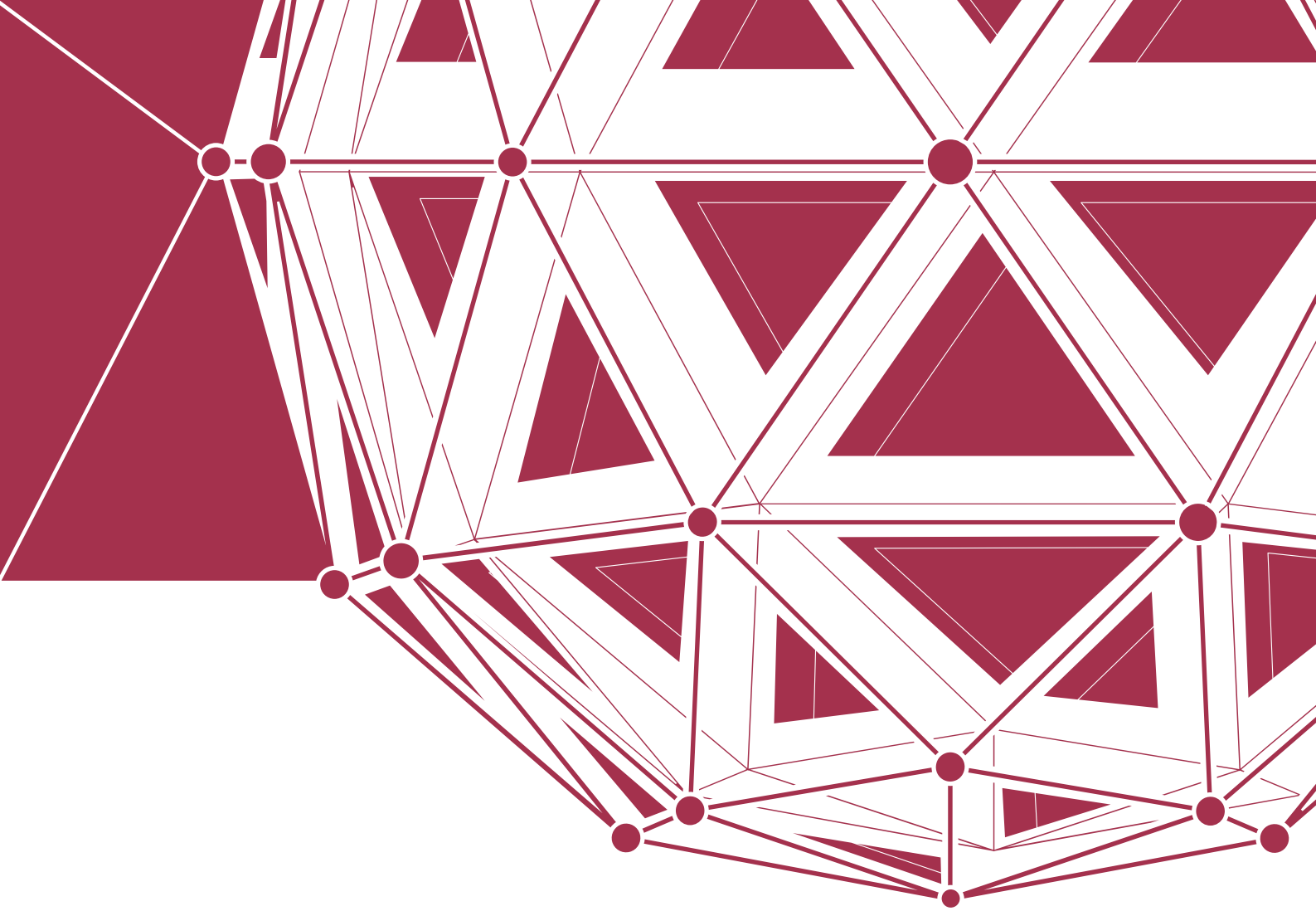

GLOBAL DIGITAL HEALTH
PARTNERSHIP

IMPROVING HEALTH INSIGHTS

GDHP Policy Environments Work Stream report on
the secondary use of health information

Acknowledgements

The GDHP would like to thank the Chair of this work stream, Dr Kim Webber (General Manager, Strategy, Australian Digital Health Agency) and Co-Chair, Tim Donohoe (Chief Technology Adviser, Department of Health and Social Care, United Kingdom), for engaging GDHP participants in discussions, meetings and other activities to drive and develop this work. The GDHP would also like to thank the countries who contributed their country profiles to this report - Argentina, Australia, Brazil, Italy, Japan, Portugal, the Republic of Korea, Sweden, Ukraine, the United Kingdom, the United States and Uruguay. The GDHP Secretariat, including Professor Meredith Makeham, Rodney Ecclestone, Jarrad King and Clara Lubbers, provided editorial support to the work stream Chair and Co-Chair, and collaborated closely with participant countries to ensure the development of this report.

About the Global Digital Health Partnership

The Global Digital Health Partnership (GDHP) is a collaboration of governments and territories, government agencies and the World Health Organization, formed to support the effective implementation of digital health services. Established in February 2018, the GDHP provides an opportunity for transformational engagement between its participants, who are striving to learn and share best practice and policy that can support their digital health systems. In addition, the GDHP provides an international platform for global collaboration and sharing of evidence to guide the delivery of better digital health services within participant countries.

GLOBAL DIGITAL HEALTH
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GDHP Policy environments work stream report on
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CONTENTS

NOTE FROM THE GDHP WORK STREAM CHAIR

This report represents the first deliverable from the Policy Environments Work Stream of the Global Digital Health Partnership (GDHP). At the inaugural February 2018 meeting of the GDHP in Canberra, five work streams were established, including the Policy Environments Work Stream, recognising the importance of policy, legislation and governance in advancing digital health initiatives to support health reform. At that initial meeting a range of pressing digital health issues were considered by the participants and the decision was made that an analysis of how countries enable "secondary uses of health information" would be both timely and useful.

Much has been achieved in the one year since the inaugural meeting and the establishment of the Policy Environments Work Stream. The Policy Environments Work Stream convened for the second time in Washington DC in April 2018 where a survey of participating countries was devised, with the survey findings presented and discussed at the October 2018 meeting in London. We have continued to discuss and analyse international approaches to secondary uses of health information and have distilled learnings into a Maturity Framework.

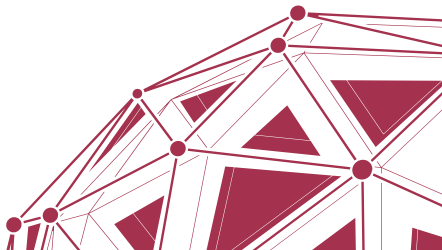
This report describes the outcomes from the deliberations and aims to share international perspectives on secondary use of health information. We hope that all countries, both participants and non-participants, will benefit from examining the solutions and lessons that have been shared here.

GDHP participant countries are aware of the importance of applying evidence to health policy and planning and can see the case for a strong data analytics functionality to support safe and effective health systems.

I want to thank the countries who contributed to the Policy Environments Work Stream discussions and in particular to thank the 12 countries that provided their country profiles to this report – Argentina, Australia, Brazil, Italy, Japan, Portugal, the Republic of Korea, Sweden, Ukraine, the United Kingdom, the United States and Uruguay.

We hope this report provides countries with guidance on the key enablers for maturing approaches to using health information for secondary purposes to benefit the health of all citizens.

Dr Kim Webber
Chair
Policy Environments Work Stream
Global Digital Health Partnership



1 EXECUTIVE SUMMARY

1.1 BACKGROUND

As healthcare services across the world are leveraging the benefits of digital technologies and implementing national digital health records, the amount of health information held is rapidly increasing. More recently, capability around data storage and AI (artificial/augmented intelligence) is making data analytics of large, complex datasets possible. Taken together, there is potential for countries to use health datasets to generate new insights and evidence about health to service their population and improve healthcare standards.

While both the data and the technology are available, there are societal and policy challenges that countries face in being able to collect, collate, analyse, use and distribute health information to deliver benefits to systems and people that result from using of health information for purposes other than the direct provision of healthcare to a patient – known as secondary uses.

This report is the result of a year-long program of work to share information across countries regarding the policy approach taken by GDHP participants when using health data and information for secondary use purposes.

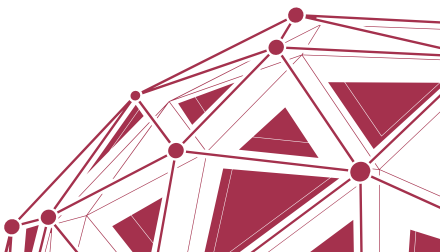
Information contained in the report was derived from three Policy Work Stream workshops held at GDHP meetings throughout 2018, Policy Work Stream teleconferences, email discussions and through a written survey on current approaches to secondary uses of health information.

The aim of this paper is to (a) explore the potential benefits for secondary uses of health information; (b) provide a baseline of the current approaches to secondary use in GDHP participant countries; and (c) guide development of mature processes and capabilities for secondary use to support healthcare systems.

1.2 KEY FINDINGS

GDHP participant countries contributed a number of case studies illustrating how secondary uses of health information have delivered benefits through:

- Prevention of ill health by identifying communities at risk of disease and allowing targeted interventions;
- Supporting health equity by identifying areas of poor service access;
- Measuring performance of health facilities and comparing outcomes;
- Understanding patient care pathways;
- Personalised medicine by identifying cohorts that respond well to specific treatments;
- Monitoring disease outbreaks allowing early response;
- Predicting and planning for public health events such as weather-induced asthma;
- Improving financial efficiency of the health system;



- Measuring efficacy of therapeutic interventions such as medicines or medical devices; and
- Supporting health and medical research discoveries and a vibrant research ecosystem.

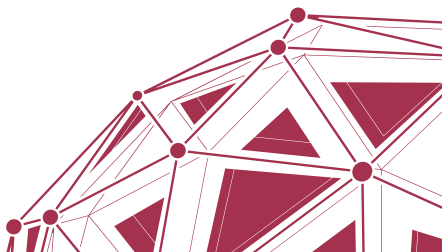
However, these benefits can only be achieved with increasing maturity of the systems, processes and policies of countries for the secondary use of health information. GDHP participant countries are at various levels of implementation with respect to the secondary use of health information and have faced difficulties in implementing processes and policies. Some countries have made significant progress while others face restrictions on their ability to use health information for secondary purposes. GDHP country experiences informed the development of a Maturity Framework to guide countries on how to proceed. The steps involved in the framework are:

1. Local data collection – collection of digitised data during health service provision;
2. National data collation and use – the ability to collate and aggregate datasets from a variety of sources into a single national dataset for use in health policy;
3. Data linkage – linking different national health datasets with each other and with other datasets to obtain a fuller picture of social and environmental factors that may be impacting on health outcomes (e.g. weather events, pollution etc.);
4. Dataset access and release – allowing the non-government research and public health community access to the datasets; and
5. Open data – a culture and an infrastructure that allow a range of third-party organisations to access the data for public good.

As each stage is able to be delivered, more and more benefits are able to be realised. In order to progress through the Maturity Framework in relation to secondary use of health information, a number of enablers need to be in place to support maturity:

- ICT infrastructure and foundations in place;
- Confidence and trust of all stakeholders;
- Established governance models;
- Public engagement, conversation and debate; and
- Limiting secondary uses of health information for the public good.

Paramount to the success of health information sharing for secondary use purposes is ensuring there is community trust and confidence in the secondary use of health information through strong governance, as well as legislative and regulatory mechanisms. These processes are required to control how data is collected, stored and released in a transparent way to those who have contributed the information, and support their ability to choose whether or not they wish their data to be used. With these underpinnings in place, people will continue to trust healthcare providers and organisations with their sensitive health information.

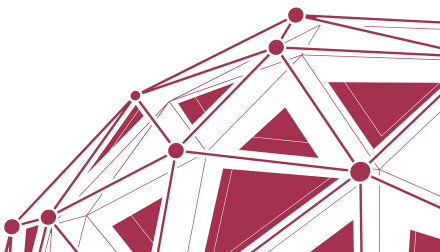


1.3 RECOMMENDED NEXT STEPS

The importance of effective, global and national approaches to governance in relation to the processing of personal health data has never been greater if the potential for society to benefit from the use of health data is to be realised. The work of the GDHP Policy Work Stream on secondary use of health information could be augmented through a range of tangible activities such as:

- sharing of appropriate health data governance frameworks to enable secondary use of health information including consent models;
- the potential to collate data from across national borders to build a dataset on rare diseases where the size of the population across the globe would strengthen the power of such studies;
- sharing methodologies for surveillance of communicable and non-communicable diseases;
- sharing approaches and insights from linking health data to non-health datasets (e.g. environmental and meteorological to better predict and plan for pollution events);
- comparing innovative approaches taken to measuring health outcomes (e.g. return to work, patient-reported measures);
- exchanging insights on how to improve services and empower consumers by publication of outcomes and costs;
- improving financial efficiency and reducing fraud through tighter control of reimbursement between hospital providers and the funder;
- ethical and policy issues involved with collection and use of genetic data to enable precision medicine and AI algorithms; and
- the challenge of developing safe open data resources of anonymous data that can power third-party innovation and industry.

The GDHP Policy Work Stream is cognisant that it will be important for this work to be consistent with and supportive of other international initiatives in the digital health space, such as the OECD work on health data governance, and the WHO's Sustainable Development Goals and related digital health initiatives required to achieve these.



2 INTERNATIONAL OVERVIEW OF SECONDARY USES OF HEALTH INFORMATION

The health sector is just at the beginning of digital transformation with countries at various levels of implementation. Digitisation in healthcare delivery promises not just improvements in efficiency and convenience for a patient, but significantly improved safety and patient outcomes. Moreover, it is anticipated that the widespread implementation of digital health will give consumers more control over their health and care.

> *Digital strategies have been formally recognized as a critical health systems strengthening strategy to help meet the Sustainable Development Goals and universal health coverage targets.* (1)

As healthcare systems across the world have computerised and adopted digital technology to support healthcare delivery, we are seeing a dramatic proliferation in the volume of real-world health data that is being captured (2).

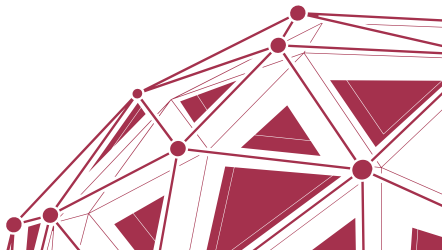
At the same time, advances in computing power and data analytics including AI (artificial/augmented intelligence) are improving the potential for such large datasets to be analysed (3). Therefore, now, more than ever, there is a real opportunity for policy makers to use these health datasets to generate new insights and evidence about health to benefit their populations.

However, there are also challenges that countries face in the collection, collation, analysis, use and distribution of health information for a range of secondary uses. Recently the OECD stressed the special and sensitive nature of health information which requires a particularly high level of protection given the longstanding principle of medical confidentiality (4). It is important to acknowledge that health information could be used to harm patients through identify theft or potential discrimination in employment or insurance and that such potential misuses are of great concern in the community.

> *The importance of effective, global and national approaches to governance of the processing of personal health data has never been greater if the potential for society to benefit from the use of health data are to be realised. (4)*

These issues are not new but in a rapidly changing environment, the need to review international approaches was seen by GDHP participants as timely, particularly given recent progress in many countries in the implementation of national digital health records.

The GDHP Policy Work Stream has focussed on building an understanding of policies and strategies that deliver a balance between legislation and regulation focussed on addressing privacy concerns, and allowing public benefit from secondary uses of health information.



2.1 SCOPE AND DEFINITIONS

This paper examines the "secondary use" of real-world patient and health data. The term "secondary use" was originally developed as the data is collected as a by-product of the primary use – the delivery of direct patient health care and health services to an individual or for administration and billing purposes. This report will not cover the issues related to data sharing for primary use but will focus only on secondary use of people's health information.

To provide clarity and context, the definitions below are used for the purposes of this report:

- **Personal Health information** – is the means any information relating to an identified or identifiable individual that concerns their health, and includes any other associated personal data (4).
- **Personal information** – information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion (4).
- **Secondary use** – use of health information for purposes other than the provision of health care. This includes, but is not limited to, analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities (2). [1]
- **Individual identifiable health data** – information that allows the identification of the person to whom it relates, either directly (e.g. by name, address, reference number), or indirectly (e.g. by some distinguishing feature such as business activity, size, location) (5) (6).
- **De-identified/pseudonymised health data** – the elimination of identifiers e.g. patient's name, medical record number, social security number, and other data fields that could directly link a person to their unit level data (2).

2.2 METHODS USED

This report is the result of a year-long program of work to share information across countries regarding the policy approach taken by GDHP participants when using health information for secondary use purposes.

Information contained in the report was derived from three Policy Work Stream workshops held at GDHP meetings throughout 2018 (7) (8) (9), Work Stream teleconferences, email discussions and through administration of a written survey on current approaches to secondary uses of health information. All GDHP countries were invited to contribute to the survey which asked the following questions:

- Does your country or territory have specific legislation governing the secondary use of citizen's health information?
- Please describe the legislation that your country or territory has implemented to govern the secondary use of health information?

[1] One of the challenges to date has been about reaching a global consensus on the definition of secondary use. The definition is constantly changing depending on how each country classifies the primary use of health information.

- What is the definition of “secondary use of health information” that is used in your country or territory?
- What types of health information are available for secondary use purposes in your country or territory?
- How is the release of secondary use health information governed in your country or territory? And include the name of the organisation that governs this process?
- What processes/tools/instruments have been developed in your country or territory to assist in the provision of access to health information for secondary use?
- What secondary uses of identifiable health information does your country or territory allow based on the following organisations?
- What secondary uses of de-identifiable health information does your country or territory allow based on the following organisations?
- What standards do you follow when de-identifying health information for secondary use purposes in your country or territory?
- What consent models does your country or territory have in place for the release of health information for secondary use purposes?
- What is your country or territory context/environment that led to your secondary use policies being developed?
- What benefits has your country or territory already seen from secondary use of health information?

The responses to these questions were synthesised and are presented in the discussion section of this report. A thematic analysis was then undertaken to draw out common themes and identify gaps described by GDHP participants.

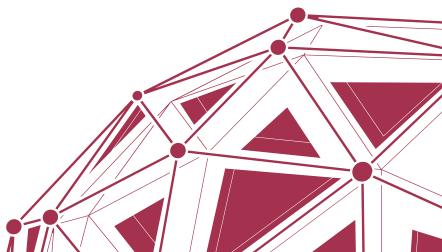
The outcomes of the survey, the workshop discussions of the GDHP meetings, together with a review of the literature were taken together to (a) identify how countries can benefit from secondary uses of health information (b) develop a Maturity Framework which describes the process leading towards an open data culture; and (c) the enablers required for country to mature their approaches to secondary uses of health information.

2.3 LIMITATIONS

This report is a descriptive analysis of GDHP participants’ responses to a survey on secondary uses of health data policy within their countries, and case study examples.

The GDHP is a growing international collaboration; however, there are a range of maturity levels in terms of developed approaches to secondary uses of health information among participants. In addition, there may be other national approaches to this question among non-GDHP participant countries and not described in the English language literature.

Furthermore, it is possible the Maturity Model and enablers identified are not appropriate for all countries and settings as a number of these issues will be context dependent.



3 RESULTS – INTERNATIONAL APPROACHES TO SECONDARY USE OF HEALTH INFORMATION

3.1 RESPONSES FROM GDHP PARTICIPANTS

At the time of this report, there were a total of 23 GDHP participating countries and territories, including the World Health Organization (WHO). Twelve countries responded to the survey and the majority were able to provide a case study.

The aim of the secondary uses of health information survey was to ascertain international approaches to health data privacy protections and consent processes for consumers to allow access to and use of their health information for secondary purposes.

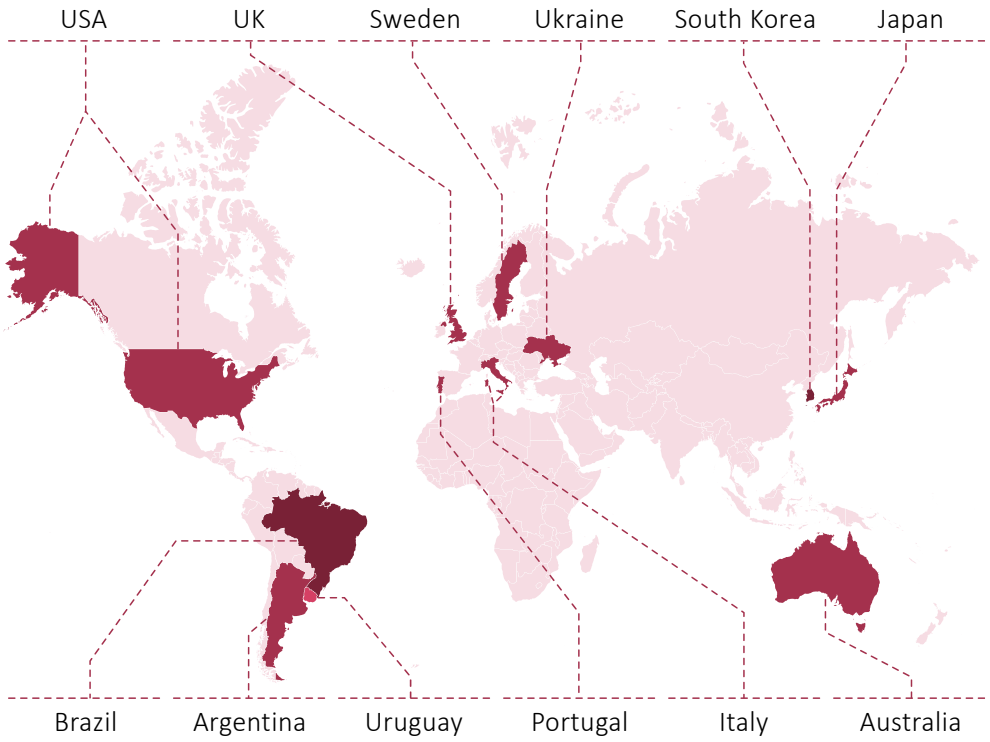


Figure 1: Country contributors to the Policy Environments Work Stream secondary use of health information survey

The following pages summarise the policy and regulatory frameworks for secondary uses of health information by (a) legislation; (b) governance; (c) different types of health information; as provided by countries.

3.1.1 ARGENTINA

Secondary use of health information in Argentina is regulated by the Personal Data Protection Law, which states that secondary use is only allowed under specific circumstances.

The use of health data by government organisations for public health policies and service planning is allowed, as this is the main function of the government organisation and the data is required to perform that function. Moreover, most data used for such purposes is recorded or submitted specifically for this goal, so these actions conform to a primary use of the data.

Legislation regulating secondary use of health information

Law on Protection of Personal Data – Protection of personal data stored in archives, registers, databanks, or by other technical means of data processing, whether public or private. This law ensures people's privacy, as well as access to the information registered about them.

The law allows for these specific secondary use cases:

- Emergency provisions;
- Public health; and
- Epidemiology studies, but only with anonymised data.

Governance

While there is no centralised health data repository in Argentina, health institutions are able to provide the information they collect as long as it is in line with the data protection law. Use of data for research studies need to be approved by institutional ethics committees.

Classes of secondary health data

Individual identifiable health data

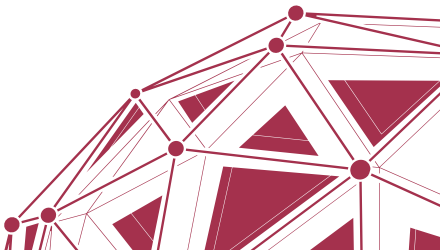
No information about individuals is shared. Individual, identifiable data is recorded in national registries for the purpose of public health use, and not shared for other uses.

Unit level de-identified/pseudonymised health data

No individual information is shared in this manner as a normal process, although the law does allow access for statistical or research purposes as long as the data is de-identified.

De-identified (aggregate) health data

Secondary use of health information is allowed for statistical or research purposes as long as the data is de-identified. Some data collected at the national level is available to external researchers as aggregated datasets.



Case study | Argentina

Impact of universal health coverage on child growth and nutrition in Argentina

Type of data used

From 2005 to 2013, two universal health coverage programs (Plan Nacer and Programa Sumar) collected high-quality information on birth and visit dates, age (in days), gender, weight (in kg), and height (in cm) for 1.4 million children in 6,386 health centres (13 million records) with broad coverage of vulnerable populations in Argentina.

The aim of the study was to estimate trends of undernutrition (stunting and underweight) among children younger than five years covered by the universal health coverage programs.

Benefit realised from using secondary health data

The prevalence of stunting and underweight decreased by 45 per cent (from 20.6 % to 11.3 %) and 38 per cent (from 4.0 % to 2.5 %), respectively, with differences identified in rural versus urban areas, gender, regions, age, and seasons. The secondary use of health data enabled the evaluation of the implementation of universal health coverage in Argentina and was able to determine that undernutrition prevalence substantially decreased in two programs in Argentina as a result of universal health coverage.

3.1.2 AUSTRALIA

Australia has a number of national collections of patient health information (predominantly billing data) along with a national electronic health record system. Most national datasets are administrative and exist due to the national government's role in funding primary health care. Other national datasets are a collation of the state datasets that state governments collect due to their role in funding and delivering community and acute care services. In addition, private health services and research institutes also collect patient health information that may be used for secondary use purposes.

The governance model around the collection, storage, use and release of health information involves a complex range of agency-level policies, human research ethics committees and specific legislation provisions. With regard to the collation of state-based datasets into a single national dataset, such collation is governed mainly by inter-governmental agreements and committees and additional regulations imposed by the data donor states.

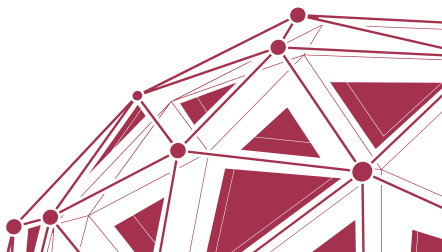
Legislation regulating secondary use of health information

In Australia, health information is considered sensitive in nature, and more specific legislation and rigorous regulation of its use is often applied as compared with other types of public data.

- Privacy Act – The central piece of legislation that governs the use of individual personal information. All healthcare organisations are bound by the Privacy Act. The Privacy Act permits the management of health information for health and medical purposes without consent from the individual. An amendment to the Privacy Act in 2012 introduced the Australian Privacy Principles. These principles do not allow agencies to use or release personal information for research or statistical purposes unless specific authorisation is sought, is authorised under a separate law, or patient consent has been obtained. The overreaching guiding principle of the Privacy Act is that the benefit of health information being released for research activities must outweigh the public interest in the protection of privacy (10).
- My Health Records Act – Legislative framework for Australia's national electronic health record system (My Health Record) providing the legislative basis for authorising the use of data for research, public health and other secondary use purposes. The legislation enshrines the rights of the patient to choose whether or not to participate in the system and with whom their data can be shared. It also grants the patient the right to choose what data is stored in the system supported by functions that allow people to remove information, and view an audit history of anyone who has interacted with their data.
- Additional national instruments – Further regulations and legislation governing health information include the Freedom of Information Act, Healthcare Identifiers Act, National Health Act, Health Insurance Act, Australian Institute of Health and Welfare Act, and the National Statement on Ethical Conduct in Human Research.

Governance

- In Australia, data custodians such as the Australian Institute of Health and Welfare, the Department of Health, the Australian Bureau of Statistics, the Department of Health and the Department of Human Services play a central role in collating, using and releasing health data for secondary purposes.



- The National Health Information Agreement between state and territory health authorities and various federal government agencies coordinates the development, collection and dissemination of health information in Australia, including the development, endorsement and maintenance of national data standards.
- The Office of the Australian Information Commissioner has investigatory and advisory roles in relation to health information including the My Health Record system.
- The Australian Institute of Health and Welfare has been specifically named as the data custodian for the My Health Record system data and a Framework for Secondary Use of My Health Record Data (11) was developed by the Department of Health after a period of public consultation. The framework specifically outlines a set of governance arrangements to be put in place by 2020.

Classes of secondary health data

Individual Identifiable health data

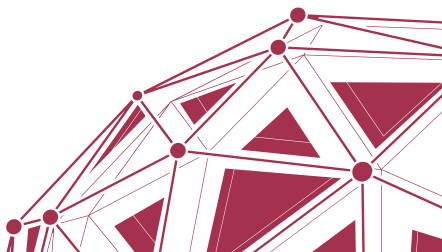
In Australia, patient consent is required in order to release individual identifiable data for secondary use purposes. This provision also applies to data within the national electronic health record system, My Health Record.

Unit level de-identified/pseudonymised health data

Unit level data is able to be de-identified and used for research and public health purposes in Australia. Release of data from the My Health Record system is governed by the secondary use framework (11) and is governed by processes described in the secondary use framework and led by the Australian Institute of Health and Welfare.

De-identified (aggregate) health data

By default, patient health information in the My Health Record can be released for secondary use purposes without patient consent. However, the patient is able to opt out of their data being used for secondary use purposes through My Health Record privacy controls.



Case study | Australia

Cost-effectiveness of primary care for Aboriginal and Torres Strait Islander Australians with diabetes

Type of data used

The study involved linking of data from a state primary care information system with hospital admission data. Further analysis of both datasets was conducted using information about the cost of primary care (obtained from the Northern Territory accounting system).

Benefit realised from using secondary health data

The data analysis was able to demonstrate that patients with diabetes who regularly visited a primary care doctor have lower rates of potentially avoidable hospitalisations and death and fewer years of life lost.

This research provided new evidence that patients have better health outcomes when their access to primary care is improved. It also provided evidence of potential significant cost savings to the health system. The savings in hospitalisations provided a measure of the value for money of primary care and created a new, compelling argument for the investment of funds in primary care in remote Australia.

3.1.3 BRAZIL

Brazil supports the use of health information for secondary use purposes, governed by legislation that manages access and protects the personal information of its citizens. Health information is stored in national databases with some datasets becoming publicly available. There is a proposal to publish specific complementary legislation on access and protection of health data. This legislation provides for the inclusion of a consent model. The governance model and the legislation used are described in more detail below.

Legislation regulating secondary use of health information

- Law of Access to Information 2011.
- Law of Protection of Personal Data 2018 – Provides for the processing of personal data, including digital media, by either a natural person or public or private legal entity, for the purpose of protecting a person's fundamental rights of freedom and privacy (12).

Governance

Brazil stores its health information on national databases. The types of information include: services performed by primary health care, specialised ambulatory home care, psychosocial care and hospitalisation; health services (facilities) and related health professionals; dispensing strategic medication; diseases of compulsory notification; birth and mortality; immunisations; and other.

The release of data for secondary use is performed through the anonymisation of sensitive data and public availability on the website of the Ministry of Health. Access to most health data for secondary use is done through public tools that can be accessed through a browser ("TABNET") or by downloading databases that can be consulted in a Microsoft environment Windows tool ("TABWIN").

In the case of need for data pairing of different databases, the linkage process is carried out by a specific division of the Department of Information and Informatics (DATASUS) and is available directly to the interested party. The pairing of databases is carried out in the tool "VINCULASUS", an own-development of the Ministry of Health.

Classes of secondary health data

Individual identifiable health data

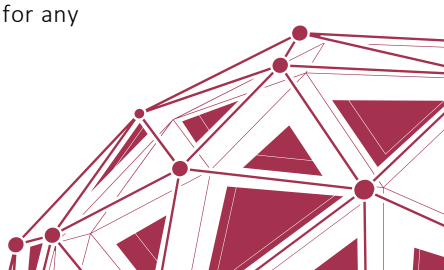
Individual identifiable health information can only be used by the government for improving health services, developing health policy and for public health measures.

Unit level de-identified/pseudonymised health data

n/a

De-identified (aggregate) health data

De-identified data is made available to the public through databases on the Ministry of Health website. Therefore, it can be accessed by anyone for any purpose.



3.1.4 ITALY

In Italy, responsibility for health care is shared between the national government and the 20 regions that provide health services. Italy has good supporting infrastructure to collate and manage health information, and there are strong established data flows that use unique patient identifiers to allow the linking of different datasets.

As part of providing health care, there are multiple registries that capture patient treatment and outcome data. These registries are then used by the research community for several purposes including drug-monitoring, and cancer prevalence and survival monitoring (10). To enable these functions, Italy maintains a comprehensive legislative underpinning that supports data sharing and ensures individual health information is adequately protected.

The biggest challenge Italy faces in terms of data sharing is the fragmented nature of the regional health services, which makes data linkage, while technically possible, quite difficult in practice. The governance model and the legislation used is described in more detail below.

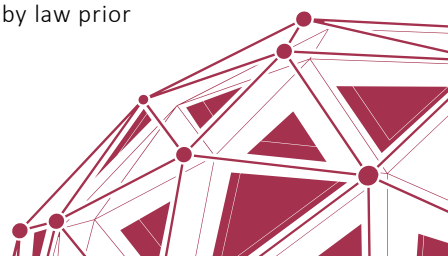
Legislation regulating secondary use of health information

- *General Data Protection Regulation (GDPR)* – The GDPR harmonises national data protection laws in the European Union, establishing new rights for individuals and imposing significant penalties for data breaches. The GDPR requires data controllers to have a lawful basis for the processing of personal information. Further processing of the data beyond that which was originally anticipated (secondary use) is only permitted if the new processing activity is not incompatible with the original purpose.
- The GDPR is supplemented by domestic legislation (which complies with the GDPR) including:
    - *Data Protection Code 196/2003* (the code) which combines multiple data protection laws and regulations into a single legislative instrument. The code includes a specific category on the processing of identifiable health data for public interest purposes, which requires individual patient consent or must be permitted by law prior to its release.

Governance

As part of Italy's National Health Service, numerous databases containing health information are available for secondary use for purposes including compiling information on specific diseases, monitoring and registries, pharmacological surveillance, and cost analysis in accordance with GDPR principles. Example datasets include the Italian Medicines Agency (AIFA) drug-monitoring registries, which oversee drug prescribing to ensure this occurs within clinical guidelines. The Italian Association of Cancer Registries also operates a cancer portal that allows the research community to monitor cancer incidence, mortality, survival and prevalence. Italy is also in the process of constructing disease registries at the national level through the consolidation of regional data, although this is proving challenging as the data is subject to regional legislation (10).

The regulation of personal information of Italian citizens is undertaken by the Data Protection Agency, supported by legislative instruments including the code. The code includes specific provisions on the processing of identifiable health data for public interest purposes, which requires individual patient consent or a permission by law prior



to its release. An example of where individual consent is not required is where obtaining consent is not possible due to the number of individuals involved.

The Data Protection Agency only allows healthcare professionals and public healthcare bodies (including universities) to process patients' health information without obtaining consent where this protects the patients' health, or the health of a third party or community. The data cannot be accessed by private organisations or profit-seeking public bodies without the authority of the Data Protection Agency or where patient consent has not been given. According to the code, the release of personal health information may be processed for medical research purposes only when it is approved by the regional ethics committee and the Data Protection Agency (10).

Italy is also in the process of implementing its national electronic health record. Discussions are ongoing about what data contained in the record will be permitted for secondary use and for what purposes. However, the agreed governance framework will be subject to the same data protection legislation that all existing datasets must comply with (10).

Classes of secondary health data

Individual identifiable health data

Third parties can only access individual identifiable patient data when informed consent from the patient is obtained or where it is permitted by law. Once consent is obtained, the third party is not required to seek the approval of the Data Protection Agency. Before the release of patient health information for secondary use, all applications must be approved by the regional ethics committee. Each of Italy's 20 regions has its own local health organisation that is responsible for the processing of all personal health information.

Unit level de-identified/pseudonymised health data

The Ministry of Health is the owner of data processing, which is conferred on the Ministry's new health information system of health (the NSIS). Procedures are defined for the interconnection, at national level, and on an individual basis, with the objective of:

a. performing functions of evaluation of the results of welfare services and medical–surgical procedures within the National Health Service;

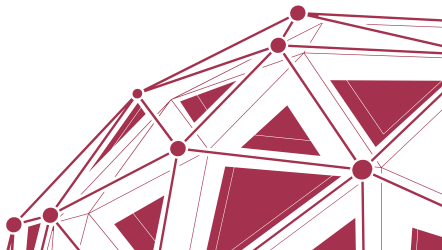
b. monitoring essential levels of assistance; and

c. statistical purposes pursued by public entities that are part of the National Statistical System (SISTAN).

Cryptographic hash functions are used to achieve pseudonymisation of personal identifiable information.

De-identified (aggregate) health data

Some aggregate data is available in open data format on the Ministry of Health website: http://www.dati.salute.gov.it



Case study | Italy

Improved methods and actionable tools for enhancing health technology assessment — 'IMPACT HTA'

Type of data used

An observational study in 12 emergency departments. In the emergency departments, the use of high-sensitivity troponin for early diagnosis of NSTEMI (Non-ST elevation myocardial infarction) is still very heterogeneous. The data is quantitative and qualitative and related to the diagnostic use of high-sensitivity troponin and its impact on NSTEMI myocardial infarction diagnosis and treatment.

Benefit realised from using secondary health data

The analysis of data will permit the definition of key elements and interdependencies between technologies, clinical variability, and organisation models that impact on organisational efficiency of hospitals.

The understanding of these mechanisms will permit the development of tools and policy guidelines to better address clinical and organisational variability.

These tools and guidelines will be validated by different panels involving clinicians, managers and policy makers.

Results of this project will have an immediate impact on the policy recommendations about the use of high-sensitivity troponin.

Further to these immediate applications, the validation process of tools and guidelines will improve management of the impact of organisational and clinical variability on hospital performance.

3.1.5 JAPAN

The concept of using healthcare information for secondary use purposes is growing in Japan due to the creation of a next-generation healthcare system that is being planned for operation towards the 2020 financial year. The goal of the new reforms is to improve the health of individuals and lengthen healthy life expectancy through introducing data and technological innovations. The governance model and the legislation used are described in more detail below.

Legislation regulating secondary use of health information

The regulatory framework governing secondary use in Japan is underpinned by the following legislative instruments:

- *Act on the Protection of Personal Information* – as the general rule, protects the rights and interests of individuals while considering the utility of personal information by establishing obligations etc. that a business operator handling personal information must fulfil (13).
- *Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development.*
- *Act on Assurance of Medical Care for Elderly People.*

The latter two acts include special rules governing secondary use of health data. The Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development governs the collection, storage and third-party provision of health information for secondary use.

Governance

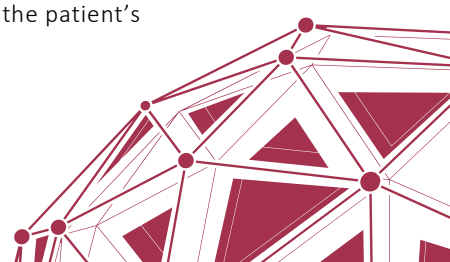
Japan's governance model in relation to secondary use of health information is developed on a case-by-case basis but is based on two different models of participation:

- Opt-in model – where an individual must give permission for their health data to be used for secondary purposes in accordance with the Act on the Protection of Personal Information (the Act does not apply to academic research where ethics committees judge adequacy of patient consent).
- Opt-out model – where the individual's health data is able to be used for secondary use purposes on an opt-out basis when medical information is anonymised by an authorised business operator and provided for research and development in the medical field under the Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development.

Classes of secondary health data

Individual identifiable health data

In Japan, patient consent is required in order to provide individual identifiable data to a third party for secondary use purposes according to a general law, the Act on the Protection of Personal Information. Patient consent must be obtained in advance of the provision to the third party. As exceptions, some special laws enable provision of identifiable health data to a third party without the patient's



consent under certain conditions. An example is the Cancer Registry Promotion Act.

Unit level de-identified/pseudonymised health data

In Japan, de-identified unit level data may be used for any purpose including research and public health purposes. For the transmission of some de-identified health data, including medical bill data, there is a limitation on the purpose and the recipients.

De-identified (aggregate) health data

Once the data is de-identified and aggregated, it can be used for any purposes, including research and public health purposes. As for medical bill data, the Ministry of Health, Labour and Welfare releases basic and versatile aggregate data on its website.

Case study | Japan

Research on the administration of antihypertensive medicine to cardiac patients with kidney impairment, through analysis of the national medical billing database (31)

Type of data used

The research analysed the national medical billing database. The database is held by the Ministry of Health, Labour and Welfare and contains data from 14.8 billion medical bills sent from healthcare institutions across the nation for the purpose of health insurance reimbursement. Researchers can apply for secondary use and, if approved, they are allowed to use the database for their research. The research identified how antihypertensive medicine is administered to cardiac patients with kidney impairment using a sample of 26,186 hospitalised patients and 155,839 outpatients.

Benefit realised from using secondary health data

The analysis showed that cardiac patients with kidney impairment tend to be under more rigorous blood pressure control through multi-drug therapy than cardiac patients without kidney impairment. It also revealed that for patients with heart failure, prescription of antihypertensive medicine tends to differ from that recommended in the Hypertension Treatment Guidelines.

3.1.6 PORTUGAL

Portugal has several national datasets of patient health information, including a nationwide electronic health record system and an electronic mortality registration system, that permit the use of de-identified data for specific purposes.

The national datasets exist mainly due to the role of the National Healthcare Service in funding and providing primary and hospital health care, as well as funding public health prevention and control programs.

These datasets are centrally managed and/or stored at the Ministry of Health Shared Services (SPMS), which is the public national health information and technology agency.

Other national datasets exist, namely health surveys through the Portuguese National Institute of Statistics. In addition, private health services and research institutes also collect patient health information that may be used for secondary purposes.

The governance model around the collection, storage, use and release of health information is based on legislative and regulatory provisions involving agency-level policies, human research ethics committees, and personal data protection regulations.

The secondary use of health information in state datasets is governed mainly by inter-governmental agreements and, in some cases, specific legislation, that define the scope and nature of secondary use.

Health information is considered sensitive in nature and more rigorous regulation of its use is often applied in Portugal, as compared to other types of data.

Legislation regulating secondary use of health information

- EU General Data Protection Regulation (GDPR, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016) – The GDPR harmonises national data protection laws in the EU, establishing new rights for individuals and significant penalties for data breaches.
- The GDPR is supplemented by domestic laws including:
    - **Portuguese Data Protection law** (Law 67/98, October 26th) – regulates the protection of personal data, transposing Directive 95/46/CE of the European Parliament and of the Council, which shall remain applicable provided that it does not conflict with provisions of the GDPR. Available at: http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=156&tabela=leis
    - **Personal genetic information and health information law** (Law 12/2015, January 26th) – defines the concepts of health information, genetic information and regulates the movement of health information. Available at: http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=1660&tabela=leis
    - **Clinical Investigation law** (Law 21/2014, April 16th subsequently amended by Law 73/2015, July 27th and Law 49/2018, August 14th) – establishes the principles applicable to clinical investigation. Available at: https://dre.pt/pesquisa/-/search/25344024/details/maximized
    - **Ethics Committee Regulation in health institutions and universities** (Law-Decree 80/2018, October 15th) – establishes the rules and principles applicable to ethics committees operating in health institutions, higher education institutions

and in biomedical research centres conducting clinical investigation. Available at:
https://dre.pt/application/file/a/116676679

Governance

- In Portugal, multiple agencies are responsible for data sharing: local, regional and national health agencies play a central role in privacy protection and use of health data for secondary purposes.
- At the national level (for National Health Service databases that are centrally stored), the Ministry of Health Shared Services (SPMS) is responsible for data sharing, but this may or may not need another agency's authorisation.
- Secondary use of health data for clinical investigation must have approval of an ethics committee. Ethics committees also have important roles in protecting health information, patient privacy and in promoting the ethical use of health data.
- Compliance with data protection rules and principles is regulated by a national office: the National Data Protection Authority.

Classes of secondary health data

Individual identifiable health data

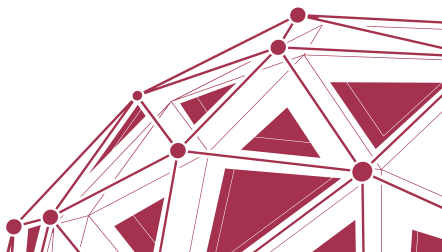
Upon the authorisation of the data subject, identifiable health data may be subject to secondary use.

Unit level de-identified/pseudonymised health data

Unit level data can be de-identified and used for research and public health purposes in Portugal.

De-identified (aggregate) health data

Anonymous data is not subject to GDPR and consent is not required. De-identified data is also not subject to GDPR, provided the research team had no role in the collection of the data with identifiers in the first place and has no access to the identifiers going forward. A data use agreement may be applicable.



e-VM electronic mortality surveillance

Type of data used

Anonymised data from electronic death certificates held in a nationwide web-based central database (SICO – *Sistema de Informação dos Certificados de Óbito*/Death Certificates Information System) that collects data on all deaths in Portugal, in real time.

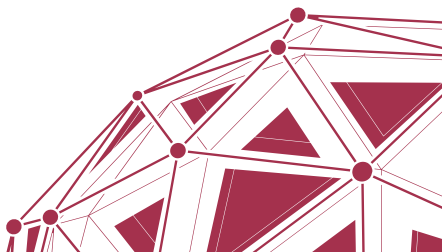
Benefit realised from using secondary health data

Data from electronic death certificates is used to monitor core public health mortality indicators, in real time. Data is available at national, regional and local levels for surveillance and prevention through an online business intelligence software (e-VM, available at http://evm.min-saude.pt), that analyses mortality data in real time.

Prevention activities are implemented by health authorities and healthcare institutions and take place through national public health programs (namely flu surveillance, heatwaves and other extreme weather conditions, and infectious diseases surveillance programs) based on surveillance data.

Additional information can be found at:

http://www.euro.who.int/__data/assets/pdf_file/0019/312319/Eurohealth-volume22-number2-2016.pdf?ua=1



3.1.7 REPUBLIC OF KOREA

The Republic of Korea has a health system built around universal health care. Approximately 97 per cent of the population is covered by a single payer health system managed by the National Health Insurance Service (NHIS) and the Health Insurance Review and Assessment Service (HIRA). As a result of the almost universal coverage of the population, the country has very comprehensive healthcare information collected from almost all hospitals, covering basic health information to disease treatments. The Republic of Korea has a secondary use management framework in place that governs how this data is collected, stored and released to various organisations within the country, underpinned by legislation.

Legislation regulating the secondary use of health information

- *Act on Provision and Activation of data use* – The Act manages the data held by public institutions, how the data can be used, and guarantees the right of individuals to access the public data (14).
- *Personal Information Protection Act 2011 (PIPA)* – The PIPA manages personal information protecting the rights and interests of all individuals (14).
- *Bioethics and Safety Act* – Provides the legislative basis for a variety of functions including the use of information that contributes to the improvement of people's health and quality of life.

Governance

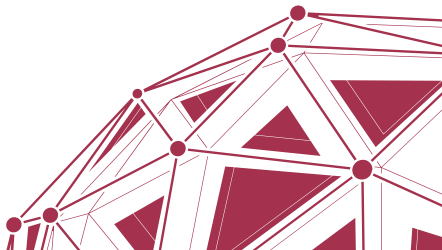
The National Health Insurance (NHI) scheme provides the basis for a large proportion of the healthcare information that is collected and that can be used for secondary use purposes. The health information collected from the NHI scheme is managed by the NHI Service and the Health Insurance Review and Assessment (HIRA) Service, who differ in their governance arrangements. As part of the health insurance system, all healthcare providers file reimbursement claims to cover the costs of their health services with HIRA, which in turn passes on that information to the NHIS. The databases managed by both organisations allow policy makers and public health researchers access to the data. For both the NHIS and HIRA databases, all requests for information are examined by a review committee.

NHIS

The NHIS database contains patient information such as treatments details, disease details and prescription information linked with a unique patient identification number. The database is able to be accessed by researchers with an academic or public policy background, but it cannot be provided to those that request the data for commercial purposes (14).

HIRA

The HIRA database, like the NHIS database, provides customised datasets and data from insurance claims made by the public.



Classes of secondary health data

Individual identifiable health data

The Republic of Korea does not permit the use of identifiable individual-level data for secondary use purposes.

Unit level de-identified/pseudonymised health data

Data collected by both NHIS and HIRA for the whole population must undergo a stringent de-identification process before being released as individual-level data to third parties. The first step in this de-identification process is removing the unique identifier given to the individual data and swapped with an alternative serial number. Other attributing values such as name and address are also removed unless they are required for data use or analysis. In situations where the research proposal relies on these attributing values, they will be de-identified through a number of techniques including pseudonymisation, data masking, data suppression and data reduction. After this process, the data of individuals is released to third parties in a de-identified form (14). Risk assessment and the final decision for provision of data for researchers are the responsibility of the Data Provision Deliberation Committee.

De-identified (aggregate) health data

Detailed aggregate statistics for the whole population are published annually, and in some cases quarterly. In the case of the Health Insurance Statistical Yearbook, both NHIS and HIRA are involved in the publication of each edition

Case study | Republic of Korea

Early detection of suspected infection cases

Type of data used

Identified information on medical treatment, drug prescription by doctors (Drug Utilisation Review information), medical resources of the medical facilities, residence of patients etc. which HIRA collated for the review and assessment of medical claims.

Benefit realised from using secondary health data

It was possible to locate real-time pathology of the patients using the Drug Utilisation Review 24/7 monitoring system (service provides real-time side-effect information to providers), which tracks doctor's prescriptions and dispensing at pharmacy. In 2015 during the MERS epidemic, HIRA with the aid of this system successfully contributed to preventing the dissemination of MERS by providing the real-time tracking of suspected patients to the Korean CDC.

3.1.8 SWEDEN

Sweden has a longstanding tradition of (national) information systems to support a wide range of civil administrative information. Public health and healthcare services (provision and use of) are at the core of the welfare system. Sweden developed population-based (and national) computerised health data registries very early on, e.g. the National In-patient registry started in 1964. The system has developed over the years, and there has been political consensus in previous and the current government (regardless of political party) to support registry-based research in general.

In Sweden (and other Nordic countries), the potential of secondary use of health data, particularly in registry-based research, has been realised in part by a longstanding and comprehensive system of routine collection of data from healthcare services, but also the Swedish personal identification number (PIN), a unique identifier which makes it possible to link health data from different registries, which has been in place since 1947. The governance model and the legislation used are described in more detail below.

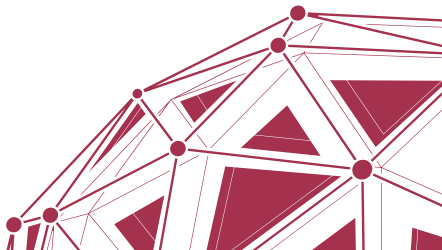
Legislation regulating the secondary use of health information

- The EU General Data Protection Regulation (GDPR) – The GDPR harmonises national data protection laws in the European Union, establishing new rights for individuals and imposes significant penalties for data breaches. The GDPR requires data controllers to have a lawful basis for the processing of personal information. Further processing of the data beyond that which was originally anticipated (secondary use) is only permitted if the new processing activity is not incompatible with the original purpose.
- The GDPR is supplemented by national legislation including:
    - The Act on Health Registries (1998:543) which states that personal information in health registries may be used for secondary use for the following purposes: production of statistics, follow-up, evaluation and quality assurance of health services, and research and epidemiological studies.
    - Disclosure and Secrecy Act (2009:400) which regulates disclosure of personal information in health registries.
    - The Act on Ethics Review of Research involving Human Studies (2003:460) which contains regulations concerning the ethical vetting of research concerning humans and biological material. It contains the consent provisions in order to conduct such research. The purpose of the act is to protect individuals and human dignity when research is conducted (15).

Governance

National health data registries

The National Board of Health and Welfare (NBHW) is a government agency responsible for the regulation of the health data registries. These registries are a valuable source of information on population health, health service performance and outcomes. The registries are collections of selected personal and organisational health information collated into anonymous aggregated statistics. There are several types of health data registries that cover a number of areas including diagnoses and procedures associated with hospital admissions and



physician visits in specialised care, cancer care, births, prescribed drugs, and dental care.

There is also a central authority (CPUA) assigned that is responsible for the processing of personal information in a health data registry. This role includes decisions on the disclosure of the registry data (case by case) and a general obligation to ensure data is processed according to current law and regulations. The NBHW is both the custodian of the national health data registers and is the CPUA for the processing of data in these registries.

Custodians of health data registries are obliged according to law to inform the public about the nature and content of the registries. To increase data collection efficiency and security, the NBHW has introduced e-services to facilitate processing of requests for data, data collection and data retrieval.

The existing legislation focuses on the purposes of collecting and holding the data, the responsibilities of authorities that hold registries (with personal information), and regulates various control mechanisms that need to be in place for the disclosure and secrecy of personal information. This system works to balance the need for transparency and accountability of the welfare system (including health care and population health), and the protection of personal integrity.

For more information please visit the NBHW website:
https://www.socialstyrelsen.se/english

National quality registries

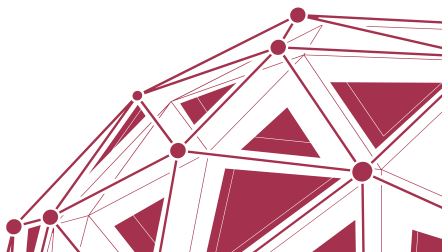
Sweden has approximately 100 national quality registries that provide the Swedish healthcare system with the ability to monitor the quality and results of their health services (8). These registries contain individualised health data (e.g. medical interventions, outcomes after treatment) based on patient encounters in health care. The quality registries are integrated into clinical workflows creating real-time data. These registries are used in clinical development work, research and management. Both individual and organisational participation in these registries is voluntary. No one organisation has responsibility for these registries, as each organisation is managed by a separate CPUA (16).

For a list of all Swedish national quality registries see:
http://www.kvalitetsregister.se/englishpages.2040.html

Classes of secondary health data

Individual identifiable health data

National health data registries can release individual-based data for research purposes only after a special review is conducted. Data from the national quality registries will only ever be released at an identifiable individual level if legal and ethical requirements are met (17).



Unit level de-identified/pseudonymised health data

Participation in the national quality registries by both individuals and organisations is voluntary. No one organisation has responsibility for these registries, as each organisation is managed by a separate CPUA. All research projects approved by the Ethical Review Board can access the registry unless the project conflicts with the Public Access and Secrecy Act. The data released is anonymous and will only ever be released at an identifiable individual level if legal and ethical requirements are met (17).

De-identified (aggregate) health data

The Act on Health Registries states that participation in population registries, such as the national health data registries, is mandatory. The data collection, as well as the secondary use of the data (for the explicitly stated purposes only), does not require the individual's explicit consent. There is no opt-out possibility.

Individual-based data for research purposes can be released after a special review is conducted. This review can take 3-6 months. It is not NBHW policy to release individual-level data to researchers abroad, but rather encourage them to cooperate with their Swedish colleagues who can apply to access the data (17).

Case study | Sweden

Participation in colorectal cancer treatment studies

Type of data used

Information obtained from the national quality registry for colorectal cancer treatment.

Benefit realised from using secondary health data

Analysing the data from the registry showed that 18 per cent of all patients diagnosed with colon cancer or rectal cancer in 2015 who were registered in the national quality register participated in a treatment study. While this trend has been increasing since 2011, the NBHW target level for trial participation is 33 per cent. As more patients participate in clinical and research trials, the better the data will be which can in turn be used to improve the quality of cancer care (29).

3.1.9 UKRAINE

Ukraine is in the early stages of digital health development. Even though some data management information systems have emerged in recent years, including certain clinical registries, the majority of the office health statistics and all official health records are still paper based.

In addition to paper based health records, there are a number of limitations that Ukraine faces in its endeavours to improve the quality of collected health information including low level of digital awareness in healthcare institutions, low numbers of individuals with a unique digital ID and little connections between State registries.

To address the current limitations, Ukraine started reforming its healthcare system with a primary aim to improve transparency and change the way the healthcare system is financed in 2017. Part of this reform includes the introduction of a centralised eHealth platform which will include nation-wide electronic health records, a number of services including electronic prescriptions and appointments, shared classifications and terminologies to be used across the digital systems in healthcare domain, etc. The main purpose of the central eHealth platform is to ensure the availability of key health records for patients and (in de-identified format) for use by authorities for analysis and planning. Another essential goal for eHealth is the linkage of health records between existing clinical registries (e.g. cancer registry, hospital registries and electronic health/medical records systems in regions).

Legislation regulating secondary use of health information

- Ukraine currently operates within the general legislation on medical privacy, without any specific legislation directly governing the secondary use of citizens' health information.
- An EU Personal Data Protection Directive led to the adoption of the *Law of Ukraine on Personal Data Protection 2010 (PDP Law)*. The fundamental principle applicable to personal data processing under the PDP Law is that all steps in data collection, storage and processing must be conducted only with the consent of the data subject. The PDP Law provides several exceptions for processing personal data without the consent of the data subject including allowing processing of medical data by healthcare providers and the National Health Service of Ukraine for the purpose of providing medical services. The PDP Law has general regulations in respect to personal data but does not specifically address health data protection (19).
- Ukraine has no specific regulations regarding the use of anonymised health-related data for statistics and associated purposes.
- The Ministry of Health plans to introduce changes to legislation with the aim of defining the secondary uses of health information.

Governance

Data on the state of the health of the population collected by the responsible Ukrainian authorities includes statistical data that describes the state of healthcare provision on a large scale. As a member of multiple international organisations, such as the World Health Organization, Ukraine is legally bound to submit the aforementioned statistical data to such intergovernmental organisations to depict the existing state of the healthcare system. These officially collected datasets are submitted by each healthcare facility to regional level and then to the health statistics unit at the Ministry of Health. In

addition to the health statistics unit, the Ministry of Health operates a number of specialised institutions responsible for the collection of health-related data e.g. healthcare professionals personal data, several clinical and population registries (cancer-register, insulin-dependent patients registry etc.).

Analysis of data from clinical registers and from the central eHealth platform often brings interesting findings. However, paper based information cannot be used for the purposes of decision making leads to "blind spots" in decision-making. The National Health Service of Ukraine (NHSU), a national health insurance organisation and strategic buyer of medical services, is expected to produce more reliable health statistics with the application of the central eHealth platform mentioned above.

Classes of secondary health data

Individual identifiable health data

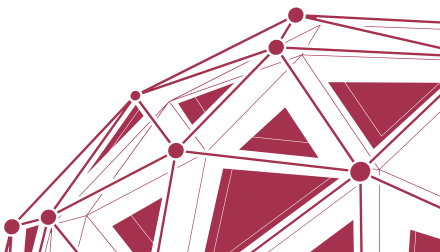
The use of individual identifiable data is permitted only with the consent of the patient. The patient must be informed of the purposes behind the data collection and which agencies will be responsible for its processing and use. Express consent is not required, however, if the personal data is used solely for provision of medical services by healthcare providers and for the case-based quality management by the NHSU.

Unit level de-identified/pseudonymised health data

There is no specific regulation for unit level de-identified/pseudonymised health data. Unit level data can be de-identified and used in the same way as aggregated statistical data.

De-identified (aggregate) health data

Statisticians at each stage of healthcare provision prepare aggregated health data from paper-based forms and electronic forms (primary sources of truth) and send to the regional level health statistics units, which, in turn, after further aggregation send the data sets to the health statistics unit at the Ministry of Health. There are no specific regulations in respect to use of such aggregated health data.



Case study | Ukraine

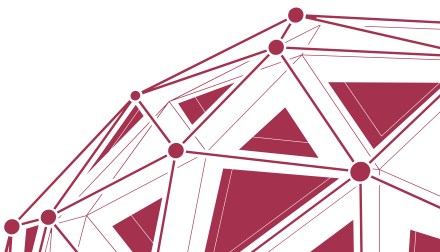
Use of 'HIV-infection in Ukraine' Medical Information System for rapid response pharmacovigilance needs and clinical recommendations

Type of data used

De-identified data from the 'HIV-infection in Ukraine' Medical Information System.

Benefit realised from using secondary health data

The data obtained using the 'HIV-infection in Ukraine' Medical Information System allowed for rapid reporting (about one week) of the effects of the application of dolutegravir (DTG), an antiretroviral medicine. National guidelines were developed and patients were rapidly transferred from DTG to other drugs in the regions of the country. Also, with the use of the system, a quick assessment of the long-term consequences of using DTG among reproductive age patients is currently being completed.



3.1.10 UNITED KINGDOM

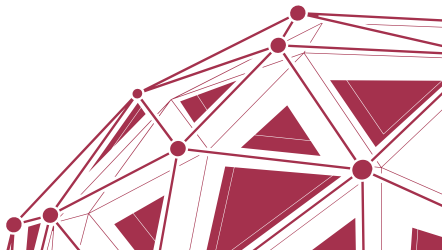
The United Kingdom (UK) is a world leader in healthcare system design, constantly looking to improve service design and delivery to patients. The UK Government was an early recogniser of the benefit to a) patients and b) service design and delivery that secondary use of health information can provide and support. Under the National Institute for Health Research, it has implemented a range of policies and strategies designed to improve the ability of researchers to access high-quality data to support their studies, while working within a robust regulatory environment that ensures patient confidence in the use of their data for research purposes. It has worked to improve the identification, discovery and approval processes to reduce the time taken by researchers to access the most appropriate data they need. The Secretary of State for Health challenged the National Health Service to make better use of technology, including making progress in patients being able to access and add to their own electronic health records. To action this, several high-level reviews were conducted including:

- The Care Quality Commission (CQC) to review current approaches to data security across the NHS to stop confidential data falling into the wrong hands;
- The National Data Guardian for Health and Care, to develop data security standards that can be applied to the health and social care system and, with CQC, devise a method of testing compliance with the new standards; and
- The National Data Guardian to propose a new opt-out for data sharing to enable people to make an informed decision about how their confidential data will be used.

By strengthening their data handling practices, the UK government allowed the public to be confident in the way their health data is managed, a key component to ensuring the successful development of a robust secondary use regulatory framework. The governance model and the legislation used are described in more detail below.

Legislation regulating secondary use of health information

- General Data Protection Regulation (GDPR) – The European Union's GDPR harmonises national data protection laws in the EU, establishing new rights for individuals and significant penalties for data breaches. The GDPR requires those who control the data to have a lawful basis for the processing of personal data. Further processing of the data beyond that which was originally anticipated (secondary use) is only permitted as long as the new processing activity is not incompatible with the original purpose.
- The GDPR is supplemented by domestic legislation (providing it complies with the GDPR) including:
    - The Health and Social Care Act 2012 – section 251 provides for the use of personal health and care data for purposes other than direct care but must be for health purposes (e.g. clinical research); and
    - The Health and Social Care (Safety and Quality) Act 2015.
- Common law duty of confidentiality – duty of confidentiality arises when information is obtained in circumstances where it is reasonable for a person to expect that it will be held in confidence. The general position is that if information is given in circumstances where it is expected that a duty of confidence applies, that information cannot normally be disclosed without the patient or service user's consent.



Governance

The NHS is a highly complex data ecosystem with comprehensive datasets covering aspects of primary, secondary and tertiary care, as well as population statistics. There are numerous organisations that disseminate personal health information at a national scale – e.g. NHS Digital, NHS England, the NHS Business Services Authority, Public Health England, the Medicines & Healthcare products Regulatory Agency, etc. The Confidentiality Advisory Group (CAG) also occupies a key role as an independent body that provides expert advice to the Health Research Authority (HRA) and to the Secretary of State for Health for non-research uses of confidential patient information.

Of these organisations, NHS Digital occupies a central role as the national information and technology partner to the health and social care system. It is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care in England. At a more local level, other organisations such as local primary care providers and NHS Trusts will also share data for certain secondary uses. The disclosure of secondary use health information is governed by the requirements of the GDPR, with compliance regulated by the national regulator, the Information Commissioner's Office.

Classes of secondary health data

Individual identifiable health data

The sharing of a patient's identifiable health data for secondary use purposes has only ever been permitted with the consent of the individual or as otherwise permitted by law.

Where the legal basis for using confidential patient information is under statutory law, an individual does not have the right to choose whether their data is used. However, statutory law providing a legal basis for processing falls into two types: those that make the disclosure of information compulsory (mandatory) and those that permit the disclosure of information. In general, most statutory provisions are permissive – i.e. they do not compel disclosure. In addition, personal and confidential information may also be disclosed where the balance of public interest favours disclosure.

Unit level de-identified/pseudonymised health data

De-identified or pseudonymised data may or may not be subject to the requirements of the GDPR, depending on the difficulty with which re-identification may be possible. Pseudonymisation enhances privacy by replacing the identifying fields within a data record with one or more artificial identifiers, or pseudonyms. The GDPR incentivises the use of pseudonymisation techniques as a way of enabling greater data utility, without the use of directly identifiable personal data.

Pseudonymised data does, however, carry a higher privacy risk and the security of the key is essential. Because the data is not truly anonymised, personal data that has been pseudonymised may fall within the scope of data protection legislation depending on how difficult it is to attribute the pseudonym(s) to an individual. Should it fall within GDPR privacy requirements, then consent would need to be obtained from the individual for the data to be used for secondary

purposes, except in limited situations where consent is not required e.g. public interest.

De-identified (aggregate) health data

Anonymised data (i.e. rendering data into a form which does not identify individuals and where identification cannot take place) is not within the scope of GDPR and thus, such data may be shared freely. The Information Commissioner's Office has published a code of practice on anonymisation: https://ico.org.uk/media/1061/anonymisation-code.pdf

Case study | United Kingdom

National Cancer Registration and Analysis Service

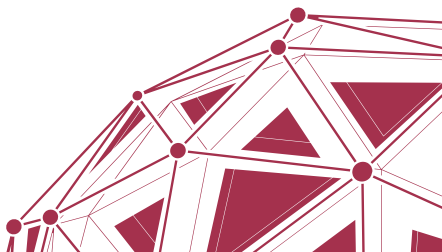
Type of data used

Public Health England's (PHE) National Cancer Registration and Analysis Service is now has the largest, most complex and sophisticated cancer registration service in the World, collecting data on 500,000 cancer patients each year. Record level data is collected from over 600 different clinical systems across the NHS, including the 2000 multidisciplinary team meetings; the cancer screening programs; and every chemotherapy and radiotherapy treatment. There are more than 1,000 potential data items for each type of cancer.

Benefit realised from using secondary health data

Benefits have been realised for patients, clinicians and the wider healthcare system:

- Patients can see their own data through a secure portal;
- Clinicians can compare their own performance with others;
- NHS England monitors the quality of care; the National Institute for Health and Care Excellence uses the data for the Cancer Drugs Fund; the Office for National Statistics and PHE produce national cancer statistics; while cancer researchers worldwide use the data to find new cures.



3.1.11 UNITED STATES

The United States (the U.S.) has a strong legislative and governance framework that underpins the collection, storage and release of health information for secondary use purposes. The law that governs secondary use is derived from both a national and state level. The Health Insurance Portability and Accountability Act (HIPAA) provides baseline privacy protection for individuals who have health information with certain healthcare entities. The governance model and the laws are described in more detail below.

Legislation regulating secondary use of health information

- **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** – Federal law that establishes a nationwide floor of privacy and security standards.
- Federal Trade Commission (FTC) enforces the FTC Act, which includes consumer protection provisions that prohibit certain acts or practices that are unfair or deceptive (e.g. deceptively failing to disclose material information about the use of personally identifiable information, or failing to reasonably secure this information).
- Some states in the U.S. have enacted health privacy rules that apply in addition to, and are more protective of patient privacy than, HIPAA. In some cases, these state laws address specific clinical conditions or circumstances (e.g. HIV/AIDS status, mental health, and alcohol and substance abuse).
- The Confidentiality of Substance Use Disorder Patient Records) (42 CFR Pt. 2) ("Part 2"). Part 2 governs restrictions concerning the disclosure and use of patient records pertaining to substance abuse treatment that federal programs maintain. Part 2 protects the confidentiality of substance use disorder (SUD) patient records by restricting the circumstances under which federally-assisted, Part 2 programs or other lawful holders can disclose such records.

Governance

Most healthcare providers and health plans and their business associates (e.g. a person or entity that performs certain functions or activities that involve the use or disclosure of health information on behalf of, or provides services to a healthcare provider or health plan) must follow the HIPAA Privacy Rule, a federal privacy law that sets a baseline of protection for certain individually identifiable health information. The Privacy Rule generally permits, but does not require, covered healthcare providers to give patients the choice as to whether their health information may be disclosed to others for certain key purposes. These key purposes include health information regarding treatment, payment, and healthcare operations. For example, while it is not required, healthcare providers may decide to offer patients a choice as to whether their health information may be exchanged electronically. HIPAA rules are enforced by the U.S. Department of Health and Human Services (HHS) – Office for Civil Rights (OCR), while criminal penalties for certain disclosures are enforced by the U.S. Department of Justice and in some cases, by a state attorney general's office.

HIPAA created a baseline or federal floor of privacy protection. It pre-empts other privacy laws that are less protective or "contrary" and leaves in effect other laws that are "more stringent". Under this legal framework, healthcare providers and certain other implementers must follow HIPAA, and other applicable federal and state laws. There are some federal and state privacy laws that require healthcare providers to obtain patients' written consent before they disclose their health information to other people and organisations, even for treatment purposes. Many of these federal and state privacy laws

protect information related to specific health conditions, such as substance use disorder information.

Classes of secondary health data

Individual identifiable health data

Under the HIPAA Privacy Rule, patient consent is not required for the sharing of most health information for treatment, payment, and healthcare operations. While consent is not required, healthcare providers may decide to offer patients a choice as to whether their health information may be exchanged electronically.

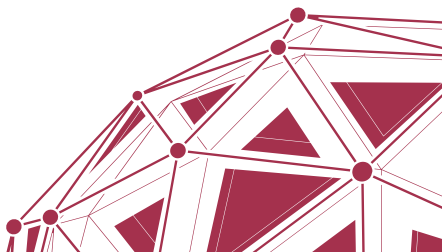
However, there are some instances where the release of patient identifiable health information is subject to patient authorisation. These purposes include the marketing or the sale of their health information and for research purposes. A further caveat to this is that some state laws require patient consent for the sharing of certain types of health information, even if consent is not required under the HIPAA Privacy Rule.

Unit level de-identified/pseudonymised health data

HIPAA provides two de-identification methods of health information: 1) a formal determination by a qualified expert where the expert has used generally accepted statistical and scientific principles and methods for rendering information not individually identifiable; or 2) the removal of specific individual identifiers as well as the absence of actual knowledge by the healthcare organisation such that the remaining information could be used alone or in combination with other information to identify the individual.

De-identified (aggregate) health data

The HIPAA Privacy Rule does not require an individual's authorisation for the disclosure of de-identified personal health information for secondary use.



Case study | United States

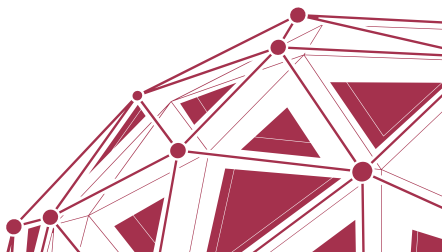
The effect of patient portals on quality outcomes and its implications for meaningful use: A systematic review

Type of data used

De-identified data was used to determine the effect of patient portals on quality or chronic-condition outcomes.

Benefit realised from using secondary health data

In this systematic review, 37 per cent of the papers reviewed reported improvements in medication adherence, disease awareness, self-management of disease, a decrease in office visits, an increase in preventive medicine, and an increase in extended office visits when a patient requested additional information (30).



3.1.12 URUGUAY

Legislation regulating secondary use of health information

Uruguay does not have any specific legislation governing secondary use.

Governance

Health data can be used in Uruguay for economic and human resource purposes, and also for providing healthcare assistance. The release of data for secondary use is managed by the Ministry of Health and DATA Uruguay. The data is released in the form of reports elaborated by the Health Ministry, public databases and web services, and the web service named “At your service” (see case study below).

The Ministry of Health has the broadest scope for the use of the information. The electronic health records (Historia Clínica Electrónica) use the opt-in model.

Classes of secondary health data

Individual identifiable health data

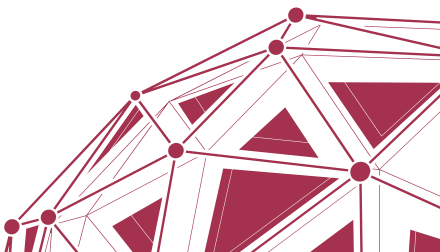
The Ministry of Health has the right to access all the clinical data of patients. Universities sign agreements with various private institutions to access their data. Private organisations do not access data for secondary use purposes.

Unit level de-identified/pseudonymised health data

Not answered.

De-identified (aggregate) health data

Not answered.



Case study | Uruguay

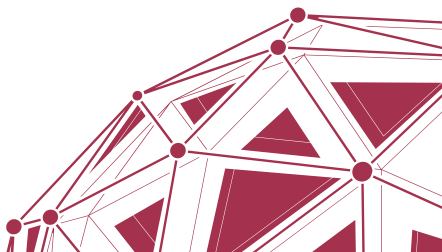
Uruguay's A Tu Servicio – Empowering citizens to make data-driven decisions on health care

Type of data used

Data on local healthcare providers including facility type, medical specialty, care goals, wait times and patient rights.

Benefit realised from using secondary health data

In February each year, all Uruguayan citizens make the decision whether to stay with their current healthcare provider. To assist Uruguayans in making their decision, in 2015 Uruguay's Ministry of Health created an online open data sharing platform that provides clear, easy-to-search health data to compare healthcare providers based on a range of parameters and indicators. The page had over 35,000 visits within the first month, resulting in a lot of media attention. The service also led to the public scrutiny of several hospital wait times leading them to change their practices. The creation of A Tu Servico has allowed citizens of Uruguay to have a more informed debate about the state of the healthcare system in Uruguay, and has provided the catalyst for potentially more open datasets in the future (28).



4 DISCUSSION

International approaches to secondary uses of health data is a rapidly evolving area with countries at different levels of maturity depending on their success in implementing digital health infrastructure. International collaboration and sharing can support a "lessons learnt" approach so that the same mistakes are not replicated in less mature jurisdictions as they progress.

4.1 KEY FINDINGS: HOW IS SECONDARY USE OF HEALTH INFORMATION SUPPORTING HEALTH REFORM?

GDHP participant countries contributed a number of case studies for how secondary use of health information has delivered benefit. These case studies, outlined below, together with the outcomes of the discussions held at the GDHP Work Stream workshops and an analysis of the literature point to a number of potential health system effects.

Developed and developing countries alike are facing a future of ageing populations and concomitant higher incidence of chronic and complex disease coupled with increasing costs of health service delivery and a shortage of healthcare providers. Secondary use of health data can play a key role in modernising, reforming and strengthening health systems to benefit countries and their people in a variety of ways to deliver the benefits as described below:

Prevention of ill health

Health systems are constantly being reviewed and transformed to be more cost-effective, with countries pivoting their focus towards prevention of illness and prevention of the exacerbation of illness, as opposed to the traditional model of only engaging with patients after illness has occurred. Essentially the aim is to keep people healthy and out of hospital.

Secondary use of health information can support prevention of ill health, including chronic disease, by allowing countries to identify "hot spots" of disease or populations at risk of health issues (20) and thus to better focus activities to prevent and delay onset within individuals or populations. Such preventative activities, which may be too expensive at a whole-of-population level, can be targeted to specific individuals or populations, reducing healthcare costs due to fewer patients requiring expensive hospital care.

Case study | **Australia**

Australia has linked data from primary care and hospital systems for secondary use. The data showed that for Aboriginal and Torres Strait Islander Australians with diabetes, have better health outcomes when their access to primary care is improved and that this resulted in significant cost savings to the health system. The savings in hospitalisations provided a measure for the value for money of primary care and created a new, compelling argument for the investment of funds in primary care in remote Australia.

Supporting health equity

Secondary use of data is critical to supporting health equity, as it allows identification of areas of poor health or low service provision, and prediction of demand for health care in areas of need (21). The secondary use of data is particularly relevant to supporting the WHO's Sustainable Development Goals, in particular SDG 3 which has a focus on healthcare equity in its objective to "ensure healthy lives and promote wellbeing for all at all ages".

Case study | **Argentina**

Argentina was able to examine the impact of Universal Health Coverage on child development in Argentina, specifically examining the impact by rural vs urban children, by gender etc. Through secondary use of health information it was determined that Universal Health Coverage improved health outcomes.

Measuring performance of health facilities

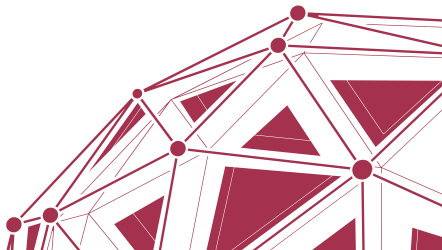
National health information datasets can be used to monitor, compare and improve performance of institutions or regions across a country. Interestingly, secondary use of health datasets can provide intelligence on different modes of health service delivery in different health facilities. In particular, better performing services can be identified with the relevant practices adopted by similar facilities or regions. Indeed, evidence suggests that measuring performance, and providing those insights to health services, results in improvements within a given facility. More recently, real-time data dashboards have become possible to support agile decision-making for health service planning.

Case study | **Italy**

Italy is currently undertaking a study across 12 hospital emergency departments looking at diagnosis and treatment regimes. As well as observing health service delivery, secondary use of data will allow an examination of how technology, clinical variability and hospital structure impact on clinical health care delivery. The understanding of these mechanisms will inform policy guidelines able to better address clinical and organisational variability.

Case study | **Japan**

An example from Japan is a research project (31) which examined the national medical billing database to determine differences in how antihypertensive medicine is administered to cardiac patients with and without kidney impairment. The data analysis already shows clinical practice for some patients with heart failure is differing to that recommended in national guidelines, warranting further investigation.



Understanding patient care pathways

Evidence of the potential benefits that come from countries investing in the use of people's health information for secondary uses is becoming overwhelming. Importantly, where a country uses a single patient identifier across a range of health services, datasets can reflect patient journeys and can deliver intelligence about patterns of health and care over time that has never been available to policy makers before.

Such patient-centred datasets hold the potential for a data revolution by providing information on the full set of health services received by a person, rather than the services provided by a single health facility. In addition, as more data on patient experience and patient outcomes are collected, true healthcare outcomes will be able to be determined.

Personalised medicine

Given the large datasets that exist at the national level, there is the ability to analyse the data to determine treatment and outcomes for specific sub-cohorts of patients within the population. This type of insight is just the start of personalised medicine, which will become more granular as more and more people's information, including genetic information, is available for analysis. International collaboration will be an increasingly important factor in this area, as the benefits of precision medicine require large datasets which will necessitate the sharing of information across international borders, for example in order to realise the benefits of tailored treatments for people with rare diseases.

Monitoring disease outbreaks

Health information datasets can be analysed to provide early and timely information regarding outbreaks of both communicable (e.g. HIV/AIDS, tuberculosis) and non-communicable diseases (20), or even to determine areas of antimicrobial resistance, allowing early intervention and response activities.

Case study | **Republic of Korea**

The Republic of Korea monitors for early detection of communicable disease using a range of indicators including medical treatment, prescriptions, geographic location of patients etc. which are all part of the administrative dataset for national health insurance. This secondary use of health information was able to support the prevention of the spread of MERS in 2015.

Predicting and planning for public health events

Secondary use of health information, particularly where health datasets are linked to environmental or weather datasets, can support new lessons and learnings on the impact of pollution or meteorological events on people's health. This can be particularly useful where weather is linked to the incidence of influenza or asthma. This is also an area where international collaboration on secondary uses will greatly enhance the benefit of analysing health data within countries, where external factors such as environmental changes such as pollution and weather do not respect international borders.

International warning systems for communicable disease outbreaks are another example of this.

Case study | **Portugal**

Portugal analyses in real time anonymised data from electronic death certificates held in a nationwide web based central database (SICO – Sistema de Informação dos Certificados de Óbito/Death Certificates Information System). The data is used to monitor core public health mortality indicators, in real time. Prevention activities are implemented by health authorities and healthcare institutions and take place according to National Public Health Programs (namely flu surveillance, heat waves and other extreme weather conditions and Infectious diseases surveillance programs) based on surveillance data.

Improving financial efficiency of the health system

Secondary use of data offers the opportunity to improve financial efficiency in the health system, including potentially allowing value and outcome-based healthcare funding models and reducing fraud through triangulation of patient health and health service provider information. Observing patterns in healthcare utilisation datasets also allows health system planning that supports areas of need, for example ensuring populations have access to services and resources in areas of greater need or with a higher prevalence of specific health issues.

Measuring efficacy of therapeutic interventions

One of the key opportunities for secondary use of data to support health system strengthening is through measuring the impact and efficacy of clinical interventions on those who are receiving such treatments, in real time with a whole-of-population sample. Such analysis provides information on the effectiveness (or non-effectiveness) of treatments, medicines and medical devices by examining a number of indicators such as severe side effects or adverse events requiring treatment or hospitalisation, or indeed, mortality.

There is also an opportunity for efficacy to be examined for specific cohorts of patients, allowing healthcare providers to deliver more personalised and precise medicine to groups of patients who may respond differently. In addition, due to the large scale of national datasets, insights into rare diseases and the health outcomes for various clinical interventions are also possible.

This kind of secondary use of health information has the potential to save lives and improve health outcomes by enabling the cost-effective, timely measurement of health outcomes for the whole of a population who are receiving the therapeutic intervention.

Case study | **Ukraine**

Ukraine has been able to quickly analyse the 'HIV-infection in Ukraine' Medical Information System for the efficacy of antiretroviral medicine, DTG and develop national guidelines in response.

Supporting health and medical research discoveries

Release of national health datasets for research can support a vibrant health and medical research community by allowing innovative data analytics methodologies to be developed as well as the opportunity for subject matter experts to have access to large datasets relevant to their research, thereby providing the opportunity for new discoveries on health and disease. In addition, secondary use of data can also allow clinical researchers to identify patients who may be candidates for state-of-the-art clinical trials.

Case study | **Sweden**

Sweden was able to examine the number of patients with a colon or rectal cancer who participated in a treatment study and identified that the numbers were relatively low at only 18%. With the target being 33%, the aim is to increase the number participating so that more data can be used to improve the quality of cancer care (29).

While this list of uses and benefits is not exhaustive, these are the key benefits raised by GDHP participants. There was agreement and optimism that secondary use of health information can support evidence-based decision-making to strengthen health systems, drive better health outcomes, prevent ill health and lower expensive hospital admissions. In short, secondary use of data presents an enormous opportunity to improve the health treatment that people receive and hence improve their health and wellbeing.

Given the opportunities for health system and health policy improvements provided by secondary use of health information as described above, the remaining sections of this report aim to describe how countries can progress with implementation of secondary use of health information and the key enablers that can support countries to mature their data analytics capability.

4.2 KEY FINDINGS: A MATURITY FRAMEWORK FOR SECONDARY USES OF HEALTH INFORMATION

Every national health system is special in its own way. This results in each country choosing to prioritise different areas, following different reform paths and investing in different digital health solutions. However, there are significant common factors that GDHP participants have considered when considering how to use health data for secondary uses.

GDHP participants discussed that while the health sector generates so much data there is a challenge in collecting, collating, analysing and using the data to support health system reform. These challenges have also been documented before. Only one half of OECD countries have national policies in place to address how data from electronic health records can monitor disease outbreaks, conduct research and improve patient safety and only one half of OECD countries regularly link their existing health datasets to monitor healthcare quality (4).

GDHP participant countries too are at various levels of implementation regarding secondary use of health information and have faced difficulties in implementing

processes and policies. Some countries have made significant progress while others face restrictions on the ability to use health information for secondary purposes.

This section of the report aims to describe a potential Maturity Framework that could allow a country to build capacity to take advantage of secondary uses of health information and satisfies the growing demand from government, research and non-government organisations to use health information for secondary purposes.

The framework is focussed on the key steps that need to be in place for secondary uses of health data that will deliver on all of the benefits outlined in the previous section including identifying new therapeutic discoveries and allowing evaluation of clinical interventions for effectiveness.

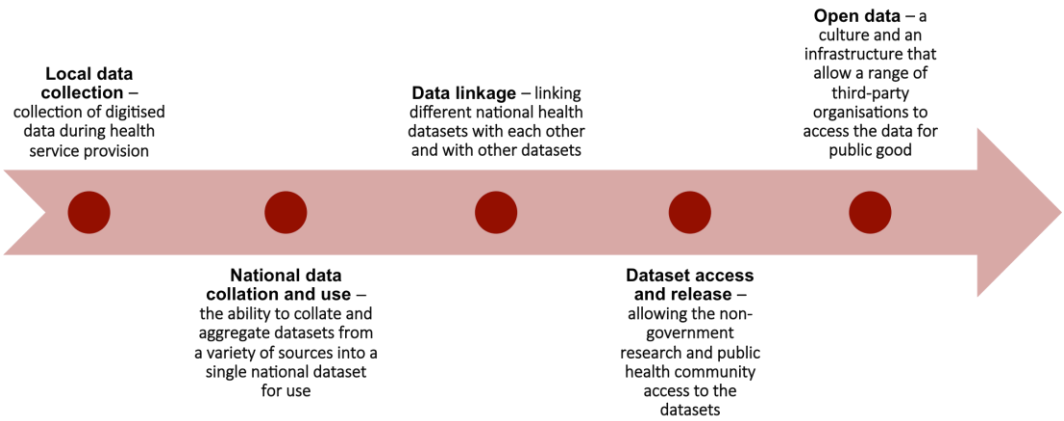


Figure 2: Maturity framework for secondary use of health information

4.2.1 COLLECT DIGITAL DATA AT THE POINT OF CARE

Some GDHP participant countries are still very much focussed on the first step in the Maturity Framework for secondary use of health data which is for local health services to have the ability to efficiently capture high-quality and relevant health and administrative data as part of delivering health care (1). This requires appropriate information and communication technologies (ICT) infrastructure and platforms as well as staff who are appropriately trained to work in a digitised healthcare environment and to collect health data.

Most countries have actively supported the digitisation of their health systems by providing or funding ICT infrastructure, or through incentive payments designed to foster digitisation of electronic medical records (22) and therefore have the infrastructure in place. Nevertheless, depending on how their healthcare system is organised, funded and governed, countries may have multiple levels of government involved in health care, multiple sectors (hospitals, pharmacies, primary care etc.), and both public and private providers. These factors can result in "patchy" digitisation in certain sectors or geographies.

Even where data is being collected at the source, fragmented and complex health systems can lead to fragmentation in how data is shared for secondary use purposes leading to data silos. These data silos can contain data of varying quality and with

different terminology and technical structure, which makes data collation a challenge. Such issues are explored more in the GDHP Interoperability Work Stream report (23).

4.2.2 COLLATE DATA ON PATIENTS FROM A VARIETY OF SOURCES TO FORM A NATIONAL DATASET

The next step in maturity from collecting digital health data is having the capability to collate or aggregate this data into a national dataset that can give policy makers a true understanding of how the health system is operating and how it can be improved.

Currently, while the amount of health data potentially available for secondary uses is increasing, much of the data remains in silos within different organisations and geographies (with laws sometimes preventing collation or sharing) (24). However, many GDHP countries have established or are establishing national data integration mechanisms, e.g. national electronic health record systems.

Even after collation, most health information is not ready for sophisticated data analytics due to the need to clean and standardise the datasets to ensure they are suitable for secondary use. This takes significant investment by countries and most GDHP countries report that they have not built this capacity for national dataset cleansing.

Countries that have invested in their secondary use data-analytic capability can point to evidence-based decision-making and benefits for their health systems (a number of case studies were provided by countries that demonstrate national use of health datasets in policy-making and most countries produce annual publications with descriptive statistics).

GDHP country survey insights

Data collected at the regional versus national level

Depending on the governance arrangements of the country, health information can be collected at a national or regional level. When collected at a regional level, data sharing can be subject to differing ICT infrastructure and information flows between the regions. This can pose challenges when attempting to share health information across different regions or to link the datasets to produce meaningful comparisons. This is seen in the regional health services of Italy and the collation of health datasets in Australia.

Ukraine has a similar model, whereby public health data is submitted from individual organisations through to regional health statistics departments and onto the central level Ministry of Health. Each time the data is further aggregated, it becomes more unreliable and subject to data manipulation. Compared to Italy and Ukraine, the Republic of Korea has a more centralised model where all health information is managed through a central agency. This agency oversees the data collection as part of the routine management of the national healthcare single-payment system.

4.2.3 LINK DATASETS TO BUILD UNDERSTANDING

Linking different sources of data is the next level of maturity in the framework. Data linkage is where different pieces of data that are thought to relate to the same person are linked together to provide a fuller impression of the person's life and experiences.

Such data linking supports the investigation of a range of social and environmental impacts on health and ill health (e.g. income, employment and remoteness). Importantly this information can be used to predict the likely onset of disease in individuals and populations and provides policy makers with the ability to focus targeted interventions.

Some countries have established data linkage units in government, which avoids the risk of having to release data with identification parameters intact. GDHP participants have a lot of interest in how data linkage can be successfully implemented.

4.2.4 ALLOW RESEARCHERS TO ACCESS HEALTH INFORMATION

Recognising the need to leverage existing expertise in health and medical research, the next level in the Maturity Framework is where digital health information is available to not only policy makers but also to researchers and others for secondary use purposes.

GDHP participant countries reported on processes and policies in relation to researchers accessing health information datasets, including ethics committees and data governance processes at facilities at the regional and jurisdictional levels.

Most GDHP countries are aware of the risks involved in releasing health information datasets and have a range of mitigation strategies, including prohibiting or limiting data released to third-party researchers. De-identified datasets are readily available for researchers, but their use is limited given it is not therefore possible for the researchers to undertake any data linkage to broaden the insights to be gained through data analytics.

The provision of identifiable data is the most advanced form of dataset release. Such releases (albeit not from government catalogues) have been the subject of recent controversies including the public outcry in 2014 after a researcher developed a Facebook personality quiz that harvested information from about 50 million Facebook users, which was then released to Cambridge Analytica. Such controversies have contributed to a risk-averse culture in many countries about the release of datasets containing personal information including health information.

Overcoming the need for release of identifiable data, one mechanism is to provide researchers with direct access to health information datasets through the use of "Safe Havens" where researchers can directly access the data for analysis but not remove it from its source.

Case study | **United Kingdom**

Public Health England's National Cancer Registration and Analysis Service is being made available to cancer researchers across the world to analyse the data and uncover new therapies and cures.

GDHP country survey insights

Different access-arrangement classes 1/2

Countries were asked to break down into three classes all the different arrangements they have in place for making their health information available for secondary use:

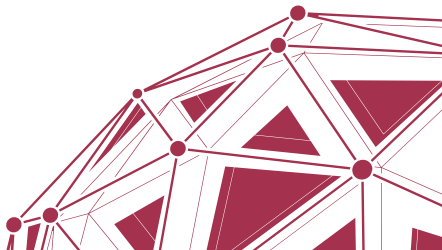
De-identified aggregate data

Data provided at the aggregate level has no personal information about an individual and poses a very low privacy risk. Therefore, countries were willing to release such data under fewer restrictions. All GDHP participant countries surveyed allowed the release of de-identified data for secondary use purposes. Under these arrangements, the data must be truly de-identified with the chance of re-identification very low. Some countries undergo a stringent de-identification process, such as the Republic of Korea which does not release de-identified data until it has undergone several processes, including the removal of the unique identifier, data masking and data-reduction techniques. Sweden and the UK have similar processes whereby the data must be truly de-identified before release. Interestingly, Australia appears to be the only country that allows people to opt out of having their data aggregated, even after de-identification, due to the highly sensitive privacy debates in that country as part of their national electronic health record system moving to an opt-out participation model.

Unit level de-identified/pseudonymised health data

The data in this class can be released to third parties with individual-level data, providing all the identifiable elements have been removed, e.g. address and name. Third parties who receive this data should be under contractual arrangements to protect the privacy of the individuals and not attempt to re-identify the individual. This data class was challenging to categorise, as most countries did not disclose any data-sharing arrangements within this class. The only country that discussed the release of unit level de-identified data was the UK. Within that context, data of this class may be used without patient consent depending on whether it is subject to the requirements of the EU's General Data Protection Regulation (GDPR). Whether or not the data is subject to the GDPR depends on the difficulty involved in re-identifying the data.

While this data class is challenging to de-identify fully, it strikes the balance between providing researchers with greater data utility, while still protecting the individual's privacy. The GDPR incentivises countries to provide data at this level but maintains that proper pseudonymisation and security of the data are paramount.



GDHP country survey insights
Different access-arrangement classes 2/2

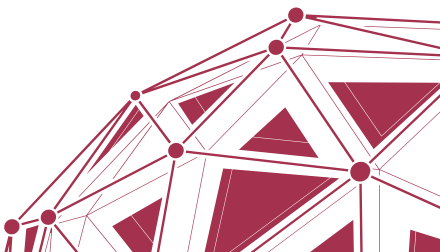
Individual identifiable health data

Data released to third parties with all identifiable patient-level features present carry the greatest privacy and security risk, but are also the most useful in terms of data linking across multiple databases. The approach to the release of identifiable data varies across all the countries surveyed. Before individual identified data is released in Italy, patient consent must first be obtained, and it must also pass through one of the country's 20 regional ethics committees. Common practice in Australia is for the request for identifiable data to be cleared by two separate ethics committees belonging to both the requesting organisation and the ethics committee of the organisation that stores the data. These committees can also approve waivers that bypass the requirement for the organisation requesting the data to obtain patient consent.

Depending on the class of data being released, each country has a different risk appetite. A good secondary use framework will have processes in place for all classes of data release, whether that be using ethics committees as a process for ensuring identifiable data is managed appropriately, placing the requesting organisations under contractual arrangements, or having good de-identification techniques to reduce the chances of re-identification.

4.2.5 OPEN DATA CULTURE

The final step in the Maturity Framework relating to secondary use is the establishment of an open data culture where data is available not only to researchers but also to other third parties and allows publication of information on health services to be provided to empower consumers in their decision-making.



Case study | **Uruguay Empowering citizens to make data-driven decisions on health care**

Each year Uruguayan citizens can choose whether to stay or not with their current healthcare provider. Since 2015 the Uruguayan Ministry of Health has provided citizens with access to an online portal 'A Tu Servicio' that allows citizens to compare healthcare providers using a number of parameters including wait times and patient rights.

The service has also led to hospitals changeing their practices to address their long wait times. The creation of "A Tu Servico" has allowed citizens of Uruguay to have a more informed debate about the state of the healthcare system in Uruguay, and has provided the catalyst for potentially more open datasets in the future (28).

Most countries are immature when it comes to an open data approach to health information, with the release of information to third parties to the private sector, not allowed or not supported.

4.3 GUIDANCE FOR ENHANCING MATURITY – ENABLERS FOR SECONDARY USE

In order to progress through the Maturity Framework in relation to secondary use of health information, a number of enablers need to be in place to support maturity. These enablers are based on the lessons and insights of GDHP participant countries.

4.3.1 ICT INFRASTRUCTURE AND FOUNDATIONS IN PLACE

In order to foster maturity towards collation and aggregation of national datasets, data needs to be collected at the site of health service delivery using ICT and be recorded and held at the level of the individual (20). In addition, to enable data linkage, a unique citizen identifier needs to be in place. GDHP participants are widely varied in their capacity to collect data at the local level, reflecting their different implementation of digital health and computerisation across countries. While technology platforms that are interoperable across health services are desirable, this is not a mandatory requirement (but it will make collation more difficult if it is not in place) (23).

4.3.2 CONFIDENCE AND TRUST IN SECONDARY USE

Secondary use of health data has the potential to improve people's healthcare experiences, but there is a need to retain public trust and confidence in those involved with the secondary use, including health service providers, government and researchers (25). Many GDHP participant countries are going to great lengths to ensure people understand and support secondary use of health data.

The rationale for maintaining trust and confidence is to ensure that those people who do not support secondary use of data will still seek care from the health system knowing that their data will not be used to harm or disadvantage them. Indeed, countries need to

be very wary of secondary uses of data that may compromise trust and confidence in the digital health systems in place.

The days of using people's data without their consent or knowledge is, for many countries, in the past, as consumers are galvanised to care about privacy and control of their data more than ever before. Some GDHP participant countries are even ensuring that people have access to information on how their data has been used for secondary purposes. The implicit assumption is that providing individuals with more detailed information about the use of their health data will improve trust in systems.

Security of information is also fundamental to confidence and trust in secondary use of data. Breaches in data security threaten to compromise support for secondary use, even when such breaches happen in other jurisdictions or sectors.

Consent and opt-out for secondary use of health information

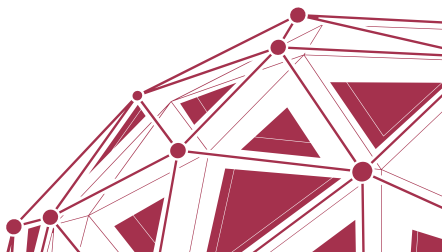
Providing an opportunity for people to opt out of having their data used for secondary purposes may also be offered to support people to control their data. Most GDHP participant countries surveyed require some degree of patient consent before identifiable patient data can be accessed.

However, routine data collections that contribute to public health, or are required as part of a national health insurance scheme, mainly have an opt-out approach as seen in the National Quality Registers of Sweden, where patient data is collected by default with the option to opt out.

There also seems to be a tension between when patient consent is required or the permission to collect the data is permitted by law. In Australia, in certain situations the management of health information for health and medical purposes without patient consent is deemed appropriate if the benefit and public interest in releasing the data outweighs the privacy protections of the individual. The Data Protection Code in Italy contains a similar provision whereby patient consent does not need to be obtained if the number of individuals whose data is being released is too high and the expectation of obtaining individual consent is not possible.

A review of how the NHS in the UK handles patient information led to the development of six Caldicott Principles. The principles outline the process organisations should undertake to ensure identifiable patient information is protected and only released when appropriate to do so. A review in 2013 led to the development of a seventh principle that looks at the tension between data sharing in the public interest and the duty to protect patient confidentiality. What remains clear in all the country responses is that this tension is often very unclear in the legislation and remains a murky proposition for both organisations holding patient data and the regulators who enforce privacy protections (26).

While consent processes and permission in law to waive consent requirements vary between countries, what is very clear is the value of clear communication and transparency to the public as to why the data is being collected. This improves patient trust in the system, which in turn allows for better quality data to be collected by organisations due to greater patient support.



4.3.3 GOVERNANCE

Robust data governance systems that inform the collection, collation, use and release of health information can address people's concerns about data use transparently and proactively.

There are already existing international laws, regulations and guidelines that promote the protection of privacy in the use of personal data in general, such as the OECD Privacy Guidelines and the EU General Data Protection Regulation.

But most GDHP countries also have their own specific legislation that provides a strong governance framework covering collection, use and release of information. Countries were asked to identify key pieces of legislation that apply to their management of health information for secondary use purposes. The types of responses varied between countries. For example, Italy's Data Protection Code not only covers the management of personal information but also includes a specific section on health information, while other countries such as Argentina do not regulate health information specifically but, rather, take a broader approach to regulating all personal data.

Legislation can also span countries as is the case with the European Union's GDPR, which has been widely adopted by many countries of the EU as their baseline privacy legislation, with some deciding to develop their own national legislation to further restrict access to health information. Within countries, there may be national legislation that provides the minimum level of data protection, as seen in the United States with the HIPAA (Health Insurance Portability and Accountability Act), but often additional state-level legislation is developed that provides extra protection. Within the United States, approximately half of the states have developed additional privacy controls.

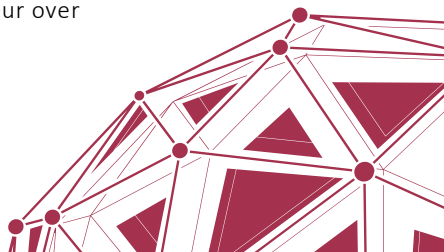
While each country has different legislation that underpins how they manage health information, what appears key to the successful management of health information is the ability for the country to recognise the benefits of regulating not only "personal information" but also specifically enabling the use of "health information" for purposes that go beyond the direct care of a patient. This could be through a specific provision in a broader privacy act such as the case with Italy, or a separate legislative instrument entirely as seen in Sweden with the Act on Health Registries. A strong legislative underpinning allows the creation of good data handling practices that not only provide health information to appropriate users to better the health system, but also generates public trust in the processes leading to greater public support for data collection.

Governance models may also include sanctions for misuse and either a regulating agency or a specific governing body (data custodian or the like) to bring focus and attention to the issues involved with secondary use of health information.

4.3.4 PUBLIC ENGAGEMENT, CONVERSATION AND DEBATE

Secondary use of data is essentially a partnership between individuals (who are fundamentally the source of the data), healthcare providers (who collect the data and have the trusted relationship with their patient), policy makers (who aggregate and use the data to develop health policy) and researchers (who access and use the data for a range of purposes including to discover new therapies).

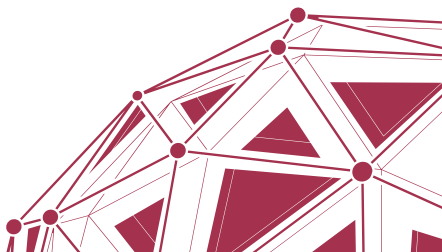
To enable secondary uses of health information, there is a need to inform and engage each of these communities and be agile to changes in sentiment that can occur over



time, particularly after media attention on privacy issues. Regular consultation with individuals and healthcare professionals to determine the appetite for data usage now and in the future is key (27). History has shown that failing to engage the broader community in the issues can have significant consequences when people become aware of how their data is being used without their knowledge and permission.

4.3.5 LIMITING SECONDARY USES OF HEALTH INFORMATION FOR THE PUBLIC GOOD

Health information is generally considered to be sensitive and care needs to be taken to understand community sentiment to uses outside of research and public health. For example, charging for access to the data and creating a market may be problematic, as is allowing access by businesses or insurers or marketers where such access might disadvantage the individual in some way (2). GDHP participant countries agreed on the need to discuss and acknowledge the need to assure that secondary uses are in line with community expectations to benefit the population.



5 RECOMMENDED NEXT STEPS FOR THE GDHP POLICY ENVIRONMENTS WORK STREAM

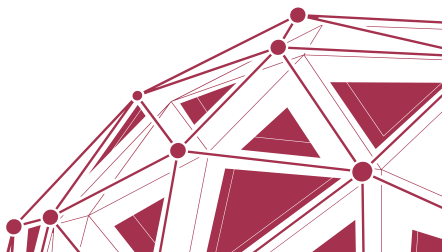
This report has outlined case studies and examples of how secondary use of health information can help policy makers improve health systems. The Maturity Framework developed for this report provides some insight into how countries can realise the benefits of secondary uses of health data and move towards an open data culture. This framework represents a reflection of the learnings and insights provided by GDHP Policy Work Stream participating countries.

The Maturity Framework is supported by a series of enablers including trust and confidence, consent models and effective governance models. These enablers are the conditions to encourage better processes so that more countries can use more health data for research, healthcare quality improvement and consumer empowerment. By considering the Maturity Framework and enablers, policy makers will be able to put in place systems that improve not only data collection and governance, but healthcare performance too.

The future secondary uses of health information are unknown. What is known is that the datasets will become larger and more comprehensive as the sources of data increase with further digitisation of health services and systems. If countries are able to foster a culture where secondary use of data is a normal part of the health system, with research outcomes then informing changes to the health system, improvements in health system delivery will occur more rapidly than ever before. Countries that recognise the opportunity for secondary use of health data and are able to build this into their health infrastructure will enable health reforms and a more sustainable health system.

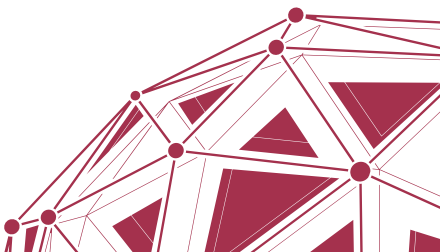
There are real opportunities for future technical collaboration among GDHP participant countries on one of the following:

- sharing of appropriate health data governance frameworks to enable secondary use of health information, including consent models;
- the potential to collate data from across national borders to build a dataset on rare diseases where the size of the population across the globe would strengthen the power of such studies;
- sharing methodologies for surveillance of communicable and non-communicable diseases;
- sharing approaches and insights from linking health data to non-health datasets (e.g. environmental and meteorological to better predict and plan for pollution events);
- comparing innovative approaches taken to measuring health outcomes (e.g. return to work, patient-reported measures);
- exchanging insights on how to improve services and empower consumers by publication of outcomes and costs;
- improving financial efficiency and reducing fraud through tighter control of reimbursement between hospital providers and the funder;



- ethical and policy issues involved with collection and use of genetic data to enable precision medicine and AI algorithms; and
- the challenge of developing safe open data resources of anonymous data that can power third-party innovation and industry.

The GDHP Policy Work Stream is cognisant that it will be important for this work to be consistent with and supportive of other international initiatives in the digital health space, such as the OECD work on health data governance, and the WHO's Sustainable Development Goals and related digital health initiatives required to achieve these.

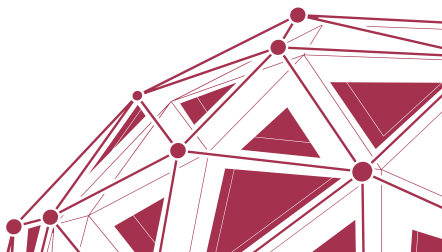


6 CONCLUSIONS

In summary, GDHP participant countries understand that the preservation of confidence and trust in the healthcare system is fundamental, and it is imperative that the relationship of trust between a patient and a healthcare professional continues. Data security breaches or misuses of personal health data can undermine trust in governments and in healthcare systems. For these reasons, there has been a general risk-averse approach to secondary uses of health information.

However, health datasets are becoming so rich and computing technology so powerful that the opportunities to use data for secondary purposes need to be progressed, for the benefit of people's health and their health systems.

An open and transparent approach, ensuring communities understand both the risks and benefits, is necessary to mature our secondary uses of health information. Importantly, engagement and communication need to continue to respond to the changing views and perspectives of individuals about what they expect from the use of their health data. In short, realising the benefits of secondary use of health data requires an open and transparent approach to data collection, use and release.



7 APPENDIX A – LIST OF GDHP PARTICIPANT CONTRIBUTORS

GDHP participant country	Country Contributor	Organisation
Argentina	Alejandro Lopez Osornio	Ministry of Health
Australia	Jarrad King	Australian Digital Health Agency
	Vicki Bennett	Australian Institute of Health and Welfare
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	Seiza Miyazaki	Ministry of Health, Labour and Welfare
	Kenshin Shimizu	Ministry of Health, Labour and Welfare
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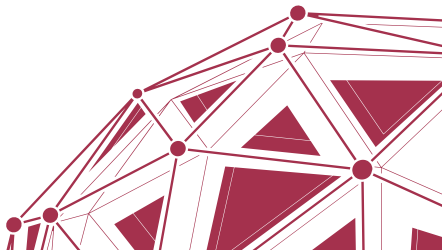
	Joao Pedro Martins	
	Catia Sousa Pinto	
The Republic of Korea	Professor Hyoung-Sun Jeong	Yonsei University
Sweden	Ylva Wide	eHalsomyndigheten (the Swedish eHealth Agency)
	Anna Bennet Bark	Swedish National Board of Health and Welfare
Ukraine	Andrii Suchyk	Ministry of Health/World Bank
	Anastasia Khaleeva	Head of eHealth Expert Group Ministry of Health
United Kingdom	Helena Feinstein	Department of Health and Social Care
United States	Elise Anthony	U.S. Department of Health and Human Services
	Kathryn Marchesini	
Uruguay	Arturo Echevarria	Ministry of Public Health
	Maria Jose Viega	AGESIC



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