Chapter 8

Progress and challenges in use of personal health data

There is optimism among most study respondents that national health information infrastructure is growing stronger and more capable of supporting health and health care monitoring and research. The technical capacity to undertake data linkage studies is growing and there is optimism about the potential for data from electronic health record systems to be used for health care quality monitoring. Respondents from six countries, however, indicated that it has become harder to use personal health data to monitor health and health care quality over the past five years. Respondents from five countries indicated that it is unlikely or impossible that any data from electronic health record systems will be used for national health care quality monitoring over the next five years. 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 turn back the clock on the progress that has been made in enabling data linkages and providing access to linked data for research. A second worry is that the quality of data within electronic health records presents a barrier to the creation of national databases. Resource limitations, and not meeting expectations of timeliness, are worries among bodies that approve project proposals and among bodies that conduct data linkages on behalf of others.

This chapter presents overall views of the participants to the OECD study of the secondary use of personal health data followed by views about the future use of data from EHR systems from participants to the OECD study on electronic health record system development.

In general, the outlook for the future is positive in terms of the opinions of the experts and researchers interviewed in this study toward their country's technical ability to undertake data linkages to monitor and report on the health of their people and the quality of their health care. Many countries were also positive about future capability of extracting data from electronic health record systems for health care quality monitoring and research. There is nearly universal agreement that data infrastructures are growing stronger and more capable of supporting this type of work. Many were also of the view that some of the growing pains associated with working with data protection authorities to arrive at ways of working effectively together were passing and that the process for seeking approval and safely and appropriately undertaking data linkage studies was getting clearer on both sides. Nonetheless, many countries still face significant challenges.

Countries where it is becoming easier to use personal health data to monitor health and health care quality

All participants to this study (see Annexes A and B) were able to express their opinion about whether it has become easier or harder to use personal health data to monitor health and health care quality over the past five years. Respondents in *Australia, Denmark, France, Malta, Norway, Poland, Portugal, Singapore and the United States* felt it was becoming easier.

In *Australia*, privacy law reforms were among the recommendations from the 2008 Australian Law Reform Commission report, *For Your Information: Australian Privacy Law and Practice* (Australia, 2008). The report recommended a range of changes to improve Australia's privacy framework and acknowledged the value of research involving data on human subjects including health, education, justice and other domains. The report also acknowledged that it is relevant to engage in data linkage to support this research. As a result of this report, there have been recommendations that would make it easier to engage in health-related data linkage studies but the first of these are only just being implemented. The Australian Government recently established a set of principles that cover the integration (linkage) of national data for statistical and research purposes. Changes in the health policy environment may increase the demand for data and linkages in the future. For example, through data linkage it should be possible to identify the population that is using mental health care services and work is underway to develop this indicator. Australia is slowly moving toward improving the indicator set which may lead to greater use of data linkage in the future.

Strengths of the *Danish* information infrastructure for data linkage include its policy applications. Data linkage studies contribute to evidence-based decisions across a range of important policies from human resource planning for the number of doctors and medical specialists that will need to be educated today to meet the health care needs of the population in the future; to how best to roll out population-based screening for cancer; to where to focus efforts to control rising health expenditures and the degree to which changes in tax rates could play a role in improving the fiscal balance. Data linkages have

helped to demonstrate the effectiveness of breast-cancer screening in real-world populations and to understand the effectiveness of drug and alcohol treatment approaches. Through data linkage, *Denmark* is able to evaluate options for consolidation of hospital services in terms of their impact on the population served.

Processes for working with external researchers have been simplified in *Denmark*. For many years it has been possible for researchers to receive data from the National Board of Health, but it was not until 2007 that a unit was established within the NBH to handle the delivery of data to researchers. Four years ago, it became possible for scientists to request a running approval from the Data Protection Authority for data linkage. With this type of approval, they may have the same linkage repeated over several years and need not reapply to the DPA each time a linkage would be needed for the same project. An example would be a linkage to death certificates every year for several years for an on-going clinical cohort study.

France has had processes in place for many years to de-identify data for research and statistical purposes. The techniques used in France provide a high level of security for the data and the application of these techniques has been more widespread in France than is the case in other countries. France is working toward ensuring that data is processed in a systematic and consistent manner to permit it to be used for statistics and research to improve the health of the population. Electronic medical records are just being introduced in France and it will take years to achieve coverage of the population and to develop the information systems necessary to manage the data. Individual electronic records for pharmaceuticals are in the planning stage. Over the past five years it has become easier to conduct data linkage projects in France as the process for project approval becomes better established and understood. On the other hand, the databases and the data linkage techniques necessary to analyse them are becoming more complex. Further, France is grappling with the problem of the use of different unique identifiers between health insurance and hospital and electronic medical records. Solving the problem will involve both technical strategies and decisions about information governance. The reform of the EU directive on the protection of information privacy still requires study; however, it is unlikely to have a substantial impact on the current practices of the data protection authority (CNIL).

In 2011, there was a public health scandal in France as a result of the use of a prescription medicine Mediator that was directed toward diabetic care and was also prescribed for weight loss. The drug had been widely prescribed and then was later determined to have increased the risk of serious cardiovascular problems and to have resulted in deaths. The scandal heightened awareness in France of the need to use databases about the health of people to monitor the health consequences of prescription medicines and to move toward resolving the problem of the lack of a unique identifier, and the associated issues about information governance, that are limiting this work at present. The Institut des Données de Santé (IDS) facilitates the use of health data for public health by bringing together the different parties that constitute the health care system in France. In December 2011, a decree was published that facilitates access to national primary care data (SNIIRAM) for both public health organisations and research centres working in the field of public health.

In *Poland*, there are commitments to protect the privacy of personal information within the constitution, as well as legislation that protects privacy in the processing of

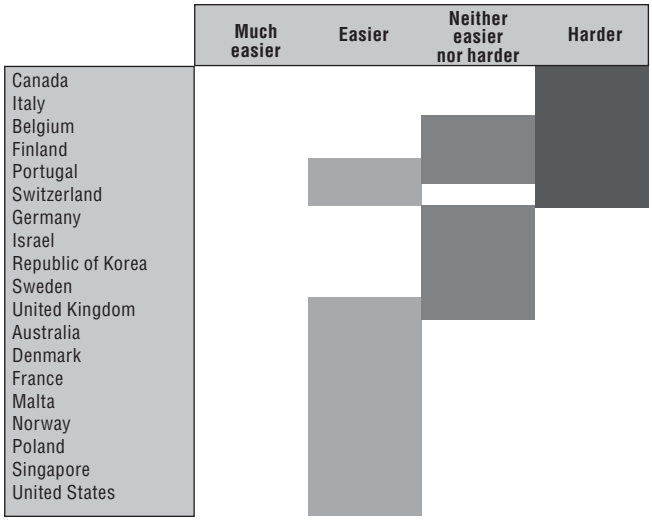
personal data. In practice, it is not possible for data custodians to share data containing unique person identifying numbers, nor to use these numbers for any data linkage projects. It is, however, possible to conduct probabilistic linkage based on other identifying information. Other limitations to data linkage projects in Poland relate to concerns with the quality, timeliness, coherence and comparability of the data. Data quality concerns include redundancy in data collection and incoherent standards for data collection and dissemination; the inability to collect information where and when it is needed; the on-going use of paper-based registries; IT systems that have not kept up with organisational changes; difficulties managing data due to incompatible IT systems across organisations; and the lack of inclusion of data users in the design of IT systems.

There is optimism in Poland, however, that it is getting easier to use personal health data to monitor health care quality. There is a pilot project to link the cancer registry to data on breast cancer screening. There is also work in progress to develop a national electronic health record system "eHealth Poland" from 2011 to 2015. The project's goals include to create IT conditions that would enable a long-term perspective to support health care policy decisions; to develop a sustainable IT system that would permit consistent data collection over time; to decrease information gaps preventing an optimal health care model; and to have a system of data collection, transformation and use that would permit data exchange; reduce redundancy in data collection; support the secondary uses of data and information for statistical purposes; and decrease the administrative burden of data collection and data collection costs.

The *United States* is behind other OECD countries in terms of infrastructure for health data linkage. It does not have a unique patient identifier for health care encounters; there are so many different data custodians; there are multiple and complex laws regarding the use of personal health data; and the United States has been slow to implement EHRs. One person was of the view that the United States is not meeting its responsibility for the public's health and that the population was unaware of the risks to their health that have resulted. For example, when an individual is in a health emergency, their care is similar to a battlefield response because their caregivers know nothing about them, including the medications they may be taking. Emergency response could be much safer with the secure sharing of medical records. There is a need to build awareness of the health consequences of not having a national health identifying number. For example, even among members of Kaiser Permanente, which has a high adhesion, people move in and out of the plan and their health records are incomplete. Medicaid recipients also move in and out of this plan. If there was a rolling back of eligibility for Medicare and Medicaid, there would be less information in the future. It is very difficult to understand health outcomes and health care quality as a result; and this problem is the worst among the most vulnerable people, because that is where long-term adhesion to particular insurance plans is the lowest.

Two of the important barriers to a UPI in the United States are the public's trust in the use of their personal information in general, and the public's trust in government's use of personal information. Another challenge is the separation of state rights from federal rights, so that the federal government may not necessarily dictate what the states must do. Further, Congress, who allocates resources for federal agencies, is not always aware of the benefits to government of information from data linkages. This awareness is starting to rise with, for example, the opportunity to analyse survey data linked to Medicare and Medicaid records to identify the utilisation of care and the cost of care for vulnerable

Figure 8.1. **Over the past five years, has it become easier or harder to use personal health data to monitor health and health care quality?**



Note: In some countries there were differences of opinion and all responses are reported. No opinion was expressed by Japan.
Source: OECD HCQI Questionnaire on Secondary Use of Health Data and Follow-up Telephone Interviews, 2011/12.

populations so that federal spending on these programmes can be allocated more efficiently.

In the United States, linkage is improving from a technical viewpoint. Computers are getting faster and there have been improvements in linkage methodologies that have made linkage projects easier to do. The analytical file from the linkage of population survey data to Medicare and Medicaid records at the NCHS is proving to be a challenging file to analyse. Methodological challenges result because the number of observations is affected by both the number eligible to link and the number eligible for government programmes and there is a project-by-project necessity to re-weight the data to correct for bias. An on-line tutorial is being developed to help researchers to use the data.

As a result of the Affordable Care Act, there will be greater need to provide evidence of the impact of the Act. There are great expectations that data linkages will help to inform health policy, particularly in the area of effectiveness of care. If linkage studies in the next few years can show benefits to policy, data linkage will take off. There is a governmental push for EHR systems. With many commercial software developers, there is a need to promote uniformity so that interoperability will be possible. On the horizon is also the use of genetic information from bio-banking in long-term epidemiological research. It may take 20 years or more of exposure to tobacco smoke, dust, and air pollution to develop diseases. It therefore will take long-term linkage studies with genetic information, information on environment exposures, and information on health and health behaviours to know what factors are responsible for disease and to develop good policy responses. Future studies may involve a greater use of devices such as accelerometers to measure physical exertion or other devices to measure air quality and noise.

In *Singapore*, the data linkage projects that have taken place have had an impact on policy. At first, there were small sub-national studies and national efforts focussed on standards for data and data coding to improve the quality of person-level health databases. Once the quality of the databases was high, the door was then open for high-quality data

linkages to monitor the performance of the health system. For example, stroke care quality is not just about care at the time of the acute event, it is about seeing how patients are doing six months later. Similarly, linkages have permitted evaluation of the effectiveness of breast cancer screening. Through linkages there is better sight on blind spots at the national level that helps with a better assessment of how the health system is performing. For example, it is possible to monitor whether persons suffering from heart attacks were known to suffer from hypertension and diabetes and whether these conditions were being well managed in primary care.

It has taken time to develop a process for application and review of research proposals in Singapore that conforms to the legislative framework; and to arrive at the establishment of a secure data lab. It is on-going work to be respectful of privacy and to find the right balance between data protection and access. This is because new types of projects keep coming up that have never been considered before, including, for example, new projects where researchers may want cross-sectoral linkages. As new models of care develop, it will be important that there remains data available to follow a patient's care path. In Singapore, a new Personal Data Protection Act came into effect in January 2013 to provide governance of the collection, use and disclosure of personal data. There is also a roll-out of a national EHR and there is a question of whether or not this could require additional legislation that would complement the Personal Data Protection Act. There is potential to create confusion with too many pieces of legislation related to data protection. Singapore has acquired a national license for SNOMED-CT and is in the midst of incorporating the terminology into the national EHR and institutional EMR systems. It will be important to ensure that coding is appropriate, so that the data quality is high and research results are valid. As more data becomes available in Singapore it may be necessary to consider a single body for conducting data linkages. The advantage would be economies of scale and standardisation of linkage methods. Running data protection offices within each data custodian is expensive. A disadvantage could result from this approach, however, if it failed to service research needs in a timely fashion.

Countries where it is neither easier nor harder today than five years ago to use personal health data to monitor health and health care quality

A second group felt that it was neither harder nor easier to use personal health data to monitor health and health care quality today than five years ago (*United Kingdom, Sweden, Israel, Korea, and Germany*). Views about the United Kingdom ranged from easier to neither harder nor easier.

Korea notes that its strength comes from a unique identifying number that is used throughout the health care system; a national system of health insurance that provides health care data for all patients; and a very strong technical infrastructure, where data is captured and stored electronically. The identifying number in Korea provides additional information to strengthen data linkages including full date of birth and place of birth. The conduct of data linkage has provided great benefits to Korea. Through analysis of health care claims, Korea is able to report on the quality of services provided by physicians, clinics, hospitals and long-term care. The Health Insurance Review Agency (HIRA) is also able to report on the cost of services and, with both quality and cost information, provide evidence for policy decisions. About ten years ago there was little discussion of protection of data privacy in Korea. With the new legislation and increased awareness, the balance between respect for patient privacy and the need for health research is sounder today.

It has never been easy to undertake data linkage studies in *Germany*. While scientists have always been aware of the benefits of data linkage studies, there is a rising awareness among authorities of the benefits to policy. The mammography screening study that was mandated by law is a good example of this rising awareness. Moreover, in 2011, legal provisions that allow data from a "morbidity-oriented risk adjustment scheme" of the statutory health insurance system were introduced that allow this data to be used for health services research and to advance the statutory health insurance system. Another point of progress are the recently awarded scientific grants from German Cancer Aid, a non-governmental organisation that awards scientific grants for research projects with cancer registry data, some of which involve record linkage with other data sources. The awards signify recognition of the scientific value of data linkages. Germany is doing well in the field of cancer registration in an international context. Since 2006, Germany has cancer registration for the complete population of 80 million people. The quality of data linkages based on pseudonyms and a limited number of other identifiers available from German cancer registries remains questioned by some. Certainly the probabilistic linkages are costly. It remains unclear whether or not the changes that would be required to enable deterministic linkages in Germany would be supported by the population.

In *Sweden*, the coverage of the health care quality registers is better now than five years ago and it has not become harder or easier to undertake data linkage studies. The project to assess the impact of guidelines on processes of care and on patient health was requested by government and the results have been taken seriously. Because there are public quality reports for hospitals by name, the conduct of the assessment alone has lead to quicker adoption of care guidelines in hospitals. There is increasing interest in the benefits of cross-sectoral studies in Sweden with data on social care and education to better understand the needs and the health outcomes of particular groups in the population and any differences in health care quality for different groups.

The government of Sweden is considering new legislation regarding access to data and data linkages. The new legislation is to address the issue of commercial interests wanting to access personal health data. In particular, insurance companies are interested in using personal data to decide on when to approve or deny coverage. While this is an important issue, the concern is that the new legislation may have a negative impact on research that is in the public interest.

In *Israel*, there remain some impediments that limit analysis of personal health data for health care quality monitoring. While Israel has an ID number that is used throughout the health care system, some of Israel's databases important for health care quality monitoring have encrypted the ID number and others have not done so. Without sharing among custodians of either the encryption methodology, or the unencrypted numbers, it is not possible to link these databases for statistical or research purposes. A further challenge is that health care quality monitoring requiring the linkage of primary care and hospitalisation data is possible within the HMOs within Israel, but is not undertaken at the national level. In general, HMOs do not share identifiable data outside of their organisation. Legal permission is necessary to receive any identifiable information in Israel and researchers external to government face this constraint.

In the *United Kingdom,* there is greater interest in and political support for data linkage studies now than five years ago. There is recognition that these studies can meet needs for greater transparency about the quality of patient care and can improve health research and

evaluation of outcomes of clinical trials. There is a new maternity strategy in Wales that has recognised there is not enough information on birth outcomes and infant health and pilot studies to evaluate whether data linkage could be used instead of primary data collection are leading to regular linkage programmes. In the future, the linking of lab data and medical images will become possible and, in Scotland, a national database for the storing of radiology images is already in place.

Compared to five years ago, the establishment of the legislative framework and the creation of the National Information and Government Board (NIGB) as a governing body helped to clarify for all researchers what is required to undertake a study and to provide a good mechanism to submit applications for consideration and approval. The new Health and Social Care Information Centre and the NWIS in Wales are now providing services to facilitate data linkages and linkages will likely be used more in the future as they are much less expensive than primary data collection. Concern was expressed about the pressure on existing resources as the research community becomes more aware of data linkage services.

From the perspective of researchers in the United Kingdom, it may seem that the approval process is long. It can take up to six months for a decision from NIGB and the Scotland NSS indicates that the average time from submission of an application to a decision is three months, with all applications finalised before six months. Resource constraints limit the Scotland NSS from being able to speed up the process. There have been a few instances of data loss in the United Kingdom that have raised public concerns about and interest in information governance, and have made data security and confidentially rules tighter and processes for applicants wishing to access databases more difficult. Recent reforms in England, such as the launch of the Clinical Practice Research Datalink and the establishment of the Health Research Authority, support researchers in navigating the approval process and improve efficiency in research approval decision making.

Countries where it is becoming harder to use personal health data to monitor health and health care quality

A third group felt that it was becoming harder to use personal health data to monitor health and health care quality (*Canada, Italy, Belgium, Finland, Portugal and Switzerland*). Views were divided in Switzerland between easier and harder; views in Portugal ranged from easier to harder; and views about Belgium and Finland ranged from neither easier nor harder to harder.

In *Canada*, data sharing among public authorities is becoming increasingly complex as new legislations are introduced at both the provincial and federal levels. Within Ontario, one of the first provinces to introduce legislation specific to the protection of health data privacy, the legislation has helped to clarify consent requirements and to end ambiguity about which law governed the work process. The introduction of electronic health records will pose new challenges.

The benefits of data linkage studies to public policy and patient care have been clearly demonstrated at the provincial level. The Institute for Clinical and Evaluative Sciences at the University of Toronto has published thousands of peer-reviewed scientific articles. Through data linkage at a population level, information is produced that informs about the effects of treatments in real-world populations with multiple morbidities which can differ

from results of controlled trials. There is evidence that research results have influenced policy and a good relationship with the Ontario Ministry of Health that appreciates that the study results help policy makers understand what can be done to improve the health care system. Further, there is rising interest among provincial policy makers in data to inform about the continuity of care and such information is made possible through data linkages.

There is growing interest in data linkages at the national level and a growing appreciation that data linkage adds information value to databases that is over and above their value as silos. The province of Ontario also reports a growing interest at the provincial and national levels in comparing across provinces and that discussion is underway on how to move forward using comparable data based on data linkage studies, and liberating data as has not been experienced previously. There is also growing interest in cross-sectoral data linkages to, for example, understanding how health effects educational outcomes of young people or to understand when a province should place driving restrictions on elderly people with Alzheimer disease. The province of Manitoba is leading the way for others in demonstrating the utility and importance of cross-sectoral linkages in Canada.

Canada notes that there is an emphasis on knowledge translation to government from research work so that research results contribute to evidence-based decisions. The inverse knowledge translation, where governments help to clarify for researchers the legal requirements related to the use of personal health data, needs the same attention. Within Canada, often people are saying the same thing but using different language and therefore not communicating clearly. There would be a benefit in developing clear definitions that are portable across provinces and in standardising the interpretation of laws.

Strengths of the *Italian* infrastructure include a large academic community and a long history of health and biological studies; established data flows for a spectrum of health services; universal health coverage which provides complete coverage of all patients in public data files; a unique identifying number that facilitates linkages; and an organisation of care where each person is assigned to a physician which makes it much easier to study their care path. A number of new databases are being developed by the Health Ministry including cancer screening, emergency services and mental health services that offer the potential to improve population health monitoring at the national level.

One of the challenges for Italy is the fragmented nature of the administration of the health system. There is no adequate mechanism to share data across territories and provinces in Italy and sharing is nearly impossible, even for official institutions. Researchers seeking funding from granting agencies for projects where individual-level data would be needed from regions face great uncertainty about whether the project they have planned could be approved. This is because the criteria used by the regions to evaluate proposals are not known. The approval process is not transparent for those without a government partner and many researchers seek funding or collaboration with public authorities in order to have confidence that their project could be approved. For example, the National Outcomes Project is linking hospital and death records to develop more accurate indicators of deaths following treatment. The National Agency for Regional Services (AGENAS) is assisting and coverage is improving, but still the linkage is occurring in only a few regions. While some regions have technical problems, many are unsure if they can legally share de-identified data for a national project. Further, the project is at risk from increasingly strict interpretations of privacy legislation that would only allow local authorities to link data for direct patient care. While regions have been authorised to

conduct research and analysis with registry data, there is a growing concern that the Privacy Guarantor may revoke this approval. This concern has put a chill on health research in Italy, as regions are becoming reluctant to participate in research studies. A concerning development is the emergence of views in Italy that there should be an irreversible split between patient identifiers and the information about patient health and health care. Should these voices influence authorities, any data linkage of individual-level data would become impossible for both regional and national governments.

Overall it is more difficult to conduct linkages in Italy today than it was five years ago. A consequence is that policy decisions are lacking a strong evidence base. For example, media reports on cases of medical errors alarm the public, but there is no national data on the extent of medical errors and whether the situation is improving or deteriorating. Policy focus is on expenditure control, and budget cuts may risk undermining health care quality or disease prevention. For example, the Abruzzo region, whose capital experienced a recent earthquake, has a large deficit and has experienced a sharp reduction in budget for health expenditures, including hospital closures and restrictions on pharmaceutical prescribing. This same region has published no report on the public health outcomes of this budget cut and lacks autonomous capacity to use its health information for public health monitoring.

Italy would benefit from clear guidelines from public authorities on the process to seek approval for a health research project and best practices in the processing of personal health information including data linkage. Greater transparency in procedures where information is shared with the public is needed, such as a check list available on a website. There is no office at the national level to fulfil this role. Further, if approval processes to link and analyse health data could be standardised among the regions, so that there was one process for approval in Italy, it would be a great improvement. Guidance from the European Union and the OECD could make clearer organisational approaches to providing access to personal health data; and the advantages for and the rights of the population in conducting analysis based on linked data. This could better inform local, regional and national authorities in Italy.

Belgium reports doing well compared with some of the challenges faced by other cancer registries. The registry has been able to satisfy the requirements of the Privacy Commission, while at the same time, preserving the quality of the registry. The new E-Health Platform provides a helpful service at no cost to the registry. The time required to attend to all of the required procedures and to prepare applications for the Privacy Commission, however, creates an administrative burden that is costly in terms of human resources. The Privacy Commission takes about three months from the receipt of a submission to render a decision. Sometimes, however, questions are returned and another three months will be needed. Further, whenever an external researcher proposes a linkage involving the cancer registry, the Privacy Commission holds the registry responsible. The cancer registry must work with the researcher to prepare the application and then have the proposal vetted by its internal review board for scientific merit and must declare to the Privacy Commission that they would be willing to provide the data.

Belgium has received a huge benefit to public health of having a registry and being able to produce indicators of health care quality. Analysis of the registry has influenced policy decisions and published results have contributed to scientific research. A further benefit of linkages is that they avoid the need to ask too much of physicians providing data

to the registry. Helping to reduce the burden on physicians is important; particularly as new disease registries emerge. Lastly, linkage and analysis of linked data provide new views of the quality of the data and reveal problems that otherwise would remain uncorrected.

Finland has invested in high-quality registers, has strong data protection legislation, and has a national identity number to facilitate linkages. Data linkages have had an impact on policy decisions in Finland. The PERFECT study on outcomes of hospital treatment in the year following the hospitalisation indicated that low birth-weight infants have higher mortality in non-university hospitals and a law was passed that all low birth-weight infants should be cared for in university hospitals. There have also been audits of lower-performing hospitals as a result of PERFECT study results. In *Finland*, there are plans underway to expand the current monitoring of the quality of hospital care to primary care, long-term care and social services.

Compared with five years ago, there is more bureaucracy around the preparation of record-linkage study proposals for approval by the Research Ethics Board (REB) and the time required to prepare the applications is not insignificant. The PERFECT project team is presenting a proposal to the REB almost every month, as any project that requires new data to be linked necessitates a new application to the REB.

Finland is challenged to keep its strength in data linkage studies. The legislation that enables the registries will need to be updated. The current legislation, from the late 1980s, enabled registries to grow and develop over time. For example, the legislation refers to data about health care activities, without narrowly specifying those activities. As a result, as new forms of care have emerged, such as outpatient care, the registries have evolved. The concern in Finland is that harmonising with EU legislation may restrict the content of the legislation when it is revised. Other concerns are related to staff and resource cutbacks that may limit the NIHW. Thus far, the NIHW has been able to find ways to keep costs down for external researchers by entering into research collaborations at no cost, and only recovering the cost of staff time for very time consuming requests.

Compared with some European countries, *Switzerland* may be viewed as behind in terms of its infrastructure for data linkage. However, Switzerland is privileged to have a full population cohort study that does not exist in many other countries. In Switzerland, there is increased sensitivity of populations to the protection of privacy and this is reflected in more restrictive guidelines that have made data linkages more difficult today than five years ago. Further, a law is being developed to create a national cancer registry. This law is likely to clarify patient consent requirements and may set the course for linkages in Switzerland with stronger patient identifiers. Nonetheless, there is concern that long-standing studies, such as the Swiss National Cohort, could be negatively affected if a determination was made that any of the limited set of identifiers the cohort team uses now for probabilistic linkages are no longer legal.

Switzerland is moving away from a questionnaire-based population census to a registry-based census. The data on the register will be updated annually and thus will provide much more up-to-date information on the population than the census did. The address register will also have Social Security Numbers (SSN). SSN are available on health insurance and mortality data. If it were ever possible in Switzerland to use an encrypted SSN to conduct deterministic data linkages, then there would be an important improvement in data quality and external researchers would be confident of linkages

executed within government. The Switzerland FSO is considering amending the ordinance to its authorising legislation to include collection of the SSN. This is as a result of a legal opinion of the Swiss Federal Data Protection and Information Commissioner's Office that the satisfaction of this condition would enable the FSO to use the SSN in data linkages. The Cancer Registry does not have SSN, however, and probabilistic linkages would continue to be necessary.

Data linkages create efficiencies and reduce the burden on health care providers. The FSO would like to extend current data linkage efforts from a focus on in-patient treatments to a focus on out-patient treatments in hospitals and day-surgery centres. This extension would increase the ability to monitor health care quality and would add valuable information that will likely increase interest in data linkage. Real statistical programmes are also more than just collections of data. The data needs to be made analysis ready with good information about the data and its quality; and the data elements included need to be of good quality and ready for use. The preparation of analysis-ready data is also part of the planning for the future of the health data programme.

Outlook on the use of data from electronic health record systems

Country participants to the OECD study (see Annex C) were divided on the extent to which it is likely that data from national electronic health record systems will be used within the next five years for national health care quality monitoring (Table 8.1). *Finland, Indonesia, Israel, Singapore, Sweden and the United Kingdom* consider it very likely that electronic health records will contribute to national monitoring over the near term. A further ten countries, *Belgium, Canada, Estonia, France, Iceland, Japan, Korea, Poland, Portugal, and Slovakia* consider this outcome to be likely. There is uncertainty in *Denmark, Slovenia, Spain and the United States*, and five countries consider this eventually to be unlikely or out of scope, *Austria, Germany, Mexico, Netherlands and Switzerland*.

Countries that view monitoring within the next five years as very likely

The national electronic health record system in *Finland* is well in operation and database creation and reporting is already incorporated within short term plans. Nonetheless, the implementation of electronic health records remains challenging as there has been on-going restructuring of the health care system. Health care providers are reluctant to invest their time and resources in updating their electronic record systems, if there is a risk that their hospital district, for example, will be reorganised in a few years time. Also, the new national EHR system is complicated and there are concerns with its usability. Further, the legal framework for health data protection and privacy in Finland is now out of date and does not cover new innovations in health care. The update of this legislation may pose challenges or changes to current practices in the secondary use of data from electronic health records. Finally, health care organisations have implemented electronic record systems from different vendors and the interoperability of all of these systems still needs further work.

The national electronic health record system is fully implemented in *Sweden* and, for many years, electronic health record data has been widely used for selected purposes and in restricted settings. However, problems with comparability and interoperability across jurisdictional settings still exist, including difficulties sharing data between social care and health care sectors. Legal requirements and restrictions on primary and secondary uses of electronic health records for specific purposes are important, as are values of openness

Table 8.1. **How likely is it that data from electronic health records will be used for national health care quality monitoring within the next five years?**

	Very likely	Likely	Unsure	Unlikely	Very unlikely
Finland					
Indonesia					
Israel					
Singapore					
Sweden					
United Kingdom					
Belgium					
Canada					
Estonia					
France					
Iceland					
Japan					
Korea					
Poland					
Portugal					
Slovakia					
Denmark					
Slovenia					
Spain					
United States					
Mexico					
Austria					
Germany					
Netherlands					
Switzerland					
Total	6	10	4	1	4

Source: OECD HCQI Questionnaire on Secondary Use of Health Data: Electronic Health Records, 2012.

and transparency. Interest in openness and transparency in government will be an important driver of the development of aggregated quality measures in health care in Sweden; especially given health care services are mainly publicly funded.

The *United Kingdom* reports very strong business drivers supporting this development through the Quality and Outcomes Framework in England. Scotland has made progress to ensure that data captured locally can feed the national information system. There remains some opposition to the development of national electronic health records from clinical groups and there are financial pressures. Patient groups, however, are supportive of the development of the EHR. There are also fair questions to be addressed about the secondary use of data from electronic health records and the need for data security, particularly safeguards against re-identification of records accessed for secondary uses.

Israel indicates that it is very likely that regular national monitoring of health care quality will take place using electronic medical records within the next five years. The implementation of the national EMR is on-going, as is the use of these records for health care quality monitoring. *Israel* is starting to monitor health care quality indicators based on electronic medical records in January 2013. New legislation was recently approved which enables the Ministry of Health to draw health information from EMRs into a national database.

The second phase of the National EHR project in *Singapore* includes secondary data analytics and aims to establish the framework and policies to support secondary data use.

There remain technical challenges to the implementation of the national EHR, as patient information within electronic medical records, and the EMR systems themselves, differ across institutions. The national EHR was primarily implemented for patient care, and the policies for secondary data use have not yet been established.

Indonesia already has a national policy to implement EHR and the system is currently under development, so it is very likely that, within the next five years, data from the EHR will be used for regular monitoring of national health care quality.

Countries that view monitoring in the next five years as likely

Estonia considers it likely that data from the electronic health record system will be used for regular national monitoring of health care quality within the next five years. Gaps in the data related to the submission of discharge summaries (epicrisis) are anticipated to be resolved within this period. Nonetheless, barriers to EHR implementation remain in Estonia, including the adequacy of financial and technical resources and resistance among some health care providers. While not an issue currently, the detection of data quality limitations may pose challenges for the analysis of data from the EHR system.

In *France,* the national EHR is being implemented, however the system still needs to be generalised to support the generation of statistics for health care quality monitoring at the national level. The main barrier to the EHR implementation relates to reluctance among health care providers. Some are unwilling to change from a paper-based or older system and others complain that contribution to the EHR is an additional administrative task that they should be paid to undertake. Each authorisation to use health data from electronic health records will be approved by the Commission on Information Technology and Liberties (CNIL). To be approved, each project will need to comply with all requirements for data security and data confidentiality protections.

In *Poland* it is likely that electronic health records that are currently contributing to the development of a large database maintained by the National Health Fund will be used to monitor health care quality at a national level over the next five years. In terms of the national electronic health record system, there remain challenges to be addressed that are mainly derived from resistance by health professionals and, partly, also some resistance among the public.

Belgium indicates that it is likely that data from electronic health records will contribute to national monitoring of some aspects of health care quality over the next five years. There will be, however, a minimum of three years needed for providers to use the system and to develop trust in the system. The use of data to monitor health care quality for specific sub-sectors of health is likely within the five year window. The creation of a "chain of trust" among health care providers is essential to the implementation of the national electronic health record system. The main barriers to the secondary use of data from electronic health records for health care quality monitoring include the potential for a lack of production of useable clinical information; the lack of structured data; and the need for specific legal provisions to allow for electronic health records to be processed for health care quality monitoring (or a specific authorisation from the Privacy Commission). In the initial deployment of the national electronic health record, making mandatory the use of electronic health records for health care quality monitoring could be detrimental to building the chain of trust and thus, these uses, should be introduced over time.

Slovakia expects that it is likely that data from electronic health records will be used for regular national monitoring of health care quality over the next five years. There is political will and public support for the effort. There remain challenges to the implementation of the national electronic health record system, including resistance among health care providers, technical barriers, and legal and jurisdictional considerations.

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 five years, with EHR data increasing in importance with time. Canada Health Infoway and the 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. Canada Health Infoway committed to a risk management approach to EHR implementation in 2005. EHR implementation projects are evaluated for risks with both a high probability of occurrence and a high impact on success. Mitigation strategies are then put in place. Risks may relate to the timeliness of project completion or involve even a failure to integrate point of service systems into the EHR and to deliver a viable and interoperable EHR solution. Change management also presents challenges, including slow adoption of clinical terminology and interoperability standards by vendors of legacy EHR systems and a reluctance of provinces and territories to change or replace legacy systems.

Barriers to the secondary use of data from electronic health records in Canada include: building the necessary technical infrastructure to support it; data privacy concerns; resistance among some members of the general physician community; financial resources to broaden the scope of the national plan to include secondary data use; some jurisdictional barriers to the adoption of standards and the replacement of legacy systems that don't meet current standards; the lack of a definition of health system use (or secondary use) of data from electronic health records; shortages of human resources with the correct skill set to undertake the work; the legacy of information silos where specific programs own the data and are reluctant to share data or to provide access to data for research; and that health system use (secondary use) is not recognised as a priority.

In *Japan*, the government's IT strategy includes the use of data from electronic health records for national health care quality monitoring and, as a result, it is likely that data from EHRs will be used for this purpose within the next five years. There remain, however, legal barriers in Japan to both the implementation of national electronic health records and to the secondary use of these records for health care quality monitoring that will need to be addressed.

In *Korea*, it is likely that data from electronic records will contribute to health care quality monitoring over the next five years. There remain, however, challenges to the implementation of electronic health records including inadequate financial resources among medical institutions to invest in electronic health records and inadequate financial incentives to encourage investments. There is also resistance among health care providers including negative options on sharing medical records, and negative feeling following the introduction of a fee-for-service payment system which reduced medical service fees. There is inadequate capability among health service providers to invest in patient information security. There is also no legal basis for collecting electronic health record data in Korea and inadequate legislation for the protection of health information privacy.

In *Iceland*, efforts are underway to improve the quality of electronic documentation within the EHR at a national level. Further, a project has been launched to evaluate the feasibility and cost of implementing the EHR at a national level (beyond the regional systems in place currently). There remain barriers to this implementation, including financial barriers and resistance among some health care providers.

Portugal also considers it likely that regular national monitoring of health care quality will take place using electronic health records within the next five years. The implementation of the national EHR is on-going, as is the use of these records for health care quality monitoring. There are, however, challenges to the full national implementation of the EHR, including financial, technical, jurisdictional and legal impediments, as well as some resistance among health care providers. None of these challenges, however, are considered to be a strong barrier to progress. There are also concerns with the quality and availability of data within the national EHR system and with ensuring data privacy and confidentiality that can pose barriers to the secondary use of the data.

Countries that are unsure monitoring will occur within the next five years

In the *United States*, the sustained support and significant interest in quality measurement using data from electronic health records is expected to result in the ability to measure high-priority quality indicators at the national level within the next five years. The United States is not implementing national electronic health records per se. Instead, it has chosen a distributed strategy, where providers are encouraged and incentivised to implement and use an interoperable EHR, and where patients use electronic personal health records. By facilitating secure, standards-based data exchange infrastructure, the United States aims to offer citizens all of the benefits of electronic health records without the need to develop and maintain a single national electronic health record system for a population exceeding 300 million.

The United States HITECH Act of 2010 and its payment incentives for meaningful use have dramatically accelerated the transition from paper to electronic records among hospitals and physicians. The payment incentives require quality measurement as part of meaningful use criteria. Building forward from substantial prior development and early experience with meaningful use criteria, public and private sector stakeholders support EHR-based quality measurement. The United States is currently working on defining the data required from electronic health records to support health care quality indicators that are crucial to driving quality improvement and that correspond with emerging payment models rewarding value of care, rather than volume of procedures. The definition of this data could lead to an expansion or refinement of the content that is minimally expected in patient summary records.

Denmark has already invested in the primary reporting of clinical and administrative data to an established system of national databases and data repositories. It is unlikely that an investment would be made again in developing databases from electronic health records unless there is a strong business case to do so. In terms of the development of EHR infrastructure, the main challenges still faced in Denmark are financial and legal.

Slovenia indicates that there are risks to the further development and use of the EHR for data quality monitoring, but there is certainly potential that this objective could be reached. The national EHR strategy is not clear and is not being executed on time. There are

jurisdictional and legal concerns and technical barriers to overcome. Health care providers are experiencing financial barriers to adoption and some lack the time or motivation to engage.

The current economic situation in *Spain* makes it difficult to plan for the future development of the EHR system. Currently, limited resources for teams and software tools are a barrier to EHR implementation. Changes in policy priorities to address the economic crisis may result in additional financial constraints. The economic situation is not, however, expected to impede progress on regulatory action. The use of data from electronic health record systems for health care quality monitoring is constrained by the absence of legislation or regulation that address the technical requirements for the secondary use of clinical information. Further, no secondary uses of data are supported by the national EHR system design. Databases would be administered by each health care authority (region).

Countries that view monitoring within the next five years as unlikely

In *Mexico*, the national electronic health record project is in an initial phase of development and priorities are focussed on clinical information more than on quality of care information. It is therefore unlikely that Mexico will be able to use data from electronic health records for national monitoring of health care quality within the next five years. Further, Mexico's national EHR project is experiencing financial challenges, as there is not a federal budget for the effort but rather the effort depends on the participating institutions, which have differing levels of resourcing for EHR development. There is also a lack of technical infrastructure and information technology know-how across the different areas of the country.

Countries that view monitoring within the next five years as very unlikely

The *Netherlands* reported that it is very unlikely that electronic health records will be used to monitor national health care quality over the next five years. The organisation has to be established; the ICT infrastructure needs to be developed; jurisdictional and legal barriers need to be addressed; decisions about patients opting-in or opting-out have to be taken; the opt-in or opt-out process must be completed; the possibility of using data from electronic health records has to be incorporated into the strategy; and the approval for using electronic health record data for data quality monitoring needs to be obtained. A new start to the development of a national electronic health record system has only recently been made. It may be that the resistance to a national EHR will be softening because government is no longer leading the initiative, nor playing a role in it. Instead, health care providers are leading the initiative and the participation of health providers is voluntary. This approach may be more promising.

In *Germany,* it is possible now for data from medical records kept by health care providers and data kept by the statutory health insurance system to be analysed for a specific approved project, as long as specific procedures for data retrieval and de-identification are followed. Electronic health records, however, may not be a good choice as a data source for health care quality monitoring, as they may never cover a large enough portion of relevant health care processes in Germany.

In *Switzerland,* it will take some years to establish an EHR system with enough structured data to be used for standardised analysis. Further, the secondary use of data from the EHR system is not addressed as part of the new national law to enable it.

Implementation of the national EHR remains challenging, due to the absence of financial incentives, unclear financing, the absence of a national law to enable the EHR; and doubts among health care providers about the benefits of exchanging records.

Austria reports that the use of data from electronic health records for national monitoring of health care quality is not in scope. The implementation of the EHR system remains challenged by financial barriers and, to some extent, by resistance to it among health care providers.