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e-Health/EHR and Clinical Research

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Conceptually the Electronic Health Record (EHR) will be a lifelong collection of health-relevant data for a (consenting) person. The main purpose of the EHR is to assist medical care by providing health professionals with the information for diagnosis and therapy where, when and how it is needed. This is particularly important in the highly specialised (and sometimes fragmented) health sector of today, where a patient is seen and treated by many different health professionals.

Uses Of EHR Go Beyond Direct Medical Care

Besides direct medical care, there are many (potential) secondary uses of the data in the health record – streamlining of organisational processes, data for management and planning in the healthcare system, epidemiology, quality control, medical research etc.

In e-health, the EHR is part of an integrated system of actively distributing and monitoring the information in the EHR. On a small scale this could mean an alert to a physician that patient data suggests a contraindication to a prescribed drug or on a national or even international scale an alert to health authorities, that an abnormal increase in the incidence rate of a infectious disease in some region might need attention and intervention.

Controlling Misuse

Of course there are also potential misuses of the EHR infringing the patients (but also the health professionals) right of privacy or informational self-determination. This shows that the policies about who might (legally) access which parts of the EHR and for what use and who (e.g. the patient) might deny or grant access to (specified parts of) the EHR and the methods to enforce these policies are of vital importance for the implementation of the EHR.

Clinical Research / Clinical Studies

Today the terms clinical research and clinical study are almost synonymous, because the well designed clinical study is the most reliable means to test a clinical hypothesis and to get dependable results.

To achieve that the study must meet a number of requirements: The hypothesis must be known beforehand, random assignment of patients to test group and control group, blinding and double blinding, clear definition of inclusion and exclusion criteria, strict formal requirements for documentation etc.

Integrating Clinical Studies in an e-Health System

In principle it should be possible to integrate clinical studies in the e-health system because a considerable part of the data needed for a clinical study are also part of the EHR and the additional data particular for the study are usually elicited in a clinical environment and could be integrated in the data capture protocols of the EHR for the time of the study. In reality for a multicentric study this is almost impossible because of differences in terminologies, policies, data formats, regulations, interfaces etc.

In a recent article in ‘Meth. Inf. Med.’ Prokosch listed the integration of medical record systems and clinical trial databases as one of the most important challenges for medical informatics. In analogy to the alerts described in the first paragraph, the e-health System could give an alert if a

patient matches the inclusion criteria of a current clinical study, thus assisting patient recruitment.

Clinical Research Outside of Clinical Studies

For different reasons, clinical studies are not always feasible. As a rule of thumb a study cannot be performed if the potential risk outweighs the potential benefit for the patient. To give a classic example: The hypothesis that an increase in the incidence rate of congenital malformations is due to a newly introduced drug cannot be tested by a prospective study! In such a case the only possibility is a careful analysis of already existingdata - hence the importance of a comprehensive documentation even of 'routine' cases.

In this case, one could in a first step retrieve all babies born after the introduction of the drug and then build four groups: Baby has no malformation and mother did not use the drug, baby has malformation and mother did not take the drug, baby has no malformation and mother did use the drug, baby has malformation and mother did use the drug.

In an integrated e-health system, such a task should not be too complicated (except if the drug is sold over the counter) and the statistical analysis would give a strong indication how to proceed (from removing the drug to dismissing the hypothesis).

An e-health system could even recognise the increased rate of malformations automatically, give a warning and then assist in the search for possible causes (finding differences in the anamnesis of babies with and without malformation). In most existing systems only the first part – finding the mothers of babies with and without malformation could be automated (but many different databases would have to be involved).

Results that are not obtained by planned clinical studies are more likely to be distorted by different forms of bias. Still the physician facing a patient must make a decision how to proceed even if information is incomplete and the therapeutic options are not perfectly validated. Clinical science cannot disregard any information that may help the physician to make a rational decision.

The Role of Classification in Clinical Care and in Clinical Research

Each patient is a unique individual and must be treated (and documented) as such. Each patient must be put in a class for rational (evidence based) treatment.

Let us start with the second of these two seemingly contradictory statements. Experience leads us to expect that a treatment that was successful in one case will be successful in a similar case. How is 'similar' defined: The two cases are not too different with respect to parameters that are (may be) relevant for the outcome, e.g. age, gender, stage of the disease, condition of the patient etc.

With these parameters one defines classes of similar cases (a typical example is the classification of tumour stages) and these classes are the basis of clinical studies, treatment protocols etc. If a tumour patient comes for treatment, the type and stage of the tumour is determined and the appropriate treatment protocol is applied.

Although this protocol has been found to be the most effective one for this class of patients, results are not uniform, some patients do not respond and relapse or develop metastases (and might have needed a different treatment). Scientists do not attribute these differences to mere chance but to causal chains that are not yet understood. It is therefore a constant aim of medical science to find these causes, the hidden parameters that make the difference and to refine the classes accordingly.

An e-health system could be used again to find patterns associated with different responses to the treatment if as many findings as possible had been collected, even if they were seemingly unrelated to the clinical problem. So even if the patient is put in a class to determine the treatment he/she must also be documented as an individual. Needless to say that in the direct communication with health professionals the patient must always be seen as an individual person and not merely as a case.

It is likely that many hidden parameters mentioned above may be attributed to differences in the genome or proteome. The linking and common analysis of genome/proteome data with clinical data is one of the big challenges in medical research and will require sophisticated and standardised databases within the e-health system.

Medical Records

The classical medical record was/is a heterogeneous collection of handwritten or typed notes from different sources about anamnesis, diagnostic and therapeutic procedures and results, discharge letters, images, lab results etc., with a relatively free format. Patient ID (or name) was the only criterion for direct retrieval. The record was for human use only and the content had to be scanned visually to extract any information. Still, as a basis for information about the individual patient it was remarkably successful.

The first electronic records were not meant to replace the paper record but to complement it with a kind of electronic summary consisting mostly of codes denoting more or less complex medical entities. From the point of view of research they did allow for some calculations, frequencies, correlations etc, but for most instances they had the important task of case finding, selecting those cases that were relevant for a problem. Then one had to retrieve those records and extract the details for the scientific analysis.

The EHR has the aim to replace the paper record. This has become a possibility for two reasons: The processing power and the storage capacity of IT-systems has increased tremendously and almost all the data are now captured in digital form because IT has been integrated in imaging devices, lab-systems, measuring devices etc. and virtually every report is written with digital text processing.

Form Follows Function (of the EHR)

The medical record has one main function, serving medical care by providing the necessary information to the different health professionals treating the patient and many secondary functions from billing to research. In the first case, the system merely presents the data for human interpretation. In most of the secondary uses the system is supposed to interpret and process the data directly and therefore needs a formalised representation

(a code) of all relevant medical concepts.

Examples are ICD (International Classification of Diseases) or SNOMED (systematised nomenclature of Medicine) but in reality codes are often local (and not explicitly seen as codes) defined as input forms with menu items etc. Choosing a code is a classification of the patient which means abstracting from (seemingly) irrelevant details. As an example, in many systems you have to select either female or male (rarely a third option is possible). But if the patient does not fall in one of these groups either physically (e.g. hermaphrodite) or mentally (transgender) this should be documented in the EHR because it is relevant to address him/she as an individual.

The functions of the EHR pose sometimes conflicting requirements to the documentation. In particular when dealing with human interpretation of findings (e.g. a radiologic report describing the position of a tumour or the abnormal run of a vessel) or human communication (e.g. describing the anamnestic details given by a patient in a psychiatric case) it is difficult to replace natural language by codes without losing important information (by the way, imagine a clinical conference where participants use only SNOMED codes to discuss a complex case).

Challenges

There is no question that e-health systems including the EHR could, and will be an important data source for clinical research, supporting clinical studies, testing clinical hypotheses and, even more importantly, generating hypotheses (e.g. about possible causes for diseases or different responses to treatments) from a linked analysis of so far unrelated data in particular including genomics and proteomics.

In addition to the necessity to define and implement data protection, communication standards etc., there is an urgent need to develop a medical ontology allowing a clear and standardised representation of medical concepts including temporal and spatial relations. In designing an information system for e-health the needs to classify patients in groups for therapy and data reuse for e.g. research on one side and to retain and document the individual details on the other side must be carefully balanced. The same is true for the use of natural language for human communication and classifying codes for selection therapy protocols and other secondary uses.

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