Strengthening Health Information Infrastructure for Health Care Quality Governance
Good Practices, New Opportunities and Data Privacy Protection Challenges

Chapter 7

Governance of national electronic health record systems data collection

The creation and analysis of national databases from electronic health records to improve the safety and efficiency of health care requires strong governance of the national electronic health record system. Of the 25 countries participating in this part of the study, one-half have a national body that is responsible for EHR infrastructure development and for setting national standards for both the clinical terminology used within the records and the interoperability, or sharing, of records. Five countries have introduced or are planning to introduce legislation requiring health care providers to implement electronic health records that conform to national standards. Seven countries reported a certification process for software vendors to comply with national standards for clinical terminology and interoperability. Eleven countries report incentives or penalties to encourage health care providers to adopt electronic health record systems conforming to national standards; and to use their EHR system and keep records up-to-date. Six countries reported auditing EHR records for the quality of the clinical information. Seven countries reported engaging third parties to centralise one or more of the following tasks: building databases from electronic health records; de-identifying data to protect privacy; and granting access to data.

This chapter explores results of the OECD study of 25 countries regarding the development of national bodies to oversee national EHR implementations; the use of legal requirements to adopt EHRs or adhere to standards; the use of incentives and penalties to encourage quality in the use of EHRs; concerns with data quality and the use of data quality auditing; and the engagement of third parties to assist with building databases, de-identifying data and approving applications for data access.

The governance of the electronic health record system design and implementation will have a significant impact on whether or not data from electronic health record systems will be eventually useable for national health care quality and health system performance monitoring. Countries that are able to aim toward a single country-wide deployment of one electronic health record system have a clear advantage. Many countries, however, are challenged in this objective because they have a decentralised health care system, where decisions are taken at a sub-national level. Success strategies typically involve setting national standards for the content of the records, such as establishing a minimum set of data, where the content of the record follows terminology standards and the data is structured to be comparable; and setting interoperability standards, so that each electronic record system deployed in the country can speak to another.

This study of 25 countries (see Annex C) explored several dimensions of the governance of the implementation and maintenance of national electronic health record systems and the governance of data use. This included the existence of a national body with primary responsibility for the national EHR infrastructure development and/or a governing body to develop and maintain standards for clinical terminology and for electronic messaging (interoperability). It also explored the existence of any legal frameworks requiring participation in national electronic health record systems; the use of incentives or penalties to encourage compliance; data quality concerns and quality auditing; and the use of third parties for database development, data de-identification, or approval of data access requests.

National bodies with responsibility for the development of National EHR infrastructure

One-half of the study participants have a national body responsible for EHR infrastructure development and who set standards for clinical terminology used within the records and standards for interoperability. Other countries have a national body in place for EHR infrastructure, but limit its role to recommending standards for clinical terminology, or to not discussing such standards. Still others have no national governing body.

In *France*, the Agence des Systèmes d'Information Partagés de Santé (ASIP santé) took responsibility in 2009 for setting all operability standards and agreements with data custodians. It is a multi-disciplinary body with representation from industry, patients, and legal and health professionals. *Austria* established in 2010 a national organisation with responsibility for co-ordinating the implementation of national EHR infrastructure, the ELGA GmbH.

Finland reported that the government, through the National Institute for Health and Welfare (NIHW), is responsible for the national EHR infrastructure. In 2004, the NIHW was involved in the national EHR as an expert. In 2008, the NIHW became responsible for the code server. Since 2011, the NIHW ensures the interoperability of the National EHR and this role is authorised by law. The NIHW consults stakeholder groups. In 2012, the Directorate

of Health in *Iceland* became responsible for national EHR development and for setting standards for clinical terminology. The Directorate is also aiming toward national standards for electronic messaging that adhere to international standards. Similarly, the Ministry of Health in *Israel*, took responsibility in 2011 for national EHR system development and for setting clinical terminology standards and defining the national minimum dataset.

The Ministry of Health in *Slovenia* took responsibility in 2008 for setting standards for clinical terminology and interoperability. In *Portugal*, a commission within the Ministry of Health was created in 2011 to set standards for clinical terminology within electronic health records. A separate technical body is responsible for interoperability standards.

In *Spain*, the Ministry of Health, Social Services and Equality, through the Medical Records in the National Health System (HCDSNS) project, took responsibility in 2006 for EHR implementation, including clinical and interoperability standards. The ministry is developing SNOMED-CT derivatives including subsets, extensions, mappings, and translations; subset browsing software; subset editing modules; health record modelling and terminology services studies; and training in interoperability, terminology resources, and clinical documentation standards. The Information Systems Sub-Commission for the national health system discusses alternatives and makes recommendations to the national Interterritorial Council (IC) regarding clinical information standards for EHRs. Its members include stakeholders (autonomous communities), health authorities, and the Ministry of Health. The IC makes decisions on clinical standards and sets priorities.

The responsibility for national EHR implementation is shared in *Sweden* between the National Board of Health and Welfare (NBHW) which sets the clinical terminology standards for electronic health records and the Swedish Association of Local Authorities and Regions (SALAR), which comprises the Center for eHealth in Sweden, and sets national standards for electronic messaging. Governance of EHR infrastructure was initiated in 2000; however the respective roles of these two bodies have evolved over time and continue to evolve. The engagement of stakeholder groups in EHR governance, such as professional groups, is not yet fully established. However, the SALAR and its Center for eHealth is responsible for all health care providers, pharmacies and suppliers while the NBHW ensures national views are represented.

In *Denmark*, the National Board of eHealth (NSI) was established in 2011 to set standards, and to develop strategies and architectures for the whole health sector. It governs eHealth across sectors including databases and registries and runs cross-sectoral projects. It sets clinical terminology and interoperability standards for the national EHR. The *Estonian* E-Health Foundation was established in 2005 and is responsible for implementing clinical terminology and interoperability standards and IT systems and for housing the central system. The foundation publishes standards, educates users and promotes co-operation among stakeholders.

In *Belgium*, the E-Health Platform was established in 2008 and sets standards for clinical terminology and interoperability in conjunction with other organisations. Working groups of the E-Health Platform develop and maintain standards for clinical information and include representatives from PFS Public Health, the National Insurance Institute and other public health related institutions. The working groups on data elements and on semantics receive requests to select particular standards; and undertake projects to analyse and prioritise these requests. The working groups may also adapt proposals to

conform better to the standards that are already in place for the country (kmehr format). Working group members include public health institutions, industry, regional networks and, for semantics, representatives from all sectors and experts working in this field. A certification system in Belgium, however, requires adherence to interoperability standards and there is also an incentive policy to improve compliance.

Poland reported that the National Centre for Health Information Systems (CSIOZ) was established in 2009. It is an agency of the Ministry of Health, responsible for implementing two major platforms for eHealth in Poland. This organisation is responsible for developing and setting standards for clinical terminology and interoperability. Clinical terminology standards are the responsibility of the National Normalisation Committee in collaboration with the European Committee for Standardisation (CEN).

In *Slovakia*, the National Health Information Centre (NHIC) took responsibility in 2008 for the development, implementation and operation of the National Health Information System, including the national EHR. Within the NHIC, the Centre for Medical Terminology and Standards is responsible for the preparation, co-ordination and guidance of the implementation of clinical standards. The NHIC is also responsible for interoperability standards. Representatives of universities, medical professional associations, health chambers, IT experts, pharmacists, linguists and others, take part in the work of the Centre for Medical Terminology and Standards.

In *Korea*, the Korea Health and Welfare Information Service is responsible for EHR infrastructure development as part of the Public Health and Medical Institution Informatisation Project. This organisation was established in 2008 and has developed the Korea Standard Terminology of Medicine (KOSTOM) which is now in use in 170 medical institutions and may become the national standard in the future. The Health Insurance and Review Board (HIRA) has developed standards for data coding using insurance claim data. These standards are developed jointly with professional associations, payers, government and medical service providers. The Public Health and Medical Institution Informatisation Project was authorised by law.

EHealth Suisse, or the Swiss Co-ordination Office for eHealth Confederation Cantons, is responsible for co-ordinating the work of four working groups on standards and architecture; pilots and implementation; and education in *Switzerland* and was established in 2008. Different organisations develop and maintain clinical information standards and they are unified within a working group on standards. In *Singapore*, MOH Holdings Pte. Ltd. was established in 2008 to provide the governance, change management, enterprise architecture and the clinical and interoperability standards for the national EHR system.

The *United Kingdom* reported that the NHS Connecting for Health was established in 2005 to be responsible for national EHR infrastructure in England, including delivering programs and managing services, and clinical terminology and interoperability standards. The Information Standards Board appraises and approves standards for clinical information. Its members include clinical, managerial and technical experts. In *Scotland*, there is no independent body established for the development of EHR infrastructure and it is managed by the Scottish Government eHealth Division. The eHealth Division recommends clinical terminology and interoperability standards and other organisations engage in the development and maintenance of these standards. The organisations consult with stakeholders.

The *Netherlands* reported that after the legal closure of the initiative to develop a national EHR in 2011, the Association of Health Care Providers for Health Care Information Sharing has, of its own volition, made a new start with the goal of establishing electronic health records that can be exchanged within regions. This association includes general practitioners, pharmacists, primary care organisations providing after-hours care, and hospitals. There is neither government involvement nor a role for government in the initiative. The Association consults with patient organisations and health care insurers in the plans for the EHR system. Three other national organisations also play a role. The National IT Institute for Health Care (NICTIZ) is a private organisation that develops national standards for electronic communications in health care. The Quality of Care Institute stimulates the development of clinical guidelines. The societies of medical specialists and general practitioners are responsible for the development of clinical guidelines and advise on the content of EHRs.

In *Canada*, the Canada Health Infoway was established in 2001 to develop a national vision and to guide the development of electronic health records in Canada (EHR blueprint). Infoway jointly invests with the provinces and territories to implement health information systems. It supports and sustains communications and technology standards that enable health information systems to share patient health information accurately and securely. Infoway works with the clinical community to foster and support the adoption and use of health information technologies by clinicians. The Canadian Institute for Health Information works with jurisdictions to encourage adoption of national standards for database content including, primary health care data content standards, and the adoption of International Residential Assessment Instrument (InterRAI) standards for mental health, long-term care, home care and rehabilitative care. Standards are available to provinces and territories and are adopted on a voluntary basis. Stakeholders engaged in Canadian EHR development include EHR vendors, health care organisations, jurisdictions, health care providers, professional associations, governments and other organisations interested in implementing standards-based EHR solutions.

The *United States* reports that there is no separate private or public entity for national EHR infrastructure. The Department of Health and Human Services adopts national standards and regulates the certification of EHR products. By statute, there is a politically appointed National Co-ordinator for Health Information Technology who heads the Office of the National Co-ordinator for Health Information Technology (ONC) and who reports directly to the Secretary of Health and Human Services. ONC was established in accordance with this statute in 2009 and is responsible for co-ordinating development of the nation's EHR infrastructure, including developing and administering regulations necessary for the Secretary to adopt standards. The ONC recommends voluntary consensus standards to the extent possible, including internationally recognised standards, such as HL7 and SNOMED-CT. Where there are no voluntary consensus standards available, the ONC works with private-sector standards development organisations and standards bodies to promote the development of standards to fill these gaps. The governance of the exchange infrastructure (interoperability) is currently being developed.

In *Germany*, Gematik is an organisation of health care providers and representatives of the statutory health insurance system that is responsible for establishing a national telematics infrastructure for health care. Gematik is expected to provide some guidance on the implementation of interoperable documentation systems. There is no organisation in Germany to set clinical terminology or interoperability standards at the national level.

In *Indonesia*, the Centre for Data and Information is responsible for developing and implementing standards related to health statistics as well as the development of information systems and databases and, since 2007, has been responsible for national EHR infrastructure development. It is not yet responsible for setting EHR terminology or interoperability standards. The Directorate General of the Health Care Effort is also involved in setting standards for clinical information.

There is no national organisation in *Mexico* that is responsible for EHR infrastructure or to set standards for clinical terminology or interoperability. In Mexico, the Direccion General de Informacion en Salud (DGIS) is responsible for the integration of health information for statistical purposes and develops and maintains standards for clinical information. There are also no national organisations in *Japan* responsible for EHR infrastructure development or standards development.

Legal requirements to adopt electronic health records and adhere to standards

A challenge for all countries is to ensure that health authorities and health care providers implement the requirements of the national electronic health record system. Some countries have introduced, or are planning to introduce, laws or regulations that require health care providers to adopt and use electronic health record systems that conform to national requirements for clinical terminology and interoperability. This is a strong stimulus toward full participation of health care providers in the national EHR system.

In Belgium, Denmark, Germany, Indonesia, Japan, Korea, Mexico, the Netherlands, Portugal, Slovenia, Singapore, Spain, Sweden, and the United Kingdom, there are no laws or regulations that require health care providers to adopt electronic health records, nor to adhere to particular standards.

French law stipulates that once a patient has an electronic health record, health care professionals must refer to it and complete it. This law, which came into effect in 2004, also binds health care providers to using SNOMED 3.5 vf standards for clinical terminology and to adopt CDA HL7/CDA R2 interoperability standards.

In *Finland and Estonia*, there are legal requirements for health care providers to adopt electronic health records and to ensure conformance with clinical terminology and interoperability (HL7) standards. Finnish legal requirements took effect in 2006 and those in Estonia took effect in 2009. In *Israel*, a Ministry of Health regulation requires health care providers to adopt electronic health records.

Slovakia is developing a law that will govern the National EHR. It is in the negotiation phase and the requirements of the law have not yet been set, however it is expected to require adoption of international standards including HL7 for interoperability. It may take effect by 2014. Similarly, there is a law in development in *Poland* that will require health care providers to adopt electronic record systems and to conform to clinical terminology standards and interoperability standards (HL7). It is expected to take effect in 2014.

A law is under development in *Switzerland*. The proposed law ensures that only certified communities of health care providers can have access to shared electronic health records. The law is not expected to require the use of electronic health records. Electronic transmission of data is only mandatory for reimbursement purposes. *Austria* is also progressing toward the introduction of legal requirements for health care providers to adopt electronic health records and plans for the requirements to enter effect by 2013.

While there is no national law requiring adoption of electronic health records nationally, some *Canadian* jurisdictions have passed laws requiring pharmacy vendors to adopt pan-Canadian HL7 drug standards as part of their drug information systems.

In *Iceland*, there are no laws or regulations requiring the adoption electronic health records, however, a Health Records Act states that health records should be electronic whenever possible.

Encouraging data quality within electronic health records

Most countries who have already implemented all or part of their national EHR are concerned with the quality of the data within the records. Noted obstacles to quality include the complexity of the EHR system, which may make it difficult to use; the complexity of the structured data elements and terminology standards, that may be a barrier to their use or to their correct use; and remaining reluctance or scepticism among health care providers to use the system or to appreciate the benefits of using the system.

Strategies to address these issues include financial incentives to implement and use records and efforts to work with vendors to increase the user-friendliness of the system (Table D.18). Very few countries, however, are auditing the clinical content of electronic records for quality yet. Audit processes for electronic billing information are more common. Processes to evaluate the usability of data from electronic health records for statistical purposes are more widely reported. For the most part, these efforts occur, hand in hand, with database creation and analysis of electronic health records.

Most countries have also explored incentives or penalties to encourage the adoption of the national EHR. Penalties include barriers to participation in the national EHR for providers with a non-conforming EHR system; and financial penalties for failure to meet commitments to EHR implementation and use requirements. Incentives include payment support to ease the transition to the national EHR solution; certification for EHR vendors whose solutions meet national requirements; and increased payments to providers implementing and using EHR solutions that meet national requirements.

Nine countries reported having instituted certification processes to ensure that the electronic health record systems available to heath care providers conform to national standards. Most require the systems to meet national standards for clinical terminology.

Eleven countries have also introduced incentives, penalties or both incentives and penalties for health care providers to adopt electronic health record systems from a certified vendor and/or to adopt EHR systems that conform to standards and use structured data (Table D.18). Seven countries have also introduced incentives or penalties to ensure that health care providers keep their electronic health records up to date.

The *United States* has a certification program for vendors of electronic health record systems pursuant to a statutory mandate that requires the adoption of standards. Legislation provides for several years of incentive payments for the adoption and meaningful use of certified electronic health record systems by physicians, including optometrists and podiatrists, and hospitals serving patients enrolled in public health insurance programs (elderly, low-income or disabled persons). Selected non-physicians who can prescribe medicines also can qualify for incentive payments if they provide services to low-income persons. Payment penalties will apply to these providers by 2015 if they cannot meet requirements for "meaningful use" of EHR technology, with the exception of providers who provide care to low-income persons under federal and state

insurance programs. The capture and use of structured data is a requirement for meeting meaningful use criteria.

Belgium reported an incentive for physicians, nurses and physiotherapists to adopt a certified EHR system of EUR 840 per year. There is also an incentive of EUR 12 000 per year for hospitals to adopt national EHR standards. Belgium's Federal Public Health Service conducts audits of hospitals for the quality of their electronic records related to reimbursement.

Portugal has a certification process for vendors of electronic health record systems that requires vendors to adopt standards and use structured data. For electronic prescribing, hospitals and primary care centres are required to install systems from certified vendors only. Assessment of provider performance depends on provision of information from electronic record systems, which acts as an incentive for providers to register with the national system and to use the required structured coding.

In *Estonia,* permission from the E-health Foundation is a prerequisite to submitting information to the central EHR system. This permission will only be granted if national standards have been followed. As a result, there is a strong incentive for software vendors and health care providers to adopt EHR systems that conform to national requirements.

Similarly, *Finland* does not have a certification process for EHR vendors; however, the national EHR is restricted to only those systems that conform to national standards. After 2014, the only possible system for health providers will be the national EHR.

France requires vendors to provide electronic health record system solutions that are compatible with the national EHR, including requirements to comply with the standards of the national EHR. In *Switzerland*, the law currently in progress will require communities of health professionals to be certified in order to access the cross-community (interoperable) EHR.

In the *United Kingdom*, Scotland has a certification process for IT systems for primary care physicians, where some aspects of the system must be accredited through the SEF process (Scottish Enhanced Functionality). In Scotland, primary care physicians are required to use a national electronic record system for payments and hospitals are required to use the national system to produce standardised mortality rates and quality indicators. England has a certification process for vendors that requires adoption of a set of relevant standards. England withholds payment for services for primary care providers and hospitals that do not use an EHR system from a certified vendor, that do not adopt required standards or do not use the EHR system and keep records up-to-date.

Canada reported having pre-implementation certification by Canada Health Infoway in certain technology classes (ambulatory care, electronic medical records, consumer health applications, diagnostic imaging, drug information systems, and client, provider and immunisation registries). Some jurisdictions have lists of certified vendors of, for example, electronic medical records for primary care physician offices. Some jurisdictions also require vendors to meet standards for structured data elements in their procurement processes. Canada also offers incentives in the form of payments from Canada Health Infoway to deploy electronic medical record systems (primary care) and to integrate electronic medical record systems and hospital information systems.

Slovakia reported planning to introduce a certification process for vendors of electronic health records that includes adoption of standards, as well as incentives or penalties to

adopt electronic health records from a certified vendor. These will be prepared after the adoption of the law through other regulations and directives.

Sweden reported requiring vendors of electronic record systems to be certified as conforming to European standards (CE certification).

There is no certification process for EHR vendors in *Mexico*; however, there is an evaluation that is required of all new EHR procurements for public institutions. A similar approach is taken in *Indonesia*.

Austria has put into place incentives for physicians, hospitals and pharmacies to adopt electronic health records by sponsoring implementation costs. These same groups face penalties for any misuse of data or discrimination against patients not participating in the electronic health record. *Japan* has an incentive for hospitals to adopt standards and use structured data in their electronic health record system through small add-on reimbursement payments.

Spain provided funding at the European Union and national level (AVANZA I and II) and through the Ministry of Health (Cohesion funds) that could be used by regions for investment in the development of electronic health record systems conforming to national standards. Further, in some communities in Spain, privately managed hospitals and health care centres that participate in public health care must assume the same obligation as public health care networks to adopt and keep up-to-date an EHR system conforming to national requirements.

Germany does not have incentives or penalties for the adoption of EHR systems or systems with particular standards in general. It does, however, have standards for billing information and certified systems must be used for billing in the ambulatory sector.

While no incentives or penalties are in place yet, *Israel* is planning to introduce penalties for health care organisations that do not conform to requirements of the national EHR system.

Data quality concerns and auditing

Many countries (16) have expressed concerns with the data quality within electronic records. Only six countries, however, are auditing the clinical content of electronic health records to verify and maintain data quality (Table D.18). Auditing processes for electronic billing information are more common.

The *Estonian* E-health Foundation audits electronic health records of physicians, hospitals and other health care providers for quality. Technical rules have been used to electronically detect data quality problems within electronic records submitted to the central system. Estonia reports that more controls, including adoption of additional rules, are needed to achieve better quality.

Iceland reports that the Directorate of Health conducts quality audits of the content of the minimum datasets used in primary health care and hospital admissions. Iceland reports concerns that data are frequently not coded in a timely manner. Further, internal data quality audits within each health care institution are often lacking.

Belgium's Federal Service for Public Health audits electronic health records in hospitals for quality in conjunction with audits of reimbursements. Belgium is concerned with under coverage and poor quality or unusable data elements within electronic health records.

Spain reports that health records are audited for quality in all health services. Audits are conducted by the Spanish Medical Inspection Body; and by internal committees within hospitals and health care provider areas. The Ministry of Health e-health governance team (HCDSNS) audits the content of the minimum dataset (CMDIC). Spain is concerned that the coverage of EHR applications and the use of the EHR by providers is irregular; that the use of standards remains limited; that support for the development of terminology standards is lacking; and that their remain patients in transition, where both paper and electronic records are being maintained.

Electronic records are also audited for quality in Portugal across all health services. The Central Administration of the Health System (ACSS) and the Directorate General for Health (DGS) conduct the audits. Data quality concerns in Portugal include the completeness and validity of the data, as well as some concerns with the potential for gaming or fraud to increase service payments.

In the *United Kingdom*, England reports quality audits of electronic health records undertaken by the UK Audit Commission as well as sometimes by the Royal Colleges. England is concerned with both the quality and completeness of electronic health records and notes that patient access to their records has highlighted the existence of potential inaccuracies. Scotland is concerned that most electronic health records are unchecked and that the quality of the records is up to the individual user's attitude and ability.

The *United States* reported that it does not audit provider's data quality per se. Providers using either paper or electronic records, however, are subject to audit of these records to assure the quality and safety of the services provided as well as the accuracy of claims for insurance reimbursement. Outcome incentives were chosen in lieu of a compliance-audit model.

Communities of health care providers in *Switzerland* are expected to undertake audits of their electronic records. Switzerland is concerned about records containing incorrect data or data that has not been kept up-to-date. There is also a worry about missing or invalid information within the records.

Poland reported that it does not audit electronic health records for quality, however, it does have control mechanisms for data associated with insurance claims, including the use of DRGs and automatic quality verification. Poland has concerns with up-coding related to DRG reimbursement, but it is very difficult to prevent these practices. Similarly, *Slovenia* reported that data is often entered into the EHR system for reimbursement purposes and can be skewed as a result.

Mexico expresses concerns with the quality of data in electronic health records and the potential impact of data quality problems on national statistics, public health decisions and other policy decisions, medical mistakes and medical services planning errors.

Finland has some concerns with coding accuracy. For the overall content, concerns with the quality of electronic records are similar to those for paper records. *Denmark* expresses a concern with the burden on clinical communities of EHR documentation that may lead to poor data quality and a misuse of physician's time.

Canada reports concerns with data quality emanating from the existence of legacy systems in hospital and primary care settings that have fallen behind in terms of recommended standards. *Singapore* expressed concern that the quality of data within electronic health records varies across institutions.

As is the case for other states in the early stages of implementation, it is too soon for *France* to determine if there are data quality concerns. Security audits are being conducted by ANSSI (Agence Nationale de la Sécurité des Systèmes d'Information) and data security and protection of data confidentiality audits are also being conducted by CNIL (National commission on information technologies and liberties). General inspectors of public social services may also audit the quality and overall efficiency of the EHR, but data quality audits are not performed for now.

The *Netherlands* is concerned that the national EHR does not yet exist and also with its eventual development. The quality of the data that will be collected through the proposed system, in terms of the creation of national databases, may be compromised by limited participation of patients, due to the possibility of an opt-in system; and a regional approach that would further limit national use of patient data. There are also concerns about the protection of patient privacy and security of stored data. The *Netherlands* reported that the EHR that can be used to share records across health care settings (interoperable) was built with a tool called EDPscan to help general practice physicians to ensure the quality of their electronic records. This tool could be used to scan medical files for completeness, structure, actuality and general quality. EDPscan for GPs is the responsibility of the Netherlands Institute for Health Services Research Scientific Institute of Quality for Health Care and the Dutch college of GPs.

There are no quality audits of electronic health records in *Germany*; however, physicians must meet standards for quality management. There are no valid data in Germany to assess the quality of electronic health records, as systematic monitoring is difficult due to data privacy concerns.

Engagement of third parties

Given the complexity of building national databases from electronic health records, a possible strategy for countries is the engagement of specialist third parties, separated from governments, insurers and health care providers, to assume responsibility of one or more difficult dimensions (Table D.19). Three areas were explored in this questionnaire, the potential use of third parties to build databases from electronic health records, to de-identify data to render the data anonymous and therefore more protective of patient privacy; or to render decisions from the potentially numerous applications for access to databases built from electronic health records for research projects and monitoring.

A small number of countries indicated that they are pursuing the engagement of third parties, the *United Kingdom, Korea, Indonesia, France, Canada, Estonia* and *Belgium*.

The National Commission on Information Technologies and Liberties (CNIL) in *France* already acts as a central decision-making body for the approval of research projects requiring access to personal health data for research and would fulfil this role for access to databases from electronic health records. *Belgium* has already established a third party that is engaged in the de-identification of data derived from electronic health records and the Belgian Privacy Commission approves or declines requests for access to databases built from electronic health records. *Estonia* has created an additional ethical committee to approve or decline requests for access to databases built from electronic health records.

In the *United Kingdom*, England reported encouraging a market of information providers that could, as third parties, assist with de-identification of databases and

requests for access to data. England has already established a third party for the approval of projects requiring access to databases developed from electronic health records.

The Health Insurance Review and Assessment Service (HIRA) in *Korea* collects patient-level insurance claims data through electronic data interchange and builds databases that are analysed to monitor health care quality. The HIRA develops databases, de-identifies the data and approves or rejects access to data.

In *Canada*, the Canadian Institute for Health Information's role is to co-ordinate national health information and it expects to play a continued role in the creation of databases from electronic health records in the future. Further, some jurisdictions have created research data centres which can act as third parties for the development and analysis of provincial and territorial databases from electronic health records.

In the *United States*, third parties exist that are or are planning to create databases from electronic health records, however, these parties (such as professional associations and public-interest organisations concerned with improving health care quality and safety and advancing clinical science) have not been established by government. The establishment of a third party to de-identify data and to approve or decline requests for access to databases from electronic health records is an approach that the ONC may consider as an element of the governance of the exchange of health information and the National Health Information Network (NwHIN).

Indonesia reports that a third party has been engaged to develop the health data warehouse from electronic health records and related business intelligence tools.