

IJBH

International Journal
on Biomedicine and Healthcare

IJBH 2016

ISSN 1805-8698

An Official Journal of the EuroMISE Mentor Association

International Journal on Biomedicine and Healthcare

Volume 4 (2016), Issue 1



Main Topic:

Electronic Healthcare Documentation

Editors:

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www.ijbh.org

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Publisher

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CZ-14000 Praha 4

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EU VAT ID: CZ25666011

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Electronic Healthcare Documentation

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Medical documentation is as old as the systematic approach to caring health problems. With the definition of rules for practicing health care, also the ethics of documentation has been covered. Elderly still remember the time of paper records in doctors' offices shelves, and doctors' reports exchanged with colleagues by postal services. Patients have been classified from a dark horse or unknown quantity to those with a rich history stored meters of folder rows.

Beside supporting health professionals' work by documenting and sharing medical facts about the patient, the record was and is also the legal evidence of all processes and related liabilities, but also the basis for reimbursement.

With the advent of information and communication technologies, the medical documentation advanced to electronic medical documentation this Special Issue is dedicated to. The papers published here are all presented to the International Conference "Electronic Healthcare Documentation" of the EuroMISE Mentor Association, 11 February 2016, Prague, Czech Republic. The event is accompanied by the EuroMISE Mentoring Course "Medical Informatics: Health Information Management". More details and the materials and presentations can be found at www.euromise.net. The conference succeeds in topic and organizational framework the EuroMISE 2004 – EFMI Symposium on Electronic Health Record, Healthcare Registries and Telemedicine, 13-16 April 2004, Prague, Czech Republic.

Containing all facts about the status of the patient and related processes, the electronic medical record (EMR) when established inside an organization, or the electronic health record (EHR) when being established across organizational borders, is the core application of complex health information systems environments. While data entry in EMRs and EHRs is managed by health orga-

nizations and their staff, building legal records, personal health records are frequently managed by patients, enabling entries, corrections, or deletions, so the record cannot meet the requirements for a legal record. Logical EHRs can be established locally, regionally, or nationally. Technical approaches to EHR solutions, i.e. systems for managing and properly deploying EHR data, range from communication platforms through the virtual record of federated systems up to centralized records system architectures. EHRs do not address just individual health documentations. Also local, regional, or even international registries for specific diseases must be mentioned here, such as cancer registries, registries for rare diseases, etc. In that context, medical data are also used for research and developments, such as clinical studies, etc.

Jan van Bommel (The Netherlands) tries in his very vivid paper "Developments in Medical Informatics – can the future be predicted from the past?" to envision further developments in health informatics and specifically regarding EHR systems and services based on the evolution of computer technologies and health informatics in the past. Bernd Blobel (Germany) discusses principles, standards and national solutions for EHR and PHR systems to best support current, but also future care paradigms such as personalized, predictive, preventive, participative care based on systems medicine, big data, analytics, etc. Such approaches increase the challenges for security, privacy, and trust. As those issue couldn't be addressed in this conference and therefore in this volume, the reader is referred to IJBH 2015;3,1. For representing, semantically communicating and understanding medical data, the underlying terminologies and ontologies are crucial. Anna Adelöf from the related International Health Terminology Standards Developing Organization (IHTSDO) (UK) shortly highlights properties and opportunities of the clinical terminology SNOMED-CT. Zvolsky et al. in-

troduce structure and procedures of the Czech National Cancer Registry (CNCR), historically integrated into the advanced cancer registration initiatives evolving in the former Eastern bloc countries. Zvára et al. designed the new model of electronic oral health record based on the ontology representing basic human dental structures. Mario Bochocchio and Lucia Vaira present in detail a new approach for improving diagnosis and therapy of fetal growth disorders by a cloud-based system for collecting and managing fetal and maternal data on a global scale and producing customized growth curves. Hynek et al. gives an overview of chorionic villus sampling (CVS) performed in fetal medicine centre over a 11-year period and to identify risk factors contributing to miscarriage after CVS. Hrachovina et al. describe the technical and methodological challenges for reducing measuring errors to guarantee data quality in body surface potential mapping for cardiac resynchronization therapy studies. Mateják et al. discuss the importance of patient's genetic data in pharmacology. They offer a pharmacogenomic module to optimize pharmacotherapy by considering the individual

genome and so supporting the current approach to personalized medicine. Ložek et al. deals with advanced health documentation software that is designated for congenital heart defect catheterization purposes. Jan Kalina and Jana Zvárová discuss clinical decision support systems and the challenges of constructing their classification rules by means of methods of multivariate statistics and/or data mining. Finally, Lhotská et al. discuss the deployment of gaming technologies as tools for actively engaging users in self-managing their health. Thereby, technological, social and psychological implications have been analyzed.

We hope that colorful bucket of contributions considering disease-specific applications, technical obstacles, social requirements as well as methodological, ethical and legal challenges in designing, implementing and appropriately deploying electronic medical documentation and EHR systems will promote this core technology across Europe and beyond, so finally contributing to improve our citizens' health and welfare status.

Developments in Medical Informatics – Can the Future be Predicted from the Past?

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Abstract

This contribution will be on the future of medical informatics, which nowadays is also known under different names, such as 'health informatics' or 'biomedical informatics', and many other branches such as 'nursing informatics'. Predicting the future of this discipline is extremely difficult, if not impossible, given the rapid changes in computer technology. But, at least, we could make ourselves aware of the pitfalls in the past so that in the future we may avoid some obstacles and have a more realistic view.

Medical Informatics is – similar to medicine itself – not a fundamental discipline, but a multidisciplinary field, in which people partake from different backgrounds, such as medicine, biology, physics, chemistry, mathematics, informatics, statistics and epidemiology and the management of biomedical engineering in general.

Keywords

Future, model, multidisciplinary, electronic health records

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IJBH 2016; 4(1):3–8

received: December 8, 2015

accepted: January 15, 2016

published: February 10, 2016

1 Evolution

Looking back, expectations in the past were sometimes far overstressed. I'm thinking of, for example, computer-based decision support and the electronic health record. In the early times, without the presence of PCs and the Internet, prediction of the future was unrealistic, partly because of the evolution of the computer itself.

Most computer users of today have no idea where we came from. Within half a century computer technology has drastically changed our modern world. The development in hardware went extremely fast. It started in the 1940's with large but slow mainframes; nowadays computer technology is small and everywhere. Today's children easily integrate the new technology in their daily life. Patients expect that their doctors routinely use computers to support health care.

Who remembers paper tapes or punched cards; magnetic memories or digital magnetic tapes? We now count the speed of computers not in kilohertz, but in gigahertz, memory size in terabytes. The number of transistors on smaller and smaller chips has doubled every two years. It is most impressive that Moore's law appears to be valid until today.

Nobody had predicted the advent of the PC in the 1970s, the Internet in the 1990s, or tablets with touch screens of today. We also had no idea of computer viruses or cybercrime so that we are now forced to look for far

better rules and measures for confidentiality and data protection. This applies in particular to the medical domain. We became more and more aware that the weak spots of computers in health care are not in the first place the hardware or the software, but people, the manware.

In health care, we have seen an exponential increase in user involvement. Patients, in particular the younger generation, have grown up in an age of computers, social media, iPods and iPads. Before consulting a doctor, patients often use the Internet first. Since the National Library of Medicine opened its data for the public at large, the use of PubMed has grown by a factor of 10 or more. This was the main reason for Jean-Raoul Scherrer to establish Health-on-the-Net, HON, in Geneva, in order to assess the reliability of medical websites.

As said, the computer revolution had great impact on health care. A typical hospital now counts thousands of computers, integrated in a hospital network with numerous servers and processors. The computer has invaded all clinical and preclinical departments, and all general practitioners are connected to networks to support primary care.

2 Rehearsal of a Model

In discussing the possibilities and limitations of research and education in Medical Informatics, I would like

to discuss once more the scheme of a building (Figure 1) that we developed in the early 1970s, when our department in Amsterdam started R&D in medical informatics. Some of the readers may have seen this model before.

The scheme can be considered as a building of six floors. On each floor typical applications of computers in health care are located. From bottom to top the applications become more complex and increasingly dependent on human involvement. As a rule, a higher level can only be reached when having passed the lower levels. I will give some examples and discuss the complexity of computer applications in medicine and health care and their dependency on human involvement. Experience over the past 40 years may have taught us some lessons for the future. The model has proven to be valid over all these years and may help to develop a realistic view on the future.

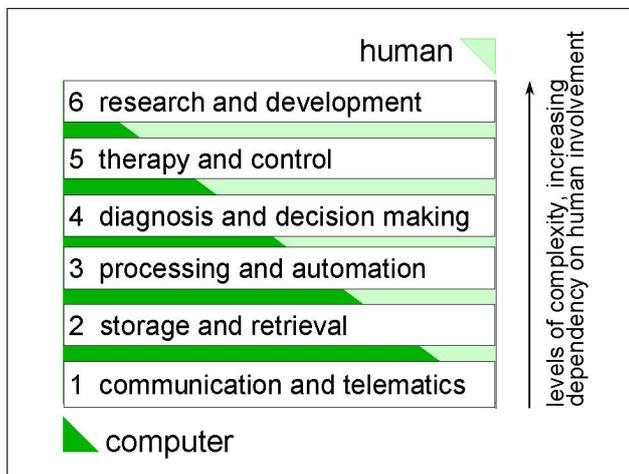


Figure 1: Scheme of computer applications in health care. The complexity and the human dependency increase from bottom to top.

Level 1

In the building different types of computer processing take place. At the lowest level, the ground floor, we find the entrance (input) and the exit (output) of the building. On this level we find communication by computers to exchange health care data. Data enter the building, are quickly transmitted without being altered, and are sometimes coded and decoded, and they leave the building immediately. All social media, the Internet and hospital networks are involved in the applications on this level. The key here is data interconnection. They are, also in society in general, the most widespread applications of computers.

Future. The crucial issue on this level is the man-machine interface. Since the advent of the touch screen, interaction got much better. Computers integrated in portable devices or robots will increase to give assistance, such as wearable devices and wrist watches. Also voice

input will further improve. Nevertheless, the interaction between two persons – think of patients and care providers – is still far better than that between man and machine. Computer support at the lowest level is very beneficial for health care.

Level 2

On the second level, data that have been entered via the ground floor, are stored temporarily or permanently on disk or in the cloud for later retrieval or further processing on the higher levels. In principle, data on this level remain unaltered, but are orderly stored so that they can be retrieved later on.

Here we find the databases of hospital information systems, or the national databases of drugs or the results from laboratory tests, thesauri such as ICD or SNOMED. Also the large literature databases of the NLM are to be found on this level. Human involvement here concerns the required intelligence behind the structure of the different databases. Successful applications are the databases from ancillary hospital departments, such as used in laboratories or radiology departments, with their own systems such as a PACS.

A hospital is a complex organization, never static, but always in dynamic development. This renders the structure of all information processing systems in the hospital very challenging. Furthermore, diagnostic and therapeutic methods are continuously changing and evolving, increasing the complexity of data storage. A difficulty remains the interchange between the databases of different clinical departments and the outside world.

On this level, we also find the data contained in electronic health records (EHRs), e.g., of GP systems in primary care, containing EHRs. GP systems, too, exchange data with laboratories, pharmacies, hospital departments, health insurance companies, etcetera. Many of the data are coded and should be protected against illegal use.

A most challenging task is to use the data of patient records for other goals than merely individual patient care. Therefore, electronic health record systems require structured coding of drugs, diagnoses and therapeutic interventions. On such data, decisions are to be made on the higher levels in the building. Electronic health records also enable telemedicine and the structuring of longitudinal patient records for the continuity of care. In principle, the data are suitable for research and development.

Future. It can be stated that health care is unable to maintain its high quality without the proper storage and retrieval of health care data. The main challenge is to develop information systems that are future-proof and are adaptable to everchanging circumstances in health care. For instance, data transferability from an information system in hospital A to another system in hospital B, or even from department X to department Y in the same hospital, remains a major task for medical informatics. Research departments in medical informatics should remain to play

a forefront role in the realization of solutions for these problems.

Level 3

We are now climbing higher up in the building and arrive at level 3, where the data are further processed. I repeat that at the ground level, data enter the building, at level 2 they are stored, but in principle are kept unchanged, and at level 3 data might be processed according to specified protocols or algorithms. Here, the complexity is much higher and human insight is required in the nature of the data and in the processes where they have been generated. Applications on this level deal, for instance, with biosignal and image processing, or laboratory automation. I will give some examples.

An early application that we developed was the support of patient monitoring on the CCU, the ICU or during open-heart surgery. Here, most physiological functions and biochemical parameters, such as respiration, pH or pCO₂, cardiac and lung function and temperature, have to be controlled. The overall interpretation of all these data is still to be done by experienced surgeons, anesthetists and well-trained nurses. A further application is the analysis of biosignals, such as ECGs, EEGs or spiromograms. The outcomes of this analysis are the inputs for decision making on the next level.

Another application of computer processing is the 4-D reconstruction of the beating heart or the 3-D construction of the human brain from MRI and/or CT scans. Analysis and interpretation of such images and quantification of the effect of interventions is still an area of fundamental research. Again, interpretation remains largely a human task and only on the next level in our building computers may give some decision support.

Future. Computers are very successful on the third level. High-quality patient monitoring, imaging and image processing would be unthinkable without support by computers, often integrated in advanced instruments. In the future, much has to be expected from further miniaturization and the integration of transducers with processors. Again, the interpretation of the results of signal and image processing is still mainly a task of experts, to be done on the next level. In particular on this level, industry plays a major role and nowadays departments of medical informatics are less involved than in the past.

Level 4

We are now climbing to the level that is most essential for medical care: decision making. Indeed, the field of diagnostics is at the heart of health care provision. Here, the interaction between patients and care providers is essential. We repeat: data are entered at the ground level, stored at level 2, processed at level 3, and finally interpreted at level 4. Forty years ago, the expectations for

computer-assisted decision-making in medicine were still sky-high, but acceptable results appeared to be very modest. The key reason is that computers require a formalized approach to data processing, which is difficult, especially in health care.

The reason why computers are far less successful here, is caused by the fact that they require a formalized and generalized approach. When treating individual patients this formalized approach is only possible in limited circumstances, that is, when such processes can be expressed in terms of mathematics and algorithms. When diagnosing the operation of a modern car, computer diagnostics are very well possible; all cars of a certain type are identical. Patients, however, are not like cars; they are all largely different. Patients show inter- and intra-individual variability; diseases are often dynamically changing and, besides, often the data, required for interpretation, are not obtainable, unless we invade the human body. But even then! This is the reason that decision-support systems, developed in the past, are very seldom in use for clinical practice. This holds for an early system such as MYCIN, but also for INTERNIST, QMR, ILIAD and many others.

This is even the case for ECG interpretation, in which we have invested much research in the past. Even when using the best systems, computerized ECG interpretation has not been completely accepted by clinicians. However, for screening purposes, serial comparison, epidemiology, and applications in primary care the benefits have been proven. The development of decision-support systems has taught us that computerized systems, even if evaluated thoroughly, still have a long way to go before being accepted in routine clinical care.

Future. The experience from the past teaches us an important lesson for the future: only processes that can be completely formalized are suitable for computer support. In all other cases, decision support should be done in interaction with medical experts. The future of applications on this level lies, therefore, in interactive systems.

Level 5

What has been said about human involvement and complexity on level 4, applies even more to level 5, where therapy take place. Except for formal processes in, for instance, patient monitoring, surgery, and drug therapy, computers can rarely be used independently from human involvement. For instance, the use of robots, such as in use in some branches of minimal invasive surgery, require the interactive control by experts. I already gave an example of monitoring on level 3. The data processing might be fully automated, until the moment that the results have to be interpreted. Important applications on this level are the assessment of drug prescriptions: interactions and contra-indications.

Future. For therapeutic support, computers cannot and should not operate without the interaction with human experts. This is here even more essential than on level 4. Research departments should play an important role in the optimization of man-machine interactions.

Level 6

On the level of R&D, human involvement is at its highest, since creativity and originality belong to man only and cannot be transferred to machines. Data and interpretations, collected at the lower levels, are the inputs for research at this highest level. Typical applications are deduction by statistics, computer modeling, knowledge extraction and processing, and assessment of the systems at the lower levels.

Future. This is the area where research departments of medical informatics carry out their R&D, in collaboration with other (clinical) departments. Lessons learned in the past are that models cannot be used outside the domain for which they were originally developed. An exciting challenge on this level is the collaboration with research in bioinformatics.

3 Summarizing Remarks

In drawing some general conclusions, whether the future can be predicted from the past and what lessons have been learned, I want to make some final and summarizing remarks on the building with its six floors: Levels 1 to 3 deal with the syntactic aspects of information, level 4 with the semantic and level 5 with the pragmatic aspects. In medicine, there is a parallel with the stages observation, diagnosis, and therapy. Some overall conclusions on the future are the following.

- On the ground level we may expect a rapid increase of personalized health information systems in which the patient is personally involved. Patients and their relatives will demand access to medical knowledge in understandable terminology. A new generation of patients and clinicians has grown up for whom computers are as common as pencil and paper. However, data reliability, confidentiality and data protection need further fundamental research. The responsibilities for the ownership of the data are not well regulated. Who has access to all these data?
- On the level of data storage, networking needs much more attention than in the past. Only few systems are able to exchange data in a standardized manner. The development of healthcare-wide electronic health records still has a long way to go. The realization and acceptance of EHRs is far more complex than was expected 40 years ago. In the future, we will see the development of hospitals without walls. Continuity of care is an ever more important issue

when an elderly population is confronted with multiple diseases, requiring longitudinal records, accessible for different care providers.

- As said, on the 3rd level a further integration is to be realized between computer intelligence and instrumentation for data processing. The hardware no longer determines the cost of processing. Industry will play a leading role on this level.
- Levels 4 and 5 form the core of health care. Here, in the past, many projects were started with far too high expectations. Many researchers have learned their lessons so that in the future we should refrain from developing fully automated decision or therapeutic support. We should not strive for the replacement of care providers by machines, but to develop interactive systems that leave human responsibilities intact.
- On the therapeutic level I expect no great breakthroughs from the use of computers or robots. As said, interactive systems should be developed, leaving the responsibility of care providers intact. There is, however, positive experience with the incorporation of alerts in information systems.
- On the highest level, research departments of medical informatics feel very much at home. In fact, all data collected at the lower levels should be usable for research. In particular, attention should be given to the increasing role of patients, in view of the challenges in health care that lie ahead.

Because of the importance of EHRs for the entire domain of health care, we will pay separate attention to this subject.

4 Electronic Health Records

In the beginning of the 1980's, we initiated our R&D for the development of EHRs. We started our developments in primary health care, and expanded later to clinical care. Let me briefly describe the different stages of our R&D and point to some important aspects that may be of wider interest.

The structure of health care provision in the Netherlands is, in a way, ideal for the introduction of EHRs. Each citizen is connected to just one primary care practice, where one or more general practitioners (GPs) coordinate her or his health care, keep a comprehensive patient record, and refer the patient, if necessary, to a specialist or a hospital. In our R&D on EHRs we concentrated from the very onset on the entire patient record, including the patient history. We had, from the beginning, a close collaboration with GPs and industrial partners. The latter were involved early on, because a university R&D department is neither able to, nor should be responsible for the implementation and maintenance of information processing systems in health care. We also had the intention of

broadening our research later on to clinical EHRs in hospitals. From the onset we also had the intention to shape a network for research. Later, we expanded our research to projects for the assessment of the quality of health care, the integration of EHR systems with decision support systems, and post-marketing surveillance of drugs.

The development of an EHR system for clinical use was based on the concept of structured data entry. This rather basic research also took us about 10 years, before it resulted in a system that could be used for all sorts of clinical care settings, thanks to its conceptual approach. The development of a clinical EHR system that ideally comprises all patient-related data, from the patient history up to diagnostic and therapeutic results, appears to be a complex enterprise. It is an area full of pitfalls and difficulties. Perhaps, the most complex issue is that an EHR system for clinical use (in contrast to that in primary care) needs to be implemented for a variety of clinical specialties. In the different clinical departments, the patient histories are often different, because of the requirements of clinicians with very different backgrounds and ideas.

There are fundamental differences between automation in health care and, for instance, in banking, traffic control, or industry. Health care processes can seldom be fully standardized, as also mentioned above. Humans enter the loop of information processing in at least two very different roles: as subjects providing patient care – the clinicians – and as subjects who are the object of care – the patients. Everyone pursuing a career in biomedical informatics needs to be very aware of this.

In our EHR research for primary care we have been very successful, and we could contribute to the fact that all GPs in the Netherlands use information systems containing an EHR, most of them exchanging their data now with other GPs, and many of them are delivering data to our research team, participating in a research network.

In clinical care there still remain major challenges. The complexity of clinical patient care is much greater, much less standardization is possible, and all clinical specialties are in a process of continuous development and change, because of the fact that medical science itself is constantly being renewed. EHRs in a clinical environment, therefore, should permit much more freedom to the clinician to implement her or his own ideas. This freedom, however, is in sharp contrast with the requirements for formalization and standardization. Our R&D in the field of structured data entry for clinical EHRs has shown that it is important not to surrender when major difficulties arise as a result of, for instance, conflicts between freedom and standardization, or are due to the lack of financial support or adequate clinical collaboration. Perseverance is essential.

5 New Branches

Just as for medical research as a whole, R&D in medical informatics is in permanent evolution. For in-

stance, it is only about 25 years ago that basic medical research was primarily concerned with problems in physiology, anatomy, or embryology; and fundamental research in biomedicine was mostly carried out at the level of organs and organisms. Nowadays, the challenges are of a totally different nature, with many research projects primarily conducted at the level of biomolecules and cells. This is partly the result of the sequencing of the genome. Genomics and proteomics have had a profound effect on modern clinical research and population-based research.

As a consequence, a new branch of informatics in medicine has emerged under the name of bioinformatics. Despite these changes, it will still take a considerable amount of time before the newly gained insights in biomolecular and bioinformatics research will be translated into clinical and medical practice, i.e., into new diagnostic and therapeutic techniques. Therefore, over the years the terms that designate our field have evolved and also encompass medical telematics, biomedical informatics and e-health.

I expect that in a couple of years medical informatics will follow the same road as other disciplines, such as medical physics, clinical chemistry and even physiology and genetics: full integration with the specialties and branches of basic and clinical medicine and health care. The involvement of patients and their families in using medical data and knowledge will continue to grow. This was the main reason why the NLM developed PubMed and Jean-Raoul Scherrer Health-on-the-Net. More and more electronic health records will contain genetic data, also of interest for one's relatives. For this reason utmost attention should be paid to privacy and security, the more so when large patient databases are collected for research and medical data are exchanged on the Internet. I also expect that the quality of health care, provided by doctors and nurses, will increasingly be monitored by computer systems to ensure that it fulfills the basic requirements for medical evidence. In time the results from medical informatics will become common practice in medicine and health care. The time of the pioneers and their direct offspring will then be over. Hopefully their best ideas will have survived for the benefit of patients and health care providers.

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EHR/PHR Systems Today and in the Future

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Abstract

Electronic health record (EHR) and personal health record (PHR) systems are core applications for enabling sharing data and knowledge about the patient and related processes between the different actors involved. For improving safety, quality, and efficiency of care delivery services, health systems are matter of organizational, methodological, and technological paradigm changes. EHR/PHR systems have to evolve appropriately to keep up with those changes. The paper introduces definitions as well as types and basic concepts for EHR/PHR systems. Some of the most important national programs and solutions are shortly introduced, and many others are directly or indirectly referenced.

Architectural approaches as well as required components and services for future proof intelligent EHR/PHR systems deploying mobile technologies, artificial intelligence, big data analytics, omics disciplines, security, privacy, safety, are shortly addressed, or references to related papers are presented.

Keywords

EHR, PHR, future EHR/PHR systems, Enterprise Architecture, interoperability

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IJBH 2016; 4(1):9–16

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Comprehensive and accurate information about the status and processes directly and indirectly related to the health of the subject of care must be provided and managed to enable safe, high quality, and efficient care services [1]. In this evolutionary process, dedicated health information systems turn towards EHR/PHR systems.

In the early nineties, the Medical Record Institute has described a step by step approach to Electronic Healthcare Records (EHCRs) over five levels from the automated medical record through the computerized medical record, the electronic medical record, and the organization-moderated electronic patient record up to the electronic health record. The first three levels have been dedicated to electronic patient data, while the others dealt with the EPR and finally the EHCR, which contains information beyond patient's care such as social aspects, health prevention, etc. A more detailed discussion can be found, e.g., in [1].

Regarding the logical and organizational structure of an EHR independent from technological and implementation details, the following basic EHR types can be distinguished:

- Organization-centric EHR

- Personally moderated EHR
- Personal Health Record (PHR)
- Legal EHR (legally secure EHR)
- Centralized EHR
- Distributed EHR

The personally moderated EHR is still legal, organization-centric, i.e., the patient is not allowed to enter information, but he/she authorizes potential users. Contrary, the PHR is not a legal record, as the patient can enter or delete information.

There are three representational streams for specifying and implementing EHR architectures: a) data approach (data representation), b) concepts approach (concept/knowledge representation), and c) process/service approach (business process / service representation). From a protocol perspective, we can distinguish communication focus (message), document focus (clinical document), and business process focus (application). According to the time dimension, an EHR can represent an episode (EHR extract) or a life-long record (EHR service).

EHR approaches can be distinguished according to the access model used (indirect vs. direct access). Techno-

logically, EHR systems can be implemented as integrated system, federated system, or service oriented system.

2 Interoperability Challenges

Dealing with the interoperability challenge for health information systems, which has started in the late eighties with the requirement for sharing data between different departments within a hospital, and has then been enhanced to cross-organizational health information sharing, enters now another round of evolution due to the paradigm changes health and social care is faced with. Those organizational, methodological, and technological paradigm changes have been discussed in different places already [2, 3, 4, 5]. In the following, they will be highlighted from an advanced interoperability perspective.

Interoperability has been originally defined at Merriam-Webster as "the ability of a system (as a weapons system) to use the parts or equipment of another system" [6]. With the triumph of information and communication technologies, IEEE enhanced the interoperability definition to "Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged" [7]. Already years ago, the author introduced a more comprehensive definition of interoperability beyond technologies to "Interoperability describes motivation, willingness, ability, and capability to cooperate for achieving common goals or business objectives" [3, 8].

The organizational paradigm change represents the move from organization-centric, through process-controlled to fully distributed, highly flexible, person-centric approaches. In organization-centric approaches, concepts, terminologies and ontologies, as well as policies are *âper order di mufti* established and endorsed. Therefore, in intra-organizational communication, sharing data is sufficient for interoperability. In the case of inter-organizational communication such as managed care or process-controlled multi-organizational collaboration in context of disease-specific disease management programs, a common set of related concepts, terminologies and ontologies, as well as policies must be negotiated and defined prior to the onset of the business cases. For endorsing them to facilitate communication and cooperation, not just data, but also the underlying concepts, terminologies and ontologies, as well as policies, i.e., the semantic information must be shared. In both settings, peer-to-peer data/information exchange was the dominating communication paradigm. In person-centric settings, the status of the subject of care, environmental and contextual conditions, his/her wishes and expectations as well as directly and indirectly interrelated actions define the care process, and therefore also all the related concepts, terminologies and ontologies, as well as policies. In other words, business process related knowledge of dynamic real world domains involved in that process and defined by domain experts must be shared. However,

the related set of knowledge in such environment cannot be shared a priori in an undefined environment. Furthermore, sharing the entirety of all the domain knowledge possibly involved is impossible due to the resulting complexity of the system. In other words, facts and knowledge must be shared and interpreted and appropriate actions must be derived in real-time, thereby also acknowledging different knowledge, skills, experiences, cultural background, jurisdictions, etc., of all actors involved. This implies the on the fly and automated harmonization of different concepts, expectations, or policies. The interoperability challenge results in the management of dynamic, open, multi-disciplinary/multi-domain systems to meet partially contradictory business objectives, involving any type of actors such as persons, organizations, devices, applications, components – or shortly principals according to the Object Management Group (OMG) definition [9]. Only a system-theory-based, architecture-centric, ontology-driven approach can solve the problem. For more information, please refer, e.g., to [3, 10, 11, 12].

Advanced EHR/PHR systems provide the informational representation of all the aforementioned systems and processes involved. In the described advanced care setting, the EHR/PHR becomes the core application, serving as communication and cooperation platform. This statement doesn't imply any implementation constraints. The aforementioned organizational paradigm changes must be enabled by related methodological and technological paradigm changes discussed as follows.

For describing the individual status of the subject of care, the methodological paradigm must change from a phenomenological approach of generally addressing health problems with one solution fitting all over the evidence-based medicine for dedicated care of populations stratified for specific clinically relevant conditions up to the level of systems medicine. Such approach enables the multi-disciplinary understanding of the mechanisms of diseases and their therapy from elementary particle to society, and by that way individually tailoring care diagnosis and therapy towards personalized, preventive, predictive, and participative (P4) medicine.

The person-centric care paradigm must be provided independently of time and location, so requesting fully distributed mobile technologies. Furthermore, the consideration of individual, environmental, and contextual conditions requires the application of wearable and implantable sensors and actuators using Nano- and bio- technologies, but also knowledge representation and management, Artificial Intelligence, Big Data and Business Analytics, Cloud Computing, and social business. More details on the aforementioned paradigm changes can be found, e.g., in [1].

According to ISO 20514 "Electronic health record – Definition, scope and context" [13], an Electronic Health Record (EHR) is defined as "a repository of information regarding the health status of a subject of care and all related processes in computer processable form. An EHR provides the ability to share patient health information

between authorized users of the EHR and the primary role of the EHR in supporting continuing, efficient and quality integrated health care”. By the same standard, an EHR system is defined as ”a set of components that form the mechanism by which electronic health records are created, used, stored, and retrieved. It includes people, data, rules and procedures, processing and storage devices, and communication and support facilities”. Finally, an EHR architecture is according to ISO 20514 ”a model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care, and may retain integrity across systems, countries, and time”. Having this definition in mind, an EHR system at best fully represents the aforementioned system of person-centric and personalized care, so forming the core application in health settings [14, 15].

Meeting security and privacy requirements and expectations is crucial in such approaches, and even more in the context of the aforementioned advanced paradigms. As this complex issue would overstress the framework of this paper, the reader is referred to an related paper of the author [16].

3 Methods

Despite of being practiced again and again, a system composed of components from different disciplines represented using the terminologies and ontologies of those disciplines (domains) cannot be represented by one domain’s ontology or even by the ICT ontology computer scientist have introduced to accommodate ICT systems (see also [16]). Instead, a domain-independent and thereby domain-crossing representation of real-world systems has to be deployed, using system theory and resulting in an abstract, generic model of a system and its architecture, i.e. its components, their functions and interrelations. For that purpose, the Generic Component Model (GCM) has been defined, published in many papers, and deployed to formally represent many standards and specifications [3, 17, 18, 19]. On that basis, any real world system domain can be managed as a system (systems medicine, systems biology, systems pathology, etc.), thereby representing that system’s components using the domain-specific ontology. To ensure that different aspects of a system investigated by different disciplines are correctly interrelated, they must refer to the same abstract architectural GCM component represented by the abstract GCM ontology. The outcome is a system-theoretical architecture-centric and ontology-driven representation of a multi-disciplinary (domain-crossing) real-world system including an advanced EHR/PHR system. Figure 1 illustrates the GCM with its dimensions system architecture (component composition/de-composition), domains, and development process. The latter refers to the Rational Unified Process [20] or ISO/IEC 10746 Open Distributed Processing – Reference Model (RM-ODP) [21]. To consider

real world domains first, before transforming them into ICT solutions represented by ICT ontologies, the Business View has been introduced additionally to the RM-ODP platform-independent viewpoints Enterprise View, Information View, Computational View, as well as to the platform-specific viewpoints Engineering View and Technology View.

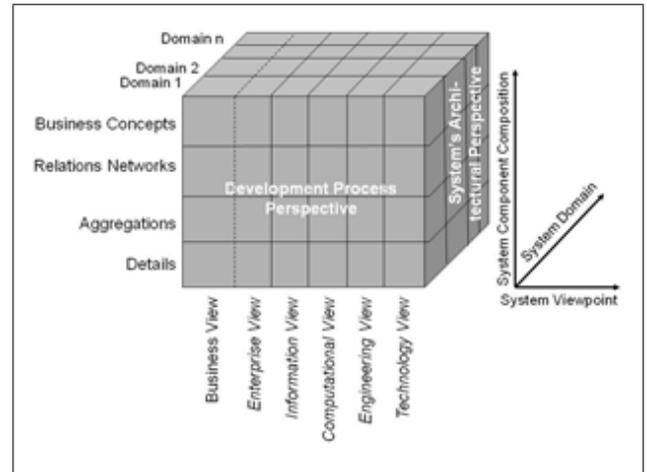


Figure 1: The Generic Component Model.

4 Results

Following, approaches to EHR/PHR systems modeling and implementation are shortly discussed.

4.1 Enterprise Architectures of EHR/PHR Systems

Having been heavily involved in the development and implementation of many countries national eHealth, and especially EHR, strategies and programs, there are clear streams to differently following the aforementioned EHR types, EHR architectures, protocols, and time scales. In common is however that in most of the countries the intended time frame has been extended several times, so demonstrating the dimension of such project. Furthermore, most of the approaches are evolutionary. While in the Mentoring Course as part of the International Conference on Electronic Healthcare Documentation most of the different national approaches to EHR systems are presented in some details [22], just some special examples can be shortly discussed in the following.

An excellent example for a national strategy, design and implementation project is offered by Canada. Based on basics elaborated by the national agency Infoway in cooperation with experts from organizations and individuals, national, regional, but also disease-specific solutions have been developed and are currently under implementation [23, 24]. The project itself is called EHR Solution, combining people, organizational entities, business processes, systems, technology and standards that interact

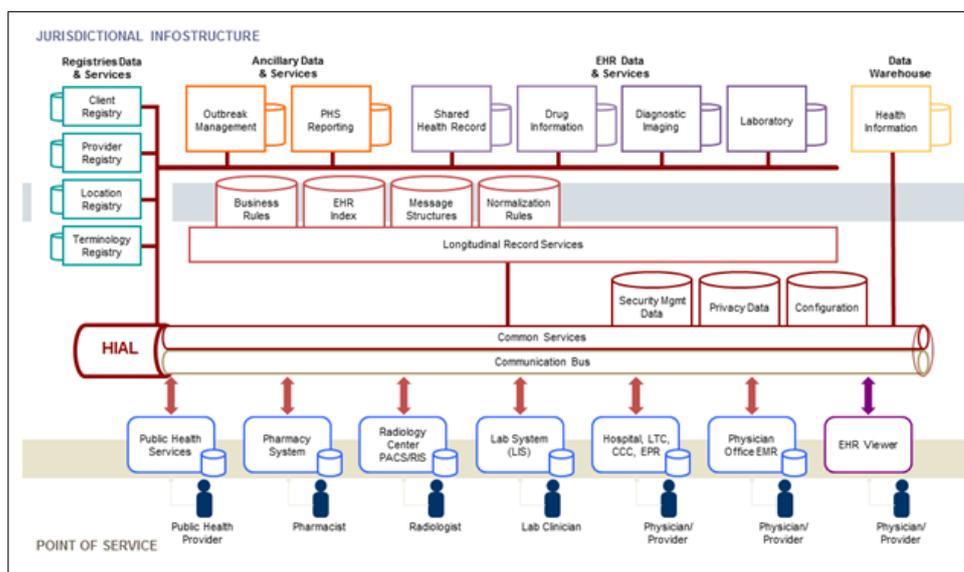


Figure 2: Canada's Infoway EHR Solution Infostructure [23].

and exchange clinical data to provide high quality and effective healthcare [23]. The technical outcome, called EHR Infostructure, is a collection of common and reusable components to support a diverse set of health information management applications. It consists of software solutions, data definitions, and messaging standards for the EHR [23]. Figure 2 shows the Canadian EHR Infostructure.

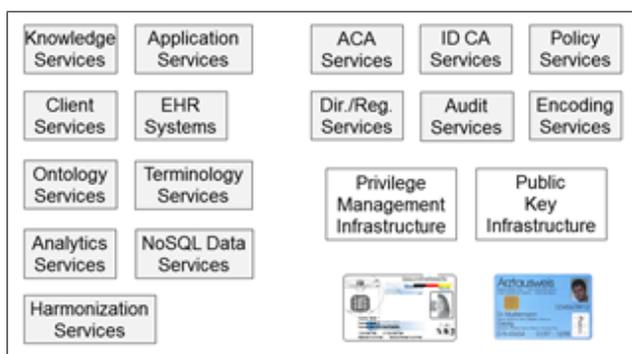


Figure 3: The German EHR Enterprise Architecture [28].

In Germany, in the early years of this century a Health Telematics Platform has been developed, where the author acted as Technical Adviser of the German Federal Ministry for Health [25]. This platform is the basis to be deployed by any following eHealth or telemedicine solution [26]. In the result of an Open Call for Tender the German Federal Ministry for Economy and Technology in coordination with the German Federal Ministry for Health, the German eHealth Competence Center, founded and led by the author, was awarded in 2007 the project to analyze existing standards and approaches to EHR systems [27], followed in 2008 by a consecutive project to establish a German Electronic Health Record enabled by standardization [28]. The Canadian approach has been reused for

those German EHR projects [28]. Additionally to that German EHR Infostructure, the author also developed a related eHealth Enterprise Architecture (Figure 3) [28], which came some years later also up in Canada, e.g., in the province Ontario, furthermore specialized into the Cancer Care Ontario Enterprise Architecture [24]. In Section 5, the eHealth Enterprise Architecture will be updated.

The evolutionary characteristic of national EHR projects was especially demonstrated in the US, starting with the Health Information Exchange Initiative [29] and the EHR Vendors Association Interoperability Roadmap [30], and the EHR Certification Program [31], and currently pushed in the context of the US Meaningful Use and Accountable Care Projects [32, 33, 34].

The objective of the Meaningful Use Project is to use certified electronic health record technologies to improve quality, safety, and efficiency of care (this exactly describes the objectives of health informatics applications, expressed in the mid-nineties in Europe e.g. by the author. In that context, disparities in health service deliveries should be reduced and the empowerment and engagement of patients and their families should be promoted. The clinical and the population health outcome should be improved with better care coordination, increased transparency and advanced deployment of health data. U.S. Healthcare Information Technology for Economic and Clinical Health Act (HITECH) [35] established incentives for adopting Meaningful Use criteria defined in the Centers for Medicare & Medicaid Services (CMS) Incentive Programs beginning in 2012, with the possibility of penalties for failure to achieve the standards by 2015. The program evolves in three stages over the years from 2011 to 2016, where Stage 1 (2011-2012) deals with data capture and data sharing, Stage 2 (until 2014) focuses on advanced clinical processes, and Stage 3 (until 2016) addresses improved outcomes [32, 33, 34].

4.2 Future Directions of EHRs

In the Report of the AMIA EHR-2020 Task Force on the Status and Future Direction of EHRs [36], five strategic objectives have been defined. The first objective deals with the simplification and speeding up of documentation. For that purpose, the data entry burdens for clinicians should be decreased by a) partially delegating documentation efforts to the care team, to the patient, and to devices and other information systems, b) separating data entry from data reporting, and c) performing research and development to improve processes and technologies for capturing and reporting clinical data. The second strategic objective requires a refocus on regulations by a) clarifying and simplifying certification procedures and Meaningful Use regulations, b) improving data exchange and interoperability, c) reducing the need for re-entering data, and d) prioritizing patient outcomes over new functional measures. The third strategic objective requires improved transparency, flexibility and streamlining of the certification process. A very important strategic objective is to foster innovations by using open, public, standard-based application programming interfaces (APIs) and data standards. In that context, the engagement of both vendors and providers on one side, and the academic community on the other side are requested. Finally, the report demands that EHR systems must support person-centered care delivery by 2020.

Summarizing, the objectives defined in the report are consistent with the requirements stated by several European institutions, such as the German eHealth Competence Center located in Regensburg, and represented in many papers including the one at hand.

4.3 Future-Proof Modeling of EHR/PHR Systems

The definitions of EHR and EHR systems as well as the other related concepts, provided for example in ISO/TR 20514, are based on information models represented using ICT ontologies. For managing existing knowledge, such approach is sufficient. For deriving new knowledge about the real world system, we have to observe and interpret that system itself. Otherwise we could be confronted with the paradox we have experienced perhaps several times in our life, when stating about our environment "Our map is correct, but the landscape is wrong".

To overcome that problem, the aforementioned GCM Reference Architecture Model enables the knowledge definition and harmonization of the domains involved in the care system. When this process has been performed, the resulting multi-disciplinary, multi-domain model of the real-world health and social care system can be easily transformed into the ICT representation using ICT ontologies. An ontology names and formally presents the concepts of a domain and their interrelations. As concepts and given names as well as relations depend on knowledge,

skills and experiences, many competing different ontologies might exist representing artifacts from the same domain. Therefore, ontology creation, harmonization, and agreements on common ontologies are crucial for communication and cooperation, i.e., for interoperability. Examples for ICT ontologies are ICT ontology of IBM [37], the HL7 Reference Information Model (RIM) including the related vocabulary [38], but also the Archetype representation of clinical facts [39, 40, 41]. A very comprehensive example of an ICT ontology is the SOA (service oriented architecture) ontology [42].

Table 1: Comparison of EHR system implementation standards (availability p-partial, y=yes, n=no, f-future [52]).

GCM Characteristics	HL7 Standards	CCR	EN/ISO 13606	openEHR	IHE XDS	DICOM SR
Development Process						
Unified process	Y	N	N	N	N	N
Business modeling	Y	N	N	N	P	N
Service orientation	P	N	N	N	P	N
View separation	P	N	N	N	N	N
Completion of ISO 10746-2	Y	N	N	N	N	N
System Architecture						
Reference information model	Y	N	Y	Y	Y	Y
Meta model	P	N	N	N	N	N
Model transformation framework	Y	N	N	N	N	N
Concept representation	Y	P	Y	Y	N	Y
Consistency of components	N	Y	Y		Y	Y
Open concept represent. language	Y	Y	N	N	N	N
Composition/decomposition	Y	N	N	N	N	N
Signature/Certificate-enabled	N	Y	N	N	Y	Y
Machine-processable	P	P	P	P	Y	Y
Multi-Domain Suitability						
Domain-independent	N	N	N	N	N	N
Domain separation	N	N	N	N	N	P
Model multiplicity	n	1	2	2	2	2
Ontology driven	N	N	Y	Y	N	N
Vocabulary	Y	N	N	N	N	N
Reference to terminology	Y	Y	Y	Y	Y	Y
Communication security services	N	Y	N	N	Y	Y
Application security services	N	Y	P	N	N	N
Inclusion of medical devices	Y	N	F	N	F	Y
Specialty-related	N	Y	N	N	Y	N
Multimedia-enabled	P	P	N	N	Y	Y
Feasibility						
Visualization support	Y	Y	N	N	N	N
Final specification available	N	Y	N	N	Y	Y
Implemented	Y	Y	N	P	Y	Y
Commercial products available	Y	Y	N	N	Y	Y

An approach to modeling future-proof EHR/PHR systems has been presented, e.g., in [3, 12, 43, 44]. In essence,

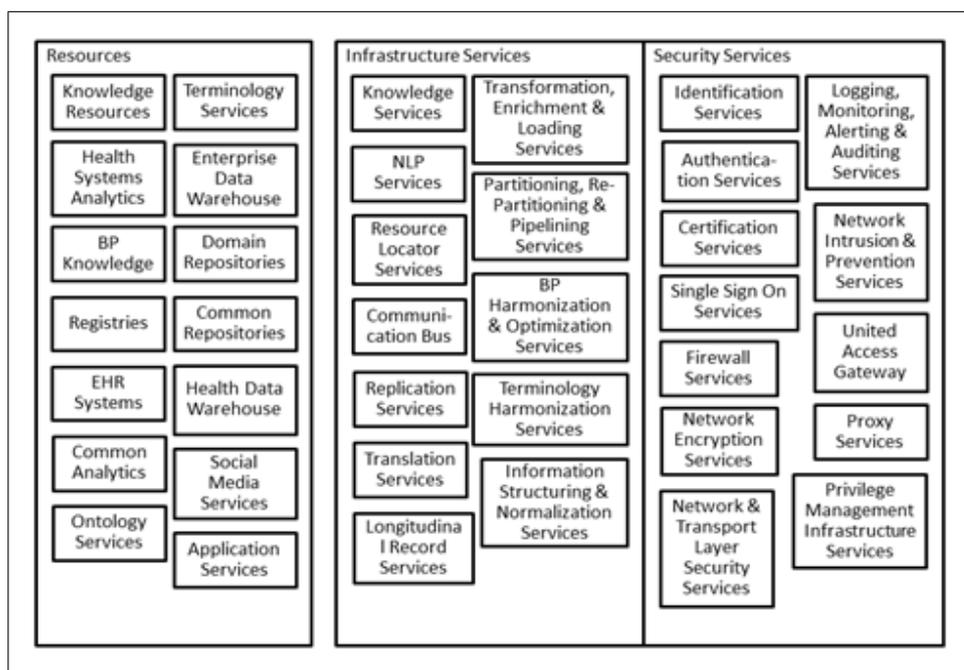


Figure 4: Essential components of a future EHR System Enterprise Architecture.

an abstract system is formally presented using universal type theory with parameters – known as the Barendregt Cube [45, 46] – describing the systems components, their functions and internal as well as external (environmental) relations, i.e., describing structure and behavior of that real-world system model.

4.4 Dominating Standards for EHR System Implementation

In the context of the aforementioned German EHR project, existing specifications for EHR system implementation have been comparatively analyzed. The following standards have been considered: HL7 messaging and Clinical Document Architecture (CDA) approach [47], ASTM Continuity of Care Record (later on harmonized with HL7 CDA to HL7 CCD) [48], ISO/CEN 13606 EHR communication [49], openEHR [40], IHE Cross-Enterprise Document Sharing (XDS) [50], DICOM Structured Reports (SR) [51]. Table 1 presents a 2008 snapshot [52]. Most of the specifications are in continuous revision, thereby partially harmonizing the different approaches. One example is the harmonization between ISO 13606, openEHR and the HL7 Clinical Information Modeling Initiative towards an Archetype approach, originally introduced by the openEHR project. Another interesting implementation project is the HL7 Fast Healthcare Interoperability Resource (FHIR) specification set. In FHIR, basic concepts are specified similar to Archetypes. They can be easily implemented, e.g., as RESTful Web services. For more details see also [53].

More explanations to Table 1 and the evaluation methodology can be found in [52].

5 Discussion

The presented approaches to local, regional, national, and global EHR/PHR systems are quite different, ranging from an HL7 standards based communication to a centralized, governmentally accredited EHR system (unthinkable for Germany) up to open systems supporting any communication protocol up to a component-based, intelligent, adaptive EHR Enterprise Architecture offering all the services mentioned to meet the person-centric, personalized health and social care paradigm. Figure 4 updates the German EHR Enterprise Architecture offered by the eHealth Competence Center in 2008 to the nowadays technologies and methodologies. Of course, with further innovations and new scientific insights, this Enterprise Architecture may be extended and adapted as well. However, the basics provided in the GCM Reference Architecture and Framework should be rather sustainable. Meanwhile, this system-theory-based, architecture-centric, ontology-driven approach - the foundation of several international standards and approved for integration in basic interoperability specification (e.g. ISO 22600, ISO 21298, The HL7 Composite Security and Privacy Domain Analysis Model, ISO 13606, ISO 12967) – has been practically deployed in different national projects and academic work [54, 55, 56].

Recently, the Commonwealth of Massachusetts announced a public-private partnership initiative to foster EHR innovations, big data analytics technologies, the Internet of Things, telemedicine, care management facilities, etc. [57, 58]. Not just here, the Meaningful Use Stage 3 preparation is running for Hospital as well as doctors' offices systems. Last but not least, the requirements specifications for EHR and PHR systems defined

at HL7 and distributed also at ISO have to be mentioned, when preparing an EHR/PHR design and implementation project: ISO/HL7 10781 HL7 Electronic Health Records-System Functional Model and ISO/HL7 16527 PHR System Functional Model.

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The Emerge of Clinical Terminology – SNOMED CT

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Abstract

SNOMED CT is the most comprehensive, multilingual clinical healthcare terminology in the world. It is a resource with comprehensive, scientifically validated clinical content.

SNOMED CT enables consistent, processable representation of clinical content in electronic health records.

Keywords

SNOMED CT, Health terminology, Health standards, EHR, Structured data.

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IJBH 2016; 4(1):17

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

What is SNOMED CT and what is it for? When implemented in software applications, SNOMED CT can be used to represent clinically relevant information consistently, reliably and comprehensively as an integral part of producing electronic health information. SNOMED CT supports the development of comprehensive high-quality clinical content in health records. It provides a standardized way to represent clinical phrases captured by the clinician and enables automatic interpretation of these. SNOMED CT is a clinically validated, semantically rich, controlled vocabulary that facilitates evolutionary growth in expressivity to meet emerging requirements. SNOMED CT based clinical information benefits individual patients and clinicians as well as populations and it supports evidence based care.

The use of an Electronic Health Record (EHR) improves communication and increases the availability of relevant information. If clinical information is stored in ways that allow meaning-based retrieval, the benefits are greatly increased. The added benefits range from increased opportunities for real time decision support to more accurate retrospective reporting for research and management.

IHTSDO proposes to hold a SNOMED CT presentation during the conference on Electronic Healthcare Documentation with the goal of increasing the knowledge about what SNOMED CT is, what it does and what the benefits are, Who IHTSDO is and how the organization is structured as well as stating what can be done and what opportunities there are in the Czech republic as the country is a national member of IHTSDO.

2 Additional Info about the Presentation

The presentation will cover the following outline:

What is SNOMED CT and what is it for? The increasing number of EHRs implemented in countries offers opportunities for improving healthcare by better using clinical data. This does pose constraints on the way in which data are collected and stored in those EHRs.

This part of the presentation will start with addressing the reasons for standardization of EHR content. SNOMED CT and its concept-based nature, explicitly separating concepts from terms and differentiating the differences between SNOMED CT and ICD. Finally, we will address steps to be taken to use SNOMED CT in practice.

IHTSDO as an organization and its interaction with other SDOs This part of the presentation presents IHTSDO as an organization, ways in which the IHTSDO works with other organisations to support interoperability. There are a number of collaboration agreements between IHTSDO and other SDOs, and profile organisations such as WHO, LOINC, ICN, HL7 and these will be described at a high level. We will discuss how to obtain SNOMED CT as well as opportunities to engage with the IHTSDO and take part in the work undertaken within the community.

SNOMED CT in Czech Republic The Czech Republic is a national member of the IHTSDO, this provides a great opportunity for anyone in the country to use and improve their healthcare documentation using SNOMED CT. This part of the presentation addresses what can be done and what needs to be done to progress with using SNOMED CT in the country.

Fetal Growth: Where Are Data? It's Time For a New Approach

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Abstract

The fetal growth assessment is a relevant matter in the prenatal care, but it can be unreliable if not properly handled, diminishing hence its diagnostic power, with an overall negative impact on the pregnancy outcomes. In literature, many studies have been conducted in order to give a comprehensive definition of "standard growth", but their effectiveness is awkward and, even considering the standard defined by the World Health Organization, it is hard to decide whether the growth has to be considered pathologic or not.

The general feeling is that, to construct suitable fetal growth curves, we need new analysis methods, better computational models taking into account more fetal and maternal characteristics and a more representative sample of the population.

In turn, this requires the ability to collect and manage larger data sets, to develop new data-harvesting techniques and to explore new strategies able to effectively "feed" those methods and models.

For these reasons, in this paper we present a system that, starting from the idea of "standard growth curves", develops a new approach and a prototype able to collect and manage fetal and maternal data on a global scale and to produce customized curves leading to better diagnoses and treatments.

Keywords

Prenatal care, fetal growth curves, data-harvesting techniques

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IJBH 2016; 4(1):18–22

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction and Background

The optimal practice in prenatal care requires an accurate assessment of the growth and the wellbeing of the fetus by analysing fetal biometric parameters trends along with gestational age.

Perni et al. in [1] demonstrated that all measurements of fetal biometry are highly reproducible both by the same and by different operators. This information is of great importance since major decisions are taken daily based on biometric results.

Biometric measurements (e.g. Femur Length, Abdominal Circumference, Head Circumference, ...) are plotted and compared with reference growth curves and are considered to be:

- normal or Appropriate for Gestational Age (AGA), with values between the 10th and the 90th percentile;
- too low or Small for Gestational Age (SGA), with values below the 5th percentile;

- too high or Large for Gestational Age (LGA), with values above the 95th percentile.

Typically, the status of the pregnancy is determined in a retrospective fashion, and there is scope for controversy in deciding which pregnancy should be defined as abnormal and excluded from the reference sample [2].

Several approaches to improve the ability of fetal biometry to detect potential high-risk fetuses have been proposed and developed in literature:

- parameters are compared with a given customized reference curve [3, 4];
- parameters are integrated into a formula (e.g. for estimation of fetal weight) [5];
- parameters are assessed each other (proportionality index) [6, 7, 8];
- parameters are measured and assessed longitudinally (speed or rate of growth) [9, 10].

A variety of techniques have been proposed in literature for constructing centile charts. The collection of fetal

biometric data necessary to develop such charts represents an important part of the diagnostic process since choosing the chart to adopt for diagnosis has a considerable effect on the interpretation of biometric data.

There are two main lines of thinking in literature: one emphasizes the need to adopt a worldwide standard, providing therefore a universal norm of how fetuses should grow when mothers are under good conditions [11]. This is the position of the INTERGROWTH-21st project [12]; the other promotes customization, stating that "one size does not fit all", since the growth depends on a variety of factors, ethnicity being the most prominent. In this field, Gardosi [3] has been the initiator since 1992.

In all cases, there is a significant heterogeneity among methods used to define and construct the different growth curves even for the same population. In particular, the choice of a suitable population sample and methodology to generate the reference charts is crucial, since it determines the accuracy of diagnosis and influences the overall number of misclassified fetuses (false positive and/or false negative). We can easily verify that, for example, using the different growth charts reported in the extensive literature review published at [13], the same fetus could be classified as normal (AGA) or pathologic (SGA or LGA) as a function of the ethnicity of parents, and nothing could be concluded in case of parents belonging to different ethnic groups.

Even more variability is introduced by the increasing mobility of people, the variety of lifestyles, the reshuffling of population, the possible pathologies affecting the parents etc., which make the ethnicity-based fetal growth curves not credible and, more in general, the use of static and location-based fetal growth charts no longer feasible.

Furthermore, the majority, if not all, of the studies related to fetal growth curves development and analysis consider cohorts of women with adequate health and nutritional status who are at very low risk of intrauterine growth restriction [14]. The usual assumption made by almost every study is about the exclusion criteria adopted for the analysis, such as diabetes, hypertension, chronic infections, smoking, lifestyles, pathologies, and so on. Whenever these eligibility criteria are violated, patients are excluded from the study, so limiting the diagnostic power of growth curves and their significance. Nothing, for example, has been found in literature for vegetarians or vegans.

A further element observed in literature, starting from the review by Ioannou et al. [15], after considering 113 papers published between 1971 and 2014 related to 46 different countries, is about the heterogeneity amongst existing methods. Such studies have to be considered as snapshots of the specific situation of a particular country; they could be perfect candidates for comparisons among populations but, definitely, cannot be accepted as reference growth curves.

All these considerations confirm and validate the necessity of new approaches and new and refined computational models in order to improve the classical meth-

ods adjusting for physiological variation in fetal size and growth, rather than assuming that one size fits all.

A simple experiment to confirm this conclusion has been performed on about 500 fetal biometric tests, collected in Italy according to the rules recommended by the WHO (World Health Organization). By evaluating the collected data against the growth curves usually adopted for European and Italian fetuses, we found that errors inherently connected to this approach could produce wrong diagnoses (false-positives and false-negatives) in more than 40% of cases [16].

We feel that in order to better diagnose how fetuses should grow without referring to static and local charts we should consider a global approach embracing the entire world production of fetal growth data.

Starting from the prototype presented in [17], we have asked to pregnant women which kind of useful/desired services they need by means of a survey on about 200 women.

Services like the "daily wellbeing log" in the classical form of a daily diary in which the pregnant can express her symptoms and take note of her wellbeing status and the "where is the nearest hospital", "which kind of clinical exams I need", ... are raised and hence implemented.

2 Our Proposal

Our proposal is mainly based on the adoption of data-harvesting techniques that allow collecting and processing data on a global scale in order to produce customized curves more suitable for diagnostic purposes.

According to [18], the size and the distributed nature of the problem points to a cloud-based system. Specific care has to be taken on privacy and confidentiality of health data (which is a worldwide constraint). Privacy and confidentiality treatment is out of the scope of this paper but, in summary, in our experiments all involved patients received written and oral information about the study and signed the informed consent authorizing us to store and manage their sensitive personal data. From a technical point of view, privacy and security issues have been addressed by adopting several techniques, such as: physical separation among personal data, clinical data and reconciliation keys; hash keys adoption for reconciliation purposes; strong authentication and authorization policies; secure communication channels; record restrictions and anonymization on open data published for statistical and analytical purposes.

A cloud-based prototype, implementing the main characteristics of the proposed approach and able to manage the fetal-growth data production in Italy (about 0.55 million newborn per year), has been created and tested to verify the technical aspects of our proposal.

2.1 System Architecture

The block architecture of the proposed system is represented in Figure 1. The "acquisition" component repre-

sents the different "channels" we implemented to collect data. The "design & storage" component represents the virtual database used to design and fine-tune the new fetal growth model. Finally, the "access" component represents the front-end that patients and physicians use for customized fetal growth tracking and diagnosis and researchers use for data analysis.

Referring to the data analysis functions, we implemented in our prototype the FGC-B&C block (Fetal Growth Curves Builder & Comparison), which is responsible for the development of customized fetal growth curves and for the comparison among the different available studies on growth curves.

The MUDIB block (Multidimensional Builder), instead, allows to interactively build and explore the multidimensional cubes representing the fetal growth data by exploiting the usual multidimensional operations (e.g. drill-down, roll-up etc.; see [19]), looking for correlations among the available measures and dimensions.

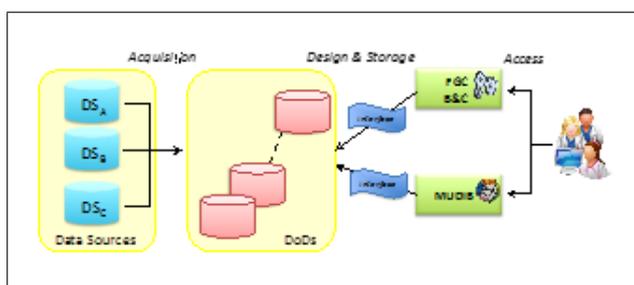


Figure 1: Block architecture of the proposed system.

2.2 Data Harvesting Techniques

Completeness of data and accuracy are common problems in any process related to data capture. To face these problems, we have paid specific attention to the data harvesting process, i.e. to the adoption of several strategies, used in parallel, to "grab" all possible data from all possible channels.

This can help to increase the overall effectiveness of physicians' time, to improve the information exchange between physicians and patients in clinical settings (in fact, there is an information gap between them due to the different adopted languages) and to improve the intrinsic quality of data.

For these reasons, we extended the prototype described in [17] by implementing five different "channels":

1. form-based input (Web pages and mobile App) to be filled by physicians and patients;
2. direct connection to ultrasound machines used for the assessment of fetal biometric parameters (e.g. DICOM metadata decoding or other data scraping techniques);

3. data extraction from ultrasound (printed/digital) pictures normally provided to the pregnant after each fetal ultrasound test);
4. smart input techniques provided to physicians to obtain relevant data from the digital devices (e.g. scales for weight, measuring sticks for height, speech-to-text software for prognoses etc.) typically available in medical offices;
5. data-scraping techniques useful to retrieve data from electronic documents (web pages, electronic forms, ...), available on non-interoperable systems,

Channel 1 is appropriate for women, which in general have a strong reason to spend their time to describe in detail and to precisely address their own problems. This channel is time-intensive, and for this reason it is rarely adopted by physicians. Furthermore, doctors do not trust very much the ways their patients may collect data via electronic devices. Finally, patients' participation can cause an overflow of irrelevant or trivial information, due to the fact that patients are typically unable to assign to data the appropriate significance (i.e. its medical meaning). Channel 1, in our prototype, has been exploited to create a visual interface suggesting in real-time to both patients and physicians which part of the anamnesis has to be completed.

Channels 2, 3, 4 and 5 allow a direct and automatic data transfer and would improve data ingestion (i.e. reduce data incompleteness which can have serious implications on fetal growth diagnosis as it could introduce a considerable bias) and reduce the causes of error.

In particular, channel 3 is based on an Optical Character Recognition (OCR) subsystem, which analyses and extracts textual data typically included in the ultrasound picture which are typically accompanied by measures (biometric parameters with the corresponding values), derived data (gestational age measured in weeks), and other info (ultrasound machine model, test date, patient's id, ...).

In our first implementation, we adopted the Microsoft Document Imaging Library (MODI) [20], achieving an overall accuracy of about 99%. Due to its limitations, we implemented a second version based on Tesseract OCR [21], which is a very accurate open source OCR engine easier to embed in and customize for online applications.

Channel 4, in the perspective of the Internet of Things, transforms medical offices into "smart rooms" which simplifies and enriches the collection of patient's data.

Channel 5 is mainly based on software techniques able to emulate a human agent interacting with the user interface of a non-interoperable software in order to insert/extract relevant data for specific purposes or for massive ingestion.

The benefits coming from the combined adoption of the five above-mentioned channels have been:

- savings of physicians' time;
- larger collection of patients' data;

- improved data quality;
- easier access to medical info for both patients and physicians.

On the other hand, the extensive adoption of these methods in real medical settings is hindered by the preference for pen-and-paper methods, current regulations related on privacy and confidentiality and strong defensive medicine reasons.

3 Results and Discussion

To validate the proposed approach and to test the developed prototype, a load test was performed.

In more detail, considering about half a million of newborns per year in Italy and 10 clinical tests per pregnancy (on average), we estimated an overall workload due to the five above-mentioned channels of about 15 thousands of transactions per day.

Then, we applied to the system an increasing number (1K/day, 2K/day, 4K/day, ...) of simulated transactions with random data (fetal growth records, ultrasound pictures, daily logs, ...) with no scalability concerns.

Tests have been performed on a Quad Intel Xeon server running at 2.66 GHz with 64 GB of RAM and 12 TB of storage space (SATA Disks).

Before extensively adopting the system on a regional/national scale, we are tuning the prototype in collaboration with the Obstetrics and Gynecology group operating at Vito Fazzi Hospital in Lecce, Italy, and the School of Health – Group of Obstetrics and Gynecology in Bari, Italy.

4 Conclusions and Future Works

Lack of data is a major problem in health database and it is due to several problems:

- the local nature of traditional data collections, managed by bureaucratic units;
- the legitimate conflict of interest among physicians (defensive medicine), patients (health protection) and Health Administration (cost reduction);
- the lack of adoption of proper data harvesting strategies and techniques.

Due to the nature of the above mentioned problems, technical solutions are not decisive by itself but can help to face the challenge.

For these reason, in this paper we have presented a new approach and a prototype, implementing five data harvesting channels, able to collect and manage large data sets about fetal growth and fetal-maternal well-being.

The prototype has been completed, a technical test has been performed and a test on the field is under preparation.

In the future, we plan to adopt it for regional/national campaigns in collaboration with two scientific societies, in the framework of a national project.

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Body Surface Potential Mapping Data in a Small Scale Study

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Abstract

The aim of the paper is to present the importance of proper data acquisition in a clinical study, in particular when a relatively low number of cases is expected. Data quality influences significantly successive steps in analysis and verification of a clinical hypothesis. Therefore, we consider this step as very important.

Keywords

Body surface potential mapping, data acquisition, data quality

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IJBH 2016; 4(1):23–25

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Clinical studies involving human patients are usually costly and/or time consuming. Collecting reliable data with minimum noise and distortion is therefore of utmost importance. This article discusses problems faced while acquiring body surface potential map (BSPM) data from human patients, and suggests ways of minimizing the risk of recording faulty and otherwise degraded data.

2 Data Origin

The data were collected as part of a Cardiac resynchronization therapy (CRT) study. The CRT study focuses on incorporating different diagnoses methods (and resulting data types) to help building a complex picture for evaluation of the level of dyssynchrony of the mechanical and electrical action of cardiac muscle. The methods used include MRI, BSPM, Holter standard ECG and 3D CARTO mapping of ventricles. As it can be seen, the volunteers in this study need to undergo four different measurement sessions, with 3D CARTO being an invasive measurement. This all means that there won't be many participants in the study (so far there have been 11 in the first year of the study) and it won't be possible to use standard statistical methods, which puts even bigger pressure on obtaining clear data. This paper will only focus on the data collected for BSPM diagnostic purposes.

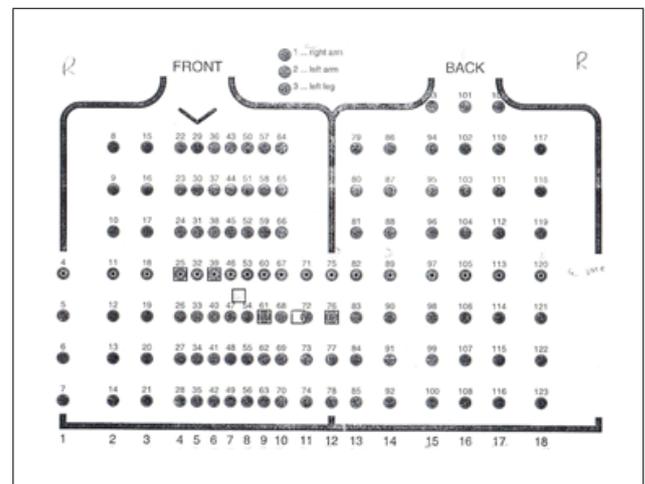


Figure 1: BSPM electrode placement.

2.1 BSPM

The aim of the BSPM part of the study is to create integral maps of biopotentials measurable around the chest and back, which then would be inversely fitted to the surface of the heart. By this we should be able to see the propagation of the activation wave along the myocardium [1].

To measure the potentials, we are using a net of 120 unipolar electrodes, which are evenly distributed along the chest and back of the patient. The signals are referenced to classical 3-lead Einthoven system. We are using a modified system from Bio-Semi, with sampling frequency

of 1024 Hz and standard 24-bit quantization, the recorded file consists of 128 channels.

3 Data Acquisition and Challenges

During measurement, special care needs to be taken to the instruments and electrode setup, otherwise the measured data could be useless. To ensure the measurements will be comparable and repeatable, a protocol was designed which was followed in each measurement.

In the actual measurements, we faced problems that we were prepared for, but also an interesting fact we did not quite expect.

3.1 Expected Difficulties

The apparatus from Bio-Semi uses a relatively high number of measuring electrodes, which come in adhesive strips of 4 to 8 equispaced electrodes. However, the electrodes positioning is defined by intercostal positions (Figure 1), so for smaller individuals the strips have to be folded to get the electrodes to the right spot. This makes the electrodes prone to improper contact with the patient's skin and the signal quality needs to be checked regularly.

As the measurements were conducted in hospital, we expected background 50 Hz mains hum induced from other devices in the room. As can be seen from Figure 2, we have experienced this noise in the first measurement. The source was found and 50 Hz noise was greatly reduced.

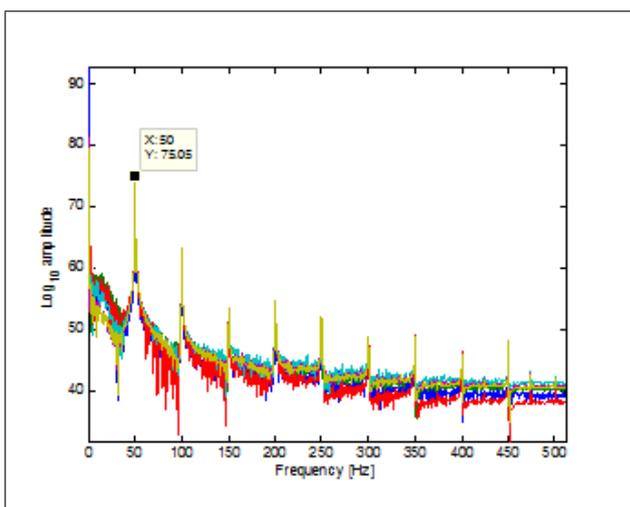


Figure 2: 50 Hz spikes visible in spectrum across all channels.

Another two aspects we considered concerned the patient. To reduce the effect of movement artefacts, the measurement was conducted while the patient was resting on his back. To reduce the effects of stress during the measurement, the patient was in a different room than the measuring apparatus and crew.

Low frequency noise from breathing movements was expected and can be seen mainly in the electrodes close to the diaphragm.

3.2 Unexpected Difficulties

Contrary to what we have expected, we found that the level of noise or attenuation of the signal varies depending on the position of the electrode. For example, one would expect that the signals measured in the area of lower ribs would suffer similar artefacts as the signals from around the collar bones. However this is not true, as demonstrated in Figure 3. The signal from the collar bone area is much more distorted. The cause of this will be studied in the next phase when we collect data from additional patients and can compare them.

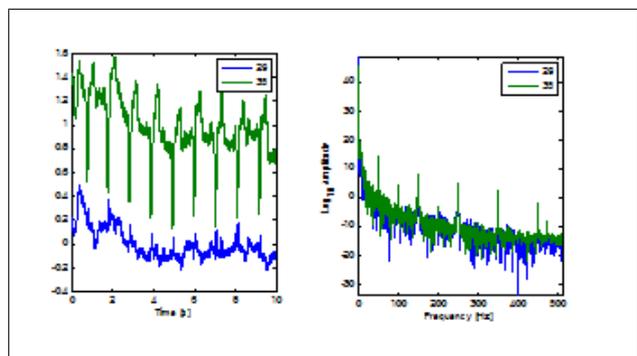


Figure 3: Difference in nature of signal in collar-bone area (channel 29) and lower ribs area (channel 35).

4 Conclusion

In the paper, we tried to present the data acquisition issue in clinical settings. Multichannel measurement and data collection represent a complex task, in particular in a limited case study. Thus data quality is of high importance. During the measurement many aspects must be considered, in particular electric noise, noise induced from breathing, patient height influencing electrode placement, and proper electrode-skin contact. With the high number of electrodes, data collection is rather difficult task. We prepared a detailed measurement protocol so that all individual required steps are easy to follow and check during the measurement process and each person performing the measurement knows them.

Protection of Human Subjects and Animals in Research

The procedures followed were in compliance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the World Medical Association Declaration of Helsinki on

Ethical Principles for Medical Research Involving Human Subjects.

Acknowledgement

The research is supported by the project No. 15-31398A "Features of Electromechanical Dyssynchrony that Predict Effect of Cardiac Resynchronization Therapy" of the Agency for Health Care Research of the Czech Republic and by grant application No. OHK3-033/16 of the CVUT SGS program.

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Chorionic Villus Sampling: An Overview of the 11-year Period in a Single Centre and Identifying Risk Factors for Miscarriage

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Abstract

Objectives: To give an overview of chorionic villus sampling (CVS) performed in fetal medicine centre over a 11-year period and to identify risk factors contributing to miscarriage after CVS.

Methods: Retrospective observational study. Information about CVS performed in our centre in 2004-2015 were retrieved from database. Overall information was assessed. The group with normal karyotype and with miscarriage within 8 weeks after CVS were compared with the group without loss.

Results: In total, 1327 CVS were performed during the period. 14 (1.1%) attempts were unsuccessful. The average number of insertions was 1.06. Mean maternal age was 34.1 years, mean CRL 64.2 mm, median BMI 23.7 and median NT MoM 1.45. Median risk for trisomy 21 was 1/80. Karyotype was normal in 945 (72.0%) cases, abnormal in 363 (27.6%) and in 5 (0.4%)

cases the cultivation was unsuccessful. Regarding the outcomes, 470 (35.4%) pregnancies were terminated, 813 (61.3%) carried on without complications, 29 (2.2%) miscarried and 15 (1.1%) were lost to follow-up. The pregnancy loss after CVS was 3.09%. The comparison of groups with and without miscarriage did not show any factor associated with the miscarriage after CVS which can be explained as there is no procedure-related risk associated with CVS.

Conclusions: The observed miscarriage rate after CVS was 3.09%. There were no significant risk factors associated with pregnancy loss after CVS.

Keywords

Chorionic villus sampling; Invasive procedure; Miscarriage; Prenatal diagnosis; Chromosomal abnormalities

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IJBH 2016; 4(1):26–29

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

Introduction

Chorionic villus sampling (CVS) represents a prenatal invasive test that can detect chromosomal abnormalities or genetic conditions of the fetus. The procedure is best performed in the first trimester between 10 and 13 weeks of pregnancy and entails the sampling of the chorionic villi via the needle inserted into the chorionic (placental) tissue, either transabdominally (through abdominal and uterine walls) or transcervically (via vagina and uterine cervix). The transabdominal approach is the only one currently used in the Czech Republic, thus in our centre (Figure 1). The whole procedure typically takes a couple of minutes, and several tens of milligrams of chorionic tissue are usually obtained. The material can be processed directly as uncultured cells or after the cultivation using common cytogenetic or molecular genetic methods. The

main limitation represents confined placental mosaicism which is found in approximately 1–2% of pregnancies [1].



Figure 1: CVS procedure. Arrows depict the needle inserted inside the chorionic tissue. Asterisk shows the fetus inside amniotic cavity.

CVS belongs together with amniocentesis (AMC) among invasive prenatal techniques. Therefore, from the beginning of its introduction in 1983, there is a common agreement that there is a certain procedure-related risk of miscarriage connected with the CVS. However, there is an inconsistency in the opinion regarding the exact procedure-related risk after CVS. The Royal College of Obstetricians and Gynaecologists states that the additional risk of miscarriage from CVS may be slightly higher than that of AMC which they mention to be about 1%, and could be in the region of 1–2% [2]. The American College of Obstetricians & Gynecologists mentions that the loss rate after CVS may be the same as for the AMC which they state less than 1 in 300–500 [3].

The assessment of true procedure-related risk remains a very challenging task. We have to bear in mind that the overall miscarriage rate after CVS includes true procedure-related miscarriages together with the miscarriages which would happen regardless of the procedure (a background risk of spontaneous pregnancy loss).

Therefore, in order to establish a procedure-related risk of miscarriage, we need to have a suitable matching control group to estimate a background risk which is very difficult. CVS is performed in women with a high risk of chromosomal anomaly and the main components of screening leading to an increased risk for such anomalies include high fetal nuchal translucency (NT), reversed a-wave in the fetal ductus venosus and low pregnancy-associated plasma protein A (PAPP-A). However, the same components are also associated with an increased risk of spontaneous miscarriage [4]. Therefore, such pregnancies are in higher risk of miscarriage even without invasive procedure and the background risk of pregnancy loss can greatly vary depending on the risk characteristics in population of women undergoing invasive procedure.

In 2015, Akolekar *et al* [5] published a systematic review and meta-analysis with the aim to identify procedure-related risk of miscarriage after CVS and AMC. Their results showed that the background risk of miscarriage calculated from controlled studies in women who did not undergo an invasive procedure corresponded to a loss rate of 2.26% (95% CI, 0.81–4.41%). Surprisingly, there was no significant difference in the miscarriage rate between CVS and control groups ($p = 0.64$), and the pooled procedure-related risk of miscarriage after CVS was estimated to be 0.22% (95%, -0.71 to 1.16%). The authors concluded that the procedure-related risks of miscarriage in centres performing a large number of procedures are considerably lower than currently quoted. These risks can be possibly unrelated to the invasive procedures, but instead may reflect the pregnancy characteristics of the women undergoing invasive tests.

The aim of this study is to give an overview of CVS performed in a single fetal medicine centre over an 11-

year period, to establish miscarriage rate after CVS, and to identify risk factors which can contribute to miscarriage after CVS.

Methods

This was a retrospective observational study. Information about all CVS which were performed in our Fetal Medicine Centre Gennet in Prague between October 2004 and October 2015 were retrieved from our databasis. The most common reasons for CVS included a high risk for fetal trisomies from the first-trimester combined test (risk 1/100 and higher) and/or fetal organ anomaly detected at the first-trimester ultrasound. Other reasons were positive family history for chromosomal anomaly or genetic disorder, and parents being known carriers for a genetic disorder.

All CVS procedures were performed transabdominally with the ultrasound guidance and using the spinal needle 18GA (1.2 mm). Chorionic tissue was aspirated directly into 10mL Vacutainer and subsequently processed using quantitative fluorescence-PCR of uncultured villi and conventional karyotyping of cultured cells. From 2015, the conventional karyotyping was replaced with single-nucleotide polymorphism array.

First, we assessed overall information regarding number of fetuses, maternal age, maternal BMI, fetal crown-rump length (CRL) at the time of procedure, number of insertions needed during the procedure, and results of the first-trimester combined test (fetal NT, serum PAPP-A, free β -human chorionic gonadotrophin (free β -hCG) and risk for trisomy 21 (T21)). We analysed pregnancy outcomes and karyotype results. Overall miscarriage rate after procedure was calculated. The miscarriage after CVS was defined as the loss of pregnancy within 8 weeks after the procedure and only the cases with normal karyotype were included in the calculation of miscarriage rate.

Second, we tried to identify possible risk factors for miscarriage after CVS. Only cases with normal karyotype from singleton pregnancies and with known outcome were included in this analysis. Two groups were defined: group with miscarriage within 8 weeks after CVS, and group without miscarriage. Both groups were compared regarding fetal CRL, maternal age, number of insertions, position of the placenta (placenta posterior versus other positions), maternal BMI, fetal NT, serum PAPP-A and free β -hCG.

Results

In total, 1327 CVS procedures were performed from October 2004 to October 2015 in our centre. Eight different operators participated over the period. The number of procedures per year is shown in Figure 2. 1278 (96.3%) procedures were in singleton pregnancies and 35 (2.6%) procedures were in twins. 14 (1.1%) attempts were unsuccessful when no chorionic tissue were obtained. In these

cases, the procedure was repeated in following days or AMC was performed instead at 16 week.

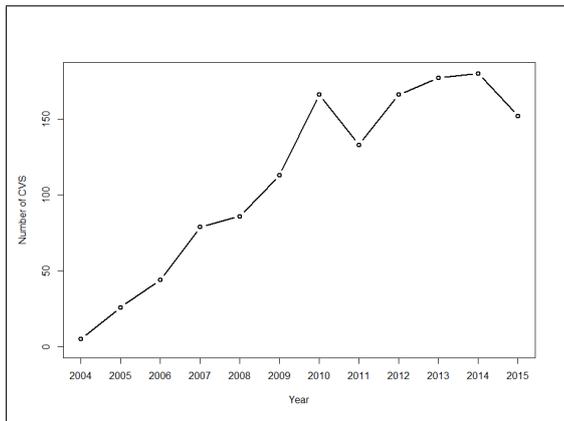


Figure 2: Number of CVS per year.

Pregnancy outcomes are presented in Figure 3. Almost one third of pregnancies after CVS were terminated because of chromosomal abnormality was found or serious organ anomaly was detected. In nearly two thirds of cases pregnancy carried on and 29 (2.2%) pregnancies miscarried within 8 weeks after the procedure.

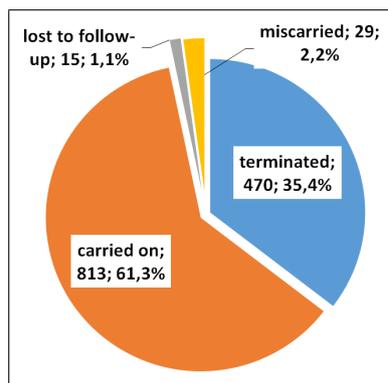


Figure 3: Pregnancy outcome after CVS.

Karyotype results can be seen in Figure 4. We were not able to give result only in 5 (0.4%) cases and all these cases were before the year 2008. Chromosomal anomaly was detected in almost one third of cases, i.e. three CVS procedures must have been performed in order to detect one chromosomal anomaly. This fact documents a very high efficacy of first-trimester combined screening test.

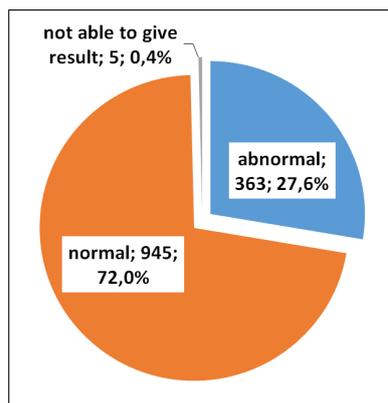


Figure 4: Karyotype results.

Overall characteristics of CVS cases are summarized in Table 1. As expected for a high risk population, mean maternal age was as high as 34 year. Similarly, median NT MoM and median free β -hCG MoM were markedly higher and PAPP-A MoM were markedly lower. In 1252 (94.4%) cases the procedure was successfully performed with only one insertion of the needle.

Table 1: Overall characteristics of pregnancies after CVS.

Characteristics	Mean/median	Range
Maternal age [year] (mean)	34.1	17.1–47.8
CRL [mm] (mean)	64.2	32.0–86.9
Maternal BMI (median)	23.7	16.1–45.4
NT MoM (median)	1.45	0.46–14.19
PAPP-A MoM (median)	0.47	0.04–5.54
free β -hCG MoM (median)	1.29	0.02–11.94
Risk for T21 (median)	1/80	
No of insertions (median)	1.06	1–3

CRL, crown-rump length; NT, nuchal translucency; PAPP-A, pregnancy-associated plasma protein A; free β -hCG MoM, free β -human chorionic gonadotrophin; T21, trisomy 21.

The estimate of miscarriage rate after CVS was based on cases with normal karyotype and known outcome. We identified 25 cases of miscarriages within 8 weeks after the procedure and 785 cases of ongoing pregnancies in which normal viable fetus was confirmed during ultrasound scan at 20–22 weeks. Therefore, the overall miscarriage rate after CVS is 3.09%. The figure is absolutely consistent with Akolekar's meta-analysis [5] where pooled analysis from seven studies presented the overall loss rate (i.e. background rate plus procedure-related losses) in CVS group of 2.36% (95%CI, 1.68–3.16%, range 0.74–5.94%).

The comparison of groups with and without miscarriage is summarized in Table 2. Out of singleton pregnancies with normal karyotype and known outcome, we had for the comparison eligible 25 pregnancies with miscarriage and 766 pregnancies without miscarriage after CVS. The compared differences did not reach statistical significance in any of compared characteristics. Thus, we failed to identify any factor which would be associated with a higher risk of miscarriage after CVS. Nor placenta posterior in which CVS is technically more difficult to perform than in other placental positions did not show to be a predictor of loss. There could be two possible explanations.

Table 2: Comparison of groups with and without miscarriage after CVS.

Miscarriage after CVS	Yes	No	
Number of cases	25	766	
CRL [mm] (mean)	64.6	65.2	$p = 0.67^*$
Maternal age [year] (mean)	35.4	34.3	$p = 0.37^*$
No of insertions (mean)	1.08	1.03	$p = 0.42^*$
Placenta posterior [%]	47.4	35.8	$p = 0.41^\dagger$
Maternal BMI (median)	22.9	24.1	$p = 0.10^\ddagger$
NT MoM (median)	1.29	1.21	$p = 0.24^\ddagger$
PAPP-A MoM (median)	0.44	0.49	$p = 0.85^\ddagger$
free β -hCG MoM (median)	1.12	1.37	$p = 0.13^\ddagger$

*t-test; $^\dagger \chi^2$ -test; ‡ Mann-Whitney U test

CRL, crown-rump length; NT, nuchal translucency; PAPP-A, pregnancy-associated plasma protein A; free β -hCG, free β -human chorionic gonadotrophin.

First, there was not the right characteristics in our comparisons and other unknown factors may contribute to the risk of miscarriage.

Second, in fact, there is no risk or negligibly low risk related to the invasive procedure, if performed by experienced hand, and the observed losses after CVS reflect simply a background risk of miscarriage resulting from the pregnancy characteristics of women undergoing CVS. Therefore, we can not possibly find any risk factors related with CVS itself predicting high chance of pregnancy loss. We personally think this explanation corresponds more to the actual state, and is also in concordance with the previously mentioned Akolekar's conclusions [5].

Conclusions

This study presented a long experience with CVS in a single fetal medicine centre. We demonstrated that CVS represents a highly effective procedure. It can be performed in 98.9% of singleton and twin pregnancies on the

first attempt and the karyotype results are available in 99.6% of cases. The observed miscarriage rate after CVS in our study was 3.09% which is consistent with other studies. We were not able to identify any possible risk factors associated with the pregnancy loss after CVS. Possible reason for this finding is that there is in fact no risk or negligibly low risk related to the invasive procedure.

Acknowledgements

The authors would like to thank all participating operators for their hard work. The work was partially supported by the grant SVV-2015-260158 of Charles University in Prague.

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Clinical Decision Support: Statistical Hopes and Challenges

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Abstract

Clinical decision support systems and the challenges of constructing their classification rules by means of methods of multivariate statistics and/or data mining are presented. More details are given about two applications: the system for selecting relevant information for decision support and decision support in psychiatry.

Finally the concept of information-based medicine is discussed.

Keywords

Decision support, data mining, multivariate statistics, psychiatry, information based medicine

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IJBH 2016; 4(1):30–35

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

The aim of this paper is to discuss clinical decision support systems and the challenges of constructing their classification rules by means of methods of multivariate statistics and/or data mining. We focus on general principles as well as on particular needs of psychiatry.

The paper has the following structure. We describe general principles of clinical decision support systems in Section 2. Statistical challenges of learning the classification rule are discussed in Section 3. To give an example of a proper approach tailor-made for high-dimensional data, we propose a new variable selection in Section 4. Further, we describe a prototype of a system called SIR as an example of a decision support system in Section 5. Another particular situation is an overview of systems for diagnosis decision making in the specialty field of psychiatry in Section 6. Finally, we present our vision that new e-health tools contribute to the transform of medicine (Section 7), while such transform has to overcome specific challenges in particular clinical fields as explained on the example of psychiatry (Section 8).

2 Decision Support Systems

Medical decision making can be described as a process of selecting an activity or series of activities among several alternatives integrates uncertainty as one of the aspects with an influence on the outcome [13]. Medical decision making is one of concepts of e3-health [19]. In

medicine, the physician solves the task of medical decision making based on data and knowledge connected to the cognition and determination of diagnosis, therapy and prognosis. The aim of this section is to overview the principles of decision support systems.

Decision support systems (DSS) are very complicated systems offering assistance with the decision making process. Using data and knowledge as main sources to obtain information, they are capable to solve a variety of complex tasks, to analyze different information components, to extract information of different types, and deduce conclusions from them. In medicine, they compare different possibilities for the diagnosis, therapy or prognosis in terms of their risk. They represent an inherent tool of e-health technologies for diagnostic and prognostic purposes capable to help during the therapy. The search for the appropriate therapy is very complex and depends on many factors and only a few decision support systems aiming at therapy have been sufficiently evaluated up to now. In practice, there exist specialized decision support systems for diagnosis and therapy in individual medicine fields and also specialized prescribing decision support systems. There has been less attention paid to decision support systems for prognosis, although prognosis would greatly benefit from reliable interdisciplinary and multidisciplinary systems.

The input components of a decision support system include the family and personal history, symptoms and signs, results of clinical and laboratory examinations in various forms (including gene expression measurements), signal and image information and theoretical knowledge

about the diseases and medicines. The knowledge used by decision support systems may be integrated from an expert system created by top-class experts but the knowledge should be also validated on real data.

Decision support systems have acquired an established place in healthcare with a certified ability to assist physicians with the decision making [9]. Various studies proved that decision support systems can be useful for improving the quality of provided care, preventing errors, reducing financial costs and saving human resources. The system may bring the physician more comfort, a higher effectiveness and more time for the patient and also a reduction of errors. It saves also significant financial costs. It may be especially favorable during stress or for treating complicated patients. Particularly (but not only) a less experienced physician in a narrow domain of medicine may benefit from using a decision support system, which exploits the level of knowledge reflecting the latest developments.

DSS offering the analysis of high-dimensional data. Actually, the physician will have the easiest way to analyze the data directly within a DSS. A clinician as the user of the decision support service is not required to understand the background of the methods. His/her aim is to determine the diagnosis of a new patient (not included in the clinical study), who can be examined on a distant place. The process of learning the classification rule will be now discussed in Section 3.

3 Learning the Classification Rule

The aim of the decision support system is to learn a classification rule allowing to assign a new patient to one of several groups. Recently, there is an increasing need to analyze data of various types. This section describes the challenges of learning a proper classification rule, which can be characterized a difficult task for both multivariate statistics and data mining [5, 7].

Let us discuss common complications of the analysis of the measured data from the statistical point of view. The following general challenges are common for data from various sources:

- Different types of data, including numerical data (continuous or categorical), often with a large number of variables (features), together with other data types (text, images, videos, graphs);
- Different formats of the output as the cause of using a proprietary software by various suppliers;
- Different units or different scale of different variables;
- High dimensionality of data (curse of dimensionality due to a large number of variables);
- Small number of samples (patients), which is a common feature in medicine;
- Available commercial statistical software can be criticized for its unreliability and delay in implementing newly proposed methods.

The analysis of complex data is difficult even if only numerical data are considered. There is an increasing trend to measure big data in medicine as discussed in [8], but in our opinion it is currently more common to encounter high-dimensional data in practice [3], i.e. data with the number of observations n exceeding the number of variables p . Commonly supervised learning, but sometimes also some authors attempted to exploit unsupervised learning such as cluster analysis [11].

Traditional statistical methods are unsuitable for the analysis of high-dimensional data. A variety of tailor-made methods for high-dimensional data has been proposed recently. However, there is no agreement concerning the suitability of particular methods, recommended classification methods are dramatically different from one paper to another and the situation prevails to be rather chaotic and controversial concerning assumptions of choice of a reliable method, its assumptions and recommended sample sizes. None of the available methods seem to perform better than the others in every situation. Data mining methods stand on statistical assumptions, although the users are often not aware of it. Statistical methods often require more strict models or assumptions which can be characterized as a prior knowledge.

Learning the classification rule of a clinical decision system is a particularly difficult task. Experience of researchers is critical mainly to neural networks of support vector machines for not being as good as presented in theoretical papers on simulated data. In addition, they do not offer a clear interpretation, which disables them for using e.g. for complicated or endangered patients. Quantifying model performance (reliability, validity) by standard means has a tendency to a false optimism due to overfitting, especially for a small number of observations, because models can appear predictive even if the data are completely random.

Last but not least, intensive attention has been paid to sensitivity of existing methods to the presence of outlying or wrongly measured observations in the data, which will be now exemplified in Section 4.

4 Robust Variable Selection

Standard dimensionality reduction methods suffer from the presence of outlying measurements (outliers) in the data, and there is a need for robust counterparts, i.e. methods insensitive to outliers [6]. We will now show an example of a robust approach for variable selection. We understand the method to be double robust, i.e. computationally stable for high-dimensional data and at the same insensitive to the presence of outliers. It exploits robust statistical methods (correlation coefficient, principal component analysis) which seem promising in real data applications [10], while other proposals of this section are novel.

Dimensionality reduction (variable selection) methods are generally recommended as the initial step of a super-

vised learning. It can actually improve the result of a consequent analysis in spite of losing some relevant information. On the other hand, it would be too strict to reduce the set of variables to a too small number of relevant ones. The variable selection proposed here itself exploits a regularized robust estimator of the covariance matrix of the data. The regularization modifies the method to be suitable for high-dimensional data. Its robustness is based on implicit weighting, just like the robust correlation coefficient r_{LWS} which will be now recalled.

Definition 1 The LWS-correlation coefficient [10] computed for a n -dimensional vector $\mathbf{X} = (X_1, \dots, X_n)^T$ and $\mathbf{Y} = (Y_1, \dots, Y_n)^T$ is defined as $r_W(\mathbf{X}, \mathbf{Y}; \mathbf{w}) =$

$$= \frac{\sum_{i=1}^n w_i (X_i - \bar{X}_W)(Y_i - \bar{Y}_W)}{\sqrt{\sum_{i=1}^n [w_i (X_i - \bar{X}_W)^2] \sum_{j=1}^n [w_j (Y_j - \bar{Y}_W)^2]}} \quad (1)$$

with weights $\mathbf{w} = (w_1, \dots, w_n)^T$ obtained by the least weighted squares (LWS) regression estimator [18], where

$$\bar{X}_W = \sum_{i=1}^n w_i X_i \quad \text{and} \quad \bar{Y}_W = \sum_{i=1}^n w_i Y_i. \quad (2)$$

Algorithm 1 (Double robust covariance matrix) Let us consider p -dimensional data vectors $\mathbf{X}_1, \dots, \mathbf{X}_n$.

1. Compute the LWS-correlation matrix

$$\mathbf{R}_{LWS} = (R_{ij}^{LWS})_{i,j=1}^p, \quad (3)$$

where R_{ij}^{LWS} is equal to the LWS-correlation coefficient between $(X_{1i}, \dots, X_{ni})^T$ and $(X_{1j}, \dots, X_{nj})^T$.

2. Compute

$$\mathbf{S}_{LWS} = (S_{ij}^{LWS})_{i,j=1}^p \quad (4)$$

as proposed in [10].

3. Compute the value of the regularization parameter $\delta^* \in [0, 1]$ as

$$\delta^* = \frac{2 \sum_{i=2}^p \sum_{j=1}^{i-1} \widehat{\text{var}}(S_{ij}^{LWS})}{2 \sum_{i=2}^p \sum_{j=1}^{i-1} (S_{ij}^{LWS})^2}, \quad (5)$$

i.e. in the same way as [16].

4. Compute

$$\mathbf{S}^* = (1 - \delta^*)\mathbf{S}_{LWS} + \delta^*\mathbf{I}. \quad (6)$$

5. Compute

$$\mathbf{R}^* = (R_{ij}^*)_{i,j=1}^p, \quad (7)$$

where

$$R_{ij}^* = \frac{S_{ij}^*}{\sqrt{S_{ii}^* S_{jj}^*}}, \quad i, j = 1, \dots, p. \quad (8)$$

Algorithm 2 (Double robust variable selection) Let us consider p -dimensional data vectors $\mathbf{X}_1, \dots, \mathbf{X}_n$.

1. Using Algorithm 1, compute \mathbf{R}^* (7).
2. Compute the eigenvalues of \mathbf{R}^* and denote them as $\lambda_1^*, \dots, \lambda_p^*$. The corresponding eigenvectors will be denoted as $\mathbf{z}_1^*, \dots, \mathbf{z}_p^*$.
3. Find r as the minimal integer fulfilling

$$\sum_{j=1}^r \lambda_j^* \geq 0.9 \quad (9)$$

and $r \leq p$.

4. Each of the observations \mathbf{X}_i is replaced by the set of the first r principal components $\mathbf{z}_1^{*T} \mathbf{X}_i, \dots, \mathbf{z}_r^{*T} \mathbf{X}_i$ for $i = 1, \dots, n$.
5. Consider each of the transformed observations in the form

$$(\mathbf{z}_1^{*T} \mathbf{X}_1, \dots, \mathbf{z}_r^{*T} \mathbf{X}_1)^T, \dots, (\mathbf{z}_1^{*T} \mathbf{X}_n, \dots, \mathbf{z}_r^{*T} \mathbf{X}_n)^T. \quad (10)$$

The robustness of the method is ensured by the robustness of each step of the computation.

5 Application 1: System SIR

Let us discuss a prototype of a clinical decision support system with a sophisticated statistical component, on which we participated [9]. The system called SIR (System for selecting relevant Information for decision support) uses a variable selection together with supervised learning methods to learn the sophisticated classification rule.

The system SIR can be described as an easy-to-use web-based generic service devoted to data collection and decision support with a sophisticated information extraction component. It is proposed for being used mainly for general practitioners in the primary care, but it is able to handle data from any area of medicine. The decision making of the SIR requires data from a (sufficiently large) clinical study in order to construct the optimal classification rule for the decision making problem.

Data collected within a clinical study represent the training database of the SIR, which can import the whole data set from the clinical study automatically together with a data model. The system cleans the data e.g. by checking if the values of the imported quantitative variables do not exceed given bounds required by the data model.

The next step in the analysis of the data from the clinical study is dimensionality reduction, i.e. variable selection, which reduces the set of all measured symptoms or laboratory measurements to a smaller set of relevant symptoms. This step, which is necessary especially for high-dimensional data obtained in genetic studies, is performed by a forward procedure optimizing a decision-making criterion.

Categorized data are considered and the contribution of a given variable (say X) to explaining the uncertainty in

the response Y (i.e. in the separation among the groups) is quantified by means of the conditional Shannon information, which is denoted as $d(Y|X)$. The first variable (say X_1) fulfils

$$d(Y|X_1) = \max d(Y|X) \quad (11)$$

over all variables X . Thus, X_1 is the most relevant variable for explaining the classification. Further on, the method successively selects the most relevant variables with the maximal value of the statistical dependence. In other words, other variables are iteratively added to the set with the best improvement of the conditional relevance. If variables X_1, \dots, X_s have been selected as the most relevant, the next variable (say X_{s+1}) is selected as the variable fulfilling the requirement

$$d(Y|X_1, \dots, X_s, X_{s+1}) = \max d(Y|X_1, \dots, X_s, X), \quad (12)$$

where all variables X not present in the set X_1, \dots, X_s are considered. Finally, we consider only such variables for the consequent analysis which contribute to explaining more than 90 % of the inter-class variability. The system allows quantifying the influence of an additional examination (variable) on the diagnostic decision. Additionally, the dimensionality reduction procedure may take into account the cost of obtaining each clinical or laboratory measurement.

The process of learning of the classification rule within the SIR has the ability to decide automatically for one of several different methods. A criterion of optimality is adaptively chosen to minimize the risk of a wrong classification result due to special properties of the data and the sample sizes. The implemented methods include the linear discriminant analysis (LDA), which is a multivariate statistical method for separating groups by means of a linear function. The same covariance structure is assumed in each group. Another approach implemented in the SIR is the empirical Bayes inference mechanism, which minimizes the aposterior Bayes risk across all groups of samples.

All variables selected by the variable selection procedure are required to enter the decision support system, which can be performed through the automatically generated interface from an electronic health record (EHR) or health information system (HIS), although a manual input of data is also possible.

The clinician must specify the prior diagnosis before entering the data to the SIR, because he/she is the only one to carry the legal responsibility for the clinical decision. Now the SIR can be used through the web service to obtain a diagnosis support. Then, the clinician is asked to manually select his/her final decision and only if it is not in accordance with the SIR, the clinician writes a short text justifying the decision.

6 Application 2: Decision Support in Psychiatry

As another application, we consider the particular field of psychiatry and present an overview of hopes and challenges of decision support systems in psychiatry. The aim of this section is to describe the beneficial impact and drawbacks of decision support systems in psychiatry. Their spread will allow profound changes of the everyday psychiatric health care towards the information-based psychiatry, which will be discussed later in Section 7.

Let us describe the beneficial impact of decision support systems in psychiatry. Numerous telemedicine tools are currently being developed for diagnostics of psychiatric diseases, exploiting modern e-health technologies for distant diagnosis, therapy and prognosis. Telepsychiatry enables to offer the psychiatric care also to patients with substance abuse problems, who would otherwise dare to search for a classical therapy. Telepsychiatric or telemental health services become popular in the United States, where they contribute to transforming the psychiatric care and help to increase access to mental health care. Telemedicine tools have the potential to be used in intensive attention as well as psychiatric assessment. They include videoconsultations between a psychiatrist and patient or mobile apps for smartphones. Without e-health tools, psychiatrists will be hardly able to use new results of clinical research which keep increasing in mass.

However, decision support systems have not become a standard tool in a routine psychiatric health care yet and the study of its reasons are a subject of intensive debates. Indeed, various attempts for diagnostic decision support systems have produced frustrations. This is true also for the rare examples of decision support systems proposed for finding the correct therapy.

Therefore, let us overview the limitations of decision support systems in the psychiatric context. Sometimes it is claimed that the health information technology is their main limitation, without acknowledging limitations also in the clinical dimension of the task. In our opinion, limitations intrinsic in the substance of psychiatry are crucial. Therefore, we present the following list of possible limitations categorized to general ones (i.e. properties of the decision support systems), specific limitations due to a specific substance of psychiatry, and finally limitations arising in the interaction between a psychiatrist and the decision support system.

Barriers due to specific properties of psychiatry:

- Unclear or unknown cause of the most common psychiatric illnesses;
- Controversy concerning the classification of psychiatric diseases;
- Too many factors would have to be investigated for diagnosis making, e.g. somatic symptoms or even non-clinical factors;
- Heterogeneity of symptoms and signs;

- Psychiatric guidelines suffer from vagueness or indeterminacy in formulations (e.g. level of cognitive impairment, delusion);
- A skilled diagnostic judgment may be an exercise of tacit knowledge;
- The system tries to determine the diagnosis based on objective checking a list of individual and conceptually independent symptoms and signs.

Barriers in the interaction between a psychiatrist and the system:

- Unrealistic expectations of the psychiatrist (e.g. no tolerance to software errors);
- Often, the psychiatrist hesitates to change his/her opinion (e.g. prejudice against software);
- The interpretation of the instructions of the system itself is subjective (e.g. it depends on understanding the text);
- Complicated interpretation of the classification rule;
- The success is determined also by the personality of the psychiatrist (mainly his/her age, sex, socio-cultural background and experience), his/her experience with psychiatric diagnosis making and with the system itself.

7 Information-Based Medicine

The concept of evidence-based medicine (EBM) is widely accepted as a unifying idea describing the ideal practice of medicine. In this section, we recall the currently popular concept of EBM and at the same time present our vision of future medicine, which emerges from the EBM but goes far beyond it. The development of decision support systems will be one of necessary (but not sufficient) requirements for the development of what we denote as information-based medicine.

The original concept of evidence-based medicine [4] is currently understood as a thorough, unique, and critical use of the best and most topical proofs in the process of decision making about the diagnosis, therapy, and prognosis for individual patients. The practice of evidence-based medicine integrates the individual clinical expertise of physicians with the best objective proofs coming from a systematically performed research [15]. It includes searching and systematic critical evaluation of publications with results of clinical research, analysis of activities, risk analysis, economic analysis of costs, or analysis of ethical and legal consequences of using a given approach. Principles of evidence-based medicine also requires physicians to demonstrate their capability to use the newest research results and exploit them in their everyday clinical practice.

Within the framework of evidence-based medicine, it is the clinical evidence (i.e. acquired by clinical research) which is understood as the main source of clinical knowledge. Clinical trials remain to be the main source of clinical knowledge. However, they have serious disadvantages,

e.g. artificial conditions or averaged results obtained by statistical methods for an averaged (virtual) patient, without taking his/her individual situation into account. Further, properly designed clinical trials with small sample sizes have been argued to be suitable by proponents of personalized health care, i.e. focused on small groups of specific patients. In reality, there is however a tendency for clinical trials to be bigger and more expensive.

In our opinion, current clinical practice is gradually undergoing improvements towards more advanced ideals described by the concept of information-based medicine [2]. This future ideal of medicine, although difficult to be clearly defined and lying still far ahead, represents a new perspective paradigm in medicine, going beyond the current concept of EBM [4, 15] and overcoming its limitations.

The concept of information-based medicine as formulated in [2] describes the effort to transform the evidence for the (imaginary) averaged patient towards a real individual patient based on his/her individual data with clinical as well genetic or metabolic parameters measured by new technology. It will exploit e-health tools to make results of basic research applicable to an individual patient. Computer technology will also allow to constantly supply the physician by quickly emerging new results of basic research.

From the statistical point of view, evidence-based medicine is devoted to averaging the results over the whole population and finding typical patterns in the clinical outcome. Information-based medicine is oriented on a more complex modeling and extracting information from massive data sets. In our opinion, such big data analysis (or it is rather spoken about big data analytics) will require primarily methods of supervised learning and regression modelling.

8 Information-Based Psychiatry

We believe that the ideals of the information-based medicine of Section 7 will develop also in the specialty field of psychiatry. We describe this vision of future psychiatry by a self-standing concept of information-based psychiatry. Even the negative experience with telemedicine tools in psychiatry in Section 5 has not lead us to negative views on the information-based psychiatry.

Constantly, we can witness a gradual transform of psychiatry, which is enabled by a vast number of technological tools recently introduced for psychiatric care, including telemedicine applications such as decision support systems. Information-based psychiatry will have to exploit available theoretical knowledge acquired in these tasks of basic (fundamental) research and to draw conclusions from measurements acquired for an individual patient, bringing the possibility of efficient therapy of psychiatric diseases. In our opinion, the development of information-based psychiatry will require a significant progress in each of the three areas:

- Basic research, including molecular genetics, cognitive neuroscience and medical image analysis [12, 14],
- Computer technology, mainly availability of reliable e-health tools,
- Reform of the everyday psychiatric health care, which will be discussed in this section.

The introduction of principles of information-based psychiatry to the clinical practice will require organization changes of the everyday psychiatric health care, which will be now described. There is a need for developing a sophisticated system of the psychiatric care allowing to access the necessary information at the point of care. This requires all providers of care (a psychiatric hospital, a community mental health center, a physician in the primary care, facilities providing rehabilitation and social services) to share the data. Psychiatric care can be successful in diagnosis or prognosis only if longitudinal data (over a longer time period) for an individual patient are available, i.e. data from the past psychiatric history, including e.g. behavioral changes or changes in magnetic resonance images. An information-based system of psychiatric care may also reduce the expenses based on a profound economic analysis and prediction of expenses and demands in hand with research in the field of social psychiatry.

The current organization of the routine health care often represents a barrier for a smooth and effective application of new technologies and blocks necessary changes in decision making of psychiatrists. An increased role of computerized technology also requires physicians, nurses and other health care professionals to attain a sufficient level of computer literacy. At the same time, the increasing need for analyzing big data in clinical decision making requires physicians to adopt positive attitudes to disciplines of data science, i.e. understanding ideas behind statistical reasoning as well as principles of common data mining methods. The education of health care specialists remains to be one of key requirements for the development of information-based psychiatry.

Acknowledgement

The work was financially supported by the Neuron Fund for Support of Science.

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Gaming Technology as a Tool for Active Engagement of Users in Self-Management of Health State

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Abstract

This paper deals with several user-centred aspects of development of mobile technologies and serious games applied in health care environment. Main discussed issues are motivation and active engagement of users in self-management of the health state, design of user interface and user involvement in the whole process.

Keywords

Health Informatics, User Acceptance, User Interface, Gamification, User-Centred Design

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IJBH 2016; 4(1):36–39

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Recently, the research and development of eHealth and ambient assisted living systems have offered many technological solutions. At the same time, there are running discussions about ethical and legal issues connected with application of these technologies. However, the question of self-sufficiency and the right moment for introducing technology for health state monitoring and home environment control have not yet been satisfactorily investigated. There can be two extreme views. The first one is too technocratic: monitor the health state of a person passively 24/7 and make the house/flat as smart as possible, introduce automation everywhere. The second one we can call minimalistic: try to use health monitoring as source of information for self-management of the health and introduce technology only in cases when the human function or ability needs obvious support or replacement. Recently, several applications have been developed that help to assess self-sufficiency of a person and recommend type of aid that can support the person's activities. However, the reality is usually more complex and the application of various tools and devices should be at least to a certain degree personalized.

With introduction of new systems we have to ask where the border is when we should start supporting the

deteriorating cognitive or physical abilities of individuals. It is necessary to distinguish between passive and active support. In particular the systems and tools determined for elderly users should have adaptive and learning features so that they can be adjusted to personal needs and motivate the user to certain activity.

2 Objectives

In our research we focused on several aspects connected with design of mobile applications that can be used in self-management of the health state. In particular, we discuss utilization of digital gaming technologies. Another issue is user interface design where besides graphical layout amount of information displayed to the user plays an important role. Active user involvement might positively influence the whole development process.

The potential users of the above mentioned technologies can be found among both children and adults. In all age groups we can find patients that suffer from chronic health conditions, e. g. diabetes, asthma, COPD. Standard approach is based on medical treatment and medication. However, it is welcome that the patients are actively involved in the treatment process. In this respect we speak about self-management of the health state. With the development of sensor systems and mobile applications it is

possible to utilize these technologies for development of individualized approach and applications motivating for active engagement in one's own health treatment.

3 Methods

3.1 Support of Active Approach - Gamification

One option is offered by digital gaming technologies and their components. Games can be used in healthcare learning applications. These applications focus on learning and skill acquisition of persons with a chronic health condition, which will enable them to improve their quality of life. The gaming solutions intend to foster a sustainable behavioural change in these persons that will lead to an enhancement of their integration in society and a better self-management of their health condition.

Recently, the development of various continuous non-invasive measurements of physiological parameters has advanced thanks to research and development of new sensor systems. In addition to physiological parameters, user's actual behavior in real life can be also measured. Then we can evaluate correlation of the health state with behavior and environmental conditions. The measurement is performed by a set of unobtrusive sensors that persons can use in their regular daily routine. The measurement data created by these sensors is collected on a mobile platform, such as a smartphone or a tablet. From there it is forwarded to a secure cloud based repository, where programs process this data and are able to identify the behaviour of the person as it relates to his/her medical, mental and physical conditions. They determine the degree to which this behaviour aligns with the desired (or recommended) behaviour. This information becomes input into the game. By improving his/her real life behaviour, the user can collect incentives and benefits that allow him to perform better in-game. The players can also experience what it means to be higher on the ladder of self-management, thereby persuading them to change their real life behaviour.

The reason why we propose to collect data in a cloud based repository is the possibility of long-term data collection from more users and successive data mining with the aim to identify both individual patterns in behaviour and group characteristics.

The mobile platform (smart phone, tablet) serves on one side as the measurement data aggregator and on the other side as interface through which the user gets the feedback. As the entire system runs in real-time, 24/7, the participant receives feedback throughout the day, thus creating a two-way communication channel across the boundary between the real and the virtual world. The app on the mobile platform will act as a virtual coach for the participant, while the focus in the main game is on co-operation between participants – helping each other.

By engaging in this game, participants are continuously encouraged to improve their behaviour as it directly relates to their condition. This occurs through the feedback they receive and by their desire to perform better in the game. While they participate, they learn about their condition and the self-management possibilities that are available to them, and they develop a greater understanding about actions that help them in their day-to-day lives – simple actions such as go for a walk, take medication, meet a friend, eat some fruit, drink a glass of water and similar actions. These can be very effective for the improvement of the condition of the participant, but many persons with chronic health conditions do not perform them regularly. For example, on average people with COPD are less than 50% compliant with their medication prescriptions. With the measurements from sensors and the user input, the game can recognize individual and group behavioural patterns with respect to psychological models that underpin changing behaviours, and the game suggests actions how to deal with that. The participants experience what it means to adhere to their recommended behaviour and experience the effects of what it means to be higher (or lower) on the society inclusion ladder through the cooperative main game.

In the area of self-management of the health state it is possible to make use of social media technology while accessing the main game and develop gamified and persuasive strategies to provide support and motivation throughout the use of the services (for example, through peer feedback, community challenges or support, and integrated reward mechanisms like achievements). In order to achieve this, the integrated services will be able to recognize and act upon specific user data patterns, thus they are able to reward the user for beneficial lifestyle behaviour, motivate them to improve further and – in return – prevent negative lifestyle influences and developments by providing interventions, when use patterns have been recognized that may lead to a decline in healthy activities by the user or even dropping out completely from using the smart coaching integrated with monitoring. The focus on presumption activities will allow us to find a way to integrate persuasive strategies in those areas and situations, which the users can best profit from, while they actively decide about their lifestyle and thereby influence their own behaviour. The involvement of users in the development process is a common procedure in user-centred design, considering them as co-producers of their health allows expanding the active role of the users also in all health related aspects after the services have been developed.

Gamification (using game design elements and game mechanics in non-gaming contexts) and persuasive strategies (inducing behavioural change) have been implemented in the domains of education, business, self-management, e-health and well-being, sustainability, or civic participation. In the foot light of this rapid adoption, research has studied its uses and its effects. However, empirical evidence is fragmented and inconclusive, and cases of effective implementations are limited to anecdotic

accounts. It is interesting to find successful design implementations and formulate best practices, particularly within the domain of physical action, in order to provide empirical evidence of gamified and persuasive strategies for a better understanding of the underlying factors that can predict successful behavioural change.

3.2 User Interface to the Technology

Human-machine interaction represents one of the key issues. If the interface is poorly designed it can influence negatively the attitude of the users of the system even if the system otherwise performs well. The interface should try to copy, to a certain extent, constructive human-human interaction; it should be designed as practical and intuitive as possible.

One of the issues that must be reasonably solved is amount of data shown to the user and the form, in which the data are visualized. The information provided to non-expert users should be aggregated and presented in understandable way. Usually precise numbers do not have the proper expressive power for the lay users who better understand graphical form (e.g. trends, deviation from normal values). The user interfaces will also differ in dependence on the main functions of the system. For example, the recommendation and suggestion systems serve mainly for informing the users (clients) about their health status in form of several numbers and/or graphs. Decision support systems used by professionals provide more detailed information in relatively standardized way. Present interfaces of some decision-support systems are uncluttered and intuitive, the "data avalanche" of accurate but irrelevant information is suppressed, and the interaction is such that users can predict in advance the consequences of their actions (and undo those actions, if necessary). In both categories it is necessary to consider the function of interaction, i.e. control input by the user. This feature must be well designed, in particular in case of interfaces other than standard keyboard and mouse. The touchscreen has many advantages but also certain disadvantages. There is an ergonomic problem, namely stress on human fingers. Users having problems with fine motor control might have difficulties when controlling an application using a touchscreen. For example, writing a message on a soft keyboard for a person with multiple sclerosis or after a hand injury could be a problem. Thus, there should be always an option in setup to select another control mode.

It is often difficult to find optimal layout of the interface, optimal number of entries required from the user, optimal volume of information the system displays to the user, etc. The challenge is linked to familiarity and repetition of task: a task that is infrequently performed needs a system that supports the user through the activity; but one that is repetitive needs a shorthand. Since this may vary from user to user the system should offer certain personalization of the interface. The simplest way is to have a choice from pre-defined options (from full support to shorthand). Additional improvement can be reached if an

adaptive component is included in the human-machine interface; learns from each interaction between the user and the system, and adjusts so that it finds the optimal (or at least sub-optimal) interaction.

3.3 User Involvement

Each of us is a personality with unique experience, background knowledge, emotional and psychological setup, acceptance and perception of other humans and also technology. Thus we will find high variation in attitude towards high tech systems. As we are so different, it is difficult to design a general system that is easily acceptable for everybody. Therefore a lot of research must be done in interaction with as large set of potential users as possible. These users must be selected from a large variety of population, i.e. city / village, healthy / motoric disabilities / visual impairment / hearing impairment / cognitive disorders – all on different levels, male / female, different age, different experience with technology (none / weak / medium / intensive).

The designer must obtain a thorough understanding of the users, in general there will be two large groups of users: care givers of all kinds and patients. Their requirements, abilities, environments, and problems can be very different. The greatest challenge for the designer is not solving the problem but fully understanding the problem. User evaluation is an essential tool for obtaining proper understanding. Technology developed for use by lay users must have such control or user interface that is easily accessible, usable and useful for its intended users. Therefore the user-centred design process must be used.

User-centred design (UCD) refers to a family of software development methodologies that emphasise the active engagement of end-users (and other relevant stakeholders) with the aim of maximising the conceptual fit, functional utility and usability of the product. Various models of UCD have been proposed, most of which integrate user engagement throughout the design lifecycle as a means of informing continuous quality improvement. Examples include those proposed by Hartson [1], Preece [2] and Cognetics [3] where the common and important characteristics are: i) Emphasis on identifying the users' needs and requirements of the system; ii) Identification and understanding of the context in which the system will be delivered, and iii) Designing products from the ground-up rather than based on developers' preconceptions or rigid procurement briefs [4]. Successful medical informatics applications have been reported following this methodology [5, 6].

In the development phase it is highly advisable to use a tool known as the Virtual Usability Laboratory for software development (<http://openvulab.org>). Such a tool is designed to unobtrusively monitor users of web-based applications remotely. At the same time the tool allows querying users after their interaction with the application. After experiments when a large number of users have tested the application the usability data is col-

lected and analyzed. This data contains, for example, browsing patterns, system invocations, user interactions. Similar approach is used in standard Usability Laboratory (<http://ulab.cz>) where tangible devices and tools are tested from all aspects of their design, i.e. functions, ease of use, ergonomics, safety, demands on cognitive and motoric abilities.

4 Conclusion

One of the contributions of this work has been the analysis of gamification as a motivating tool leading to more active engagement of users in self-management of the health state. In addition, games can support social interaction among more isolated people, in particular elderly population. Technology may be advantageous when monitoring persons' health state and activities in their homes continuously because it supports self-sufficiency and independent living. We have shown that before starting implementation of such systems it is necessary to perform a detailed acceptance study and thorough evaluation of the study's findings. The aim is that the lay users (often elderly people or people with different impairments) will be willing to use the technology, will accept it and it will not cause them any problems. The designers and developers have to have in mind that the design must be user centered.

Acknowledgements

The authors are indebted to the EFMI WG PPD members, and to all supporters of the WG PPD work in past and present. Research of Lenka Lhotska has been supported by the AZV MZ CR project No. 15-25710A "Individual dynamics of glycaemia excursions identification in diabetic patients to improve self managing procedures influencing insulin dosage".

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Advanced Collection and Elaboration of Catheterization Data

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Abstract

This paper deals with advanced health documentation software that is designated for congenital heart defect catheterization purposes. Presented software collects data directly from medical measuring devices. The calculation of hemodynamic parameters is automatically provided within the catheterization procedure.

The software contains several assistive modules such as a real-time display unit and a material management module, but also a data transfer module for report exporting into the central clinical database.

Keywords

Health Informatics, Health Documentation, Catheterization Data, Data Collection, Hemodynamic Parameter

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IJBH 2016; 4(1):40–43

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Congenital heart defect (CHD) cardiology is a very specific branch of medicine that has extended requirements for patient documentation. [1] Health care may be improved by optimal procedure documentation using advanced software applications.

The aim of author's achievement is to design a software application (CathApp) for providing collection, analysis and elaboration of whole catheterization data. The CathApp system is tailored to workplace's needs with wide possibilities of modification, focusing on clarity of interface, reduction of human errors by minimizing manual data entry.

2 Objectives

Catheterization procedures produce three categories of recordable data: hemodynamic data (directly measured and calculated), procedure registration (e.g. type of anaesthesia, vascular approach, medication summary), and material management.

Diagnostic catheterization of complex CHD includes about 100 numerical or textual items that have to be archived for medical purposes. [1] The management of

used material is required for health insurance reporting, auditing purposes and stores management.

3 Methods

The CathApp software system is based on the database principle of data recording. The programming environment deployed is Microsoft Access with Visual Basic extension. The control interface is compiled of form and report objects that are linked with main database tabs.

3.1 Structure of Software Application

The software application is based on a client-server architecture. The server database contains tables of raw catheterization data, data of material management and code-lists (e.g. diagnose list, procedure list, staff list). The client application provides interactive forms, reports and executive functions. The client application provides interfaces to different components such as display, data collection and main management. This software is capable of duplex mode data transfer with the central clinical database. System structure, data flows and control commands are shown in Figure 1.

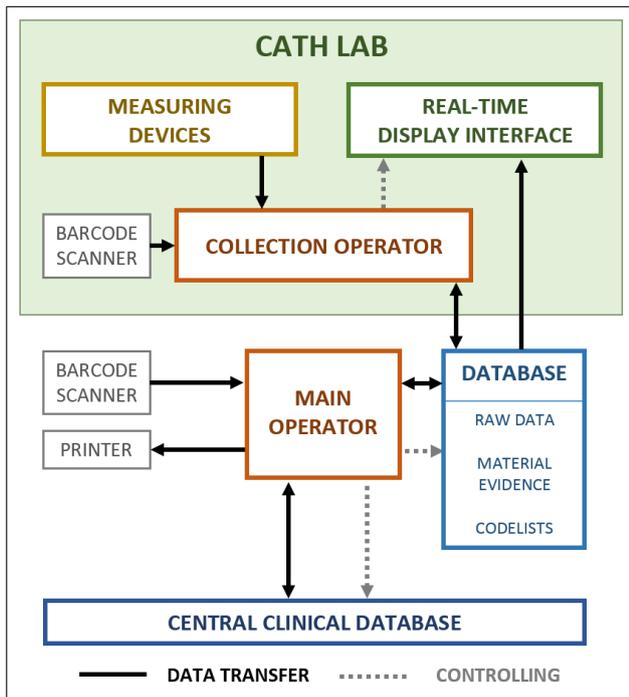


Figure 1: Principle diagram of software structure.

3.2 Data Organization

Each registered catheterization procedure is stored in a database record that is marked with a unique local identifier. Database records contain patient information, hemodynamic data and procedural information (e.g. used material or medication management).

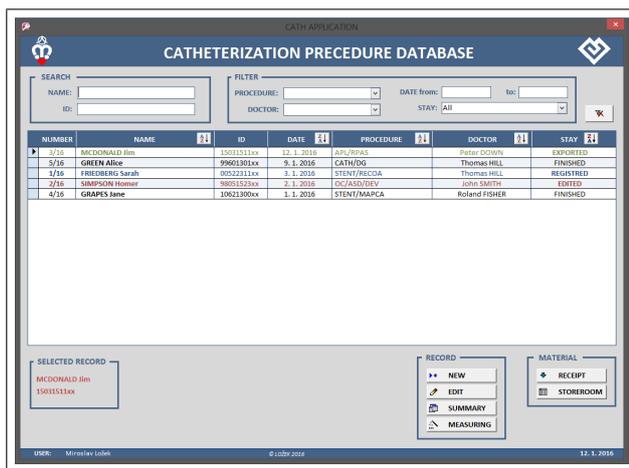


Figure 2: Database window demonstration (all patient data are fictional).

Patient information (name, ID, diagnosis, lab reports etc.) can be manually entered or retrieved from central clinical database using SQL. Each record contains a unique patient ID number (assigned by the central clinical database) for record linking between CathApp and the central clinical database. This is necessary for updating

CathApp patient data and for exporting catheterization reports. A server application screenshot is shown in Figure 2.

Hemodynamic data can be divided into a directly-measured part and a calculated part. Calculations are performed using the Fick principle for cardiac output determination. Therefore, it is necessary to measure the saturated oxygen (SO2) parameter of all heart chambers. SO2 and blood pressure are the main directly-measured parameters. Algorithms enable calculating derived parameters (e.g. cardiac index, shunt ratio, vascular resistance). [1, 2] The CathApp allows creating up to 4 independent record sets in one procedure file. Standard record consists of: baseline evaluation, post-interventional evaluation, O2 test evaluation and Flolan medication test. The main operator screenshot is shown in Figure 3.

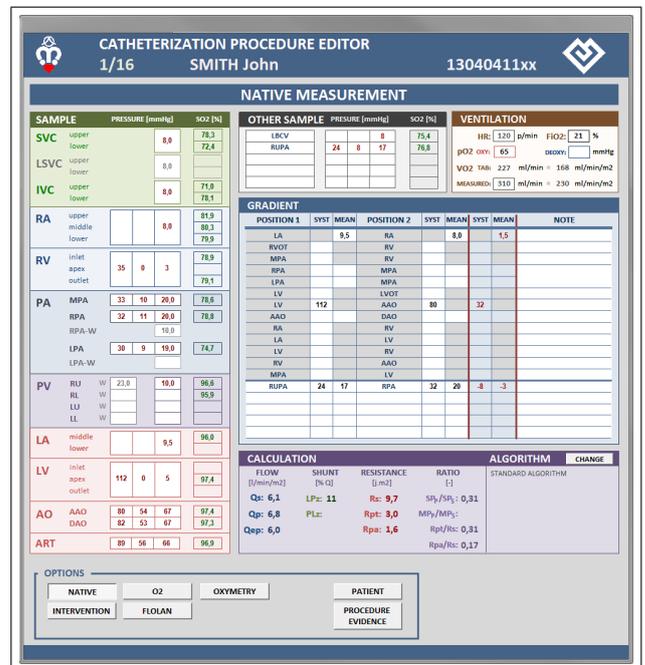


Figure 3: Main operator screenshot (all patient data are fictional).

The procedure report includes additional information about the catheterization procedure. This report describes the circumstances of catheterization (type of anaesthesia, vascular approach, etc.). The medication record is stored with time markers. Furthermore, there is a software assistance for drug dose calculation. The list of materials (material take off) is linked with the store management database tables. Used material can be identified using a barcode, or determined from a store management list.

3.3 Data Collection

One of the main ideas behind the CathApp system is the minimization of manual data entering. Therefore, data collection system is designed as online connector to

medical measuring devices. Operator interaction is necessary for data annotation and verification only. For example, the SO₂ parameter is measured using an oxymeter device that is able to send acquired data via serial link. The operator (nurse or technician) annotates the received SO₂ item by a defined marker (e.g. Right atrium blood sample) in the CathApp software.

3.4 Real-time Display Unit

The CathApp system is designed for real-time collection and processing of data during an ongoing catheterization procedure. The large display panel is placed in the catheterization laboratory as a smart assistive device for the cardiologist. The display unit shows mainly actual measured data and calculated parameters (see Figure 4). Control of the display unit is provided by the operator via the Collection Operator system that is also placed in catheterization laboratory.

1/16		SMITH John		130404	
weight: 44 kg		height: 150 cm		VO ₂ : 230 ml/min/m ²	
SAMPLE	NATIVE		OTHER SAMPLE		
	SO ₂	PRESSURE			
SVC	upper	78,3	LBCV 75,4		
	lower	72,4		RUPA 76,8	
IVC	upper	71,0			
	lower	78,1			
RA	upper	81,9			
	middle	80,3			
RV	lower	79,9			
	inlet	78,9			
RV	apex		35 / 0 / 3		
	outlet	79,1			
PA	MPA	78,6	33 / 10 (20)		
	RPA	78,8	(W: 10) (20)		
PA	LPA	74,7	30 / 9 (19)		
	RU	96,6	(W: 23) (10)		
PV	RL	95,9			
	LU				
PV	LL				
	LA	96,0	(9,5)		
LA	lower				
	inlet				
LV	apex	97,4	112 / 0 / 5		
	outlet				
AAO	97,4	80 / 54 (67)			
DAO	97,3	82 / 53 (67)			
Art	96,9	89 / 56 (66)			
actual date: 12.1.2016				time: 14:57	

GRADIENT	
LV - AAO	32
LA - RA	(1,5)
RUPA - RPA	8 (3)

CALCULATION			
Qs:	6,1	LPs:	11,0
Qp:	6,8	PLs:	
Qep:	6,0		
Rs:	9,7	Pp/Sp:	0,31
Rpt:	3,0		
Rpa:	1,6		

Figure 4: Real-time display unit snapshot (all patient data are fictional).

3.5 Material Management Module

The material management module is a database application that is intended for the management of catheterization material. This module has a similar database structure (client â“ server) as the CathApp software. Database of material management raw data is shared with CathApp software. Material is usually logged according to a REF number and a LOT number which can be entered using barcode scanner (see Figure 5).

Figure 5: Material card screenshot (all patient data are fictional).

3.6 Catheterization Report Generation

Catheterization reports are automatically generated according to a predefined template. The content of the report is inspected by the cardiologist who also writes the medical summary. It is possible to print the report. All data of the report are exported into the central clinical database. The report is ready for preview or re-print in the same form anytime.

4 Conclusion

We present an application (CathApp) designed for a catheterization laboratory specialized on congenital heart defect (Childrenâ™s Heart Centre, Motol University Hospital in Prague). CathApp is advanced software that allows direct data collection from measuring device, real-time calculation of hemodynamic parameters and generation of catheterization reports. The application has several assistive modules, for example online projection of hemodynamic data on a display unit placed in catheterization laboratory.

Acknowledgements

This paper has been supported by the project (Ministry of Health, Czech Republic) for conceptual development of research organization 00064203 (Motol University Hospital, Prague, Czech Republic) and by Ministry of

Health of the Czech Republic, grant nr. 15-28029A. All rights reserved. The author indebted to sincerely thank the staff members of Motol University Hospital for their constructive comments that helped to design the CathApp software application.

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The Public's Acceptance of eHealth in the Czech Republic – Condition for Success

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Abstract

The aim of our paper is a theoretical analysis of the conditions for the acceptance and support of eHealth in the Czech Republic. The aim is to find the types of projects that would be accepted by Czech public. It is important to create an overall concept of eHealth which would be accessible, transparent and especially attractive for Czech patients/citizens.

We consider that it is essential to accurately define the selected projects and to present a comprehensive roadmap for how to achieve their goals. In our paper we also address the funding of so-called platform and modular projects. Our article can be considered to be as a solution of ethical issues related eHealth.

Keywords

eHealth, IZIP, electronic personal medical file, medical user application

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IJBH 2016; 4(1):44–45

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 The Condition Analysis for the Public's Acceptance of eHealth in the Czech Republic

The situation for the implementation of eHealth in the Czech Republic is not very good. The citizens still remember an unsuccessful eHealth project called IZIP. This project had been heavily funded by public resources and it had not found support in Czech Health care. Czech citizens perceive this eHealth project very negatively. Therefore, before the forming of specific proposals for eHealth projects in the Czech Republic, it is better to discuss and to select the best strategy for the promotion of eHealth in the Czech Republic, which is based on the motivation of the biggest stakeholders in Health care. Considering the top five stakeholders in the Health care system (patients, doctors, insurance companies, the government, and companies), eHealth should gain the biggest support just from patients. This might be very difficult to achieve due to the negative experience with the IZIP eHealth project in the past.

The main priority for eHealth must be in searching and generating such tasks which are in line with the public's interests. Only these public tasks will be accepted and supported by the Citizens of the Czech Republic. Ac-

ording to public research conducted in Canada (Infoway Survey, November 2010),

Canadians want especially these from eHealth:

1. View their own medical information
2. Better communication with health care providers
3. Better management of medication renewals
4. Better booking of their appointments with health care providers

We assume that these results can be applied to the environment of the Czech Republic. For the purpose of our article, we call these results as the four main public tasks of eHealth in the Czech Republic.

2 Platform and Modular Projects

We suggest dividing eHealth projects into platform and modular ones. The platform project should include standards and rules development, the creation of communication protocols and so on. Considering the fact that these projects should be paid from public resources, some public tender must be set up to choose a serious company which will develop the platform eHealth system. The selected company will form the basis of the Czech eHealth and give a functional platform system to Czech Health

care. The modular projects can operate on a commercial basis. They may be funded and owned by companies, insurance companies or Czech regions. The platform eHealth system can incorporate opened for other projects that can be modularly connected to the platform projects via defined interfaces. The owner of the platform eHealth system should be the public health care system of the Czech Republic (Figure 1).

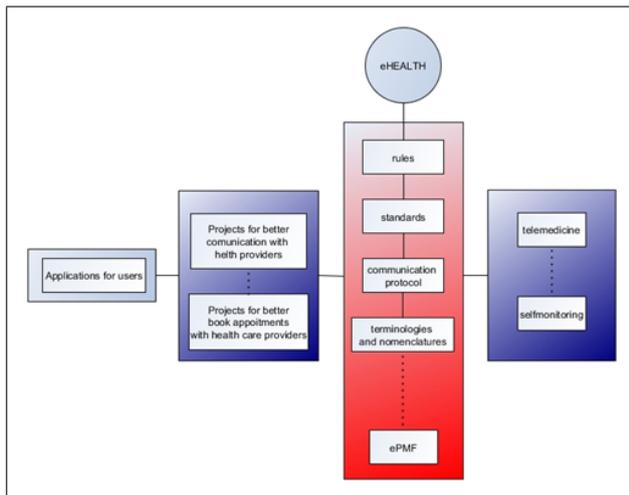


Figure 1: Platform projects (red ones) and modular project (blue ones).

3 ePersonal Medical File (ePMF)

Furthermore, we propose creating a very important pillar project, which meets the first public task (see own medical reports, laboratory results, CT and X-ray scans), and sets up an electronic personal medical file (ePMF) for every patient-citizen. ePMFs are stored on the PC drives of patients or on their accounts on the web-based storage.

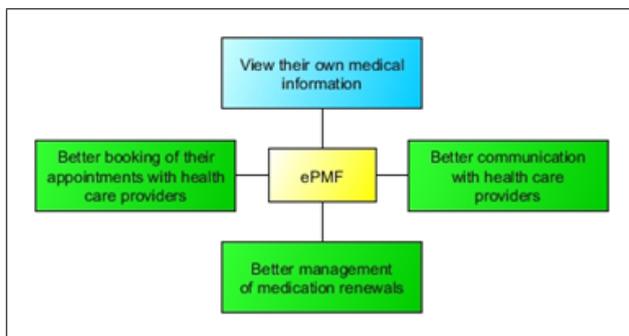


Figure 2: Public task that can be executed via ePMF immediately (blue color one), public tasks that can be executed using ePMF in the near future (green color ones).

The fundamental idea is to create a medical file with copies of medical reports and results. A patient or an authorized doctor can view or print required information from the ePMF. The big advantage of ePMF as proposed is the ability to integrate this project in the developing Czech eHealth network in the near future and thus fulfill the second, the third and the fourth public tasks (Figure 2)

4 Medical User Application (MUI)

It is an application in which it will be possible to open an ePMF and to see personal medical records. The default version of MUI should be freely available and free of charge for both patients and doctors. The patient will get the medical record not only in the paper form but also in electronic form at the hospital or at the clinic. Electronic medical record will be sent onto their account and could be possible to open via MUI and properly integrate into the ePMF.

5 Advocacy of eHealth in the Czech Republic

The patients-citizens must want eHealth first. They will require the eHealth projects from their doctors. Only such eHealth projects have a chance to spread and develop. Another condition for success must be transparency, which means to openly speak about all costs allocated for the development and the management of the platform eHealth projects. It is not good to speak about Czech eHealth as a large IT project, but as an important medical project which shall improve the quality of Health care, patient safety and the overall efficiency of the Czech health care system. The selected projects, their goals and the ways for how to achieve them should be presented and explained by experts on the public relations.

"eHealth is the continual availability of requested medical information in the course of care"

Acknowledgements

Supported by grant application No. OHK3-033/16 and MH CZ – DRO (Nemocnice Na Homolce – NNH, 00023884), PVI7501IPMZ

Genetic Data of Patient in Pharmacology

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Abstract

Personalized medicine that is based on genetic testing opens new possibilities for better pharmacological treatments of a patient, even for physicians or pharmacists who are not familiar with the interpretation of genetic data. Genetic data can be automatic processes that use knowledge from many already accessible databases, collecting results from many scientific studies. This paper presents the idea of a system for the personalized optimization of drug dosing using the integration of pharmacogenomics, pharmacokinetics and pharmacodynamics.

For such a system, it is necessary to store the genetic data of the patient as a set of the patient's alleles of selected genes.

Keywords

Pharmacogenomics, personalized medicine, genetic test, personalized pharmacokinetics, personalized pharmacodynamics, genetic health records

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IJBH 2016; 4(1):46–49

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Proteins are the base molecules of the biochemical processes in the human body, processes such as enzymatic chemical reactions, membrane transports, receptor signalizations, allosteric regulations, etc. All metabolic or signalling pathways are composed of these processes. However, a selected protein in these processes should not be exactly the same for each subject. The variability and concentration of these proteins is caused by variabilities of the genes where it is encoded. These small changes between the alleles of the gene are translated into small changes in the protein structure and, therefore, also into different electro-chemical properties of the protein. In other words, "the same processes" can have different rates and different equilibria for different patients.

Modern pharmacology should already be built on the biochemistry of the complex physiological processes that are composed from the metabolic or signalling pathways. Critical processes are described using many of the proteins that are involved with only one or a few of them, which are rate-limiting. In pharmacology, the metabolism of the effective drug into the non-effective metabolite is typically the most critical process. Different drugs have different rate-limiting metabolic enzymes, which are typically coded by only one gene. This gene can have different alleles in different subjects, which means a different metabolic speed of the drug for different patients.

2 Structured data

HUGO Gene Nomenclature Committee (HGNC) already specifies the names of all human genes [20]. However, each gene or group of genes can have its own committee for its alleles and mutation names, e.g., The Human Cytochrome P450 (CYP) Allele Nomenclature Database [22]. Typically, if somebody discovers a new allele of a gene, then he can push its description to the gene's committee. This is very useful for finding out more information about this mutation in the future. The identification of alleles is the first step to personalized medicines. This is because known alleles can have described properties such as Michaelis-Menten coefficient of encoded proteins.

Nowadays, the usage of allele's properties is very simplified. In practice, the most spread nomenclature for laboratory and clinical observations is Logical Observation Identifiers and Codes - LOINC [3], which is compatible with HL7 standards [1]. Instead of coding chemical rate coefficients, only a few categories of enzyme speeds are used - Ultrarapid, Extensive, Intermediate or Poor Metabolizer. Recognizing that the mutation of an enzyme is faster, slower or in normal rate is also very useful information.

Genetic testing is becoming cheaper and cheaper. However, it is still not so cheap that it can be repeated before each prescription of new drugs. Archived results of genetic testing can be reused because inherited DNA code

remains almost the same throughout a subject’s life. As the usage of this information can be improved to the level of complex simulation, such as Physiomodel [12, 13, 14] or HumMod, it is much better to store the names of the identified alleles rather than only the codes of a few categories such as in the mentioned case of the enzyme’s rates. Today, format and data media for storing these genetic patient’s health records can almost be completely accessible such as QR codes named as ”Safety-code” [21], mobile phones, a USB disk, a smart card, an ambulant computer, a network server and so on. Data media should be preferred as everybody can have access to this information at anytime and anywhere such as a person’s QR code in his health insurance card. This can quickly give information to each physician, rescuer or pharmacist about the personal genetic prerequisites of a selected treatment.

Table 1: Rate-limiting enzymes.

Gene	#alleles	Protein family description
ACE	1	Angiotensin converting enzyme
ADH1B	1	Alcohol dehydrogenase
ADH7	1	
ALOX5	1	Leukotrienes synthesis (AA)
COMT	4	Catecholamine catabolism
CYP1A1	4	Cytochrome P450 (monooxygenase)
CYP1A2	20	
CYP2A6	12	
CYP2B6	36	
CYP2C19	37	
CYP2C8	4	
CYP2C9	20	
CYP2D6	16	
CYP2J2	1	
CYP3A4	13	
CYP3A5	15	
CYP4F2	1	
PTGIS	1	
DPYD	15	
G6PD	6	Glucose-6-P metabolism
GSTM1	1	GSH S-transferase
GSTP1	2	
HMGCR	11	Mevalonate/cholesterol pathway
MTHFR	2	Thymidine/methionine synthesis
NAT1	7	N-acetyltransferase
NAT2	8	
NQO1	2	NAD(P)H dehydrogenase
PTGS2	3	Prostaglandin G/H synthase (AA)
SULT1A1	3	Sulfotransferase
TPMT	5	Thiopurine methyltransferase
TYMS	2	Thymidylate synthase
UGT1A1	11	UDP Glucuronosyl transferase
UGT2B15	1	
UGT2B7	1	
VKORC1	10	Vitamin K activator

For example, it is known that a dosing of Warfarin is dependent on the mutations of the genes VKORC1, CYP4F2, GGCX, CYP2C9, CYP3A4, CYP2C18, CYP1A1, CYP1A2 and CYP2C19 [4, 5, 7]. With enough information about their alleles, it is possible to estimate

the optimal dosing or whether it is better to use other anticoagulant drugs. The logic of decision is based on the metabolic pathways of the pharmacokinetics and pharmacodynamics of the selected drug. Even these data are already accessible as an output of The Pharmacogenomics Knowledgebase – PharmGKB [6], where much research is collected together for these purposes. For the calculation of optimal drug dosing, specialized tools can be used such as MW-Pharm [19]. For this purpose, there are also non-commercial alternative academic simulation tools such as Chemical library [17], Physiolibary [8, 9, 16, 17], etc.

The base of pharmacogenomics is the selection of proteins, which are rate-limiting in pharmacokinetics and pharmacodynamics pathways. Examples of the base set of genes of these proteins are in Tables 1, 2, 3, 4. Most drugs are metabolized to a non-effective metabolite using Cytochrome P450. These enzymes bind the oxygen molecule to the drug molecule using a porphyrin ring with an iron atom in the middle, which is attracted to the oxygen molecule. Binding the oxygen molecule to the iron slightly changes the shape of the ring such as in other hemoproteins [8, 17]. If the drug molecule is inside the enzyme cavity, then this option will insert the oxygen to the specific place in the drug molecule. A created metabolite is non-effective in contrast with the original effective drug.

Table 2: Receptors.

Gene	#alleles	Protein family description
ADRB1	2	β receptors
ADRB2	3	
AHR	1	Aryl hydrocarbon receptor
DRD2	4	Dopamin receptor
NR1I2	1	Nuclear receptor
P2RY1	2	G-protein coupled receptor
P2RY12	4	

Table 3: Membrane channel transporters.

Gene	#alleles	Protein family description
ABCB1	7	ABC transporter
ABCC2	6	
KCNH2	5	K+ voltage-driven channel
KCNJ11	1	
SCN5A	3	Na+ voltage-driven channel
SLC15A2	4	Oligopeptide transporter
SLC19A1	5	Folate transporter
SLC22A1	9	Organic cation transporter
SLC22A2	5	
SLC22A6	1	
SLCO1B1	22	Organic anion transporter
SLCO1B3	2	
SLCO2B1	1	

3 Pharmacogenomics integration

Integration of the pharmacogenomics data described in the previous section leads to a complex system that au-

tomatically predicts the patient’s status during selected treatments. Thus, a better estimation of drug dosing can be done using a patient’s genetic data. This is a result of the integration of drug pharmacokinetic and pharmacodynamics pathways with the knowledge of specific alleles of genes of rate-limiting proteins.

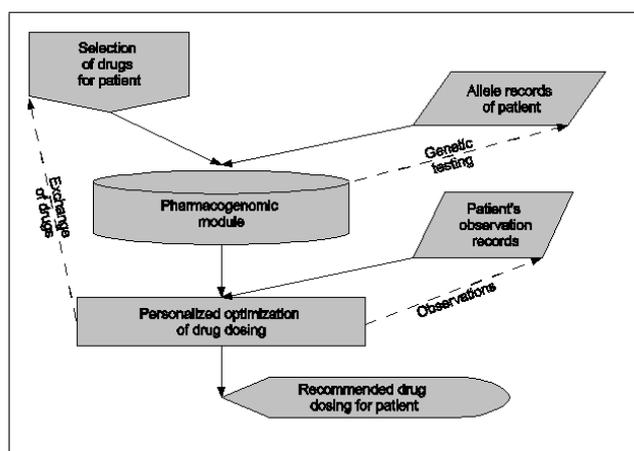


Figure 1: Scheme of usage integrated pharmacogenomic module in personalized optimization of drug dosing.

As usual, the physician must conduct the diagnosis and carry out the initial selection of the drugs to treat the patient. If the patient does not have sufficient genetic records for the selected drugs, then the genetic testing can provide the patient’s alleles. As in Figure 1, the pharmacogenomics module represents the knowledgebase from which the set of genes that are necessary for genetic testing can be automatically expressed. When some alleles for the drugs are known, the pharmacogenomics module can give the inputs for the personalized optimization of the drug dosing. These inputs can be as simple as only categorizing the enzymes into a fast, slow or normal rate.

Table 4: Signalling proteins.

BRCA1	16	Breast cancer 1
F5	1	Coagulation factor V
IL28B	1	Interferon-λ 3
HLA-B*1502	2	Human leukocyte antigen complex (MHC)
HLA-B*5701	1	

The recommendation to drug dosing is provided using the pharmacogenomics module outputs and data of previous patient treatment observations. Other result of personalised drug dosing can be also recommendation not to use the selected drugs or frequency of next patient observations during treatments.

4 Discussion

Pharmacogenomics is a new progressive discipline that integrates a huge amount of physiological approaches together [2]. It will soon be included in the medical prac-

tice of personalized medicine because each patient is genetically different. These differences must be taken into the account, especially in communities of different populations.

Additionally, simple markers can be very useful because they can predict overdosing, effectivity or insufficient dosing, even for minor communities of patients. They can also predict some side effects of drugs, etc. As a result, the physician will know if there are any necessary additional observations.

In future, it could be that this approach will give a sufficient amount of information to the more complex simulation of a patient’s status. This can be used to cure complex symptoms, where such treatments are almost impossible today [18].

However, the knowledge of pharmacogenomics is still insufficient and most of the approaches are not exact enough to be accepted even by the scientific community. The development of such a system to use known information can generate new questions and answers because there is a huge space for improvements.

Extensions of this pharmacogenomics system can be for statistical purposes, where genetic and observation data from many patients can validate or improve the knowledge of pharmacogenomics.

The system that uses the last versions of many scientific databases closes the loop between development and clinical practice. Each currently published study that is exact enough to be stored on any of these knowledge databases can be immediately used to provide new recommendations of optimal drug dosing for a patient’s genotype.

Conflicts of interest

The authors are not in any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their actions.

Acknowledgments

The authors appreciate the funding of this work by project ”Centrum of pharmacogenomic informatics” 4.2PT03/1211, PHJ s.r.o. Praha 6.

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Health Care Documentation – Could we Integrate Medical Doctors and Nurses Documentation?

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IJBH 2016; 4(1):50–51

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

We performed an evaluation study in 2010 with the objective to evaluate the usability of the national nursing documentation model and four widely used nursing documentation systems in Finland, and to study their usefulness in multi-professional collaboration and information exchange between medical doctors and nurses. The study has been reported in detail in publications [1, 2, 3, 4, 5].

In the study, we used qualitative usability evaluation study methods covering user scenario walkthroughs, contextual inquiries, thematic interviews and expert reviews in the users' clinical context and heuristic evaluations by usability experts.

The results of our study showed that the nursing process model was applicable in the nursing practice, but the Finnish Nursing Classification (FinCC) was considered to be too detailed, multi-layered and difficult to understand and use by the nurses. The four evaluated nursing documentation systems had many usability problems which resulted in discomfort in usage, extra workload in documentation and difficulties in applying the classification. Major improvements would be needed in these systems both in the interaction design and user interface design levels.

2 Discussion

A very important result from our study was that the documentation systems did not support multi-professional care and information exchange between the nurses and the medical doctors – though they are both involved in the care of the same patient. Medical doctors enter their notes and care documentations in the electronic health record (EHR) and the nurses in the nursing documentation systems (NDS). These systems are separate and they apply different coding and classification systems. The medical doctors considered that the nurses' documentations would be very essential and important for their own work, the

doctors even could make treatment decisions based on the nurses' documentation and utilize these documentations while preparing e.g. the discharge summaries. But, as the systems are separate and the patient information is documented with different contents and format, its utilisation is weak. The NDSs are very complicated to use by medical doctors. The doctors also had difficulties to understand the documented information because it was documented and presented in a very complex and detailed manner. The doctors would prefer to see a holistic view on the patient's nursing care, but this was not possible when the information had been documented using the very detailed and multilayer classification.

This research demonstrated that the nursing documentation systems, as they are today, do not support well collaboration between the nurses and the medical doctors. The nursing model and NDSs do not implement the physicians' needs for nursing information, on the contrary they present the patient's information to the medical doctor following the nursing model and classification. The physician's primary need would, however, be to have a broad, holistic view on the patient's situation and status and especially to have the changes in the status clearly presented.

An important goal of healthcare documentation is to make the documented information accessible, usable and useful for all those medical professionals who are involved in the specific patient's care. Would it be possible in the future to have only one electronic patient document that involves both medical doctors' and nurses' documentation and makes the information understandable and useful for all those professionals who are involved in the patient's care? Should we forget the numerous nursing classification systems and focus on developing a generic documentation, coding, classification for patient care data? And, when the patients have access to their own EHR, how can we make information understandable for them?

Various health professionals have various needs for the patient's documentation information contents and infor-

mation representation. By now, utilisation of information has evidently not been a design principle in the current nursing model and classifications. The models are very clearly targeted to nurses' documentation needs and to legal protection, but not even to the nurses' information needs. The important point is, that this current way of documenting patient data does not fulfil the needs of shared care, integrated care and information exchange between medical professionals.

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Semantic Interoperability Challenges for Electronic Health Records

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Abstract

The standard-based semantic interoperability challenges of electronic health records were analysed with a restricted literature review. The results show that the standards are able to build semantic interoperability, but their approaches are different and they are not compatible with each other. The approaches are different in terms of technical solutions, profiles used, terminologies adopted, and this situation is influenced by architectural decisions in eHealth deployment, including culture, domain, country, implementation timeline and the interoperability layers addressed.

There is a need to achieve an international consensus on a common reference information model for eHealth deployment. Thus, semantic interoperability remains still a challenging problem, despite of many efforts. Further harmonisation is essential and experiences could be adopted from other industries. Interoperability will most likely result from progressive refinement processes across different perspectives.

Keywords

Electronic health record, Interoperability, Standards

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IJBH 2016; 4(1):52–54

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Electronic health record (EHR) is a health IT system targeted to the systematized collection of longitudinal patient's health information in a digital format. The content and format of patient data in EHR as well as access and disclose of data are settled and controlled by legislation. An EHR provides a lifelong documentation of a patient's health data: Demographic data, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics and all treatments, operations, decisions and actions taken by medical professionals.

EHRs have the purpose to store patient data accurately, keep it safe and secure, and to capture the state of a patient over lifetime and across health care organizations, and to make this patient information accessible where and when needed to those who have the right to access or disclose this information. EHRs also provide important information for secondary purposes, such as health policy planning. Data stored in EHRs can be shared across different health care settings and professionals following the legal framework on confidentiality and privacy of health-related patient information. EHRs have been developed for decades, they are widely used in healthcare in the developed and even in developing countries. The EHR is used by different health care professionals, i.e. by physi-

cians, nurses, radiologists, pharmacists, laboratory technicians and radiographers. Also patients may have an access, either fully or partly, to their own EHR [1].

Currently, data stored in EHRs is utilised and exchanged with the use of prevalent standards. Technical interoperability has been today well achieved in EHRs as data can be transmitted between the various EHRs as long as they follow the same standard [2]. However, most current EHR systems are very unlikely to fully understand the information they receive from other EHRs. Therefore, demands for full interoperability between EHRs have arisen because it is necessary to understand the meaning of the accessed or disclosed data. True semantic interoperability between the EHRs means that concepts, attributes, terms and relations have the same interpretation in different systems. Semantic interoperability is one of the key factors in EHRs to support continuity of care, integrated care and full utilisation of patient data where and when needed.

Interoperability in general means the ability of health information systems to work together within and across organizational boundaries in order to advance the health status of, and the effective delivery of healthcare for individuals and communities [3].

Semantic interoperability means that the precise meaning of exchanged information is understandable by any other application that was not initially developed for

this purpose. Semantic interoperability enables systems to combine received information with other information resources and to process it in a meaningful manner [4, 5, 6]. In other words, semantic interoperability is to ensure that the information exchanged between systems makes sense to all participating in the exchange. This means that the information system understands the semantics of information request and those of information source [7]. The information shared by systems should be understood at the level of formally defined domain concepts so that information is computer process able by the receiving system [8].

The EU-funded epSOS project (<http://www.epsos.eu>) has changed the way we think about cross-border eHealth services, and on interoperability. The European Interoperability Framework finally [5] formulated the strategic vision that recognizes technical, organizational, semantic and legal interoperability. Technical interoperability means that there are agreed technical specifications that enable linking of IT systems and services. Semantic interoperability means that precise meaning and format of information exchanged is preserved and understood between the IT systems. Organisational interoperability means integration of business processes and meeting of users' requirements with different organisations in such a way that the organisations achieve agreed goals. Legal interoperability means that incompatibilities between legislation in different Member States need to be aligned.

We discuss in this paper the challenges of semantic interoperability of the EHRs based on a restricted literature review [2].

2 Methods and Materials

The method used was a restricted literature analysis. We made searches in scholar.google.fi with keywords: electronic health record, semantic interoperability, interoperability levels, means for interoperability in EHR [2].

The searches resulted in materials: articles, standards, specifications and EHR project materials. There were some problems with standards, as standards are not open access and are costly to acquire. In these cases, standards were replaced by reviews or other publications on these standards. Another problem was that commercial health IT systems are proprietary and very expensive, and it is difficult to have access to detailed information on them.

3 Results

Our analysis resulted in that archetypes and HL7 are the two major standard approaches in current EHR development [9, 10, 11], but their approaches to semantic interoperability are very different. It is very difficult for health IT systems adopting different approaches to communicate.

These two approaches, HL7 and archetypes, are sufficient to support semantic interoperability. Both ap-

proaches have their own set of standardized terminologies. In ISO 13606, reference archetypes and terminologies are defined in part 3 [11], while terminologies in a specific domain are determined by specific archetypes. In HL7, vocabulary domains specify terminologies used in the HL7 Reference Information Model (RIM) [10]. References to external terminologies are available in both approaches.

Some of the differences found in these two standards are listed below [2]:

Scope: Archetype methodology has a narrower scope than HL7 methodology. HL7/v3 is designed for whole health domain and HL7 CDA focuses on clinical document exchange under the big picture without addressing exchanging method. Archetype methodology shares a similar scope as CDA but its subject is EHR.

Architecture: The architectural differences between the two approaches are evident. Archetype methodology uses a dual-model to separate technical and domain concerns. In an archetype-based system, Reference Model is implemented in software and archetypes used by the system are developed and maintained by health domain experts. HL7/v3 uses a multi-model approach aiming for a solution for the whole health information domain. HL7 models are developed based on HL7 RIM in the process of HL7 Development Framework (HDF) for different purposes in different domains.

Terminologies: The internal terminologies of the two approaches are different though both support referencing to other terminologies, but their ways to achieve this are very different.

Domain knowledge governance: Domain knowledge is managed in different ways between two approaches. Archetype approach enables creating and changing the knowledge in the archetype by domain experts [7]. Archetypes need to be standardized for semantic interoperability between health areas and specialist fields, even between various organisations. HL7 specifies domain knowledge in standards (HL7 Normative Edition), which aims for global use with the ability to change according to local or regional requirements [10].

Use: Use of archetypes is more flexible because archetypes can either be developed locally or adopted from standardised archetypes and further customised. Archetypes can be used in runtime, while HL7 normative standards have to be implemented in software.

Implementation: Implementing the two approaches is different. HL7 standards are complicated with detailed specifications. ISO 13606 [11] is rather abstract. When developing an archetype-based system, archetypes are either locally developed or

adopted from standardised archetypes. While implementing HL7-based system, developers have to choose from the version 3 standards that satisfy local requirements, and the chosen standards can be adapted for local uses [10].

To solve the incompatibilities between the two approaches, there are harmonisation efforts to alleviate the problem. Further harmonisation is, however, essential and experiences could be adopted from other industries, otherwise competing and overlapping standards will continue to exist – which does not support overall interoperability.

4 Conclusions

Currently, the two major standard approaches can respectively support semantic interoperability. However, the adoption of these approaches is influenced by many factors, policy, culture, health system, and further determined by local requirements. For example, HL7 standards are developed according to the western medicine practices, so they are obviously a ready-to-use option for health providers in the western world. However, HL7 cannot satisfy requirements of other health and medical system, such as oriental medicine. Archetypes approaches with its flexible domain knowledge governance may be more capable of tackle the varying and heterogeneous local requirements.

The very different approaches of current standards provide solutions to semantic interoperability of electronic health record. The prerequisites of semantic interoperability [5, 6] can be fulfilled by these approaches. Despite the differences in architecture, terminology and knowledge management, the discrepancy can be alleviated and the two approaches can cooperate with the continuous efforts on harmonization.

Higher level of semantic interoperability requires further harmonization of the two approaches. The identified differences demonstrate that currently the two approaches are incompatible. The current harmonisation is focused on a consistency of knowledge between the two approaches. It is unlikely that one of the approaches will dominate in the near future.

The convergence to a fully harmonized set of eHealth interoperability standards at international or European level is a preferable long-term vision. Different approaches in terms of technical solutions, standards and profiles used, terminologies adopted, are not seen as the result of right or wrong choices, but rather as the natural consequence of the many factors influencing architectural decisions in eHealth deployment, including culture, domain, country, implementation timeline and the interoperability layers addressed.

There is no real semantic interoperability when existing systems using different standard approaches cannot cooperate. Interoperability will finally be a result of progressive refinement processes across different perspectives.

Conflicts of Interest

The authors have no financial and personal relations with people or organisations that could inappropriately influence their actions.

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Electronic Oral Health Record in Dental Care

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Abstract

Structured representation of dental information in an electronic oral health record is important for reuse of information in medical decision support, statistical analysis of data, interoperability issues and automatic speech recognition. We developed an ontology representing basic human dental structures and designed the new model of electronic oral health record based on this ontology. The software prototype for electronic oral health record with Lifelong Dent Cross user interface was developed.

It can display information in four languages (Czech, English, German and Spanish). It has been applied in dental care at the Department of Stomatology, 2nd Faculty of Medicine of Charles University and University Hospital in Prague-Motol and in forensic dentistry. For English and Czech languages Lifelong Dent Cross user interface can be controlled by voice.

Keywords

Electronic health record, user interface, dentistry, structured information, oral health

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IJBH 2016; 4(1):55–57

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

Electronic health record (EHR) that is based on common information architecture with highly standardized data definitions [1] will play the key role in electronic healthcare. It makes possible to describe, collect and store information about patient state and given procedures in a structured and consistent way [2, 3], and to use patient information for computer-supported decision-making, automated medical-error detection, and rapid patient population analyses for medical research, public health statistics and examination of quality of healthcare services.

Main goals of EHRs are supporting continuing, efficient and high quality integrated healthcare by sharing patient health information between authorized users. For that purpose, EHR contains all patient medical information from multiple sources, which is retrospective, concurrent and prospective. In addition, EHRs may contain data about medical referrals, medical treatments, medications and their application, demographic information and other non-clinical administrative information. In the ideal situation, the information in EHR is continuously updated and current. Terms commonly used in describing the EHR include interactive user interfaces and structured data entries, interoperability and standards, real-time and point-of-care usage, privacy enhancing techniques improving security aspects, semantic interoperability by ontology based approaches, or decision support systems. By meeting specific prerequisites, the EHR allows

collection of data for other reasons than for direct patient care, such as quality improvement, outcome reporting, resource management and public health communicable disease surveillance, but also research and development (see e.g. [1, 4, 5, 6, 7, 8]).

To enable data entry into the EHR systems during examination of a patient, the systems should be supported by user-friendly interfaces.

The part of EHR focused on oral health information is called Electronic Oral Health Record (EOHR), see [9]. In healthcare establishments with dental clinics, EOHR can retrieve additional information such as past medical history or laboratory test results from the hospital EHR directly.

The first pilot application of an EHR for dentistry with the user interface DentCross was developed for permanent dentition and presented in [10] and [11]. In the following, we describe the new model of EOHR for lifelong dental care. It enables to enter data not only for permanent, but also for mixed and deciduous teeth, with support of the user interface Lifelong DentCross.

2 Methods

Based on our extensive experience with the interactive DentCross component for permanent dentition, we have created a brand new object-oriented model compatible with HL7 RIM, thereby implementing the EHRcom

hierarchical structure. It includes the possibility of entering the data not only for permanent, but also for mixed and deciduous teeth. We call this model Electronic Oral Health Record for Dentistry (EOHR-Dent). The Lifetime DentCross software prototype was developed [12], implementing the EOHR-Dent model with a new graphical design (Figure 1).

The EOHR-Dent model represents the ontology of basic human dental structures. It is based on the premise that the model should be able to describe all valid situations and not to lose any substantial information. A model instance in the form of linked objects provides a static view of patient's dentition at the given time. The model, and hence the implemented software Lifelong DentCross, includes the possibility of entering data not only for permanent, but also for mixed and deciduous teeth. Each existing tooth is described using the basic anatomical structures - a crown, root and suspension system of the tooth.

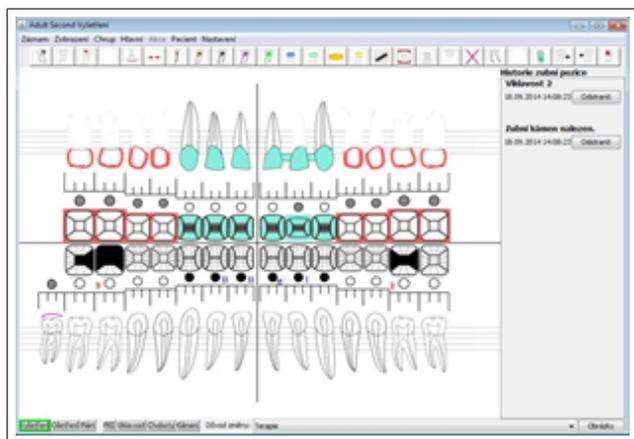


Figure 1: Lifetime DentCross user interface.

The Lifelong DentCross user interface is dominated by a graphical dental cross. In addition to the basic information needed to identify the patient (name, surname and ID number), one can also find user interface controls. These controls are designed to ease the management of the treatment history and treatment plan, also allowing other forms of periodontal detailed examination, such as recording the presence of tartar, the depth of periodontal pockets, and looseness of the teeth and gums condition called PBI (papilla bleeding index).

Dentists can complete all this structured data by dental reports in free text. In the study on 126 patients [13], dentists added textual comments very rarely. Due to the sufficient amount of information provided in structured data, there was no need to enrich the EOHR-Dent model with information from dental reports [14]. The user interface Lifelong DentCross can display information in four languages: Czech, English, German and Spanish.

Now we will present an example how to structure information in dentistry and store information in EOHR-Dent.

Figure 2 (German version of the Lifelong DentCross) shows the example where - by the combination of crown denture and pontics - we can design bridges from available

components and simultaneously mark a material composition. The system offers a selection of crown casing, veneered and combined as appropriate bridge. After recording, all data are stored in the EOHR-Dent with the time stamp.

Although it was one of the main objectives of this applied research to provide the most complete structuring of dental information, it was not possible to relinquish the possibility of notes in the form of free text. Despite the growing importance of structured information in any data processing, we cannot completely avoid notes in the form of free text in medicine. The physician must always be able to record any identified individual patient information.

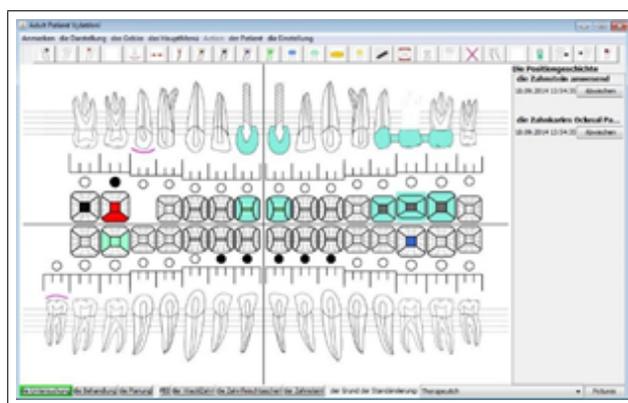


Figure 2: Combination of implants, crowns and bridge.

3 Results

We have developed a fully interactive graphical user interface to store dental information in EOHR-Dent. Nowadays, the software prototype working with the Lifelong DentCross user interface includes the option of entering data not only for permanent, but also for mixed and deciduous teeth. For that purpose, the ontology model of dental medicine was extended. The user interface for dentistry is based on a new software prototype of the interactive Lifelong DentCross component [12]. In [13], the comparison of three methods for the time-consuming data entry in dentistry was performed on 126 patients: a) dental registration in the WHO card, b) EOHR-Dent controlled by keyboard or, c) EOHR-Dent controlled by voice.

In clinical practice, it is required to find ways to avoid the manual operation using a keyboard, mouse or touch screen. Therefore, the added automatic voice recognition allows the dentist to use the software without performing manually. This eliminates the need for a second person entering data or redundant hygienic procedures (washing hands, changing gloves, etc.).

Nowadays, the Lifelong DentCross interactive user interface for EOHR-Dent is running in four languages. These languages are Czech, English, German and Spanish. Each language has its set of definitions, which contains about 300 dental terms. The Lifelong DentCross

software prototype has been developed in Java and can run on Java-enabled PCs. Hardware requirements for the application are: quality wireless headset (Plantronics devices have been used, needed only for voice recognition), and a common computer with MS Windows XP or newer. The voice recognition software requires about 300MB disk space (proprietary scientific-use-only license). The underlying database can be local (Derby – JavaDB) or a client-server architecture (e.g. MySQL). Access to data is accomplished by object-relational data mapping using an extended JPA-like Software Developer proprietary approach.

Dental expertise occupies an important position in the identification process, and is necessary especially when alternatives such as the results of DNA analysis and fingerprint comparison are not available. Properly conducted dental documentation is often the key to successful identification of unknown persons or skeletal remains. Not only the teeth, but also the analysis of the materials used to rehabilitate our teeth with the help of modern technology can lead to a clear identification of the individual. The electronic oral health record in dentistry can support a rapid identification of unknown individuals [11] as well as decision making in oral health (see e.g. [10, 15, 16]).

4 Conclusions

Using a structured data entry and human voice to control computer or other devices arose in typical manual-focused environments such as dentistry is very helpful. The problems with entering data in the EOHR-Dent during an examination of a patient led us to further research in the area of medical informatics and dentistry.

The interactive Lifetime DentCross component for recording oral health information was applied in dental care at the University Hospital in Prague-Motol and in forensic dentistry, supporting daily work and research in both units. That way, the usefulness of the EOHR-Dent model could be justified. Successful deployment of the multilingual Lifetime DentCross software based on an object model demonstrates that robust object modeling is a feasible way of storing structured information such medical data and presenting it in different languages.

Competing interests

The authors have no financial and personal relationships with other people or organizations that could inappropriately influence (bias) their actions.

Acknowledgements

The present study was supported by the grants PR-VOUK P28/LF1/6, P29/LF2 and SVV 26015 of Charles University in Prague.

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Structured and Standardised Data Collection in the Czech National Cancer Registry

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Abstract

The Czech National Cancer Registry (CNCR) is one of the oldest nationwide population-based cancer registries in Europe. Trained expert staff at regional offices of CNCR input structured record for each cancer case based on standardized form and international classifications (International Statistical Classification of Diseases and Related Health Problems, International Classification of Diseases for Oncology, TNM Classification of Malignant Tumours).

With 2.2 million cases it is a valuable data source for monitoring the epidemiological situation of neoplasms, for health policy planning and international comparisons.

Keywords

Registries, data collection, classification, clinical coding, medical oncology

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IJBH 2016; 4(1):58–60

received: January 5, 2016

accepted: January 15, 2016

published: February 10, 2016

1 Introduction

The Czech National Cancer Registry (CNCR) is one of the oldest nationwide population-based cancer registries in Europe. CNCR contains population data for the whole spectre of neoplasm diagnoses since 1977. This means total of about 2.2 million cancer cases. With the growing incidence, about 90 thousand cases are reported into CNCR every year. Reporting of cancer cases into CNCR is mandatory in the Czech Republic by the Act no. 372/2012. The outputs from the register are used for monitoring the epidemiological situation of neoplasms, for health policy planning and international comparisons.

2 CNCR Data Structure and used Standards

CNCR stores the cancer case reports in the form of a structured database record. The basic structure of the record uses classification systems and methodology for the collection of cancer cases information defined by recommendations of International Association of Cancer Registries (IACR) and European Network of Cancer Registries (ENCR). CNCR is an active member of these organizations. CNCR is also involved in many international projects, which process cancer registries data.

Data collection in CNCR is based on IACR Standards documents [1], Standards and Guidelines for Cancer Registration in Europe [2] and A Proposal on Cancer Data Quality Checks: One Common Procedure for European Cancer Registries [3].

3 Used Clinical Classifications

Each case is classified according to the latest version of the recommended international classifications: ICD-10, ICD-O-3 and TNM7.

The International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) is worldwide standard for classifying and coding diagnoses. It is issued by the World Health Organization (WHO). In the CNCR and other cancer registries, it is used for basic submission of the case into the category of neoplasms. More information can be found at WHO website dedicated to ICD. [4]

Table 1: ICD versions and period of validity in the CNCR.

ICD version	Validity in CNCR
ICD-7	1. 1. 1958–31. 12. 1967
ICD-8	1. 1. 1968–31. 12. 1978
ICD-9	1. 1. 1979–31. 12. 1993
ICD-10	1. 1. 1994–

International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3) is used for detailed description of the disease case in the categories of topography and morphology axis. It also defines the biological behaviour of the tumour, its cellular differentiation (in solid tumours) and cellular type (in hematologic neoplasms). ICD-O-3 is issued and maintained by WHO and IARC. More information can be found at. [5]

Table 2: ICD-O versions and period of validity in the CNCR.

ICD-O version	Validity in CNCR
ICD-O-1	1. 1. 1984–31. 12. 1993
ICD-O-2	1. 1. 1994–31. 12. 2004
ICD-O-3	1. 1. 2005–

TNM Classification of Malignant Tumours is international staging system issued by the Union for International Cancer Control (UICC). It allows describing the extent of disease in the patient with solid tumour by defining the size of the tumour, involvement of lymphatic nodes, and distant metastasis, i.e. the spreading to other organs. This allows categorizing cancer cases in one of several clinical stages and the use of proper treatment based on the latest clinical knowledge. More information can be found at the UICC webpage dedicated to TNM. [6]

Table 3: TNM versions and period of validity in the CNCR.

TNM version	Validity in CNCR
TNM2	1. 1. 1976–31. 12. 1981
TNM3	1. 1. 1982–31. 12. 1994
TNM4	1. 1. 1995–31. 12. 2000
TNM5	1. 1. 2001–31. 12. 2004
TNM6	1. 1. 2005–31. 12. 2010
TNM7	1. 1. 2011–

4 Process of the Data Collection

Because of the complexity of the information required and the lack of a structured clinical record in common hospital information systems, data collection is done using standardized paper forms.

Regional CNCR offices operate on county level. Specially trained staff of these offices enter incoming reports into the CNCR central database using a web application. At the incidence of a cancer case, the report is entered into CNCR with a National Identification Number identifying the patient. CNCR protects personal data of patients by technical and organizational means, which prevent from their abuse.

The electronic entry web form (Figure 1) allows a clear description of the case by collecting various classifications codes with checking and validating its consistency. The

application enables only allowed combination of classification code values. Before storing into the database, the record is checked for possible logical errors and, if necessary, the user is required to correct the form.

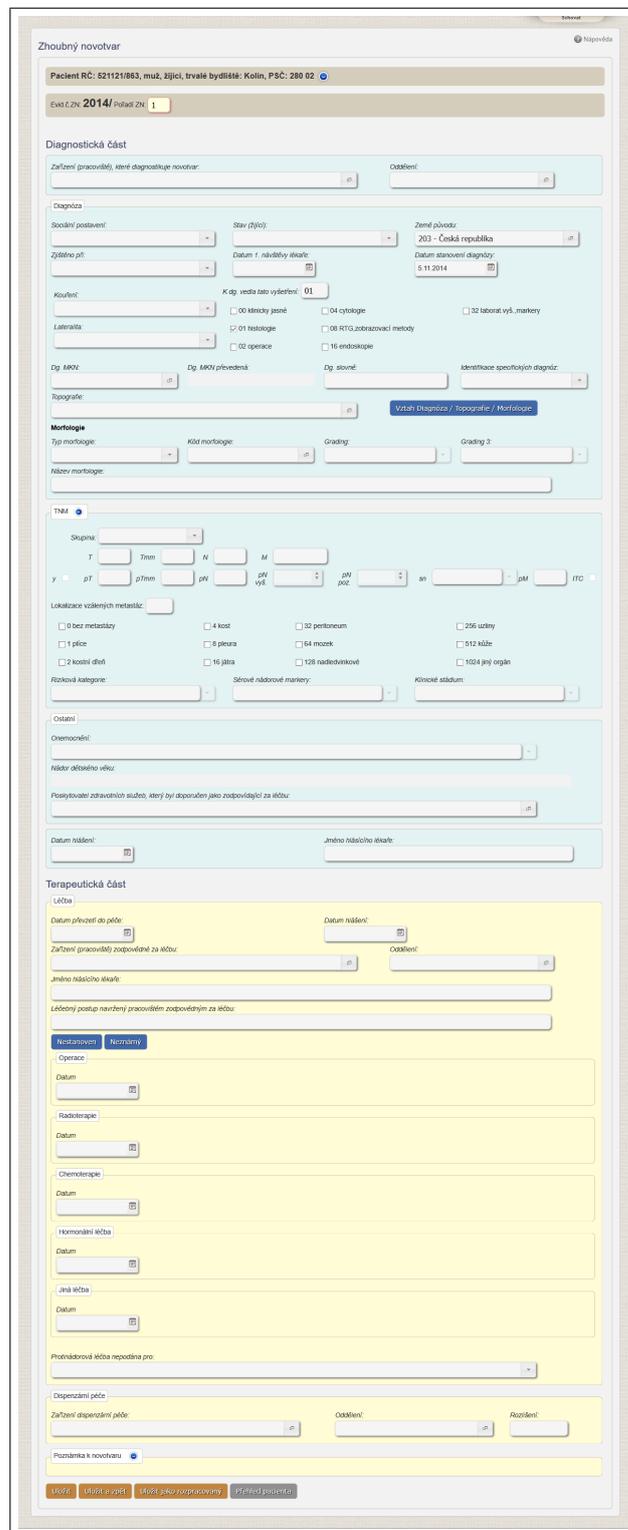


Figure 1: CNCR web form.

Cancer case reports can arrive from several sources. The regional CNCR office is responsible for the integrity

and completeness of the record, using information from various phases of the process of care for cancer patients by retrieval of missing information from hospitals and physicians.

The future aim is to allow data mining from the Electronic Health Record (EHR) and sending electronic reports to the CNCR automatically from hospital information systems.

5 Conclusion

CNCR is a huge data source of the structured health information. It is based on international standards and international health classifications (ICD-10, ICD-O-3, TNM7). Records are transferred from paper-based forms into the CNCR database at regional offices level. Specially trained staff and standardized web application for data input allow the high quality of data and personal data protection. CNCR with its long term data contributes to international cancer research projects and supports health policy planning in cancer care in the Czech Republic.

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