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Telemedical Management System of Structured Clinical Documentation - Application for Quality Assurance and Multicenter Clinical Trials

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The paper presents telematic system designed for providing secure medical data communication through the Internet. Security is achieved by strong encription. The data transmission between remote hospitals and center can be done in both directions. Transmitted data may be of different type especially HTML forms. The HTML forms filled in hospitals are automatically loaded to tables of relational database in the center. Generated in the system HTML forms meet structured clinical documentation needs. The telematic system was applied in project financed by government based on WHO standards for quality assurance system in obstetrics and neonatology. The system covers 40 hospitals and 13 regional health authorities for mother and child. 40 000 records concerning maternal, fetal and infant health status during pregnancy, delivery and pospartum period were stored. Collected data are used for developing indications for monitoring and evaluating perinatal health in Poland.

Introduction

Health care services that could be provided using telemedicine and describes exist in three categories: 1. store-and-forward telemedicine; 2. self-monitoring/testing; 3. clinician-interactive telemedicine.

Ad 1. Store-and-forward telemedicine differs from face-to-face encounters in that a history and physical examination is not performed by the clinician. Rather, the clinician gets a report of the history and physical examination along with audio or video data.

Ad 2. Self-monitoring/testing is most commonly used for management of chronic diseases or specific conditions, such as heart disease, diabetes mellitus, or asthma.

Ad 3. Clinician-interactive telemedicine is used in more heterogeneous clinical specialities than store-and-forward. A large variety of clinician-interactive telemedicine services are currently provided, such as history and physical examination, psychiatric examination, and ophthalmologic assessment.

Objectives and Methods

The National Research Institute of Mother and Child in Warsaw (NRIMC), on the Ministry of Health (MH) order, developed and implemented the quality assurance system in obstetrics and neonatology.

Basic activities of the system named P-OBSQID are remote collecting and management of structured clinical documentation and other files of data including static images. Thus the system belongs to store-and-forward telemedicine class.

The aim of the P-OBSQID project was to set indicators for monitoring and evaluating perinatal health care in Poland concerning maternal, fetal and infant health during pregnancy, delivery and the postpartum period, as well as the health consequences of events that occur in the perinatal period. These indicators also include measures of the demographic, medical, social and health system factors that influence perinatal health.

Measures and methods for evaluating perinatal health and the quality of health services are not available in all countries. In the EU countries many perinatal health indicators are not fully comparable because of differences in definitions and data collection procedures, heterogeneity in birth and death registration, and variation in medical practices.

Our specific objectives were to:

- define indicators of perinatal health and its determinants in Poland ensuring comparability with European norms and standards;
- assess the ability of existing data collection systems to construct these indicators and specify methods publication of the indicators;
- establish methodology and statistical techniques for deepened analysis.

The P-OBSQID system is built on the basis of such techniques as data warehouses, medical documentation management and internet transmission.
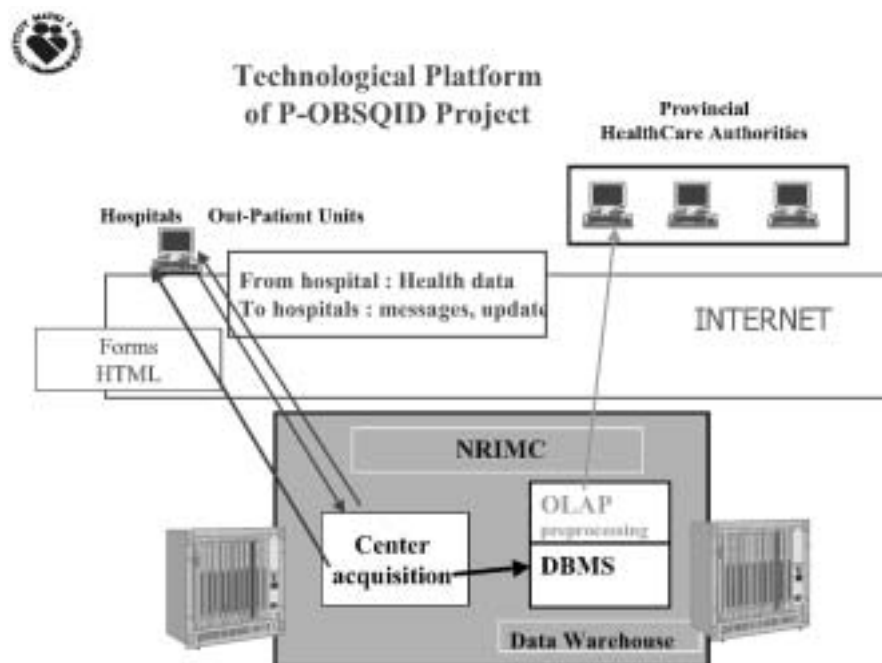
**Technological Platform
of P-OBSQID Project**

Fig. 1.

After evaluation of documentation management systems in Internet version (by HTML or XML standard) available on the market we decided to develop the proprietary system, called AKSON - to which NRIMC has the full copyrights and ownership rights. This reduces greatly costs of its operation and development as well as enables passing it for free to hospitals and various health care institutions

AKSON system is a software package designed for completion HTML medical documentation in remote hospitals and secure data transmission through the Internet. Any implementation of the AKSON system consists of one center and many clients (installed in hospitals). The communication can be done in both directions - from hospital to center (HTML completed documents, static images, other files) and from center to hospitals (HTML template of forms, their updates, messages).

Security of communication is achieved by strong enctription of the transmitted data.

Medical documentation is made up as set of forms including one or more windows. Forms are hierarchically or parallel ordered. A form can have many variants chosen automatically depending on the data completed before. Full validation during completing forms is automatically performed. Hierarchical large dictionaries can be also attached to forms. Creation and updating HTML templates and joining new dictionaries can be done in easy way.

Completion of form is working in the off-line mode, Internet communication is activated temporarily. During Internet connection not only the data from hospital are exported, but also updates of HTML templates, errors messages are receiving by hospitals. Other important functionalities of center are - archiving completed HTML forms,

transition HTML forms to relational tables of data warehouse repository and maintenance of quality gathered data.

P-OBSQID project motivated us to master and introduce method known as the data warehouse. According to Oracle definition a data warehouse is an enterprise structured repository of subject oriented, time-variant historical data used for information retieval and decision support. The data warehouse stores atomic and summary data. Presented above system AKSON fulfilled activities ETL (extraction, transmition and loading). Subsequent stages of the processing were organised using ORACLE 8i tools. The repository was organised including tables of facts, dictionaries and suitable aggregate tables. Diverse mechanisms facilitated performance and analysis (visualised views, multiple time hierarchies) were widely used.

For reports and current assessment situation in perinatology OLAP-technology (online analytical processing) was used. We used ORACLE tools - Divscoverer Administration and End User Stage of pre-processing was performed by qualified specialists in NRIMC. Mechanisms for generating of final reports including tables, figures, plots with drilling feature were available for managers and physicians in remote hospitals and medical centres.

Results

The basis for the project is world-wide quality assurance system for obstetrics and neonatology conducted by European Regional Bureau WHO as OBSQID project. Poland took part in the OBSQID project and contributed in high degree in development of its assumptions. On the OBSQID project basis we developed polish version applying newest

telematic technology, and integrating it with legacy national systems in obstetrics and neonatology

This had certainly to lead to differences between the original OBSQID and our version, referred to later as P-OBSQID.

We tried to keep data set comparability of P-OBSQID with original OBSQID (designed by WHO). Nevertheless, necessity of integration with other national systems and consideration of their requirements caused amendments in data set of P-OBSQID. Analysis of results during the year-lasting execution of project also caused the further modifications

The various suggestions concerning data set modifications and widening have been submitted by various P-OBSQID users during its yearly execution.

For example, hospitals proposed to introduce additional information necessary for settlements with the insurance houses and for obligatory national reporting Regional Health Authorities recognised as important demographic issues and the deepen analysis of deaths in hospitals and dead births. The separate topic, which can be initiated by P-OBSQID is the general register of newborns and children, and special care children register.

In 2000 - 2001 year P-OBSQID system covered 40 hospitals in the whole country and 13 regional health authorities for mother and child.

Currently more than 40 000 perinatal medical records including ca 100 facts concerning mother and ca 70 newborn were collected.

The accomplishments of the first stage are:
- adaptation to polish realities quality assurance system for obstetric and neonatology recommended by European Regional Bureau WHO;
- acquisition of knowledge according electronic health care record, data warehouse;
- achievement of technological and organisational maturity of telematic system.

After mastering the phase of data acquisition and collection, the phase of data processing, analysis and presentation will now become more important in P-OBSQID project. We currently focus on high efficiency of register and quality of collected data developing and improving mechanisms of data validation and integrity. The verification of P-OBSQID register completeness by comparison it by capture recapture method with independent birth register kept for screening examination was introduced for this purpose. Quality of collected data and efficiency of system operation depend on qualifications, motivation and good work of engaged people, both in NRIMC and in hospitals. We conduct training for this purpose - using www sites and e-mail communication - and remain in personal contact with these persons in hospitals, which complete electronic forms.

Gathered file of 40 000 perinatal medical records allows us to assess the ability of P-OBSQID data set for construction indicators, revision recommended by WHO indicators as well as to begin deepened statistical analysis.

Conclusion

The quality assurance idea experiences currently in Poland reluctance and actions which hinder its implementation in hospitals and outpatient health service. This is caused by wrongly and inconsistently conducted reform of health care. Nevertheless the recent decisions of Ministry of Health allow us to be more optimistic. The Public Health Department of MH has declared the wish of P-OBSQID program enhancement to all hospitals in Poland from the beginning of 2003 year. The P-OBSQID program as interdisciplinary venture consolidating clinical epidemiology, electronic patient record, telematic system and advanced statistical analysis occurred to be complicated enterprise.

The success of the program will give way for other ventures in the field of quality assurance in health care system. The authority of the WHO as well as connections with this organisations and with the European Union institutions, will be of great assistance for introduction the health care quality assurance in Poland. On the basis of accomplishments obtained so far we expect the success the program broadened to all hospitals in Poland.

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