OECD HEALTH POLICY BRIEF

BETTER POLICIES FOR BETTER LIVES

Strengthening Health Information Infrastructure For Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges: Key Findings

Balanced privacy rights and rights to health and health care are needed to enable the regular use of health data to improve health outcomes and the performance of the health care system

Privacy-respectful uses of data for health, health care quality and health system performance monitoring and research must become widespread, regular activities

Health data is a significant potential resource in OECD countries: to improve population health and to improve the effectiveness, safety and patient-centeredness of health care systems, as well as to promote innovation and economic development in an increasingly significant part of the economy.

Some countries have been able to balance privacy rights and rights to health and health care in a way that permits privacy-respectful data use for monitoring population health and the quality of health care. There are very good reasons for allowing data use, including to improve health outcomes and patient safety and to make good decisions about the wise use of health care resources. In other countries, well-intended laws and policies to protect privacy and to reduce the potential misuse of personal health information have limited data use.

The consequence is a big difference in the ability of countries to monitor and improve health care quality and health system performance. For example, one-half of OECD countries surveyed have regular programs of health care quality monitoring involving linked patient data and one-half of countries are only beginning to use data from electronic health records for health and health-care monitoring.

Variation in country practices is linked to risk management in granting an exemption to patient consent requirements when seeking consent is impossible or infeasible; in sharing identifiable data among government authorities; and in project approvals and granting access to data.

Policies and practices enabling privacy-respectful data use are needed to strengthen national information infrastructure. To develop international studies comparing health care quality and health system performance, actions are needed to reduce unnecessary differences in data protection practices.

When reforms are proposed, their impact on health and health care statistics and research must be given consideration. In so doing, there can be a conscious balancing of both privacy rights and rights to health and to safe and effective health care.

Strengthening health information infrastructure matters

Understanding the quality of health care and the performance of health care systems requires the ability to monitor the same individuals over time, as they receive treatments, experience improvements or deteriorations in their health and live or die. It also requires understanding the distribution of health and health outcomes across different groups in the population and understanding variations in care quality and health outcomes.

This work has a few, very important, prerequisites. First it depends on the collection and storage of data at the level of individual patients (for an entire population of patients or

for a representative sample). Second, it relies on the capacity to follow individual patients across the care continuum. Following patients through different events to understand, for example, adverse drug reactions, medical errors, poor primary health care, deaths following treatments, and ineffective treatments often requires the linkage of patient records across databases. This evidence can be used to improve health outcomes and patient safety, to improve guidance to clinicians on the most appropriate care and to make good decisions about the wise use of health care resources.

National information infrastructure is improving

National data infrastructure is improving across countries and the technical capacity to analyse and report from personal health information data assets is greater today than it was five years ago.

National databases with individual-level records are available across the spectrum of health care administration, as well as from population health surveys and registries/censuses (Table 1). To follow patients through the care pathway, and thus from one database to another, identifying variables are required. Many countries have a unique patient identifying number or UPI available for patients or persons within national hospital in-patient, primary care, cancer registry, prescription medicines and mortality databases (Table 1). A greater number of countries reported other identifying variables, such as names, dates and addresses that may also be used to enable data linkages.

Case studies included the OECD report demonstrate how countries protect patient privacy whilst linking and analysing personal health data to report on the quality and cost-effectiveness of treatments; to address underuse, overuse and misuse of therapies; to reduce variation in care practices; to assess and revise clinical care guidelines to ensure that recommended clinical practices are really the best practices; and to manage health expenditures (See Box I).

Table 1: Number of countries reporting linkable data and reporting data use

	Hospital in-patient data	Primary care data	Cancer registry data	Prescription medicines data	Mortality data	Formal long-term care data	Patient experiences survey data	Mental hospital in-patient data	Population health survey data	Population census or registry data
National database available…	19	16	17	14	19	16	11	17	19	19
Contains records for patients or persons	16	13	16	12	17	13	7	14	16	16
Contains a UPI that could be used for data linkage	14	12	13	12	14	11	1	12	11	11
Contains other identifying variables that could be used for data linkage	14	12	16	12	16	12	3	15	11	15
Is used for data linkage studies	14	10	13	12	15	11	1	8	10	11
Is used regularly for data linkage studies	12	8	11	10	15	6	1	7	7	11
Is used regularly for data linkage studies to *monitor health care quality*	12	4	11	7	12	4	1	5	4	4

Note: The data custodian should be a national authority and data should be included even when it does not cover 100% of the nation.

Source: OCED HCQI Questionnaire, Secondary Use of Health Data, 2011/12.

Country variation in data use linked to differences in risk management

Half of OECD countries surveyed are engaged regularly in data linkage studies to monitor health care quality (Table 1) and about half are beginning to use data from electronic health records for national health and health care monitoring. Risk management in any decision-making process involves identifying the risks and evaluating their potential costs and benefits. It does not imply avoiding all risks, but making an informed decision under uncertainty. Uncertainty is unavoidable in decision-making about the collection and use of personal health data. The core challenge is for countries to identify and weigh the tradeoffs among data risks and data utilities. This balance is reflected in Figure 1 as the point where best practices in data collection, linkage and analysis are identified and implemented, providing the optimum risk/return trade-off. This trade-off will be specific to the context of individual countries.

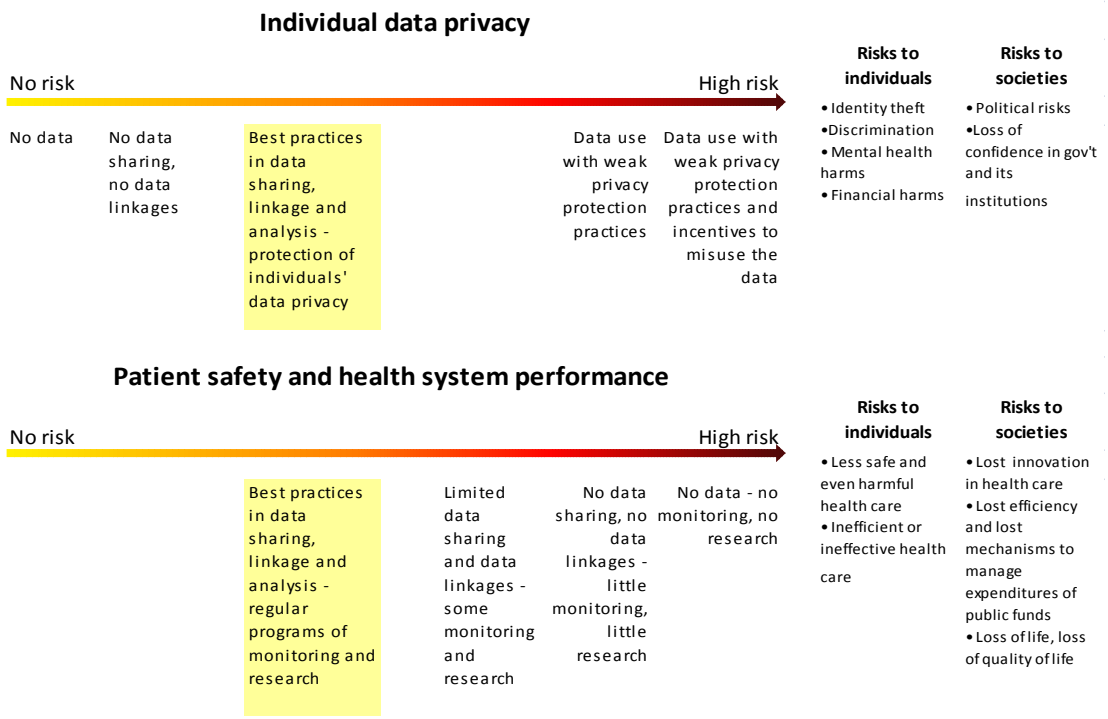
To protect the population from the spread of infectious diseases, many countries have weighed the risks and have incorporated terms within their legislative frameworks to make explicit the need for some loss of individual data privacy in the event of a disease outbreak. ***For the monitoring of the quality and safety of health care, the weighing of risks in decision-making about legislative frameworks has not always received the same attention.*** This OECD study revealed three key areas where significant cross country differences in the use of personal health data could be attributable to differences in risk management: (1) use of personal health data when obtaining patient consent is impossible or cost prohibitive; (2) sharing of identifiable personal health data among government authorities; and (3) approval of projects involving the linkage of personal health data.

Informed consent has become the pillar for protecting individual's autonomy where research involves human subjects. Informed consent requirements in legislation build from professional codes of practice. Informed consent presumes the ability to indicate clearly to a participant the use and the purpose of a particular research activity. This is feasible for a purpose-specific study, such as an invitation to patients to participate in a clinical trial or a survey.

The requirement to obtain patient consent presents ***significant challenges for health and health care monitoring and research involving large, historical population and patient databases.*** These databases were originally collected for other purposes, such as administering the health system or providing clinical care and represent hundreds of thousands to millions of persons. The retrospective collection of patient consent implies that useable data will be biased toward younger/healthier patients and those who are easier to re-contact, which can reduce the validity and the utility of the findings. Further, attempting to reach large cohorts can be impractical and requires, often significant, financial resources.

This OECD study found considerable variability across countries in responding to the problems involved in retrospective patient consent for studies requiring the linkage of patient records among historical and large personal health databases. While some allow for exemptions to patient consent requirements for projects in the public interest, others do not.

Figure 1: Risks associated with the collection and use of personal health data



While providing a unifying framework, ***the EU Data Protection Directive (Directive 95/46/EC) left considerable freedom to EU countries regarding whether to apply, restrict or extend the rules on processing sensitive data***. Several European countries indicate that approval to use the data without patient consent would be granted at the level of the national data protection office and that it is very difficult to obtain approval without first introducing authorizing legislation for the project itself (Belgium and Italy). In Germany, personal health data may only be used with patient consent or when authorised by law or regulation. In Portugal, record linkage is illegal in the absence of authorizing legislation. Poland has not established a legal basis for national data linkages and has no reportable national data linkage projects.

In some European countries (France, Sweden, Denmark, Finland and the United Kingdom) data protection legislations set out the framework within which identifiable data may be processed without informed consent. Decision-making on individual projects may be delegated to data custodians or to national approval bodies who weigh the risk trade-off between individual privacy and monitoring and research that is in the public's interest.

Other federal countries, such as the United States, Canada, and Australia, have a complex web of legislations at the level of the nation, states/provinces, and local areas. In general, national data custodians in these countries may have their role incorporated within legislation that then enables them to set up an internal process for decision-making for individual projects.

Korea and Singapore have legislative frameworks that set out conditions where public data custodians may process personal health data without consent. Japan, on the other hand, has not established a legal basis for national data linkages and has no reportable national data linkage projects.

Data sharing and project approval mechanisms are necessary

Databases of key health information may be in the custody of various actors within countries, such as national statistical offices, ministries of health, regional health care authorities, research organisations, insurers, hospitals etc. Each of these custodians has the authority necessary to collect, analyse and disseminate information for monitoring health and health care and play a critical role in decisions about data use. ***Where there are multiple data custodians, there must also be*** legal frameworks and information custodian policy frameworks that provide for ***the possibility of safely sharing identifiable personal health data.***

There are difficulties in negotiating data sharing arrangements among government ministries, with negotiations either unsuccessful or taking years to negotiate. Concerns about legislative barriers to the sharing of identifiable personal health data were signalled by Poland, Portugal and Italy. Lengthy and complex processes to reach agreement for data sharing among public authorities were reported in the United States, Canada, Australia and Germany.

In all countries where governments engage in linkages of personal health data, there are processes to consider approval of data linkage projects proposed by researchers within and outside of government, such as academic researchers. There are variations across countries in the decision-making authority for projects. In some countries, the decision to approve the use of personal health data for a data linkage project is made at the level of the data custodian (Australia, Canada, Singapore, Finland, Sweden, Scotland, and the United States). Other countries delegate the approval of data linkage projects to a national authority. In Belgium, Finland and Denmark, the national data protection authority approves data linkage projects proposed by government ministries and by private entities. In England, a national decision-making body has been delegated this responsibility.

In countries with decentralized administration of health, there is also often decentralized decision-making on the approval of projects involving personal health data (Australia, Canada, Germany, Italy and the United States). For example, in Australia, there are efforts underway to permit data collected and linked at the state level to be amalgamated at the national level, creating the potential for analysis and reporting at a national level and also for data linkage projects with national data in the custody of the National Institute for Health and Welfare. The project is challenging because legislation and governance vary across the Australian states.

Multi-country studies have been limited

Multi-country studies can provide a rich source of information for the benefit of the public's health and the management of health systems. ***Multi-country projects*** also ***pose challenges for data protection,*** as the data custodians involved typically have no legal recourse to exert any penalties for misuse of data by a foreign entity. Multi-country projects are also difficult for research teams to implement, as the data protection requirements of each participating data custodian must be respected.

In some EU countries study respondents noted that their data protection legislations make it possible to share identifiable data with another EU country. Nonetheless, few European countries have engaged in projects where de-identified health micro data were shared across borders.

Outside of Europe, the United States National Centre for Health Statistics can provide a foreign researcher with access to de-identified individual-level data; however, the process of de-identification is very strict.

There are examples of parallel studies where researchers within several countries each independently conducted analysis of linked personal health data following a common study protocol. Most of these studies were related to cancer treatment outcomes and survivorship. The European Health Care Outcomes, Performance and Efficiency project (EuroHOPE) stands out as it aims to evaluate the performance of European health care systems in terms of outcomes, quality, use of resources and costs through the linkage of hospital, pharmaceutical, cancer registration and mortality databases and the EUropean Best Information through Regional Outcomes in Diabetes (EUBIROD) project stands out as it aims to implement a sustainable European diabetes register.

Data security and access efforts are extensive and costly

In all countries, ***data security and the protection of data confidentiality are given considerable attention by data custodians.*** Nonetheless there is variation across data custodians in the data security measures that have been put into place. Challenging areas for data custodians include finding acceptable mechanisms to de-identify data, so that it can be accessed and used for monitoring and research and still protect privacy; and finding appropriately safe mechanisms to give researchers access to the data.

In many countries, data custodians are responsible for vetting project proposals for the use of data; maintaining a technical capacity to undertake data linkages and to de-identify data; providing data access modalities to internal and external researchers; and ensuring that through all of their activities the legal requirements for data security and data privacy protection are respected**.** ***In several countries, fulfilling these responsibilities is expensive and pressure is mounting to trim expenditure*****.** Expenses are particularly heavy in countries with decentralised administration of the health system.

A few countries provide interesting examples of centralising the difficult tasks of linking data, de-identifying data, approving access to data and supervising access to data. In the United Kingdom, Belgium, Australia and Finland, trusted third parties have been engaged to conduct data linkages and to de-identify linked data for use by government and external researchers. The development of dedicated linkage centres is a strategy that could be further explored to both enhance and standardize data privacy protection and to reduce costs otherwise born by individual data custodians. The United States, Canada and Singapore have established secure supervised facilities where researchers can access de-identified data that carries a higher re-identification risk. The United States and Australia have also established a secure remote data access option for researchers where they may submit programs to analyse de-identified data and receive outputs. Canada is piloting this approach and such an approach is part of a new initiative in Scotland.

Implications and next steps

Requiring patient consent for each project involving the processing of large existing population databases is a barrier to setting up comprehensive and evolving programs of health care quality monitoring and research. Some countries legislative and policy frameworks for data protection allow for the possibility of an exemption to the requirement for patient consent for projects in the public's interest. Those countries without such provisions should consider having them.

Another key element of this issue involves defining what constitutes acceptable patient consent as countries move forward to collect new population health and health care administrative data that may be used for future health and health-care monitoring and research. More generalised patient consent approaches

would enable a broader range of future monitoring and research.

Data from decentralized systems must be brought together to support national information infrastructure and capacity for data linkages at the level of the country. When data-sharing agreements take years to negotiate or cannot be negotiated, there will be fewer initiatives to monitor health and health care quality requiring data linkages.

If, as a result of a lack of centralisation, government ministries and private entities must seek approval from many different data custodians to conduct one project, it will be very difficult to undertake a national project involving the use of personal health data***. Data custodians are challenged in meeting all of the requirements of data protection legislations and policies,*** due to resource constraints and a lack of recognised best practices in difficult areas such as data de-identification processes, and secure data access modalities. Further complicating the approval process are factors such as inconsistent or unavailable communication from data custodians on the process to seek approval, on the requirements of an applicant, or on the access modalities that are possible.

New forms of centralised approaches to project proposal review and data linkage services are very interesting developments. Not only do these help to standardize requirements and practices for both the government and external researchers, they have the potential to be more efficient.

Managing risk is clearly difficult in the area of multi-country projects and there has been little progress. The benefit of developing legal and practical mechanisms to enable multi-country projects to proceed in a manner that minimizes risks to the privacy of personal health data would be to promote improvement across OECD countries in patient safety and health system performance. Further, it is very difficult to understand and uncover data quality problems in international data comparisons when the underlying data cannot be viewed or evaluated.

A particular worry across countries today is that legislative reforms that are on the horizon, or that may be stimulated due to the implementation of electronic health record systems, ***may limit the progress that has been made in enabling access to and use of personal health data for research.*** A second worry is that a transition to reliance on data from electronic health record systems has the potential to set back the quality of national databases, by creating holes in the health care pathway or lowering the quality of the data elements, such as the coding of diagnosis. A widely reported barrier to the use of data from electronic health record systems is concerns with the quality of the data, including both a lack of coded data and poorly coded data.

In the coming years, the OECD will continue to support countries in reaching the goal of strengthening health information infrastructure so that privacy-respectful uses of data for health, health care quality and health system performance monitoring and research become widespread, regular activities.

An important step will be to ***support countries in reducing unnecessary obstacles to data use*** that can arise from differences in legislations regarding the protection of health information privacy and differences in the interpretation of what is necessary and helpful to assure that patients' privacy rights are respected in the conduct of health monitoring and research. Future work will aim to examine whether a risk classification of data and data uses can be applied to identify cases of higher risk to patient's information privacy and to associate recommended data privacy protection practices to be used for research and monitoring.

Box I: From data use to evidence for decision-making

The PERFECT study in Finland ***monitors the content, quality and cost-effectiveness of treatment episodes*** in specialised medical care and thus contributes to monitoring health-system performance. Indicators and models were created to monitor the whole cycle of care and outcomes for disease groups and procedures (stroke, premature newborns, hip fracture, breast cancer, schizophrenia, acute myocardial infarction, and orthopaedic endoprosthesis including hip and knee replacement surgery, and invasive heart surgery). Results have contributed to changes in law and government policy and have been used within hospitals to improve the quality of care.

Korea's quality assessment of medical services includes assessment of the clinical appropriateness and cost effectiveness of health care by ***reporting on quality and inducing service providers to make improvements in response to the evidence***. Indicators include thirty-day case fatality for acute myocardial infarction; thirty-day post-operative mortality for major types of surgery; hospital re-admissions for mental-health patients; prescribing patterns and outcomes in primary care; and health outcomes of prescribing to mental-health patients. The program aims to identify underuse, overuse and misuse of therapies and to reduce variation in care practices through the regular reporting of quality indicators. There are also quality and efficiency assessments of clinical care guidelines in Sweden. For areas of care subject to national guidelines, such as cardiac and stroke care, data linkages are undertaken to develop indicators to evaluate the effectiveness of recommended therapies and the evidence contributes to revisions of the care guidelines.

In Germany there are projects to ***evaluate the effectiveness and safety of breast cancer screening***. A new follow-up of both women who participated in a clinical trial involving screening and those who were unscreened will assess the benefits and potential adverse effects of exposure to mammography screening to provide evidence to develop early detection guidelines for mammography screening. Belgium also has several studies underway where data linkages are generating new information about quality of care and outcomes for cancer patients.

Israel is linking data to ***examine quality of care for colon surgery patients*** by measuring post-operative infections, re-hospitalisations and deaths. Israel has also explored mortality among psychiatric patients in order to improve community mental health care.

Data linkage projects in the United Kingdom were initiated to ***overcoming gaps in existing information*** to provide a more comprehensive and consistent picture of maternity outcomes. England monitors hospital standardized mortality ratios that will be replaced, in future, with a summary hospital-level mortality indicator (SHMI). England produces a thirty-day post-operative mortality rates for patients following colorectal cancer surgery. Scotland reports using linkage to monitor outcomes of care, such as readmissions and deaths among coronary heart disease patients.

Australia has explored ***care transitions for older people with chronic health conditions*** including the factors influencing pathways and, particularly the entry into residential care. A new study in Australia is investigating the health effects of exposure to low-dose radiation from CT scans in childhood. To extend the information available about pathways of stroke care beyond the acute care setting, a pilot data linkage project is underway in Canada. Denmark is exploring wait times in cancer treatment pathways.

Singapore reports a national program to ***monitor the quality of primary care for chronic disease management*** by examining health care providers' adherence to recommended care processes as well as their success in preventing hospitalisations related to chronic condition. Singapore regularly monitors health care quality through indicators including annual rates of 30-day mortality inside and outside of hospital following hospitalisations for Acute Myocardial Infarction and Stroke.

There are also initiatives underway to build a firmer foundation upon which studies of health system performance may be based. To ***monitor and study health care consumption and expenditures*** to inform policy decisions, Belgium and France have developed a permanent sample of socially insured persons via the linkage of health care reimbursement invoice data to create longitudinal histories of health care encounters. In Switzerland, a linkage of population census data and mortality data is enabling a better understanding of the socio-economic and socio-demographic characteristics of mortality and life expectancy and forms a base cohort from which additional data may be linked for specific, approved, studies, such as ***socio-demographic differences in cancer survivorship and outcomes***.

In the United States, the National Center for Health Statistics has built ***a platform to support health and health services studies***, including a repository of surveys that have been prepared to support linkage projects and two key linkages: the linkage of population health survey data to mortality data; and the linkage of population health survey data to data on health care encounters for Medicare and Medicaid insurance beneficiaries. In England, there is an initiative to support health care quality improvement by facilitating research involving personal health data that is in the public's interest. The service can both produce tabulations and conduct data linkages on behalf of clients with approved projects.