The medical information system and its application for quality assurance programs in cytology – Georgian experience

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Abstract. The paper addresses the presentation of the medical information system and describes its application for quality assurance (QA) programs under the conditions of Georgia rules. 100 gynecological cytology cases were randomly selected. Digital images were obtained on all cases. All 100 cases (medical data and images) have been uploaded into the medical information system and labeled "QA". Diagnosis of glass slides and digital images were done independently in a double-blind manner by 3 certified cytologists, commencing with the diagnosis of "QA" cases followed by diagnosis of glass slides 3 months later. All 3 cytologists have an experience to work with digital images and medical information system. Diagnoses of "QA" cases correspond with initial diagnoses made in routine manner. Digital images are suitable substitutes for glass slides; the paper shows how digital images can be used in cytology quality assurance programs; medical information system can be applied as a platform for cytology online quality assurance programs allowing achieving higher efficiency, time saving and lowering cost for hospitals and medical centers.

Keywords: Medical information system, Digital image, Quality assurance, Cytology

Introduction

There is a very clear need for the expanded application of information technology (IT) in healthcare. Clinical workflow still depends largely on manual, paper-based medical record systems, which is economically inefficient and produces significant variances in medical outcomes. Quality assurance programs in cytology are one of the most important methods to maintain and improve the diagnostic acumen of cytotechnologists and cytologists, but there are difficulties in carrying out such programs. A long turnaround time for the circulation of glass slides is a major drawback. It is well known, that it is prolonged in the case of large number of participants and widely spread institutions. The use of photographed slides has been a partial, but unsatisfactory solution because of costs and delays in preparation. Nowadays digital images acquire more and more importance for morphology practice.

Background

Digital images can be easily captured by the conventional digital camera, by the use of specific hardware (slide scanner, robotic microscope and etc.). By application of digital images the distance consultations in cytology became reality and are implemented routinely. Most studies reviewing digital images and their application for telecytology have focused on usage of robotic microscopes and online microscopy. Other studies have evaluated the use of digital images of slides. There is no previous study examining the application of digital images for implementation of quality assurance programs.

Medical information system (MIS) is at the heart of IT implementation policies in healthcare systems around the world. Most of these policies are based on beliefs about the positive value of MIS rather than on the available empirical evidence; as a result, policy documents comprise aspirational statements rather than detailed and realistic expectations.

It is obvious and well known that the field of healthcare informatics is rapidly evolving. The new models and protocols of MIS are well developed. They are based on implementation of profiles such as HL7 and DICOM. Despite of obvious advantages and benefits, practical application of MIS in everyday practice is slow. Research and development projects are ongoing in several countries around the world to develop MIS: examples include Canada, Australia, England, the United States, and Finland. MIS is used primarily for setting objectives and planning patient cares, documenting the delivery of care and assessing the outcomes. It includes information regarding patient needs during episodes of care provided by different healthcare professionals. The amount and quality of information available to healthcare professionals in patient care has an impact on the outcomes of patient care and the continuity of care. The information included in MIS has some functions in the decision-making process in patient care. It also supports decision making in management and in health policy. There is no previous study examining the application of MIS for online quality assurance programs in cytology.

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The MIS has been created with .Net technology and SQL database architecture. It involves a multiuser web-based approach. This ensures local (Intranet) and remote (Internet) access of the system and management of databases. .Net technology can be installed on computers running Microsoft Windows operating systems. It includes a large library of coded solutions to common programming problems. .Net technology is a Microsoft offering and is intended for usage by most new applications created for the Windows platform. Version 3.0 of the .Net technology included with Windows Server 2008 has been used for creation of MIS. The MIS is object-oriented software. It is realizing client-server concept. Its architecture provides a secure, robust, and extensible system for managing multiple medical terminals within a centralized repository. The MIS has a flexible architecture that can run on numerous combinations. The recommended server operating requirement is Windows Server 2003. Hardware requirements are the following: memory 1 GB; disk space 1 GB. Internet explorer 6.0+ and/or Mozilla Firefox 2.0+ can be used as client browsers. The medical information system was started in December 2007, and the draft version was released in April 2008. After some tests and corrections, the application ready-for-use version of the medical information system was issued in October 2008.

The medical information system consists of three key modules:

- Administration and configuration module
- Working module for medical personnel
- Reporting module.

The administration and configuration module is dedicated for setting up users' basic rights. It allows users registration or blocking, defining, and configuring of their rights. All medical forms (consultation, clinical investigation, diagnosis, prescription, treatment, etc.) are generated by this module. It is a database useful for staff too. Each employee is provided by a unique code, alongside with gathering biographical and professional data. Using the working module, patients medical history can be generated, edited, and updated by medical personnel. At generation, a unique code is given to medical history. It consists of text and multimedia files – images, video, and billing invoices. Planning of patient visits and schedule of working staff are also implemented by this module as well. Medical history and medical forms (consultation, examination report, etc.) can be fully or partially exported by the reporting module. The documents can be exported in various file formats, including pdf, rtf, and jpg. This module also implements statistical analysis of medical data (patient's age, sex, diagnosis, date of investigation, treatment parameters, etc.). It can be used for quality control of medical services.

For the online quality assurance program in cytology we randomly selected 100 gynecological cytology cases (benign – 52; atypical squamous cells of undetermined significance (ASCUS) – 28; low-grade squamous intraepithelial lesion (LSIL) – 7; high-grade squamous intraepithelial lesion (HSIL) – 13). The randomization has been done by application of the Research Randomizer. This is a free service offered to students and researchers interested in conducting random assignment and random sampling. This service is available at www.randomizer.org. Cases were diagnosed routinely by 3 certified cytologists with an experience of work with digital images and usage of medical information system who provided cytology diagnoses. All participating cytologists have more than 7 years of cytology and up to 2 years experience to work with digital images and medical information system. The most worrisome cells or groups in each case were selected and marked by all participating cytologists. These areas were photographed with 2.0 USB digital eyepiece microscope camera with resolution 3.0 by cytologist. The images had a resolution 2048x1536 pixels. The mean number of selected fields and digital images for each case were 5 (range 5-7) and 20 (range 18-22), respectively. Each series of images began with a general view (magnification x40), followed by higher magnification (x100) of diagnostically interesting areas as directed by the cytologist. The images were stored in a personal computer and uploaded at medical information system (MIS) together with necessary medical data. The upload to the medical information system was done 100% successful. There was no image distortion identifiable after the upload process. Created cases were labeled “QA”.

100 electronic medical records (EMRs) with cytology diagnosis, illustrated by images and labeled “QA” were created. Email notifications that cases are available for review have been sent to cytologists who already diagnosed these cases in routine manner after creation of the EMRs. These cytologists have been registered as users at MIS.

Diagnoses of “QA” cases were recorded in 4 categories: (1) benign; (2) ASCUS; (3) LSIL; (4) HSIL. Additional information, including comments on adequacy of images, total time required for review and problems encountered in diagnosing “QA” cases, and whether there was a need for low-magnification digital images, was recorded by each participating cytologist.

Diagnoses of "QA" cases correspond with initial diagnoses made in routine manner. The mean diagnostic time was 125.8 minutes (range 115-142 minutes) for glass slides and 47.3 minutes (range 38-62 minutes) for "QA" cases. Low magnification (x40) of digital images was recorded as not necessary by all participating cytologists. The inability to focus at different levels to examine the architectural and cellular details of overlapping cellular groups was recorded as an impediment to diagnosis in "QA" cases.

Discussion

Healthcare IT models are constantly evolving as the industry expands. The medical information system is a comprehensive solution that automates the clinical, administrative, and supply-chain functions. It enables healthcare providers to improve their operational effectiveness, to reduce costs and medical errors, and to enhance quality of care. The aim of the medical information system was and is as simple as relevant: to contribute to and ensure a high-quality, efficient patient care. The relevance of "good" medical information system for high-level quality of care is obvious. Without having appropriate access to relevant data, practically no decisions on diagnostic, therapeutic, or other procedures can be made. In such a situation, consequences may be seriously fatal for patients. The medical information system has been launched in Georgia. The draft version was available since August 2008. After some tests the necessary corrections and editions have been made and the working version was made available since October 2008. The medical information system is used by the medical center “Neoclinic” since October 2008, by the medical laboratory “Neolab” since May 2010 and by medical center “Test Diagnostics” since May 2013. All medical organizations are located in the capital of Georgia, Tbilisi. Primary goal of the MIS is patient management. However, the system also targeted at creating a unified information space in the framework of the wider medical organization.

It is obvious, that digital imaging can be used in many areas of anatomic pathology, including the photography of gross and microscopic findings in both surgical and autopsy pathology. It is practical and cost-effective and provides many advantages over traditional morphology practices. Digital imaging also is the first step toward opening the door to many future applications and improved diagnostic, educational, and quality assurance activities. It is obvious, that digital imaging is rapidly becoming an integral part of the healthcare activities in many hospitals and clinics around the world. In many cases it accounts for over 50% of all eHealth activities. There are many advantages of using digital images for quality assurance in cytology. The major advantage is rapid turnaround time. Transmission of digital images through the internet undoubtedly is faster than the conventional method of circulating glass slides, especially when the availability of cytologic smears is limited compared with that of histologic material. Slow turnaround of glass slides during quality assurance exercises is a serious problem. It is reality that glass slides were circulated among more than 20 institutions throughout the country. This exercise alone took at least 3 months. Sometimes participants have to attend the meeting without viewing the slides.

The use of digital images ensures the assessment of identical fields, avoiding the problem posed by differences in field selection. The main aim in cytology quality assurance programs is to test participants’ ability to make the correct decision on a specific abnormal finding rather than the ability to screen an entire slide. Thus, digital images circumvent the problem of field selection and assess interpretation. The time that would be spent for searching the slide for abnormal cells is eliminated. In the present study, the mean diagnostic time was reduced by more than half for "QA" cases (47.3 minutes) compared with glass slides (125.8 minutes).

It should be noted and emphasized, that the main aim in cytology quality assurance programs is to test participants' ability to make correct decision on a specific pathology finding. It is well known, that the specialty of cytology, the analysis of cellular morphology and architecture for the presence and nature of pathology, is involved in the care of virtually every patient who seeks medical attention. In a typical medical center studies have indicated that 70% of the clinical data in the electronic medical record are from cytology. Significantly, clinical decision support programs are highly dependent on cytology data. Much of the analysis performed in the cytology lab is visual; therefore cytology imaging has become an important and growing area of medical imaging environment. However, cytology imaging presents a number of unique challenges. Some of these challenges include the fact that cytology image quality is a function of many processes (many of which are outside the traditional realm of imaging). For example, image quality is a function of the processing of cellular group(s), the staining of the slide, and the ability of the microscope to form a clear, in focus image worthy of capturing. These functions and tasks are unified and standardized. Therefore the selection of the diagnostically important area is the routine procedure during screening of the entire slide and can be easily and effectively performed by the certified cytologist. The most important is the ability to correctly diagnose the concrete pathology finding. This ability usually correlates with a professional experience and development of this skill is the task of the cytology quality assurance programs.

Cost savings is another advantage. Implementation of quality assurance programs in cytology by usage of digital images reduces the expenses of postal or courier slide circulation and the cost and delays of photography slide preparation. Easy and continuous access to the case material from the medical information system is yet another advantage over glass slides, which have to be returned to the owner institution. After the quality assurance exercise, the digital images are still available for reference and teaching purposes. These advantages, together with the acceptable levels of diagnostic accuracy and reproducibility, strongly support the use of medical information system and digital images for cytology quality assurance programs.

By the term "EMR" we describe a computerized legal medical record created in the clinic. Usually, however, the term "electronic health record" (also electronic patient record or computerized patient record) is used. EMRs are a part of the medical information system that allows storage, retrieval, and manipulation of data. This is an evolving concept defined as a longitudinal collection of electronic health information about individual patients or populations. Such records may included a whole range of data in comprehensive or summary form, including demographical data, medical history, medication and allergies, immunization status, laboratory test results, radiology images, and billing information. In accordance with our model, EMRs are generated and maintained within clinic. This is a complete record that allows managing and follow-up workflow in healthcare settings and to increase patient safety through evidence-based decision support, quality management, and outcome reporting. EMRs can be continuously updated. A centralized data server is used for EMR's storage.

Before practical application of the medical information system, education and training of staff is essential. The system is a very useful and easy-to-use tool. It ensures a situation where healthcare professionals spend more time for creating knowledge from medical information than managing of medical information. Further, medical information system holds the potential to reduce medical errors.

Today, application of digital images in cytology seems to be basic solution for organization of quality assurance programs. Conventional cytology with glass slide has many limitations. For example, they may be easily broken; their stain is unstable and could fade with time, and etc. In such situation, the best replacement for conventional slide cytology is digital imaging. The appearance never changes as long as the data integrity is maintained. However, despite of mentioned advantages, digital imaging in Georgia is not popular. In this study we evaluated the application of the medical information system and digital images for implementation of online cytology quality assurance programs under conditions of Georgia. It has been revealed that the mentioned system can be easily and effectively applied as a platform for cytology quality assurance programs. The data from the present study support the use of digital images for implementation of online cytology quality assurance programs too. Diagnostic concordance was high (100%) for “QA” cases. The data revealed no differences between routine diagnostic versus diagnostic with digital images, supporting the reliability of using digital images displayed on a computer monitor to render accurate diagnoses and undergo online cytology quality assurance programs. It should be noted, however, that although there was a relatively large number of cases in this study, there were only three cytologists. The study would have had more power if there had been more cytologists.

Image quality was generally rated as excellent to good (98%). One interesting finding was that neither diagnostic decision nor diagnostic confidence was highly correlated with ratings of color, sharpness, or with viewing time. The present study illustrates that digital image include potentially eliminating the need for glass slides (at least at the point of examination), allowing annotation to be added to images, and the ability to rapidly transmit and remotely share images electronically. As it was noted above, low magnification (x40) of digital images was recorded as not necessary by all participating cytologists. The inability to focus at different levels to examine the architectural and cellular details of overlapping cellular groups was recorded as an impediment to diagnosis in "QA" cases. It has been proposed to obtain several images focusing different levels of overlapping cellular groups. This might be a solution for examination of the architectural and cellular details of such groups.

We can separate out two main groups of theories, which we can call micro and macro. At the micro level, the MIS and digital image technology might influence behavior in organization through, for example, improved scheduling, better clinical and administrative communications, and localized structural change. These are three possible programs theories in Pawson’s method. Another theory is that modern electronic services appear to work in more subtle ways as well, for example by aiding education and learning on the job. The key general point here is that there is no agreed set of theories, or mechanisms, whereby MIS influence clinical or administrative work.

Macro effects arise as a consequence of a network operating across many sites, rather than just one. Commercial ventures such as Amazon and eBay provide compelling examples of this kind of network effect, exploiting economies of scope and scale to offer lower prices than shops for books, CDs, and other goods. The mechanisms whereby network services might exert their effects in organizational settings have not been extensively researched, but it seemed reasonable to expect to find papers examining them, giving the central place of electronic networking in information technology policies around the world.

Conclusion

Our study revealed that digital images are a suitable substitute for cytology quality assurance programs. Medical information system is a useful platform for implementation of cytology quality assurance programs. But it should be also noted, that perspectives and strategies for medical information system and its practical application in routine work of the medical organization are currently evolving, as emerging operative requirements would allow self-sustainable large scale exploitation while recent technological developments are available to support integrated and cost-effective solutions to such requirements. However, as far as we know few pilot projects have proceeded to large scale exploitation, even after successful technological demonstration phases.

The medical information system is the most important background for ensuring the safe and effective medical care through the appropriate organization of medical information storage and exchange. But instead of management of medical data and clinical workflow by itself the medical information system has the potential for offering the worldwide medical community the qualitative and quantitative improvements.

The medical information system is able to reduce healthcare costs in the following ways:

- Reduction of operating costs through centralization and optimization of resources (expertise, laboratories, and etc.).
- Reduction in travel cost and time for specialists visiting other hospitals and centers for consulting.
- Reduction in costs for training and updating, improvement of specialists' qualifications through eLearning and access to medical databases.

The medical information system introduces added value and a positive impact at social, economic and cultural levels. As a result, it is initiating to have an important influence on many aspects of medical service in countries with low and middle income.

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