Nationwide Health Data Management System: A Novel Approach for Integrating Biomarker Measurements with Comprehensive Health Records in Large Populations Studies

Ruth Sepper,*,† Peeter Ross,‡ and Madis Tiik†

The Institute of Clinical Medicine, Akadeemia tee 15A, Tallinn 12618, Estonia, and Estonian eHealth Foundation, Lastekodu 6A, Tallinn 10113, Estonia

Received July 27, 2010

The nation-wide electronic health record database acts as an interoperable repository of health data obtained throughout citizen contacts with health care providers. This system improves accessibility for citizens and researchers to health data with the ability to assign context to disease development. In that system, individual patients who are members of the large population-based health database can be assessed as individuals or as a population in prospective studies of prospective diseases.

Keywords: Health Information System • National Electronic Health Record • COPD • Lung Cohort Study • Protein Biomarkers • eHealth • X-Road

Introduction

The study of health and disease in large populations is an important global endeavor that demands large-scale resource investment into infrastructure, surveillance programs, and education and training activities within various levels of society. Most often, even when sponsored on a national scale, such types of health evaluation are conducted at a local level, at individual health care centers that may not be at all aligned with similar activities at other local health care centers. At the level of care, assessment and treatment of individual patients, and quite often the historical data of clinical management, are fragmented between many different health care facilities that have come in contact with individual cases. Clinical assessment requires access to both laboratory and clinical measurements such as computed tomography (CT) scans, lung function, and clinical chemistry evaluations. The rising costs of health care could be partially addressed by systems that allow clinical data to be collected and shared centrally by health care providers irrespective of the location of the data acquisition. Such systems could act as repositories of all important clinical measurements taken throughout an evaluation and treatment period. An important aspect of this system would be to classify disease using standardized scales of nomenclature that could most accurately describe the form and stage of the disease being assessed as well as reference to previous disease or comorbidities of disease. Chronologically following the response to treatment and thus further enabling strategies for clinical decision support could attain a further clinical advantage.

Why then would such an electronic data management system be of interest to the clinical proteomics community or to clinicians? This question is most often posed as either “What value do protein biomarkers have in clinical management?” or “What forms of clinical presentation are associated with specific markers?” There are currently global activities addressing these important questions that will require testing and validation in large population-based studies to establish the usefulness of protein marker measurements in routine clinical practice. However, the actual importance of individual measurements (both quantitative and qualitative) of protein biomarkers, as prognostic indicators can only be evaluated by first establishing ranges of normal values, in population based studies. Then, these normal scores can align with contexts of disease presentation, other clinical measurements that address structural and functional abnormalities, and with eventual clinical outcome. At this point, the true value of a digital health database begins to be appreciated as a valuable resource in not only clinical research but, first of all, as a essential clinical measurement tool. Why again? Through its ability to assign context to disease development in individual patients who are members of large population based on data sets that can be assessed as individuals or as populations.

Estonian Countrywide Health Information System. Preparation for Estonian e-health system started in 2002 with the assigned purpose to develop a nationwide framework (database) that encompasses different medical documents in the digital format to facilitate the exchange of diffuse health information. In 2005, the Estonian Ministry of Social Affairs launched a new e-health concept by phasing in four projects: Electronic Health Record (EHR), Digital Images, Digital Registration, and Digital Prescription, forming the National Electronic Health Record (EHR) with the gradual development until 2013. The Health Services Organisation Act and Associated Acts Amendment Act, accepted by the Parliament on 20th December in 2007, provides that as of September 1st of 2008 the health care service providers are obligated to forward medical data to the EHR. EHR is a database that is part of the Estonian State Information System (www.ria.ee), the data associated with the
health care field is processed in this database to conclude and execute the contract for providing health care services, to ensure patients rights and to protect public health and the quality of health care services, including maintaining the registers reflecting health conditions and managing health care. According to the Health Information System Statute, the processor of the EHR is the Ministry of Social Affairs and the authorized processor of the EHR is the Estonian e-Health Foundation (www.e-tervis.ee) (Figure 1).

Estonian Electronic Health Record System. The Estonian EHR is globally unique because it engages the whole country (population ~1.34 million inhabitants), registers virtually all residents’ medical history from birth to death, and is based on the comprehensive state-developed basic IT infrastructure. The three largest Estonian hospitals, Ministry of Social affairs, The Estonian Society of Family doctors, The Estonian Hospital Union and The Association of Ambulance Doctors were the founders of Estonian e-Health Foundation. The operating principle of health information system is to reuse as much as possible of the existing components of public ICT (Figure 2). To collect and process all of the necessary data in the EHR, all healthcare providers are connected to the X-Road. X-Road applies a number of standard tools that have been developed for the eServices, capable of simultaneously integrating and interoperating data derived from different databases. These services enable reading and writing data and to perform most common data processing operations. Proceeding from this principle, several extensions have been developed for the X-Road: writing operations to databases, transmission of large data sets between information systems, successive search operations of data in different data sheets, and the ability to provide services via web portals, etc. (www.ria.ee/indexphid27309).

EHR in Practice. Entry into the EHR is obtained for citizens and entitled health care personnel through the use of a chip card, the Estonian ID card, which are issued by The Citizenship and Migration Board. Estonian ID cards are issued to all Estonian citizens as well as foreigners who reside in Estonia on the basis of a residence permit. Over one million cards have been issued, which marks the biggest ID card rollout in Europe. The ID card is used for securing authentication off and for digital signature of the person. These digital signatures have the same legal consequences as a hand-written signature. The ID card is a mandatory document for all Estonian residents from the age of 15. The card is valid for 10 years and can be used as an identification and travel document within EU. Each card is embedded with an electronic tamper-proof chip that contains a personal data file, certificate for authentication, and certificate for digital signature. The ID card is used as a common key to access different services, and it performs automated checks from the Estonian Population Registry. Data processing and storage in the EHR has been developed in a way that patients’ personal data in connection with the medical data is visible only to legally authorized parties. To date, permission to carry out certain clinical trial from local ethical committee is mandatory. Access right to EHR is allowed to

Figure 1. Databases and information systems.

Figure 2. EHR central functions.
medical professionals; there are no differences between specialties. Authentication is allowed only with ID card; all logs are stored and monitored. By law, access to patient data is legal only if there is a current relation between the health care professional and patient. An attending physician is a health care employee registered with the Health Care Board who is currently associated with patient’s treatment. A family physician is the attending physician on permanent basis to all patients in his/her practice list. The attending physician may hold different positions related to specific case (replacement physician, on-call physician, consulting physician, etc.), and regardless of the position, the physician is still considered to be the attending physician. Citizens can access their own data through Patient’s Portal, where they can also declare their intentions and preferences. The patient has a right to set access restrictions to documents, cases of illness and to all his/her information in the EHR. The access ban can be set to one specific document or applied to complete data in the EHR. The EHR system will record information about how and why the data was used (logging audit trail information) enabling citizens to monitor visits to the EHR (Figure 3).

**Standardization.** To support interoperability and to build an open architecture for future interdisciplinary integration, mostly all input medical data is coded and classified based upon international standard protocols of defined nomenclature that must be used when entering patient data into EHR. Medical history, disease history, and clinical status are in certain extent coded using SNOMED-CT (www.ihtsdo.org); diagnoses are coded using ICD-10 (www.who.int/classifications/icd-en); laboratory tests are coded using LOINC (www.loinc.org); and prescriptions are coded using ATC (www.whocc.no). Integration as well as mutual usage of medical data based on state-central health information system provided by Estonian eHealth Foundation is supported based on XML based HL7 CDA v3 standard message transactions. Implementation of standards provided by HL7 (HL7 and its members provide a framework and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. v3.x of the standards, which supports clinical practice and the management, delivery, and evaluation of health services, are most commonly used in the world. The priority of the Estonian Electronic Health Record project has increased on the national level, and the number of medical documents that will be digitized has also increased during the project. A large volume of additional documents will be added throughout the following phases of the Electronic Health Record (EHR) project, and this will set high requirements for standardization of medical documents, for interfacing organisations business processes and adaptation of their information systems, as well as for the development of the EHR central system.

**Utility of Health Information System in Population Based Studies: Prospective Studies of Prospective Diseases.** Cigarette smoking is the most important risk factor in the development of a number of major life threatening diseases including cancer, COPD, coronary heart disease, and stroke. To date, smoking prevalence in Estonia in adults in 2005 was 28% (42% in male, 21% in female) and in youth 24% (boys 30% and girls 18% from age 15–18). Quite often smokers develop clinical complaints related to smoking long after pathological damage has begun. Diseases related to smoking are heterogeneous within individual patients with a wide variety of comorbidity involving any and all of the above-mentioned disorders. The time frame required for disease development also differs between individuals by smoking history, age, gender, diet, genetic background, and environmental exposure. The staging of disease is most often determined by clinical symptoms using a variety of measurement devices.
research articles

Chronic obstructive pulmonary disease (COPD) is a major concern worldwide (www.goldcopd.com). Clinical COPD patients experience breathlessness, productive cough, shortage in many life functions especially those associated with constitutional capability. The diagnostic tools currently address structural (CT lung density scan, CT airway wall thickness) and functional abnormalities (spirometry for expiratory flow, residual volume, total lung capacity, forced residual capacity). Although some technological modalities, for example, body plethysmography, measuring static lung volumes instead of dynamic can provide additional information to functional disability of smokers without COPD complaints, these diagnostic approaches are valid in the more advanced COPD leaving; however, the early onset of lung functions decline in chronic smokers who are destined to, but have not yet, developed irreversible changes in lung structure and function. The development of new protein biomarker assays that could diagnose early ongoing diseases are a great assistance and add context to and complement the existing diagnostic tools. The CT scans that are typically used in lung density measurements in smokers will provide information on the distribution of emphysema but will not differentiate between older inactive emphysema lesions and early active areas of current parenchyma destruction. Protein measurements capable of providing quantitative information on current ongoing lung tissue matrix destruction would be invaluable assets in monitoring progression of disease in the context of the CT scans, measuring emphysema and the functional tests. The validity of these associations could never be established in small case-controlled studies. This level of power can only be achieved in large cohort studies that are logistically not in place in most instances for these applications. The country-wide digital health information database provides the means to form virtual large cohort studies by combining subjects from throughout the registry. Stored retrospective samples could be collected and queried in biomarker assays, and these measurement values could be correlated with clinical measurements as mentioned above. The power of such population studies could be used to test the hypotheses that equilibrate marker measurements with disease development and eventual outcome.

Identifying Diseases in Early Phase of Onset. An even further advantage of the digital health information database would be to identify and treat subjects with symptom-free early disease among the at risk groups in the population. There are currently no laboratory tests that can detect the smokers’ susceptibility toward the deleterious effects of smoking on lung function. Smoking cessation is still the only proven tool to stop lung function decline and, as several studies have shown, that it is especially beneficial in early quitters. At the most basic level, the digital health information database can identify smokers at a relatively early age, and these smokers could be counselled with smoking cessation programs to reduce risk factors. The database could also be used to form epidemiological cohorts from younger smokers with no complaints that continue to smoke despite counselling to follow certain disease development and early entry into treatment and therapy to reduce potential disease burden. The overall benefit is not only to the individual patient but also to the society by limiting the costs of long-term hospital care necessitated by advanced disease as well as achieving higher levels of quality of life for both symptom-free and clinically burdened subjects.

Conclusion

The interoperable digital health information system improves accessibility for citizens and researchers to health data. Public and private sectors, clinical care providers, and researchers all benefit from the accelerated delivery of comprehensive health data.

Summary

Studies of health or disease in a large population demand large-scale resource investments. Estonian National Electronic Health Record (EHR) was established with the assigned purpose to develop a comprehensive framework that encompasses different medical data in the digital format to exchange health information. EHR system acts as repository of health data obtained throughout citizen contacts with health care providers. EHR system can be of interest to the clinical proteomics community. The interoperable digital health information system improves accessibility for citizens and researchers to health data, with the ability to assign context to disease development in individual patients who are members of large population-based health database that can be assessed as individuals or as a population in prospective studies of prospective diseases. Public and private sectors, clinical care providers, and researchers all benefit from the accelerated delivery of comprehensive health data.

References


PR1007784