Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

# EVIDENCE SYNTHESIS:

## Information management arrangements for national health and social care data collections

OCTOBER 2022

# Version

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## About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority 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.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, 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 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 health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these 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 services, in conjunction with the Department of Health and the HSE.

## Overview of the health information function of HIQA

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is, therefore, very important that information is managed in the most effective way possible in order to ensure a high-quality safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has an important role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under Section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under Section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving its quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to promote quality and safety in health and social care settings is available when, and where, it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in health and social care services in Ireland is highly fragmented with major gaps and silos of information. This results in individuals being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is an overreliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information in Ireland, based on standards and international best practice. A robust health information environment will allow all stakeholders — patients and service users, health professionals, policy-makers and the general public — to make choices or decisions based on the best available information. This is a fundamental requirement for a highly reliable healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services.

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## Glossary of abbreviations

| | |
|---|---|
| **ABS** | Australian Bureau of Statistics |
| **AIHW** | Australian Institute of Health and Welfare |
| **ALB** | Arm's Length Body |
| **AR-DRGs** | Australian Refined Diagnosis Related Groups |
| **CIDR** | Computerised Infections Disease Recording |
| **CIHI** | Canadian Institute of Health Information |
| **CRDM** | CIHI Reference Data Model |
| **CSO** | Central Statistics Office |
| **DAB** | Digital Advisory Board |
| **DAPB** | Data Alliance Partnership Board |
| **DASSL** | Data Access, Storage, Sharing and Linkage |
| **DQS** | Data Quality Statement |
| **DQMI** | Data Quality Maturity Index |
| **EHDS** | European Health Data Space |
| **GDPR** | General Data Protection Regulation |
| **HDRN** | Health Data Research Network (Canada) |
| **HIPE** | Hospital Inpatient Enquiry |
| **HISO** | Health Information Standards Organisation (New Zealand) |
| **HPO** | Healthcare Pricing Office |
| **HIQA** | Health Information and Quality Authority |
| **HL-7** | Health Level Seven |
| **HRB** | Health Research Board |

| | |
|---|---|
| **HSE** | Health Service Executive |
| **ICD-10** | International Statistical Classification of Diseases and Related Health Problems, Tenth Revision |
| **ICT** | Information and communications technology |
| **IHI** | Individual Healthcare Identifier |
| **ISO** | International Organization for Standardization |
| **NCAMP** | National Collections Annual Maintenance Project |
| **NHIA** | National Health Information Agreement |
| **NHRA** | National Health Reform Agreement |
| **NHI** | National Health Index |
| **NHS** | National Health Service |
| **NOCA** | National Office for Clinical Audit |
| **OECD** | Organisation for Economic Co-operation and Development |
| **PHIPA** | Personal Health Information Protection Act |
| **SNOMED CT** | Systematized Nomenclature of Medicine Clinical Terms |
| **TEHDAS** | Towards the European Health Data Space |

# 1 Introduction

## 1.1 Background

National health and social care data collections are defined as national repositories of routinely-collected health and social care data. This can include administrative data sources, censuses, surveys and patient registries. They play a crucial role in disease surveillance and in monitoring health and social care service use and needs. National health and social care data collections can be used to inform decision-making and policy; organise health and social care services and plan for future needs, both at national and local levels; and conduct high-quality research.(1)

The importance of using data for decision-making was highlighted in the Sláintecare Implementation Strategy.(2) However, existing health and social care data collections in Ireland have evolved over time in a largely uncoordinated fashion without strong governance structures or national oversight arrangements. As a consequence, issues around data quality, duplication, access, and sub-optimal use of information frequently arise. With significant costs associated with the collection, use and storage of health and social care information, it is imperative that data collected is of the highest quality and used to its full potential.(3)

A robust health information system is a key feature of a cohesive and integrated healthcare system. This requires clear strategic direction, strong leadership and governance, legislation, and adequate investment.(3) In line with its statutory remit relating to health information, HIQA has sought to drive improvements in the collection and use of health information in Ireland by developing *Information Management Standards for National Health and Social Care Data Collections*,(4) and by formally reviewing individual national data collections for compliance against the standards.(5) The primary purpose of these standards is to ensure that national health and social care information is of the highest possible quality, the availability of which will ultimately drive improvements in patient safety.

## 1.2 Purpose of this evidence synthesis

The aim of this evidence synthesis is to describe current structures and information management arrangements for national health and social care data collections in Ireland and internationally, and to summarise the latest evidence relating to the development and implementation of standards and guidance for national health and social care data collections. This information will be used to support and inform a revision of HIQA's *Information Management Standards for National Health and Social Care Data Collections*.

## 1.3 Methodology

There are two parts to this evidence synthesis. Firstly, an 'as-is' analysis was carried out to understand the current structures and arrangements in Ireland for national health and social care data collections. This is presented in Chapter 2.

Secondly, evidence relating to the approaches taken to managing national health and social care data collections in eight countries was outlined, with a particular focus on any recent developments and changes in practices since the publication of the previous international review in 2016.(6) An in-depth review of evidence from the following countries was conducted:

- Australia
- Canada
- England
- New Zealand.

These countries were chosen for an in-depth review as they have advanced information management structures in place for health and social care information. In addition, they have publicly-funded health systems, similar to Ireland, as well as having relevant documents such as guidance and frameworks available in the English language. In addition, a brief review of evidence from the following countries was conducted:

- Korea
- Singapore
- Sweden
- Denmark.

Evidence relating to the information management arrangements in place for national health and social care data collections in each country was gathered. A grey literature search was performed, including documents from government websites and key managing agencies of national health and social care data collections. Information for each country was verified by contacting individuals working at the key organisations.

For each country, the following are described:

- the legislative context and organisational governance arrangements
- existing guidance and frameworks available to support improvements in data quality and information governance
- other national arrangements for health information, including practices in relation to the use of health identifiers, data linkage classification, national data dictionaries, and classification and terminology
- future plans in relation to national health and social care data collections.

# 2 A summary of current structures and arrangements for national health and social care data collections in Ireland

## 2.1 Legislative context and organisational governance arrangements

### 2.1.1 Key organisations and committees

There are several organisations across Ireland with varying responsibilities in relation to national health and social care data collections. While multiple government departments, independent organisations, charities, hospitals and universities play important roles, the most relevant organisations for the purpose of this review are:

- Department of Health
- Health Service Executive (HSE)
- Central Statistics Office (CSO)
- HIQA.

In a survey of 23 countries within the Organisation for Economic Co-operation and Development (OECD), Ireland was reported to have 10 of 13 key national health datasets. Of these, four were managed by an office or agency of the HSE, two by an office or agency of the Department of Health, two by the CSO, one by the Health Research Board (HRB), and one by HIQA.(7)[*]

The latest update of HIQA's catalogue of national health and social care data collections, published in October 2022, included a total of 128 data collections.(8) They were categorised as follows:

- Data collections with national coverage (n=84)
- National surveys or censuses (n=14)
- Other data collections (n=30).

#### 2.1.1.1 Department of Health

The Department of Health is the government department with overall responsibility for health services and for developing national strategies, policies and legislation for health information in Ireland. In addition to its key strategic roles in delivering healthcare policy and managing the health budget, the Department of Health

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[*] The 13 national datasets asked about in the OECD survey included 10 healthcare datasets (hospital inpatient, mental hospital inpatient, emergency healthcare, primary care, prescription medicines, cancer, diabetes, cardiovascular disease, mortality and formal long-term care); patient experiences survey, population health survey and population census and or registry.

compiles and maintains key population health and health system data from various sources through a number of data collections, including Health Statistics, Healthy Ireland Survey, and Health in Ireland – Key Trends. Data from these collections is included in the Department's annual reports of key statistics in several areas, including population health and hospital and primary care,(9) and health service structures, processes and outcomes.(10)

The HRB is a State agency that sits under the Department of Health and is responsible for funding health and social care research across Ireland and providing evidence to inform policy and practice. It also maintains a number of health and social care data collections relating to: alcohol and drug treatment and deaths; disability service use and need; and psychiatric admissions and discharges.(11)

The National Cancer Registry Ireland (NCRI) is also a State agency under the aegis of the Department of Health.(12) The NCRI has been collecting data and publishing information on cancer in Ireland since 1994. It has its own governance structures in place and is accountable to the Minister for Health.

#### 2.1.1.2 Health Service Executive

The HSE is responsible for delivering public health services in Ireland. A number of key national health and social care data collections are managed by various departments and offices within the HSE. These include, but are not limited to: hospital inpatient data, managed by the Healthcare Pricing Office (HPO) through the hospital inpatient enquiry (HIPE) dataset;(13) health system performance data, managed by the Planning and Business Information Unit;(14) infectious diseases data, managed by the Health Protection Surveillance Centre (HPSC) through the Computerised Infections Disease Recording (CIDR) system; and primary care and prescription medicines data, managed by the Primary Care Reimbursement Service.(15)

In addition, the HSE funds the National Office for Clinical Audit (NOCA) which is responsible for managing a portfolio of clinical audit data collections and morbidity and mortality registers across the Irish healthcare system.(16) NOCA has its own governance structures in place, with an independent voluntary board and operational support from the Royal College of Surgeons in Ireland (RCSI).

#### 2.1.1.3 Central Statistics Office

The Central Statistics Office (CSO) is Ireland's national statistics agency and the custodian for a number of key national health data collections, including those relating to births and deaths, COVID-19, and the Irish Health Survey.(17) The Statistics Act 1993 provides that the CSO may collect data in fulfilment of its statutory functions both through surveys and through the use of secondary data, garnered from the records of public authorities.(18)

#### 2.1.1.4 Health Information and Quality Authority

HIQA is an independent statutory authority 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. HIQA has a statutory remit to develop recommendations to support decision-making for the Irish eHealth and health information landscape, and it drives improvements in the quality of data and information by developing national standards and guidance for national health and social care data collections within the HSE, the Child and Family Agency (Tusla) and service providers, and assessing compliance with these national standards.(4) HIQA maintains a catalogue of national health and social care data collections in Ireland, which was last updated in October 2022.(8) In addition, HIQA is the custodian of data collected through Ireland's National Care Experience Programme,(19) as well as the Irish database of statutory notifications from social care.(20)

### 2.1.2 Legislative context

The national health and social care data collection landscape in Ireland is influenced by both Irish and European Union (EU) legislation, as shown in Table 1.

**Table 1: Relevant Irish legislation**

| Name of Act or Regulation | Description |
|---|---|
| Health Acts 1947, 1953 | Give responsibility and authority to the Medical Officer of Health to investigate and control notifiable infectious diseases.(21,22) |
| Health (Duties of Officers) Order 1949 | Describes the additional responsibilities of the Medical Officer of Health in relation to infectious diseases.(23) |
| The Infectious Disease Regulations 1981 | Requires all medical practitioners to notify certain diseases, and for the HPSC to be notified via the CIDR system.(24) |
| Data Protection Acts 1988 – 2018 | Governs the collection and processing of personal data in Ireland. The 2018 Amendment gave effect to the GDPR, established a new Data Protection Commission, and provides for the Health Research Regulations 2018 (described below).(25) |
| Statistics Act 1993 | Provides a legislative basis for the compilation and dissemination of official statistics, through establishing and outlining the functions of the CSO and giving it a mandate to co-ordinate the publication of official statistics compiled by public authorities.(18) |
| The Health (Provision of Information) Act 1997 | Allows for the provision of information to the NCRI without the consent of individuals as cancer prevention is considered an overriding public interest.(26) |

| | |
|---|---|
| The Health Identifiers Act 2014 | Provides for the assignment of unique health service identifiers to individuals to whom a health service is being, has been, or may be provided and for the assignment of unique identifiers to health services providers; permits providers and certain other entities to provide an individual's identifier to an authorised disclosee in order to enable the processing of such information for a 'secondary purpose'. Authorised disclosees include the CSO and health profession regulatory bodies.(27) |
| The Health Research Regulations 2018 | Outlines the mandatory suitable and specific measures for the processing of personal data for health research; provides a definition of health research for the purposes of the regulation; provides for the possibility of applying for a consent declaration for new research; provides for the establishment and operation of a the Health Research Consent Declaration Committee.(28) |
| Data Sharing and Governance Act 2019 | Clarifies and strengthens the data sharing rights and obligations of public bodies; provides a legal basis for the sharing of administrative data between public bodies, including the HSE and government. Fully enacted on 31 March 2022.(29) |

As outlined in Table 1, there are a number of pieces of legislation that inform how health and social care information can be collected, used and shared in Ireland. To date, specific legislation for health information has not been enacted. In 2007, the Health Information Bill was first published and it aimed to bring legal clarity to the secondary uses of health information. It subsequently evolved to become the Health Information and Patient Safety Bill, and underwent a public consultation in 2017. Multiple concerns were raised during the public consultation, including the potential for buying and selling of personal health data and compliance with the GDPR. Consequently, it was not enacted in its original form.

In April 2022, the Minister for Health received Cabinet approval to develop the General Scheme of a Health Information Bill. In a press release, the Department of Health stated that the proposed Bill will help ensure that Ireland has a "fit-for-purpose national health information system that enhances patient care and treatment and supports better planning and delivery of health services" and noted the proposed appointment of a National Health Information Guardian and the proposed introduction of a National Health Information Centre. The Department stated that clearly-specified functions and governance rules in relation to the collection and processing of health information for population health purposes, and research and innovation, would lead to better outcomes for patients. At the time of writing, no further details have been provided on the remit and role of these new structures.(30)

### 2.1.2.1 The General Data Protection Regulation 2018

The GDPR came into effect across the European Union on 25 May 2018.(31) An accompanying Directive establishes data protection standards in the area of criminal offences and penalties. This is known as the Law Enforcement Directive. The GDPR and the Law Enforcement Directive provide for significant reforms to current data protection rules. They provide for higher standards of data protection for individuals and impose increased obligations on organisations that process personal data. They also increase the range of possible sanctions for infringements of these rules.

The GDPR sets out seven general principles which must underpin the collection, use and sharing of personal data:

- **Lawfulness, fairness, and transparency**: there must be a legal basis for the collection, use and sharing of information and it should be used in a fair and transparent manner.
- **Purpose limitation:** information must only be collected for specific purposes, and should not be further used and shared unless it is compatible with the original purpose and in line with individuals' reasonable expectations.
- **Data minimisation**: the collection, use and sharing of information should be limited to only what is necessary for the purposes for which it is required.
- **Accuracy:** information must be accurate and steps must be taken to ensure any inaccuracies are dealt with promptly and appropriately.
- **Storage limitation:** information should only be stored for the minimum time necessary.
- **Integrity and confidentiality**: appropriate measures should be in place to ensure the integrity and confidentiality of information.
- **Accountability**: ensures compliance with data protection principles and appropriate processes and records are in place to demonstrate accountability.

Article 9 of the GDPR specifically deals with the processing of special categories of personal data, including data concerning health. Under the GDPR, personal data includes identifiable and pseudonomysed data (data which has a link back to enable identification); however, if the data has been anonymised and can no longer be linked back to an identifiable individual, it is not considered personal data and is not subject to the GDPR.

Under article 9 of the GDPR, there are a number of conditions under which personal data concerning health can be processed, including:

- the data subject has given explicit consent to the processing of their personal data for one or more specified purposes
- processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller

- processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent
- processing is necessary for reasons of substantial public interest
- processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services
- processing is necessary for reasons of public interest in the area of public health; processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.(31)

## 2.2 Guidance and frameworks to support improvements in data quality and information governance

### 2.2.1 HIQA guidance documents

As part of its health information function, HIQA has published a number of key guidance documents and online learning modules in recent years in relation to data quality and information governance for national health and social care data collections, including:

- *Developing a data quality framework – an online learning module* (2021)(32)
- *Introduction to data quality – an online learning module* (2020)(32)
- *Guidance on a data quality framework for health and social care* (2018)(33)
- *Self-assessment tool for national data collections* (2017)(34)
- *Guiding principles for national health and social care data collections* (2013)(35)
- *What you should know about data quality: a guide for health and social care staff* (2012)(36)
- *Guidance on information governance for health and social care services in Ireland* (2012).(37)

### 2.2.2 Information management standards for health and social care data collections

HIQA's *Information Management Standards for Health and Social Care Data Collections* (4) complement the *National Standards for Safer Better Healthcare*.(38) Collectively, both sets of standards aim to provide a roadmap to improve the quality of health information and data across Ireland and ultimately contribute to the delivery of safe and reliable health and social care. Ten outcome-based standards have been structured within six themes and there is a list of features included under each standard statement. The six themes and 10 standard statements are summarised in Table 2. Data collections that fall under the remit of these standards are those held by the HSE, Tusla and health and social care service providers.

HIQA has also established a structured programme to assess compliance with the information management standards within its legislative remit.(5) To date, five major national data collections have been reviewed by HIQA with regard to their information management practices and their compliance with the information management standards, including Breastcheck,(39) the HIPE scheme,(40) the Primary Care Reimbursement Service,(41) the CIDR system,(42) and the National Incident Management System within the HSE.(43)

At the time of writing of this evidence synthesis, an updated version of the information management standards was being developed by HIQA.

**Table 2: Overview of HIQA's Information Management Standards (2017)(4)**

| | |
|---|---|
| **Theme 1: Person-centred** | |
| **Standard 1** | The managing organisation of the national health and social care data collection has effective arrangements in place to protect the privacy of people about whom it holds information. |
| **Theme 2: Governance, Leadership and Management** | |
| **Standard 2** | The managing organisation of the national health and social care data collection has effective governance, leadership and management arrangements in place, with clear lines of accountability to ensure that its objectives are met. |
| **Standard 3** | The managing organisation maintains a publicly available statement of purpose that accurately describes the aims and objectives of the national health and social care data collection. |
| **Standard 4** | The managing organisation of the national health and social care data collection is compliant with relevant legislation and codes of practice. |
| **Theme 3: Use of Information** | |
| **Standard 5** | The managing organisation of the national health and social care data collection complies with health information standards and nationally agreed definitions to enable comparability and sharing of information. |
| **Standard 6** | The managing organisation of the national health and social care data collection systematically assesses, monitors and improves the quality of the data it holds to ensure its objectives are met. |
| **Standard 7** | The managing organisation of the national health and social care data collection disseminates data and information appropriately and ensures that data users can access data and information in a timely manner to meet their needs. |
| **Theme 4: Information Governance** | |
| **Standard 8** | The managing organisation of the national health and social care data collection has effective arrangements in place for information governance which ensure that personal information is handled legally and securely. |
| **Theme 5: Workforce** | |
| **Standard 9** | The managing organisation of the national health and social care data collection plans, organises and develops its workforce to effectively deliver its objectives. |
| **Standard 10** | The managing organisation of the national health and social care data collection plans and manages the allocation and use of resources to ensure its objectives are met. |

### 2.2.3 CSO Quality Policy

The CSO Quality Policy is set out in *Quality in Statistics - A Handbook of Quality Standards and Guidelines*, which was published in 2021.(44) This handbook provides information and recommendations on best practice and contains clear guidelines to ensure that the quality of the CSO's processes and outputs are of the highest standard. The CSO's quality framework is based on the European Statistics Code of Practice, which is made up of 16 principles covering the institutional environment, the statistical production process and the statistical outputs.(45)

## 2.3 Other national arrangements for health information

### 2.3.1 Health identifiers

The Health Identifiers Act 2004 provided a legislative basis for the creation of individual health identifiers (IHIs), which are unique personal numbers used across public health and social services.(27) The Access to Information and Health Identifiers Service programme within the HSE is responsible for delivering core functions to support the roll-out of national health identifiers in Ireland. Although the technical infrastructure for the Health Identifier Index is in place and already populated with 6.7 million IHIs relating to current and former residents of Ireland, IHIs have not yet been rolled out across the health service and are not yet being used in national health and social care data collections.

### 2.3.2 Data linkage

The lack of a comprehensive infrastructure for secure data access, storage and sharing in Ireland has been a major barrier to the linkage of different health and social care data collections.(3) Different managing organisations, the lack of a unique health identifier being consistently used across health and social care data collections, the lack of health information legislation, and concerns around data protection have also been implicated.(46) With the exception of the CSO, which has both the statutory powers and the technical infrastructure to link data from different domains in a secure, confidential and transparent manner, most other managing organisations are currently unable to carry out complex data linkage projects.

Following the publication of a report outlining the difficulties faced by health researchers in linking various data collections in 2016,(47) the HRB funded a project that aims to investigate a proposed Data Access, Storage, Sharing and Linkage (DASSL) model for Ireland. With this funding from the HRB, the Irish Centre for High-End Computing (ICHEC), along with collaborators from the RCSI, the HSE, and Trinity College Dublin is working on developing the proof-of-concept technical infrastructure for the DASSL model. The findings of this project are due to be published at the end of 2022.(48)

### 2.3.3 National data dictionary

The HSE's Office of the Chief Information Officer (CIO) is leading on the development of a Health and Social Care Data Dictionary for all national health and social care data in Ireland. This will act as a 'single source of truth' for health and social care data and will be an assured reference point for approved data definitions and key health service terms and concepts.(49) There is also work underway to develop a 'toolkit' to support the standardisation of data, which will help ensure that all staff in the Irish health service have access to agreed standard definitions for medical and health service terms. The aim is that staff across the health service will be able to access the data dictionary and use it to ensure they have the same understanding of relevant health service terms.(50)

### 2.3.4 Classification and terminology

The aggregation terminologies (or classifications) currently used in Ireland include:

- International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM);
- Australian Classification of Health Interventions; and
- International Classification of Primary Care, Second Edition.(51)

The reference terminologies most widely used in Ireland are:

- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT); and
- Logical Observation Identifiers Names and Codes.(51)

Following recommendations from HIQA,(52) the Irish Government adopted SNOMED CT as a national terminology standard and became a member of SNOMED International. The Irish National Release Centre, situated within the Enterprise Architecture function of the HSE's Office of the CIO, is responsible and has the delegated authority to licence the SNOMED CT Irish Edition and derivatives.(53)

In its position paper on health information, published in 2021, HIQA identified an absence of a strategic road map in relation to terminologies and classification in Ireland, with multiple organisations responsible for different aspects of healthcare terminologies and classifications. HIQA has recommended the development of a national interoperability strategy that incorporates all national health information standards and is governed by a single organisation.(3)

## 2.4 Future plans

The Oireachtas Sláintecare Report, published in 2017, and subsequent plans and strategies, have acknowledged the importance of high quality data and information to drive improvements in the future of healthcare in Ireland.(54,55) The effective management of information across the health and social care system is essential to achieving the Sláintecare vision of providing the right care, in the right place, at the right time, and ensuring a high-quality safe service for all. The proposed Health Information Bill (described in section 2.1.2) has the potential to transform the health information landscape in Ireland and assist with the full implementation of the Sláintecare reform programme. In August 2022, HIQA published 'Key considerations to inform policy for the collection, use and sharing of health and social care information in Ireland'.(56) This piece of work collates key findings informed by international evidence, a review of the current situation in Ireland, and engagement with a broad range of national and international stakeholders. The document outlines key considerations for health information to enable change, progress and developments in health information and is aimed at informing the forthcoming Health Information Bill and the Department of Health's overall Health Information Strategy.

# 3 Summary of the international evidence

| | Australia | Canada | Denmark | England | New Zealand | Singapore | South Korea | Sweden |
|---|---|---|---|---|---|---|---|---|
| **Population** | 25.7 million | 38.5 million | 5.8 million | 55.0 million | 5.1 million | 5.6 million | 51.8 million | 10.4 million |
| **Key organisation** | Australian Institute of Health and Welfare (AIHW) | Canadian Institute of Health Information (CIHI) | The Danish Health Data Authority | NHS England/ NHS Digital | Ministry of Health | Ministry of Health | Ministry of Health and Welfare | National Board of Health and Welfare |
| **Overview and governance** | A mostly centralised model, with the AIHW as the key custodian of national data collections (currently around 150). Other key collections are held by the Australian Bureau of Statistics and Department of Health. | A mostly centralised model, with the Canadian Institute for Health Information (CIHI) and the Public Health Agency of Canada each responsible for around 30 national data collections relating to the health system and disease surveillance, respectively. | A centralised model, with a well-established system of national health registers, all managed by the Danish Health Data Authority within the Ministry of Health. | Mostly centralised, with NHS England having statutory power to direct NHS Digital to collect information from health organisations; NHS Digital currently maintains approximately 234 national data collections. | A centralised model, with the Ministry of Health responsible for key health and disability data collections, obtaining data from different parts of the health sector and from national population health surveys. | A centralised model, with the Ministry of Health responsible for major health data collections. | A mostly centralised model, with the Ministry of Health and Welfare or its agencies responsible for major national health data collections. | A mostly centralised model, with The National Board of Health and Welfare responsible for major national health data collections, including key national health registers. Over 100 national quality registers exist, managed by Registry Centres in each healthcare region. |

| | **Australia** | **Canada** | **Denmark** | **England** | **New Zealand** | **Singapore** | **South Korea** | **Sweden** |
|---|---|---|---|---|---|---|---|---|
| **Unique identifiers** | Yes, exist for healthcare; not yet widely used in data collections. | Yes, exist for healthcare and insurance purposes; not yet widely used in data collections. | Yes, a national identifier is used in all national data collections. | Yes, NHS number. Used in all NHS data collections. | Yes, the NHI number. Routinely used in health data collections. | Yes, the National Registration Identity Card number. Used in the majority of national data collections. | Yes, the resident registration number. Used in all national data collections. | Yes, the personal identity number. Used in all national data collections and registries. |
| **Data linkage capabilities** | Well-established systems for probabilistic data linkage, with the AIHW as the national authority, and data linkage units in each state and territory. | Linkage across provinces can be challenging, but CIHI has well-established processes in place for linking its data collections. | Well-established systems for data linkage using the national identifier; linkage of data collections occurs frequently. | Well-established processes for linking NHS data collections using the NHS number; linkage of data collections occurs frequently. | Linkage of data collections held by the Ministry of Health occurs frequently using the NHI. Probabilistic techniques used for linkage across sectors. | Linkage of data collections is possible using the National Registration Identity Card number but only a minority of data collections are linked on a regular basis. | Well-established systems for linking datasets across sectors. | Well-established systems for data linkage using the personal identity number; linkage of data collections occurs frequently. |
| **Organisations responsible for classification and terminology** | The Independent Hospital Pricing Authority and The National Clinical Terminology Service | CIHI and Canada Health Infoway | Danish Health Data Authority | The Data Standards Assurance Service (within NHS Digital) | The Health Information and Standards Organisation (within the Ministry of Health) | Ministry of Health | Statistics Korea | National Board of Health and Welfare |
| **National Data Dictionary** | Yes, METeOR. | None identified. | Yes, eSundhed. | Yes, NHS Data Model and Dictionary. | No, currently in development. | None identified. | None identified. | None identified. |

# 4 Australia

## 4.1 Introduction

**Population:** 25.7 million.(57)

**Government:** Three levels: the federal government (Australian Parliament); the six state and two territory governments; and local governments, also referred to as shires or municipalities. The federal government holds responsibility for managing the health budget and funding the health system, mainly through Medicare (Australia's universal healthcare scheme), while the state, territory and local governments share responsibility for the management and administration of the health services.(58)

**Healthcare:** Australians have free or low-cost access to all necessary healthcare through Medicare, including primary care services, public hospital care, and medicines. Individuals can pay out-of-pocket or use private health insurance to pay for services not covered by Medicare and to cover the costs of hospital treatment as a private patient.(58)

## 4.2 Legislative context and organisational governance arrangements

In Australia, governmental responsibility for health and social care data collections is shared between the federal and the state and territory governments. At each level of government, there are a range of agencies with responsibility for specific datasets and there is no overarching health data governance framework.(7) In a survey of 23 OECD countries, Australia was one of 11 countries to report having at least 12 of 13 key national health datasets. Of these, seven were managed by the Australian Institute of Health and Welfare (AIHW), three by the Australian Bureau of Statistics (ABS), and two by the Department of Health.(7)[†]

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[†] The 13 national datasets asked about in the OECD survey included 10 healthcare datasets (hospital inpatient, mental hospital inpatient, emergency healthcare, primary care, prescription medicines, cancer, diabetes, cardiovascular disease, mortality and formal long-term care); patient experiences survey, population health survey and population census and or registry.

### 4.2.1 Key organisations and committees

There are a number of key organisations with varying responsibilities in relation to national data collections and information management standards in Australia. The most relevant for the purpose of this review are:

- The Health Council
    - The Health Chief Executives Forum
- Australian Bureau of Statistics
- Australian Institute of Health and Welfare
    - National Health Data and Information Standards Committee
    - Strategic Committee for National Health Information
- Australian Digital Health Agency
- National Health and Medical Research Council.

#### 4.2.1.1 The Health Council

The Health Council is comprised of all federal government Ministers, state and territory government Ministers and Ministers from the New Zealand Government with direct responsibility for health matters. It promotes a consistent and coordinated national approach to health policy development.(59) The Health Chief Executives Forum, formerly the Australian Health Ministers' Advisory Council, is the advisory and support body to the Health Council.(60)

#### 4.2.1.2 Australian Bureau of Statistics

The Australian Bureau of Statistics (ABS) is Australia's official statistical organisation. It is an independent statutory federal government agency, and its legislative functions include operating as a central statistical authority for the federal government and providing statistical services for state and territory governments, and collecting, compiling, analysing and disseminating statistics and related information.(61)

#### 4.2.1.3 The Australian Institute of Health and Welfare

The Australian Institute of Health and Welfare (AIHW) is an independent statutory federal government agency. The main functions of the AIHW are to:

- collect and manage data on health and welfare issues from federal, state, and territory agencies
- analyse and report data to support policy and service delivery decisions
- make data available to federal, state, and territory agencies, including universities, research centres and non-government organisations.(62)

The AIHW is responsible for receiving, validating and disseminating information and is recognised as the key national custodian of administrative health data collections in Australia. At the time of publication of this report, the AIHW managed over 150 data collections, including both administrative data sets and survey-based collections covering diverse fields such as:

- **Perinatal health**, such as the National Perinatal Data Collection
- **Disability**, such as the ABS Survey of Disability, Ageing and Carers
- **Cancer**, such as the Australian Cancer Database
- **Hospital activity**, such as the Elective Surgery Waiting Times National Minimum Dataset
- **Alcohol and drugs**, such as the National Drug Strategy Household Survey
- **Mortality**, such as the National Death Index.

All data collections are authorised by a privacy regulatory body or a research ethics committee, often in addition to legislative authorisation.(7) While some health data collections included in the AIHW holdings are mandated and do not require individuals' consent, others do not have a legal mandate and operate under different consent models, including both opt-in and opt-out consent approaches.(7) All are approved by the AIHW Ethics Committee, and the assessment process for each collection includes a comprehensive assessment of any impact on individuals' privacy.(63)

#### 4.2.1.4 The Australian Digital Health Agency

The Australian Digital Health Agency is a statutory authority established as a Corporate Commonwealth entity under the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016.(64) The Australian Digital Health Agency is tasked with implementing Australia's National Digital Health Strategy and is also the system operator of the My Health Record system.

#### 4.2.1.5 National Health and Medical Research Council

First established in 1926, the National Health and Medical Research Council (NHMRC) was established as an independent statutory agency in 2006, under the NHMRC Act 1992.(65) The NHMRC is a key driver of health and medical research in Australia, and its *National Statement on Ethical Conduct in Human Research* sets out the relevant ethical principles and values by which all research should be designed and conducted and to which all human research ethics committees should refer when reviewing research proposals.(66)

### 4.2.2 Relevant legislation

There are a number of pieces of legislation which provide a legal basis for the operation of health and social care data collections in Australia (Table 3).

**Table 3: Summary of relevant legislation in relation to the operation of health and social care data collections in Australia**

| Name of Act | Description |
|---|---|
| Australian Bureau of Statistics Act 1975 | Established the ABS as an independent statutory authority; defines the functions of the ABS; establishes the office of Australian Statistician.(67) |
| Australian Institute of Health and Welfare Act 1987 | Established the AIHW as a statutory authority to serve as a custodian of major national health and welfare data collections; and ensures that the data collections which are managed by AIHW are kept securely.(68) |
| Privacy Act 1988 | Outlines 13 principles ('Australian Privacy Principles') which all public, private and governmental organisations must comply with.(69,70) Some states and territories have enacted their own privacy Acts or developed standards relating to privacy and information management.(71-78) |
| Healthcare Identifiers Act 2010 | Sets out the detail and requirements regarding the operation of the healthcare identifiers service; specifies that healthcare identifiers are to be used for healthcare and related management purposes only.(79) |
| National Health Reform Act 2011 | Acts as the key mechanism for the transparency, governance and financing of Australia's public hospital system.(80) Since its enactment, the first National Health Reform Agreement (NHRA) was published in 2011,(81) and the 2020-25 Addendum in May 2020.(82) All jurisdictions have signed this Addendum which includes an action to scale up a national approach to data governance arrangements, structures and processes.(82) |
| The My Health Records Act 2012 | Established the My Health Record system and the role and functions of the My Health Record System Operator; outlined a registration framework for individuals and healthcare providers to participate in the My Health Record system; and a privacy framework (aligned with the Privacy Act 1988).(64) Key legislative changes were made in 2015 and 2016 following stakeholder consultation; most notably, any unauthorised use or disclosure of became subject to civil and criminal penalties.(83) |
| Public Governance, Performance and Accountability Rule 2016 | Established the Australian Digital Health Agency, following which it became the System Operator of the My Health Record System.(64) |
| Data Availability and Transparency Act 2022 | Establishes a new scheme for sharing Australian Government data, underpinned by strong safeguards and simplified processes; focused on increasing the availability and use of Australian Government data both directly to data users and through intermediaries, such as AIHW.(84) |

### 4.2.3 The National Health Information Agreement

The National Health Information Agreement (NHIA) is an agreement between the federal government and all the state and territory government authorities which sets out to coordinate the development, collection and dissemination of health information in Australia, including the development, endorsement, and maintenance of national data standards.(85) The current NHIA commenced on 1 October 2013. The specific objectives of the NHIA are to:

- promote the collection, compilation, analysis and dissemination of relevant, timely, accurate and reliable health information in accordance with nationally agreed protocols and standards
- develop and agree on projects to improve, maintain and share national health information
- cooperate in the provision of resources necessary to address national health information development priorities efficiently and effectively
- provide the information required to research, monitor and improve health and the delivery of health services
- provide the information required to facilitate nationally agreed projects which promote the development and reform of the healthcare system in accordance with the priorities of the Health Chief Executives Forum
- promote the extension of the range of national health information and encourage other groups and individuals in government and non-government sectors to participate by making available information that they hold
- work towards improving consistency in data definitions, classifications and collections between health, community services and housing assistance.(85)

**Under the terms of the NHIA, the AIHW is responsible for:**

- receiving, validating and disseminating information as the key national custodian of administrative health data collections
- managing data in accordance with the AIHW Act 1987, and other relevant legislative requirements
- in consultation with the ABS, developing specialised statistical standards and classifications relevant to health and health services
- undertaking performance reporting on the healthcare system
- assisting other parties to the NHIA in using and interpreting national health information
- ensuring that the National Health Data Dictionary and other quality control standards are maintained and enhanced
- undertaking the role of metadata registrar for the NHIA
- making METeOR education and training resources available to stakeholders.(85)

## 4.3 Guidance and frameworks to support improvements in data quality and information governance

Under the terms of the NHIA, responsibility for the quality and completeness of national data collections remains with the data provider. Most organisations develop their own data quality policies which are based on the ABS Data Quality Framework.

### 4.3.1 ABS Data Quality Framework 2009

The ABS Data Quality Framework was published in 2009 for use by a range of data users and providers, including government agencies, statistical agencies, and independent research agencies.(86) It is based on the Statistics Canada Quality Assurance Framework (87) and the European Statistics Code of Practice.(45) It consists of seven dimensions (institutional environment; timeliness; accessibility; interpretability; relevance; accuracy; and coherence) and forms the basis of many data quality frameworks that have subsequently been developed.(88-91)

### 4.3.2 AIHW Data Collection Management Principles

The AIHW Data Collection Management Principles, developed in 2011 and updated in 2012, make explicit how all AIHW data collections should be managed (Table 4). In 2016, a data custodian self-assessment checklist was developed based upon the seven principles. In 2019, this self-assessment checklist was merged with the monitoring reports that are submitted to the AIHW Ethics Committee on an annual or bi-annual basis depending on the level of risk associated with the data collection. The Data Collection Monitoring Report and Checklist is used to record progress and compliance for all data collections that are approved by the AIHW Ethics Committee.

**Table 4: AIHW Data Collection Management Principles**

| | |
|---|---|
| **Principle 1** | Data collections are established and managed effectively, appropriately and consistently, with clear accountability requirements and governance arrangements. |
| **Principle 2** | Data receipt processes ensure the security and integrity of the data during transfer. |
| **Principle 3** | Data are stored securely and regularly backed up. |
| **Principle 4** | Integrity of the data is maintained. |
| **Principle 5** | Controls for persons and entities having access to the collection exist and are implemented. |
| **Principle 6** | Data transmission or dissemination from the collection to any source (internal or external) is conducted in a manner which ensures its accuracy, integrity and security. |
| **Principle 7** | End of data lifecycle or use is appropriately managed. |

### 4.3.3 AIHW Data Governance Framework 2021

While there is no national framework for the governance of health and social care data collections in Australia, the AIHW has a framework which applies to data which has been collected or enhanced by AIHW, collected on AIHW's behalf, or obtained from external sources. First published in 2014,(92) the framework was comprehensively revised and updated in 2020 to reflect changes in the AIHW operating environment and governance landscape, followed by a minor update in 2021 to reflect policy changes.(63) The key components of the AIHW Data Governance Framework are outlined in Table 5. Further detail on the framework is included in Appendix 1.

**Table 5: AIHW Data Governance Framework 2021**

| | |
|---|---|
| **Part 1** | Introduction |
| **Part 2** | Key concepts in data and data governance |
| **Part 3** | Legal, regulatory and governance environment |
| **Part 4** | AIHW organisational structures and roles in data governance |
| **Part 5** | AIHW systems and tools that support data governance |
| **Part 6** | AIHW data-related policies, procedures and guidelines |
| | Establishment of a new data collection |
| | Acquisition of data |
| | Access and use of data within the AIHW |
| | Sharing and releasing data outside the AIH |
| | Data archiving, return, collection retirement and destruction |
| **Part 7** | Compliance |

### 4.3.4 AIHW Data Quality Statements

The quality of AIHW data collections is recorded and reported by way of Data Quality Statements (DQSs) which are made available to the public via METeOR and by inclusion in publications.(93) It is AIHW policy that DQSs are produced for all collections for which the AIHW acts as the data custodian.

A DQS provides information on a range of aspects of the quality of the data being included in the data collection. The intention is to enable users to understand any data limitations and to make informed judgements about use of the data. The AIHW's approach to DQSs aligns with the ABS Data Quality Framework.(86)

When completing the DQS, users are first ask to summarise the key issues relating to their dataset that users should be aware of when using the data, before describing its main features, and moving on to completing the seven data quality dimensions taken from the ABS Data Quality Framework: institutional environment, relevance, timeliness, accuracy, coherence, interpretability, and accessibility.(93)

### 4.3.5 Framework for Australian Clinical Quality Registries

Australia has well-developed frameworks and systems in place for clinical quality registries, defined as specific types of clinical registries that collect healthcare data on specific populations and utilise this to assess care provision over time and implement quality improvements where required.

In 2014, the Australian Commission on Safety and Quality in Health Care developed a Framework for Australian Clinical Quality Registries, following its endorsement by all Health Ministers.(94) The framework outlined guiding principles that clinical quality registries should meet in order to achieve best practice operations. These principles are outlined in Appendix 2.

The Australian Commission on Safety and Quality in Health Care maintains the Australian Register of Clinical Registries which provides summary information on the purpose and organisation of clinical registries in Australia. Clinical registries are added to this online register on an ongoing basis.(95) It has also published a prioritised list of clinical domains for potential development of national clinical quality registries.(96)

In November 2019, the Australian Commission on Safety and Quality in Health Care commissioned an update to the 2014 Framework to strengthen guidance on clinical quality registry governance arrangements. As part of the revision of the Framework, the group sought advice on all federal and state and territory privacy laws and other relevant legislation that may affect the operation of clinical quality registers, and commissioned a report in to this matter. The report, prepared by an external agency, summarises: the privacy legislation and regulatory considerations for all data custodians of clinical quality registries across Australia; identifies the role and function of data custodians; describes how data is stored and shared, in what format, and for how long, it should be stored; and describes the requirements for establishing a clinical quality register.(97)

Building on the 2014 Framework, a 10-year national strategy for clinical quality registries and virtual registries was published in 2020.(98) The Strategy was developed in partnership with the Australian and state and territory governments, together with the Australian Commission on Safety and Quality in Health Care, the AIHW and an Expert Advisory Group. A national public consultation process, carried out in 2019, informed its development. The Strategy for clinical quality registries outlines a set of agreed national priorities and actions to be implemented between 2020 and 2030. The ultimate goal is to integrate clinical quality registries into Australia's healthcare information systems. It is hoped that this will drive patient-centred improvements in the quality and value of healthcare.

### 4.3.6 Guidelines for the Disclosure of Secondary Use Health Information for Statistical Reporting, Research and Analysis

In 2017, the *Guidelines for the Disclosure of Secondary Use Health Information for Statistical Reporting, Research and Analysis'* were updated.(99) These guidelines outline principles and techniques regarding the disclosure of secondary use health information for statistical reporting, research and analysis and apply to health information held by all NHIA signatories, including both unit record and aggregate data, as well as the output of data linkage projects.

The guidelines provide general advice to assist data custodians in the management of risks relating to the identification of individual patients, clients or health service providers. A number of principles that apply to disclosure of health information for statistical reporting, research and analysis are outlined, as well as the techniques that are available to reduce the risks associated with secondary data use.(99)

### 4.3.7 Framework to guide the secondary use of My Health Record system data 2018

Following the implementation of the My Health Record system, a framework to guide the secondary use of data within the system was published.(100) The framework outlines a series of guiding principles that should be used to guide the release of data for secondary use purposes. A cautious approach was deliberately taken in order to build public trust in the process of secondary data use, including identifying the realised benefits.

The framework covers:

- secondary use of de-identified My Health Record system data
- identified data if the consent of the individual has been obtained.

The framework does not permit the following secondary uses:

- Use of the data for commercial and non-health-related purposes
- Provision of the data to insurance agencies
- Use of the data for clinical trials recruitment (unless an explicit consent option becomes available).

The framework includes a governance model for secondary use of data within the My Health Record system which would oversee the availability, access and release, usability, integrity, and security of My Health Record system data for secondary use. This includes the formation of a 'My Health Record Secondary Use of Data Governance Board', comprising representatives from the AIHW, the Australian Digital Health Agency and a range of independent experts and consumer advocates, to implement the framework. The Board is responsible for assessing applications for access to My Health Record system data for secondary use purposes.(100)

### 4.3.8 Information management standards

There are no national information management standards that are specific to health and social care data collections in Australia. Some states and territories have developed general information management standards and policies. For example, the Victorian Government has produced an Information Management Governance Standard, the purpose of which is to define a common approach to information governance across government departments.(101) They have also produced a Data Quality Standard, which requires departments to establish and maintain a standard of data quality for critical and shared data sets.(69) Both standards apply to all government departments, including the Department of Health and Human Services. The Government of Western Australia has produced an Information Management Policy Framework that specifies all the information management requirements and relevant legislation that all health service providers must comply with.(89)

## 4.4 Other national arrangements for health information

### 4.4.1 Health identifiers

The Federal Government Department of Health operates the national Healthcare Identifiers Service which was established as a foundation service for e-Health initiatives in the country, including the My Health Record system.(102) This is a national system for uniquely identifying healthcare providers and individuals. As part of the Healthcare Identifiers Service, every Australian resident is allocated a unique 16-digit individual healthcare identifier. Healthcare providers are allocated a healthcare provider identifier-individual (HPI-I) and organisations that deliver healthcare are allocated a healthcare provider identifier-organisation (HPI-O). The Healthcare Identifiers Act 2010 specifies that healthcare identifiers are to be used for healthcare and related management purposes with penalties in place for misuse.(79)

### 4.4.2 Data linkage

Healthcare identifiers are not yet widely used in Australian national health datasets and data collections. As such, dataset linkages rely on probabilistic linkage techniques which involve the use of combinations of personal information, such as date of birth and address, to link datasets.(7)

In Australia, an Integrating Authority is an agency that undertakes statistical data integration projects. The rights and responsibilities of integrating authorities around the management of datasets for data integration projects have been clearly outlined.(103) The overriding principle is that they must comply with the relevant privacy and data protection legislation, and ensure that they have the necessary legislative protections in place prohibiting disclosure of identifiable data, other than where allowed by law. They must also ensure that all projects are feasible and that all necessary approvals are obtained, before the data custodians give final approval for the project. This may include undertaking a Privacy Impact Assessment for projects that present a very high risk. Additionally, integrating authorities undertaking high-risk projects must be accredited. Accredited Integrating Authorities are assessed by the Cross Portfolio Integration Oversight Board as having the infrastructure and capability to undertake high-risk data integration projects, such as the linkage of national datasets, by meeting a set of criteria. Accreditation assures that the data integration will take place in a safe and secure manner. Integrating authorities are also responsible for using the Public Register of Data Integration Projects to register any data integration project which is done for statistical and research purposes and involves Commonwealth data.(103)

The AIHW is one of seven Accredited Integrating Authorities in Australia, accredited to undertake high risk, complex data integration projects involving data from national, state and territory agencies. Data linkage is one of the core services offered by the AIHW, through its Data Integration Services Centre.(104) This unit works to ensure that access to linked data for researchers is provided in line with privacy obligations and that processes and infrastructure are in place to support data custodians and researchers in undertaking efficient data linkage. The Data Integration Services Centre can link datasets held at AIHW, as well as datasets from external data custodians. Data integration projects undertaken by the AIHW or using AIHW data can only proceed with AIHW Ethics Committee approval.

The federal government has published *'A Guide to Data Integration Projects Involving Commonwealth Data for Statistical and Research Purposes'*, which was updated in 2018 and includes a *'Confidentiality Information Series'* and a '*Data Linking Information Series'.* This guide provides guidance for, and outlines the rights and responsibilities of, all those involved in data integration projects.(105)

While the AIHW is the national authority for data linkage in Australia, there are a number of data linkage units operating at the state and territory level. Data Linkage Western Australia, formerly known as the Western Australia Data Linkage System, was established in 1995 and is internationally recognised as being a pioneer of innovative data linkage techniques and associated policies, and was involved in initiating some of the first large-scale data linkage projects in Australia.(106)

Other states have since developed their own data linkage units, following funding from the federal government to support a national approach to data linkage. These include: the Centre for Health Record Linkage, located in New South Wales;(107) the Centre for Victorian Data Linkage;(108) Data Linkage Queensland;(109) the Tasmanian Data Linkage Unit;(110) and SA-NT Datalink,(111) which provides data linkage services to South Australia and the Northern Territory.

Each state's data linkage unit, together with the AIHW as the national linkage unit, has formed a national network to strengthen data linkage capabilities in Australia, referred to as the Population Health Research Network.(112) This network was established in 2009 and implemented through the National Collaborative Research Infrastructure Strategy, an initiative of the Australian Government.

### 4.4.3 National data dictionary

The AIHW manages METeOR, Australia's online repository for national metadata standards for health, housing and community services.(113) The NHIA mandates that METeOR is used by all signatories.(114)

METeOR is based on the international standard for metadata registries (ISO/IEC 11179).(115) This standard specifies the semantics used for data descriptions and how they are represented and registered. This helps standardise, harmonise and manage metadata, ensures quality, and improves accuracy and comparability of data, regardless of the originating organisation. National minimum datasets are also available through METeOR.

A new version of METEoR went live in April 2022 and replaced the previous system. In addition to the new system, a new Operating Model and a support framework is being explored to ensure that the technology, its metadata, people and processes are properly supported going forward.(113)

### 4.4.4 Classification and terminology

The Independent Hospital Pricing Authority, an independent statutory agency that was established to play a key role in the implementation of activity based funding in Australian public hospitals, is responsible for developing Australian modifications to existing classifications and for introducing new classifications to the Australian healthcare system.(116) Classifications currently used in Australia include:

- ICD-10-AM
- Australian Classification of Health Interventions
- Australian Coding Standards
- Australian Refined Diagnosis Related Groups (AR-DRGs)

- The Australian Mental Health Care Classification.(116)

The National Clinical Terminology Service is managed by the Australian Digital Health Agency.(117) It is responsible for defining a national approach to clinical terminology and making clinical terminology available and usable in across the Australian healthcare system. Clinical terminology solutions used in Australia include:

- SNOMED CT - Australian Release (SNOMED CT-AU)
- Australian Medicines Terminology, which codes and describes all commonly used medicines to support electronic medication management.(117)

## 4.5 Future plans

At the time of writing, the *Australian Data Strategy*, the Australian Government's 'whole-of-economy vision for data', was being finalised following a period of public consultation.(118) The strategy sets out the government's intentions and efforts over the period to 2025, focusing on three themes: maximising the value of data; trust and protection; and enabling data use. Optimising the use of health data, including the promotion of data linkage and complex analytics to identify priority cohorts, is an important focus of this strategy.

## 4.6 Summary of Australia's approach

### Legislative context and governance arrangements

Responsibility for national health and social care data collections is shared between the federal and state or territory governments. There is a move towards better integration of national data collections and health information through the National Health Information Agreement (NHIA), under which the Australian Institute of Health and Welfare (AIHW) is recognised as the key custodian of major national data collections.

### Guidance and frameworks for data quality and governance

Under the terms of the NHIA, responsibility for the quality and completeness of national data collections remains with the data provider. Most organisations develop data quality policies based on the Australian Bureau of Statistics (ABS) Data Quality Framework. The AIHW updated its Data Governance Framework in 2020 and 2021.

### Unique identifiers and data linkage

Unique health identifiers are mandated for use in healthcare but are not yet widely used in national health data collections. In the absence of a unique identifier, there are well-established processes in place for probabilistic data linkage. While the AIHW is the national authority for data linkage in Australia, each state and territory also has its own data linkage unit.

### National data dictionary

The AIHW manages METeOR, Australia's online repository for national metadata standards for health, housing and community services.

### Classification and terminology

The Independent Hospital Pricing Authority is responsible for classifications, while the National Clinical Terminology Service, within the Australian Digital Health Agency, is responsible for defining a national approach to clinical terminology.

### Clinical quality registries

Australia has well-developed frameworks and systems for clinical quality registries. A 10-year national strategy for clinical quality registries and virtual registries was published in 2020, with the ultimate goal being to integrate clinical quality registries within healthcare information systems.

### Secondary uses of health information

Guidelines for the secondary use of health information for statistical reporting, research and analysis were updated in 2017. A framework to guide the secondary use of data within the My Health Record system was also published in 2018.

# 5 Canada

## 5.1 Introduction

**Population:** 38.5 million (119)

**Government:** A constitutional monarchy, with three levels of government: the federal government, comprising the Queen, the Senate, and the House of Commons; the 10 provincial and three territorial governments; and the municipal, or local, governments.(120) While the federal government plays a key role in providing financial support for healthcare to the provinces and territories, responsibility for the delivery of healthcare is largely given to the provincial and territorial governments.(121)

**Healthcare:** Known to Canadians as "medicare", Canada's publicly-funded health care system provides access to a broad range of health services, including medically necessary hospital and doctor's services, without direct charges at the point of service; supplementary health services are largely financed privately.(121)

## 5.2 Legislative context and organisational governance arrangements

In Canada, governmental responsibility for health and social care data collections is shared between the federal governments and the province and territory governments. While the development of a pan-Canadian health information system infrastructure has been a priority since the 1990s,(85) it is acknowledged that there continue to be significant gaps in Canada's health data ecosystem, largely due to the lack of a co-ordinated national approach to health information management and sharing.(122) In light of this, an Expert Advisory Group, comprising experts from across the country, was formed and published their first report on the Pan-Canadian Health Data Strategy in 2021. The objective of this strategy is to strengthen Canada's health data foundations. The final strategy will focus on modernising health data collection, sharing and interoperability, streamlining and updating the approach to privacy and access for the digital age, and clarifying accountability, sovereignty, and health data governance to bring meaningful change in the way governments share health data across Canada.(123)

Due to the high level of decentralisation in Canada, provinces and territories control the administration and governance of their health and social systems and the respective data collections. In recent years, however, Canada has been working on implementing a national approach to health information infrastructure. This includes the establishment of Health Data Research Network (HDRN) Canada,(124) and the development of the Strategy for Patient-Orientated Research Canadian Data Platform in 2019-20.(125) Funded by the Canadian Institutes of Health Research, this platform has been established to provide a single portal through which researchers can request access to a multitude of administrative, clinical, and social data collections from various sources from across the country. The associated Data Access Support Hub acts as a 'one-stop shop' for researchers to request access to data from multiple provincial, territorial and pan-Canadian collections. These services are provided by a multi-centre coordination team from various provincial and territorial data centres and pan-Canadian organisations, including CIHI and Statistics Canada.(126)

In a survey of 23 OECD countries, Canada reported having 11 of 13 key national health datasets, of which six were managed by CIHI, four by Statistics Canada, and one by the Canadian Primary Care Sentinel Surveillance Network.(7)[‡] In the report of this OECD survey's findings, Canada was commended for regularly linking all key national health datasets for monitoring and research.

While the provinces and territories control the administration of their health systems and the respective data collections, they are obliged to submit certain data to various data collections that are maintained at a national-level, mostly by CIHI and the Public Health Agency of Canada.

### 5.2.1 Key organisations and committees

There are a number of key organisations with varying responsibilities in relation to national data collections and information management standards in Canada. The most relevant for the purpose of this review are:

- Government of Canada Health Portfolio
    - Health Canada
    - The Public Health Agency of Canada
    - The Canadian Institutes of Health Research
- Statistics Canada
- Canadian Institute for Health Information
- Canada Health Infoway
- Health Data Research Network Canada.

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[‡] The 13 national datasets asked about in the OECD survey included 10 healthcare datasets (hospital inpatient, mental hospital inpatient, emergency healthcare, primary care, prescription medicines, cancer, diabetes, cardiovascular disease, mortality and formal long-term care); patient experiences survey, population health survey and population census and or registry.

### 5.2.1.1 Health Canada

The Canadian Government's Health Portfolio comprises a number of independent agencies, including Health Canada, the Public Health Agency of Canada, and the Canadian Institute of Health Research.

Health Canada is the federal department with overall responsibility for helping Canadians maintain and improve their health.(127) Within Health Canada, the Access to Information and Privacy Office is responsible for administering the *Access to Information Act* and the *Privacy Act*, and it reports to Parliament annually on Health Canada's administration of both Acts.(128)

### 5.2.1.2 The Public Health Agency of Canada

The Public Health Agency of Canada focusses on preventing chronic and infectious diseases and responding to public health emergencies. It has a mandate to collect, analyse and disseminate information relating to disease surveillance. At the time of writing, the Public Health Agency of Canada maintains approximately 30 data collections relating to different aspects of surveillance, including:

- **Infectious diseases**, for example the Canadian Measles/Rubella Surveillance System, FluWatch – Influenza Surveillance, and HIV/AIDS surveillance.
- **Patient safety**, for example the Blood Safety Contribution Program and the Canadian Nosocomial Infection Surveillance Program.
- **Child health**, for example the Canadian Paediatric Surveillance Program.
- **Maternal health**, for example the Canadian Perinatal Surveillance Program.
- **Injuries**, for example the Canadian Hospitals Injury Reporting and Prevention Program and Injury Surveillance Online.(129)

The Public Health Agency of Canada also maintains the Canadian Chronic Disease Surveillance System, a collaborative network of provincial and territorial surveillance systems.(130) This surveillance system enhances the scope of data on chronic diseases in Canada and supports the planning of health resources and the development of health policies and programmes. It collects data on all residents who are eligible for provincial or territorial health insurance and can generate national estimates and trends over time for over 20 chronic diseases, including:

- **Cardiovascular diseases**, for example heart failure, hypertension, ischemic heart disease and stroke.
- **Chronic respiratory diseases**, for example asthma and chronic obstructive pulmonary disease.
- **Mental illnesses**, for example mood and anxiety disorders and schizophrenia.
- **Diabetes**

- **Musculoskeletal disorders**, for example osteoarthritis, juvenile idiopathic arthritis, osteoporosis, and osteoporosis-related fractures.
- **Neurological conditions**, for example dementia, epilepsy, multiple sclerosis, and Parkinson's disease.

Data for the Canadian Chronic Disease Surveillance System are sourced from provincial and territorial health insurance registry records which are linked using a unique personal identifier to the corresponding physician billing claims, hospital discharge abstract records and prescription drug records.(130)

### 5.2.1.3 The Canadian Institutes of Health Research

The Canadian Institutes of Health Research is Canada's premier federal agency for health research. It funds and supports a number of important initiative relating to health information and data collections.(131)

### 5.2.1.4 Statistics Canada

Established in 1971, Statistics Canada is Canada's central statistical office.(132) Its functions include: collecting, compiling, analysing and publishing statistical information on the economic, social and general conditions of Canada and its people; operating numerous health-related surveys and statistical programmes such as the Canadian Health Measures Survey and the Canadian Cancer Registry; and developing methodologies and techniques related to statistics and survey design.(132)

### 5.2.1.5 Canadian Institute for Health Information

Established in 1994, and funded through the federal, provincial and territorial governments, the Canadian Institute for Health Information (CIHI) is an independent, not-for-profit organisation with a legal mandate to:

- collect, analyse and disseminate information on healthcare, health system performance and population health across Canada
- provide comparable and actionable data and information that are used to accelerate improvements in healthcare, health system performance and population health across Canada.(133)

CIHI plays a significant role in the overall management of national data collections in Canada and works to improve the quality and availability of Canadian health information. It has a mandate to collect, analyse and disseminate information on healthcare, health system performance and population health across Canada and as such, is recognised as the key national custodian of administrative health data collections.

At the time of writing, CIHI maintains approximately 30 data holdings relating to different aspects of the health system, including:

- **Hospital care**, for example the Hospital Morbidity Database, the National Rehabilitation Reporting System.
- **Community care**, for example the Home Care Reporting System.
- **Specialised care**, for example the Hospital Mental Health Database, the Canadian Organ Replacement Register.
- **Pharmaceutical**, for example the National Prescription Drug Utilization Information System Database.
- **Patient experience**, for example the Canadian Patient Experiences Reporting System.
- **Patient safety**, for example the National System for Incident Reporting.
- **Health workforce**, for example the National Physician Database, the Health Workforce Database.
- **Spending**, for example the National Health Expenditure Database, the Canadian Patient Cost Database.
- **International comparisons**, for example the Commonwealth Fund Survey.
- **Access and wait times**, for example Wait Times.(134)

### 5.2.1.6 Canada Health Infoway

Established in 2001, Canada Health Infoway (Infoway) is a not-for-profit federally-funded organisation that has a mandate to:

- accelerate the development, adoption and effective use of eHealth solutions
- work with partners, including the governments and industry stakeholders, such as technology vendors, provincial electronic health agencies, industry associations and healthcare organisations, to strategically invest, support and accelerate the development and use of eHealth in Canada.(135)

All federal, provincial and territorial governments in Canada are Infoway members.

### 5.2.1.7 Health Data Research Network Canada

HDRN Canada was established as a not-for-profit entity in 2020 to connect individuals and organisations across the country to share expertise, and identify opportunities for collaboration and to maximise the use and potential of Canada's provincial, territorial, and pan-Canadian data assets and expertise.(124) It is made up of multiple organisations that hold and manage population-wide health and health-related data infrastructure that is used by analysts and researchers across Canada. The specific objectives of HDRN Canada are to:

- connect data infrastructure across provinces and territories by building on existing expertise, structures and processes

- support knowledge creation that is informed by local connections between researchers, policy-makers and decision-makers, building on the strength of provincial resources
- make research more efficient and timely by establishing research data infrastructure and processes for multi-jurisdictional studies
- increase the robustness of studies, and the capacity of researchers and policy and or decision-makers to use data by bringing together experts from across Canada to establish and implement common approaches to multi-province analyses.(124)

### 5.2.2 Legislative context

There are a number of pieces of legislation which provide a legal basis for the operation of health and social care data collections in Canada (Table 6).

**Table 6: Summary of relevant legislation in relation to the operation of health and social care data collections in Canada**

| Name of Act | Description |
|---|---|
| Statistics Act 1971 | Provides Statistics Canada with a legal mandate to meet the statistical needs of government and the private sector for research, policy formulation, decision making and general information; sets out the position of Chief Statistician.(136) |
| Canada Health Act 1984 | Outlines the responsibilities of the provincial governments in relation to the delivery of health services and the information they need to manage the health systems.(137) |
| Privacy Act 1985 | Governs how federal government institutions handle personal information that they collect, use and disclose; gives Canadians the right to protection of that information against unauthorised use.(138) |
| Access to Information Act 1985 | Gives Canadian citizens and corporations located in Canada the right to access information contained in federal government records.(139) |
| Personal Information Protection and Electronic Documents Act 2000 | Governs how private sector organisations across Canada handle personal information in the course of their commercial activity.(140) |

All provinces and territories have Acts in place that set clear and detailed rules regarding the collection, use and disclosure of personal health information in their jurisdiction. These include:

- Alberta Health Information Act
- British Columbia Freedom of Information and Protection of Privacy Act
- Manitoba Personal Health Information Act
- New Brunswick Personal Health Information Privacy and Access Act
- Newfoundland Personal Health Information Act
- Northwest Territories Health Information Act
- Nova Scotia Personal Health Information Act
- Nunavut Access to Information and Protection of Privacy Act
- Ontario Personal Health Information Protection Act (PHIPA)
- Prince Edward Island Health Information Act
- Quebec Act respecting Access to documents held by public bodies and the protection of personal information
- Saskatchewan Health Information Protection Act
- Yukon Health Information Privacy and Management Act.

#### 5.2.2.1 Legislation, agreements, and disclosing Data to CIHI

CIHI is authorised under Ontario's Personal Health Information Protection Act (PHIPA) to receive personal health information as a prescribed entity. As a prescribed entity under PHIPA, CIHI can receive personal health information from health information custodians in Ontario (such as the Ministry of Health, hospitals, and doctors) without individual consent, for the purpose of analysing and compiling statistical information for the management of the health system. This status as a prescribed entity is also important for other jurisdictions, as Ministries of Health and other data providers across the country acknowledge CIHI's status as a prescribed entity under PHIPA as a reflection of its stringent privacy and security programme.(141)

In addition, CIHI enters into data-sharing agreements with data providers from across the country. These agreements facilitate the flow of data to CIHI and support CIHI's mandate. In some cases, such as when a request is for a significant volume of record-level data and when the need for the data is ongoing or related to a broader programme of work, CIHI may also enter into a data-sharing agreement or another legally binding instrument with a data requestor.(141)

## 5.3 Guidance and frameworks to support improvements in data quality and information governance

### 5.3.1 CIHI's Health Data and Information Governance and Capability Framework 2020

In 2020, CIHI published its first edition of an overarching data governance and capability framework,(142) along with a toolkit to assist with its implementation.(143) The audience for this framework is health information organisations in Canada, such as ministries and departments of health, health agencies and authorities, health delivery organisations and health-related research organisations. It consists of four subject areas, each covering a subset of 28 capabilities which are classified as core, foundational, supplemental, or enabling (Table 7).

**Table 7: Subject areas of CIHI's Governance and Capability Framework**

| |
|---|
| **Strategy and Governance** |
| Capabilities within this subject area provide the overall direction, accountability and oversight for an effective health data and information programme, including a clearly articulated strategy, governance and accountability models, and processes to monitor and report compliance. |
| **Policies and processes** |
| Capabilities within this subject area define activities for appropriate collection, processing, analysis and sharing of trusted health data and information. They include data management, quality, conformance, privacy, security, access and partnerships that collectively define the way the organisation operates. |
| **Assets and standards** |
| Capabilities within this subject area establish the health data and information assets required by the policies and processes to enable strategic and operational outcomes, including enterprise data assets, standards, data models and analytics insights that form the collective data foundation of the organisation or network. |
| **People and knowledge** |
| Capabilities within this subject area empower people to facilitate and evolve policies, processes, designs and governance to be effective and sustained. They include engagement, education and internal and external communication. |

The current version of the framework, along with its companion toolkit, enables health information organisations to:

- self-assess their current health data and information governance capabilities
- envision a related target state that will meet the needs of the organisation
- prioritise areas of improvement for investment
- develop an effective and pragmatic action plan for improvement informed by commonly used health data and information practices and artefacts.

### 5.3.2 CIHI's Information Quality Framework 2017

Data quality is embedded into CIHI's vision and mandate. While the responsibility for data quality falls to the data suppliers in each jurisdiction, CIHI recognises that improving data and information quality is a collaborative effort and works with its data suppliers to support improvement activities.(144)

CIHI's Information Quality Framework, published in 2017, evolved from and replaces CIHI's previous Data Quality Framework (which was introduced in 2001 and updated in 2009).(145) The new framework, based on international standards,(146,147) is broader in scope, providing an overarching structure to integrate all quality-related activities across CIHI. It signifies an important shift in focus from data to information quality and to managing not just the quality of the data coming into CIHI but also the quality of the information products that CIHI releases.(144)

The Information Quality Framework provides a structure for CIHI's information quality management practices. It encompasses, and draws together, a range of processes, practices and tools. The framework is guided by CIHI's five quality dimensions (relevance; timeliness and punctuality; comparability and coherence; accessibility and clarity; and accuracy and reliability) and quality principles.(145)

The information life cycle (Capture, Submit, Process, Analyse, and Disseminate) is central to the framework, and describes the steps for turning data into information. The four components of the framework (foundation, activities, outputs and outcomes) represent different aspects of quality management that are required to manage quality within the information life cycle:

1. The **foundation** component of the framework consist of resources, tools and practices that provide a strong base for operationalising quality assurance activities across the organisation and for understanding, assessing and communicating the quality of data and information.
2. The **activities** component of the framework includes all prevention, monitoring, evaluation, and improvement activities that are carried out to improve quality.

3. The **outputs** component of the framework describes the key artefacts produced in the course of conducting quality assurance activities, including: quality reports and indicators; improvement action plans; and metadata.
4. The **outcomes** component of the framework describes the desired impacts of using the elements within the framework, including increased knowledge, increased trust, increased use and increased quality.(145)

### 5.3.3 CIHI's Data Source Assessment Tool

CIHI's Data Source Assessment Tool provides a set of criteria to assess the quality of CIHI's data sources across the five dimensions of quality, and enables appropriate determination of a given data collection's quality or fitness for use.(148)

This tool contains two sets of criteria:

1. A **general set** for assessing the quality of all types of data sources. It is a comprehensive set of criteria and is designed to be used flexibly, as not all criteria will apply to all data sources.
2. A **supplementary set**, to be used in addition to the general set, for assessing the quality of survey- or sampling-specific components of data sources that contain survey results or sample data.

The results of an assessment using this tool can guide appropriate data use and inform analytical plans, and they can also contribute to the creation of key quality indicators and other metrics for reporting.(148)

## 5.4 Other national arrangements for health information

### 5.4.1 Health identifiers

Currently, there is no pan-Canadian unique identifier. Unique health card numbers are utilised within each jurisdiction, with each person possessing an individual health insurance number. These numbers are linked to individuals' health cards, and are used for public healthcare and public healthcare insurance purposes only.

### 5.4.2 Data linkage

Due to the lack of a pan-Canadian unique identifier, linkage across provinces and territories is challenging.(7) One of the goals of HDRN Canada and is to facilitate data linkage and expand the types of data and linkages that are available, through providing the necessary infrastructure.(124,125)

In 2015, CIHI implemented a linkage standard to be used for the linkage of records created in 2010-2011 or later. This standard uses encrypted health card numbers and the issuing province for record linkage (linkage keys). For the linkage of records that do not include an encrypted health card number and the province or territory that issued the health card numbers, the linkage mechanism is determined on a case-by-case basis.(149)

For CIHI data holdings, individuals or organisations can request data from CIHI to facilitate health or health services research and or analysis. For projects that involve data linkage, either within a single CIHI data holding, across CIHI data holdings, or between one or more CIHI data holdings and an external cohort, linkage approval must be obtained from the CIHI Privacy, Confidentiality and Security Committee.(150)

### 5.4.3 Data dictionary

Canada has no central repository for metadata standards; however, each national data collection has its own data dictionary to ensure consistent data is submitted from all data providers. For example, data dictionaries and database manuals for each of CIHI's data holdings are available on the CIHI website. In addition, the CIHI Reference Data Model (CRDM), last updated in 2021, includes a data dictionary.(151) The CRDM outlines data concepts (or categories of data) that are of interest to CIHI (such as people, things, places or events), relationships between the concepts, and core attributes (or key information) for each concept. The metadata associated with the CRDM, including the concept definitions, core attribute definitions, value domains, and concept relationship descriptions are outlined in detail in the CRDM data dictionary. The CRDM contributes to CIHI's goal of having shared terminology and meaning across its data holdings, which will facilitation better integration and linkage of datasets as well as increased use of health information in health system decision-making.(151)

### 5.4.4 Classification and terminology

CIHI is responsible for clinical classifications and setting the standards for morbidity reporting across Canada. Classifications currently used in Canada include:

- ICD-10 - Canadian modification (ICD-10-CA)
- The Canadian Classification of Health Interventions.(152,153)

The responsibility for setting standards for clinical terminologies lies with Canada Health Infoway. Clinical terminology solutions used in Canada include:

- SNOMED CT
- Pan-Canadian Observation Code Database/Logical Observation Identifiers Names and Codes (pCLOUD/LOINC).(154)

## 5.5 Future plans

There are a number of proposed legislative changes that will have an impact on the health information landscape in Canada. The federal government has proposed amendments to the Personal Information Protection and Electronic Documents Act,(141) while the province of Quebec is amending its privacy legislation, making it more stringent and more prescriptive than the EU's GDPR.(141)

The scope of HDRN Canada is growing as it works with a number of partners to identify COVID-19 data gaps and needs in order to further support multi-jurisdictional research. It is also engaging with the Canadian Institutes of Health Research, national cohort studies, and networks such as the Canadian Primary Care Sentinel Surveillance Network to accelerate Canada's response to COVID-19. A particular focus of HDRN Canada is identifying opportunities to facilitate more timely and complete access to: health administrative data; data standardisation, integration and linkage across jurisdictions; and filling data and information gaps.(124)

Following the publication of its first report on the current state of health data in Canada,(122) the Pan-Canadian Health Data Strategy Expert Advisory Group will continue its work to progress the strategy, including targeted consultations and online engagement activities.(155)

## 5.6 Summary of Canada’s approach

### Legislative context and governance arrangements

Responsibility for the administration of health and social care services and for the respective data collections lies primarily with the provincial and territory governments. All provinces and territories are mandated to provide data for certain pan-Canadian data collections, including to the Canadian Institute for Health Information (CIHI) and the Public Health Agency of Canada.

### Guidance and frameworks for data quality and governance

CIHI is internationally regarded as a leader in data quality, and its Information Quality Framework was published in 2018, providing a structure for CIHI’s information quality management practices. Following calls for a strategic and coherent approach to organising and governing Canada’s health data assets, CIHI’s Health Data and Information Governance and Capability Framework, along with a toolkit to assist with its implementation, were published in 2020. The Public Health Agency of Canada has its own Data Quality Framework.

### Unique identifiers and data linkage

In the absence of a pan-Canadian unique health identifier, there are well-established systems in place for probabilistic data linkage.

### National data dictionary

Canada has no national data dictionary or central repository for metadata standards; however, each national data collection has its own data dictionary to ensure consistent data is submitted from providers.

### Classification and terminology

CIHI is responsible for clinical classifications and setting the standards for morbidity reporting across Canada, while Canada Health Infoway is responsible for setting standards for clinical terminologies.

### Current initiatives

Health Data Research Network Canada (HDRN Canada) was established in 2020 in an attempt to connect individuals and organisations across the country to maximise the use and potential of Canada’s provincial, territorial, and pan-Canadian data assets and expertise. In addition, an Expert Advisory Group has been tasked with developing a Pan-Canadian Health Data Strategy that involves establishing a protocol for improving Canada's ability to collect, protect and use health data so that it may inform healthcare and public health system adaptation and improve processes for data sharing.

# 6 England

## 6.1 Introduction

**Population:** Approximately 55.0 million.(156)

**Government:** England is a constituent country of the United Kingdom (UK) which is a constitutional monarchy.(157) The UK Government funds England's national health service (NHS), primarily through general taxation (national insurance). Local governments (county councils and district, borough or city councils) are responsible for the organisation of a range of other services, including social care services, in defined areas of England.

**Healthcare:** Healthcare in England is primarily delivered through the NHS which entitles English residents to healthcare that is 'free at the point of use'. A government agency, NHS England, oversees and allocates funds to Integrated Care Boards, which govern and pay for NHS services at the local level.(158) Local governments or local authorities are primarily responsible for social care services which are delivered by a wide range of organisations. Adult social care services are not free of charge for all. Further, general practice and community care is largely provided through a network of GPs, community nursing and associated community health and care professionals.

## 6.2 Legislative context and organisational governance arrangements

### 6.2.1 Key organisations, committees and appointments

The Department of Health and Social Care is the government department with responsibility for health and social care policy in England. It has a number of agencies and partner organisations, also known as arm's-length bodies (ALBs), that have various roles and functions in relation to the health and social care system and national health and social care data collections.(159) ALBs include a wide range of public bodies which have various roles that are set out in law. They are categorised as executive agencies, non-departmental public bodies, and non-ministerial departments.(160)

For the purpose of this review, the six most relevant ALB's are:

- NHS England
- NHS Digital
- UK Health Security Agency

- Office for Health Improvement and Disparities
- Health Research Authority
- Care Quality Commission

In addition, the Data Alliance Partnership Board (DAPB) and National Data Guardian for Health and Social Care are also relevant in terms of arrangements for national health and social care data. Details will be provided in 6.2.1.7 and 6.2.1.8 respectively.

#### 6.2.1.1 NHS England

NHS England is an executive non-departmental public body which leads and oversees the funding, planning and delivery of the NHS in England. Large volumes of data are collected everyday across NHS services and are used to compile national data collections that are used for various purposes.(161)

Within NHS England, the Chief Data Officer's team is responsible for the development and delivery of a strategy for the use of data at every level of the organisation. The Secondary Uses Service (SUS) is the primary, comprehensive repository for healthcare data in England which enables a range of reporting and analyses to support the NHS in the delivery of healthcare services.

SUS information is also useful to commissioners and providers of NHS-funded care for 'secondary' purposes (purposes other than direct or 'primary' clinical care), such as:

- healthcare planning
- commissioning of services
- national tariff reimbursement
- development of national policy

SUS is a secure data warehouse that stores this patient-level information in line with national standards. Access to SUS is managed using role-based access controls which grant appropriate access levels to identifiable, anonymised or pseudonymised data based on the user's job role.(162)

#### 6.2.1.2 NHS Digital

NHS Digital is described as 'the national digital, data and technology delivery partner for the NHS and social care system'.(163) It has responsibility for standardising, collecting and publishing data and information from across the health and social care system in England. NHS Digital has also been tasked with delivering many of the commitments set out in the national strategy, 'Personalised Health and Care 2020', which set out a framework for how data and technology could be used to transform outcomes for patients.(164) It also maintains NHS Spine which supports the IT infrastructure for the health and social care system in England.(165)

NHS Digital collects and compiles data from almost every provider of health and social care in England, including from care records, systems and organisations. It currently maintains approximately 234 national data collections covering many aspects of health and social care,(166) including:

- **Medicines**, such as the Medicines Dispensed in Primary Care data collection and Antibiotic Consumption Data
- **Waiting times**, such as the Diagnostic Waiting Times and Activity data collection, the Referral to Treatment Waiting Times data collection, and the Cancer Waiting Times data collection
- **Hospital activity,** such as the Quarterly Bed Availability and Occupancy data collection**,** the Monthly Referral Return data collection, the Monthly Situation Reports data collection
- **Mental health**, such as the Serious Mental Illness data collection
- **Care experience,** such as the Friends and Family Test data collection
- **Chronic diseases,** such as the National Diabetes Audit
- **Immunisation,** such as the Cover of Vaccination Evaluated Rapidly surveillance scheme
- **Smoking,** such as the Smoking Status at Time of Delivery, the Stop Smoking Services, and the Tobacco Dependence data collections
- **Alcohol,** such as the Alcohol Dependence data collection
- **Workforce,** such as the National Workforce Data Set and the Staffing Nursing Midwifery and Care Staff data collection.

Through data visualisation and online dashboards, NHS Digital provides secure access to aggregate data for a variety of public and private uses.(167) It also produces over 300 open-data and statistical publications annually. These publications provide insights into the health and wellbeing of the population of England, and inform research, policy development and operational planning. Publications are issued in accordance with 'The Code of Practice for Statistics' which sets the standards that producers of official statistics should follow. The framework for the Code of Practice is based on three pillars – trustworthiness, quality and value.(168) Each pillar contains a number of principles and detailed practices that producers commit to when producing and releasing official statistics.

The Data Standards Assurance Service within NHS Digital is responsible for ensuring that every data collection is efficient and needed, reducing the burden on health and social care providers wherever possible. This is deemed to be necessary given the number of data collections covering many aspects of health and social care in England.(169) More recently, the need to reduce 'data burden' on health and social care staff was highlighted in the Department of Health and Social Care's policy paper on health and social care data.(170)

#### 6.2.1.3 UK Health Security Agency

The UK Health Security Agency is responsible for surveillance and reporting of infectious diseases in England. It is tasked with planning, preventing and responding to external health threats, and providing intellectual, scientific and operational leadership at national and local level, as well as on the global stage.(171)

#### 6.2.1.4 Office for Health Improvement and Disparities

The Office for Health Improvement and Disparities (OHID) is responsible for building the scientific evidence, leading and developing the policy, and delivering core services with the aim of improving health, preventing poor health, and tackling health disparities across England. OHID is tasked with leading on public health data management and analysis, publishing official statistics and statistical reports. It is also responsible for the surveillance of non-communicable disease in England.(172)

#### 6.2.1.5 Health Research Authority

The Health Research Authority is an independent ALB of the Department of Health and Social Care.(173) It has various responsibilities relating to the regulation and governance of health and social care research across the United Kingdom. Within the Health Research Authority, the Confidentiality Advisory Group provides independent advice to researchers and others who intend to use confidential patient information without consent. It also provides advice to the Secretary of State for Health for non-research uses of confidential patient information.

#### 6.2.1.6 Care Quality Commission

Care Quality Commission is the independent regulator of health and adult social care in England. Their remit is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and encourage care services to improve.

#### 6.2.1.7 Data Alliance Partnership Board

The Transformation Directorate at NHS England brings key national organisations that use health and social care data together into the Data Alliance Partnership. The DAPB supports Data Alliance Partnership member organisations achieve its goals. DAPB is a cross health and social care governance board which acts with delegated authority from the Data Alliance Partnership and directly from the Secretary of State as the main governance route through which data and standards requirements are agreed and priorities assigned. Some of its responsibilities include:

- identifying and reducing duplication of data collections;
- increasing the benefits from data already held by making data accessible for legitimate purposes within existing legislation;
- increasing transparency by making clear what data the health and care system holds and how it is used;
- ensuring there is a legal basis for data to be collected;
- approving information standards, data collections and extractions to be used across the health and adult social care system in England;
- maintaining a list of approved national information standards and data collections, including extractions for use across the heath and adult social care system.(174)

The DAPB operating remit covers the Department of Health and Social Care, all ALBs, health and adult social care services, and structures its membership to support this remit. A main focus is on improving the interface between health and social care, and supporting the links between community health and primary care.

#### 6.2.1.8 The National Data Guardian for Health and Social Care

The role of the National Data Guardian (NDG) for Health and Social Care in England was established in November 2014 to be an independent champion for patients and the public on confidential health and social care information. Under section 1 (2) of the Health and Social Care (National Guardian) Act 2018,(175) the NDG has a remit to provide guidance about the processing of health and adult social care data in England. Although sponsored by the Department of Health and Social Care, the NDG acts as an independent advocate for patients and service users about how their data is used. It does not hold any regulatory function or enforcement powers. The current NDG was appointed in March 2021 and is supported by an independent group of experts, known as the NDG panel, which meets 12 times each year. The first review completed by the NDG in 2016 made recommendations aimed at keeping health and care information secure and ensuring the public can make informed choices about how their data used.(176) A set of new data security standards for the NHS and social care were also proposed in this review and have since been widely implemented (section 6.3.1).

### 6.2.2 Relevant legislation

There are a number of pieces of legislation which provide a legal basis for the operation of health and social care data collections in England (Table 8).

**Table 8 Summary of relevant legislation in relation to the operation of health and social care data collections in England**

| Name of Act | Description |
|---|---|
| Health and Care Act 2022 | Establishes NHS England as a single regulatory body responsible for overseeing the funding, planning, delivery, transformation, and performance of NHS healthcare in England. Includes a number of provisions that have implications for health information and national data collections, as follows:<br>▪ Allows for the publication of mandatory information standards relating to the processing of information (including its transfer, collection, and storage) and extends the provisions to private providers. It now requires organisations to comply with the standards.<br>▪ Allows health and social care public bodies to require anonymous information from other health and social care public bodies and from others who are commissioned by public bodies to provide health and adult social care services.<br>▪ Allows NHS Digital to require data from private providers of healthcare (when directed to do so by the Secretary of State for Health and Social Care).<br>▪ Introduces a new power for the Secretary of State to require regulated adult social care providers to provide information relating to themselves, their activities, or individuals they have provided care to. It enables the powers to be delegated to NHS Digital or another organisation.<br>▪ Introduces powers for the Secretary of State to impose a financial penalty to those private providers who fail to comply with an information standard, fail to comply with a requirement to provide information, or provide false or misleading information in response to such a requirement.<br>▪ Enables NHS Digital to collect a range of information about the use of medicines and their effects in the UK and hold this data in one or more information system(s).(177) |
| Data Protection Act 2018 | The Data Protection Act is the UK's implementation of GDPR.(25,178)It allows personal data to be shared between those offering care directly to patients but it protects patients' confidentiality when data about them are used for other purposes. These secondary uses of data are acknowledged as being essential in order to run a safe, efficient and equitable health service. They include reviewing and improving the quality of care provided; researching what treatments work best; commissioning clinical services; and planning public health services. |
| Health and Social Care (National | Placed the National Data Guardian role on a statutory footing and granted it the power to issue official guidance about the processing of health and adult social care data in England.(175) |

| | |
|---|---|
| Data Guardian) Act 2018 | |
| Care Act 2014 | Provides a legal basis for processing confidential patient information where approval has been granted by the NHS Health Research Authority.(179) |
| Health and Social Care Act 2012 | Provides the Health and Social Care Information Centre (which trades under the name NHS Digital) with a legal basis for requiring the submission of data.(180) Sets the legal framework for NHS Digital's collection and dissemination of data. Prohibited NHS Digital from releasing data to other bodies that is weakly pseudonymised, unless there are controls to prevent re-identification and in circumstances where the data inadvertently identifies an individual; there must be a clear legal basis for this. Has been superseded by the Health and Care Act 2022 (see above). |
| Access to Health Records Act 1990 | Establishes a right of access to health records by the individuals to whom they relate and other persons; to provide for the correction of inaccurate health records and for the avoidance of certain contractual obligations; and for connected purposes.(183) |

## 6.3 Guidance and frameworks to support improvements in data quality and information governance

A number of resources have been developed to support information governance regarding health and social care data in England, including toolkits, policies and codes of practice.

### 6.3.1 The National Data Guardian's Data Security Standards

The NDG's 10 Data Security Standards were set out in its 'Review of Data Security, Consent and Opt-Outs'.(176) The data security standards are clustered under three leadership obligations to address people, process and technology issues,(184) as follows:

1. **People:** ensure staff are equipped to handle information respectfully and safely, according to the Caldicott Principles.
2. **Process:** ensure the organisation proactively prevents data security breaches and responds appropriately to incidents or near misses.
3. **Technology:** ensure technology is secure and up-to-date.

### 6.3.2 The Caldicott Principles

The Eight Caldicott Principles are guidelines applied widely across the field of health and social care information governance to ensure that people's data is kept safe and used appropriately (see Appendix 3). One of the principles recognises that the duty to share information for individual care is as important as the duty to protect patient confidentiality. This recognises the importance of sharing information, within the framework set out by the principles, both to support safe and effective care but also for secondary use by national data collections which contribute to the overall delivery of health and social care or serve wider public interests.(185)

In 2021, the NDG published guidance for health and social care organisations about the appointment of Caldicott Guardians, their role, responsibilities, competencies, knowledge, training, and continuous professional development.(186) A Caldicott Guardian is responsible for protecting the confidentiality of health information in an organisation and making sure it is used appropriately. All NHS organisations and local authorities which provide health and social care services must have a Caldicott Guardian and include their contact details on the Caldicott Guardian register which is maintained by NHS Digital. The UK Caldicott Guardian Council is the national body for Caldicott Guardians and operates as a sub-group of the NDG expert panel. The UK Caldicott Guardian Council is also responsible for encouraging consistent standards and training, as well as developing guidance and policies relating to the Caldicott principles.

### 6.3.3 Data sharing

Safe haven is a term used to explain an agreed set of arrangements that are in place in an organisation to ensure personal information (for example, patients' and staff information) can be communicated safely and securely. All NHS organisations need to have a safe haven policy to ensure the privacy and confidentiality of information and to adhere to the legal restrictions placed on them, especially concerning sensitive information (for example, a person's medical condition). NHS organisations must document the procedures they have in place to ensure confidential information is only accessed by relevant staff. The Caldicott Guardian for the organisation must approve this policy.(187) Under the NHS Act 2006,(181), an Accredited Safe Haven is an accredited organisation or part thereof, which is contractually and legally bound to process data in ways that prevent the identity of individuals to whom the data relates, from being identified. Linkage of identifiable data from more than one organisation for any purpose other than direct care must only be done within an Accredited Safe Haven, such as NHS Digital.

The data sharing activities of health and social care organisations are also informed by the 'Data Sharing Code of Practice', which was published by the Information Commissioner's Office in 2021, and provides practical advice to businesses and organisations on how to carry out responsible data sharing in compliance with data protection law.(188) It is aimed at all organisations and individuals that are responsible for sharing personal data. The NHS Information Sharing policy, published in 2019, outlines the policy and high-level procedures for information sharing. This policy sets out the requirements placed on NHS England staff when sharing personal information within the NHS and between the NHS and other bodies.

### 6.3.4 NHS Digital's approach to data quality

NHS Digital has a statutory data quality role and undertakes a range of data quality activities, including setting and maintaining data standards. The Data Quality team within NHS Digital assesses the quality of data submitted by providers. A data quality steering group, made up of ALBs, meets regularly to discuss changes to the way data quality is measured, and investigates ways to improve data quality throughout the system.

NHS Digital's 'Data Quality Assurance Framework for Providers'*,* published in 2020, sets out how data quality assurance products and services would be developed to support national data collections and the NHS provider organisations required to collect and submit the data.(189) The framework covers five main themes: oversight, process, people, systems, and measures. The core component of the Data Quality Assurance Framework is to enable provider organisations to identify and act upon quality issues in the data.

Data quality across NHS Digital is supported by the publication of the Data Quality Maturity Index (DQMI) that applies standard data quality dimensions to critical data items across a range of national data collections.(190) The DQMI is a monthly publication and has been incorporated into key contractual and performance frameworks to enable providers, commissioners, and regulatory bodies to monitor data quality at a provider and national level. The Data Quality team summarise findings within the DQMI and report findings on a quarterly basis.(191) If poor data quality is identified by the DQMI, the data quality team work with providers to encourage greater attention to data collection and submission. In addition to the DQMI, a number of bespoke data quality strategies are implemented within specific data collections periodically.

The Data Security and Protection Toolkit Guidance has been developed to support NHS provider organisations to establish data quality processes locally that align with the NDG's Data Security Standards, including Assertion 1.7 that *"Data quality metrics and reports are used to assess and improve data quality."*(192) The Data Security and Protection Toolkit is an online self-assessment tool that enables organisations to measure and publish their performance against the standards. All organisations must use this if they have access to NHS patient data and systems in order to provide assurance that they are practising good data security and that personal information is handled correctly.(193)

### 6.3.5 UK Policy Framework for Health and Social Care Research

The 'UK Policy Framework for Health and Social Care Research' sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards. The document is aimed primarily at individuals and organisations with responsibilities for the management and conduct of research. It is a benchmark for good practice that the management and conduct of all health and social care research in the UK are expected to meet.(194)

### 6.3.6 Information management standards

There are no national information management standards that are specific to health and social care data collections in England. NHS Digital's internal audit assurance team and Quality Council look for evidence of compliance with International Organization for Standardization (ISO9001:2015 Quality Management Systems) standards. The 'NHS Records Management Code of Practice', published in 2021, also provides guidance on how to keep records, including how long to keep different types of records.(195)

## 6.4 Other national arrangements for health information

### 6.4.1 Health identifiers

An NHS number is given to every citizen registered with the NHS in England. It is allocated at birth for England born citizens, or upon registration at GP practice if not born within England. The NHS number is used to identify individuals across all NHS provided services and is incorporated into all new electronic systems within the NHS.

### 6.4.2 Data linkage

The Chief Data and Analytics Officer Directorate within NHS England is responsible for the linkage of data held by NHS England. This is carried out primarily by the Data Services teams. In addition, every NHS Trust and Integrated Care System has their own business intelligence teams who carry out data linkage activities.(196)

Linkage of NHS data collections is facilitated through the use of the NHS number. When it is not possible to use the NHS number for linkage, other data linkage methods are used. NHS Digital makes use of an algorithm known as the Master Person Service to enable linkage across multiple data collections.(197) Specific assets may also be created using previous linkage approaches for consistency with prior releases, or following bespoke criteria to meet particular needs. Linked data assets provided for research use are pseudonymised once linkage has been completed.(198) Individuals have the option to opt-out of their information being used for research and planning through the 'national data opt-out'. If they choose to do so, their personal data will not be used for purposes beyond their individual care.(196)

NHS Digital continues to investigate how data linkage methods across outputs can be improved and standardised. This work follows UK Government guidance on best practices in data linkage.(199) In addition, the list of approved national data collections that is being developed and maintained by the DAPB will improve data linkage capabilities through the development of metadata tools.

The Data Collections Service, provided by NHS Digital, manages requests for new, and or changes to, national data collections. The service works with commissioners of data collections to establish requirements, advise on appropriate data collection methodologies and platforms, develops and sets up collection forms and templates, to aid submission of data, and issues coordinated communications to data providers on new and/or changes to data collections.

The NHS Data Access Request Service (DARS), which is managed by NHS Digital, offers clinicians, researchers and commissioners the data that is required to help improve NHS services. The DARS team only share special categories of personal data to organisations that have the appropriate legal basis according to data protection laws and that such data sharing will be of benefit to health and social care.(200) There is a checklist, which individuals and organisations can use, to ensure they meet strict data governance standards required to access data.(201)

### 6.4.3 National data dictionary

The NHS Data Model and Dictionary provides a reference point for approved content used in data sets, data collections and information standards to support health care activities within the NHS. It has been developed for everyone who is actively involved in the collection of data and the management of information in the NHS.(202) The content of the NHS Data Model and Dictionary is used across NHS IT systems, including in data warehouses, Patient Administration Systems, and reference data tables in the Secondary Uses Service within NHS England.

The NHS Data Model and Dictionary Service uses the 'Big Data Institute Oxford University' who provide the 'Mauro Data Mapper tooling' and expertise to publish the NHS Data Model and Dictionary.(203) The Mauro Data Mapper (previously known as the Oxford Metadata Catalogue) is used to develop and maintain linked, versioned descriptions of data standards, datasets, and questionnaires. These descriptions capture essential structure and context together with a detailed account of each variable, comprising: name, natural language definition, data type, and multiplicity.

### 6.4.4 Classifications and terminologies

NHS Digital is responsible for clinical classifications and terminologies use across English health services, including:

- ICD-10
- OPCS Classification of Interventions and Procedures (OPCS-4)
- SNOMED-CT
- Healthcare Resource Groups (HRGs)

NHS Digital is the UK National Release Centre for SNOMED-CT and the UK World Health Organisation – Family of International Classifications (WHO-FIC) Collaborating Centre.(204)

A range of messaging standards are currently in use for health and social care data exchanged for numerous purposes, including Health Level Seven (HL-7).

The National Disease Registration Service (NDRS) was integrated within NHS Digital's portfolio of functions in 2021 and manages the National Cancer Registration and Analysis Service (NCRAS) and the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS). For these population based registration services data is collected, curated and quality-assured from every patient in England diagnosed and/or treated with these registerable conditions.

## 6.5 Future plans

The NHS Long-term Plan makes specific reference to the use of data and digital technology, under 'Making better use of data and digital technology'. NHS England is addressing this by making improvements with respect to the planning and delivery of services based on the analysis of patient and population data.(205) A review, commissioned by the UK Government's Department of Health and Social Care, was published in 2022 and identified ways of delivering better, broader and safer use of NHS data for analysis and research.(206) Key recommendations of this review, known as the 'Goldacre Review', centre on platforms and security; modern open working methods for NHS Data; data curation and knowledge management; NHS Data Analysts; Governance; and approaches and strategy.

'Data Saves Lives', the data strategy for health and social care, published in June 2022, sets out the UK government's plans to harness the potential of data in health and care, while maintaining the highest standards of privacy and ethics.(170) Plans to increase data linkage capabilities are referenced within this strategy. The strategy also outlines progress on data standards work across government, with learning shared across health and social care. This includes the Government Data Quality Framework,(207) and the work of the Data Standards Authority which works to improve how the public sector manages data.(208)

The ‘Data Saves Lives’ strategy also outlines the policy development and implementation of Secure Data Environments. The use of Secure Data Environments for access to NHS health and care data has been identified as being key to supporting the highest standards of information governance, transparency and security by removing the need for data to be physically shared between different users. It is anticipated that they will allow for a range of health and care data sources to be linked at scale and facilitate the analysis of linked data in a standardised and collaborative way. The NHS England Transformation Directorate, together with the Department of Health and Social Care is bringing together partners across the system to define the role and function of Secure Data Environments in the health and care system.

## 6.6 Summary of England's approach

### Legislative context and governance arrangements

NHS Digital is the national provider of information, data and IT systems for health and social care and has a statutory responsibility for collecting data from across the health and social care system. Recent developments in the legislative context include the updating of data protection legislation, and the enactment of the Health and Care Act 2022.

### Guidance and frameworks for data quality and governance

The National Data Guardian's Data Security Standards and the Caldicott Principles are applied widely across health and social care services to ensure that people's data is kept safe and used appropriately. NHS Digital's Data Quality team assesses the quality of data submitted by providers, summarising findings within the Data Quality Maturity Index. The Data Security and Protection Toolkit has been developed to support NHS provider organisations to establish data quality processes locally that align with the Data Security Standards.

### Unique identifiers and data linkage

All users of NHS services are assigned an NHS number at the time of birth or their first contact with an NHS service; this provides capabilities to link data across all centrally held data collections.

### National data dictionary

The NHS Data Model and Dictionary provides a reference point for approved Information Standards Notices to support NHS activities.

### Classification and terminology

The Data Standards Assurance Service is situated within NHS Digital and supports use of classifications and terminologies in national data collections. The Data Alliance Partnership Board has responsibility for the assurance and approval of information standards, data collections and data across all health services and adult social care.

### Future plans

The NHS Long-Term plan makes specific reference to 'better use of data and digital technology'. The strategy, 'Data Saves Lives' outlines plans regarding national health and social care data including improvements to linkage capabilities and learning from developments across the public sector in relation to data and information management.

# 7 New Zealand

## 7.1 Introduction

**Population:** Approximately 5.1 million.(209)

**Government:** New Zealand is a parliamentary democracy, an independent country and a constitutional monarchy.(210) The Minister of Health, with the cabinet and government, develops policies and provides leadership for the health and disability sector.(211)

**Healthcare:** New Zealand has universal health coverage through a mostly publicly-funded and regionally-administered system. Te Whatu Ora (Health New Zealand) manages all health services, including hospital and specialist services, and primary and community care. Hospital and specialist services are planned nationally and delivered across the country. Primary health, wellbeing and community-based services are planned and then purchased through four new regional divisions of Health New Zealand. Services provided free of charge include hospital inpatient and outpatient care, mental health services, and long-term care, as well as some prescription drugs and diagnostic tests. Primary care operates primarily on a fee-for-service basis.(212)

## 7.2 Legislative context and organisational governance arrangements

In New Zealand, the Ministry of Health leads and has overall responsibility for the health and disability system and also has responsibility for national health and social care data collections.(213) A reform of New Zealand's health system took place in July 2022, including the establishment of Health New Zealand, a new Maori Health Authority and a new Public Health Agency within the Ministry of Health, and the dis-establishment of District Health Boards. Under this reform, Health New Zealand took responsibility for some of the functions of the Ministry of Health, and it is likely that it will have implications for how national health and social care data collections are managed going forward.(214)

In recent years, a number of functional leads have been assigned to develop and improve designated areas across the New Zealand government.(215) These include the Government Chief Digital Officer and the Government Chief Data Steward, who are responsible for overseeing the development and management of digital practice across the public sector and supporting the use of data across government to help deliver better public services, respectively. The Digital Government Partnership, a partnership of public sector agencies, including the Ministry of Health, was established by the Government Chief Digital Officer in 2015. This partnership helps the Government Chief Digital Officer and Government Chief Data Steward to develop and improve the digital and data system across the public service.

### 7.2.1 Key organisations and committees

There are a number of key organisations and boards with varying responsibilities in relation to national health and social care data collections in New Zealand. These include:

- Ministry of Health
    - Health Information Standards Organisation
    - Health Information Governance Expert Advisory Group
    - Digital Advisory Board
- Stats NZ.

#### 7.2.1.1 Ministry of Health

The Ministry of Health leads New Zealand's health and disability system, and has overall responsibility for the management and development of that system.(216) It is also responsible for national health and social care data collections and health surveys. The Ministry of Health collects data from different parts of the health sector, mostly from routine administrative systems used by the health services and from national population health surveys. Reporting for some national collections, such as the national cancer registry, is mandated.

The Health Information Standards Organisation (HISO) is a group that sits within the Ministry of Health. HISO supports and promotes the development and adoption of fit-for-purpose health information standards for the New Zealand health system.(217) The work of HISO involves maintaining relationships with international and national organisations involved in standards development. Its governance includes a Health Information Standards Committee which comprises eight members. It has a terms of reference and is accountable to the Chief Technology and Digital Services Officer within the Ministry of Health.(218) HISO is supported by the Architecture and Standards Team that sits within the Data and Digital Directorate of the Ministry of Health.

The Digital Advisory Board (DAB) aims to help the Ministry of Health understand the potential benefits of existing, in-progress and future digital and information-related technologies and to support the development of the strategies needed for their systematic uptake.(219)

The data collections that are hosted by the Ministry of Health can be broadly categorised as follows:

- **Core National Collections or National Data Assets**, for example, The Mortality Collection and The New Zealand Cancer Registry.
- **Screening data collections**, for example, breast screening, bowel screening.
- **COVID data collections**, for example, COVID-19 tracer app statistics, ICU statistics.
- **Vaccination data,** for example, National Immunisation Register.
- **Auxillary datasets**, for example, National Health Index, Medical Warning System.
- **Other data collections**, for example, Virtual Hepatitis C Register, Virtual Diabetes Register.

The Ministry of Health also collects, maintains and analyses data from national population health surveys.(220) Current and past surveys run by the Ministry of Health include:

- New Zealand Health Survey
- Alcohol and Drug Use Survey
- Nutrition Survey
- Oral Health Survey
- Mental Health Survey
- Tobacco Use Survey.

Some of the data included in the data collections held by the Ministry of Health is captured locally (for example, by public hospitals) and some is captured centrally (for example, pharmacy claims and maternity claims). There is a secure network between the Ministry of Health and service providers for the transfer of data and all national collections data is stored in the Ministry's data warehouse. The recording of information is done in accordance with guidelines set by HISO.

Information on each individual data collection is provided on the Ministry of Health website. Information presented on each data collection includes purpose, commencement date, availability and technical details on identity reporting, ethnicity, geographical coding, coding systems, data limitations and data quality measures.

#### 7.2.1.2 Stats NZ

Stats NZ is a government department and New Zealand's official data agency. It collects information from people and organisations and uses it to provide insights and data about New Zealand. Stats NZ releases information about injuries, disabilities, abortions, and life expectancy in New Zealand.(221) The Integrated Data Infrastructure is a large research data collection hosted by Stats NZ. Data from various sources, including data on education, income, benefits, migration, justice, and health, are linked to form the Integrated Data Infrastructure.(222)

### 7.2.2 Relevant legislation

There are a number of pieces of legislation which provide a legal basis for the operation of health and social care data collections in New Zealand (Table 9).

**Table 9: Summary of relevant legislation in relation to the operation of health and social care data collections in New Zealand**

| Name of Act | Description |
|---|---|
| Health Act 1956 | Gives the Ministry of Health the function of improving, promoting and protecting public health. It contains specific provisions in section 22 governing the disclosure of health information about identifiable individuals by and between health service providers and other agencies with statutory functions.(223) |
| Official Information Act 1982 | Established to make official information more freely available. Its relevance is when a request for information held by the Ministry of Health is from someone who is not the subject of the information or their personal representative.(224) |
| Cancer Registry Act 1993; Cancer Registry Regulations 1994 | Mandates the reporting of cancer cases to the New Zealand Cancer Registry.(225) |
| Health (Retention of Health Information) Regulations 1996 | Introduced to set a minimum period of 10 years for which health information has to be held by health or disability service providers. It also covers the form in which health information is to be retained and the obligations associated with the transferring of health information, for example, when a service provider ceases business.(226) (See also the Public Records Act 2005 below.) |
| New Zealand Public Health and Disability Act 2000 | Describes one of the objectives of the Ministry of Health as being to facilitate access to, and the dissemination of information to deliver, appropriate, effective, and timely services. Outlines that the Ministry of Health is obligated to collect data and is responsible for the collection and dissemination of health-related information within New Zealand.(227) |
| Public Records Act 2005 | Provides a comprehensive framework for the systematic creation and preservation of public archives and local authority archives. In particular it gives the Chief Archivist, who is also the Chief Executive of Archives New Zealand, powers of direction with respect to archiving and disposal decisions over health information held by the public sector.(228) |

| | |
|---|---|
| Privacy Act 2020 | Establishes certain principles with respect to the collection, use, disclosure of, and access to, information. Applies to public and private sector agencies. Established the role of Privacy Commissioner.(229) |
| Health Information Privacy Code 2020 | A Code of Practice issued by the Privacy Commissioner which gives extra protection to health information because of its sensitivity. It covers all health agencies, including the Ministry of Health, and protects all personal health information.(230) |

## 7.3 Guidance and frameworks to support improvements in data quality and information governance

The Ministry of Health drives improvements in data quality through work carried out by the data quality analysts, the provision of technical guidance documents and education and support services. There are also initiatives in place across governmental departments in New Zealand to support data and information quality and governance.

### 7.3.1 New Zealand Government Data Toolkit

The Government of New Zealand has developed a 'data toolkit' which provides information on ensuring good practices in relation to national data.(231) The toolkit is applicable to all national data including data pertaining to health. Guidance and resources on data management related to effective data management are available within the toolkit. The toolkit provides resources and guidance on:

- Data ethics
- Data governance
- Data management
- Data standards
- Data stewardship
- Data storage
- Open data
- Policy
- Privacy, security and confidentiality
- Data capability framework
- Data practice communities.

Within the toolkit, there is a Data Capability Framework.(232) The Data Capability Framework helps to define data and analytical capabilities. The Framework is for managing capabilities at individual, team or organisational level. The framework comprises seven categories of capability (Plan; Collect; Describe; Store; Analyse; Use; Save and or destroy).

As a complement to the guide, the New Zealand Government has also developed a Data capability assessment questionnaire.(233) The assessment tool covers each capability, with the individual, team or organisation indicating their level of proficiency ('New', 'Proficient', or 'Expert') for each capability.

A data stewardship framework and toolkit has also been developed to support implementation of the framework.(234) Data stewardship is 'the careful and responsible creation, collection, management, and use of data'.(235) The framework was developed to suit New Zealand's data system.

Within the toolkit, various data practice communities are hosted which provide a forum for those working in this area to share ideas on data management.(231) The forums in place are:

- Open data community forums
- Government analytics network
- Data and digital standards community of practice.

### 7.3.2 HISO Health Information Security Framework

HISO published a Health Information Security Framework in 2015 which sets out security management requirements for health provider organisations. It has been designed to support health and disability sector organisations and practitioners holding personal health information to improve and manage the security of that information. The areas addressed by the framework include:

- governance
- organisation of information security
- information security policies
- asset management
- human resources security
- physical and environmental security
- communication security
- operations security.(236)

The Framework includes advice on how health information is created, displayed, processed, transported and disposed of to ensure that the information's confidentiality, integrity and availability is maintained. (236)

### 7.3.3 Ministry of Health National Collections Annual Maintenance Project

The National Collections Annual Maintenance Project (NCAMP) is a work programme that has been in operation since 2012 that aims to implement notified changes to the Ministry of Health's national data collections and to ensure they meet their ongoing statutory obligations. Each project in the programme has an 18-month cycle. The process involves submitting ideas for change to the national collections throughout the year, followed by an assessment, consultation and evaluation process. There is an ongoing review of the maintenance schedule to ensure the national collections meet the changing needs of the healthcare system and its users.(237)

### 7.3.4 Ministry of Health Analytical Operating Model

The Ministry of Health has developed an Analytical Operating Model to standardise the way that analysts use health data. The focus of the work of the Analytics Operating Model has been on standardising approaches and establishing a community and flow of information across the different levels. The model identifies a number of focus areas to target to facilitate use of New Zealand's statistics. The focus areas are:

- Data
- Tools
- Standards
- Capability
- Community.

### 7.3.5 New Zealand Data and Information Management Principles

On 8 August 2011, the New Zealand government approved principles for managing the data and information it holds. These standards apply to all governmental departments within New Zealand.(238) The New Zealand Data and Information Management Principles, which reflect national legislation and international obligations, are:

- **Open:** Data and information held by government should be open for public access unless grounds for refusal or limitations exist under the Official Information Act or other government policy. In such cases they should be protected.
- **Protected:** Personal, confidential and classified data and information are protected.
- **Readily available:** Open data and information are released proactively and without discrimination. They are discoverable and accessible and released online.
- **Trusted and authoritative:** Data and information support the purposes for which they were collected and are accurate, relevant, timely, consistent and without bias in that context. Where possible there is an identified authoritative single source.
- **Well managed:** Data and information held and owned by government effectively belong to the New Zealand public, are a core strategic asset held by government as a steward on behalf of the public; and should only be

collected or generated for specified public policy, operational business, or legislative purposes.

- **Reasonably priced:** Use and re-use of government held data and information is expected to be free. Charging for access is discouraged. Pricing to cover the costs of dissemination is only appropriate where it can be clearly demonstrated that this pricing will not act as a barrier to the use or re-use of the data. If a charge is applied for access to data, it should be transparent, consistent, reasonable and the same cost to all requestors.
- **Reusable:** Data and information released can be discovered, shared, used and re-used over time and through technology change. Copyright works are licensed for re-use and open access to and re-use of non-copyright materials is enabled, in accordance with the New Zealand Government Open Access and Licensing framework.

## 7.4 Other national arrangements for health information

### 7.4.1 Health identifiers

The National Health Index (NHI) number is a unique number assigned to patients when using health and disability services in New Zealand. This identifier has been widely used in electronic clinical systems since the 1990s and is now one of the foundational enablers (along with the health provider identifier) for associating care events to a specific individual.(239) The NHI is used in all national data collections hosted by the Ministry of Health.

### 7.4.2 Data linkage

Linkage occurs across all of the national data collections held by the Ministry of Health. The preferred method of linkage is through the NHI number. Within the Ministry of Health, there is a data quality team responsible for verifying identity and NHI numbers. Where data is to be used outside of the health sector, an alternative approach to using the NHI is taken, or specific encryption algorithms are developed. Stats NZ have used probabilistic matching from administrative datasets across government to verify and modify census results.

A Data Governance Group within the Ministry of Health is responsible for overseeing applications for any identifiable health data. The Data Governance Group meets regularly and receives requests for data linkage and the provision of identifiable data to external organisations. Requests for identifiable data are often also submitted to the Health and Disability Ethics group.(240) The Ministry of Health requires all staff to undertake training in Health Information Privacy before being granted access to identifiable data.

The Ministry of Health can also provide organisations with encrypted NHIs, meaning the organisations do not know the patient's identity but can determine if the patient has had several of the same events in the dataset. The Ministry of Health use various algorithms of encrypting NHIs so that not all researchers or organisations have the same NHIs. The Health Information Privacy Code includes guidance on data linkage.(230)

A successful example of data linkage is the creation of the Virtual Diabetes Register in the absence of a national diabetes data collection. Data from six data collections in the Ministry of Health is linked by the NHI to generate data on diabetes prevalence, which is sent to the patients' GPs for a final validation.(241) Another example was the development of a 'COVID-19 pipeline of data' whereby nine datasets across government were linked in order to generate statistics and information relating to COVID-19 in New Zealand, including information relating to people working and arriving at the New Zealand border, testing and results, managed isolation, and genomic testing.

### 7.4.3 National data dictionary

The Ministry of Health publishes data dictionaries online for each national collection that it maintains. There are ongoing plans to build an online data dictionary and terminology service and publish national code sets as set out in the New Zealand interoperability roadmap.(242)

### 7.4.4 Classification and terminologies

HISO is an expert advisory group for standards, and works to advise on, identify, scope, develop and endorse standards.(243) Technical standards to support exchange of medical information are updated and published by HISO. HISO's areas of focus include ensuring security of information, the use of health identifiers, eMedications standards, and the use of the standard laboratory test codes.

Classifications and terminologies currently used in New Zealand include:

- ICD 10 - Australian Modification
- Australian Classification of Health Interventions
- Australian Coding Standards
- Australian Refined Diagnosis Related Groups (AR-DRGs)
- SNOMED CT.

Key technical standards used within New Zealand are:

- Health Level Seven v2, including Health Level Seven Clinical Document Architecture documents, Health Level Seven, Fast Healthcare Interoperability Resources

- Logical Observation Identifiers Names and Codes (LOINC).

Support is available to data providers from the Ministry of Health which hosts a coding query service and maintains an online historical database of queries and associated responses.(244)

## 7.5 Future plans

The Data and Information Strategy for Health and Disability: Roadmap 2021-2024 was published in December 2021.(245) This Roadmap identifies specific actions to be taken at both national and local levels to improve the way the system manages data and partners with key stakeholder groups to involve them in the decisions about their data. The strategy outlines three initial horizons for delivery, corresponding to short, medium and longer-term goals. The Strategy also presents the actions required to support the development of each of the priority areas.

The Strategy identifies five priority areas in which the system needs to improve to derive greater value from data and information. These focus areas are:

- **data foundations** - ensuring that data are more accessible and stored in more consistent formats, enabling data access and sharing so the system can develop and use real-time insights for decision-making
- **equity and data sovereignty** - prioritising opportunities to target inequity, and improve health outcomes, through an improved understanding of inequities and the use of digital and data capabilities to address them
- **consumer participation** - ensuring that consumers are represented in data governance and that decisions about health data management are made in a consumer-centric manner
- **people and leadership** - ensuring a skilled and proficient workforce
- **data accessibility** - highlighting the need effective data sharing frameworks, contract requirements and consent and delegation frameworks, along with mechanisms to better support innovation and research.

## 7.6 Summary of New Zealand's approach

### Legislative context and governance arrangements

New Zealand has a centralised model for its national collections, with all the key national health data collections housed within the Ministry of Health. The New Zealand health sector has undergone a restructure and a new organisation called Health New Zealand will take responsibility for some of the functions of the Ministry of Health.

### Guidance and frameworks for data quality and governance

The New Zealand Government has developed a 'data toolkit' which provides information on ensuring good practices in relation to all national data, including data pertaining to health. HISO has published further guidance specifically for health and disability sector organisations and practitioners in the form of the Health Information Security Framework. The Ministry of Health has developed an Analytical Operating Model to standardise the way that its analysts use health data. It also runs a work programme called the National Collections Annual Maintenance Project which ensures that all its data collections are meeting their statutory obligations.

### Unique identifiers and data linkage

The National Health Index (NHI) number is a unique number assigned to patients when using health and disability services. The NHI is widely used in Ministry of Health data collections for data linkage. Linkage occurs across all of the national collections held by the Ministry of Health. A data governance group within the Ministry of Health is responsible for releasing and linking identifiable health data.

### National data dictionary

The Ministry of Health has published a number of data dictionaries for the national data collections that it maintains. Development of a national data dictionary is underway.

### Classification and terminology

HISO supports and promotes the development and adoption of fit-for-purpose health information standards for the health system.

### Future plans

There are plans in place to enable more sharing of data across government. Evidence of this can be seen in New Zealand Government publications and initiatives to support information governance and data quality across New Zealand government data. This will facilitate continued advances in areas such as virtual registries and improving the overall capability of the national data collection systems.

# 8 Other countries

## 8.1 Denmark

The population of Denmark is approximately 5.8 million.(246) Denmark has a universal healthcare system in place, based on the principles of free and equal access to healthcare for all citizens.(247)

### 8.1.1 Governance arrangements

In a survey of 23 OECD countries, Denmark was one of just three countries to report having all 13 key national health datasets. Of these, nine are hosted by the Danish Health Data Authority.(7) Denmark has a well-established system of registration of life and health events through its national health registers. Through these registers, all managed by the Danish Health Data Authority, health data on all residents is registered when they visit a GP, hospital specialist, buy medicine at a pharmacy or receive health services in the community. Each register has been established to serve a particular purpose, for example to monitor the development of a particular disease or the effect of a treatment.(248)

The Danish registries are founded on a national initiative, mandated by law and regulated by national government, but financed and owned by regional governments. Each registry has to be approved by the Danish Health Data Authority every three years, where it is determined whether or not it continues to fulfil national criteria for functionality, data safety and methodology.(249) The Danish Clinical Quality Program for National Clinical Registries constitutes the infrastructure of the Danish clinical quality registries and the Danish Multidisciplinary Cancer Groups. The primary objective of this programme is to ensure continued improvement in the utilisation of the Danish clinical registries for clinical, managerial, and research purposes.(249)

### 8.1.2 Legislative context

A new Data Protection Act was enacted in Denmark in 2018 to supplement the GDPR.(250) This Act outlines situations where health information can be used without explicit consent, including for certain statistical purposes. National health and social care data collections in Denmark, including its national health registers, operate under the provisions of both the GDPR and the Danish Data Protection Act 2018.

### 8.1.3 Health identifiers and data linkage

The existence of a unique personal identification number assigned to all Danish residents at birth or upon emigration (referred to as a ‘CPR number’) enables individual-level linkage between registers. In comparison to other countries, Denmark was highlighted as an exemplar for regularly linking all key national health datasets for health system monitoring and research purposes.(7)

### 8.1.4 National data dictionary

The Danish Health Data Authority hosts 'eSundhed' which is a data bank of all the health data that it holds.(251) This includes extensive documentation for all the Danish registries, including definitions of words and concepts used and a detailed description of all the variables included. Information on the legislative basis for each register, as well as code sheets and other documentation files are also included on the eSundhed website. There is also a search function which enables the user to search for specific variables and identify the registers in which they are included.

### 8.1.5 Classification and terminology

The Danish Medical Classification System ('Sundhedsvæsenets Klassifikations System') is the responsibility of the Danish Health Data Authority.(252) The Danish classification system is based on ICD-10, with some national extensions. The Danish Health Data Authority is also the national release centre for SNOMED CT which is used across the Danish health system.(253)

## 8.2 Korea

The population of Korea is approximately 51.8 million,(254) and the country has had a system of universal health coverage since 1989.(255) The Ministry of Health and Welfare coordinates and oversees health and welfare related affairs and policies.(256) The national health insurance programme is managed by the National Health Insurance Service and reviewed by the Health Insurance Review and Assessment Service.

### 8.2.1 Governance arrangements

In a survey of 23 OECD countries, Korea was reported to have twelve of thirteen key national health datasets. Of these, eight are managed by the Health Insurance Review and Assessment Service, two by the National Statistics Office, one by the Centre for Disease Control and Prevention, and one by the National Cancer Centre.(7) Statistics Korea is responsible for overseeing the use of classifications and terminologies in healthcare.(257)

### 8.2.2 Legislative context

The majority of health datasets in South Korea are authorised by a privacy regulatory body or a research ethics committee, often in addition to legislative authorisation. Relevant legislation that applies to health information includes:

- Personal Information Protection Act 2011(258)
- Cancer Control Act 2003(259)
- The Act on Promotion of the Provision and Use of Public Data 2013.(260)

The Personal Information Protection Commission has Standards for Safety Security of Personal Information,(261) and guidance on health data anonymisation and use.(262)

### 8.2.3 Health identifiers and data linkage

All Korean citizens are given a resident registration number at birth or when they become a Korean resident.(263) This is used across national health datasets in Korea, and linkage of these datasets is carried out regularly.(7) In recent years, Korea has placed considerable resources into developing health datasets and strengthening data linkage capabilities. In 2018, the Ministry of Health and Welfare established a Healthcare Big Data Policy Deliberation Committee which is responsible for data development, use, and linkage. This Committee supervises and manages the Korea Health Industry Development Institute, which is responsible for information strategy planning. Korea's ability to use real-time data across key parts of the healthcare system and linking patient data with databases outside of the health system have been highlighted as examples of data-driven responses to infectious disease control and prevention.(7)

## 8.3 Singapore

The population of Singapore is approximately 5.6 million.(264) Singapore has a universal healthcare system and the Ministry of Health is responsible for developing the necessary infrastructure for the effective running of the national health system.(265)

### 8.3.1 Governance arrangements

Governed by the Statistics Act, the Singapore Government's Department of Statistics is responsible for official statistics on the economy and population, while responsibility for data and statistics on specific subject matters is with the various ministries. The Department of Statistics has published guidelines for national statistics, the aim of which is to maintain and ensure quality, integrity and expertise in Singapore's national statistics (Table 10).(266)

**Table 10: Singapore Government Department of Statistics Guiding Principles**

| | |
|---|---|
| **Professionalism & Expertise** | We adhere to professional ethics and develop statistical competency to produce quality statistics that comply with international concepts and best practices. |
| **Relevance & Reliability** | We produce statistics that users need and trust. |
| **Accessibility** | We facilitate ease of access to our statistics |
| **Confidentiality** | We protect the confidentiality of individual information. |
| **Timeliness** | We disseminate statistics at the earliest possible date. |
| **Innovation** | We constantly seek ways to improve our processes. |
| **Collaboration** | We engage users on data needs, data providers and respondents on supply of data, and undertake the role of national statistical coordination. |
| **Effectiveness** | We optimise resource utilisation, leveraging administrative and alternative data sources to ease respondent burden. |

The Ministry of Health is responsible for all aspects of health data and statistics. In a survey of 23 OECD countries, Singapore was one of just three countries to report having all 13 key national health datasets.(7) Of these, all are hosted by the Ministry of Health, except for mortality data which is held by the Immigration and Checkpoint Authority, and population census data which is held by the Department of Statistics. In the report of this OECD survey's findings, Singapore was identified as one of four countries that facilitates individuals to opt out of the majority of national health data collections.

### 8.3.2 Legislative context

While the Personal Data Protection Act 2012 governs the collection, use, and disclosure of individuals' personal data in Singapore,(267) there are other laws for specific matters, including disease registers. The National Registry of Diseases Act was passed in December 2007 and allows the National Registry of Diseases Office, set up by the Ministry of Health, to access medical information and collect data without obtaining explicit consent from individuals for inclusion of their data into the registries and any subsequent use.(268) At present, registries for cancer, chronic kidney failure, stroke and acute myocardial infarction are managed by the National Registry of Diseases Office.

### 8.3.3 Health identifiers and data linkage

Singapore has a system of allocating unique identifiers to citizens and permanent residents aged 15 years and older. The National Registration Identity Card is a permanent identifier issued by the Singapore Government, primarily for public administration purposes and to facilitate transactions with the government.(269) The National Registration Identity Card number is included in at least 90% of Singapore's national health data collections and can be used for data linkage; however, dataset linkages are conducted with only a minority of datasets on a regular basis.(7)

### 8.3.4 Classification and terminology

The Ministry of Health is responsible for standards, classifications and terminologies that are used across the public healthcare system in Singapore. At present, ICD-10-AM and SNOMED CT are used. LOINC is currently being rolled out and will be fully implemented by 2025. A number of national data standards have also been developed and implemented, including the Singapore Drug Dictionary and the National Healthcare Data Dictionary which are used in the area of drugs and demographics, respectively.

## 8.4 Sweden

The population of Sweden is approximately 10.4 million.(270) Sweden's universal health system is nationally-regulated and locally-administered, with the Ministry of Health and Social Affairs responsible for setting overall health policy.(271)

### 8.4.1 Governance arrangements

Statistics Sweden is the national statistics agency responsible for official and other government statistics, and the National Board of Health and Welfare ('Socialstyrelsen'), a Government agency under the Ministry of Health and Social Affairs, is responsible for producing official statistics relating to health and medical care and social services.(272) The National Board of Health and Welfare also produces and develops regulations and knowledge for health and medical care and social services in Sweden.(273)

Sweden has a long history of collecting epidemiological data through registry-based research. Swedish registers can be broadly categorised as: 1) national public authority registers; and 2) national quality registers. National public authority registers exist at various Swedish national public authority and contain data that has been collected as part of the authorities' activities. National public authority registers related to health are hosted by the National Board of Health and Welfare, including registers for cancer, acute myocardial infarctions, and hospital inpatient diagnoses.(274)

National quality registers are those that have been set-up within specific areas of the healthcare system. Currently, more than 100 national quality registries exist across Sweden. Each registry is supported by an organisation of healthcare professionals and patient representatives who are jointly responsible for developing and maintaining the registries. They contain patient-level data about common and rare medical conditions, interventions, procedures and outcomes, and are integrated into clinical care with the capacity to generate data in real time.(275) In each healthcare region, there is a Regional Registry Centre (sometimes referred to as 'Competence Centers') in which several registries co-exist and share the costs for staff and infrastructure.(276) The Office for National Quality Registers provides support to the national quality registers.(277)

In a survey of 23 OECD countries, Sweden was reported to have 12 of 13 key national health datasets.(7) Of these, eight are hosted by the National Board of Health and Welfare, one by the Public Health Agency of Sweden, and one by Statistics Sweden. The remaining two are managed at a local or regional level through Sweden's system of national quality registries.

### 8.4.2 Legislative context

In 2018, the Swedish parliament adopted a new legislative act, the Data Protection Act, with complementary provisions to the GDPR; this replaced the Personal Data Act 1998.(278) Sweden's national quality registries operate under the provisions of both the GDPR (31) and the Data Protection Act 2018.(279) The Swedish Data Protection Authority is the supervisory authority of both pieces of legislation.

### 8.4.3 Health identifiers and data linkage

The success of Sweden's national health registers can be attributed to their use of a unique identifier (a 'personal identity number') assigned to everyone once they are registered in the Swedish Population Register.(280) The personal identity number is used across the entire Swedish healthcare system and is included in all registers, facilitating regular data linkage.(281)

### 8.4.4 National data dictionary

There is no national data dictionary in place in Sweden. However, the National Board of Health and Welfare hosts a statistical database on its website where users can produce tables, charts and maps from the registers and other data sources which it hosts.(282) Lists of the variables that are included in each of these registers and other data sources are available on the website. In addition, most national quality registers have websites hosted by their own managing organisations where information relating to the included variables can be located.

### 8.4.5 Classification and terminology

The National Board of Health and Welfare is also responsible for classifications that are used throughout the Swedish healthcare system, including the Swedish version of ICD 10.(283) It is also the national release centre for SNOMED CT which is used across the Swedish health system.(284)

# 9 Conclusion

The findings of this evidence synthesis highlight practices internationally in relation to national health and social care data collections. While it is evident that different approaches are taken in each country depending on many factors, including the political and social context, there are some common elements, particularly relating to legislation, governance, use of unique identifiers and data linkage.

In each of the countries reviewed, there is a key organisation that has a statutory obligation to manage the majority of key national health and social care data collections. In most cases, this organisation is also responsible for classifications and terminologies; data dictionaries for national data collections; setting standards for health information management; and providing guidance and resources on data quality and information governance in the context of health and social care. The key organisations in each country included in this review were:

| | |
|---|---|
| **Australia:** | Australian Institute of Health and Welfare |
| **Canada:** | Canadian Institute of Health Information |
| **England:** | NHS England |
| **New Zealand:** | Ministry of Health |
| **Denmark:** | Danish Health Data Authority |
| **Korea:** | Ministry of Health and Welfare |
| **Singapore:** | Ministry of Health |
| **Sweden:** | National Board of Health and Welfare |

Similar arrangements for health and social care information were observed in Australia and Canada. Both countries have a similar governmental structure, with both federal governments and state and provincial or territory governments; however, they have taken a mostly centralised approach to the governance of national health and social care data collections, with a key organisation responsible for the majority of key collections.

In New Zealand, Korea and Singapore, the national Ministry of Health takes responsibility for the majority of key national health and social care data collections, while in England, this falls within the remit of NHS England. Denmark and Sweden are both characterised by their well-established systems of national health registers; however, they take a different approach to governance. In Denmark, the Danish Health Data Authority holds all the national health registers, while in Sweden, the majority of the national quality registries are managed by registry centres in each of the healthcare regions.

Examples of good practice relating to the use of unique identifiers for data linkage were observed in England, Sweden, Denmark and Korea. Each country has a system of allocating a unique identifier to all citizens and permanent residents. In England, residents are assigned an NHS number soon after they are born or the first time they access an NHS service. In each country, these numbers are fully-integrated across all data collections, which facilitates linkage of multiple data collections. This system is particularly well-established in Denmark and Sweden where unique identifiers for all citizens have been included in patient registries since the 1970s. This has facilitated a wealth of epidemiological and health services research relating to both common and rare diseases from both countries. Singapore also has a system of allocating unique identifiers to residents; however, these are not allocated to individuals until they reach 15 years of age, and although they are included in most data collections, data linkage activities in Singapore are limited.

Unique identifiers are not yet widely used in the majority of national health and social care data collections in Australia and Canada; however, in both countries, there is excellent governance in place regarding data linkage, managing organisations with overall responsibility for data linkage activities, and well-established processes for anonymization and probabilistic data linkage.

## 9.1 Recent developments in each country

### Australia

- The AIHW Data Governance Framework was updated in 2020-21.
- The Guidelines for the secondary use of health information were updated in 2017.
- A framework to guide the secondary use of data within the My Health Record system was published in 2018.
- A 10-year national strategy for clinical quality registries and virtual registries was published in 2020.

### Canada

- CIHI’s Health Data and Information Governance and Capability Framework was published in 2020.
- CIHI’s Information Quality Framework was published in 2017 to replace the previous Data Quality Framework.
- Health Data Research Network Canada (HDRN Canada) was established in 2020.
- The first report of the Pan-Canadian Health Data Strategy was published in 2021.

**Denmark**

- The new Data Protection Act was enacted in 2018 to supplement the GDPR.

**England**

- Updates to the Health Act in 2018 placed the National Data Guardian role on a statutory footing and granted it the power to issue official guidance about the processing of health and adult social care data in England.
- The Health and Care Act was enacted in 2022 which introduced significant reforms to the organisation and delivery of health and care services in England and has a number of provisions which have implications for health information and national data collections.

**New Zealand**

- The Privacy Act was updated in 2020.
- Data linkage capabilities across health data sets were expanded.

**South Korea**

- In 2018, the Ministry of Health and Welfare established a Healthcare Big Data Policy Deliberation Committee which is responsible for data development, use, and linkage.
- Korea demonstrated its data linkage capabilities and its ability to produce real time health data in its approach to managing the COVID-19 pandemic.

**Singapore**

- Amendments to Singapore's Personal Data Protection Act 2012 were passed in November 2020 and began to take effect in February 2021.

**Sweden**

- A new legislative act, the Data Protection Act, was enacted in 2018. This Act has complementary provisions to the GDPR.

## 9.2 Future plans - the European Health Data Space

Following the enactment of the GDPR in May 2018, countries across Europe passed legislation designed to supplement EU legislation. This includes new Data Protection Acts in Denmark,(250) Sweden,(279) and Ireland.(25) Each of these Acts contain provisions for health data situations where health data can be used for reasons beyond which it was originally collected. National health and social care data collections, including registries, in all European countries must operate within both the GDPR and their country's own data protection legislation.

The EU is currently progressing with plans to enact the Data Governance Act which aims to increase trust in data sharing across Europe and facilitate the re-use of certain data health by the public sector, including certain health data.(285) Concurrently, the European Commission has identified the creation of a European Health Data Space (EHDS) as a priority for 2019-2025.(286) The overarching aim is to develop a common approach and set of principles for the sharing of health data across Europe. The EHDS will be built on three main pillars:

1) Strong data governance
2) Data quality
3) Strong infrastructure and interoperability.

The aim is that this will lead to improvements in how health information is used for purposes related to direct care, as well as for uses beyond direct care, including research and policy development. Launched in February 2021, a joint action project, 'Towards the European Health Data Space' (TEHDAS), is engaging with stakeholders from all member states to continue the dialogue about the EHDS.(287) The findings of the TEHDAS project will inform the European Commission's legislative proposal for the EHDS. The project is divided into eight work packages which are led by organisations from across Europe. Work packages 1-3 are linked to the execution and co-ordination of the project, while work packages 4-8 are thematic work packages linked to the secondary use of health data (See Appendix 4).

## 9.3 Upholding the rights and interests of individuals

Trust has been identified as a fundamental enabler of the success of the EHDS, and central to this is the need to ensure that personal health data is protected by measures to safeguard the fundamental rights and interests of individuals. Data protection is a fundamental right set out in Article 8 of the EU Charter of Fundamental Rights.(288) Other specific rights of individuals in respect of their personal data include, but are not limited to: right to access, right to be informed (transparency), right to rectification and right to object.(289) Successful governance of data and metadata is necessary to reduce risks for human rights violations at a national and European level.(290)

A human rights-based approach to data also facilitates the bringing together of all relevant stakeholders and promotes improvements in the quality, relevance and use of data and statistics consistently with international human rights and norms.(291) The United Nations has developed a preliminary set of principles, recommendations and good practices underpinning a human rights-based approach to data, under six headings: participation; data disaggregation; self-identification; transparency; privacy; and accountability.(291) Ultimately, the processing of health information should always follow a human rights-based approach, meaning that an emphasis is placed on protecting and promoting people’s rights. This involves respecting privacy but also autonomy, dignity, values, preferences and diversity. However, data protection is not an absolute right so it must always be balanced against other values, fundamental rights, human rights, or public and private interests.(289)

As health and social care data is likely to play an increasing role in the delivery and management of, and planning for, health and social care services, it is imperative that attention is given to ensuring that levels of trust in the systems used to process such data are maintained, and that services and organisations that process health and social care data and information respect the privacy of individuals about whom the data relates to. All organisations that collect, use and share health and social care data and information in Ireland also need to be responsive to the significant changes occurring in this area nationally and internationally, including developments outlined in the Sláintecare strategy, the planned establishment of the EHDS and the proposed changes to European and national legislation, including the Health Information Bill, all of which have the potential to transform the health information landscape in Ireland.

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# Appendices

## Appendix 1: AIHW Data Governance Framework 2021

**1. Key concepts in data and data governance**

Key terms and concepts that are commonly used in data governance and data management are introduced in the framework, and context is provided for the AIHW-specific data governance arrangements.

**2. Legal, regulatory and governance environment**

The key features of the legal, regulatory and governance environment that the AIHW operates under are described, including all the relevant legislation.

**3. AIHW organisational structures and roles in data governance**

The various organisational structures (such as the AIHW Board, Ethics Committee, and the Risk, Audit and Finance Committee) and roles (such as the AIHW Chief Executive Officer, AIHW Governance Committees, Group Heads, Data Custodians, and Privacy Officers) that support the AIHW data governance system are described.

The AIHW Ethics Committee plays a central roles in AIHW's data governance arrangements. The functions and responsibilities of the Ethics Committee are defined in legislation, and include: considering ethical matters relating to AIHW activities; advising on ethical matters relating to the collection and production of health or welfare related information or statistics; granting approval for the release of certain data; granting waivers of consent for the collection, use or release of certain data. The AIHW Data Governance Committee, chaired by the Deputy CEO of the AIHW, provides oversight for review of all data-related legal instruments and policies.

**4. AIHW systems and tools that support data governance**

The AIHW ICT framework is outlined, including all aspects of the development and governance of AIHW's digital technologies. These include the AIHW data catalogue, METeOR, VAlidata™, and EthOS™.

Validata™ is a tool developed by the AIHW specifically for the secure receipt of data and for checking incoming data against a set of validation riles to ensure the quality of incoming data is fit for purpose.

EthOS™ is a web-based application through which researchers may apply for access to AIHW data and for data linkage services. It supports oversight by maintaining an auditable record of past and current authorisations, providing prompts for annual reviews for multi-year projects.

**5. AIHW data-related policies, procedures and guidelines**

These are designed to: ensure compliance with the legal and regulatory environment under which the AIHW operates; adherence to relevant Australian and international standards and classifications; and compliance with ethical considerations and obligations. AIHW data-related policies, procedures and guidelines are outlined in terms of the data life cycle.

**6. Establishment of a new data collection**

New AIHW data collections can be established following an internal or external request; not all proposals are successful. The AIHW Ethics Committee must approve all proposals to create or amend an AIHW data collection. The Data Collection Management Principles make explicit the expectations of the Ethics Committee regarding how all AIHW data collections are to be managed. The Data Collection Monitoring Report and Checklist is used to record progress and compliance for data collections approved by the AIHW Ethics Committee.

**7. Acquisition of data**

In accordance with the Data Collection Management Principles, data is collected and stored with appropriate metadata and have data dictionaries to accurately define and describe them. *Guidelines for the custody of AIHW data* have been prepared for data custodians to outline the requirements in terms of maintaining up-to-date documentation. The AIHW has a standardised approach to data quality, and it works with its data suppliers to maximise the quality of all its data collections in a number of ways, including:

- the use of built-in data quality checks in its online data receipt and validation tool, Validata$^{\text{TM}}$;
- reviewing data as it is acquired;
- supporting the production of national data standards, datasets and metadata, and making these standards, datasets and metadata available online through the METEoR;
- providing data providers and users with information and guidance relating to data quality;
- reviewing the statistical content of publications;
- recording and reporting the quality of AIHW data collections in Data Quality Statements.

The AIHW Security Plan exists to ensure all data is held securely, and multiple levels of security exist to gain access to AIHW-held data.

**8. Access and use of data within the AIHW**

Data custodians are responsible for approving access to, and use of, the data collections for which they have delegated authority. Access by any external persons to identifiable data held by the AIHW, or for linkage with AIHW-held data, for the purpose of research also requires prior approval by the AIHW Ethics Committee. The separation principle, a mechanism to protect the identities of individuals and organisations, is applied in accordance with the AIHW Separation Principle Policy. It is achieved in two ways: physical separation (separate storage of identifying and content information) and virtual separation (users are given permission to see only the identifying or the content information, never both).

As an accredited Integrating Authority, AIHW adheres to stringent criteria relating to data linkage, covering project governance, capability, data management, privacy and confidentiality. The AIHW applies a rigorous management approach to each project to ensure appropriate risk mitigation mechanisms are applied.

**9. Sharing and releasing data outside the AIHW**

The AIHW differentiates between data sharing and data release. Data sharing refers to making data available to another agency, organisation, or person under agreed conditions, while data release is making data publicly available with few or no restrictions. Data release occurs in the form of publications and on-line releases, which can include detailed supplementary tables and data cubes, and other aggregate data. From a data governance perspective, authors of AIHW publications and online releases are responsible for obtaining approval from the relevant data custodians for the use of the data, and ensuring the relevant data quality statement is included with all releases.

The sharing or release of any data held by AIHW must be approved by the AIHW Ethics Committee. While the Ethics Committee can issue a waiver for the sharing or release of personal information for medical research, waivers for sharing or release of personal data are rare. In most cases, sharing or release of data will require that the data are de-identified. The AIHW De-identification Policy details the AIHW approach to de-identification for all instances of data sharing and release. This policy outlines how the Five Safes framework(292) is applied to assess and mitigate the risk of re-identification until there is no reasonable likelihood of re-identification occurring.

Arrangements to share AIHW data externally are generally agreed either through an MOU, agreement or contract, or in response to direct requests from researchers. The AIHW does not publicly release Statistical Linkage Key information, and will only share such information in confidence in exceptional circumstances. The AIHW data custodians and the DISC maintain a register of all data shared or released.

**10. Data archiving, return, collection retirement and destruction**

Most data collections are approved as ’ongoing’, and in these cases, there are no requirements to return or destroy the data. For data collections that have a ‘limited life’, the AIHW follows the National Archives of Australia guidelines on retaining, managing and disposing of data and datasets.(293)

**11. Compliance**

The AIHW regularly monitors compliance with its data management and security arrangements, and undertakes half-yearly validation of the data catalogue through the Data Custodians, to ensure all holdings are listed and their data custodian is current. The AIHW Ethics Committee also requires regular monitoring of progress of projects it has approved. The AIHW has in place rigorous controls and protocols in respect of information security, privacy and confidentiality.

# Appendix 2: Framework for Australian Clinical Quality Registers

## Strategic Principles

**Principle 1**

Consumers, clinicians, management and governments receive regular reports from clinical quality registries on appropriateness of care (process and compliance with guidelines), or effectiveness of care (patient outcomes) to support ongoing improvement of healthcare in Australia.

**Principle 2**

Clinical quality registries, operating in close coordination with expert clinical groups, provide an effective mechanism for:

- design of indicators of quality of care
- comprehensive data collection and analysis
- outlier management within a sound clinical governance framework.

**Principle 3**

National data governance arrangements and best practice infrastructure provide support for comprehensive reporting, monitoring and management of clinical practice variance.

**Principle 4**

Where existing data flows do not support analyses of quality of care, Australian clinical quality registries are efficient and effective in providing consumers, clinicians, management and government with information for managing and improving delivery of health services.

**Principle 5**

Dedicated investment in Australian clinical quality registries supports infrastructure, data cleansing, reporting and analysis of quality of care, based on succinct datasets captured routinely by clinicians at the point of care.

**Principle 6**

Australian clinical quality registries have sound governance arrangements with strong clinical leadership and a demonstrated framework for quality improvement.

| **Principle 7** |
|---|
| Prioritisation of Australian clinical quality registry support is premised on gaps in existing data flows, the significance of the national burden of disease and the cost of interventions, the existence of variation in practice and outcomes, the ability to improve quality of care including reduction in practice variation, availability of national clinical leadership and consideration of existing data, and cost-benefit options. |
| **Principle 8** |
| Data governance for the collection, holding and analysis of patient-level, Australian clinical quality registry information is managed as part of the national health information agenda, in a framework that protects patient privacy and complies with regulation. National data governance arrangements are essential to making the data collection, ethics approvals and reporting activities of Australian clinical quality registries more efficient. |
| **Principle 9** |
| A secure, future-proof and scalable Australian clinical quality registry design and infrastructure should support and host multiple registries. Efficiency and best practice are best achieved through the operation of a small number of Australian clinical quality registry systems or centres. |
| **Principle 10** |
| Australian clinical quality registries must meet the requirements of national Operating Principles for Clinical Quality Registries. |

## Appendix 3: The Caldicott Principles

**Principle 1: Justify the purpose(s) for using confidential information**

Every proposed use or transfer of confidential information should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed by an appropriate guardian.

**Principle 2: Use confidential information only when it is necessary**

Confidential information should not be included unless it is necessary for the specified purpose(s) for which the information is used or accessed. The need to identify individuals should be considered at each stage of satisfying the purpose(s) and alternatives used where possible.

**Principle 3: Use the minimum necessary confidential information**

Where use of confidential information is considered to be necessary, each item of information must be justified so that only the minimum amount of confidential information is included as necessary for a given function.

**Principle 4: Access to confidential information should be on a strict need-to-know basis**

Only those who need access to confidential information should have access to it, and then only to the items that they need to see. This may mean introducing access controls or splitting information flows where one flow is used for several purposes.

**Principle 5: Everyone with access to confidential information should be aware of their responsibilities**

Action should be taken to ensure that all those handling confidential information understand their responsibilities and obligations to respect the confidentiality of patient and service users.

**Principle 6: Comply with the law**

Every use of confidential information must be lawful. All those handling confidential information are responsible for ensuring that their use of and access to that information complies with legal requirements set out in statute and under the common law.

**Principle 7: The duty to share information for individual care is as important as the duty to protect patient confidentiality**

Health and social care professionals should have the confidence to share confidential information in the best interests of patients and service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

**Principle 8: Inform patients and service users about how their confidential information is used**

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.

## Appendix 4: TEHDAS thematic work packages

| **Outreach, engagement and sustainability** |
|---|
| Engaging in dialogue with national health authorities of the participating countries and international stakeholders and incorporating their views into the project. Ensuring that the project's results are integrated into future EU health legislation. |
| **Sharing data for health** |
| Developing options for governance models for the exchange and secondary use of health data between European countries. Providing recommendations for European countries on planning national legislation to enable exchange and secondary use of data. |
| **Excellence in data quality** |
| Providing solutions for the trustworthy secondary use of health data with a view to promoting the digital transformation of European health systems. Developing guidance on ensuring data quality such as anonymisation of data and handling of data disparity. |
| **Connecting the dots** |
| Providing options for the technical interoperability for the secondary use of health data. Encouraging the participation of future users of the EHDS in co-designing the services. |
| **Citizens** |
| Seeking to obtain a better understanding of citizens' attitudes towards sharing their health data. Identifying ways to inform people about the use of their health data and raise awareness of the benefits that the secondary use of data offers. |

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