

## International review

# Secondary use of health and social care data and applicable legislation



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# Executive summary

## Secondary use of health and social care data in reviewed countries

### Purpose of the international review

Secondary use of health care and social welfare data relates to information collected in the course of providing health care or social welfare services (referred as health and social care), but being used for purposes other than direct patient care, i.e. research and development.

This report aims to clarify how the secondary use of health and social care data has been arranged in UK (England), Netherlands, New Zealand, Israel, Canada and Australia and what legislation regulates the use of data. The aim of the review is also to identify the operational environment and key organizations relating to the secondary use of health and social care data in each of the six countries.

The purpose of the international review is to support the work of Finnish Innovation Fund Sitra and its ongoing [Isaacus – the Digital Health HUB](#) - project, but also support the preparation of new legislation on secondary usage of health and social care data in Finnish Ministry of Social Affairs and Health.

The report utilizes only publicly available information and data sources that are available from Finland. The main challenge of the review is the quality and extent of available information, including coverage of authorities' sources and lack of regulations in social sector.

### Regional highlights

The report has undertaken the review for all of the six countries focusing on the overview of the countries health and social care system and key organizations, primary use and creation of health and social care data, individual's rights and consent management and, finally, secondary use of the health and social care data. The review concerns to social and health care data and registers that include identifiable microdata. The report has reviewed all the countries individually and table 1 presents summarized regional highlights.

## Isaacus – the Digital Health HUB

Finnish Innovation Fund Sitra is facilitating a new initiative to create a national health and well-being data operator to Finland that will

- provide single access point to data
  - Isaacus will provide data gathered from various registers and sources from a single access point
  - Special attention will be paid to privacy protection and data security
- improve the efficiency of service production and research
  - Unhindered use of the full range of data generated by society will lead to better care and treatment with more impact
- take attendant rights into account
  - Individual is the key decision-maker on how the data is used and by whom
  - Citizens will be able to view their own data, as well as using it to maintain their own well-being and access services based on better data than now

The operator is planned to be ready in 2017.

**Table 1. Regional Highlights**

Country	Highlights
<b>UK (England)</b>	Massive reorganization of the public health and social care system took place on 1 April 2013, when the Health and Social Care Act 2012 came into force. The Act defines that public healthcare is delivered by the NHS England, which was established in 1948 to provide health services for all citizens free at the point of delivery. To help improve the sharing of important information about patients, NHS in England is using an electronic patient record called the Summary Care Record. Health and Social Care Information Centre is the national provider of information, data and IT systems and offers secondary uses service for health information.
<b>Netherlands</b>	A major health care reform in 2006 introduced a single compulsory insurance scheme, in which multiple private health insurers compete for insured persons. Private health care providers are primarily responsible for the provision of services. The Dutch Healthcare Authority supervises and sets regulations for health and social care organizations and health insurance institutes. National federated electronic health record was rejected by the Parliament due to privacy concerns in 2011.
<b>New Zealand</b>	The new structure and funding of public health and disability services are set out in the New Zealand Public Health and Disability Act 2000. District health boards are responsible for providing or funding the provision of health services in their district. Currently data is spread over different systems and repositories, but government's goal is universal electronic access to a core set of residents' personal health information in the near future. The Ministry of Health is responsible for national collections of health and disability information.
<b>Israel</b>	National Health Insurance Law 1995 defines the characteristic of the health system. Health insurance is mandatory and services are provided through four non-profit-making health plans. All health plans and hospitals have sophisticated information systems and Israel was the world's first to implement a health information exchange system, enabling creation of patient files that could include data and information input from various treatment sources.
<b>Canada</b>	The organization of Canada's health care system is largely determined by the Canadian Constitution. The federal government's roles in health care include setting and administering national principles for the system and are set under the Canada Health Act. Canada does not have a single national health care plan, but rather a national health insurance program Medicare. Canadian Institute for Health Information CIHI collects comparable data on different aspects of the health system for secondary use and offers metadata for every dataset.
<b>Australia</b>	The complex health system involves both levels of government states and territories, as well as public and private providers set in National Health Reform Act 2011. The universal public health insurance scheme Medicare is the basis of funding and providing Australia's health care system and covers many health care costs. My Health Records Act 2012 creates the legislative framework for the Australian Government's My Health Record system.

### Main findings

It can be concluded that all of the reviewed countries have started to pay attention to collected health records and finding ways how to use electronic health records more effectively and utilize all the information to support decision-making. Although, privacy issues have caused challenges in many countries.

There is no own separate legislation for secondary use of health and social care data in any of the countries. In all of the reviewed counties privacy laws defines how the personal health and social records can be used. Based on the international review, it can also be concluded that countries that are most interesting from Finland's point of view are UK (England) and Canada.

# Introduction

## Background

For decades, health records has been collected and shared for health care delivery and public health purposes. However, today electronic health records (EHRs), data sharing, big data, data mining and secondary use are enabling exciting opportunities for improving health and social care. They also contribute to new concerns over privacy, confidentiality and data protection. Data privacy laws and data protection set limitations on how data can be used, as the guiding principle for a current advanced legal systems is to protect the individual interest for privacy. Data handling is typically governed by the specific provisions of law. Furthermore, the general regulatory approach is that an express consent from the data subject can be a tool for providing opportunities for various data handling purposes.

Number of countries have started to reform their health and social care systems to operate more efficiently. Efficiency is a typical driver for the reform, but there is also a desire to utilize in new ways the information that is collected with increasingly improving technological solutions. The aforementioned reflects also to legislation concerning data processing, especially regarding handling of sensitive information.

## Primary and secondary use of data

The definition of electronic health records is that it includes any and all identifiable information relating to the physical and mental health of the individual in electronically-stored and digital format. It covers any information relating to an individual that is collected for or in connection with the provision of a health or social care services. It can be identifiable e.g. by a name, a date of birth, an address, an assigned number such as a medical record number or any other code that has been assigned to code the information.

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**Secondary use of health and social care data relates to information collected in the course of providing care, but being used for purposes other than direct patient care.**

Electronic health records ceases to be personal only when it has been anonymized to the point that it can no longer be linked to any known individual meaning the removal of all possible identifiers and ensuring that any other data or combination of data could not identify the individual. As a general rule, information should only be used for the purpose for which it was collected – that is, the primary purpose. Primary use of health and social care data relates to information which has been collected and is being kept by a custodian for the

purpose of protecting, promoting, maintaining or meeting the physical and mental health needs of an individual. [1]

Secondary use of health care and social welfare data relates to information collected in the course of providing health care or social welfare services (referred as health and social care), but being used for purposes other than direct patient care. Health and social care data can be used for many valuable secondary purposes aside from research, which bring benefits to the patient population as a whole. Secondary uses include using information for audit and quality assurance purposes, performance monitoring, service planning and epidemiology. However, in many cases, identifiable information is used for secondary purposes in which case it must be treated with the appropriate respect. A number of developments have taken place in an attempt to protect the rights of individual's. [1]

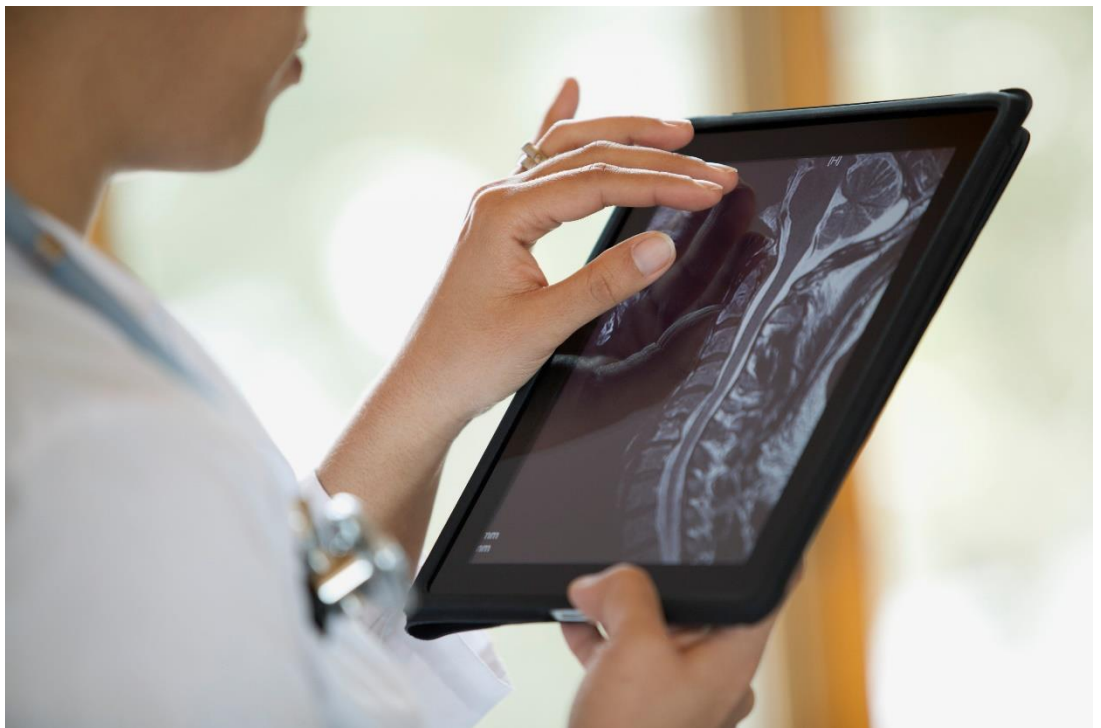
### Purpose and limitations of the review

This report aims to clarify how the secondary use of health and social care data has been arranged in UK (England), Netherlands, New Zealand, Israel, Canada and Australia and what legislation regulates the use of data. The primary aim of the review is also to identify the operational environment and key organizations relating to the secondary use of health and social care data in each of the six countries. The review also aims to identify the applicable legislation regarding health records, privacy and confidentiality.

The purpose of the international review is to support the work of The Finnish Innovation Fund Sitra and its ongoing [Isaacus – the Digital Health HUB](#) -project, but also support the preparation of new legislation on secondary use of health and social care data in The Finnish Ministry of Social Affairs and Health.

The report seeks to ascertain the overview of the countries health and social care system and key organization, primary use and creation of health and social care data, individual's rights and consent management and, finally, secondary use of the health and social care data. The review concerns to social and health care data and registers that include identifiable microdata.

The report utilizes only publicly available information and data sources that are available from Finland. The main challenge of the review is the quality and extent of available information, e.g. coverage of authorities' sources and lack of regulations in social sector. The purpose of the review is to be a concise overview on the above-mentioned countries' operational environments and legislation. The execution of the international review is accomplished by Kristiina Heinonen and Toni Oras in Deloitte Oy.



# United Kingdom (England)

## General

The United Kingdom (UK), literally The United Kingdom of Great Britain and Northern Ireland, consists of four home countries namely England, Scotland, Wales and Northern Ireland, each having a separate national health system. The Parliament of the United Kingdom of Great Britain and Northern Ireland is the supreme legislative body for the United Kingdom, British Crown dependencies and British overseas territories. [2]

Each of the three major jurisdictions of the United Kingdom – England and Wales, Scotland and Northern Ireland also has its own laws and legal system. In the UK, the Prime Minister leads the government with the support of the Cabinet and ministers. The population of England is 64,6 million and of which by far the largest part, 54,3 million, locates to England. [2], [3]

## Health and social care system

The Health and Social Care Act 2012 sets out specific obligations for the health system and its relationship with care and support services in England. Massive reorganization of the public health system took place on 1 April 2013, when the legislative changes came into effect. It gives a duty to NHS England, clinical commissioning groups, monitor and health and wellbeing boards to make it easier for health and social care

services to work together. The Act also allows NHS to set the standards needed to create an electronic database of people's care assessments, and their care and treatment needs. [4]

The Care Act published in 2014, provides the legal framework for changes to the social care system. [4] The Act introduced a new national level of care and support needs to make care and support more consistent across the country, new support for careers and deferred payment agreements for care costs. [5] The National Health Service Act 2006 sets out the structure of the National Health Service in England and was significantly altered by the Health and Social Care Act 2012. [6]

The Department of Health is responsible for strategic leadership and funding for both health and social care in England. The Department of Health is a ministerial department, supported by 15 arm's length bodies and a number of other agencies and public bodies. The Secretary of State has overall responsibility for the work of the Department of Health. The Department of Health provides strategic leadership for public health, the NHS and social care in England. [7], [8]

Each of the four countries of the United Kingdom has a publicly funded health care system referred to as the National Health Service (NHS). In England public healthcare is delivered by the NHS England which was established in 1948, to provide health services for all citizens free at the point of delivery. NHS England sets the priorities and direction for the whole NHS system and encourages and informs the national debate to improve health and care. The NHS system consists of NHS England, NHS Scotland, NHS Northern Ireland and NHS Wales. NHS England is publically fund and shares out more than £100 billion in funds and holds organizations to account for spending this money effectively for patients and efficiently for the tax payer. The NHS provides the majority of healthcare in England, including general practitioner (GP) services, hospital services, emergency and urgent care, mental health services, dental services, eye care services, pharmacy services and social care. [9], [10]

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Massive reorganization of public health system took place on 2013, when the Health and Social Care Act came into effect.



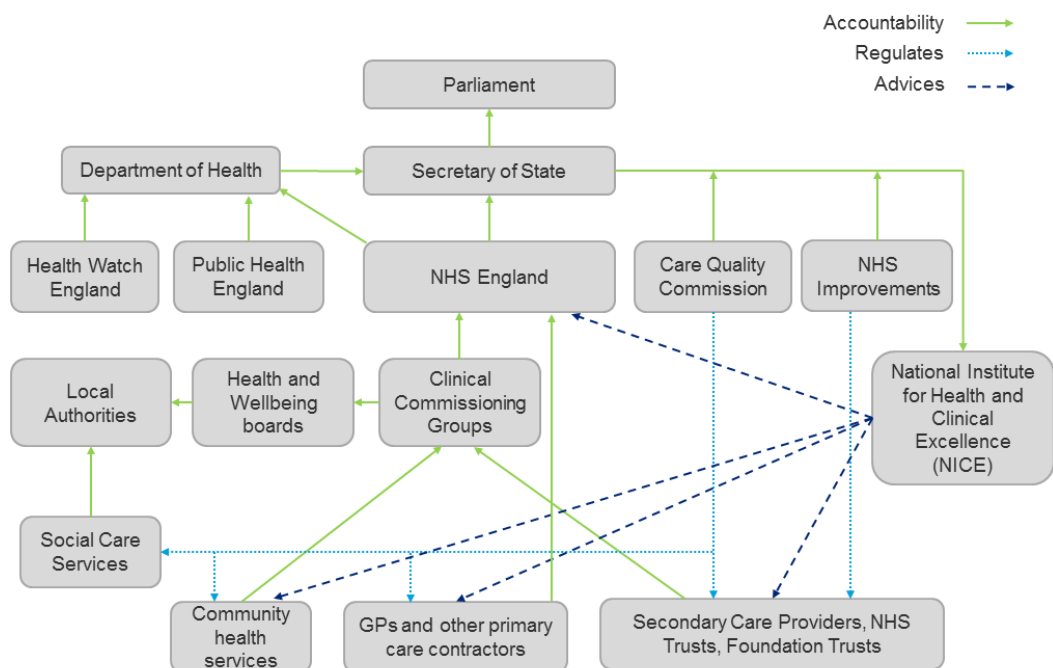
The main aim of the NHS England is to improve health outcomes and deliver high-quality care for people in England by providing national leadership for improving outcomes and driving up the quality of care, overseeing the operation of Clinical Commissioning Groups (CCGs), allocating resources to

## NHS England provides health services for all citizens free at the point of delivery.

clinical commissioning groups, commissioning primary care and directly commissioned services, like specialized services, offender healthcare and military healthcare. [11]

The [Health and Social Care Act 2012](#) replaced the previous system of primary care trusts with 211 clinical commissioning groups (CCGs) that are designed to be

clinically led and responsive to the health needs of their local populations. They are membership bodies made up of GP practices in the area they cover. The members set out in their constitution the way in which they will run their CCG. Constitutions are agreed with NHS England and published. [11] CCGs plan and pay for local services such as hospitals and ambulance services. [9]



**Picture 1:** Organization of the Health and Social Care System in England [12]

CCGs can commission any service provider that meets NHS standards and costs. These can be NHS hospitals, social enterprises, charities or private sector providers. However, they must be assured of the quality of services they commission, taking into account both National Institute for Health and Care Excellence (NICE) guidelines and the Care Quality Commission's (CQC) data about service providers. [7] NICE provides also national guidance and advice to improve health and social care. It develops guidance, standards and information on high quality health and social care. It also advises on ways to promote healthy living and prevent health problems. Formerly the National Institute for Health and Clinical Excellence, NICE's name changed on April 1 2013 to reflect its new role as a non-departmental public body and additional responsibility to develop guidance and set quality standards for social care, as outlined in the [Health and Social Care Act 2012](#). [13]

The Care Quality Commission (CQC) is the independent regulator for health and social care in England. It makes sure services such as hospitals, care homes, dentists and GP surgeries provide people with safe, effective, compassionate and high-quality care, and encourages these services to improve. The CQC monitors and inspects these services, and then publishes its findings and ratings to help people make choices about their care. [14] On a local level some Clinical Commissioning Groups



(CCGs) have started to integrate patients' health and social care records to improve the overall care they provide in their area and to ensure more joined up care is given to patients. This is called Integrated Digital records. [15]

152 local authorities are responsible for organizing social care. Social care services includes services that are provided in pursuance of the social services functions of local authorities, for example home care, residential care, financial support and support for carers. Social services are means-tested and may be associated with payments depending on customer's assets. However, there has been set an upper limit on the size of the population. [16]

Public Health England (PHE) is an executive agency of the Department of Health that began operating on 1 April 2013. PHE provides national leadership and expert services to support public health, and also works with local government and the NHS to respond to emergencies. Its Chief Executive is accountable to the Secretary of State for Health. Its formation came as a result of reorganization of the National Health Service (NHS) in England outlined in the [Health and Social Care Act 2012](#). It took on the role of the Health Protection Agency, the National Treatment Agency for Substance Misuse and a number of other health bodies. [17], [7]

Healthwatch England promotes patient interests nationally. In each community, local Healthwatches support people who make complaints about services; quality concerns may be reported to Healthwatch England, which can then recommend that the Care Quality Commission (CQC) take action. In addition, local NHS bodies, including general practices, hospital trusts, and CCGs, are expected to support their own patient engagement groups and initiatives. The Department of Health owns NHS Choices, the primary website for public information about health conditions, the location and quality of health services, and other information. [12]

Monitor is an executive non-departmental public body of the Department of Health. As the sector regulator for health services in England, Monitor's job is to make the health sector work better for patients. Monitor's responsibility is to make sure that independent NHS foundation trusts are well-led so that they can provide quality care on a sustainable basis, essential services are maintained if a provider gets into serious difficulties, the NHS payment system promotes quality and efficiency and procurement, choice and competition operate in the best interests of patients. [18] Monitor ensures foundation hospitals, ambulance trusts, and mental health and community care organizations are run well, so they can continue delivering good quality services for patients in the future. [19]

Every upper-tier local authority has also established a health and wellbeing board to act as a forum for local commissioners across the NHS, social care, public health and other services. The boards are intended to increase democratic input into strategic decisions about health and wellbeing services, strengthen working relationships between health and social care but also encourage integrated commissioning of health and social care services. [7] The ambition behind the health and wellbeing boards is to build strong and effective partnerships, which improve the commissioning and delivery of services across NHS and local government, leading in turn to improved health and wellbeing for local people. The [Health and Social Care Act 2012](#) has created a framework, by requiring the establishment of a health and wellbeing board for every upper tier local authority. [20]

## Creating and using health and social care data in primary use

[The Data Protection Act 1998](#) gives rules for handling information about people. The Act controls how personal information is used by organizations, businesses or the government. Everyone responsible for using data has to follow strict rules called data protection principles. They must make sure the information is: used fairly and lawfully, used for limited, specifically stated purposes, used in a way that is adequate, relevant and not excessive, accurate, kept for no longer than is absolutely necessary, handled according to people's data protection rights, kept safe and secure and not transferred outside the European Economic Area without adequate protection. There is also stronger legal protection for more sensitive information, such as ethnic background, political opinions, religious belief, health, sexual health and criminal records. [21] The [Access to Health Records Act 1990](#) provides qualified right of access to the record of a deceased individual where the person seeking access has an interest in the estate of the deceased. The Act covers manual health records made since 1 November 1991. [22]

In order for an institution like GP or hospital to host medical records including electronic health records, it must hold an appropriate license and be subject to NHS contractual conditions in England. The licensing requirements and contractual conditions will reflect the standards required to provide a health care service and to host medical records whether in paper or electronic form. The law mandates that a medical record must be created for every patient who is seen or treated by a medical professional. [2] The NHS currently holds patient information in a variety of settings, both in paper form and electronically. Electronic records are stored by GPs, hospitals – notably in radiology and pathology, mental health providers and in some community care settings. There is great variation in the type and use of electronic record systems between geographical regions and even between departments within hospitals. At present, only a few electronic records are shared between providers. [23]

To help improve the sharing of important information about patients, the NHS in England is using an electronic record called the Summary Care Record (SCR). Every patient will have SCR unless they choose not to have one. SCR contains basic information; medicines that the patient is taking, allergies and bad reactions that patient may have to certain medicines. It also includes patients name, address, date of birth and unique NHS Number which helps to identify patient correctly. [15] NHS Summary Care Record (SCR) was first introduced nationally in 2008. The SCR is stored as read-only pdf files on a central NHS computer, called the NHS Spine, and accessed nationally, based on strict access control measures, by authorized healthcare staff. SCR is created by extracting a subset of information

from the detail record held by a GP. [2] NHS Spine is a collection of national applications, systems and directories that support the NHS in the exchange of information across national and local systems. [24] Clinical commissioning groups and NHS Trusts in Bristol, Somerset and Gloucestershire have also created the Connecting Care program, which shares electronic records between primary, secondary and social care in these areas. [23]

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## To help improve the sharing of important information about patients, NHS England is using an electronic record called the Summary Care Record.

### [The NHS Care Record Guarantee for](#)

[England](#) sets out the rules that govern how patient information is used in the NHS and what control the patient can have over this. It is based on professional guidelines, best practice and the law and applies to both paper and electronic records. The NHS Care Record Guarantee includes information on people's access to their own records, how access to an individual's healthcare record will be monitored and policed and what controls are in place to prevent unauthorized access, options people have to further limit access, access in an emergency and what happens when someone is unable to make decisions for themselves. [25]

The Government's target is to introduce a comprehensive system of electronic health records in England by 2020. The intention is that each patient's electronic record will include information about his or her medical history, care preferences and lifestyle such as diet and exercise. The records should be accessible to all health and social care providers and updated in real-time. Patients should be able to view and annotate a version of their health record online. Patients should also be able to book appointments and order repeat prescriptions online. In England, electronic health record planning is managed by NHS England, the National Information Board and the Health and Social Care Information Centre (HSCIC). Together they are developing national standards for electronic health records, but local areas can choose their own systems. [23]

In 2013, the United Kingdom launched care.data program, an NHS England initiative to combine patient records, stored in the machines of general practitioners (GPs), with information from social services and hospitals to make one centralized data archive. One aim of the initiative is to gain a picture of the care being delivered between different parts of the healthcare system and thus identify what is working in health care delivery, and what areas need greater attention and resources. In this program, NHS England could direct the HSCIC to collect health and social care data from all NHS-funded care sources, including information from GP records, and store it in one national database. The data would be stored and maintained by the HSCIC rather than NHS England. However, program has faced multiple challenges due to its mismanagement and miscommunications, inadequate protections

for patient anonymity, and conflicts with doctors. [26] Full implementation has been delayed because of mentioned concerns, but piloting in 265 general practices started in 2014. [12]

## Individual's position and consent management

[Freedom of Information Act 2000](#) covers any recorded information that is held by a public authority in England, Wales and Northern Ireland, and by UK public authorities based in Scotland. Public authorities include government departments, local authorities, the NHS, state schools and police forces. However, the Act does not necessarily cover every organization that receives public money. For example, it does not cover some charities that receive grants and certain private sector organizations that perform public functions. However, the Act does not give people access to their own personal data such as their health records or credit reference file. If a member of the public wants to see information that a public authority holds about them, they should make a subject access request under the [Data Protection Act 1998](#). The Information Commissioner's Office is the UK's independent authority responsible for upholding the [Data Protection Act](#) and [Freedom of Information Act](#). [27]

The [Code of Practice on Confidential Information](#) is provided in response to the [Health and Social Care Act 2012](#) section 263 that requires: "The Health and Social Care Information Centre to publish a code of practice on the actions to be taken in relation to the collection, analysis, publication or other dissemination of confidential information concerning or connected with the provision of health services or of adult social care in England. [28] The guidance document stresses the point that patients must be effectively informed. Patients must be made aware that the information they give may be recorded, may be shared in order to provide them with care, and may be used to support local clinical audit and other work to monitor the quality of care provided. The Code also emphasizes consent and the fact that patients must be provided with choice. Patients have the right to choose whether or not to accept a form of care and the information disclosure needed to provide that care, and to choose whether or not identifiable information can be used for non-healthcare purposes. [1]

According to the [Caldicott Principles](#) that define how information can be shared, implicit consent to the sharing of patient information is only applicable in instances of direct care, and only relevant information should be shared between professionals in support of their care. Further consent should be obtained before sharing a patient's whole care record with other registered and regulated health and social care professionals for the purposes of direct care. [2], [29]

NHS Choices will serve as a single point of access for patients to register with a GP, book appointments and order prescriptions, access apps and digital tools, speak to their doctor online or via video link, and view their health records. [12] Since April 2015 all GPs in NHS England should offer their patients' online access to summary information of their GP records, previously mentioned Summary Care Record (SCR). The NHS is committed to modernizing its services so that they are as efficient and effective as possible and put patients in the driving seat of their care. The ambition is that by 2018 every citizen will be able to access their full health records at the click of a button, detailing every visit to the GP and hospital, every prescription, test results, and adverse reactions and allergies. [15] SCRs are created by implicit consent. Individual can choose to opt out of having an SCR. Patient consent is required every time an SCR needs to be accessed, however, in certain situations when a patient is unable to give consent an SCR can be accessed. Patients must also explicitly consent to changes in categories of information stored in their SCR. Also additional information can be added to the SCR with the consent of the patient, however, some types of data are automatically excluded because they are considered too sensitive (e.g. HIV AIDs data or sexual disease, termination of pregnancy). [2]

## Health and social care data in secondary use

The [Research Governance Framework for Health and Social Care](#), published in 2005 by the Department of Health, defines the broad principles of good research governance and is key to ensuring that health and social care research is conducted to high scientific and ethical standards. The rights of the data subject are covered under ethics and responsibilities and accountability. The importance of keeping information confidential is addressed under the heading of ethics. It is noted that the appropriate use and protection of patient data is paramount. All those involved in research must be aware of their legal and ethical duties and particular attention must be given to systems for ensuring the confidentiality of personal information and to the security of those systems. The new UK Policy Framework for Health and Social Care has now been drafted and issued for public consultation. [30]

British Medical Association has also published advisory document for the [Requests for disclosure of data for secondary purposes](#), which states that identifiable data may be disclosed for secondary uses without express consent if the disclosure of identifiable information has been authorized by the National Information Governance Board's Ethics and Confidentiality Committee under Section 251 of the [National Health Service Act 2006](#) or it is a disclosure made under the [Confidentiality and Disclosure of Information Directions 2013](#) or it is otherwise required by law.

Health and Social Care Information Centre (HSCIC) is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. HSCIC was set up in April 2013 and is an executive non-departmental public body, sponsored by the Department of Health. [31] HSCIC manages a number of data collections covering many aspects of health and social care. The Centre collects information from the records health and social care providers keep about the care

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## Health and Social Care Information Centre is the national provider of information, data and IT systems and offers secondary uses service for health information.

and treatment they give and can only provide access to identifiable information if it will be used to promote health or support improvements in the delivery of care services in England or the government decides it's an emergency or in the public interest. HSCIC collect from a wide range of providers across England ranging from hospitals to general practices. Data collections include for example Patient Online Management Information, Social Care Collections and Pharmacy Collection. HSCIC has also legal responsibilities for collecting different types of information. Some of these rules

are set out in the [Health and Social Care Act 2012](#), the [Care Act 2014](#) and their [Code of Practice on Confidential Information](#) and [The Common Law Duty of Confidence](#). Each request for data, other than for anonymous data, is evaluated by the Data Access Advisory Group (DAAG). Applications made under Section 251 of the [National Health Service Act 2006](#) are overseen by the Confidentiality Advisory Group (CAG), part of the NHS Health Research Authority. [32]

HSCIC offers also The Secondary Uses Service (SUS) that is comprehensive repository for healthcare data in England which enables a range of reporting and analyses to support the NHS in the delivery of healthcare services. SUS can be accessed by any healthcare provider that submits patient data to SUS (NHS and independent sector), organizations that commission data from SUS or organizations that check healthcare compliance and consistency with national standards, such as Area Teams. SUS is a data warehouse containing this patient-level information. Data can be patient identifiable, anonymized or pseudonymized as required for the user's needs. NHS providers and commissioners can use this data for secondary uses; purposes other than primary clinical care. SUS provides a range of services and functionality which you can use to analyze, report and present this data. SUS data are held in a secure environment that maintains patient confidentiality to national standards. [32] Collected information includes ethnicity and any data from the previous four months about referrals, prescriptions or health information such as diagnoses. These diagnoses relate to health conditions such as diabetes, heart disease, stroke, cancers (including bowel, breast, and cervical), chronic liver disease, chronic kidney disease, asthma, damage to the retina of the eye, high blood pressure and dementia. Information that is not included are codes that relate to sensitive information including HIV/AIDS, sexually transmitted infections, termination of pregnancy, IVF treatment, marital status, complaints, convictions, imprisonment, and abuse by others. [2]

SUS and previously presented SCR are part of The NHS Spine that is a collection of national applications, services and directories which support the health and social care sector in the exchange of information in national and local IT systems. Spine includes also The Personal Demographics Service (PDS), which is the national electronic database of NHS patient demographic details such as name, address, date of birth and NHS Number. The PDS does not hold any clinical or sensitive data items such as ethnicity or religion. [32], [33]

Also Public Health England (PHE) provides many high quality data and analysis tools and resources for public health professionals. The PHE data and knowledge gateway provides direct and single point of access to these resources. The resources help local government and health service professionals make decisions and plans to improve people's health and reduce inequalities in their area. They can be used by anyone with an interest in understanding the health of the population and how it varies across the country. Most of the datasets and tools are free to access by anyone. However, some tools require eligible users to register and login, to protect certain types of data. The resources cover a wide range of public health areas, including specific health conditions – such as cancer, mental health, cardiovascular disease, lifestyle risk factors, such as smoking, alcohol and obesity, wider determinants of health, like as environment, housing and deprivation, health protection, and differences between population groups, including adults, older people, and children. [34]

National Institute for Health and Care Excellence (NICE) provides also access to a range of information services to ensure that health and social care professionals have quick and easy access to reliable information. To access all NICE databases requires an OpenAthens account that gives access to a range of resources including healthcare databases, e-journals and ebooks. To gain OpenAthens account, users must supply an application that will be reviewed against [the eligibility criteria](#) to ensure that user receives the appropriate level of access. OpenAthens access is mainly for employees, workers and contractors of NHS organizations and private citizens cannot be granted to access. [35]

NHS Choice is the primary public facing website of the NHS. It includes directories of local health services, information on a wide range of conditions and treatments and accessible public health information. The site also provides comparative data about healthcare providers, to help people make informed choices about their healthcare. NHS Choice is also taking an active role in making data available to the public and those interested in improving the NHS. NHS Choices allows users to compare information for hospitals. Information includes indicators of the quality and safety of a hospital, as well as information about facilities provided, such as the cost and availability of car parking. Procedure-specific information is available for a number of the more common procedures carried out in England, such as hip and knee replacement or procedures for varicose veins. Hospital and GP indicators files include data published by NHS Choices. [36]

The UK Statistics Authority is an independent body operating at arm's length from government as a non-ministerial department, directly accountable to Parliament. It was established on 1 April 2008 by the [Statistics and Registration Service Act 2007](#). [37] The UK Statistics Authority promotes and safeguards the production and publication of official statistics that serve the public good. It also promotes and safeguards the quality and comprehensiveness of official statistics, and ensures good practice in relation to official statistics. [38]

The Office for National Statistics (ONS) is the UK's largest independent producer of official statistics and the recognized national statistical institute of the UK. It is responsible for collecting and publishing statistics related to the economy, population and society at national, regional and local levels. It plays a leading role in national and international good practice in the production of official statistics. ONS provides statistics and multiple datasets on health and social care, for example causes of death, health care systems, disabilities and health and wellbeing. ONS works with the UK Statistics Authority. [38], [39]

Data.gov.uk offers open data to help people understand how government works and how policies are made. Some of this data is already available, but data.gov.uk brings it together in one searchable website. There are datasets available from all central government departments and a number of other public sector bodies and local authorities. The catalogue contains 27,500 and counting datasets. There is also publicly available health and social care data that can be reused to any purpose. [40]



# Netherlands

## General

The Netherlands is a constitutional monarchy and a parliamentary democracy. Officially called The Kingdom of the Netherlands (Koninkrijk der Nederlanden) consists of the Netherlands and its overseas islands - Netherlands Antilles and Aruba. The hereditary monarch is the head of state and the prime minister is the head of government. The Dutch Parliament is called the States General. There is a bicameral legislature, which means it consists of two chambers; the Senate (Eerste Kamer der Staten-Generaal) and the House of Representatives (Tweede Kamer der Staten-Generaal). [41]

The Senate, literally “First Chamber” is the upper house of States General, the legislature of the Netherlands. Members of the deliberative upper house, the 75-seat First Chamber, are elected by the 12 provincial councils. Administratively, the country is divided into 12 provinces, which have their own capital, own self-rule and administration. [41]

The 150 members of the House of Representatives, the “Second Chamber”, are directly elected by Dutch voters every four years. Both houses have a number of rights to allow them to perform their duties effectively. Legislation can only come into force after it has been passed by both the Senate and the House of Representatives. [42] In 2016 the population of Netherlands is 17 million [43] and its social and health care system is based on mandatory health insurance. [44]

## Health and social care system

In Netherlands the national government has overall responsibility for setting health care priorities, introducing legislative changes when necessary, and monitoring access, quality and costs. It also partly finances social health insurance for the basic benefit package, through subsidies from general taxation and reallocation of payroll levies among insurers through a risk adjustment system and the compulsory social health insurance system for long-term care. Prevention and social support are not part of social health insurance but are financed through general taxation. [12]

Private health care providers are primarily responsible for the provision of services. Health care can be divided into preventive care, primary care, secondary care and long-term care. Preventive care is mainly provided by public health services. Disease prevention, health promotion and health protection fall under the responsibility of municipalities. There are 29 municipal health services (Gemeentelijk Gezondheidsdiensten, GGDs) that carry out these tasks for all 443 municipalities. Primary care has a wide variety of providers, such as GPs, physiotherapists, pharmacists, psychologists and midwives. The GPs function as gatekeepers, which means that hospital care and specialist care (except emergency care) are only accessible upon referral from the GP. Secondary care encompasses those

forms of care that are only accessible upon referral from a primary care provider and are mainly provided by hospitals and mental health care providers. Long-term care is mainly provided by nursing homes, residential homes and home care organizations. [45]

A major health care reform in 2006, introduced after almost two decades of

preparation, has brought completely new regulatory mechanisms and structures to the Dutch health care system. The reform introduced a single compulsory insurance scheme, in which multiple private health insurers compete for insured persons. [45] Every person who lives or works in the Netherlands

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**Major health care reform in 2006 introduced a single compulsory insurance scheme.**

is legally obliged to take out standard health insurance to cover the cost of, for example, consulting a general practitioner, hospital treatment and prescription medication under the Healthcare Insurance Act (Zorgverzekeringswet, ZVW) and the Long-Term Care Act (Wet langdurige zorg, Wlz). The government decides on what the standard package covers. Health insurance companies are legally obliged to offer at least this basic package and cannot reject anybody who is applying for it. Individuals can also decide to purchase additional insurance if they need extra medical care. [44]

Standard health insurance covers the costs of normal medical care, such as visits to the doctor, hospitalization and pharmacy prescriptions. Everyone who has the standard health insurance is also insured under the Long-term Care Act (Wet langdurige zorg, Wlz), which covers the costs of exceptional and particular expensive care, such as long-term nursing care and homecare. [46] Since 2015, all long-term care is provided under the Long-Term Care Act, which is strictly intended for the most vulnerable categories of people. [47] The National Health Care Institute (Zorginstituut Nederland, ZIN) is responsible for ensuring that everyone who is legally obliged to take out public health insurance does so. [48]

The Health Care Allowance Act (Wet op de zorgtoeslag, WZT) took effect at the same time as the Healthcare Insurance Act (Zorgverzekeringswet, ZVW). Under the Health Care Allowance Act, people receive an allowance if the nominal premium is deemed excessive relative to their income. The Dutch Tax and Customs Administration pays out the allowances. The income of a person's partner is taken into consideration when determining whether somebody qualifies for an allowance. [47]

On 1 October 2006 followed the Health Care Market Regulation Act (WMG). According to the explanatory memorandum, the Act contributes to changes in the Dutch health care system, permitting more room for consumer choice and competition among health care providers and health insurers. The Health Care Market Regulation Act contains regulations designed to arrive at an effective system of appropriate health care, to control the growth of health care cost and to protect and promote the position of consumers. [49]

The Social Support Act and the Youth Act were introduced more recently, having entered into force in their present form in 2015. Under the Social Support Act, the responsibility of providing support to people with disabilities has been transferred to the local authorities; this includes people with physical, mental or psychological disabilities, including people with learning disabilities and the elderly. The support is designed to ensure that people can continue to be productive members of society and to enable them to continue living at home. Furthermore, under the Social Support Act, local authorities can provide sheltered accommodation and support to people who have no other options or who are unable to live at home. [47]

The Youth Act, provides for the decentralization of support, assistance and care for children and adolescents, for which local authorities are currently responsible. The Youth Act covers support, assistance and care for young people and their families coping with parenting and developmental issues, psychological problems and disorders. Young people who require ongoing support, for example due to a severe mental disability, are not covered by the Youth Act but under the Long-Term Care Act. The type of care provided ranges from general prevention to specialized voluntary or compulsory care. In enforcing the Youth Act, the local authorities aim for children to grow up in safety and in good health, become independent and become productive members of society based on their own abilities. [47]

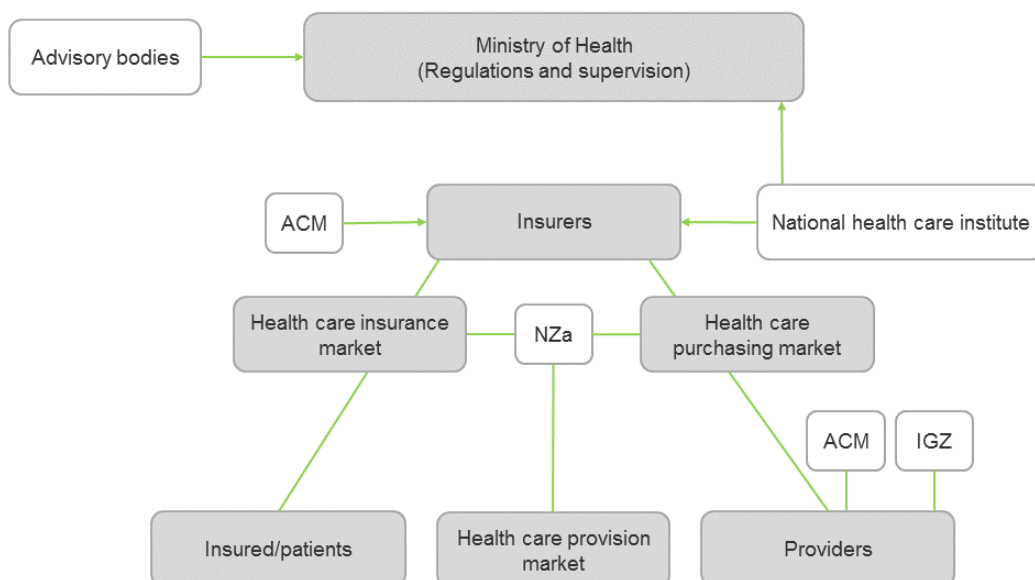
The government changed its role as a part of the health care reform from direct steering of the system to safeguarding the process from a distance. Responsibilities have been transferred to insurers, providers and patients. [45] Ministry of Health, Welfare and Sport (Ministerie van Volksgezondheid, Welzijn en Sport, VWS) is responsible for controlling health and care at national level. Together with health insurers, health care providers and patient organizations, the Ministry of VWS ensures that there are sufficient facilities and that people have sufficient choices. [50]

The Minister of Health is responsible for the preconditions towards access, quality and costs of the health system, and has an overall responsibility for priority setting and may, when necessary, introduce legislation to set these strategic priorities. A number of arm's-length agencies are responsible for setting operational priorities. At the national level, the Health Council advises government on evidence-based medicine, healthcare, public health, and environmental protection; the newly established National Health Care Institute (Zorginstituut Nederland, ZIN) integrates knowledge of various institutes



involved and has the power to inform change. [51] The Medicines Evaluation Board oversees the efficacy, safety, and quality of medicines. [12]

Also other ministry, the Ministry of Social Affairs and Employment (Ministerie van Sociale Zaken en Werkgelegenheid, SZW) has its own responsibilities for health-related social security schemes covering sickness benefits and disability benefits. The main tasks of the ministry are to stimulate employment, encourage modern labor relations and oversee social security policy. To realize these tasks, the Ministry collaborates with other ministries. [45], [52]



**Picture 2:** Organization of the Health and Social Care System in the Netherlands [12]

The Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa) is an autonomous administrative authority, falling under the Dutch Ministry of Health, Welfare and Sport. The duties and tasks of the NZa have been laid down in the Healthcare Market Regulation Act (Wet marktordening gezondheidszorg, Wmg). The NZa determines what types of health care can be charged to patients by health care providers, and what such health care may cost at the most, for example treatments by GPs

or dentists, or health care provided to people with disabilities. It also supervises and sets regulations for health and social care organizations and health insurance institutes. [53]

## The Dutch Healthcare Authority supervises and sets regulations for health and social care organizations and health insurance institutes.

The Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ) promotes public health through effective enforcement of the quality of health services, prevention measures and medical products. It advises the responsible ministers and applies various measures, including advice, encouragement, pressure and coercion, to

ensure that health care providers offer only responsible care. The Inspectorate investigates and assesses in a conscientious, expert and impartial manner, independent of party politics and unaffected by the current care system. [54] IGZ primarily enforces quality standards for the provision of healthcare. [55]

The Netherlands Authority for Consumers and Markets (ACM) makes sure that businesses compete fairly with one another, and it protects consumer interests. It also supervises competition in healthcare in the interest of patients and insured parties. ACM follows the rules of [the Dutch General Administrative Law Act](#) (Algemene wet bestuursrecht, Awb). [The Establishment Act of the Netherlands Authority for Consumers and Markets](#) was amended on August 1, 2014. [56]

## Creating and using health and social care data in primary use

The main rules for handling personal data are laid down in the Personal Data Protection Act (Wet bescherming persoonsgegevens, WBP). [57] The obligations laid down in article 13 and 14 of the WBP set that if the hosting institution acts as a processor of personal data the responsible party, like healthcare provider, has to make sure that this hosting institution implements appropriate technical and organizational measures to secure all personal data against loss or any form of unlawful processing. [55]

The Dutch Data Protection Authority (College bescherming persoonsgegevens, CBP) supervises processing of personal data in order to ensure compliance with laws that regulate the use of personal data. The most important laws in addition to Dutch Data Protection Act are the Police Data Act (Wet politiegegevens, Wpg) and the Basic Registration of Persons Act (Wet Basisregistratie Personen, BRP). In the execution of its powers, the Dutch Data Protection Act is bound by the standards enshrined in the General Administrative Law Act (Awb). [58]

The new Dutch Data Protection Authority began to operate 1 January 2016. Comparing to the former operating organization, The Dutch Data Protection Authority has the ability to impose substantially higher fines for a broader range of violations of the Dutch Data Protection Act. Another important change is the introduction of various data breach obligations into the Act, including the obligation to notify such breaches to the Personal Data Protection Act and affected individuals. [59]

After investing almost a decade and several hundred million euros in developing a national federated EHR, the underlying legislation presented by the Ministry of Health was rejected by the Parliament due to privacy concerns. [60] The first proposal for the implementation of the Electronic Patient Dossier (EPD, Elektronische patiëntendossier), national electronic health record containing the medical data of a patient, was turned down by the Dutch parliament, a majority of health professionals and the Dutch citizens in 2011 due to the concerns of privacy, as serious doubts of the security of personal medical

data existed. As the EPD was not 100 percent safe for hackers, it caused fear of exposing personal medical data to persons who were not authorized to view the data. This was the main reason why the implementation of the EPD was declined. [61]

Three years after the EPD was turned down, two GP's, together with developers, are creating an alternative for the EPD. This new

version requires the patient dossier to stay at the GP of the patient and the patient needs to give his or her approval each time their data being shared with other health care professionals. Together with the GP, a patient will decide what will be shared and what will not. This means that the dossier will be managed regionally and it cannot be saved by health care professionals other than the GP. This way, the patient and his GP will stay in control of patient's dossier, while only few relevant health care professional will have access to the patient's. [61]

However, the new plan for nationwide EHR is not actually a real EHR because there is no central database in which patient data is stored. It would rather be a collective term for ICT applications to support health care, prevention, medical care and logistics. There is no specific legislation with respect to the type of data that must or may be included in an EHR because the rules can be found in the Medical Treatment Contracts Act (WGBO), the Data Protection Act (WBP) and the Proposal on patient's rights with regard to electronic data processing (Proposal Patient's rights). [55]

Currently there are several systems in place for the electronic exchange of patient data inserted in EHRs. For example at the local level there are systems that connect the information systems of general practitioners, GPs out-of-hours surgery and pharmacists, for example OZIS-ring (Open Zorg Informatiesysteem). There are also systems that connect data of medical specialists or other healthcare providers who are active in the same chain of care (for example for cancer or diabetes). [55]

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## National federated EHR was rejected by the Parliament due to privacy concerns in 2011.

One of the current initiatives, launched by the Association of Healthcare providers for Health communication (Vereniging van Zorgaanbieders voor Zorgcommunicatie, VZVZ) is responsible for a system for the electronic exchange of medical data between healthcare providers. The exchange of medical data between the healthcare providers takes place via a National Switch Point (LSP) which provides a reference index for routing, identification, authentication, authorization and logging. The LSP can be compared to a traffic-control tower which regulates the exchange of patient data between the healthcare providers. At this moment LSP mainly connects general practitioners, GPs out-of-hours surgery, pharmacists and a few hospitals. This system has the potential to be a nationwide system, but at the moment it is not. Besides this it should be clear and stated that the government is not involved in this system. There are no specific laws or action plans to regulate EHRs. [55]

National IT Institute for Healthcare (NICTIZ) works as the center of expertise for standardization and eHealth in the Netherlands. NICTIZ works towards better healthcare through better information and supports the healthcare sector in the use of IT to improve quality and efficiency within healthcare. NICTIZ is financed by the government, to assist the healthcare sector with interoperability. [62] Netherlands initiated a program called AORTA in the year 2007 to establish a nationwide health informatics infrastructure providing secure access to healthcare information of patients across the country. AORTA has a decentralized architecture. It is because the law in Netherlands prohibits primary care practitioners from transferring medical records of a patient to other doctors. These legal restrictions prohibit any possibility of storing the entire healthcare information centrally over the nationwide infrastructure. [63]

Hence, AORTA infrastructure connects all healthcare information sources with a secured link on which patients, healthcare providers, and healthcare insurers can access medical records without actual transfer of the records. It also takes care of privacy and security through nationally identified mechanisms. The Netherlands standardized EPR for clinical domains like Radiology, Dentistry, Diabetic, Acute Care, and so on. EPR catering to a particular domain adheres to the standards suggested by the EPR Committee. [63]

Authorities are working to establish a central health information technology network to enable information exchange across providers. All Dutch patients have a unique identification number (Burger service nummer). Virtually all general practitioners have a degree of electronic information capacity, for example, they use an electronic health record, and can order prescriptions and receive lab results electronically. [51]

At present, all hospitals have an electronic health record. Electronic records for the most part are not nationally standardized or interoperable between domains of care, reflecting their historic development as regional initiatives. In 2011, organizations representing general practitioners, after-hours general practice cooperatives, hospitals and pharmacies set up the Union of Providers for Health Care Communication (De Vereniging van Zorgaanbieders voor Zorgcommunicatie) responsible for the exchange of data via an IT infrastructure AORTA. Patients must approve their participation in this exchange, and have the right to withdraw. The network stores a patient's general practice file and information about use of medications. Patients need to ask a provider for access to the medical file. In 2012, organizations representing insurers and patients (Nederlandse Patiënten Consumenten Federatie), and several others signed an agreement to promote further development of the national healthcare IT infrastructure. [51]

Netherlands Institute for Health Services Research (NIVEL) is a key research and knowledge institute in the Netherlands, distinguished by the quality and broad scope of its health services research and its contribution to policy and to the body of scientific knowledge. NIVEL carries out research at national and international level with a focus on the need for health care. [45]

NIVEL Primary Care Database (NIVEL Zorgregistraties eerste lijn) uses routinely recorded data from health care providers to monitor health and utilization of health services in a representative sample of the Netherlands population. The aim of NIVEL Primary Care Database is to do research on developments in health and the use of primary health services in the Netherlands. NIVEL Primary Care Database collects data that is routinely recorded in the health care provider's electronic health record system. This includes data on health problems and treatment. NIVEL handles the data in accordance with the Dutch Data Protection Act. The access for the database is restricted only for the use of health care professionals, more specifically general practitioners, physiotherapists, exercise therapists,

dieticians, speech therapists, primary care psychologists and professionals in GP out-of-hours services and health centers. This data is combined and supplemented with information about pharmaceutical care and secondary level care collected by other organizations. Also the researchers have no access to identifiable patient information and the results cannot be traced back to individual persons, health care providers or health care organizations. [64]

### Individual's position and consent management

Patients' rights are high on the policy agenda in Netherlands. Many of the patient laws date from the end of the last century. These laws seem to contain shortcomings where the patient's rights to appropriate and coherent care are concerned. The Dutch Health Ministry is preparing legislation in these areas. One of the issues is whether patients' rights and obligations are in fact guaranteed sufficiently, considering the new role they will have to play in the changing health care system. There will continue to be a policy focus on the subject of complaints and the treatment of complaints. [65]

The Medical Treatment Contracts Act (Wet op de geneeskundige behandelingsovereenkomst, WGBO) makes it mandatory for healthcare professionals to keep a medical record, whether electronically or on paper. The Medical Treatment Contracts Act does not require the patient's explicit consent for this. Access to or copies of documents from the record may only be provided to the patient himself and to third parties with the patient's consent, but this does not apply to the parties who are immediately involved in the execution of the treatment contract and the party who acts as a deputy of the healthcare professional, insofar as the disclosure is necessary for the work that is to be done by those parties within that context. [55]

Code of Conduct Electronic Data Exchange in Health care (Gedragcode Elektronische Gegevensuitwisseling in de Zorg, EGIZ) applies to information systems that are used for exchanging personal data between healthcare providers. It lays down requirements specific to the Data Protection Act as well as technical requirements with regard to (1) the rights of the data subject, (2) informed consent, (3) authorization of healthcare providers and patients with regard to health data and (4) information security and logging. The code also takes the stand how patients should be informed and how consent can be obtained depends on the method used for the exchange of data. [55]

The Code of Conduct makes a distinction between pull traffic and push traffic. The term pull traffic is used if a healthcare provider discloses data from his medical file to a group of healthcare providers. In general, it is not usually clear in advance which particular healthcare providers will consult that data. Push traffic involves the sending of personal data by the source record coordinator to one or several particular healthcare providers who have a treatment relationship with the person in question, or with whom a treatment relationship is intended. In that case, the party disclosing the data takes the initiative. The patient must explicitly grant his or her consent in advance for data processing, i.e. for the disclosure of patient data in case of pull traffic. In case of push traffic, prior consent is not required, although the patient may object to his data being exchanged. Code of Conduct Electronic Data Exchange in Health care is not legally binding. However, supervisory authorities refer to these documents when executing their supervisory responsibilities. On request, the patient has the right to access or copy all his personal and health data, which the healthcare provider makes available through an electronic exchange system, in an electronic way. [55]

On 4 January 2013, the Minister of Health, Welfare and Sport introduced the Proposal Patient's Rights. This proposal aims at giving clients more rights when electronic records are compiled, when healthcare providers exchange data and when data is requested. The proposal applies to the use of electronic exchange systems, i.e. systems which enable healthcare providers to consult records, parts of records or information from records from other healthcare providers, using electronic means. In order to avoid doubt, the proposal does not apply to internal systems used by a healthcare provider to keep an EHR up-to-date. [55]

In November 2013, the ministry also issued a general administrative regulation with regard to the electronic exchange of data between healthcare providers. This general administrative regulation is supplementary to the Personal Data Protection Act and the Proposal on Patient's rights. It lays down functional, technical and organizational measures with respect to the electronic exchange of health data and it explicitly prescribes that the electronic exchange systems, the network connections, and the logging of the system must comply with Netherlands Standardization Institutes (NEN) standards. [55]

## Health and social care data in secondary use

The Medical Treatment Contracts Act (Wet op de geneeskundige behandelingsovereenkomst, WGBO) article 456 allows for the use of information in medical files for statistical or scientific research as part of the execution of the Treatment Contract or, under certain conditions, without the consent of the patient. The act regulates the right of patients to be informed and to give consent and how to deal with confidential patient data. [55] For example secondary use of human tissues are regulated by the Medical Treatment Contracts Act and the [Code of Conduct for Proper Secondary Use of Human Tissue](#) of the Dutch Federation of Biomedical Scientific Societies. Patients have the right to opt-out of further use of their residual tissue, but the procedures for objection and the provision of information involved are not regulated by statute.

The National Institute for Public Health and the Environment (RIVM) is an independent branch of the Ministry of Health, Welfare and Sport (VWS). RIVM works to prevent and control outbreaks of infectious diseases. It promotes public health and consumer safety, and helps to protect the quality of the environment. RIVM collects and collates knowledge and information from various sources, both national and international. Its independence is guaranteed by statute – the so-called RIVM Act. The Institute carries out research in close collaboration with universities and research centers worldwide, provides advice and recommendations, and directs and implements prevention and control responses. The scientific quality of work is monitored by the Scientific Advisory Board. [66]

Statistics Netherlands is responsible for collecting and processing data in order to publish statistics to be used in practice, by policymakers and for scientific research. In addition to its responsibility for official national statistics, Statistics Netherlands also has the task of producing European community statistics. On 3 January 2004, Statistics Netherlands became an autonomous agency with legal personality. The legal basis for Statistics Netherlands and its work is the [Statistics Netherland Act](#) of 20 November 2003 last amended by the Act of 15 December 2004 governing the central bureau of statistics. [67]

Statistics Netherland offers multiple services for policymakers, public and researchers. For example microdata service enables conducting research using data from Statistics Netherlands. Under certain conditions, Statistics Netherlands' Centre for Policy Related Statistics (CvB) can make microdata, which means anonymous data at the level of individual persons and businesses, available for statistical research. To use these data, the organization must be granted access by the director general of statistics. In some cases approval by the Central Commission for Statistics (CCS) is also required. A separate application must be submitted for each project requiring access to microdata. All datasets remain on the secure network environment at Statistics Netherlands. [67] Statistical results can be exported by CvB staff for use outside Statistics Netherlands secure environment.

Statistics Netherlands also maintains a StatLine -online service that is the electronic databank of Statistics Netherlands. It enables users to compile their own tables and graphs. Developers can combine open data from Statistics Netherlands with other data and use them for new applications. The information can be accessed, printed and downloaded free of charge. The databank contains 3,400 datasets with a total of 14 billion cells and has been available as open data since July 2014. There are also multiple health and social care datasets available. [67]

LINH is the Netherlands Information Network of General Practice. The LINH database holds longitudinal data on morbidity, prescribing and referrals of about 350.000 individuals. Data is collected in a representative network of about 150 general practitioners, evenly distributed over the country. LINH started in 1992 recording only referrals. It gradually developed into a system recording all patient contacts and all interventions, including diagnoses. In its present form LINH started in 2001, which means that the LINH database holds information about more than three million patient years. The aim of LINH is to develop and maintain a high quality longitudinal database on morbidity and GP care in the Netherlands and to use this database for health services research and quality of care research. [68] LINH takes pride in the fact that its database is used for a wide range of national and international research projects. Data is extracted twice a year from the electronic medical records used in the practices to file patient information. Recording data for LINH hardly interferes with daily practice. LINH holds data about GPs' record data on all patient contacts, including diagnoses, referrals and prescriptions. Diagnoses are coded using the ICPC (International Classification of Primary Care). Patient gender, age, type of health care insurance and place of residence are recorded as well. [68]



# New Zealand

## General

New Zealand has a population of approximately 4 million and is governed by a parliamentary democracy and constitutional monarchy system. The head of state is a sovereign, currently Queen Elizabeth II. The Queen is represented in New Zealand by the Governor-General. Government is formed from a democratically elected House of Representatives. The government is fully integrated nationally with no separate states or territories. [69]

The system is based on the principle that power is distributed across three branches of government — Parliament, the Executive, and the Judiciary. Parliament makes the law and the Executive administers the law. The Judiciary interprets the law through the courts. New Zealand has no single written constitution or any form of law that is higher than laws passed in Parliament. The rules about how system of government works are contained in a number of Acts of Parliament, documents issued under the authority of the Queen, relevant English and United Kingdom Acts of Parliament, decisions of the court, and unwritten constitutional conventions. [70]

## Health and social care system

Beginning with passage of the [Social Security Act in 1938](#), a consensus has developed in New Zealand that government has a fundamental role in providing for the population's health care needs. At the same time, there is continued public support for a private sector role as well. Government plays a central role in setting the policy agenda and service requirements for the health system and in setting the annual publicly funded health budget. [12]

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## The structure and funding of public health and disability services are set out in the New Zealand Public Health and Disability Act 2000.

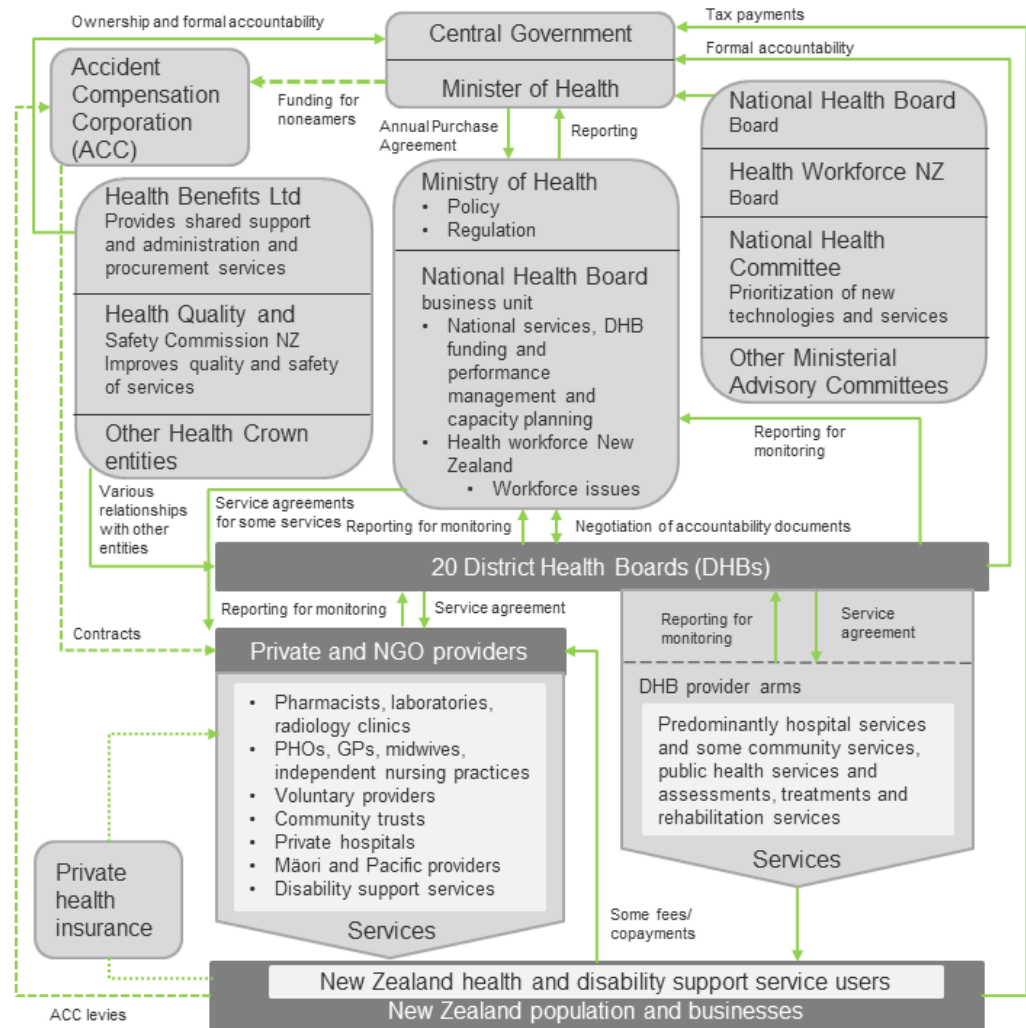
The Labour-Alliance Coalition Government of New Zealand initiated a health system reform in 2000. The new structure and funding of public health and disability services are set out in the New Zealand [Public Health and Disability Act 2000](#). With the introduction of the Act, the Ministry of Health became the principal agency responsible for policy advice, funding and monitoring the health and disability sector. Also the Health Funding Authority was abolished, with its functions transferred to the newly restructured Ministry of Health. 20 District Health Boards (DHBs)

replaced the Hospital Health Services and took responsibility for the purchase and provision of health services. [The Primary Health Care Strategy 2001](#) guided the reorganization of GPs and Independent Practitioner Associations (IPAs) into Primary Health Organizations (PHOs). [71] Responsibility and authority for funding exists at national, regional, and local levels. The Ministry of Health manages the national planning and funding of information technology, workforce planning, and capital investment in DHBs. DHBs carry out local and regional planning and management in these areas. [72]

The Ministry of Health works across the health sector to deliver better health outcomes for New Zealanders and has overall responsibility for the management and development of that system. The Ministry of Health's regulatory responsibilities within the health and disability system include administering legislation and associated regulations. [73] The Ministry of Social Development has the

responsibility as a government department to lead social development but also manages and administers the compliance with the [Social Security Act 1964](#). [74]

Most health and disability services in New Zealand are publicly funded for eligible people. Health services means personal health services and public health services and disability support services includes goods, services and facilities provided to people with disabilities for their care or support or to promote their inclusion and participation in society, and independence or provided for purposes related or incidental to the care or support of people with disabilities or to the promotion of the inclusion and participation in society, and independence of such people. Government funding of health and disability services means that eligible people may receive free inpatient and outpatient public hospital services, subsidies on prescription items and a range of support services for people with disabilities in the community. [75]



**Picture 3:** Organization of the Health and Social Care System in New Zealand [12]

District health boards (DHBs) are responsible for providing or funding the provision of health services in their district. There are 53 districts in New Zealand. Disability support services and some health services are funded and purchased nationally by the Ministry of Health. There are 20 DHBs in New Zealand and each DHB is governed by a board of up to 11 members. DHB boards set the overall strategic direction for the DHB and monitor its performance. The New Zealand [Public Health and Disability Act 2000](#) created DHBs. [76]

DHBs hold contracts and agreements with organizations that provide the health services required to meet the needs of the DHB's population. For example, primary health care services are funded by DHBs through primary health organizations (PHOs). These services are then provided by general practices or other primary care services belonging to that PHO. DHBs are publicly funded. [76]



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## District health boards are responsible for providing or funding the provision of health services in their district.

[The Crown Entities Act 2004](#) requires District Health Boards to produce a statement of intent and an annual report to Parliament. Monitoring and accountability of individual DHBs is achieved through Crown funding agreements with the Minister, a district strategic plan and a district annual plan. Population based funding was introduced on 1 July 2003. Previously, DHBs were funded to provide hospital services and to administer contracts for providers who were based in their districts. [71]

The Government's primary healthcare strategy has been to reform the primary health system by encouraging GPs to join non-profit, community-based Primary Health Organisations (PHOs). PHOs comprise doctors, nurses and other health professionals in the community, such as Maori health workers, health promotion workers, dietitians, pharmacists, physiotherapists, psychologists and midwives. Their role is to serve the health needs of their enrolled populations. PHOs contract to DHBs on a per capita basis to provide primary health care services, including preventative services. The funding is based on the demographic details of the people enrolled with them. Many health and disability support services are delivered by non-government organizations. There are 60 PHOs in New Zealand. [71]

The National Health Board (NHB) is a whole-of-system health planning, advice, and funding organization made up of a Ministerial appointed Board and is supported by the National Health Board Business Unit within the Ministry of Health. NHB work directly with the DHBs, clinicians, and the sector as a whole to improve health outcomes, increase access to quality care, improve financial and clinical sustainability, and to develop an even more unified health system. NHB and its two subcommittees the Capital Investment Committee and the IT Health Board were established to improve the quality, safety and sustainability of health care for New Zealanders. These committees, along with Health Workforce New Zealand, work with the Ministry to consolidate planning, funding, workforce planning and capital investment, as well as supervise public funding spent on hospitals, primary health services and important national health services. [77]

The National Health Committee (NHC) advises government on priorities for new and existing health technologies. Its role is to assist the health and disability sector to spend its funding in the most effective way and enable it to continue to improve the health of New Zealanders within the country's financial resources. The National Health Committee was reconfigured into this role in 2011. All new diagnostic and non-pharmaceutical treatment services and significant expansions of existing services are referred to the NHC for evaluation and advice. The committee also provides advice on what technologies are obsolete or no longer provide value for money. The National Health Committee is a statutory Advisory Committee under section 11 of the New Zealand [Public Health and Disability Act 2000](#). [78]

The Health Quality and Safety Commission (HQSC) goal is to ensure that New Zealanders receive the best health and disability care possible given available resources. It is also towards achieving the New Zealand Triple Aim for Quality Improvement; improved quality, safety, and experience of care, improved health and equity for all populations and better value for public health system resources. Committees' role has been defined in [New Zealand Public Health & Disability Amendment Act 2010](#) and it is in charge with leading and coordinating improvements in safety and quality in health care and providing advice to the Minister of Health on how quality and safety in health and disability support services may be improved. [79]

### Creating and using health and social care data in primary use

[The Privacy Act 1993](#) provides the general framework for promoting and protecting individual privacy. It does so by establishing principles with respect to the collection, use, disclosure of and access to information relating to individuals. It applies to public and private sector agencies. It also established the role of Privacy Commissioner to investigate complaints about interferences with individual privacy. [The Health Information Privacy Code 1994](#) is a Code of Practice issued by the Privacy Commissioner

under section 46 of the Privacy Act which gives extra protection to health information because of its sensitivity. [The Health Information Privacy Code](#) has the force of law. It covers all health agencies, and protects all personal health information relating to an identifiable individual. The Ministry has a responsibility to ensure it complies with this Code in respect of all health information entrusted to it. [80]

The Privacy Commissioner's Office works to develop and promote a culture in which personal information is protected and respected. The Office is an independent Crown Entity and was set up in 1993. The Privacy Commissioner administers the [Privacy Act 1993](#). The Privacy Act applies to almost every person, business or organization in New Zealand. The Act sets out 12 privacy principles that guide how personal information can be collected, used, stored and disclosed. In respect of the secondary use of information it is principles ten and eleven that are of primary importance. Principle ten places restrictions on the use of personal information while principle eleven places limits on the disclosure of personal information. The Privacy Commissioner notes that there are two key concepts addressed in the [Health Information Privacy Code 1994](#) – purpose and openness. The first means that agencies must know why they are collecting health information and only collect the information they need. Once health information has been collected for a particular purpose, it can be used or disclosed for that purpose without additional consent. [1]

Since 2010, the National Health IT Board has led the development of New Zealand's current EHR policy, which seeks to balance enterprise systems and single subject systems via common information and technology standards. Information captured at the point of care can be made available to other health professionals and patients via patient and provider portals, through a range of electronic messages such as referral and discharge summaries, and on a GP to GP basis for exchanging health records. Currently data is spread over different systems and repositories, but can be assembled on-demand through the use of common identifiers such as the National Health Index (NHI) and the Health Provider Index (HPI). [81]

Under the guidance of the National Health IT Board, clinical information has started to become stratified into national regional and local solutions – and we have mechanisms in place to link these different repositories to create a virtual EHR. According to a review New Zealand's Electronic Health Records Strategy conducted by Ministry of Health, the current virtual EHR approach in New Zealand has not reached its full potential, and further benefits are possible. However, more mature healthcare systems have relinquished virtual EHR strategies in favor of single EHR strategies to drive tangible increases in productivity and quality. Under such an approach, core EHR information would be consolidated in a single physical repository, instead of being spread across multiple disparate systems. This would offer a single view of patient information and support care coordination across the continuum. [81]

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## Government's goal is universal electronic access to a core set of residents' personal health information in the near future.

The government's goal was universal electronic access to a core set of residents' personal health information by 2014. However, the goal was failed because of the complexity of implementing a national patient portal. Clinicians and vendors are working together on numerous projects: there is a larger emphasis on supporting and enabling integrated care, and a shift toward regional investment decisions and solutions. However, challenges with legacy

systems remain. Increasingly, primary care IT systems provide services such as structured electronic transfer of patient records, electronic referrals, decision support tools with patient safety features, and patient access to health information in a secure environment. In the near future, there will be more emphasis on facilitating secure sharing of patient information among community, hospital, and specialist settings, including common clinical information; providing all consumers with an online view of their information; and supporting the development of shared-care plans, in which a number of health professionals are involved in a person's care. However, current levels of interoperability are limited.

[12]

## Individual's position and consent management

[The Code of Health and Disability Service Consumers' Rights](#) is a regulation issued in 1996 under the [Health and Disability Commissioner Act 1994](#). It sets out ten rights applicable to all health and disability consumers, including those involved in research. Two of these rights are particularly relevant to the secondary use of information: the right to be treated with respect and the right to be fully informed. The right to be treated with respect specifically states that consumers have the right to have their privacy respected. The right to be fully informed includes notification of any proposed participation in teaching or research, including whether the research requires, and has received, ethical approval. Before making a choice or giving consent, every consumer has the right to the information they need to make an informed choice or give informed consent. [1]

The National Ethics Advisory Committee's (NEAC) statutory functions are to provide advice to the Minister of Health on ethical issues of national significance regarding health and disability research and services, and to determine nationally consistent ethical standards and provide scrutiny for such research and services. The Committee was set up in 2001. Its full name is the National Advisory Committee on Health and Disability Support Services Ethics. NEAC published revised ethical guidelines for health and disability research in July 2012; [Ethical Guidelines for Intervention Studies](#) and [Ethical Guidelines for Observational Studies](#). These guidelines set out the established ethical standards that all researchers must meet when undertaking health and disability research, whether or not that research requires health and disability ethics committee review. [82]

National Health IT Plan has a vision for integrated healthcare enabled by health information technology that each patient will have a virtual health record, with information stored electronically and accessible regardless of location by linking to: existing systems run by health care organizations, like general practice, hospital - based systems, a regional clinical results repository and a shared care record. [83] The National Health IT Board is working with Primary Health Organizations (PHOs) and GPs to give patients access to their health information through a patient portal. In April 2015, Health Minister launched a campaign to raise awareness of the benefits of patient portals and introduces guide for GP to introduce a patient portal. One of the portals is ManageMyHealth that can receive information from doctors system and allow access to personal health information for individuals. [84]

## Health and social care data in secondary use

Most health research in New Zealand has to be approved by an official ethics committee, which will inquire into any privacy issues apparent in the scope and conduct of the proposed program and may set limits in those areas. Health information can then be used in, and disclosed for, a research program which has received ethics committee approval, but even so any disclosure for the purpose of such a research program can only go ahead in the absence of the individual's authorization if it is not practicable or not desirable to obtain that authorization. [85]

Although, it should be noted that there is no prohibition on the use or disclosure of statistical information which is not identifiable about any individual. Where information about an identifiable individual is to be disclosed for use in statistical surveys, but nothing will be published in a form that could be expected to identify the individuals covered, this can proceed without the individual's authorization if it is not desirable or practicable to obtain that authorization. [85]

The Ministry of Health is responsible for national collections of health and disability information. There are nine major pieces of legislation that have a direct bearing on the work of the National Collections and Reporting group. National collections provide health information to support decision-making in policy development, funding and at the point of care. Data is gathered through a variety of methods. The majority of the data the Ministry of Health holds is collected through established routine administrative systems, e.g. hospital events and prescriptions. These are known as the National Collections. The Ministry of Health's Information Group has operational responsibility for national collections of health and disability information. National collections provide valuable health information to support decision-making in policy development, funding and at the point of care. This information contributes to improving the health outcomes of New Zealanders. [86]

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## The Ministry of Health is responsible for national collections of health and disability information.

On request, data from national collections can be made available to researchers and the public. There are 15 national collections; General Medical Subsidy Collection, Laboratory Claims Collection, Medical Warning System, Mortality Collection, National Booking Reporting System, National Booking Reporting System Data Warehouse, National Immunisation Register, National Maternity Collection, National Minimum Dataset

(hospital events), National Non-Admitted Patient Collection, New Zealand Cancer Registry (NZCR), Pharmaceutical Collection, Primary Health Organization Enrolment Collection, PRIMHD – mental health data and National Patient Flow. [86]

In addition to data from routine sources, the Ministry of Health also actively gathers data through population-based health surveys. The data is produced by Information Services that responds to data requests and publish information from the National Collections, Health & Disability Intelligence (HDI) that produces and maintains the data from the New Zealand Health Surveys and Environmental Science & Research (ESR), which produces and maintains data on infectious diseases. There are nine major pieces of legislation that have a direct bearing on the work of the National Collections and Reporting group; [New Zealand Public Health and Disability Act 2000](#), [Health Act 1956](#), [Privacy Act 1993](#), [Health Information Privacy Code 1994](#), [Health \(Retention of Health Information\) Regulations 1996](#), [Official Information Act 1982](#), [Cancer Registry Act 1993](#), [Cancer Registry Regulations 1994](#) and [Public Records Act 2005](#). [86]

The Health Research Council of New Zealand (HRCNZ) is responsible for managing the Government's investment in health research. HRCNZ is established under the [Health Research Council Act 1990](#) and are responsible to the Minister of Health. The HRCNZ ensures that all research involving human participants is based on good science, meets ethical standards, and complies with international best practice. All health and disability research involving human participants funded by the HRC requires appropriate ethical approval from an approved ethics committee in New Zealand and HRC-funded clinical trials, innovative treatment evaluation or community intervention studies are adequately monitored, to ensure the safety of participants and the integrity of the collected data is protected. The HRC Ethics Committee requires that ethical approval from an approved ethics committee is obtained before HRCNZ funding for any proposed research may commence. The HRC Data Monitoring Core Committee ensures that trials which require data and safety monitoring are adequately monitored. [87]

Statistics New Zealand is New Zealand's national statistical office. Statistics New Zealand is the leader of the Official Statistics System and is the major producer of official statistics in New Zealand. Statistics New Zealand's role is defined in the [Statistics Act 1975](#). The Government Statistician, who is also the Chief Executive of Statistics New Zealand, has a legally mandated role to coordinate statistical activity across government. Statistics New Zealand provides access to microdata to support research. Access to microdata is carefully managed to protect confidentiality and requires a separate research permit. There are four sections of the [Statistics Act 1975](#) which make it possible to provide access to microdata researchers. Under Section 37C of the Act, individual schedules (e.g. microdata) can be disclosed in certain circumstances. Researchers must have "the necessary research experience, knowledge and skills to access and use the information contained in the schedules". Each researcher must also sign a Declaration of Secrecy. Under Section 37B, information that is collected jointly by Statistics New Zealand and another government department, local authority or statutory body may be shared between those organisations. Employees from the other organisations involved in collecting or processing the data are required to sign a Declaration of Secrecy. Obligations under the Act will extend to any agency involved in a joint collection. Under Section 37A, information may be disclosed if consent is obtained in writing from the person supplying it. This section of the Act outlines several other circumstances in which the Government Statistician may authorise access to microdata. Under Section 37D, where the Government Statistician has classified documents as historical, she or he may authorise disclosure after 100 years. [88]

New Zealand's Government Information Services at the Department of Internal Affairs also owns and maintains open data service data.govt.nz that is a directory of publicly-available New Zealand government datasets. Data.govt.nz service holds also multiple datasets about health and social care, but do not contain any personalized or sensitive data. [\[89\]](#)

# Israel

## General

The State of Israel was established in 1948 and is a democratic state with a parliamentary, multi-party system [90] consisting of legislative, executive and judicial branches. Its institutions are the presidency, the Knesset (parliament), the government (cabinet of ministers) and the judiciary. The system is based on the principle of separation of powers, in which the executive branch, the government, is subject to the confidence of the legislative branch, the Knesset, and the independence of the judiciary is guaranteed by law. [91]

The Knesset may pass laws on any subject and in any matter, as long as a proposed law does not contradict an existing 11 basic law and the legislative process is carried out as required by the law. The Prime Minister of Israel is the head of government and elected by the Knesset. [91] Israel is a small country, with population just over 8 million and its population density is among the highest in the western world. [92]

## Health and social care system

The defining characteristic of the health system in Israel is its governance by the National Health Insurance (NHI) law that was passed in 1995. This law ensures health coverage to every resident of Israel and defines the government's responsibility to provide health services to every person without

discrimination. In other words, health insurance is mandatory, and all residents of Israel must be insured. [93]

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## National Health Insurance Law 1995 defines the characteristic of the Israel's health system.

In addition to financing insurance, government also provides financing for the public health service, and is active in areas such as control of communicable diseases, screening, health promotion and education, and environmental health, as well as

providing various other services provided directly by the government. It is also actively involved in financial and quality regulation of key health system actors, including health plans, hospitals, health care professionals, and others. [12]

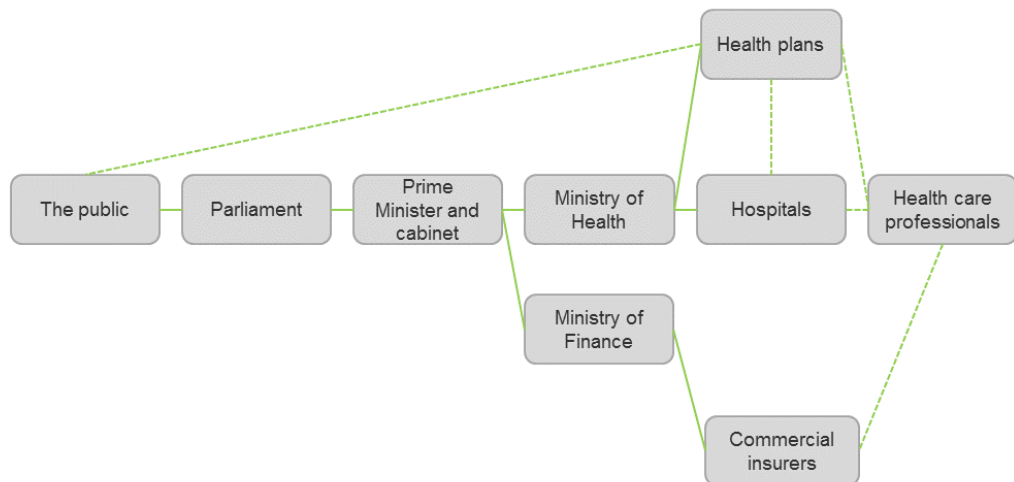
National health insurance is funded primarily through a combination of a special income-related health tax and general government revenues, which in turn are funded primarily through progressive income-related sources such as income tax. Employers are required to enroll any foreign workers, whether documented or undocumented, in private insurance programs, whose range of benefits is similar to that of NHI. [12] The NHI Law ensures that all Israelis are covered by health insurance and spells out the list of benefits to which they are entitled. The National Insurance Institute (NII) collects the health tax that plays a major role in the financing of the NHI system. [92]

Parliament, called the Knesset, adopts and amends legislation related to the health system in Israel. Since the mid-1990s, the Knesset has been very active in health-related legislation, passing such laws as the NHI Law of 1995 and the Patients' Rights Law of 1996. [92] The Cabinet, comprising a selection of Knesset members from the ruling parties, has executive responsibility for the government as a whole, including the Ministry of Health. [12]

The Ministry of Health, is responsible for population health and the overall functioning of the health care system. It also owns and operates a large network of maternal and child health centers, about half of the nation's acute care bed capacity, and about 80 percent of its psychiatric bed capacity. [12] The ministry determines the policy on matters of health and medical services, and is in charge of planning,



supervision and control, licensing and coordination of the health system's services. The ministry provides health services in the fields of hospitalization and preventive medicine, and insures the population on matters of mental health, geriatrics, public health and rehabilitation devices. [94]



**Picture 4:** Organization of the Health and Social Care System in Israel [12]

Health services are provided through the health funds. Every citizen or permanent resident in Israel is free to choose among four competing, non-profit-making Health Plans (HPs), known in Israel as health funds: Clalit, Maccabi, Meuchedet, and Leumit. Each fund has branches throughout the country. The health funds provide their members with access to a benefits package that is specified within the NHI Law. [93]

## Services are provided through four non-profit-making health plans.

The Basket of Health Services consists of a range of essential medical services, including treatments, medications, and equipment which each health fund is obligated to provide to its members.

Services included in the Basket are free of charge or discounted. The government distributes the NHI funds among the health funds according to a capitation formula that is based primarily on the number of members within each plan and their age mix. The health funds provide a broad network of easily accessible community-based clinics with salaried physicians and other health care personnel. [93], [95]

Within HPs, patients have a great deal of freedom in choosing their community-based physicians, both primary and specialist, from among those physicians affiliated with the HP. In most specialties, and in most areas of the country, each HP is affiliated with numerous physicians so that there is real choice in practice. Nevertheless, there are some specialties (e.g. child psychiatry) and regions (e.g. the Negev) where choice is more limited. If a member wants to see a physician not affiliated with the HP, access is not guaranteed through the basic benefits package, but in many circumstances partial coverage is available for those who have enrolled in supplemental insurance programs. In July 2015, mental health services were added to the set of services that the HPs must provide to their members, and the government substantially increased the level of funding to cover the costs expected to be incurred by them because of this new responsibility. [92]

Primary care is provided almost exclusively by salaried physicians and other professionals employed by the HPs, and independent physicians with whom the HPs contract. Primary care doctors play a gatekeeping role for access to secondary care. Nurses also play an extensive role in primary care in areas such as preventive health care, counselling, triaging of urgent cases, home care, chronic disease management and the handling of clinical paperwork related to the patients' eligibility for various social benefits. [92]



Most specialized ambulatory care is provided in community settings, despite recent hospital efforts to attract activity to their outpatient departments. In contrast, the hospitals are the main source of emergency care, with a relatively small but growing role for community-based providers. While all Israeli hospitals operate outpatient clinics, most specialized ambulatory care has traditionally been provided in community-based settings, and in recent decades there has been a further shift towards the community. This because HPs felt that they often lost control of treatment plans and expenditure when their patients were cared for at hospital outpatient clinics but also the HPs were able to provide and/or purchase community-based specialty care at costs well below those of the hospitals. [92]

In 1986 the Israeli Parliament enacted the Community Long-Term Care Insurance (CLTCI) Law, in response to concern over the growing need for long-term care. In the Long-Term Care area, Israel has a well-developed system of day-care centers for the elderly, a growing system of supportive neighborhoods, legislation that provides for government financing of non-professional home care, and a relatively high level of Long-Term Care insurance coverage. In 2011, the Ministry of Health put forward a detailed plan for a major reform of the LTC system. The plan was not adopted at the time, but it is now being reconsidered by the government. [92]

Israel's comprehensive welfare system is based on legislation which provides for a broad range of national and community services. Care of the elderly, support programs for single parents, children, and youth, prevention and treatment of substance abuse, and assistance for new immigrants comprise a large part of available social services. Under the Social Welfare Law 1958, municipalities and local authorities are required to maintain a department responsible for social services, 75 percent of whose budget comes from the Ministry of Labor and Social Affairs. Nationwide services such as adoption, probation frameworks and residential institutions for the developmentally challenged are funded and run by the ministry. The ministry determines policy, initiates legislation, enacts regulations for the operation of social services and supervises those offered by public and private organizations. An amendment to the National Insurance Law provides long-term care for elderly persons dependent on daily help, either at home or in residential facilities. [96]

The Israeli Law, Information and Technology Authority (ILITA), was established as Israel's data protection authority by the Ministry of Justice of Israel in September 2006. ILITA's mission as the reinforcement of personal data protection, the regulation of the use of electronic signatures, and the increase of the enforcement of privacy and IT-related offenses. ILITA also acts as a central knowledgebase within the Government for technology-related legislation and large governmental IT projects, such as eGovernment. [97], [98]

## Creating and using health and social care data in primary use

In Israel privacy is a constitutional right under Article 7 of [Basic Law: Human Dignity and Liberty](#). There is also [Protection of Privacy Law](#) that entered into force in 1981 and contains specific privacy legislation. The Protection of Privacy Law 1981 is the main Israeli law dealing with the collection and use of personal data. Under the Protection of Privacy Law a database must be registered with the Database Registrar, a unit of ILITA, if it contains: (1) data concerning more than 10,000 data subjects; (2) sensitive information; (3) data which have been collected from third parties; (4) data used for direct marketing services; or (5) data in a public sector database. The term database refers to a collection of data processed by computer but excludes information consisting solely of basic contact details if such details are not in themselves likely to infringe an individual's privacy. [99]

The registration system is based on registration of databases, as opposed to data controllers. Hence, if a data controller has several databases, such as human resources, customer data, and suppliers, it must register each database separately. In 2014, ILITA amended the database registration procedures, requiring the filing of a far more detailed application form than before, specifying, amongst other things, the methods and sources of data collection and the types of data in a database. [99]

The Health Plans, which are both insurers and providers, are essentially the sole source of primary care and the main source of specialty care. This structural integration of services provides the foundation for provision of relatively seamless care for all the insured, including complex and chronically ill patients. The health plans' health information systems link primary and specialty care providers, and a new national health information exchange is linking the health plans and the hospitals. [12]

Increasingly these provide access to electronic health records at the point of care. In addition, the health plans have put forth several targeted management programs that aim to provide comprehensive integrated care for complex patients with chronic conditions. These make extensive use of the plans' sophisticated information systems, videoconferencing, and other innovative techniques. Generally speaking, integration is still limited among the various components of the long-term care system and between long-term care and other components of the health care system. [12]

All HPs and the hospitals have sophisticated information systems that include electronic health records, data on activity levels, services provided and quality of care. All GPs work with an EHR. Hospitals are also computerized but are not fully integrated with health plan EHRs. Each of these organizations makes extensive use of their own data systems at both the individual care level, and to make broader policy decisions. In addition, there are several systems for aggregating data across providers so that the data can be used to monitor and analyze overall national developments, including Infectious disease surveillance system, Disease registries, National Hospitalization Database, Hospital activity data, Specific information systems on areas that benefit from government financial support, Cause of death statistics and many more. [12], [92]

The Ministry of Health's NAMER project is one of the largest hospital administration information systems projects in Israel. The project covers all 11 governmental hospitals and has continued to extend its reach in 10 general hospitals. It provides admissions, transfers and discharge data, billing, ward management, patient acceptance and discharge capabilities. In addition, it is tied into a picture archiving and communication systems, operating rooms, laboratory and local hospitals and electronic medical records and has a module for multicasualty incidents. [92], [100]

The biggest advance has been in the implementation of a clinical electronic medical record system, which has been implemented in eight hospitals and in 80 wards, resulting in "pen-less" wards. The system enjoys a unique backup system which ensures that, should a disaster occur and the hospital's generator and disaster-recovery system are down or inaccessible, each ward can continue to operate for four hours on its own power. The NAMER system is an integrated ERP system, which controls processes and the flow of information from start to finish, enabling clarity of organizational processes. The system is also linked to the National Insurance Institute and to the Ministry of the Interior. [92], [100]

Israel Clalit Health Services was the world's first to implement a health information exchange (HIE), enabling creation of patient files that could include data and information input from various treatment sources, such as clinics and hospitals. Data is not stored centrally; instead all information remains in its original format, location, system, and ownership. On demand, relevant information from anywhere in the system is instantly integrated and delivered point-of-care. The HIE only contains specific clinical data transmitted from various systems in the healthcare community according to strict rules filtering

certain conditions, procedures, etc. According to Patients' Rights Act of 1996. All documents in this system is read-only files; no document can be altered, modified, copied or printed, thus preventing malice. Israel was also one of the first countries to use telemedicine and to introduce electronic clinical decision support system and online indicators for medical and service quality. [101], [102]

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## Israel Clalit Health Services was the world's first to implement a health information exchange system.

The Ministry of Health leads a major national health information exchange project to create a system for sharing relevant information across all hospitals and health plans. In 2014, the Ministry of Health launched a national health information exchange for sharing clinical patient data across all of Israel's general hospitals, HPs and additional providers. This provides Israeli clinicians with the world's first national data exchange programme, enabling secure authorization-based sharing of clinical data. In particular, the system facilitates the flow of information between hospital-based providers and providers based in the community. Citizens can opt-out, if they do not wish for their data to be accessible. [92]

The project was set to include all patients across the country by 2015 and the initiative is based on a program launched by Clalit Health Services the years earlier called the OFEK -program (horizon in Hebrew). In the year 2011 Ministry of Health decided to adopt and use OFEK as a national HIE platform in Israel. The same system is now in the process of expanding to include all four health plans and all hospitals in the country. An ambitious project will place Israel as one of the only countries with a country-wide health information exchange system. [103], [104]

### Individual's position and consent management

The [Patients' Rights Law](#), enacted in 1996, emphasizes that patients have rights above and beyond the right to health care alone. Also enshrined in the Law is the patient's right to review and transfer the information in her or his health record. The Law aims to offer solutions to many difficult issues facing patients prior to and during treatment. Among these issues, that of informed consent to receive treatment, received particular attention during the legislation process, and is dealt with in Part D of the Law. The consent of the patient is a prerequisite to receiving medical treatment. Every adult is entitled to decide what is or is not performed on his or her body, therefore any procedure done without his or her explicit consent, or with a fraudulently obtained consent, may be construed as bodily assault and is therefore illegal. In 2008, the Law on Equal Rights for People with Disabilities 2005 was amended to require that, within 12 years, all public buildings will be accessible to the disabled and that all new buildings must provide such access from their inception. [92], [105] The government has also proposed a new law whose purpose is to define the usage of the national computerized health records system and set rules for managing the computerized records. [105]

In Patient's Rights Law the sections 17 and 18 refer to the management of medical records, the obligation to maintain medical confidentiality and the transfer of the information to the patient and others. The law states that "The patient shall be entitled to obtain from the clinician or the medical facility medical information concerning himself, including a copy of his medical records. A member of a clinical team may pass on to the patient medical information from within his own specialization only and in coordination with the head of the team." [105], [106]

The section 20 of the law also defines about disclosing medical data to a third person. A clinician or medical facility may pass on medical information to a third person in defined situations. The patient has consented to the disclosure of the medical information or in some cases the clinician are legally obliged to pass on the information without the explicit consent. Disclosing medical data to a third person in research purpose, the law states that: "Disclosure is for the purpose of publication in a medical journal, or for research or teaching purposes, in accordance with the Minister's directions on this matter, and all details identifying the patient have been suppressed; Data shall be disclosed under the provisions of Sub-Clause 20 only to the extent that the case requires, making every effort to suppress the identity of the patient or a person receiving medical information under the provisions of Sub-Clause 20 shall be subject to the provisions of Clause 19 and the provisions of this clause, *mutatis mutandis*." [105], [106]

Each citizen has a unique identification number, which functions as a unique patient ID. Patients have the right to get copies of their health records from hospitals and health plans, and patients can access some components of their EHR online, but the full records are not generally available. Efforts are under way to set up secure messaging systems linking patients and their GPs. [12] In [Public Health Regulations](#) section records keeping defines how and for how long the health records should be retained. [105]

All of the health funds provide extensive mobile applications, striving to emulate what they already offer in a web setting. Services include booking appointments with all clinicians, specialists, dieticians and therapists; accessing full laboratory results and laboratory history going back over 10 years, and ordering recurring prescriptions and medications with their complete history. Patients can view relevant imaging, can request confirmation and make payment for procedures carried out at other providers, and can check their vaccination history. Another major improvement has been the secure e-mail connection to PCPs, thereby eliminating unnecessary visits for routine items or to ask a question. In summary, patients are able to initiate end-to-end health care-related interaction cycles, both clinical (e.g. e-visits and e-prescriptions) and administrative (e.g. billing), through a secure, personal health account. [92]

Clalit has also implemented a highly popular “doctor online” videoconferencing service that connects patients with pediatricians backed up by the children’s hospital. A 100 000 appointments are booked online per year. A new initiative allows for doctors to send out relevant health care materials by e-mail in conjunction with a patients’ visit, and this has reached a million e-mailings per year. New data-mining initiatives have been used, for example to identify hospital patients who are most at risk for re-hospitalization, and this initiative has reportedly lowered re-admissions. [92]

## Health and social care data in secondary use

In 2001 The Israeli Protection of Privacy Regulations limited cross-border transfer of personal data from Israel, specifying that “a person shall not transfer, nor shall he enable, the cross-border transfer of data from databases in Israel, unless the law of the country to which the data is transferred ensures a level of protection no lesser, mutatis mutandis, than the level of protection of data provided for by Israeli law”. [107] The Transfer Regulations apply to both inter- and intra-entity transfers of personal data outside of Israel. They permit transfers to: (1) EU Member States; (2) other signatories of Council of Europe Convention 108; and (3) a country “which receives data from Member States of the European Community, under the same terms of acceptance”. [99]

The Scientific Council of the Israel Medical Association is responsible for the specialty certification programs and examinations, in coordination with the Ministry of Health. The Council for Higher Education is responsible for the authorization, certification, and funding of all university degree programs, including those for training health care professionals. [12] Centers such as the Myers-JDC-Brookdale (MJB) Institute and the Gertner Center, along with various university-based research units, play a pivotal role in the monitoring and evaluation of health care services in Israel. In the past decade, the two largest HPs have also established research institutes. [92]

In 1994, the Ministry of Health established the Israel Center for Disease Control (ICDC). Its primary goal is to collect and analyze updated health-related data, with the aim of providing health policy-makers with the evidence base necessary to make informed decisions. The ICDC plays important data collection, monitoring and analysis roles with regard to both communicable and non-communicable diseases, including ongoing reporting of surveillance data from the HPs for early identification of outbreaks. According to OECD study, Israel have not included secondary use of data from EHRs within their national development plans or policies and no uses from national EHRs were not reported. Most secondary uses explored here are undertaken by analyzing data from electronic medical records in hospitals or other health maintenance organizations. [92]

The Central Bureau of Statistics (CBS) operates by the power of the Statistics Ordinance. The Statistics Ordinance defines the tasks of the CBS, its mode of operation, the obligation of the public to provide information to the CBS, the obligation of the CBS to safeguard the confidentiality of the information obtained, and the obligation of the CBS to publish the results of its statistical activities. The CBS is headed by the Government Statistician, who also serves as the Director of the CBS, with a Public Council for Statistics accompanying him. CBS performs statistical activities and projects regarding the State and its population, also in the fields of health and wellbeing. Three main guiding principles of CBS activities are independence, reliability and strict confidentiality of personal data. The CBS does not transmit any personal information about residents, or any specific business information about companies and corporations. CBS data are available to a variety of target groups and for various possible uses, such as the government sector and the local authorities, international organizations, bodies of research, private and public companies, journalist and media, students and pupils and citizens. [108]

The National Health Insurance Law (1994) established a Health Council whose functions include supervision over the implementation of the law, management of research, surveys and professional expert opinion carried out by an institute selected by the Minister. In June 1995, the Health Council selected the Israel National Institute for Health Policy Research (NIHP) to fulfill these tasks with the Minister of Health’s recommendation. NIHP is an independent organization that gathers together researchers, managers and policy makers from the different sectors of the health arena: the Ministry of Health, health maintenance organizations, hospitals, universities and research institutes. Its main fields of research are health policy, organization of healthcare services, health economics and quality of healthcare services. The NIHP issues an annual Call for Proposals (CFP) for research and scholarship applications. The CFP is distributed publicly among all academic institutions and other research

organization in the field and is advertised in the media. All applications complying with the Institute's research agenda are subjected to a thorough peer-review evaluation process by appropriate experts from both Israel and abroad and the final approval is given by the NIHP's Research Board. [\[109\]](#)

# Canada

## General

Canada's population of approximately 34 million people is governed as a parliamentary democracy consisting of a federation of ten provinces and three territories. The federal government is responsible for matters that concern Canada as a whole, such as international trade and national defense. [1] Parliament for Canada consist of three distinct elements: the Crown, the Senate and the House of Commons. However, as a federal state, responsibility for lawmaking in Canada is shared among one federal, provincial and territorial governments. [110]

The power to enact laws is vested in a legislature composed of individuals selected to represent the Canadian people. The federal legislature is bicameral; it has two deliberative houses — an upper house, the Senate, and a lower house, the House of Commons. The Senate is composed of individuals appointed by the Governor General to represent Canada's provinces and territories. Members of the House of Commons are elected by Canadians who are eligible to vote. [110]

Canada is also a constitutional monarchy, in that its executive authority is vested formally in the Queen through the Constitution. Every act of government is carried out in the name of the Crown, but the authority for those acts flows from the Canadian people. The executive function belongs to the Governor in Council, which is, practically speaking, the Governor General acting with, and on the advice of, the Prime Minister and the Cabinet. [110]

## Health and social care system

The organization of Canada's health care system is largely determined by the Canadian Constitution, in which roles and responsibilities are divided between the federal, and provincial and territorial governments. The Constitution of Canada includes the [Constitution Act 1867](#), and the [Constitution Act 1982](#). It is the supreme law of Canada. The federal government's roles in health care include setting and administering national principles for the system under the [Canada Health Act](#). The federal government is also responsible for some delivery of services for certain groups of people. Publicly funded health care is financed with general revenue raised through federal, provincial and territorial taxation, such as personal and corporate taxes, sales taxes, payroll levies and other revenue. [111], [112] In addition, the federal government also has important responsibilities in the domains of public health, health research and health data collection. [113]

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Canada does not have a single national health care plan, but rather a national health insurance program Medicare.

Canada does not have a single national health care plan, but rather a national health insurance program, which is achieved by a series of thirteen interlocking provincial and territorial health insurance plans, all of which share certain common features and basic standards of coverage. Under the [Canada Health Act](#), national health insurance program is designed to ensure that all residents of Canada have reasonable access to medically necessary

hospital and physician services on a prepaid basis, and on uniform terms and conditions. Canada's national health insurance program is often referred to as Medicare. Roles and responsibilities for Canada's health care system are shared between the federal and provincial-territorial governments. [114]



The provincial and territorial governments have most of the responsibility for organizing and delivering health and other social services. Each provincial and territorial health insurance plan covers medically necessary hospital and doctors' services that are provided on a pre-paid basis, without direct charges at the point of service. [114] The provincial and territorial governments fund these services with assistance from federal cash and tax transfers. Provinces may also charge a health premium on their residents to help pay for publicly funded health care services, but non-payment of a premium must not limit access to medically necessary health services. Each province determines its own structure for the coordination of health and social care services. Many have established regional health authorities that plan and deliver publicly funded services locally. Generally, those authorities are responsible for the funding and delivery of hospital, community and long-term care, as well as mental and public health services. Nearly all health care providers are private. [12], [111]

The federal government co-finances provincial and territorial programs, which must adhere to the five underlying principles of the [Canada Health Act](#) that sets standards for medically necessary hospital, diagnostic, and physician services. These principles state that each provincial health care insurance plan needs to be: 1) publicly administered; 2) comprehensive in coverage; 3) universal; 4) portable across provinces; and 5) accessible without any user fees. [12], [111]

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## Canada Health Act sets standards for medically necessary hospital, diagnostic, and physician services.

Provinces and territories are required to provide reasonable access to medically necessary hospital and doctors' services. The Act also discourages extra-billing and user fees. Extra-billing is the billing of an insured health service by a medical practitioner in an amount greater than the amount paid or to be paid for that service by the provincial or territorial health

insurance plan. A user charge is any charge for an insured health service other than extra-billing that is permitted by a provincial or territorial health insurance plan and is not payable by the plan. The federal government provides cash and tax transfers to the provinces and territories in support of health through the Canada Health Transfer (CHT), which provides long-term predictable funding for health care. [111], [115]

The Canadian social safety net covers a broad spectrum of programs, and many of programs are run by the provinces. The Canadian Social Transfer (CST) is the primary source of federal funding in Canada that supports provincial and territorial social programs. It includes support of post-secondary education, social assistance and social services, and early childhood development and early learning and childcare. [116]

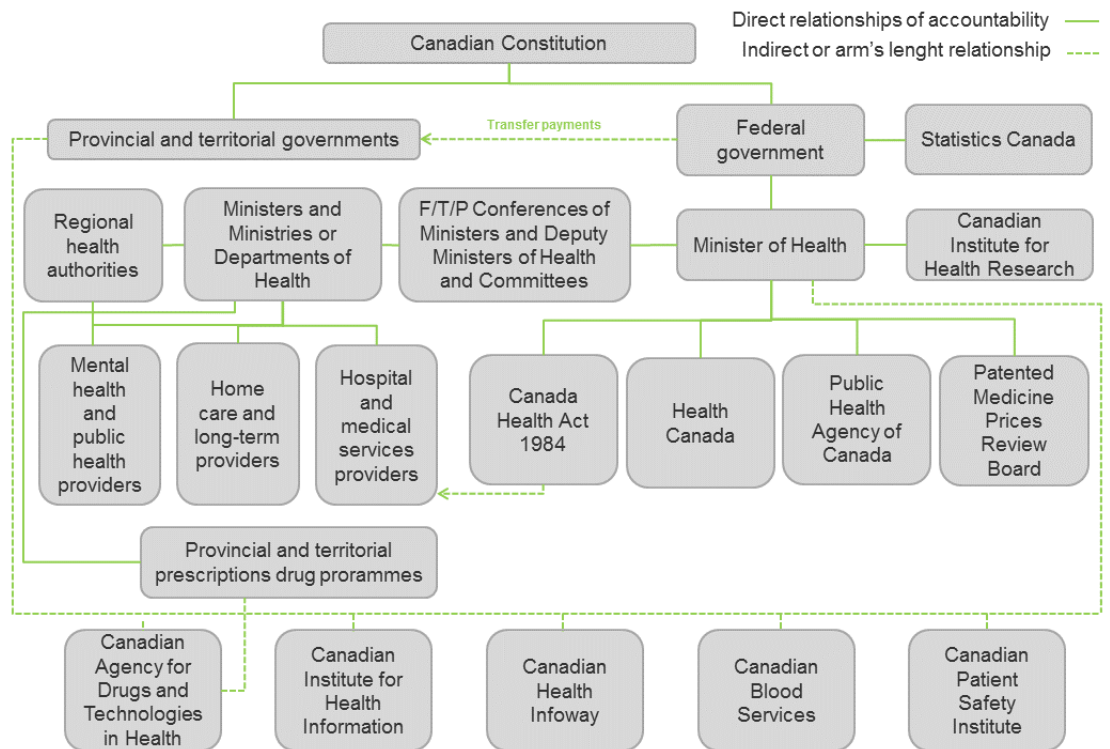
Under section 24.3 of the [Federal-Provincial Fiscal Arrangements Act](#), to receive their full share of funding, provinces and territories must meet the sole criterion that no person is required to live in a province or territory for a minimum period before becoming eligible to receive social assistance. The Act also states that the CST is to be provided to finance social programs in a manner that gives provinces and territories flexibility, and encourages federal, provincial and territorial governments to coordinate the development of shared principles and objectives for these social programs. [117] The Social Insurance Number (SIN) is a nine-digit number that a person needs to work in Canada or to have access to government programs and benefits. [118]

In November 2015, The Canadian Association of Social Workers (CASW) issued [A New Social Care Act for Canada](#) that provides an in-depth history of Canada's social policy trajectory and paints a picture of the Canada that might have been before it was derailed by a climate of austerity and budget-balancing-at-any-cost mentality. [119]

Because of the high level of decentralization, provinces have primary jurisdiction over administration and governance of their health systems. The federal ministry of health, Health Canada, plays a role in promoting overall health, disease surveillance and control, food and drug safety, and medical device and technology review. [Department of Health Act](#) sets out the powers, duties and functions of the Minister of Health, which extend to all matters covering the promotion or preservation of the health of Canadians over which Parliament has jurisdiction. The Public Health Agency of Canada is responsible



for public health, emergency preparedness and response, and infectious and chronic disease control and prevention. [12] The Patented Medicine Prices Review Board is a quasi-judicial body that protects consumers and contributes to health care by ensuring that the manufacturers' prices of patented medicines are not excessive. [120]



**Picture 5:** Organization of the Health and Social Care System in Canada [12]

When Canadians need health care, they most often turn to primary health care services, which are the first point of contact with the health care system. In general, primary health care serves a dual function. First, it provides direct provision of first-contact health care services. Second, it coordinates patients' health care services to ensure continuity of care and ease of movement across the health care system when more specialized services are needed. The majority of Canadian hospitals are operated by community boards of trustees, voluntary organizations or regional health authorities established by provincial or territorial governments. Hospitals are generally funded through annual, global budgets that set overall expenditure targets or limits negotiated with the provincial and territorial ministries of health, or with a regional health authority or board. Although global funding continues to be the principal approach for hospital reimbursement in Canada, a number of provinces have been experimenting with supplementary funding approaches. [111]

The Canadian Agency for Drugs and Technologies in Health oversees the national health technology assessment process, which produces information about the clinical effectiveness, cost-effectiveness, and broader impact of drugs, medical technologies, and health systems. The Agency's Common Drug Review reviews the clinical effectiveness and cost-effectiveness of drugs and provides common, nonbinding formulary recommendations to the publicly funded provincial drug plans (except in Quebec) to support greater consistency in access and evidence-based resource allocation. [12]

Canadian Institute for Health Information (CIHI) is an independent, not-for-profit organization that provides essential information on Canada's health system and the health of Canadians. Their stakeholders use our broad range of health databases, measurements and standards, together with evidence-based reports and analyses, in their day-to-day decision-making. CIHI protects the privacy of Canadians by ensuring the confidentiality, integrity and availability of our health care information. [121]

The Canadian Patient Safety Institute (CPSI) develops evidence-informed products, provide excellent stewardship of resources, ensure clear and open communication, deliver measurable results, celebrate the successes of our partners, nurture successful partnerships, and are passionate about safe

healthcare for all Canadians. CPSI customizes patient safety and quality products and services for the frontline, middle managers, senior leaders, and boards. [122]

Canada Health Infoway was created in 2001 as an independent, federally funded, not-for-profit organization that helps to improve the health of Canadians by working with the Canadian provinces and territories to co-fund the implementation of electronic medical records and other digital health projects. Infoway's members are Canada's 14 federal, provincial and territorial Deputy Ministers of Health. [123], [124]

Nongovernmental organizations with important roles in system governance include professional organizations such as the Canadian Medical Association, provincial regulatory colleges, which are responsible for licensing professions and developing and enforcing standards of practice, and Accreditation Canada. Most providers are self-governing under provincial and territorial law; they are registered with professional associations that ensure that education, training, and quality-of-care standards are met. The professional associations for physicians are also responsible for negotiating fee schedules with the provincial ministries of health. Most provinces have an ombudsperson providing patient advocacy. [12]

### Creating and using health and social care data in primary use

Data protection legislation has emerged across Canada with different requirements applying at provincial, territorial or federal level. Despite the fragmentation of legislation most data protection laws are generally modelled on the internationally accepted Guidelines on the Protection of Privacy and Transborder Flows of Personal Data developed by the Organization for Economic Cooperation and Development (OECD) in 1980. The Canadian Standards Association has reformulated these guidelines into the [Model Code for the Protection of Personal Information](#). [1]

Canada has two federal privacy laws, the [Privacy Act](#), which covers the personal information-handling practices of federal government departments and agencies, and the [Personal Information Protection and Electronic Documents Act](#) (PIPEDA), the federal private-sector privacy law. The [Privacy Act](#) relates to an individual's right to access and correct personal information the Government of Canada holds about them or the Government's collection, use and disclosure of their personal information in the course of providing services. The Privacy Act only applies to federal government institutions listed in the [Privacy Act Schedule of Institutions](#). It applies to all of the personal information that the federal government collects, uses and discloses — be it about individuals or federal employees. The [Personal Information Protection and Electronic Documents Act](#) sets out ground rules for how private sector organizations may collect, use or disclose personal information in the course of commercial activities. [125]

PIPEDA also applies to federal works, undertakings and businesses in respect of employee personal information. The law gives individuals the right to access and request correction of the personal information these organizations may have collected about them. The principal obligations related to processing personal information are: (1) Identifying Purposes: The purposes for which personal information is collected shall be identified by the organization at or before the time the information is collected; (2) Consent: The knowledge and consent of the individual are required for the collection, use, or disclosure of personal information, except as otherwise authorized by law; (3) Limited Collection: The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means; (4) Accuracy: Personal information shall be as accurate, complete, and up-to-date as is necessary for the purposes for which it is to be used; and (5) Safeguards: Personal information shall be protected by security safeguards appropriate to the sensitivity of the information. [125], [126] The Office of the Privacy Commissioner (OPC) is overseeing compliance with both the Privacy Act and PIPEDA. OPC is an Officer of Parliament who reports directly to the House of Commons and the Senate. [127]

Canadian privacy laws impose a legal obligation on health information custodians and trustees to identify the purpose, for which they collect, use and disclose, or retain information. This may include purposes other than treatment and care; so-called secondary purposes, for example research. Information notices given to patients, are intended to give individuals a sense of what uses are permissible. [1]

On June 18, 2015, the Canadian Parliament passed the [Digital Privacy Act](#) (DPA) into law. The Act introduces a number of amendments to the Personal Information Protection and Electronic Documents Act, most of which are now in force. [125] The DPA introduces a graduated standard for obtaining valid consents. The DPA stipulates that an individual's consent will only be valid "if it is reasonable to expect that an individual to whom the organization's activities are directed would understand the nature, purpose and consequences of the collection, use or disclosure of the personal information to which they are consenting." The DPA also introduces several additional exceptions covering PIPEDA's consent and knowledge requirements and a new mandatory data breach notification requirement, which applies to organizations subject to PIPEDA when "...any breach of security safeguards involving personal information under [that organization's] control [occurs,] if it is reasonable in the circumstances to believe that the breach creates a real risk of significant harm to the individual." The DPA revises the definition of personal information to refer only to "information about an identifiable individual" and introduces a separate definition of the term "business contact information." Finally, DPA enhances the powers of the Canadian Privacy Commissioner in several respects. Most significantly, it enables the Commissioner to form compliance agreements with organizations that the Commissioner has reasonable grounds may have committed, or is about or likely to commit, a breach of the PIPEDA. [125], [128]

To support system-wide planning, provincial governments have invested in health ICT infrastructures with plans to create EHRs for all provincial residents. As befits its federal character, Canada has a plurality of information systems in place for the collection, reporting and analysis of health data. At the provincial and territorial level, governments have been collecting detailed administrative data since the introduction of universal hospital and medical insurance plans. At the federal level, Statistics Canada has been collecting population health data through both the national census taken every five years and large-sample health surveys. [113]

Uptake of health information technologies has been slowly increasing in recent years. Provinces and territories are responsible for developing their electronic information systems, with support from Canada Health Infoway; however, there is no national strategy for implementing electronic health records and no national patient identifier. According to Canada Health Infoway, provinces have systems for collecting data electronically for the majority of their populations. [12] Advancing eHealth has been a focus of attention in Canada. Electronic health technologies, such as electronic health records and telehealth, are significant drivers of innovation, sustainability and efficiency in the health care system by improving access to services, patient safety, quality of care, and productivity. The implementation and use of electronic health records contributes to primary health care renewal by facilitating the effective coordination and integration of services amongst care providers. [111]

### Individual's position and consent management

The [Access to Information Act](#) gives Canadian citizens and corporations located in Canada the right to access information contained in federal government records. The [Privacy Act](#) provides Canadian citizens, permanent residents, or individuals present in Canada with the right to access their personal information held by the government and protection of that information against unauthorized use and disclosure. [129], [130] The collection and use of personal health information are inherently privacy-intrusive activities in which judgments are continually made as to whether the public good of obtaining, analyzing and using such data outweighs the potential intrusion on an individual's confidentiality and privacy. Since jurisdiction over health information is shared among federal, provincial and territorial governments, the result is a patchwork of health information and privacy laws in Canada. These laws sometimes address three issues – privacy, confidentiality and security – in the same legislation, or at other times in separate laws within the same jurisdiction. The Health Canada's Access to Information and Privacy Office is responsible for administering both laws as well as associated Treasury Board policies and directives. [113]

Generally, research uses of health information are not permitted without explicit consent of an individual, unless an exemption is granted by a research ethics board. However, there is considerable overlap in the boundaries between research and quality improvement, public health, and systems management. [131] The Canadian Institute of Health Research has published [Ethical Conduct for Research Involving Humans](#) that is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research

Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). [132]

Legislative frameworks in Canada permit individuals to express their wishes to limit use and/or disclosure of their personal health information for some purposes. Consequently there is a legal obligation to respect the individuals' wishes for use and disclosure of their personal health information. Health records must be able to record a person's consent directives. Canadian Health Infoway has proposed to design and implement a Consent Management Solution (CMS) which allows a consent directive recorded in one system to be applied as the individual expects – in that system and anywhere else in the digital health ecosystem that the PHI is accessed. [133] However, Infoway is only investing with jurisdictional ministries of health, regional health organizations and others to enable these consumer health services across Canada.

### Health and social care data in secondary use

According to OECD research, administrative health data is widely used in Canada for secondary analysis; however, secondary analysis of data from electronic health records is not yet wide spread. Both will be used for national health care quality monitoring over the next years, with EHR data increasing in importance with time. Canada Health Infoway and Canadian Institute for Health Information are working with various levels of government to plan and implement a vision for moving the Secondary Use of Health Data Agenda forward. [134]

Canadian privacy laws govern the collection, use, management and disclosure of personal health information. These laws generally permit secondary use of health data, whether paper or electronic, for management and planning of the health system. In most instances, use is and will continue to be based on data that has been de-identified to respect the privacy and confidentiality of patients. The implementation of privacy-by-design principles and other technological advances can facilitate consent management and the de-identification of health data to help ensure that health system use of data complies with health information privacy laws. [135]

While federal, provincial and territorial laws generally allow researchers to access data that do not include identifiable information, this term is not always defined precisely. This makes it confusing to base data sharing guidelines on the notion that non-identifiable data can be used freely. As well, data custodians may interpret their legal duty to protect privacy as precluding access. Laws on sharing data across provinces and territories and countries differ or are lacking, which can also make researchers and research ethics boards uncertain as to whether data can be shared. The lack of legal clarity has contributed to cautious and conservative interpretations of allowable access in many Canadian organizations. While the law provides specific limits for data custodians, it is less specific in other areas. And although provincial and federal laws lay out broad rules about when and how data can be used or shared, often they are silent on specific questions about whether data should be so used in specific settings. [136]

In Canada, providing statistics is a federal responsibility. As Canada's central statistical office, Statistics Canada is legislated in [Statistics Act](#) to serve this function for the whole of Canada and each of the provinces and territories. Statistics Canada aims to ensure that the information it produces provides a consistent and coherent picture of the Canadian economy, society and environment, and that its various datasets can be analyzed together and in combination with information from other sources. [137]

Statistics Canada provides alternative way to access health data. Research Data Centres (RDC) provide researchers with access to the microdata from the Canadian Community Health Survey (CCHS), the National Population Health Survey (NPHS), the Canadian Health Measures Survey (CHMS), the Canadian Cancer Registry (CCR), the Vital Statistics - Birth Database, and the Vital Statistics - Death Database. The Data Liberation Initiative (DLI) is available to participating post-secondary educational institutions, allowing their faculty and students unlimited free access to numerous Statistics Canada public use microdata files (PUMFs), a special collection of aggregate data tables, databases, and geographic files. The Real Time Remote Access (RTRA) system is an on-line remote access facility allowing researchers to run SAS programs, in real-time, against microdata sets located in a central and secure location. Researchers may also apply for remote access to the Canadian Community Health Survey and the National Population Health Survey through a service

offered by Health Statistics Division. Custom tabulations for all Health Statistics Division Surveys are also available on a cost recovery basis. [137] Long recognized as one of the world's premier statistical agencies, Statistics Canada is a pioneer in the gathering of health statistics as well as in the development of indicators of health status and the determinants of health. Data collection has been extended considerably through Statistics Canada's partnership with the Canadian Institute for Health Information. [113]

The Canadian Institutes of Health Research (CIHR) is Canada's premier federal agency for health research. Its objective is to create new knowledge that can be translated into improved health for Canadians, more effective health services and products and a strengthened health care system. CIHR was created in 2000 under the authority of the [Canadian Institutes of Health Research Act](#). CIHR's mandate is to "excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system." It is an independent agency and is accountable to Parliament through the Minister of Health. [138]

Canadian Institute for Health Information (CIHI) collects comparable data on different aspects of the health system. Established in 1994, CIHI was a response to the desire of federal, provincial and territorial governments for a nationally coordinated approach to gathering and analyzing their respective financial and administrative data. Its core functions include identifying and defining national health indicators and frameworks, coordinating the development and maintenance of Canadian data

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## Canadian Institute for Health Information collects comparable data on different aspects of the health system for secondary use.

standards, developing and managing health databases and registries, and disseminating health data through research reports. By 2016, CIHI was maintaining a total of 27 databases and clinical registries, including the National Health Expenditure Database, the National Physician Database, the Hospital Morbidity Database, the Discharge Abstract Database and the National Prescription Drug Utilization and

Information Systems Database. Researchers, decision-makers and health managers can request specific data from CIHI's databases to suit their information needs. There is also metadata descriptions for each data holding. Approximately 80% of CIHI's funding comes from Health Canada and the remaining funds from provincial governments. CIHI also has an ongoing partnership with Statistics Canada, as well as a strong advisory relationship with the Conference of federal, provincial and territorial Deputy Ministers of Health through its 16-member board of directors. [113], [139]

The Canadian Institute for Health Information (CIHI) and others (e.g. CIHR, Natural Sciences and Engineering Research Council of Canada, NSERC and Social Sciences and Humanities Research Council, SSHRC) have been working to ensure that appropriate safeguards are taken to protect the data against unauthorized disclosure. CIHI has done extensive work to develop international standards for the use and disclosure of health-related information, including ISO DTR 22221, which extends the secondary use of EHR-sourced data. CIHI also develops best practices for organizations involved in the secondary use and disclosure of data. [140]

The federal government also provides the majority of funding for major research initiatives that are governed independently, including Genome Canada and the Canadian Health Services Research Foundation (CHSRF). Genome Canada's objective is to make Canada a world leader in research capable of isolating disease predisposition and developing better diagnostic tools and prevention strategies. CHSRF focuses on research in health services aimed at improving health care organization, administration and delivery as well as acting as knowledge brokers between the research and decision-making communities. [113]



# Australia

## General

Australia, formally the Commonwealth of Australia, is both a representative democracy and a constitutional monarchy with Queen Elizabeth II as Australia's head of state. Australia is further divided into states and territories. There are six states that joined together to form the Commonwealth of Australia, they still each retain the power to make their own laws over matters not controlled by the Commonwealth. Territories are areas within Australia's borders that are not claimed by one of the six states. Eight territories can be administered by the Australian Government, or they can be granted a right of self-government. Unlike the states, whose powers are defined through the Constitution, the powers of these territories are defined in Commonwealth law which grants them the right of self-government. [141]

This also means that the Parliament can alter or revoke these powers at will. Constitutional responsibility for local government lies with the state and territory governments. Consequently, the roles and responsibilities of local government differ from state to state. Local governments are also known as local councils. Population of 24 million, Australians have access to comprehensive health care of a high standard. The mainly tax-funded health system achieves reasonably cost-effective health care and good health outcomes, and generally enjoys public support. [141], [142]

## Health and social care system

In August 2011, the Council of Australian Governments (COAG), the peak intergovernmental forum in Australia of which members are the Prime Minister, State and Territory Premiers and Chief Ministers and the President of the Australian Local Government Association, agreed to major structural reforms to the organization, funding and delivery of health care, and new financial and governance arrangements for Australian public hospital services, to enable the future sustainability of the Australian health system. The Commonwealth and all state and territory governments entered into the [National Health Reform Agreement](#) and [National Health Reform Act 2011](#) outlining their shared intentions to work together to establish the foundations of Australia's future health system. Under the Agreement, the Commonwealth, state and territory governments are jointly responsible for funding public hospital services through either activity based or block funding. [143]

The complex health system involves both levels of government, as well as public and private providers. The Australian Government funds rather than provides health services. The states fund, administer and provide and private medical practitioners provide most community-based treatment, and there is

a large private health sector. [141] That is why Australia's health-care system is a multi-faceted web of public and private providers, settings, participants and supporting mechanisms. Health providers include medical practitioners, nurses, allied and other health professionals, hospitals, clinics and government and non-government agencies. These providers deliver multiple services across many levels, from public health and preventive services in the community, to primary health

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**The complex health system involves both levels of government, as well as public and private providers.**

care, emergency health services, hospital-based treatment, and rehabilitation and palliative care. Private sector health service providers include private hospitals, medical practices and pharmacies. Private health insurance is not compulsory. Private health insurance is available for those who wish to fully or partly cover the costs of being admitted to hospital as a private patient and/or the costs of other



ancillary health services. [144] Private Health Insurance is governed by the [Private Health Insurance Act 2007](#).

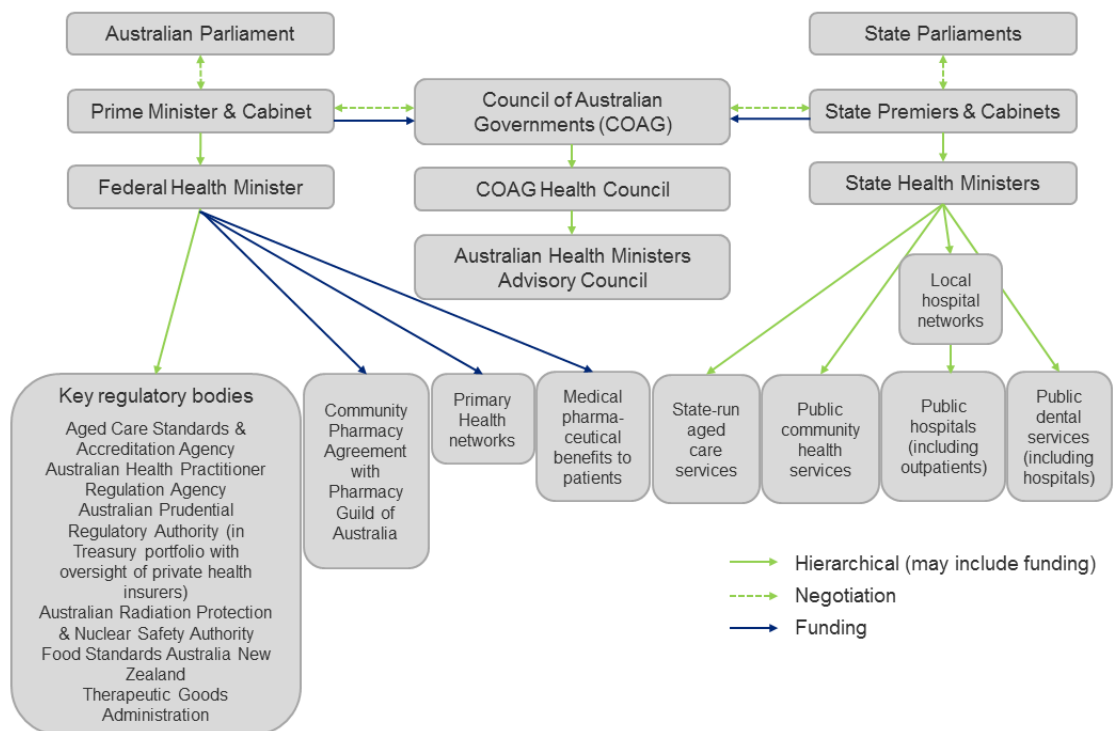
The Australian Government's funding contributions include a universal public health insurance scheme, Medicare. Medicare is the basis of Australia's health care system and covers many health care costs. Medicare was introduced in 1984 to provide free or subsidized treatment by health professionals such as doctors, specialists and optometrists. A person can have Medicare cover only, or a combination of Medicare and private health insurance coverage. The Medicare system has 3 parts: hospital, medical and pharmaceutical. The major elements of Medicare include free treatment for public patients in public hospitals, the payment of benefits or rebates for professional health services listed on the Medicare Benefits Schedule, and subsidization of the costs of a wide range of prescription medicines under the Pharmaceutical Benefits Scheme. A person can choose to be treated as a public patient, even if you are privately insured. [144], [145]

## The universal public health insurance scheme Medicare is the basis of Australia's health care system and covers many health care costs.

Approximately half of the population has private health insurance that provides access to private hospitals, and private facilities in public hospitals, and also covers services that are not in the Medicare benefits package such as dentistry, eye care and complementary medicine. [146]

Three levels of government are collectively responsible for providing universal health care: federal; state and territory; and local.

The federal government mainly provides funding and indirect support to the states and health professions, subsidizing primary care providers through the Medicare Benefits Scheme (MBS) and the Pharmaceutical Benefits Scheme (PBS) and providing funds for state services. It has only a limited role in direct service delivery. States have the majority responsibility for public hospitals, ambulance services, public dental care, community health services, and mental health care. They contribute their own funding in addition to that provided by federal government. Local governments play a role in the delivery of community health and preventive health programs, such as immunization and regulation of food standards. [12] Local government bodies do not have the law enforcement. [113]



**Picture 6:** Organization of the Health and Social Care System in Australia [12]

Intergovernmental collaboration and decision-making at the federal level occur through the Council of Australian Governments (COAG), with representation from the Prime Minister and first ministers of each state. The COAG focuses on the highest-priority issues, such as major funding discussions and the interchange of roles and responsibilities between governments. The COAG Health Council is responsible for more detailed policy issues and is supported by the Australian Health Ministers Advisory Council. The federal Department of Health oversees national policies and programs such as the Medicare Benefits Schedule (MBS) and The Pharmaceutical Benefits Scheme (PBS). Payments through these schemes are administered by the Department of Human Services. The Pharmaceutical Benefits Advisory Committee (PBAC) provides advice to the Minister for Health on the cost-effectiveness of new pharmaceuticals. [12] The department of health administers large number of laws related to health and social care, e.g. [National Health Act 1953](#), [National Health Security Act 2007](#), [Healthcare Identifiers Act 2010](#). [147]

For most people their first contact with the Australian health system when they become ill is a visit to a general practitioner (GP). A person does not routinely need a referral for this level of care, which includes services provided by general medical and dental practitioners, nurses, Indigenous health workers, pharmacists and other allied health professionals such as physiotherapists, dietitians and chiropractors. The primary health-care system does not operate in isolation. It is part of a larger system involving other services and sectors, and so can be considered as the gateway to the wider health system. Through assessment and referral, individuals are directed from one primary care service to another, and from primary services into secondary and other health services. GP may refer them to a specialist or a public hospital, order diagnostic testing, write them a prescription or pursue other treatment options. Secondary care is medical care provided by a specialist or facility upon referral by a primary care physician. It includes services provided by hospitals and specialist medical practices. In Australia, hospital services are provided by both public and private hospitals. [144]

The Australian social care system is not universal and government assistance focuses on those with low incomes. The services provided are based on an assessment of an individual's need, and charges are determined by a means test. A range of services are offered by national and local government. These include residential care for individuals with high complex care, equipment and therapy needs and low everyday accommodation and some personal care services care needs, like community care packages for those who are eligible for residential care, but prefer to stay at home; and home and community care (HACC), a lower level of support, often for less than two hours a week, that includes cleaning and personal care. Social care services are mainly financed through tax revenue and user charges. Wealthier people often pay the full cost of their care out of pocket, up to the government defined limit, and it is difficult to buy private insurance to cover these costs. Non-profit organizations are the main providers of social care in Australia, with a small amount of for-profit and government provision. [146]

### Creating and using health and social care data in primary use

The [Privacy Act 1988](#) regulates how personal information is handled. The Privacy Act includes thirteen [Australian Privacy Principles](#) (APPs), which apply to some private sector organizations, as well as most Australian and Norfolk Island Government agencies. The Privacy Act also regulates the privacy component of the consumer credit reporting system, tax file numbers, and health and medical research. Health information is regarded as one of the most sensitive types of personal information. For this reason, the Privacy Act 1988 provides extra protections around its handling. For example, an organization generally needs an individual's consent before they can collect their health information. In addition, all organizations that provide a health service and hold health information (other than in an employee record) are covered by the Privacy Act. [148]

The Privacy Act has regulated the handling of personal information held by all health service providers in the private sector since 2001 with the [Privacy Amendment \(Private Sector\) Act 2000](#). This includes GPs, private hospitals, pharmacists and allied health professionals. It does not cover public healthcare providers such as public hospitals or their staff, which are instead governed by state or territory legislation. A number of states have also enacted specific legislation to govern their private sector health providers. There is no specific health information legislation at a national level. In the absence of this some states and territories have enacted specific health information legislation. One example is the New South Wales [Health Records and Information Privacy Act 2002](#) that governs the handling of

health information in the public sector and it also seeks to regulate the handling of health information in the private sector in New South Wales (NSW). [1]

The Office of the Australian Information Commissioner (OAIC) is an independent statutory agency within the Attorney General's portfolio. The OAIC was established under the [Australian Information Commissioner Act 2010](#) and it is responsible for privacy functions that are conferred by the Privacy Act and other laws. Under the Privacy Act a person can make a complaint to OAIC about the handling of their personal information. The OAIC has three primary functions; privacy functions, conferred by the [Privacy Act 1988](#) and other laws, freedom of information functions, in particular, oversight of the operation of the [Freedom of Information Act 1982](#) and review of decisions made by agencies and ministers under that Act and government information policy functions, conferred on the Australian Information Commissioner under the [Australian Information Commissioner Act 2010](#). [149]

Approaches to improving integration and care coordination include the Practice Incentives Program (PIP), which provides a financial incentive to providers for the development of care plans for patients with certain conditions, such as asthma, diabetes, and mental health needs. The Primary Health Networks (PHNs) were established in July 2015 with the objective of improving coordinated care, as well as the efficiency and effectiveness of care for those at risk of poor health outcomes. These networks are funded through grants from the federal government and will work directly with primary care providers, health care specialists, and Local Hospital Networks (LHNs). Care also may be coordinated by Aboriginal health and community health services. [12] The mechanisms for the secure use of identified data for linking purposes already exist in the broader Commonwealth data management framework. [150]

The National eHealth Transition Authority has been working to establish interoperable infrastructure to support communication across the health care system. A national e-health program based on personally controlled unique identifiers has commenced operation in Australia, and 2.5 million patients and nearly 8,000 providers have registered. The record supports prescription information, medical notes, referrals, and diagnostic imaging reports. Following a review, government is taking a number of steps to increase uptake by both patients and providers, which has been poor to date, by improving usability, clinical utility, governance and operations. In addition, an opt-out approach will be tested to replace the current opt-in approach. The new Australian Commission for eHealth will begin oversight in July 2016, taking on the e-health roles of the Department of Health and the National eHealth Transition Authority. The current PIP eHealth Incentive, which aims to encourage GPs to participate, also will be reviewed for potential improvements. [12]

### Individual's position and consent management

The [Privacy Act 1988](#) includes provisions that generally allow an individual to access information held about them. The Office of the Australian Information Commissioner (OAIC) also regulates the handling of health information held in an individual's My Health Record, and the handling of healthcare identifiers. Australians are able to register for their own My Health Record. My Health Record is an electronic summary of a person's health information. Healthcare providers are able to add information about a consumer's health to their My Health Record, in accordance with the consumer's access

controls. This may include information such as medical history and treatments, diagnoses, medications and allergies. Consumers can control their own My Health Record, including by choosing to restrict which healthcare provider organisations can access it and what information is included. Individual can also list allergies, adverse reactions and medical conditions that may help healthcare providers give better advice and treatment for the patient. [151], [152]

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## My Health Records Act 2012 creates the legislative framework for the Australian Government's My Health Record system.

The [My Health Records Act 2012](#), [My Health Records Rule 2016](#) and [My Health Records Regulation 2012](#) create the legislative framework for the Australian Government's My Health Record system. The My Health Records Act limits when and how health information included in a My Health Record can be

collected, used and disclosed. Unauthorised collection, use or disclosure of My Health Record information is both a breach of the My Health Records Act and an interference with privacy. The Office of the Australian Information Commissioner (OAIC) regulates the handling of personal information under the My Health Record system by individuals, Australian Government agencies, private sector organisations and some state and territory agencies. [151] Also [Personally Controlled Electronic Health Records Act 2012](#) contains provisions dealing with decision-making concerning the collection, use and disclosure of personally controlled electronic health records — referred to as eHealth records. [153]

The Healthcare Identifiers Service issues unique identifiers to all individuals who receive healthcare in Australia. The aim is to help healthcare providers accurately communicate information with each other and identify and access patient records in the My Health Record system. The purpose of Healthcare Provider Identifiers is to identify providers accessing the Healthcare Identifiers Service database and to link records with the right healthcare provider, at the right location. The handling of healthcare identifiers is regulated by the [Healthcare Identifiers Act 2010](#) and [Healthcare Identifier Regulations 2010](#). Healthcare providers may only access, use and disclose healthcare identifiers for the limited purposes permitted under the Healthcare Identifiers Act. The main permitted purpose is to communicate or manage health information when providing healthcare to an individual. However, there are other limited purposes for which healthcare identifiers may be used or disclosed, including for the management and evaluation of healthcare and for approved research. The Healthcare Identifiers Service is operated by Medicare that publicly funded universal health care scheme in Australia. The [Human Services Legislation Amendment Act 2011](#) integrated Medicare Australia into the Department of Human Services on 1 July 2011. [154], [155]

## Health and social care data in secondary use

The basis for governing the secondary use of health information in Australia is primarily legislation in the form of the federal privacy act and state-level legislation in respect of privacy and specific health information legislation that has been developed in most states. The significance of health information, the role it plays in ensuring high level quality and safety, and appropriate governance structures has been on the Australian health agenda since the 1993 National Health Information Agreement (NHIA). The current [National Health Information Agreement](#) commenced on 1 October 2013. [1]

National Health Information Standards and Statistics Committee has also revealed [Guidelines for the Disclosure of Secondary Use Health Information for Statistical Reporting, Research and Analysis](#) that states that if the dataset contains identifiable or re-identifiable data, it will only be disclosed where there is patient consent or for purposes for which the use or disclosure of personal information is permitted by its policies and legislation, or if the dataset is non-identifiable data, in the sense that the identity of individual patients is not apparent, and cannot reasonably be ascertained from the dataset either on its own or in combination with any other information to which the user may reasonably be considered to have access.

The Royal Australian College of General Practitioners (RACGP) has been an advocate for a national shared electronic health record system and understands the clinical benefits of healthcare providers accessing healthcare information not available via normal communications channels. From legal point of view, GPs are required to make decisions about secondary use of data under the Commonwealth Privacy Act 1988, which states that personal information about an individual can only use or disclose the information for the particular purpose for which it was collected, unless an exception applies. Doctors in Victoria, New South Wales and the Australian Capital Territory should also be familiar with their state's health records Acts. For example in Victoria, responsibilities are further clarified under the Health Services Commissioner's guidelines on the collection and use of health information for research. The Australian Government is currently reviewing national privacy laws and draft legislative changes are under consideration. [156]

The Australian Institute of Health and Welfare (AIHW) and the Australian Bureau of Statistics (ABS) are the major providers of health data. AIHW is a major national agency set up by the Australian Government under the [Australian Institute of Health and Welfare Act 1997](#) to provide reliable, regular and relevant information and statistics on Australia's health and welfare. The Act ensures that the data collections we manage are kept securely and under the strictest conditions with respect to privacy and confidentiality. AIHW is an independent corporate Commonwealth entity established in 1987, governed by a management board, and accountable to the Australian Parliament through the Health portfolio. Its

primary roles is to collect, analyze and report information drawn from health services, community services and housing assistance services. The Institute also plays a role in developing and maintaining national metadata standards and providing access to health related data. The AIHW Ethics Committee was established by the AIHW Act. The Committee's functions are prescribed by the [Australian Institute of Health and Welfare Ethics Committee Regulations 1989](#) which give the Committee the power to assess the ethical acceptability of internal research activities and the activities of the AIHW's partner institutions. [157]

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## The Australian Institute of Health and Welfare and the Australian Bureau of Statistics are the major providers of

The Australian Bureau of Statistics (ABS) is Australia's national statistical agency, providing trusted official statistics on a wide range of economic, social, population and environmental matters of importance to Australia. It also have an important leadership role, coordinating statistical activities and collaborating with official bodies in the collection, compilation, analysis and distribution of statistics. This assists in maximizing the value of government

investment on these activities, and ensures outputs are fit-for-purpose. The principal legislation determining the functions and responsibilities of the Australian Bureau of Statistics are the [Australian Bureau of Statistics Act 1975](#) and the [Census and Statistics Act 1905](#). The [Australian Bureau of Statistics Act 1975](#) establishes the ABS as an independent statutory authority, defines the functions of the ABS, establishes the office of Australian Statistician and describes the terms under which the Australian Statistician can be appointed to, and removed from, office. The [Census and Statistics Act 1905](#) provides the Australian Statistician with the authority to conduct statistical collections, including the Census of Population and Housing, and, when necessary, to direct a person to provide statistical information. The Act requires the ABS to publish and disseminate compilations and analyses of statistical information and to maintain the confidentiality of information collected under the Act. [158]

My Health system has also the potential to be an important resource for health and medical research. Use of the data for research purposes is consistent with the objects of the [Personally Controlled Electronic Health Records Act 2012](#), which states that reduce the occurrence of adverse medical events and the duplication of treatment and improve the coordination and quality of healthcare provided to consumers by different healthcare providers. However, there is no specific legislation for the secondary usage of PCEHR data in research. Research Australia has proposed that the provision of data for research be more explicitly recognized in the Personally Controlled Electronic Health Records 2012 and [Individual Healthcare Identifiers 2010](#) Acts. [150]

# Conclusions

## Secondary use of health and social care data on agenda in many countries

All of the reviewed countries have started to pay attention to collected health records and finding ways how to use EHRs more effectively and utilize all the information to support decision-making. Ministries of Health and health research organizations in all of the countries have started to make strategies enabling to combine and link EHR and health databases with another. The health information exchange between providers is key issue almost in every country. Consequently national EHR systems are under way in many countries due to more effective primary and secondary use of health and social care data.

Although, privacy issues have caused challenges in many countries. For example in England and Netherlands, national EHR plans have faced multiple challenges and delays due to mismanagement, miscommunications and inadequate protections for sensitive health information. Also individuals are more aware of their health information and want to control the use; consent management and clear legal framework is needed in order to avoid misuse. Patient portals that enabling access to personal health records and other eHealth services are increasing and involving patient more.

## The main findings of the review

From the reviewed countries, Australia and Israel can be seen as pioneers in eHealth and telehealth services. Israel has national health information exchange system that enables the exchange of electronic health records between all of the health plans and has also developed a number of enhancing telehealth services for health care. Whereas Australia has developed national My Health Record system, which is an electronic summary of a person's health information. Consumers can control their own My Health Record, including by choosing to restrict which healthcare provider organisations can access it and what information is included. There is also great potential for the secondary use of My Health Record data.

However, England has the most successfully managed to enable secondary use of health and social care information. In England, Health and Social Care Information Centre is offering secondary use service for health and social care data that facilitates the research and access to relevant data.

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**There is no separate legislation for secondary use of health and social care records in any of the reviewed countries.**

Countries that are most interesting from Finland's point of view are UK (England) and Canada that do have separate government institutions offering "one-point-access" to health information.

There is no separate legislation for secondary use of health and social care records in any of the countries. In all of the reviewed countries, privacy laws defines how the personal health records

can be used. Some countries do have more detailed legislation or code of conducts for the use of EHRs and sensitive information.

Tables 2 and 3 presents key resources for references; relevant laws and key organizations. The regulatory framework consists of legislation concerning health and social care system and further on privacy and use of EHRs.



**Table 2. Regulatory framework**

Country	Health and Social Care System	Privacy and use of EHRs
<b>UK (England)</b>	<ul style="list-style-type: none"> <li>• Health and Social Care Act 2012</li> <li>• Care Act 2014</li> <li>• National Health Service Act 2006</li> </ul>	<ul style="list-style-type: none"> <li>• Data Protection Act 1998</li> <li>• Common Law Duty of Confidence</li> <li>• Access to Health Records Act 1990</li> <li>• NHS Care Record Guarantee for England</li> <li>• Freedom of Information Act</li> <li>• Code of Practice on Confidential Information</li> <li>• Research Governance Framework for Health and Social Care</li> <li>• Statistics and Registration Service Act 2007</li> </ul>
<b>Netherlands</b>	<ul style="list-style-type: none"> <li>• Healthcare Insurance Act</li> <li>• Long-Term Care Act</li> <li>• Health Care Allowance Act</li> <li>• Health Care Market Regulation Act</li> <li>• Social Support Act</li> <li>• Youth Act</li> </ul>	<ul style="list-style-type: none"> <li>• Personal Data Protection Act</li> <li>• Police Data Act</li> <li>• Basic Registration of Persons Act</li> <li>• Code of Conduct Electronic Data Exchange in Health care</li> <li>• RIVM Act</li> <li>• Statistics Netherland Act</li> </ul>
<b>New Zealand</b>	<ul style="list-style-type: none"> <li>• Public Health and Disability Act 2000</li> <li>• Public Health &amp; Disability Amendment Act 2010</li> <li>• Social Security Act 1964</li> <li>• Crown Entities Act 2004</li> </ul>	<ul style="list-style-type: none"> <li>• Privacy Act 1993</li> <li>• Health Information Privacy Code 1994</li> <li>• Code of Health and Disability Service Consumers' Rights</li> <li>• Health (Retention of Health Information) Regulations 1996</li> <li>• Official Information Act 1982</li> <li>• Cancer Registry Act 1993</li> <li>• Cancer Registry Regulations 1994</li> <li>• Public Records Act 2005</li> <li>• Health Research Council Act 1990</li> <li>• Statistics Act 1975</li> </ul>
<b>Israel</b>	<ul style="list-style-type: none"> <li>• National Health Insurance Law 1995</li> <li>• Patients' Rights Law 1996</li> <li>• Community Long-Term Care Insurance Law 1986</li> <li>• Social Welfare Law 1958</li> </ul>	<ul style="list-style-type: none"> <li>• Basic Law: Human Dignity and Liberty</li> <li>• Protection of Privacy Law</li> </ul>
<b>Canada</b>	<ul style="list-style-type: none"> <li>• Constitution Act 1867</li> <li>• Constitution Act 1982</li> <li>• Canada Health Act</li> <li>• Federal-Provincial Fiscal Arrangements Act</li> <li>• A New Social Care Act for Canada</li> <li>• Department of Health Act</li> </ul>	<ul style="list-style-type: none"> <li>• Privacy Act</li> <li>• Personal Information Protection and Electronic Documents Act</li> <li>• Digital Privacy Act</li> <li>• Access to Information Act</li> <li>• Ethical Conduct for Research Involving Humans</li> <li>• Statistics Act</li> <li>• Canadian Institutes of Health Research Act</li> </ul>
<b>Australia</b>	<ul style="list-style-type: none"> <li>• National Health Reform Act 2011</li> <li>• Private Health Insurance Act 2007</li> <li>• National Health Security Act 2007</li> </ul>	<ul style="list-style-type: none"> <li>• Privacy Act 1988</li> <li>• Privacy Amendment (Private Sector) Act 2000</li> <li>• Australian Information Commissioner Act 2010</li> <li>• Freedom of Information Act 1982</li> <li>• My Health Records Act 2012</li> <li>• Personally Controlled Electronic Health Records Act 2012</li> <li>• Healthcare Identifiers Act 2010</li> <li>• Human Services Legislation Amendment Act 2011</li> <li>• Australian Institute of Health and Welfare Act 1897</li> <li>• Australian Bureau of Statistics Act 1975</li> <li>• Census and Statistics Act 1905</li> </ul>

**Table 3. Key organizations**

Country	Authority or organization	Description
<b>UK (England)</b>	Department of Health	Responsible for strategic leadership and funding for both health and social care in England.
	NHS England	Deliver of public healthcare, sets the priorities and direction for the whole NHS system and encourages and informs the national debate to improve health and care.
	National Institute for Health and Care Excellence	Develops guidance, standards and information on high quality health and social care.
	Care Quality Commission	Independent regulator for health and social care.
	Health and Social Care Information Centre	National provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care.
	UK Statistics Authority	Promotes and safeguards the production and publication of official statistics that serve the public good.
<b>Netherlands</b>	Ministry of Health, Welfare and Sport	Responsible for controlling health and care at national level.
	Ministry of Social Affairs and Employment	Responsibilities for health-related social security schemes.
	Health Council	Advises government on evidence-based medicine, healthcare and public health.
	National Health Care Institute	Integrates knowledge of various institutes.
	Dutch Healthcare Authority	Determines what types of health care can be charged to patients by health care providers.
	National IT Institute for Healthcare	Works as the center of expertise for standardization and eHealth.
	Netherlands Institute for Health Services Research	Key research and knowledge institute.
	Statistics Netherlands	Responsible for collecting and processing data in order to publish statistics.
<b>New Zealand</b>	Ministry of Health	Principal agency responsible for policy advice, funding and monitoring the health and disability sector.
	District Health Boards	Responsible for providing or funding the provision of health services in their district.
	Ministry of Social Development	Responsibility as a government department to lead social development.
	National Health Board	Whole-of-system health planning, advice, and funding district health boards.
	Health Research Council of New Zealand	Responsible for managing the Government's investment in health research.
	Statistics New Zealand	Leader of the Official Statistics System and is the major producer of official statistics in New Zealand.
<b>Israel</b>	Ministry of Health	Responsible for population health and the overall functioning of the health care system.
	Health plans	Non-profit-making health funds: Clalit, Maccabi, Meuchedet and Leumit.
	Israeli Law, Information and Technology Authority	Central knowledgebase within the Government for technology-related legislation and large governmental IT projects.
	Scientific Council of the Israel Medical Association	Responsible for the specialty certification programs and examinations, in coordination with the Ministry of Health.
	Israel Center for Disease Control	Collecting and analyzing updated health-related data.
	Central Bureau of Statistics	Performs statistical activities and projects regarding the State and its population, also in the fields of health and wellbeing.

<b>Canada</b>	Health Canada	Federal ministry of health, promoting overall health, disease surveillance and control, food and drug safety, and medical device and technology review.
	Public Health Agency of Canada	Responsible for public health, emergency preparedness and response, and infectious and chronic disease control and prevention.
	Canadian Institute for Health Information	Independent, not-for-profit organization that provides essential information on Canada's health system and the health of Canadians.
	Canada Health Infoway	Federally funded, not-for-profit organization <b>working</b> with the Canadian provinces and territories to co-fund the implementation of electronic medical records and other digital health projects.
	Statistics Canada	Central statistical office.
	Canadian Institutes of Health Research	Premier federal agency for health research.
	<b>Australia</b>	Council of Australian Governments
COAG Health Council		Responsible for more detailed policy issues and is supported by the Australian Health Ministers Advisory Council.
Department of Health		Oversees national policies and programs.
Office of the Australian Information Commissioner		Responsible for privacy functions that are conferred by the Privacy Act and other laws.
National eHealth Transition Authority		Working to establish interoperable infrastructure to support communication across the health care system.
Australian Institute of Health and Welfare		National agency to provide reliable, regular and relevant information and statistics on Australia's health and welfare.
Australian Bureau of Statistics		National statistical agency, providing trusted official statistics on a wide range of areas.

# Additional information

There are many useful and interesting reports, research papers and other sources of information available related to the matter of this report. Next there is listed some of the relevant sources of additional information for all of the reviewed countries that are available. All the additional information is in English and freely available on the internet.

## All countries

- [International Profiles of Health Care Systems 2015](#)
- [International Review of Secondary Use of Personal Health Information 2012](#)
- [Code of practice on secondary use of medical data 2015](#)
- [Strengthening Health Information Infrastructure for Health Care Quality Governance](#)

## UK (England)

- [NHS Choices](#)
- [NHS Health Research Authority: Research legislation and governance](#)
- [UK Department of Health](#)
- [Health & Social Care Information Centre](#)
- [Overview of the national laws on electronic health records in the EU Member States, National Report for the United Kingdom \(England\), 2014](#)

## Netherlands

- [Netherlands Ministry of Health, Welfare and Sport](#)
- [Netherlands institute for health services research](#)
- [The National Health Care Institute](#)
- [The Dutch Healthcare Authority](#)
- [Overview of the national laws on electronic health records in the EU Member States, National Report for the Netherlands, 2014](#)

## New Zealand

- [New Zealand Ministry of Health](#)
- [National Health IT Board](#)
- [Independent review of New Zealand's Electronic Health Records Strategy, 2015](#)

## Israel

- [Health Systems in Transition, Israel 2015](#)
- [Israel Ministry of Health](#)
- [Health Services in Israel, 2015](#)

## Canada

- [Accessing Health and Health-Related Data in Canada 2015](#)
- [Canada Health Act Annual Report 2014-2015](#)
- [Health Systems in Transition, Canada 2013](#)
- [Health Canada](#)
- [Canadian Institute for Health Information](#)

## Australia

- [Australia Department of Health](#)
- [Health Systems in Transition, Australia 2006](#)
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