systems and EHRs.⁽⁵⁰⁾ Under current policy, data holders, such as hospitals and GPs, are responsible for collecting and reporting the required data for all registries using forms and templates and pushing it to the relevant managing organisation.

Sciensano, Belgium’s national public health institute, makes information on all registries available through the healthdata.be platform, which it manages. The healthdata.be platform was established in an effort to centralise the data needed for

registries. The platform is funded by the NIHDI.⁽⁵¹⁾ Organisations with responsibility for managing several registries are outlined below.

- The **Federal Public Service (FPS) for Public Health, Food Chain Safety, and the Environment** (FPS Public Health) is a federal public body in Belgium which sits under the authority of the Minister of Social Affairs and Public Health.⁽⁵²⁾ It oversees and organises the healthcare system in Belgium, including hospital financing and healthcare policy. It manages the minimum hospital datasets which are used to determine the needs and organise the financing of hospitals.⁽⁵³⁾
- The **National Institute for Health and Disability Insurance** (NIHDI) is responsible for administering Belgium's compulsory national schemes for health insurance and disability benefits and managing a compensation fund for medical accidents.⁽⁵⁴⁾ It also oversees reimbursements, sets healthcare standards, and regulates services for quality and accessibility. It has direct responsibility for the management of several registries relating to healthcare encounters, expenditure, medical devices, and medicines. It also provides funding for many registries which are managed by other organisations. Overall, the NIHDI sets the direction of registry policy in Belgium and plays a central role in determining which registries are financed.
- Working closely with the FPS Public Health and NIHDI, **Sciensano**, Belgium's national public health institute, is responsible for several surveillance systems and registries relating to infectious diseases, including HIV, rotavirus and influenza. In relation to rare diseases, it hosts a number of disease-specific registries, including the cystic fibrosis, neuromuscular disease and rare bleeding disorders registries. However, it is aiming to centralise data on rare diseases into the Central Registry of Rare Diseases.⁽⁵⁵⁾ Sciensano is also responsible for keeping the Orphanet database for Belgium up-to-date. In addition, Sciensano plays a role in the monitoring of chronic disease in Belgium through the use of surveys, cohort studies and databases. For example, in relation to diabetes, Sciensano monitors its prevalence through a Health Interview Survey it conducts every year to gain an overview of the health of Belgians. In order to monitor the quality of diabetes care, Sciensano oversees the Initiative for Quality Improvement and Epidemiology in Diabetes Care and manages an associated database.⁽⁵⁶⁾
- The **Belgian Cancer Registry** is an independent entity, funded by the federal and regional governments.⁽⁵⁷⁾ As well as data on cancer incidence, it submits several other datasets to the healthdata.be platform, including databases of cancer treatment, quality of life, and long-term outcomes.
- The **Intermutualist Agency/Common Sickness Funds Agency (AIM-IMA)** collects data and manages registries relating to reimbursed healthcare

services and prescription medications from the seven sickness funds in Belgium.⁽⁵⁸⁾

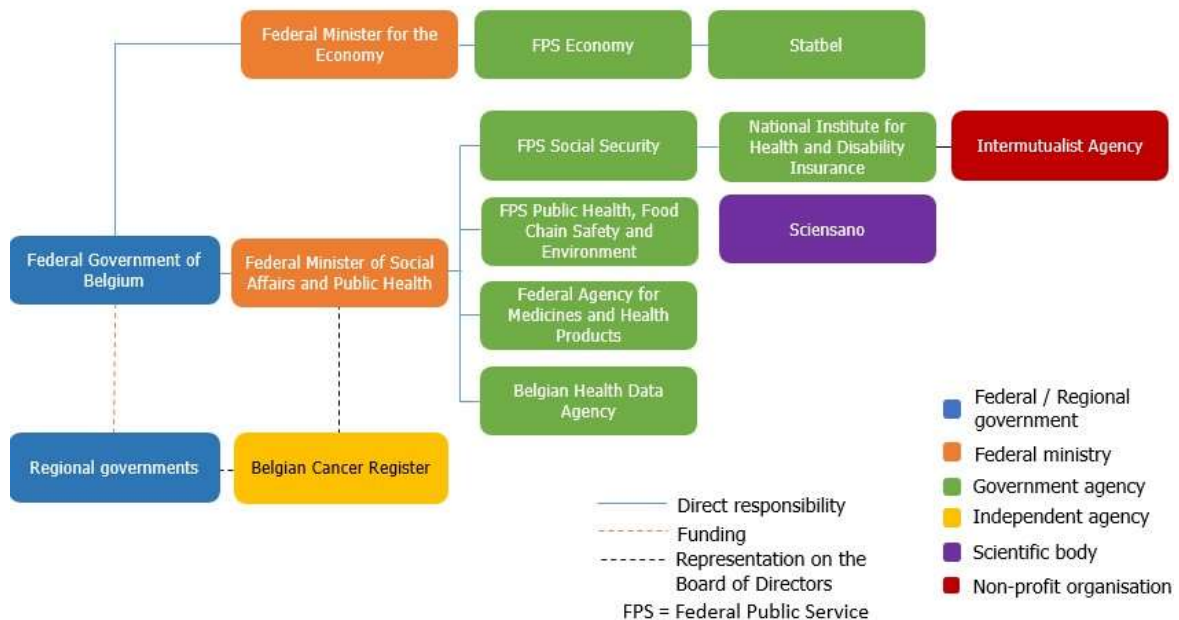
- The **Federal Agency for Medicines and Health Products** is the Belgian competent authority with responsibility for ensuring the quality, safety and efficacy of medicines and health products, including medical devices, and it manages a number of associated registries.⁽⁵⁹⁾
- **Statistics Belgium (Statbel)** is the country’s official statistical institution, with responsibilities relating to collecting, processing and disseminating data and statistics.⁽⁶⁰⁾ It manages the Belgian National Register of Natural Persons which contains data on births and deaths. From the Register of Natural Persons, Statbel compiles data into several other registries.⁽⁶¹⁾

There are several other organisations that submit data for single registries to the healthdata.be platform, including:

- Belgian Cerebral Palsy Registry
- Belgian Diabetes Registry
- Belgian Hematological Society
- Belgian Association for Cardio-Thoracic Surgery.

A full list of the Belgian registries that were identified is included in Appendix G.

Figure 1. Summary of the key organisations and the oversight structures for registries in Belgium



4.3.1.2 *Denmark*

Established in 2015 as a unit of the Ministry of the Interior and Health, the **Danish Health Data Authority** is responsible for health data governance in Denmark. One of its core tasks is to manage and oversee the country's system of population-based registries (referred to as national health registers), including the following:

- National Cancer Register
- National Child Health Register
- Causes of Death Register
- Shared Medication Register
- Birth Register
- National Patient Register
- National Organ Donor Database.

The Danish Health Data Authority is responsible for the provision of health statistics and analysis of causes of death, disease patterns, medicine and activity across Danish health services. It uses the data from its registries to produce regular statistics and reports on the health of the population and the Danish healthcare system.

The full list of population-based registries managed by the Danish Health Data Authority is included in Appendix B.

The Danish Health Data Authority also plays an oversight role and is responsible for approving the establishment and operation of Denmark's medical and mortality registries (referred to as clinical quality registries) which are managed by the Danish Healthcare Quality Initiative (DHQI).⁽⁶²⁾ The **DHQI**, established in January 2025, is a collaboration between the five Regions in Denmark.⁽⁶³⁾ This new institute has merged the Danish Health Technology Council (previously responsible for assessing treatments and health technologies) and the Regions' Clinical Quality Development Program (RKKP; previously responsible for overseeing the country's system of national clinical quality registries). It has taken over the responsibilities of these organisations and currently oversees approximately 85 medical and mortality registries, including the following:

- ADHD Database
- Danish Head and Neck Cancer Database
- Danish Childhood Cancer Registry
- Danish Diabetes Database
- Danish Cardiac Arrest Registry
- Danish Stroke Register
- Danish Registry for Acute Coronary Syndrome
- Cerebral Palsy Follow-up Program.

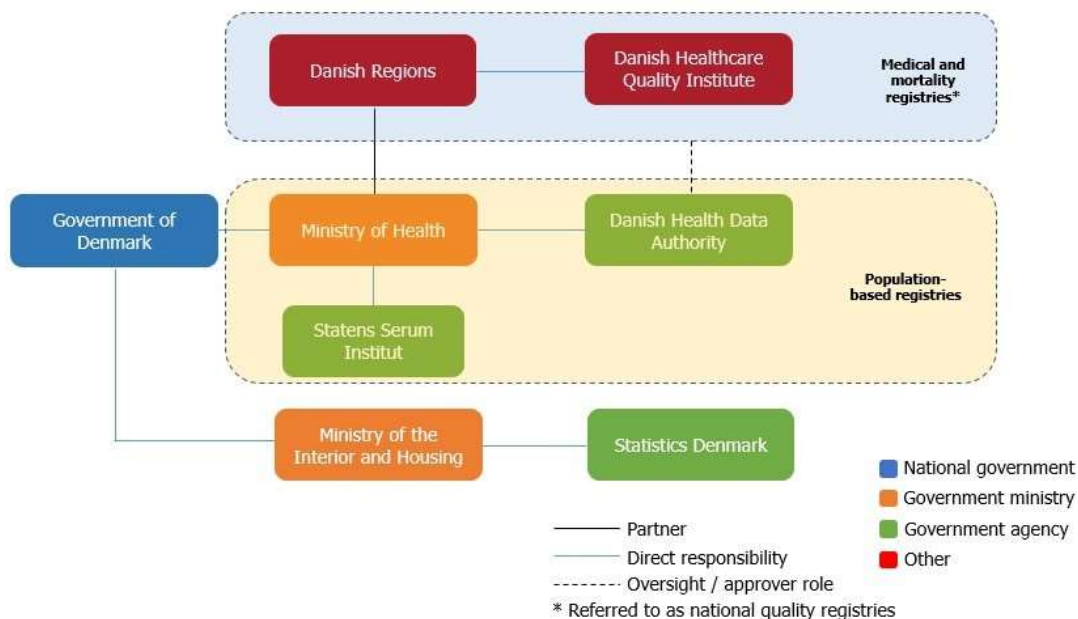
The DHQI produces daily reports for the relevant clinicians and health service managers to allow for quality improvement and benchmarking. It also publishes an annual report for each registry, and undertakes thematic analyses and extractions of data for specific purposes as required.

The full list of registries managed by the DHQI is included in Appendix J.

Several registries for genetic and rare diseases are in operation at hospitals and government agencies throughout the country. For example, the Danish Cytogenic Central Register (a registry of all prenatal and postnatal karyotypes carried out) is managed by the Department of Clinical Genetics at Aarhus University Hospital, the Danish Huntington Register is managed at the University of Copenhagen, and the Danish Cystic Fibrosis Registry is maintained by the two national cystic fibrosis centres in Denmark.^(64,65,66) The RAREDIS database for genetic diseases was established in 2007 and managed by the two Centres for Rare Diseases in Denmark; however, the current status of this database is unclear.⁽⁶⁷⁾ In regulatory terms, these other registers, which operate outside of the Danish Health Data Authority and the DHQI, are either research registries or serve as supplements to the electronic patient health record. If operating as a research project, informed consent is required.

Other relevant organisations in Denmark include the **Statens Serum Institut** which sits under the Danish Ministry of Health and has responsibility for infectious disease surveillance in the country.⁽⁶⁸⁾ It is also responsible for managing the Danish Vaccination Register.⁽⁶⁹⁾ **Statistics Denmark** is the country's statistical institute.⁽⁷⁰⁾

Figure 2. Summary of the key organisations and the oversight structures for registries in Denmark



4.3.1.3 *Estonia*

Health data is collected and held by several different organisations in Estonia. The **Ministry of Social Affairs** is the government department with responsibility for health. Together with the **Center of Health and Welfare Information Systems** and the **Estonian Health Insurance Fund (EHIF)**, it holds the country's centralised database of a nationally agreed set of data generated in the healthcare system, known as the Health Information System (HIS). The Ministry of Health also has direct responsibility for the management of two population-based registries: the Myocardial Infarction Register and the Causes of Death Register.

An agency of the Ministry of Health, the **National Institute for Health Development** is Estonia's public health institution. It is the main source of health and healthcare statistics in Estonia. It collects and analyses data on health status, the healthcare workforce, as well as the use of healthcare services and other resources in healthcare.⁽⁷¹⁾ The National Institute for Health Development is responsible for several population-based registries, as follows:

- Cancer Registry
- Cancer Screening Registry
- Medical Birth Record Registry
- Abortion Registry
- Tuberculosis Register
- Drug Treatment Register.

In addition to holding the Estonian HIS, the **Center of Health and Welfare Information Systems** is also responsible for the Patient Portal and all other eHealth services across the country.⁽⁷²⁾ The **Estonian Health Board**, which also sits under the Ministry of Social Affairs, is the state authority for surveillance, prevention and control of communicable diseases. It has responsibility for several registries, including:

- Patient Safety Register
- Communicable Diseases Register
- Medical Devices and Aids Register.

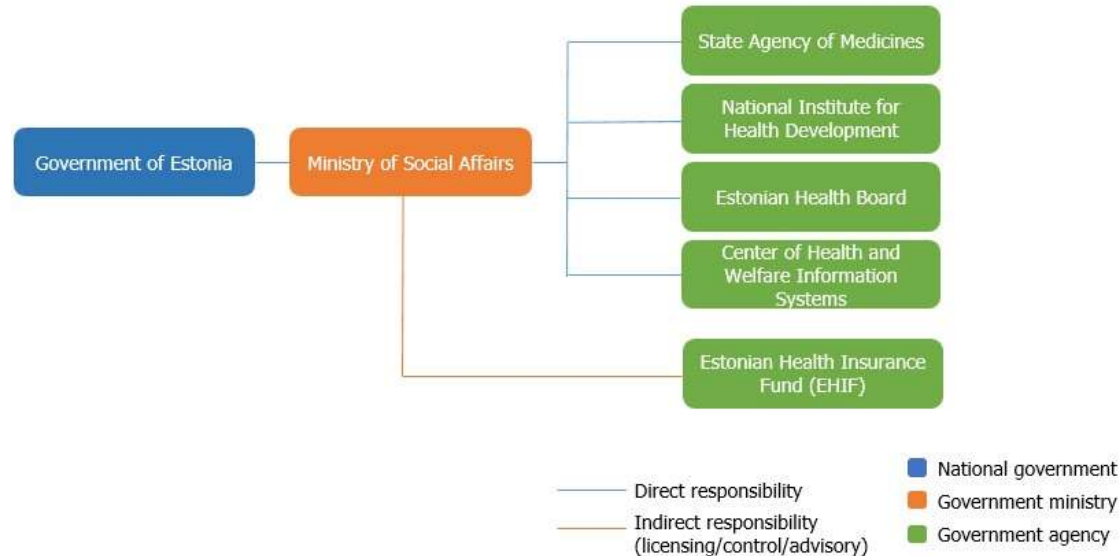
See Appendix C for a full list of the registries managed by agencies of the Ministry for Social Affairs. Individual consent is not required for any of these registries; they all operate on the basis of public interest.

The **Estonian Health Insurance Fund (EHIF)** is a public insurance programme that covers all residents.⁽⁷³⁾ The fund provides comprehensive health cover including medical consultations, hospitalisation, diagnostic tests, prescription drugs, and preventive care. In addition to play a role in the Estonian HIS, the EHIF hosts an

administrative database containing claims data from all public and most private Estonian healthcare providers. The EHIF also plays a role in assessing the clinical quality of health services.

Some medical and mortality registries operate in university hospitals and other organisations across Estonia, such as the **University of Tartu** and **Tartu University Hospital**. There are no national registries for rare disease in Estonia. Rare disease data is collected in the country's central health information system and the database of the Genetic Centre of **Tartu University Hospital** which is responsible for Estonia's contribution to the Orphanet database.⁽⁷⁴⁾

Figure 3. Summary of the key organisations and the oversight structures for registries in Estonia



4.3.1.4 Finland

The **Finnish Institute for Health and Welfare**, an independent health research institute which sits under the Ministry of Social Affairs and Health, is responsible for maintaining population-based registries in Finland, including:

- Finnish Cancer Registry
- Cancer Screening Registry
- Care Register for Health Care
- Register of Primary Health Care Visits
- Vaccination Register
- Medical Birth Register
- Infectious Disease Register.^(75,76)

It also manages a number of social welfare registries, including the Register of Child Welfare.

In 2019, a proposal was published for a funding, organisation and governance model to centralise and coordinate national quality registries in Finland. One of the aims of the proposal was to address some of the recognised shortcomings relating to a lack of national strategy in this area.⁽⁷⁷⁾ This report estimated the costs of establishing and supporting 10 national quality registries to be €760,000 annually.⁽⁷⁷⁾ It was estimated that €8.45 million would need to be invested in technical infrastructure over a four-year period to support these registries. Additionally, it was estimated that the digital infrastructure and professional supports required to maintain the registries would cost an additional €320,000 per register per year.⁽⁷⁷⁾ In 2022, the Finnish Institute for Health and Welfare was given specific powers by the Ministry of Social Affairs in relation to the management of nine healthcare quality registers, as follows:

- Diabetes Register
- HIV Register
- Kidney Disease Register
- Psychosis Treatment Quality Register
- Back Register
- Oral and Dental Treatment Quality Register
- Cardiac Register
- Intensive Care Quality Register
- Inflammatory Rheumatic Diseases Quality Register.⁽⁷⁸⁾

See Appendix D for a full list of the registries managed by the Finnish Institute for Health and Welfare.

In the 2019 report, it was set out that patient consent was no longer a sufficient legal basis for collecting data for quality registers and that the need for consent for these registries was associated with certain limitations.⁽⁷⁷⁾ This was one of the reasons for making the maintenance of quality registers a new statutory task for the Finnish Institute for Health and Welfare. Therefore, the 2022 amendments to the Act on the National Institute for Health and Welfare give the Institute a legislative basis to collect data for the quality registers under its remit without the consent of individuals.

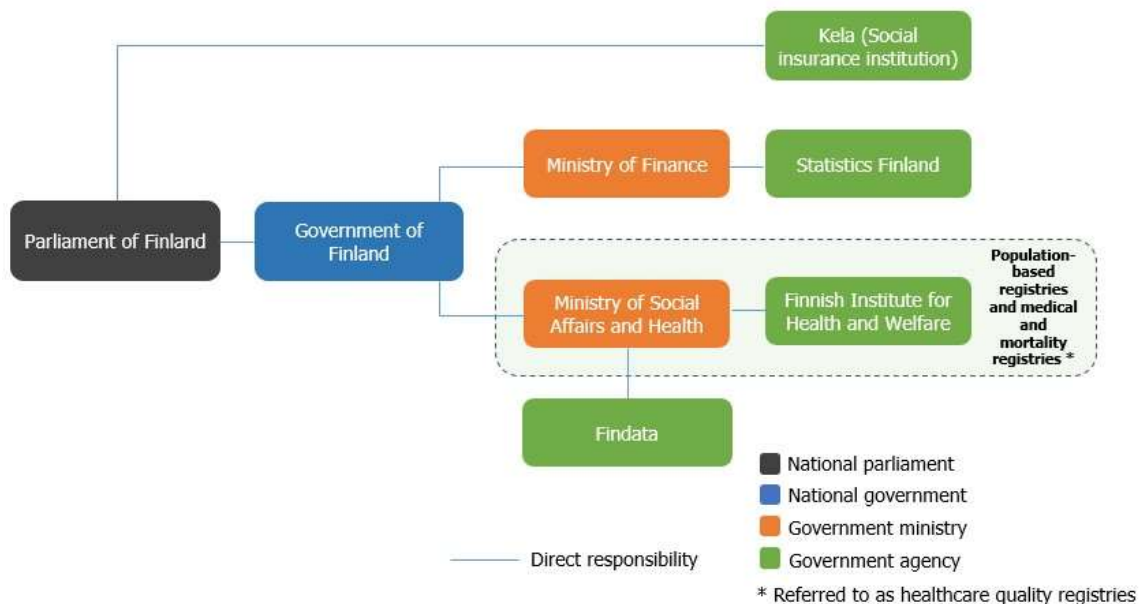
The Finnish Institute of Health and Welfare is responsible for Finland's contribution to the Orphanet database; however, there is currently no central rare disease registry in Finland. Several disease-specific registries operate at both a national and regional level.

The **Social Insurance Institution of Finland (Kela)** maintains the Kanta Services, a centralised repository for all social welfare and healthcare data collected from both public and private providers of health care and social welfare services, and by pharmacies. Data collected in the Kanta system forms the basis for a number of national registers managed by the Finnish Institute for Health and Welfare.⁽⁷⁹⁾ Kela manages a number of registries, including the Drug Reimbursement Register and the Social Benefits Register.

Each region in Finland has a data lake where data from health services is made available for secondary use. These data lakes are located at university hospitals, the largest being located at **Helsinki University Hospital (HUS)** and known as the HUS Data Lake.⁽⁸⁰⁾ This data lake is essentially a patient register that compiles data from all parts of the health system. It holds data on all encounters at HUS, including data on care episodes, laboratory results, medical imaging, genomics, surgeries and medications. It brings together and organises data from different patient administration systems and quality registries, but it does not combine registries. The regions' data lakes act as the data source for the national registries managed by the Finnish Institute of Health and Welfare, with systems established to facilitate transfers of data from the data lakes to the institute.

Other relevant organisations include **Statistics Finland** which is the country's national statistical institute that manages the national Cause of Death Register, and **Findata**, the country's centralised data permit authority.^(81,82)

Figure 4. Summary of the key organisations and the oversight structures for registries in Finland



4.3.1.5 *Sweden*

The **National Board for Health and Welfare (Socialstyrelsen)**, a government agency under the Ministry of Health and Social Affairs, is the largest health data holder in Sweden. It plays a key role in the management of 13 population-based registries (referred to as national health registries), including the following:

- National Cancer Register
- National Medical Birth Register
- National Patient Register
- National Cause of Death Register
- National Prescribed Drug Register
- National Dental Health Register.⁽³⁸⁾

Registries managed by the National Board of Health and Welfare are population-based registries regulated by the Health Data Register Act, with mandatory reporting from all the regions. Individual consent is not required and they operate on the basis of public interest, as opposed to specific research questions.

The **Public Health Agency of Sweden** is another independent public authority under the Ministry of Health and Social Affairs. It is responsible for infectious disease surveillance and manages two population-based registries in the areas of infectious diseases and vaccinations. It uses data from these registries to report on official statistics in the areas of public health and communicable diseases.⁽⁸³⁾

Sweden's **eHealth Agency**, also sitting under the Ministry of Health and Social Affairs, is responsible for collecting and providing data on pharmaceutical sales across the country. This includes both prescription and non-prescription medications. It is responsible for the management of population-based registries of prescription and non-prescription medications and medical products.⁽⁸⁴⁾

See Appendix E for a full list of the population-based registries managed by the National Board of Health and Welfare, the Public Health Agency of Sweden and the Swedish eHealth Agency.

Sweden's comprehensive system of over 100 medical and mortality registries (referred to as national quality registries) is coordinated by the **Swedish Association of Local Authorities and Regions (SALAR)** which enters into an annual agreement on the operation of these registries with the Swedish government.⁽⁸⁵⁾ With voluntary participation, and all patients having to be informed about the registry and given the opportunity to refuse to have their data included, these registries are used for monitoring and evaluating quality among healthcare providers and for assessing treatment options and clinical practice in the regions. Each registry is linked to a national programme area, which consists of experts with

broad expertise and representation from all health regions. The national programme areas lead the knowledge management work in their respective areas and are responsible for ensuring cooperation with the relevant registries.

The organisation of each national quality registry in Sweden comprises the following:

1. A central data protection authority (CPUA), which is typically a regional government or hospital that is a healthcare provider in the legal sense and is legally responsible for the registry. Ultimately, the CPUA has the final responsibility for each registry's technical operation, personnel and finances.*
2. A registry holder and associated registry management team which works on behalf of the CPUA and is responsible for designing and developing the registry in collaboration with participating healthcare providers and national programme areas and for the day-to-day running of the registry.
3. A registry steering group, appointed by the CPUA, which plays an advisory role.⁽⁸⁶⁾

Furthermore, each registry is supported by a regional registry centre. These centres assist with the technical operation and analytical work of the national quality registries and enable multiple registries to share overlapping costs and resources. There are currently six regional registry centres across Sweden:

- Stockholm Quality Registry Centre
- North Register Centre
- Central Sweden Register Centre (Uppsala Clinical Research Center)
- Västra Götaland Register Centre
- South Register Centre
- South East Register Centre.⁽⁸⁷⁾

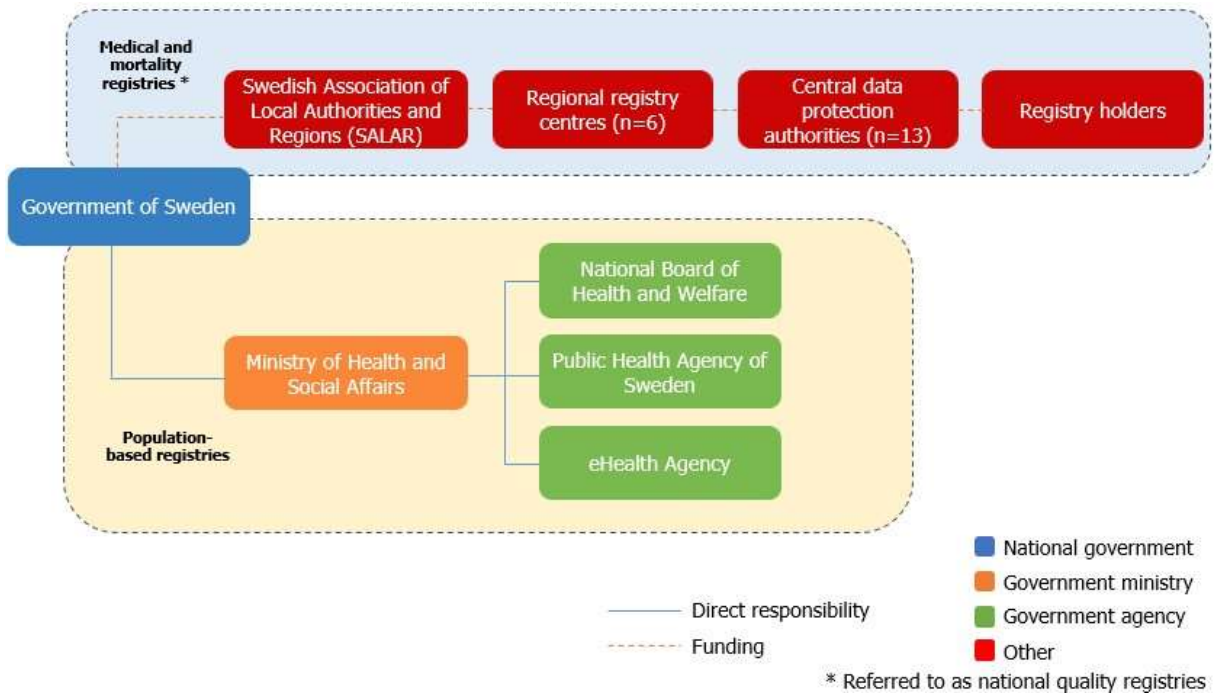
As well as the six regional registry centres, there are a further six regional cancer centres which play a role in supporting national quality registries in the field of cancer.

See Appendix E for a full list of the national quality registries currently in operation in Sweden.

Similar to Estonia, Finland and Denmark, there is no central rare disease registry at either a national or regional level in Sweden. Instead, disease specific registries exist within the country's system of healthcare quality registers.

* There are currently 13 CPUAs responsible for the personal data management of quality registries; however, there are plans in place to reduce the number of CPUAs with the overall aim of having one CPUA in each of the six healthcare regions.

Figure 5. Summary of the key organisations and the oversight structures for registries in Sweden



4.3.1.6 *Wales*

There are multiple data holders and various organisations with roles to play with regard to the management and oversight of registries in Wales, all of which collect data from multiple health sources and providers. **Health and Care Research Wales**, a networked organisation, is supported and funded by the Health and Social Services Research & Development Division of the **Welsh government**. It brings together partners from across **NHS Wales** and other organisations and has responsibility for health and social care research policy, strategy and funding.⁽⁸⁸⁾

Established in 2021 as part of NHS Wales, **DHCW** is developing national digital and data services to support the delivery of health and social care services across the country.⁽⁸⁹⁾ It hosts the National Data Resource (NDR) platform which sets out to bring together data from across all health and social care services in Wales over the coming years. Once fully operational, the NDR will comprise a data repository; a national data and analytics platform; an interface to facilitate secure movement of data between the platform and other systems; and a secure data environment. In 2025, the DHCW Data Request Service was launched. This is a centralised platform to enable efficient and simplified access to health and care data for secondary use, while improving users' experiences.⁽⁹⁰⁾

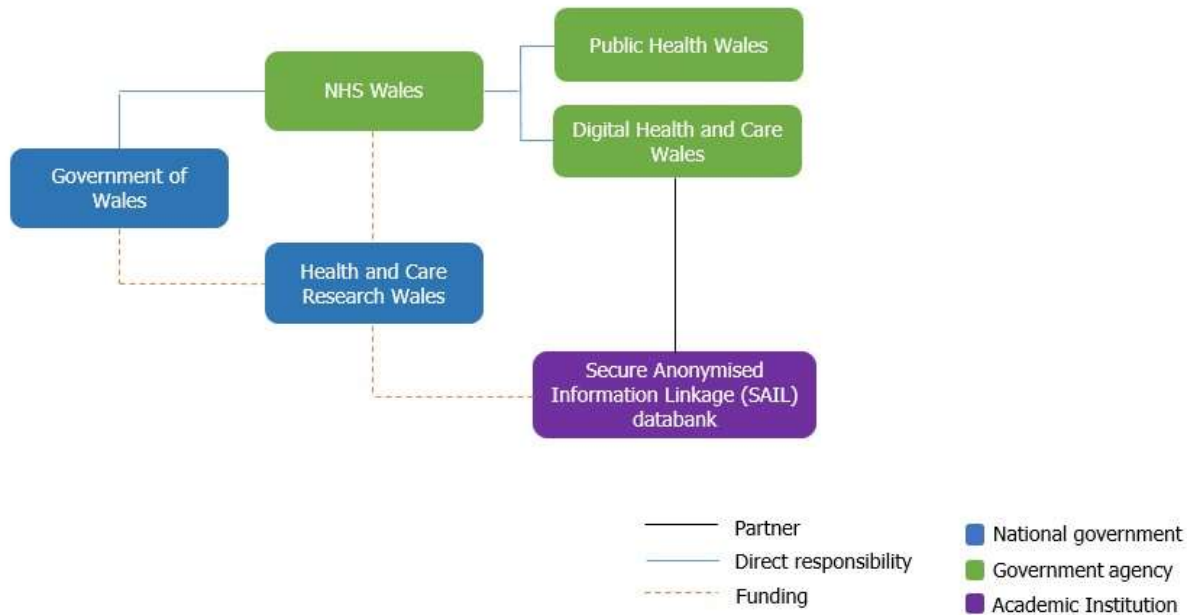
Funded by the Welsh government's Health and Care Research Wales and hosted by Swansea University, the **Secure Anonymised Information Linkage (SAIL) Databank** is a national repository of de-identified datasets about the population of Wales.⁽⁹¹⁾ The SAIL Databank's repository of data can be searched using the Health Data Research (HDR) UK Innovation Gateway.⁽⁹²⁾ Organisations identified as holders of Welsh registry data are outlined below.

- **Public Health Wales** is the country's national public health agency. It is responsible for operating the Welsh Cancer Intelligence and Surveillance Unit, which is the National Cancer Registry for Wales.⁽⁹³⁾ It also hosts the Congenital Anomaly Register and Information Service (CARIS). As well as congenital anomaly data, CARIS also includes data on certain rare diseases, including conditions detected by the newborn bloodspot screening programme.⁽⁹⁴⁾ The Adult Rare Disease Register for Wales is also managed by the CARIS team at Public Health Wales.⁽⁹⁵⁾
- **NHS Wales** is the publicly funded national health service of Wales. It delivers government strategy and health services via the seven local health boards, three NHS Trusts and two special health authorities. As the single provider of public health care in the country, NHS Wales is a key data holder.⁽⁹⁶⁾
- The **Healthcare Quality Improvement Partnership (HQIP)** is an independent, not-for-profit organisation which manages and commissions a series of national quality improvement programmes on behalf of NHS England and the Welsh government.⁽⁹⁷⁾ This includes several national clinical audits and outcome review programmes, as well as registries such as the National Joint Registry.
- The **National Institute for Cardiovascular Outcomes Research (NICOR)**, commissioned by NHS England and NHS Wales, produces statistics and reports on the quality of care and outcomes of cardiovascular patients. It currently manages 10 national cardiac clinical audits and health technology registries.⁽⁹⁸⁾
- The **Clinical Practice Research Datalink** sits within the National Institute for Health and Care Research (NIHR) in the UK.⁽⁹⁹⁾ It is a real-world research service that collects and reports anonymised patient data from a network of GP practices across the UK, including Wales. This data is integrated with a range of existing data sources to create releases for observational research.

Various healthcare providers, including hospitals and individual GP practices, also submit their data to SAIL with support from DHCW.

See Appendix F for a full list of the Welsh registries and national clinical audits that were identified.

Figure 6. Summary of the key organisations and the oversight structures for registries in Wales



4.3.2 Legislation

In all of the countries reviewed, national legislation underpins both the roles and responsibilities of organisations with regard to the management of registries and the obligations of providers with regard to the reporting of data for such registries. The relevant legislation is described in the following section.

Belgium

In Belgium, there is a legislative basis for the majority of population-based registries, including those held by NIHDI and IMA, with compulsory submission of hospitals' data required to these organisations and the submission of data linked to funding. The law establishing Sciensano was passed in 2018 and gives the institute the legal mandate to operate registries for the purposes of public health surveillance, without the need for individual consent.⁽¹⁰⁰⁾ Other registries operate on a consent basis. As part of Belgium's framework for implementing the GDPR, the Information Security Act was passed in 2018, under which an Information Security Committee was established as a separate body to grant certain authorisations for data sharing between federal authorities.⁽¹⁰¹⁾ This committee determines what data can be shared and under what security conditions. Other national legislation adhered to by organisations that manage registries in Belgium includes the Patients' Rights Act,

The Health Care Quality of Practice Act and The Belgian Data Protection Act.^(101,102,103,104)

Denmark

In Denmark, the Danish Health Act provides the legislative basis for data to be collected for all registries, including population-based registries, medical and mortality registries, and product and device registries, without the need for consent from individuals. Under this Act, healthcare providers have an obligation to report the required data for the registries to the Danish Health Data Authority, and in turn, the Danish Health Service Quality Institute. In addition, data from Danish registries is routinely made available for approved research projects without individual consent, as permitted under the Danish Health Act and Danish data protection law.

Estonia

In Estonia, data for the population-based registries is collected under national legislation without the need for consent. Relevant legislation includes the Health Services Organisation Act, Public Health Act, Estonian Health Insurance Fund Act, Medicinal Products Act, Public Information Act, and the Establishment of Cause of Death Act.^(105,106,107,108,109,110)

Finland

In Finland, the responsibilities of the National Institute for Health and Welfare with regard to the management of the country's system of population-based registries are set out in the Act on the National Institute for Health and Welfare. Since 2022, the institute has also been responsible for the management of nine healthcare quality registries, under a decree issued by the Ministry of Health and Social Affairs.⁽⁴²⁾ Under the Act on the National Institute for Health and Welfare, the Institute can operate the registries without the need for consent from individuals. Other relevant legislation includes the Personal Data Act and the Act on National Personal Data Registers Kept under the Health Care System.⁽²⁸⁾

Sweden

In Sweden, all healthcare providers are mandated to provide information to the registries hosted by the National Board of Health and Welfare under the Health Data Register Act (1998:543) — individual consent is not required for these registers.⁽¹¹¹⁾ Other registries are defined and regulated under the Patient Data Act, and there is a requirement for consent to be obtained from individuals before their data is included in these registries.⁽¹¹²⁾

Wales

Public Health Wales was established in 2009 by an act of parliament, and under this Act, has a statutory remit to operate the cancer registry, CARIS, and other registries.⁽¹¹³⁾ Individual consent is not required for the registries under its remit. Other relevant legislation includes the UK GDPR, the Data Protection Act 2018, and the Common Law Duty of Confidentiality and Consent.^(114,115,116)

4.3.3 Accreditation

Across the six countries included in this review, the best example of a system of accreditation for registries was from Sweden, where there is a certification system for the registries that are managed under the country's system of national quality registries, with four different certification levels. From lowest to highest, the certification levels are: Candidate (K), 3, 2, and 1.⁽¹¹⁷⁾ The certification system aims to ensure the quality of the registries and clearly show their opportunities for further development. The criteria are set on the basis of what is considered important for a registry to be well-functioning and useful, such as population coverage, data quality, and facilitation of monitoring and research (see Appendix M for full criteria).

The level of certification of the registries is monitored and reassessed every year, and is linked to the process of allocating funds. Decisions on the level of certification and allocation of funds are made by the National Collaboration Group for Data and Analysis. Each application for a change in certification level must be accompanied by an up-to-date report on how the registry meets the criteria. Between 2021 and 2023, the number of registries at certification level 1 increased, which indicated an increase in the quality of the registries.⁽¹¹⁸⁾ Within five years of being approved as a registry candidate, a registry must meet the criteria for certification level 3 in order to be granted continued funding.⁽¹¹⁷⁾

In Denmark, all clinical quality registries must re-apply to the Danish Health Data Authority for continued approval every three years. In order to maintain approval, a registry must demonstrate continued and complete data reporting, documented contributions to quality improvement in healthcare, and sustained professional engagement.

4.3.4 Summary

- In all six countries, there was at least one organisation identified that played a key role in overseeing and managing registries at a national level. In most cases, there were also other organisations that played related roles, for example in managing a subset of registries.
- In each country, national legislation underpins both the roles and responsibilities of organisations with regard to the management of registries

and the obligations of providers with regard to the reporting of data to these registries.

- The best example of a system of accreditation for registries was from Sweden, where the level of certification of the registries is monitored and reassessed every year and is linked with the allocation of funds.

4.4 Electronic health records and the provision of data to registries

In a European Commission report published in 2025, Belgium, Estonia and Denmark featured in the top three most mature countries in terms of their eHealth capabilities.⁽¹¹⁹⁾ This report considered maturity in terms of the availability of electronic access services, accessibility of health data (such as ePrescription data), availability and coverage of eHealth technology (such as EHRs) and access for certain categories of people such as children, the elderly and people with disabilities. Measured on a composite eHealth indicator score for 2024, Belgium and Estonia were the European leaders scoring 100%, with Denmark scoring 98%, well above the EU average score of 83%. Finland scored slightly above the EU average with 85%, while Sweden scored 78%, not changing between 2023 and 2024. Ireland received a score of 25%. The majority of countries in the report improved their year-on-year rating.

In recent years, many countries have attempted to maximise the potential and utility of registries through leveraging the increasing potential of digital health and EHRs. In some cases, this has led to improvements and increased efficiency with regard to how data is collected for registries, with some countries having centralised data platforms that pull data from EHRs.

4.4.1 Belgium

In Belgium, despite being the most mature country in terms of eHealth capabilities and having a fully digitalised healthcare system, the health data landscape remains somewhat fragmented with multiple data holders in operation at both federal and regional levels. There is no central repository of EHR data, and EHRs are generally not widely used as the source of data for registries. Multiple EHR vendors and the collection of unstructured data means that EHRs are not always fit-for-purpose when it comes to populating registries with the required data. Instead, data holders, such as hospitals, submit data to registries using individual forms and templates and push them directly to the institutions managing the registries. Despite linkage being possible through the use of the social security number, it occurs only on an ad hoc basis due to legal and regulatory barriers.⁽⁵⁰⁾

4.4.2 Denmark

The digitisation of the Danish healthcare system has benefited and supported the collection of data for registries in a more efficient and streamlined way. Data for the population-based registries is delivered to the Danish Health Data Authority directly from healthcare providers' IT systems which are integrated with electronic patient records, and from there, data is provided to the Danish Health Service Quality

Institute for the clinical quality registries. A minority of the clinical quality registries also have some manual reporting.

Hosted by the Danish Health Data Authority, the National Service Platform is the infrastructure that enables the use of registries in patient care.⁽¹²⁰⁾ Through this platform, healthcare professionals have access to several population-based registries and national services. The eHealth portal, sundhed.dk, enables citizens to access information from the national health registries.⁽¹²¹⁾

4.4.3 Estonia

A nationally agreed set of data collected across the healthcare system is transmitted and stored in the Estonian nationwide Health Information System (HIS). This is a secure centralised database to which healthcare providers are required to submit data on all services provided to patients. Through the HIS, healthcare providers across Estonia, including GPs, hospitals and pharmacies, can access their patients' health data in real time. The HIS collects health data centrally from healthcare providers using the X-Road platform, a free and open-source data exchange layer software that has been used in Estonia since 2001 to facilitate the safe sharing of data between government departments, public sector authorities and private sector organisations.⁽¹²²⁾ The X-Road platform operates on the once-only principle whereby citizens only have to enter data once before it can be re-used efficiently.⁽¹²³⁾ It allows for different systems to communicate with one another and facilitates the secure internet-based exchange of data between different information systems.[†]

At present, two registries that are managed by the Ministry of Social Affairs — the Myocardial Infarction Register and the Causes of Death Register — comprise data from the HIS; however, most registries, including the majority of the population-based registries managed by the National Institute for Health Development, obtain data directly from the healthcare providers in a variety of ways as the HIS does not contain the necessary data in the required structured format. Where possible, the X-Road platform is used as the means of data sharing between data holders and registries. For example, the cancer registry obtains data from hospitals' information systems using X-Road.

Consideration is currently being given to combining the Estonian Health Insurance Fund (EHIF) and the Medical Prescription Center databases with the HIS over the coming years. There are also plans to explore the feasibility of using the HIS as the basis of more registries and ultimately, to reduce the number of individual registries

[†] It is estimated that X-Road saves approximately 1,400 years of working time annually in Estonia by eliminating unnecessary paperwork and granting timely access to reliable information. Developed in Estonia, X-Road has since been adopted by several countries including Finland, Iceland and Japan.

in Estonia. Work is ongoing to ensure the HIS collects sufficient data to meet the data requirements of as many registries as possible.

4.4.4 Finland

In Finland, similar to the HIS in Estonia, Kanta is a centralised repository for individuals' health, wellbeing and social welfare data.⁽¹²⁴⁾ Data from all healthcare encounters is captured and transferred to the Kanta service, and from there, used for various purposes. Patient data, for example, is transferred directly from healthcare providers' patient information systems to the Patient Data Repository of Kanta.⁽¹²⁵⁾ While at present various data collection systems are used for registries in Finland, it is anticipated that systems will become more streamlined as Kanta is increasingly utilised.

A pilot carried out in 2022 demonstrated the usability of the Patient Data Repository in the Kanta services as the data source for the Diabetes Register, maintained by the Finnish Institute of Health and Welfare.⁽¹²⁶⁾ While some further work was required to obtain all data required for the Diabetes Register, this pilot paved the way for the Kanta services to be used as the basis for several other national registers. As outlined in section 4.3.1.4, in recent years Finland has taken a more coordinated approach to its system of quality registries, establishing a national quality register centre within the Finnish Institute for Health and Welfare and working to set up a mechanism for a single transfer from Kanta to the registers.⁽⁷⁷⁾

The Kanta system does, however, have some limitations with regard to being used for registries and other secondary purposes. Due to the fact that the system was designed to enable the primary use of data, it contains a significant amount of unstructured data and there are difficulties associated with converting data to the format required and setting up automated data transfers for the registries.

4.4.5 Sweden

Despite Sweden having a fully digitalised healthcare system and a rich health data and registry landscape, data sources continue to exist in silos with no centralised national repository for EHR data. EHR data is stored at regional and municipal level, and to a certain extent, the use of the data is limited.⁽⁵⁰⁾ Data for the national registries is submitted by different data holders. For example, the National Board of Health and Welfare obtains data for its population-based registries directly from the regions and private healthcare providers. Healthcare providers are responsible for the patient administration systems used to compile the data and the systems used to extract and submit the data; however, systems can differ between providers.⁽¹²⁷⁾ It has also been acknowledged that there are some inefficiencies with regard to how data is reported to the national registries, with providers sometimes being required to report the same data multiple times for different registries. Similarly, there are

multiple different platforms used for Sweden's system of quality registries. Reporting to these registries is currently done using manual processes, where data is first documented in the various health information systems and then to the relevant registry.⁽⁸⁵⁾

4.4.6 Wales

In Wales, EHRs have been instrumental in capturing health data that can be securely transferred electronically into the SAIL platform by data holders with the support of DHCW as the trusted third party.⁽¹²⁸⁾ The SAIL Databank now collects all patient data recorded in Welsh hospitals and secondary care settings and 85% of data collected in GP practices.⁽¹²⁹⁾ There is variation across the health system in terms of the information systems and EHRs in use, and individual systems to automate the transfer of each dataset to the SAIL Databank have been established.

4.4.7 Summary

- Of the EU countries included in this review, Belgium, Estonia and Denmark are the most mature countries in terms of their eHealth capabilities. All have national EHR systems and most have attempted to leverage and utilise their EHR repositories as a key data source for registries, with varying degrees of success.
- A number of barriers to using EHR repositories as the primary data source for registries were reported, including the presence of multiple EHR vendors, a predominance of unstructured data, and a lack of interoperability between systems.

4.5 Prioritisation of registries

4.5.1 Recent prioritisation

In each of the six countries included in this review, there was variation with regard to the types of registries that have been prioritised in recent years, and the approaches or frameworks used to prioritise them.

The following sections provide information on some of the specific types of registries that have been prioritised in recent years, as well as future plans for prioritisation.

4.5.1.1 Belgium

It was noted that the large number of registries and databases in Belgium is a result of a somewhat uncoordinated approach to prioritisation taken to date. In the new vision for the future of registries in Belgium under the EHDS (see Section 4.8.1), it is proposed to have two types of registries: permanent registries of which there will be a small number, and temporary registries which will be set up on an ad hoc basis to answer specific research or policy questions. If approved, a period of time will be spent prioritising which registries are designated as permanent registries and selecting a limited number of variables for each.

4.5.1.2 Denmark

Over the years, different types of registries have been prioritised in Denmark, with political priorities sometimes playing a role. For example, cardiac registries were prioritised throughout the 1990s in an effort to improve the quality of cardiac care in the country, and cancer registries were prioritised throughout the 2000s in response to poor outcomes for cancer care in Denmark relative to other countries at the time. The Danish Health Care Quality Institute manages 22 different cancer registries, each focused on a different type or aspect of cancer and cancer treatment.

Currently in Denmark, registries in the field of psychiatry are being prioritised. This prioritisation has resulted from agreements between the government, Danish Regions and the Association of Danish Municipalities on the implementation and follow-up of the 10-year plan for psychiatry and mental health. As a result of these agreements, the Danish Health Care Quality Institute has been tasked with updating and expanding the existing psychiatric registries and establishing two new registries for children, adolescents and adults: a registry for eating disorders and a registry for electroconvulsive therapy and neurostimulation.

Beyond this focus on psychiatry registries, the Danish Health Data Authority is also currently considering the expansion of a number of existing national registries. Areas under consideration include registries relating to community care, GP referrals and health provider discharge.

4.5.1.3 Estonia

Prioritisation of registries in Estonia is based on the strategic objectives of the Ministry of Social Affairs and the priorities set by the Estonian government. Strategic priorities in the health sector arise from the eHealth strategy, the latest of which was published in January 2025 and is being implemented by an eHealth steering committee, led by the Ministry of Social Affairs. Data policy priorities are being specified in the latest data strategy which is expected to be completed later in 2025. The latest registry to be prioritised for development was a donor registry to capture information on fertility treatment. This has come about due to the introduction of new legislation placing limits on sperm and egg donations. The long-term vision is to develop the HIS database further so it is more suitable for secondary uses, including as the basis for more health registries. Development of the HIS database would include the collection of more standardised and structured data.

4.5.1.4 Finland

In 2022, Finland's Ministry of Social Affairs and Health designated nine national quality registries to be maintained by the Finnish Institute for Health and Welfare:

- Diabetes Register
- HIV Register
- Kidney Disease Register
- Psychosis Treatment Quality Register
- Spine Register
- Oral and Dental Treatment Quality Register
- Heart Register
- Intensive Care Quality Register
- Inflammatory Rheumatic Diseases Quality Register.⁽⁷⁸⁾

These registries were prioritised by Finland's Ministry of Social Affairs and Health on the basis of their public health significance, the ability to be rapidly utilised based on the availability of existing data, and current data protection legislation. It was intended that this list of nine registries would be updated in the future as necessary.⁽⁷⁸⁾

4.5.1.5 Sweden

In recent years, the further development of Sweden's National Patient Register across a number of areas has been prioritised. This included the addition of fields relating to the administration of medicines in hospitals, as well as increased data on psychiatric care. Planning is underway to develop a framework to support the National Board of Health and Welfare's ability to prioritise new registries. While the Swedish government is responsible for prioritisation at present, forthcoming

legislation, including the new Health Data Register Act and the new Social Services Data Act, will give the National Board of Health and Welfare new powers with regard to the prioritisation and development of certain registries.

Since 2022, Sweden's National Collaboration Group on Data and Analysis has been tasked with strengthening and developing the ongoing work of monitoring and analysing Swedish health and medical care data, including the national quality registries. Work is ongoing to automate the processes for information provision between health information systems and the quality registers, to develop a strategy to reduce the number of IT platforms used by the quality registers, and to reduce the number of CPUAs in operation. The ultimate aim is to increase the use of the data collected for the national quality registries.⁽⁸⁵⁾

4.5.1.6 Wales

In Wales in 2024, the CARIS was expanded to include adults affected by rare diseases. Adult registries were expanded, with DiGeorge Syndrome being the first to be validated. Decisions around which adult registries to prioritise were made based on clinical insight from the Rare Diseases Implementation Network.⁽¹³⁰⁾

As outlined in section 4.3.1.6, DHCW has developed the National Data Resource (NDR). This digital platform is in the process of becoming the single national clinical repository of health and care data in Wales. Initially, the primary focus will be moving health and social care data held by DHCW to the NDR. In the future, a key aim for the NDR is to prioritise the addition of local data stores, reference demographics and medicines data.⁽⁸⁹⁾

4.5.2 Prioritisation criteria

Standardised approaches for prioritising registries were identified in Finland and Denmark.

4.5.2.1 *Finland*

In 2019, a report published by the Finnish Institute for Health and Welfare set out the following criteria as the basis for decision-making in relation to prioritising, developing, evaluating and carrying out research on quality registers:

- The societal **relevance** of the register
- The **feasibility** of collecting the necessary data
- The **validity** of the data
- The **cost-effectiveness** of designing, implementing, analysing and reporting the data.⁽⁷⁷⁾

In 2022, the Ministry of Social Affairs and Health designated nine registries to be maintained by the Finnish Institute for Health and Welfare. These nine registries were selected based on the following criteria:

- **Need to improve care:** the registries targeted areas (patient groups, diseases, or services) where there was a need to develop and improve quality and effectiveness of care.
- **Vulnerable groups:** the registries represented a large number of people or a group in need of special protection.
- **Several data sources:** the registries represented areas for which it was essential to combine data from several sources in order to assess the quality and effectiveness of care.
- **Alignment with strategy:** the registries were aligned with national strategies and programmes in the social and health care sector.
- **Need for quality information:** the registries represented areas where there was a need for quality information at the different levels of the health and social care systems.
- **Future potential:** the registries represented areas in which there was potential to collect comprehensive, high-quality data in a structured format from health information systems, using the principle of single entry, and from other data sources.
- **Legislation:** changes in data protection legislation meant the status of existing registry practices needed to be updated.
- **Recognised need:** the registries represented areas in which it was not possible to obtain this data in another way.⁽⁴²⁾

4.5.2.2 *Denmark*

The Danish Health Service Quality Institute has a transparent process which it follows when deciding which applications for registries should be approved. All applications are reviewed and assessed on the basis of the following:

- **Support from professional bodies:** the level of support from professional societies for the development and subsequent operation of a registry is assessed. Registries with higher levels of support from relevant professional societies are prioritised.
- **The value and relevance of the database:** the opportunity for quality improvement and targeting inequality of care (geographical or social) and disease areas that do not get much attention is assessed — areas of inequality are prioritised.
- **Presence of clinical guidelines:** registries for treatment pathways and interventions that have nationwide clinical guidelines are prioritised.
- **Possibility to define populations/ensure valid data:** it must be possible to clearly define the population and ensure the validity and accuracy of the data.
- **Severity/impairment:** registries that cover relatively serious conditions are prioritised.
- **Interdisciplinary/cross-sector/complex processes:** registries that cover the entire course of treatment that a patient with a particular condition goes through are prioritised.
- **Volume:** registries that cover more patients are prioritised. The registry must cover a minimum of 90 per cent of the relevant patient population that meets the inclusion criteria.
- **Coverage of the specialty/area with databases or other systematic follow-up on the population, such as registers or statistics:** Preference is given to registries that cover areas where there are no other measures or where quality follow-up cannot be done through an extension of an existing registry.
- **Patient involvement/patient centrality:** The patient perspective should be a fundamental part of the development of a registry.⁽¹³¹⁾

The Danish Health Service Quality Institute strongly emphasises the importance of professional support in both the establishment and running of registries. Professional agreement and consensus on the right indicators for the quality of care is imperative, and without such agreement and consensus, registries will not be established or maintained. Each registry under the remit of the institute has a steering group that is responsible for the content and development of the registry, including the selection of the relevant quality indicators, and includes professionals from different clinical areas, as well as patient representatives. The institute also has

a process it follows for the closure of quality registries. The closure of a registry generally takes place when the goals of the registry have been met or when clinicians cannot achieve consensus on what the right indicators of quality of care are for that particular registry.

See **Table 3** for a summary and comparison of the Danish and Finnish approaches to prioritising registries.

Table 3. Comparison of the prioritisation criteria used by the Danish Health Service Quality Institute and the Finnish Institute for Health and Welfare

Consideration	Country	
	Denmark ⁽¹³¹⁾	Finland ⁽⁴²⁾
Societal need	Priority is given to serious diseases affecting large numbers of people. Areas of inequality are also prioritised.	Priority is given to groups where a specific need has been identified and a level of public health significance has been identified.
Validity	Populations must be defined and data validation must be possible.	The design, analysis and implementation of a registry must follow strict methodological protocols.
Feasibility	Support structures must be in place through professional bodies.	High-quality data must be available in a structured and usable form, and it must be feasible to implement the registry within a reasonable timeframe.
Comprehensiveness	Databases capable of covering the entire course of treatment for individual patient are prioritised.	Quality registries targeting diseases, treatment or use of services for which it is essential to combine data from several different sources to assess the quality and effectiveness of services are prioritised.
Professional support	Databases with higher levels of support from relevant professional societies are prioritised.	Clinicians assess the suitability of data sources.
Patient involvement	Patients are involved in the development of clinical quality databases.	Views of patient groups should be sought prior to the establishment of quality registries.
Cost-effectiveness		Cost-effectiveness analysis is recommended.
Alignment with legislation and policy	The Danish Health Act provides a legislative basis for establishment of registries.	The Act on the Finnish Institute for Health and Welfare gives the institute responsibility for the maintenance of registries.
Existence of data gaps	Preference is given to registries that cover areas where there are no other measures or where quality follow-up cannot be done through an extension of an existing registry.	The registry represents an area in which it is not possible to obtain this data in any other way.

4.5.3 Summary

- In all countries included in this review, there was variation with regard to the types of registries that have been prioritised in recent years, and the approaches or frameworks used to prioritise them.
- Key organisations in Denmark and Finland have outlined several considerations when prioritising registries, such as societal need, the availability of professional support and the existence of data gaps.

4.6 Relevant strategies and plans

4.6.1 Data and eHealth strategies

Belgium

Belgium's *e-Health Action Plan (2022-2024)* aimed to enhance the country's healthcare system through digital transformation.⁽¹³²⁾ The plan sets out how, from 2025 onwards, under the EHDS Regulation, Belgium would be able to more easily exchange health data, including electronic patient records and genomic data, and make them more accessible, for the benefit of better healthcare but also for registries.

Denmark

Denmark's most recent *Digital Health Strategy (2018-2022)* was extended until 2024 and aimed to strengthen digital health collaboration and create a patient-centred and coherent healthcare system.⁽¹³³⁾ Denmark is also implementing a government strategy titled *Strategy for life science towards 2030*.^(134,135) A key part of this strategy is the vision for a better use of health data.⁽¹³⁶⁾ This strategy aimed to circumvent some of the barriers to using Denmark's health data registries to their fullest extent, such as facilitating timely access to data and enabling linking of data held by different organisations. It set out plans for the Ministry of the Interior and Health and the Danish Health Data Authority to establish a new national contact point for access to health data for researchers, healthcare professionals and public health authorities, as well as a national analytics platform, aligning with the EHDS vision.

Estonia

Estonia's *eHealth Strategy 2025-2030*, published in January 2025, sets out how although the country ranks highly in terms of its eHealth capabilities, practices relating to the use of data remain sub-optimal.⁽¹³⁷⁾ The strategy aims to build consensus on the priority areas to overcome some of the barriers to the use of data. Central to the strategy is the need to improve the accessibility of data to support decision-making, promote innovation, and improve services. It identifies data as being the key to driving improvements in eHealth, and sets out the need to improve data quality through standardisation and the reduction of fragmentation in existing systems. The country aims to start using a common international data standard and to replace providers' existing information systems with a common architecture that is linked to the nationwide HIS. Under this strategy, Estonia also sets out to improve the availability of data for research. An eHealth Steering Committee has been established by Ministerial decree to manage the implementation of this eHealth strategy.

One of the key aims of Estonia's *National Health Plan 2020-2030* is to integrate Estonia's health information systems to ensure comprehensive and accurate data collection.⁽¹³⁸⁾ The plan sets out how this will be achieved by implementing standards and protocols to ensure that data from different sources are interoperable. A second key area of focus of this plan is to improve resource allocation in the health system. Registries are highlighted as important tools for achieving this objective under the plan.

Sweden

The Swedish health and social care system is working towards achieving objectives of the strategy on a *Vision for eHealth 2025*. The strategy was published in 2016, and sets out Sweden's ambition to become the world leader in digital health by the end of 2025.⁽¹³⁹⁾ Endorsed by the Swedish government and SALAR, this strategy aims to harness the opportunities offered by digitisation and eHealth to make it easier for people to achieve good and equal health and welfare and sets out a number of strategic objectives to achieve this.

Sweden has also developed a life sciences strategy to support patients through research, innovation, higher education, the development of pharmaceuticals, medical devices and treatments, as well as prevention, implementation and monitoring.⁽¹⁴⁰⁾ This strategy places an emphasis on the development of a national digital infrastructure across the health care system that is aligned with EHDS requirements.

Wales

In February 2024, DHCW published its first strategy, *Digital Health and Care Wales Organisational Strategy 2024-2030*.⁽¹⁴¹⁾ It sets out DHCW's aim to have all of its digital health systems and major social care systems flow data to, and from, the NDR platform by 2030. The organisation also aims to expand the digital health and care record to all settings throughout Wales. This strategy views the NDR's future model as a single health data platform that gives access to a single digital health and care record, which will become the foundation for all digital health services and applications in Wales. Once fully established, the NDR is likely to act as a key data source for registries.

4.6.2 Rare disease strategies

A number of rare disease strategies published in the countries included in this review had themes or actions relating to registries and data, including:

- Belgium's *National Plan for Rare Diseases*, which was published in 2013 and led to the development of a central registry for rare diseases.⁽¹⁴²⁾
- Denmark's first *Strategy for Rare Disease*, which was published by the Danish Health Authority in 2014 and evaluated in 2023.^(143,144) The evaluation found

that efforts to establish systems for universal registration of rare diseases are underway; however, a number of decisions about the direction and the need for data are pending.

- Finland's *National Programme for Rare Diseases 2024-2028*, which outlined a strategic objective to build registers and standardise data collection for rare diseases.⁽¹⁴⁵⁾
- The *Wales Rare Diseases Action Plan 2021-2026*, which had a theme of improving awareness of rare diseases with data. As part of this plan, there was an action to expand the CARIS to include adults affected by rare conditions, commencing with a pilot of one adult rare disease registry.⁽¹⁴⁶⁾ There were also actions relating to confirming the metrics to be used when reporting on rare diseases and utilising data to explore geographic differences in rare diseases. In the 2023-2024 progress report, data and surveillance was identified as one of the priority areas for the following 12 months.⁽¹⁴⁶⁾

4.6.3 Summary

- All of the countries included in this review have published eHealth strategies within the last number of years. A key focus for each country has been the leveraging of health data to drive improvements across the health system.
- In Belgium, Denmark, Finland and Wales, rare disease strategies were identified which included themes or actions relating to registries.

4.7 The impact of the EHDS on registries

In the five EU countries included in this review, ministerial decisions are still awaited with regard to where HDAB functions will sit under the EHDS Regulation. However, it is likely that organisations which have already been established will play important roles.

At the time of this review, it was evident that the key organisations in most countries were still assessing how the EHDS Regulation would impact on their functions and how they currently operate. With the exception of Belgium, there were not yet any definite plans in place to change practices and policies relating to registries. Plans to transform registry policy in Belgium are outlined in the following section.

4.7.1 A new vision for the future of registries in Belgium

In March 2025, the National Institute for Health and Disability Insurance and the Federal Public Service for Public Health, Food Chain Safety and the Environment set out recommendations for the development of a new vision for the future of registry policy in Belgium. These recommendations have been developed within the context of the implementation of the EHDS Regulation, the establishment of the Health Data Agency, and various other national and federal investment and initiatives.⁽¹⁴⁷⁾ At the centre of the recommendations is the evolution of registry policy towards a more flexible system for data collection, storage and use, based on the principles of federated data sharing and processing.

Under the proposed policy, registries in their current form, where data is centralised and managed in a single location in electronic databases, will be replaced by federated data sharing and processing. Under this system, data will remain with the data holders and rather than being centralised and permanently managed in single registers, it will be temporarily grouped together for specific purposes. Data holders, such as hospitals and GPs, will retain control over their data but will be encouraged to make available as much high-quality data as possible. Under this new policy, data will be collected for the most part from the computerised patient record and the electronic medical record. The Belgian Integrated Health Record is also central to this new policy, and the proposal sets out how the data within that must be standardised and interoperable to ensure it meets the needs of the registries.⁽¹⁴⁸⁾ Overall, the proposal sets out how Belgium can move from static registries to more dynamic, real-time data collections.

Under the new policy, there will be two types of registries:

1. **Permanent (base) registries** – these will be continuously maintained and made available to authorised users, generally for the purposes of managing the health system. The number of permanent registers will be as small as

possible, and they will contain a limited number of predefined variables. They will all have a legislative basis.

Under the new policy, hospitals will form data networks to facilitate structured, standardised data exchange for the permanent registries which will be managed by a small number of organisations. Work is currently underway to create and develop these processes for data exchange.

A federal body will be appointed as the facilitator of the permanent registries. To ensure independence, the facilitator will not be a data holder. They will publish a catalogue of the registers available and will handle requests from data users.

2. **Temporary registries** – these will be set up on an ad hoc basis, generally for research and ad hoc policy questions. They will have a broader scope of data than that included in the permanent registers and where appropriate, will be built up from the permanent registers by adding additional data fields or sources. Temporary registers may be converted to permanent registers if deemed appropriate and supported by a legislative framework.

Under the new policy, a facilitator will also be appointed to support data requests for the temporary registers. It is likely that Belgium's coordinating HDAB will be given this role. To ensure independence, the coordinating HDAB will not act as a data holder for any of the temporary registries. Before data users can create and use temporary registers, an approved data processing authorisation is required. This describes precisely how the requested data may be used, and by whom, within the scope of the application, and will be issued by the HDAB and granted in accordance with a legal framework.

Under the new policy, there will also be designated trusted third parties who will play a role in supporting the exchanged of data between parties, as well as secure processing environments for facilitating access to the registry data in a secure and controlled way.

A working group involving the National Institute for Health and Disability Insurance, Sciensano and other key stakeholders has been established to identify which of the current registries to retain as permanent registries and temporary registries and which registries to discontinue. Criteria for this process are being developed and factors such as the legal basis, current utility of data and functioning of registries are being considered. Engagement with key stakeholders is also being undertaken to inform the process.

4.7.2 Other ongoing initiatives

Below is an outline of a number of ongoing projects in respect of registries:

- The **Value from Nordic Health Data (VALO)** project, launched by government representatives from Sweden, Denmark, Norway, Iceland and Finland, aims to establish common principles for the implementation of the EHDS regulation and streamline research development and innovation opportunities across the Nordic countries.⁽¹⁴⁹⁾
- **FinRegistry**, a joint research project of the Finnish Institute for Health and Welfare and the University of Helsinki, is developing statistical and machine learning models to use registry data to better understand and predict disease occurrence. Data from national registries is being combined with data from a range of other sources.⁽¹⁵⁰⁾
- The **FinHITS** project, led by Findata, is supporting Finland's integration into the EHDS. This project is co-funded by the EU and aims to strengthen Finnish health data ICT and data quality for the secondary use of health data.⁽¹⁵¹⁾
- In Belgium, the **BE-SURVID** project, led by Sciensano, commenced in 2025 and sets out to strengthen infectious disease surveillance in Belgium by enhancing current systems for collecting data and implementing automated systems for data transfer from EHRs and other sources.⁽¹⁵²⁾
- A number of countries are leveraging efforts to use registry data for **real-world evidence (RWE)** studies.^(153,154) For example, in Finland, the HUS data lake makes real-world data cohorts available for use in scientific research.⁽¹⁵⁵⁾
- The potential to use **artificial intelligence (AI) tools** to enhance the value of registries and reduce the time and effort required to maintain them is being explored in some countries. Potential uses of AI tools in registries include identifying, extracting and analysing data, and ultimately, maximising the use of the data.^(156,157) In Denmark, the Danish Health Data Authority is planning to pilot the use of AI to perform data validation on registry data.

4.7.3 Summary

- In the five EU countries included in this review, ministerial decisions are awaited with regard to where HDAB functions will sit.
- At the time of this review, it was evident that the key organisations in most countries were still assessing how the EHDS Regulation would impact on their functions and how they currently operate.

- In Belgium, the National Institute for Health and Disability Insurance and the Federal Public Service for Public Health, Food Chain Safety and the Environment have set out recommendations for the development of a new vision for the future of registry policy in Belgium, proposing a move towards a more flexible system for data collection, storage and use, based on the principles of federated data sharing and processing. Under this proposal, the number of individual registries in operation will be significantly reduced.

5. Discussion

This review explored six countries' approaches to registries, with a particular focus on definitions and terminology, governance arrangements, digital health and health information system maturity and how registries are operated within the context of these systems, approaches to prioritisation and planned future developments, particularly within the context of the EHDS Regulation.

5.1 Categorisation

While there was some variation between the countries with regard to the terminology around registries, in general, the EHDS category of population-based health registries aligns with what are commonly referred to as national registries, particularly in the Nordic countries. In Denmark, Estonia, Finland and Sweden, all registries that fall into this category are managed by one or two organisations and have a legislative remit to operate without individual consent.

The EHDS category of medical and mortality registries aligns with what are generally referred to as quality registries, particularly in the Nordic countries. While often not referred to as registries, national and regional programmes of clinical audit generally also fall into this category. For example, in Wales, the National Clinical Audit Programme, led by the Healthcare Quality Improvement Partnership (HQIP) holds several datasets that fall into this category. In Denmark and Sweden, all registries in this category are coordinated and managed by a single organisation, while Finland is moving towards this approach. These types of registries are less common in Estonia, where there is no system for monitoring quality of care and outcomes at a national level.

The differentiation between the different categories of registries is less clear in Belgium, with the country's system of registries having evolved over time, with less coordination in comparison to the Nordic countries.

5.2 Governance

An effective system for the management and oversight of registries is dependent on appropriate governance structures. As observed in the Nordic countries, a small number of organisations are granted a legislative remit to operate registries and play a strategic role in advancing developments. The effectiveness of such a structure is apparent in Denmark, Finland and Sweden. In both Denmark and Sweden, one organisation has responsibility for the majority of population-based registries while another coordinates each country's system of medical (quality) registries. In Finland, one organisation is responsible for both, with the Finnish Institute for Health and Welfare expected to be given responsibility for further registries over the coming years.

Under the EHDS regulation, holders of registry data will be responsible for providing their metadata to the HDAB service and will be obliged to share their data in the required format following a request from a data user. As indicated through this review, effective governance structures and arrangements are key to ensuring these obligations can be met by data holders.

5.3 Legislation

The effectiveness of having a strong legislative remit for registries was evident in Denmark, Finland and Sweden. In each country, the roles and responsibilities of the key organisations are clearly set out in national legislation. In Sweden, under this legislation, the national registries operate without the need for individual consent, while the quality registries operate on a consent basis. In both Finland and Denmark, the national and quality registries that are under the remit of the coordinating organisations all have a legislative basis to operate without the need for consent from individuals.

5.4 Digital health and health information system maturity

All of the countries included in this review are mature in terms of their eHealth capabilities. With well-established systems for EHRs in place for a number of years, many countries are now focusing on improving the effectiveness and efficiency of the methods used to populate registries. In Estonia and Finland, for example, there are plans in place to use the HIS database and the Kanta services, respectively, as the basis for more registries and to automate systems for extracting data from one system to another. Both systems are associated with certain limitations, however, with the predominance of unstructured data in these systems limiting the potential to use them for registries and other secondary purposes and necessitating the need to obtain data for registries in other ways.

An important finding of this review is that although EHRs are a rich source of data, there are certain limitations and barriers to their use for registries. Two recurring issues for countries identified through undertaking this review were: the presence of different systems and vendors across healthcare providers; and the predominance of unstructured data, such as discharge summaries and diagnostic imaging reports, in EHR repositories. Both factors lead to challenges with regard to interoperability of systems and interpretation of data and introduce requirements for manual systems for data collection.

Therefore, a key finding of this international review was that digital health maturity does not always correlate with mature systems for registries and that a predominance of unstructured data and poor interoperability of systems can minimise the potential to use data from various health technologies for secondary purposes. This finding highlights the importance of ensuring that digital health

records are designed in a way that facilitates the use of data for secondary purposes. The finding also underscores the importance of the EHDS Regulation which aims to address these issues across the EU over the coming years.

5.5 Prioritisation

There are a number of similarities between the Finnish and Danish prioritisation frameworks for quality registries. In both countries, quality registries are prioritised in line with the needs of their respective healthcare systems in terms of the number of people affected by the disease or condition and its public health significance. Consideration is also given to data gaps and data validity and the feasibility of establishing, implementing and maintaining the registry in the long term, with the importance of having the right expertise in place to maintain the registers effectively also featuring strongly.

The importance of involving patients and considering the views of patient groups during the development of quality registries is featured in both frameworks. Input from professionals on the types of registries, the best data sources and the most appropriate quality indicators is also key. This was particularly apparent in Denmark, where the Danish Health Service Quality Institute strongly emphasises the importance of professional support in both the establishment and running of quality registries, including the selection of the relevant quality indicators. Without ongoing professional support, the institute may make the decision to close a registry.

It was evident that there is an element of subjectivity to the prioritisation process, and although prioritisation frameworks have been developed, political priorities sometimes play a role in determining what gets prioritised. For example, a decision might be made to prioritise a quality registry for a disease due to poor clinical outcomes in comparison to other jurisdictions.

There are initial plans in place for Belgium to move towards a more federated approach, with a small number of permanent registries and other registries established on an ad hoc, temporary basis. A programme of work is taking place to identify which registries to retain permanently. In contrast, the Nordic countries are continuing with their current models of having a large number of individual registries for various morbidities.

As observed in some of the countries reviewed, in order to maximise the potential and utility of registries to drive improvements in healthcare quality and outcomes, support national policy developments and facilitate research, key registries are prioritised. While cancer quality registries feature strongly in both Denmark and Sweden, registries in the areas of psychiatric care, cardiac treatments, inflammatory bowel diseases and rheumatic diseases are becoming more common. Notably, the national patient registries in Finland, Denmark and Sweden have the potential to act

as the basis for statistics on several diseases and morbidities, as well as a source of data on important healthcare indicators such as inpatient lengths of stay and emergency department waiting times.

5.6 Use of registry data

Given the significant time, costs and resources that are involved in maintaining a registry, it is important that the use of registry data is maximised to promote safer better care and lead to improved outcomes and overall wellbeing for the entire population. This review identified several examples of best practice with regard to the use of registry data.

In Denmark, for example, the Danish Health Service Quality Institute produces daily reports for clinicians and health service managers to allow for quality improvement and benchmarking, as well as publishing annual reports for each registry. In Finland, the Finnish Institute for Health and Welfare uses data from its national registries to produce statistics on various topics, such as alcohol and drug consumption, cancer, access to healthcare services and sexual and reproductive health. This statistical data, together with indicators of health, welfare and functioning of the health system, can be browsed on a web platform hosted by the institute. Similarly, in Sweden, data from the national registries is used by the National Board of Health and Welfare to produce official statistics, facilitate analysis and development of Swedish health care and social services. For many of the registries, the National Board of Health and Welfare makes statistical databases available on a regular basis, providing statistics on various topics such as abortion, acute myocardial infarction, cancer and causes of death. In Wales, the Cancer Reporting Tool, hosted on the Public Health Wales website, holds official statistics for cancer incidence, mortality and survival. It includes an interactive dashboard to enable the user to explore the data in different ways.

A key feature of each of these countries is the use of a unique identifier across all datasets that facilitates routine data linkage. Infrastructure to facilitate data sharing and data linkage, as well as adequate ICT tools and resources to facilitate the use of the data (such as interactive web-based dashboards) are also mature in each country.

5.7 Public trust

Across the three Nordic countries of Denmark, Finland and Sweden in particular, one of the key drivers of the success of their long-running systems of registries is the high levels of public trust in the institutions responsible for managing their health data. Public confidence in how secondary health data is used has been built over many years with the general perception that it is for the common good. Public

engagement features, for example, in prioritisation processes to identify new registries.

5.8 Future developments

In those countries that have the most developed health data infrastructure in place, including systems of unique identifiers, the focus is now moving towards improving the efficiency of data collection methods and maximising the use of registry data for real-world evidence studies. It is anticipated that real-world data will become an integral part of healthcare and regulatory decision-making in the near future. Work is also underway to establish how AI methods can be used to identify, extract and analyse data.

With regard to the EHDS Regulation, it was evident that most countries are still establishing whether or not it will impact on their registry landscapes. Across Member States, discussions and planning are ongoing with regard to its implementation and the implications it will have for existing organisations, systems and structures. It is likely that some countries will embed HDAB functions within existing organisations which are also data holders. Under such arrangements, it is unclear how the HDAB functions will be kept separate from the data holder functions and how the independence of the HDAB will be assured.

Belgium is progressing with plans to move from the traditional model of centralised data collection to a system of federated data sharing and processing where data holders, such as hospitals and GPs, will maintain control of their data at its original source but make it available for authorised access when requested. This represents a fundamental shift in how registries are managed in Belgium and will lead to a significant reduction in the number of individual registries in operation. Under this proposed system, the country's coordinating HDAB will play the role of facilitator of the temporary registers, but will not be a data holder, ensuring that data holder and HDAB roles are kept entirely separate.

5.9 Conclusion

This review has highlighted different models for registries in place in other jurisdictions and changes that are planned for implementation in these countries over the coming years. Examples from more mature registry systems in Europe show that coordinated and interoperable infrastructure with appropriate legislative and governance arrangements are associated with more effective systems. Notably, within those countries, registries are not siloed and there is adequate access to data, including national population-level data, as required by different stakeholders such as health and social care professionals, national-level decision-makers and policy-makers.

5.9.1 Next steps

The overarching aim of this international review was to produce evidence for national health information policy to inform a future roadmap for prioritisation and investment in registries and other national health and social care data collections in Ireland. Building on the international review, the second stage of the project is to conduct an As-is analysis describing the current registry landscape in Ireland. This will be followed by the development of prioritisation criteria and areas for consideration for Ireland.

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7. Table of abbreviations

Abbreviation	Explanation
AI	Artificial intelligence
AIM-IMA	Intermutualist Agency/Common Sickness Funds Agency
CARIS	Congenital Anomaly Register and Information Service
CPUA	Central Data Protection Authorities
CPR	Central Person Register
DHQI	Danish Healthcare Quality Institute
EHR	Electronic Health Record
EHDS	European Health Data Space
EHIF	Estonian Health Insurance Fund
HIS	Health Information System
FPS	Federal Public Service
GDPR	General Data Protection Regulation
HDR	Health Data Research
HIS	Health Information System
HSE	Health Service Executive
HIQA	Health Information and Quality Authority
HDAB	Health Data Access Body
HQIP	Healthcare Quality Improvement Partnership
HUS	Helsinki University Hospital
IMA	Intermutualist Agency
IT	Information Technology
NDR	National Data Resource
NHS	National Health Service
NIHDI	National Institute for Health and Disability Insurance
NIHR	National Institute for Health and Care Research

NICOR	National Institute for Cardiovascular Outcomes Research
RKKP	Regions' Clinical Quality Development Programme
RWE	Real World Evidence
SAIL	Secured Anonymised Information Linkage
SALAR	Swedish Association of Local Authorities and Regions
VALO	Value from Nordic Health Data

8. Appendices

Appendix A. Information related to the review methodology

Organisations included in the searches

Belgium

1. Health Data Agency
2. Sciensano
3. Federal Public Service (FPS) – Health, Food Chain Safety, and Environment
4. Federal Public Service (FPS) – Social Security
5. Statistics Belgium (Statbel)
6. The Belgium Healthcare Knowledge Centre
7. The National Institute for Health and Disability Insurance
8. The Insurance InterMutualistic Agency
9. The Belgian eHealth platform

Denmark

1. Danish Health Data Authority
2. Danish Health Services Quality Institute
3. Statistics Denmark

Estonia

1. The Estonian Health Insurance Fund
2. The National Institute for Health Development
3. Estonian Catalogue of Public Sector Information
4. The Health and Welfare Information Systems Centre
5. The Estonian Health Board
6. Statistics Estonia
7. The Estonian Biobank

Finland

1. Findata
2. Finnish Institute for Health and Welfare
3. Valvira
4. Fingenious
5. Social Insurance Institution of Finland
6. Statistics Finland

Sweden

1. National Board of Health and Welfare
2. Public Health Agency of Sweden
3. Swedish Research Council

4. Vardanlys
5. Swedish Association of Local Authorities and Regions (SALAR)
6. Swedish eHealth Agency
7. Knowledge Management in Health and Medical Care

Wales

1. Digital Health and Care Wales
2. SAIL Databank
3. Social Care Wales
4. NHS Wales
5. Public Health Wales

Data extraction form

Country	[name of country, and region if applicable] <i>DUPLICATE THIS TABLE IF MORE THAN ONE ORGANISATION IS IDENTIFIED.</i>
Organisation	[name of organisation]
Main website link	[hyperlink]
Oversight and governance of registries	<p>Description:</p> <p>Hyperlink to source(s):</p> <ol style="list-style-type: none"> 1. 2. <p>Any other relevant detail and links</p>
Strategies for registries	<p>Description:</p> <p>Hyperlink to source(s):</p> <ol style="list-style-type: none"> 1. 2. <p>Any other relevant detail and links</p>
Prioritisation of investment in registries and other NDCs	Description:

	Hyperlink to source(s): 1. 2. Any other relevant detail and links
Concept of high value data sets	Description: Hyperlink to source(s): 1. 2. Any other relevant detail and links
Notes	
Data extractor	[Name]

Interview Schedule

Country:	
Name of organisation:	
Name and role/s of interviewees:	
Date of interview:	

1. Can you tell us about <name of country>'s current approach to patient registries?

Prompts

- What are the key organisations involved? What roles do they play?
- What infrastructure is in place for registries? How is data collected? How is the EHR utilised?
- Is data linkage routinely carried out? What are the barriers/facilitators to this?
- What works well?
- What doesn't work well?

2. Are there any specific patient registries that have been prioritised with regard to investment in recent years?

Prompts

- What has guided this prioritisation/investment?
- What changes have been or are currently being implemented?
- How was the impact of this investment measured?
- How has this investment been received by data holders, data users and the general public?

3. Are there any relevant plans or strategies that have guided <name of country>'s approach to registries in recent years?

Prompts

-

4. Is <name of country>'s approach to registries changing in light of the EHDS?

Prompts

-

5. Are you familiar with the concept of high-value datasets?

Prompts

- Is the concept of high-value datasets utilised in <name of country> within the context of health and social care data?

Appendix B. Danish registries

Registries managed by the Danish Health Data Authority

1. National Abortion Register
2. National Alcohol Treatment Register
3. National Database of Advanced Directives for Medical Care
4. National Child Health Register
5. National Cancer Register
6. Register for Danish Citizens Treated outside Denmark
7. Cause of Death Register
8. Shared Medication Record
9. Birth Register
10. Register of Rehabilitation according to The Danish Act of Health
11. National Medical Implants Register
12. National Register on Treatment with Heroin and Methadone
13. National In Vitro Fertilisation Register
14. Clinical Laboratory Information Register
15. National Patient Register
16. National Database of Living Wills
17. Register of Pharmaceutical Sales
18. National Child Odonatology Register
19. The Cost Database
20. National Organ Donor Database
21. Danish Pathology Register
22. Psychiatric Treatment Register
23. Bed Capacity and Occupation Rate
24. National Catalogue of Health Organisations
25. National Hospital Medication Register
26. National Register of Coercive Measures in Psychiatric Units
27. National Register of Coercive Measures in relation to the Treatment of Disabled Patients
28. National Database of Non-Consent to the Use of Tissue Samples for Scientific Purposes

Source: Danish Health Data Authority website (List extracted April 2025)

Appendix C. Estonian registries

Note: the Estonian Health Information System (HIS), the main repository of health data in Estonia, is jointly controlled by the Ministry of Social Affairs, Health and Welfare Information Systems Centre and the Estonian Health Insurance Fund (EHIF).

Registries managed by government agencies

Ministry of Social Affairs

1. Myocardial Infarction Register
2. Causes of Death Register

National Institute for Health Development

1. Medical Birth Record Register
2. Abortion Record Register
3. Cancer Register
4. Tuberculosis Register
5. Cancer Screening Register
6. Drug Treatment Register
7. New Psychoactive Substances Early Warning Information System

State Agency of Medicines

1. Register of Medical Products
2. Register of Activity Licences
3. Cells and organs data

Estonian Health Board

1. Health Board Laboratory Register
2. Patient Safety Register
3. Poison Information Center Information System
4. Environmental Health surveillance data
5. Communicable Diseases Register
6. Healthcare Management Information System
7. The Health Board's procedural system
8. Water Health Safety Information System
9. Medical Devices and Aids Register

Agencies external to the Ministry of Social Affairs:

Estonian Health Insurance Fund (EHIF)

1. EHIF database
2. Medical Prescription Center

Source: Estonian Ministry for Social Affairs (list obtained April 2025)

Appendix D. Finnish registries

Registers managed by the Finnish Institute for Health and Welfare

Healthcare registries

1. Finnish Cancer Registry
2. Cancer Screening Registry
3. Care Register for Health Care
4. Medical Birth Register
5. Register of Congenital Malformations
6. Finnish Arthroplasty Register
7. Register of Visual Impairment
8. Register of Primary Health Care visits
9. Register of Induced Abortions and Sterilisations
10. Vaccination Register
11. Infectious Disease Register

Social welfare registries

1. Count of Regular Home-Care Clients
2. Register of Child Welfare
3. Care Register for Social Welfare
4. Register of Social assistance

Quality registries

1. Diabetes Register
2. HIV Register
3. Kidney Disease Register
4. Psychosis Treatment Quality Register
5. Back Register
6. Oral and Dental Treatment Quality Register
7. Cardiac Register
8. Intensive Care Quality Register
9. Inflammatory Rheumatic Diseases Quality Register

Source: Finnish Institute for Health and Welfare website (List extracted May 2025)

Appendix E. Swedish registries

Registries managed by the National Board of Health and Welfare

1. National Patient Register
2. National Cancer Register
3. National Medical Birth Register
4. National Prescribed Drug Register
5. National Cause of Death Register
6. National Dental Health Register
7. National Register of Interventions in Municipal Health Care
8. National Register of Care and Social Services for the Elderly and Persons with Impairments
9. National Register of Municipal Support and Service for Persons with Certain Functional Impairment
10. National Register of Measures for Children and Young persons
11. National Register of Social Assistance
12. National Register of Care for Substance Abuse
13. National Register of Authorised Healthcare Professionals

Statistical databases/registries made available based on data from the national registries managed by the National Board of Health and Welfare (listed above)

1. Abortion
2. Acute Myocardial Infarctions
3. Cancer
4. Cause of death
5. Healthcare practitioners
6. Inpatient care diagnoses
7. Basal Cell Cancer
8. Congenital Anomalies

Source: National Board of Health and Welfare website (List extracted June 2025)

Registries managed by the Public Health Agency of Sweden

1. National Registry for Communicable Diseases
2. National Vaccination Registry

Source: Public Health Agency of Sweden website (List extracted June 2025)

Registries managed by the eHealth Agency

1. National Register for Medicinal Products
2. Produce and Article Register (VARA)
3. Identification Register (licensed prescribers)

Source: eHealth Agency website (List extracted June 2025)

Appendix F. Welsh registries

Welsh population-based registries

1. Welsh Cancer Registry/Welsh Cancer Intelligence and Surveillance Unit
2. Welsh National Breast Screening Register (Breast Test Wales)
3. Cervical Screening Wales
4. Congenital Anomaly Register and Information Service
5. Adult rare diseases register
6. National Community Child Health Database
7. Births register
8. Welsh Demographic Service Dataset

UK-wide registries/audits

1. Deaths registration (including causes of death) dataset for Wales and England
2. Clinical Practice Research Datalink Pregnancy Register
3. UK Cystic Fibrosis Registry
4. UK Inflammatory Bowel Disease Registry
5. UK National Joint Registry
6. UK National Major Trauma Registry
7. UK Renal Registry
8. HQIP National Vascular Registry
9. HQIP National Bowel Cancer Audit
10. HQIP National Audit of Primary Breast Cancer
11. HQIP National Audit of Metastatic Breast Cancer
12. HQIP National Oesophgo-Gastric Cancer Audit
13. HQIP National Ovarian Cancer Audit
14. HQIP National Pancreatic Cancer Audit
15. HQIP National Non-Hodgkin Lymphoma Audit
16. HQIP National Clinical Audit of Psychosis
17. HQIP National Early Inflammatory Arthritis Audit
18. HQIP Falls and Fragility Fracture Audit
19. HQIP National Emergency Laparotomy Audit
20. HQIP National Asthma and COPD Audit
21. HQIP Epilepsy clinical audit
22. HQIP National Neonatal Audit
23. HQIP National Paediatric Diabetes Audit
24. HQIP National Adult Diabetes Audit
25. HQIP National Audit for Care at the End of Life
26. HQIP National Audit of Dementia
27. HQIP National Respiratory Audit Programme
28. HQIP Sentinel Stroke National Audit Programme
29. HQIP National Early Inflammatory Arthritis Audit
30. HQIP Paediatric Intensive Care Audit Network
31. NICOR National Adult Cardiac Surgery Audit
32. NICOR National Audit of Percutaneous Coronary Interventions
33. NICOR National Audit of Cardiac Rhythm Management
34. NICOR National Congenital Heart Disease Audit

35. NICOR National Heart Failure Audit
36. NICOR Myocardial Ischaemia National Audit Project
37. NICOR Structural Heart Intervention Registries (Left Atrial Appendage Occlusion; Percutaneous Foramen Ovale Closure; Transcatheter Aortic Valve Implantation; and Transcatheter Mitral and Tricuspid Valve procedure)

Appendix G. Belgian registries

Population-based registries

Belgian Cancer Registry

1. Belgian Cancer Registry
2. Cancer Screening Registries (cervical cancer, breast and colon cancer)

Intermutualist Agency

1. Population (demographic) database
2. Healthcare expenditures database
3. Outpatient medicines expenditures database

Statistics Belgium

1. Births registry
2. Deaths registry
3. Still births and deaths of children under one year registry

National Institute for Health and Disability Insurance (NIHDI)

1. Registries of medical services provided – based on health insurance claims (multiple registries)
2. Pharmanet (registry of medicines dispensed in public pharmacies)
3. Registry of medicines administered in hospitals

FPS Public Health

1. Registries of hospital activity (Minimum Hospital Datasets) (multiple registries)
2. Mobile Emergency Group Database (MUGREG)
3. Belgian maternal mortality audit system

Medical and mortality registries – managed by NIHDI or Sciensano

1. Fertility preservation treatments registry
2. Belgian Cystic Fibrosis Registry
3. Belgian HIV-AIDS Cohort Study
4. Central Registry for Rare Diseases
5. Belgian Neuromuscular Diseases Registry
6. Belgian Neuromuscular Diseases Registry: Spinal Muscular Atrophy
7. Belgian Cerebral Palsy Registry
8. Belgian Rare Bleeding Disorders Registry
9. Belgian Treatment Demand Indicator Registry
10. Care Trajectories: Chronic Kidney Disease
11. Care Trajectories: Diabetes Mellitus Type 2

12. Initiative for Quality Improvement and Epidemiology in Diabetes
13. Belgian Early Warning System for Drugs
14. Belgian Genetic Tests database
15. Belgian National Registry on Treatments for Degenerative Spinal Disorders (Pilot)
16. Registry of Next-Generation-Sequencing test for oncology
17. Belgian Registry of Joint Replacements
18. Mandatory registration of Spine Surgery
19. Surveillance of Infectious diseases by sentinel laboratories
20. National Hand Hygiene Campaign
21. National Surveillance of Antimicrobial Use in Belgian Hospitals
22. National Surveillance of Healthcare Associated Infection in Intensive Care Units
23. National Surveillance of Septicaemia in Hospitals
24. National Surveillance of Surgical Site Infections
25. Quality indicators for hospital hygiene in acute care hospitals
26. Sentinel Hospitals for Severe Acute Respiratory Illness
27. Surveillance of Clostridium difficile Infections
28. Creutzfeldt-Jakob disease surveillance
29. Surveillance of infectious diseases in children by paediatrics and GPs
30. Ventricular Support Material
31. Predictive Tests for a Therapeutic Response
32. Belgian Molecular Profiling programme of metastatic cancer for clinical decision and treatment assignment
33. TARDIS Registry for Rheumatoid arthritis treatment
34. Barometer for General Practice: Diabetes
35. Barometer for General Practice: Antibodies
36. Barometer for General Practice: Chronic Kidney Disease
37. Belgian Sexual Assault Care Centres: Monitoring and Evaluation

Medical and mortality registries managed by other organisations

1. Belgian Diabetes Registry
2. Belgian Trauma Registry
3. Belgian Registry of acetabular and pelvic fractures
4. Belgian Register of patients with familial hypercholesterolemia
5. Belgian Obstetric Surveillance System
6. Belgian Lynch syndrome registry
7. Belgian Familial Adenomatous Polyposis Registry
8. Belgian Registry of Primary Immunodeficiencies
9. Belgian Association for Cardio-Thoracic Surgery Registry
10. Belgian Pulmonary Hypertension Registry

11. Belgian Register for Assisted Procreation
12. Belgian Registry for Substitution Treatment
13. Central Registry of the Traceability of Implants

Medicinal product and device registries

- Quality Electronic Registration of Medical acts, Implants and Devices registries, managed by NIHDI, including:
 1. Defibrillators
 2. Pacemakers
 3. Endoprosthesis
 4. Coronary stents
 5. Coronary Angioplasty
 6. Orthoprote – hip, knee and femur prosthesis
 7. Amputation
 8. Implantable nets for prolapse repair
 9. Neurostimulators for chronic pain
 10. Implantable continuous glucose monitoring
 11. Endobronchial valve
 12. Spine surgery
 13. Material for ventricular support

Source: List compiled in May 2025 from various sources, including the websites of the Belgian Cancer Registry, Intermutualist Agency, NIHDI, FPS Public Health, Health Data Agency, Sciensano, and the fair.healthdata.be platform.

Appendix H. Population-based health data registries identified in each country

	Belgium	Denmark	Estonia	Finland	Sweden	Wales
Cancer registry	✓	✓	✓	✓	✓	✓
Cancer screening registry	X	✓ ^a	✓	✓	X	✓
Registry of pregnancies and births	✓	✓	✓	✓	✓	✓
Registry of causes of deaths	✓	✓	✓	✓	✓	✓
Registry of abortions	+	✓	✓	✓	+	+
Register of congenital malformations/anomalies	+	+	+	✓	+	✓
Registry of all hospital encounters	#	✓ (National Patient Register)	*	✓ (Care Register for Health Care)	✓ (National Patient Register)	X
✓ Registry in operation. X Registry not in operation. ^a Included in Denmark's system of quality registries. ^ No standalone registry but the Kanta system is a source of this data		+ No standalone registry, but data/statistics available from existing registries. # No standalone registry but the NIHDI and AIM-IMA datasets are sources of this data; * No standalone registry but the HIS and EHIF databases are a source of this data				
Other national registries						
Registries relating to illegal drug or alcohol use/treatment	Belgian Early Warning System for Drugs	National Register on Treatment with Heroin and Methadone	Drug Treatment Register	X	National Register of Care for Substance Abuse	X

Evidence for policy: International review of approaches to registries in health and social care
Health Information and Quality Authority

	Belgium	Denmark	Estonia	Finland	Sweden	Wales
		National Alcohol Treatment Register	New Psychoactive Substances Early Warning Information System			
Registries relating to child health and welfare	X	National Child Health Register National Child Odontology Register	X	Register of Child Welfare	National Register of Measures for Children and Young persons	X
Registries relating to the care of the elderly or people with disabilities	X	National Register of Coercive Measures in relation to the Treatment of Disabled Patients	X	Register of Social Assistance	National Register of Care and Social Services for the Elderly and Persons with Certain Functional Impairment National Register of Municipal Support and Service for Persons with Certain	X

Evidence for policy: International review of approaches to registries in health and social care
Health Information and Quality Authority

	Belgium	Denmark	Estonia	Finland	Sweden	Wales
					Functional Impairments	
Registries relating to assisted reproduction	Belgian Register for Assisted Procreation	National In Vitro Fertilisation Register	X	X	X	X
Registries relating to psychiatric care	X	Psychiatric Treatment Register	X	X	X	X
		National Register of Coercive Measures in Psychiatric Units				
Other registries relating to healthcare utilisation	X	Register of Rehabilitation	X	Register of Primary Health Care Visits	National Register of Interventions in Municipal Health Care	X
Other registries.		National Database of Advanced Directives for Medical Care	Tuberculosis Register	Register of Sterilisations		Adult Rare Disease Register
		Register for Danish Citizens Treated	Register of Activity Licences		Register of Authorised	Welsh Demographic

Evidence for policy: International review of approaches to registries in health and social care
Health Information and Quality Authority

	Belgium	Denmark	Estonia	Finland	Sweden	Wales
		outside Denmark			Healthcare Professionals	Service Dataset
		National Medical Implants Register	Register of Medical Products		Dental health register	
		Clinical Laboratory Information Register	Cells and organs data		National Register of Social Assistance National Register of Authorised Healthcare Professionals	
		National Database of Living Wills	Health Board Laboratory Register			
		Register of Pharmaceutical Sales	Patient Safety Register			
		Cost Database	Poison Information Center Information System			

Evidence for policy: International review of approaches to registries in health and social care
Health Information and Quality Authority

	Belgium	Denmark	Estonia	Finland	Sweden	Wales
		National Organ Donor Database	Environmental Health surveillance data			
		Danish Pathology Register	Communicable Diseases register			
		National Catalogue of Health Organisations	Healthcare management Information System			
		Bed Capacity and Occupation Rate	The Health Board's procedural system			
		National Database of Non-Consent to the Use of Tissue Samples for Scientific Purposes	Water Health Safety Information System			
			Medical Devices and Aids Register			

Appendix I. National quality registries in Sweden

1. Amputation and prosthesis registry
2. Respiratory Failure Registry
3. The Childhood Obesity Registry in Sweden
4. Breast Implant Registry
5. Better Addiction Treatment
6. Endovascular treatment of stroke
7. Pregnancy registry
8. Hand Surgery Quality Register
9. InfCareHepatitis
10. InfCareHIV
11. Quality register ECT
12. Cystic Fibrosis Quality Registry
13. Quality Registry for MMC, Other Neural Tube Defects and Hydrocephalus
14. The Respiratory Registry
15. National Diabetes Registry
16. National Cataract Registry
17. National Stroke Quality Registry
18. National Prostate Cancer Registry
19. National Heart Failure Registry
20. National quality registry for acute lymphoblastic leukaemia
21. National quality registry acute myeloid leukaemia including acute unclassified leukaemia
22. National Quality Registry for Assisted Fertilization
23. National Quality Registry for Bipolar Disorder and Psychosis
24. National Quality Registry for Breast Cancer
25. National quality registry for pancreatic cancer
26. National quality register for gallstone surgery and ERCP
27. National quality registry for brain tumours and the central nervous system
28. National quality registry for hip fractures
29. National Quality Register for Catheter Ablation
30. National quality registry for chronic myeloid leukaemia
31. National quality register for vascular surgery
32. National quality registry for lung cancer
33. National Quality Register for Cleft Lip, Jaw and Palate
34. National Quality Register for Mammography Screening
35. National Quality Registry for Esophageal and Gastric Cancer
36. National quality registry for kidney cancer
37. National Quality Register for patients with difficult-to-heal wounds
38. National Quality Registry for Primary Immunodeficiencies
39. National Quality Registry for Testicular Cancer Seminoma
40. National quality registry for thyroid cancer
41. National quality registry for bladder cancer
42. National quality register for healthcare and social care
43. National quality register for ear, nose and throat care
44. National quality registry for skin melanoma
45. National quality register in gynaecological surgery

46. National quality registry for chronic lymphocytic leukaemia
47. National Lymphoma Quality Registry
48. National Quality Registry Myelodysplastic Syndrome
49. National quality register for myeloma
50. National quality registry for myeloproliferative disorders
51. National Quality Register of Pain Rehabilitation
52. National Quality Registry for Cervical Cancer Prevention
53. National registry for cardiac intensive care, coronary angiography, PCI, cardiac surgery and secondary prevention
54. National Registry for Inflammatory Bowel Disease
55. National registry for congenital heart diseases
56. National Penile Cancer Registry
57. National Forensic Psychiatry Quality Register
58. Registry for Systemic Treatment of Psoriasis
59. The Registry for Congenital Metabolic Diseases
60. Scandinavian Obesity Surgery Register
61. Scandinavian Quality Register for Thyroid, Parathyroid and Adrenal surgery
62. Swedish Osteoarthritis Registry
63. Swedish Childhood Cancer Registry
64. Swedish Pediatric Kidney Registry
65. Swedish Pediatric Rheumatology Registry
66. Swedish Cornea Registry
67. Swedish Foot Surgery Registry
68. Swedish Fracture Registry
69. Swedish Hemophilia Registry
70. Swedish Cardiopulmonary Resuscitation Registry
71. Swedish Pituitary Registry
72. Swedish Intensive Care Registry
73. Swedish Internet Processing Register
74. Swedish Colorectal Cancer Registry
75. Swedish Quality Registry for Gynecological Cancer
76. Swedish Arthroplasty Registry
77. Swedish Macular Registry
78. Swedish National Ankle Registry
79. Swedish neuroregister
80. Swedish pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH) Registry
81. Swedish Palliative Care Registry
82. Swedish Registry for Liver, Gallbladder and Biliary Tract Cancer
83. Swedish Register for Cognitive Disorders/Dementia Disorders
84. Swedish Spine Registry
85. Swedish Shoulder and Elbow Registry
86. Swedish Sleep Apnea Registry
87. Swedish Trauma Registry
88. Swedish Cruciate Ligament Registry
89. Swedish Rheumatology Quality Register
90. Swedish Hernia Registry
91. Swedish Quality Register for Behavioral and Psychological Symptoms in Dementia

- | | |
|---|--|
| 92.Swedish quality registry for head and neck cancer | 96.Swedish Kidney Registry |
| 93.Swedish Quality Register for Caries and Periodontitis | 97.Swedish Pediatric Orthopedic Quality Register |
| 94.Swedish Quality Register for Rehabilitation in Visual Impairment | 98.Swedish Perioperative Registry |
| 95.Swedish Neonatal Quality Register | 99.Swedish Register for Rehabilitation Medicine |
| | 100.Cerebral Palsy Follow-up Program |

Source: Knowledge Management in Health and Medical Care website, www.kunskapsstyrningvard.se (List extracted April 2025)

Appendix J. Clinical quality registries managed by the Danish Health Service Quality Institute

1. The ADHD Database
2. The Emergency Surgery Database
3. Atrial fibrillation in Denmark
4. DANARREST - Cardiac arrest in hospital
5. Danish Head and Neck Cancer Database
6. Danish Ablation Database
7. Danish Acute Leukemia Database
8. Danish Anesthesia Database
9. Danish Bipolar Database
10. Danish Bladder Cancer Database
11. Danish Childhood Cancer Registry
12. Danish Database for Integrated Dual Diagnosis Treatment
13. Danish Database for Chronic Myeloproliferative Neoplasias
14. Danish Depression Database
15. Danish Diabetes Database
16. Danish EsophagoGastric Cancer database
17. Danish Fetal Medicine Database
18. Danish Gynecological Cancer Database
19. Danish Hernia Database
20. Danish Heart Registry
21. Danish Cardiac Rehabilitation Database
22. Danish Cardiac Arrest Registry
23. Danish Heart Failure Database
24. Danish Hip Replacement Registry
25. Danish Hysterectomy and Hysteroscopy Database
26. Danish Intensive Care Database
27. Danish Clinical Quality Database for Dementia
28. Danish Knee Replacement Registry
29. Danish Colorectal Cancer Database
30. Danish Cruciate Ligament Reconstruction Registry
31. Danish Chronic Lymphocytic Leukemia Database
32. Danish quality database for diabetic retinopathy
33. Danish Quality Database for Births
34. Danish Quality Database for Inflammatory Bowel Diseases
35. Danish Quality Database for Cervical Cancer Screening
36. Danish Quality Database for Mammography Screening
37. Danish Quality Database for Newborns
38. Danish Quality Database for Early Pregnancy and Abortion
39. Danish Quality Database for Elderly People with Frailty
40. Danish Liver and Biliary Tract Cancer Database
41. Danish Lung Cancer Registry
42. Danish Lymphoma Database
43. Danish Melanoma Database
44. Danish Myelomatosis Database
45. Danish Nephrological Society National Registry
46. Danish Neuro-Oncological Registry
47. Danish Palliative Care Database
48. Danish Pancreatic Cancer Database
49. Danish Parkinson Quality Database
50. Danish Prostate Cancer Database

51. Danish Psoriasis Database
52. Danish Registry for Acute Coronary Syndrome
53. Danish Asthma Registry
54. Danish registry for Chronic Obstructive Pulmonary Disease
55. Danish Renal Cancer Database
56. Danish Forensic Psychiatric Database
57. Danish Rheumatology Quality Database
58. Danish Back Database
59. Danish Registry for Acute Coronary Syndrome
60. Danish Sarcoma Database
61. Danish Shoulder Alloplasty Registry
62. Danish Stroke Registry
63. Danish Bowel Cancer Screening Database
64. Danish Testicular Cancer Database
65. Danish Trauma Registry
66. Danish Multidisciplinary Registry for Hip Fractures
67. Danish Urogynecological Database
68. Database for Emergency Hospital Contacts
69. Database for the Treatment of Severe Obesity
70. COVID-19 database
71. Familial Hypercholesterolemia database
72. National Schizophrenia Database
73. Epilepsy Database
74. Skin Cancer Database
75. Breast Cancer Quality Database
76. Nationwide clinical quality database for the Cerebral Palsy Follow-up Program
77. National Register of Karbase
78. Myelodysplastic Neoplasia Database
79. Organ donation database
80. Prehospital Database
81. Multiple Sclerosis Treatment Register
82. Thyroid Database

Source: Danish Health Service Quality Institute website (List extracted April 2025)

Appendix K. Most frequently occurring medical and mortality registry types identified across the six countries

	Belgium	Denmark ^a	Estonia	Finland ^b	Sweden ^c	Wales
Diabetes	✓	✓	X	✓	✓	✓ ^d
Kidney disease	✓	X	X	✓	✓	✓ ^e
Cardiac	✓	✓	✓	✓	✓	✓ ^f
Trauma	✓	✓	X	X	✓	✓ ^g
Intensive care	X	✓	X	✓	✓	✓ ^d
Breast cancer	X	✓	X	X	✓	✓ ^d
Cerebral palsy	✓	✓	X	X	✓	✓
Rheumatology	X	✓	X	✓	✓	✓ ^d
Psychiatric care	X	✓	X	✓	✓	✓ ^d
Hip fractures	✓	✓	X	X	✓	✓ ^d
Cystic fibrosis	✓	✓ ^h	X	X	✓	✓ ^d
Inflammatory bowel disease	X	✓	X	X	✓	✓ ^d
<p>✓ Registry in operation. X Registry not in operation. ^a List is based on the quality registries managed by the Danish Health Service Quality Institute ^b List is based on the quality registries managed by the Finnish Institute for Health and Welfare ^c List is based on the country's system of national quality registries ^d HQIP National Clinical Audit Programme; ^e UK Renal Registry; ^f NICOR Cardiac Audit Programme; ^g National Major Trauma Registry; ^h managed by the two national CF centers in Denmark</p>						

Appendix L. Registries of medicinal products and medical devices

Registry type	Belgium	Denmark	Estonia	Finland	Sweden	Wales
Vaccination	No national-level registry in place.	Danish Vaccination Register	No national-level registry in place.	Finnish Vaccination Register	Swedish National Vaccination Register	No national-level registry in place.
Prescribed drugs	No national-level registry in place.	National Hospital Medication Register; Shared Medication Record	Medical Prescription Center dataset	No national-level registry in place.	National Prescribed Drug Register	No national-level registry in place.
Joint replacement	Belgian National Arthroplasty (Hip and Knee) Registry	Danish Hip Replacement Registry; Danish Knee Replacement Registry	No national-level registry in place.	Finnish Arthroplasty Register	Swedish Arthroplasty Register	National Joint Registry
Cardiac devices	Multiple databases held by the National Institute for Health and Disability Insurance	Danish Pacemaker Register; Danish implantable cardiac defibrillator register	No national-level registry in place.	No national-level registry in place.	Swedish implantable cardiac defibrillator and pacemaker Registry	Implantable cardiac defibrillator Database National Pacemaker Database

Appendix M. Certification criteria for national quality registries in Sweden

Certification level 1

1. Coverage and adherence rates should be higher than 85 per cent (based on the relevant patient group and calculated from adequate data sources).
2. The register contributes data to open comparisons/healthcare in numbers.
3. Specific information about the registry and its results is publicly available for patients to access and understand.
4. The register shall actively enable and facilitate research on register data, quality monitoring and innovation.
5. The register is actively used by participating units and can report this through, for example, user surveys at the operations.
6. The registry has validated its data quality and conducted adequate dropout analyses.
7. The register is connected to the Swedish Research Council's tool RUT and complies with the FAIR principles.

Certification level 2

Certification level 2 includes criteria for certification levels 3 and K.

1. Coverage and adherence rates are higher than 60 per cent (based on the relevant patient group and calculated from adequate data sources).
2. The register has statistical displays of information in relevant time formats that can support and contribute to improvement work in the register's operations.
3. Open reporting of indicators on the registry's website, in the annual report and healthcare in numbers.
4. Reporting on improved performance or process indicators (locally and or nationally) together with a description of how the register is considered to have contributed to these.
5. Identification of which metrics and target values are particularly important for indicating good quality in the area.
6. Open and accessible reporting of patient-reported measures, if relevant.
7. Established collaboration to highlight the patient perspective.
8. Active systematic work to ensure data quality.
9. The register contributes data for quality monitoring and research.
10. The register links to relevant evidence-based guidelines and participates in guideline work and follow-up of these, for example with NPOs.
11. A plan has been developed for connection to the Swedish Research Council's tool RUT.
12. Follow-up indicators of care progress are available.

Certification level 3

Certification level 3 includes criteria for certification level K.

1. Registration/data collection has begun.
2. The amount of registrations is sufficient to verify functionality, conduct preliminary analyses, test indicators and further develop the register.
3. Reporting on ongoing work on developing functions for statistical displays to participating units and open reporting of results.
4. Reporting of plan for how data will be validated.
5. Account of how the registry's design and logical system facilitate high data quality.
6. Description of how the registry will obtain the patient perspective, for example via patient associations.
7. The annual report for the previous calendar year is available.
8. The register's variable list is published at the Register Centre, on its own website, RUT or similar.
9. The register must be able to demonstrate that they are developing towards a higher level of certification. A plan must be presented for how they will meet the criteria for certification level 2 within four years.

Candidate (K)

Quality registers that have not yet been certified.

1. High relevance as a national quality register.
2. Approval by a central data protection authority, CPUA.
3. The registrar and steering group are appointed together with the CPUA.
4. Established collaboration with Regional Registry Centre or Regional Cancer Centre.
5. Anchored in the healthcare sector with good geographical spread, for example via professional associations and national networks.
6. The register has active collaboration with the neighbouring national programme areas, NPO, which are included in the regions' systems for knowledge management in healthcare.
7. A description has been developed for the area the register intends to follow and how the register will contribute to better care.
8. A description has been developed for calculating the degree of connection and coverage.
9. A description has been developed for calculating process and performance measures.
10. Mapping of other nearby registers so that overlap can be avoided and collaboration established.
11. The register writes an activity report for each calendar year, which shows how the register is developing.
12. A plan has been developed for how the register will meet the criteria for certification level 3 within two years. Does not apply to registers with a higher certification level.

Source: Knowledge Management in Health and Medical Care website (obtained April 2025)



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(HIQA)**

For further information please contact:
Health Information and Quality Authority
George's Court
George's Lane
Smithfield
Dublin 7
D07 E98Y

+353 (0)1 814 7400
info@hiqa.ie
www.hiqa.ie