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Synopsis

Quality of Healthcare: The Role of Informatics

Introduction

From the very beginning, the promoters of computer use in medicine emphasized the potential of medical computing to improve medical care. Early adopters such as Pipberger et al [1], who introduced data processing methods for electrocardiogram analysis rigorously examined how well the computer would perform and compared its abilities with those of the best experts in the field. The fathers of the early hospital information system HELP at LDS hospital built a system centered around decision rules [3] and noted that the system helped to reduce severe adverse drug events from 41 in 1990 to 12 in 1991 [4]. In 1992 they performed a controlled study to find out that the system had prevented 982 patients from staying on average 1.94 days longer in hospital due to an adverse drug event. They calculated that LDS hospital thus would save more than one million dollars in treatment costs in a single year. McDonald continued such work and evaluated the Regenstrief Medical record in another controlled study to show that physicians would react to 51 percent of adverse events in patient condition such as elevated blood pressure or required liver enzyme controls when the computer generated an alert compared to only 22 percent when no alert was given [5]. Other studies such as the influencing work of deDombal et al [6], who showed that the computer might even perform better than physicians in diagnosing acute abdominal pain were discussed controversially. Transfer of the results to other institutions proved difficult and despite favorable evaluation results, the system was not well received in different environments.

Today there are more controlled trials [7,8,9] and even systematic reviews [8,9] which let us believe with some confidence that, in medical computing, we have tools to improve process quality in medical care. The analysis of Johnston et al in 1994 [8] concludes that there is strong evidence that several computer applications will improve the treatment process. This is shown for computer assisted drug dosing as well as preventive care reminders (e.g. to give required vaccinations or perform scheduled screening procedures) and for protocol or guideline based alerts (e.g. in hypertensive care, diabetes care etc). Two years later Balas et al [9] confirm in a meta-analysis based on nearly 100 randomized clinical trials that reminder functions will improve physician performance and that computer assisted drug dosage surveillance may outperform the physician. They note that interactive patient education or instruction programs will also be successful. Other applications such as computer assisted diagnosing or simple access to computerized medical records however did not show significant influence on patient care in this analysis.

We do have some evidence that not only the quality of the treatment process but also patient outcome may be influenced positively when computer functions are employed. Some of this evidence is rather weak as in [10], when the computerized reminder seemed to reduce the frequency of urinary incontinence in elder persons, some is stronger, e.g. in [11]. There, White et al. examined the influence of a computerized decision support system on patients receiving warfarin and found a reduced length of stay.

Under these circumstances it is enlightening to read the work of Bates et al [12] in this section who take up the conclusions of the November 1999 report of the Institute of Medicine: *To Err is human: Building a Safer*

Health System [13]. The IOM report estimates that an incredible number of more than a million injuries and between 44.000 and nearly 100.000 deaths per year alone in the US are actually attributable to medical errors. Clearly, information technology has a potential to prevent some of those medical errors. But Bates et al., besides citing many positive effects of medical computing, tempt us also with the demanding question of what errors are caused by the use of information technology. Quite simply, the information system might be faulty. But there is also another inherent source of errors: As systems become more reliable, we tend to rely on them. But what, if the system just misses to send an alert in a certain condition and we rely solely upon the system abilities? In this case the system is not "faulty", it has just (like humans) overlooked some facts. Bates and his colleagues cite the survey of the institute for safe medical practice (ISMP) [14] that performed a field test in 1998 to prescribe deadly drug doses within several different computerized pharmacy prescription systems. Fatally it turned out that the majority of those computer systems failed to detect those life threatening situations and did not generate an alert. Clearly physicians and pharmacists must double check suchprescriptions and should detect the dosing error. But their attention might diminish in view of an otherwise effective computerized prescription system. Bates et al consequently propose a set of recommendations to ensure safe and valuable clinical decision support. Those recommendations center not only on reinforced use of clinical information systems e.g. in order entry and computerized prescribing in order to detect and prevent human error, but simultaneously the authors recommend to put the new technology itself rigorously under test in order to assure that it works correctly and does not induce new errors. The latter has been emphasized by other authors before: "*Clinicians would be unwise to use any system unless it has been shown to be safe and effective*" [15].

This implies continuous measurement of quality. Consequently, the other papers in this section deal extensively with the evaluation of information technology regarding value and effectiveness. The three papers of Vasallo et al [16], van't Riet et al. [17] and Roine et al [18] demonstrate the difficulties one faces in the attempt to assess information technology splendidly. The three evaluation studies range from a simple descriptive case study which demonstrates positive effects of a telemedicine link between the UK and a developing country [16] on to a qualitative evaluation of a patient information system for children with amblyopia and their parents [17] and to a sophisticated review study of controlled studies on the effects of telemedicine [18].

The topic of system evaluation has been discussed extensively in medical informatics [see e.g. 19-23]. Several authors have promoted the idea to use not only descriptive evaluation (the system is evaluated as is) but to concentrate on formative evaluation as well (evaluation results influence system layout and design directly in order to lead to an improved and accepted system) [21,22,23]. Evaluation strategies have been presented for various situations and topics [21,22]. Problems of evaluation have been discussed and methods to overcome them have been described [21,22,23]. For brief recapitulation we may just cite a few conclusions from those papers:

- Goals of the evaluation must be clearly stated [21,22]
- The evaluation object is complex [23]
- The evaluation environment is complex [23]
- There is no generic solution for evaluation. Different evaluation goals demand different evaluation strategies [22]
- Full control of environmental factors is not possible in all evaluations [22]
- High quality studies rely on a mix of multiple evaluation methods [21,22]
- High evaluation quality may impose a high workload and evaluation costs [22]
- Information systems induce a change process which must be understood [21]
- Consequently study design must be adapted to capture changes over time [21]
- Evaluation builds on user interaction which must be understood [21, 23]

The paper by Vasallo and colleagues [19] describes a case study which is used to evaluate the benefit of a telemedicine link for a rehabilitation center in a developing country. All 27 telemedicine referrals made during a 12 month study period are qualitatively assessed regarding the benefit for the patient and the referring institution. The authors cite cost effectiveness of the telemedicine link as the goal for their evaluation. Their evaluation does not control environmental effects, but mainly restricts to a comparison between costs of equipment and perceived benefits. The merits of this study are clearly a proof of feasibility for the use of high tech telemedicine equipment under adverse circumstances and a proof of user acceptance at least during study period. To show both is very appropriate in an area where either new technology is implemented or proven technology is transferred to a different environment which is the case in this example. The proof of cost effectiveness, a cited goal of the authors, however is rather weak. The authors do not only totally omit the expense in time and money for the physicians in the UK who deal with the referrals beside their normal clinical

activity, obviously without extra payment. Nor do the authors really compare a situation with telemedicine link with a situation where another effort of comparable size is undertaken to improve patient care at the referring institution. Nevertheless, we should not overemphasize these weak points. The study is a valuable formative evaluation in a setting where modern technology is used for the first time under adverse situations to improve patient care. It demonstrates practical feasibility of the underlying approach and good user acceptance at least during the study period. On a case by case base, positive effects for individual patients and the referring institution itself are shown. We may conclude that a telemedicine approach such as this one may be a feasible and potentially even cost effective approach to improve quality of health care in a developing country. Clearly further studies of improved design are needed to confirm the latter.

Van't Riet et al. [17] face a different situation. They are asked to perform an external evaluation study for an existing patient information system. In principle they have the choice to either perform a descriptive evaluation of the system or to use a formative approach. Typically, in this situation where the evaluation object is a completed system, most evaluators would decide in favour of a descriptive evaluation. Then proven evaluation tools such as controlled trials, approved questionnaire designs etc. could be used. However, van't Riet and colleagues decided differently. In order to define evaluation criteria and to come to grips with the patient information system they started with a qualitative assessment as a pilot study instead. A small group of 14 families with 15 children affected by amblyopia were included in a study design which relied on direct observations, virtual observations of computer based chatting and semi-structured open-ended interviews. The researchers noted that actual use of the information system was weak and from their study results concluded that there was a misfit between the content and functionality of the information system and the needs and capacities of the target group. Besides, several specific flares such as inappropriate operation times of the chat room and inappropriate assumptions which were programmed into the information system could be pinpointed. Van't Riet et al. conclude that the system is not addressing the users' needs at all. As those results came somewhat late to influence system design (which would be the goal of a typical formative evaluation study), they led to the discontinuation of the examined information system, thus preventing unnecessary further expenditure. Obviously, in this case the information system did not influence the quality of healthcare, but we hope with the authors that succeeding projects will build on the evaluation results, thus leading to improved patient information.

When we think about descriptive evaluation of procedures and applications in healthcare we should refer to methodologies developed in the context of evidence based medicine [24,25]. Sacket [24] defines evidence-based medicine as

> "The central demand to link best individual clinical knowledge with best available external, scientific evidence to achieve optimal patient care."

Scientific evidence in this context relies on preferably exact knowledge. Applications in medical informatics, if influencing patient health directly, must at least demonstrate that they do not harm the patient [12,15]. More rigorous evaluation of clinical software may become a must in the future, when within new regulations software programs are considered to be medical devices [26]. In an ascending hierarchy improved scientific evidence originates when higher levels of the following study designs are achieved:

I. *At least one systematic review based upon methodically sound RCT's (randomized controlled trials)*
II. *At least one methodically sound RCT of sufficient size*
III. *Methodically sound non randomized or non prospective controlled trials*
IV. *More than one methodically sound non experimental trial*
V. *Gold standard, experts opinion, descriptive studies*

In this hierarchy the review of Roine and colleagues [18] adapts the highest level of scientific evidence in order to assess potential effects and cost effectiveness of telemedicine applications. In a comprehensive literature search the authors include 50 out of 1124 studies on telemedicine applications for a systematic review. They reject non-controlled studies and feasibility studies as well as studies giving insufficient outcome data. However, within those 50 selected papers they could pinpoint only six RCTs whereas the other included studies varied between non-randomized controlled studies, cohort studies, case control studies and descriptive studies. Due to different evaluation goals within the 50 studies as well as different study designs, Roine et al refrain correctly from a meta analysis and restrict their review to a description of the study results, grouped into the areas of telemedicine in medical consultation, telemedicine in patient monitoring, teleradiology and telemedicine in various clinical areas. The researchers conclude that the data about effectiveness and cost-efficiency in telemedicine derived from the 50 examined studies is still poor. They find evidence for the effectiveness of telemedicine applications in the areas teleradiology, teleneurosurgery, telepsychiatry, trans-

mission of electrocardiographic images and electronic referrals between primary and secondary healthcare providers. Regarding cost-efficiency, the researchers quote "economic analyses suggest that teleradiology, especially transmission of CT images, can be cost saving". Their final suggestion: "Based on current scientific evidence, only a few telemedicine applications can be recommended for broader use".

What can we learn from this review? It is a well known fact that even systematic reviews of RCT's, albeit on the highest evidence level, cannot deliver good evidence if the underlying RCT's have poor quality or insufficient data. When looking at the highly structured review studies of the Cochrane Collaboration [27] on medical treatment of patients, we find many which recommend that further large-sample controlled trials are needed in order to come to a final conclusion regarding scientific evidence pro or contra a certain treatment strategy (see e.g. [28]). Based on only six RCT's on telemedicine applications one would be very lucky to gain clear evidence about effectiveness and cost-efficiency of such applications. The review of Roine and colleagues does give us hints that we may improve quality of healthcare effectively using telemedicine applications and should encourage to continue research and evaluation in this area towards a stage where we may be able to find clear evidence, thereby advancing such applications beyond the current pilot project phase.

Within this section *Quality of Healthcare: The role of Informatics* we have seen four different papers.

- A strong recommendation to make extensive use of information technology to avoid human error, paired with the urgent suggestion to improve this technology and to assess its effects on patient safety [12].
- A descriptive case study for the use of a known technology in a new area presenting a positive picture of feasibility, but clearly asking for further methodically sound evaluation studies to confirm effectiveness and cost-efficiency [16]
- A formative evaluation of an application which does not meet the needs of its projected users [17].
- A review study on a modern information technology which indicates positive effects without being able to demonstrate conclusive evidence that the new technology is superior to other methods [18].

From these and many other cited sources [4-11,28] a picture emerges. If we consider medical informatics as a young field, which it clearly still is compared to other medical fields, we find many indicators and increasing evidence that information technology will and must play an important role in improving the quality of healthcare now and in the future. When deDombal et al [6] evaluated a decision support system in 1971, they were still among the first to do such work and no one would have recommended to use such systems everywhere at that time. Today instead, some areas of information processing are made mandatory in medicine, for example the use of computerized physician order entry systems in Californian hospitals [29]. We notice that there is a change in argumentation: In the future we may find ourselves in a situation where we do not need to demonstrate why we used information technology, but instead we may be asked why we did not use this technology. Thanks e.g. to Pipbergers work [1] the computerized ECG machine which delivers an automated assessment of the ECG stripe is a fact today. Hardly anyone would argue with the machine regarding QRS time span and signs of ventricular blockage in its printed assessment. This does not mean that we may refrain from further checks and just accept the use of information technology. The more we use such technology in areas which directly affect patient care, the more rigorously we must perform evaluations and prevent technology from becoming harmful. Information technology implies a change process [21]. This renders evaluation difficult in many cases and requires continuing effort [21-23]. We must adapt our methods to the evaluation object and we will not always be able to measure effects with RCTs or review studies. Examples of other methods can be found in this section [17] and in literature (e.g. [22,23]). It will certainly be interesting to see more studies emerge which demonstrate that no harm is done by an information technology which then is commonplace.

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