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ORIGINAL ARTICLE

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Systems integration in the operating room: the challenge of the decade

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Abstract In the past 50 years the equipment of operating rooms has changed enormously due to technological innovation and new surgery methods. In particular the establishment of minimally invasive therapy has led to a considerable increase in equipment and instruments that have to be used during surgery. The development of new equipment and instruments has had priority over the past 10–15 years, whereas now the manifold different equipment require systems integration and networking. Systems integration and networking of different OR (operating room) system components are very important current technological challenges in operative medicine. While certain technologies like robotic and navigation are still in the early stages, image documentation is an excellent starting point for systems integration because of the advanced development stage and the need for all operative disciplines. The Department of Obstetrics and Gynecology at the University of Tübingen in Germany (UFK) is delving into systems integration and networking in the operating room. In addition to the central control and monitoring of different systems, operating tables and lighting, the image documentation of intraoperative results is a principal topic. The UFK project is part of the Center of Competence for Minimally Invasive Medicine and Technology Tübingen-Tuttlingen (MITT), which is promoted by the German Federal Ministry of Education and Research. This article presents the importance and potential of systems integration and networking in health care, the current stage of development and future trends, considering image documentation as an example.

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Introduction

On the one hand progress in operative medicine is based on the manual skills and experiences of surgeons, and on the other hand on continuous enhancements of medical instruments, equipment and systems. An outstanding example of technological enhancement is the development of operative endoscopy over the past 20 years, as operative endoscopy is part and parcel of minimally invasive therapy. Enhancement of discrete equipment and instruments has been the main focus of attention for developers and operators over the last 10–15 years. Nowadays the manifold different pieces of equipment in the operating room (OR) require systems integration and networking [1–3].

Parallel to proceedings in medical technology, economic efforts gain in importance because of the pressure of rising costs in health care [4–6]. In the next few years the development of clinical pathways as well as implementation of electronic patient records and electronic health records will lead to increased efficiency in health care organisations and will also significantly affect technological developments in operative disciplines. The importance of the connection between systems integration and economy is also shown in the SOMIT-program, which was advertised in 2003 by the German Federal Ministry of Education and Research (BmBF). It is the aim of this program to develop user-friendly, integrative OR systems that fulfill the requirements of end-users [7].

The Department of Obstetrics and Gynecology at the University of Tübingen in Germany (UFK) is delving into systems integration and networking in the operating room. This project is a subproject in the BmBF Center of Competence for Minimally Invasive Medicine and Technology Tübingen-Tuttlingen (MITT). In order to contribute to an efficient application of limited resources in health care, the UFK analyses and optimises units for central control and monitoring of different OR systems as well as image documentation systems. As the central control of OR equipment, the efficient development of clinical workflows, customisation and optimisation of information and data flow will be a challenge for the next 10 years, this publication should point out the relevance and potential of systems integration and networking in health care, present the actual development status and highlight future trends. These aspects are exemplified by the integration of an intraoperative image documentation system in the operating room.

Relevance of intraoperative image documentation

In Germany medical documentation is a statutory obligation. The medical professional code includes requirements regarding medical documentation in §10(1):

> Ärztinnen und Ärzte haben über die in Ausübung ihres Berufes gemachten Feststellungen und getroffenen Maßnahmen die erforderlichen Aufzeichnungen zu machen. Diese sind nicht nur Gedächtnisstützen, sie dienen auch dem Interesse der Patientinnen und Patienten an einer ordnungsgemäßen Dokumentation. (Physicians have to document "necessary records" of the observations made and the measures taken in the pursuance of their profession. This documentation does not only serve as a memory aid, but it is also in the patients' interests to have proper documentation.) [8].

This means, that if a health care organisation classifies image documentation as a "necessary record", documentation has to be carried out in an adequate manner. So there is no explicit statutory obligation for image documentation of intraoperative results. As OR image documentation makes a huge contribution to quality assurance by optimisation of patient care and legal covering, more and more health care organisations classify OR image documentation as a "necessary record".

Besides §10(1) of the medical professional code, §301 of the Social Security Code V, the roentgen ordinance, criminal and civil law, as well as criminal and civil procedures, are also concerned with medical documentation in Germany.

Image documentation of intraoperative results is vitally important, because it concerns all operative disciplines. By the establishment of charge-coupled device cameras, digital image documentation complies with the technological requirements in all operative disciplines. Image documentation is not only important for operative disciplines, but also for other disciplines like radiology and sonography [9, 10]. Different disciplines have different requirements for image documentation.

Health care organisations prefer still pictures to moving pictures for image documentation of intraoperative results, because still pictures allow a quicker insight into the situs of surgery. Videos are mainly recorded in case of rare diagnostic results or rare surgery methods and are particularly used for medical education and training. But there are also physicians who are of the opinion that every surgical treatment should be completely documented by video. The image documentation format (still picture/video) is not specified by law. It is determined, however, that routine documentation has to comply with the statutory obligation for documentation. The acquisition and long-term archiving of "necessary records" form part of these regulations.

Long-term archiving of image documents

The compulsory period of record keeping in health care is differently defined in a set of laws and regulations. In Germany the compulsory period for legal evidence is 30 years, because according to the German Civil Code claims become statute-barred after this period of time [11, 12]. In regard to image documentation of intraoperative results, there are two possibilities for complying with this compulsory period of record keeping. Either the relevant images can be printed and added to the paper-based patient record or the images can be digitally be archived long term.

Electronic signature

The integrity and authenticity of electronic documents can be ensured by qualified electronic signatures according to the German digital signature law. These electronic signatures are almost equivalent to handwritten signatures. According to §292a of the code of civil procedure, electronic signatures appear to be authentic. Due to open questions regarding secure long-term archiving and quality of evidence, the legal equality of the electronic signature with the handwritten signature has not been achieved in Germany so far [11–15].

Within the scope of the joint research project "ArchiSig", which is promoted by the German Federal Ministry of Economic Affairs and Employment, organisational concepts and technical solutions are to be developed to enable a probative, practicable and economical generation, archiving and utilising of electronically signed documents over a period of 30 years or more [15]. The "ArchiSig" project is presented at the internet address http://www.archisig.de.

Data migration

Attention should be paid to the long-term archiving of electronic documents and digital images, because the archiving media can change several times during the compulsory period of 30 years of record-keeping. Each replacement of an archiving medium implicates a migration of all data that are less than 30 years old. This involves considerable efforts and costs [16, 17].

Combination of digital images and electronic patient records

In the past, fundamental research and developments in the field of digital image documentation took place alongside electronic patient records. Now a stage has been reached at which a combination of digital images and electronic patient records is required to make all therapy-relevant information available to the physician [18]. This integration seems to be relatively uncomplicated in the age of digital technology. But image documentation in health care is very complex as it is meaningful for patient care, quality assurance, science and teaching. Moreover, different medical disciplines have various workflows and specifications. A standardisation of data transfer and collection of data has not yet been completely realised. Statutory obligations, economic aspects and the communications structure of health care organisations have to be considered further [16, 18].

Image documentation systems in medicine

Picture archiving and communication systems in radiology

The enhancements in digital technology have given new impulses to radiology over the past few decades. Some examination methods, like computed tomography and magnetic resonance imaging, which generate an image from measured data in an image processor, have been made possible by means of digital technology. But also conventional, film-based radiology has been more and more replaced by corresponding digital methods. In 1998 already 40% of all radiological examinations were digitally documented [19].

The causes of the increase in digital imaging constituted the following advantages for radiography [19]:

- Separate optimisation of image taking and reproduction
- Optimisation of image display by image processing
- Immediate image display and diagnostics by means of monitors
- Digital image storage and transmission
- Lossless reproducible images

In large German hospitals, which have mainly been built according to the “pavilion principle”, the central service providers like radiology are partly organised in a decentralised way. This fact and the early spread of digital radiological methods were the reasons why radiology was the first medical discipline to approach the problem of image storage and archiving with the aim of replacing film-based images by digital image documentation. In the early 1980s, radiology associations developed the first concepts to manage digital images. Based on these concepts, the so-called PAC (picture archiving and communication) systems were developed. At first they had very limited functions, but now complex, hospital-integrated PACS are realisable [9, 20–22].

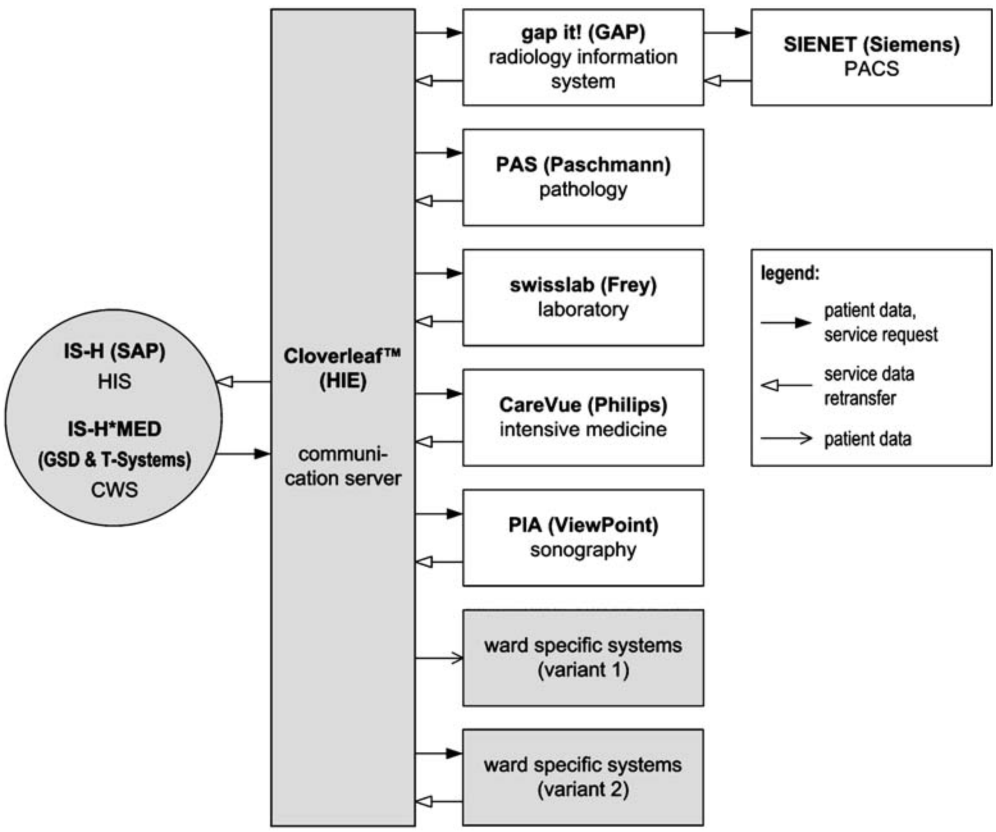

Fig. 1 Communication structure at the University Hospital of Tübingen, Germany

Ward-specific image documentation systems

Apart from the radiological PACS there have been image documentation systems for other wards on the market for a short time. Because of their usually lesser complexity, they are often called “mini PACS” [23]. The term “mini PACS” is not only used for ward documentation systems outside radiology, it is also used for smaller radiologic PACS solutions [24, 25]. There are additional terms like “micro PACS” [24], “large-scale PACS” [24, 26] and “hospital integrated PACS” [26, 27]. Up to now there has been no standard definition of criteria for assigning an image documentation system to the categories micro, mini, large-scale or hospital-integrated PACS.

The development of ward-specific systems is connected with the minimisation of logistical costs and the various ward-specific requirements for image documentation systems. The radiological PACS, for example, is used for diagnosis as well as for image documentation. It replaces the conventional film-based radiogram. As diagnosis has to be made on PACS, the images must be of high quality. Unlike the PACS, the OR image documentation system is not utilised for diagnosis and it does not replace a conventional documentation method. Instead it supplements the textual OR report with image documentation. OR image documentation systems contribute to quality assurance, legal evidence, optimisation of patient care, training and further education of physicians, as well as science and teaching.

Central image archiving

The distribution of non-radiologic ward systems has been increasing for some years for reasons of quality assurance. Before long the question of central image archiving in health care organisations will become urgent. Central image archiving, however, is a consequence of the growing implementation and establishment of hospital information systems (HIS) and clinical workstation systems (CWS). The networked HIS/CWS systems provide communications structures in health care organisations that immediately make all necessary clinical data available for treatment. Therefore, images from ward systems should in the near future be accessible to physicians in a fast and workstation-independent way too.

In a health care organisation HIS/CWS is the superior system. The other systems have to communicate with HIS/CWS (see Fig. 1).

If an OR image documentation system is to be optimally integrated into a clinical communications structure, an interface to HIS/CWS is needed. In this way the OR image documentation system can receive patient data from HIS and provide therapy-relevant images to CWS. The images are not stored in CWS, only the image references are saved. The images themselves can be filed in ward-specific image documentation systems or in an archiving system. Due to the increasing number of image documentation systems from different manufacturers, the trend in health care organisations will be to go to central image archiving. For this there are two possibilities: the images can either be sent to an extended PACS image archive or to a central, PACS-independent archiving system, where text documents are stored too. A standard image format should be defined in both cases. At present the DICOM (Digital Imaging and Communications in Medicine) format is widely accepted in medicine.

The advantages of archiving non-radiologic images in PACS compared with other archiving systems are:

- The available, cost-intensive PACS-infrastructure (long-term archive, server, network) is used by all ward systems
- All imaging disciplines can be supported by one central team
- It is possible to establish standards for structured data management, which is the basis for an electronic patient record

Due to these advantages, the PACS extension is preferable to other archiving concepts. Because of the interconnection of PACS and CWS, physicians get workstation-independent, rapid access to patients’ image data.

Fig. 2 Systems integration in an operating room at the Department of Obstetrics and Gynecology, University of Tübingen. Room functioning, total endoscopic equipment and the Advanced Image and Data Archiving System (AIDA system) are networked to the Storz Communication Bus (SCB)—the central system operating unit. The SCB also has an interface for performing video conferences

Ward-unspecific image documentation system

Contrary to the centralised archiving of image data, the substitution of the different ward systems with a single ward-unspecific image documentation system is not to be expected any time soon. The various requirements for image documentation systems, the amounts of maintenance and further development are counterarguments. The object of a health care organisation to reduce the variety of heterogeneous systems will lead to the establishment of the same image documentation systems in wards of comparable disciplines.

Systems integration and networking

The increasing importance of systems integration and networking in medicine is exemplified by the series of lectures of the same title held at the annual conferences of the German association of computer- and robot-assisted surgery (CURAC), the BmBF-advertised SOMIT programme and the development of complete solutions like OR1 (Operating Room 1) from the company Karl Storz in Tuttlingen, Germany.

The OR image documentation system is one of numerous software-based systems used in health care organisations. Because of the increase in the variety of systems available it is getting more and more important to network the systems used in therapy process in order to optimise patient care and the efficiency of health care organisations.

Moreover, systems integration and networking improve workflows and so reduce costs in health care. It is also a fundamental pre-condition for implementation of electronic patient records and electronic health records. The change from paper-based to electronic patient records is taking place in many health care organisations, because paper-based records have various inadequacies, like difficult availability, illegibility and insufficient structuring [12, 28]. A total displacement of paper-based documents will, however, still take some time. Not before electronically signed documents are fully equivalent to manually signed documents will the necessary basic conditions for solely electronic patient records be present. Organisational concepts and technical solutions for equality of electronic signatures are being developed in the research project “ArchiSig” [15].

But systems integration and networking not only means transmission of data from or to the central HIS/CWS. Some systems directly communicate and interact with each other. One example of this is the integration of the Advanced Image and Data Archiving System (AIDA system) and the Storz Communication Bus (SCB) [1, 2]. SCB is a communications system based on a standardised field bus, through which equipment data, parameters and status signals can be exchanged bidirectionally. Furthermore, all endoscopic equipment and room functioning can be centrally operated via an SCB computer. The Karl Storz AIDA and SCB can be operated by a single touchscreen (Fig. 2). The switch-over is done by pressing buttons on the user interface. The remote communication allows AIDA functionalities to be activated in the SCB. The choice of camera signal and image shooting are examples of such commands.

While due to the establishment of interface standards data transfer between systems hardly causes any problems today, there are some difficulties with remote communication. For example, a system disorder often cannot be clearly attributed to one system by clinical users. So it is very difficult to query the cause of the disorder and the troubleshooting takes a long time. Many disorders have to be checked by a technical service that has special knowledge of interface communication between the integrated systems.

Another aspect of systems integration is networking various wards by bidirectional transmission of image and sound signals. At the University Hospital of Tübingen a physician has to leave his ward in order to give a consultation to another surgery discipline. As some wards are situated up to 3 km apart, it can take some time for the physician to reach the OR. In many cases this workflow can be optimised by bidirectional transmission of image and sound signals from the OR to the consultant. The installation of an appropriate infrastructure is being planned in Tübingen.

Prospects

Systems integration and networking provide a huge potential and will enormously improve communications structures and efficiency in health care organisations. Primary difficulties with data exchange between systems have nearly completely been solved. But remote communication can still lead to problems that should not be disregarded. In this field, there is a conspicuous need for optimisation. Until there is a certain and reliable remote communication, such systems integrations have to be scrutinised and the advantages and disadvantages have to be carefully considered.

Systems integration and networking are still in the initial stages. After clinical networking comprehensive networking will gain acceptance in the future. In the field of innovations in medical technology the aim of the combination of navigation, simulation, robotics, OR scheduling, systems communication and image documentation can be realised in this way. The better integration of therapy-relevant data will lead to more careful therapy and economically optimised treatment.

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