

Impact of CPOE on Mortality Rates — Contradictory Findings, Important Messages

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Summary

Objective: To analyze the seemingly contradictory results of the Han study (Pediatrics 2005) and the Del Beccaro study (Pediatrics 2006), both analyzing the effect of CPOE systems on mortality rates in pediatric intensive care settings.

Methods: Seven CPOE system experts from the United States and Europe comment on these papers.

Results: The two studies are not contradictory, but almost non-comparable due to differences in design and implementation. They demonstrate the range of outcomes that can be obtained from introducing informatics applications in complex health care settings. Implementing informatics applications is a socio-technical activity, which often depends more on the organizational context than on a specific technology. As health informaticians, we must not only learn from failures, but also avoid both uncritical scepticism that may arise from drawing overly general conclusions from one negative trial, as much as uncritical optimism from limited successful ones.

Conclusion: The commentaries emphasize the need to promote systematic studies for assessing the socio-technical factors that influence the introduction of increasingly sophisticated informatics applications within complex organizations. The emergence of evidence-based health informatics will be based both on evaluation guidelines and implementation guidelines, both of which increase the chances of successful implementation. In addition, well-educated health informaticians are needed to manage and guide the implementation processes.

Keywords

Evaluation studies, CPOE, evidence-based health informatics, mortality

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Introduction

Computerized physician order entry (CPOE) that supports, among other options, the electronic ordering of drugs by physicians, has been an important area in medical informatics research for several years. A renewed interest has recently come largely as a result of the publication of the report by the Institute of Medicine estimating that thousands of deaths from medication errors may partially be prevented by using computerized order entry [1].

Original investigations [2, 3] have shown the benefits of using CPOE systems for optimizing medication ordering and reducing adverse drug events (ADEs). More recent studies have confirmed these findings [4–7]. However, it has not yet been concluded that reduction in medication errors and ADEs leads to an improvement in patient outcome such as decreased mortality rates, as Garg and colleagues have noted [5].

Two recent studies have focused on the effect of CPOE on the mortality rates of intensive care patients in pediatric hospitals. The first paper, by Han et al. [8] in 2005 from the University of Pittsburgh, analyzed mortality rates 13 months pre-implementation and five months post-implementation of a commercial CPOE system. Their study was restricted to children that were admitted to the Children's Hospital of Pittsburgh via interfacility transport for specialized, tertiary-level care. It was found that after

CPOE introduction, the mortality rates increased dramatically from 2.8% (39 of 1394) to 6.6% (36 of 548). Han and colleagues suggested that reasons for the increased mortality rate included the inability to pre-register patients and to submit orders before patient's arrival, the increased amount of time needed to enter orders, the reduction of oral communication between physician and nurses after CPOE implementation, the relocation of drugs from the ward to a central pharmacy, and technical problems with stability and performance of network connections. The authors concluded that "institutions should continue to evaluate mortality effects" in order to detect and prevent such problems. The Han paper caused a lot of discussion among researchers and practitioners, as reflected by commentaries [9] and letters to the editor in subsequent issues of Pediatrics.

In 2006, Del Beccaro and colleagues in Seattle [10] performed a study similar to Han. The Del Beccaro group retrospectively analyzed the mortality rates 13 months pre-implementation and five and 13 months post-implementation of the same commercial CPOE system at the Children's Hospital of Seattle. Their study included all patients that were admitted to their pediatric hospital. No significant changes in mortality rates were found after CPOE implementation and it was concluded that "implementation of a CPOE system, even in the early months after implementation,

was not associated with an increase in mortality”.

Both studies used comparable methods to assess the effects of the same commercial CPOE system on mortality rates for pediatric intensive care patients, but their conclusions differed. Without having a clear explanation for those differences, health informaticists will not be able to learn from these case studies. The objectives of this paper are to analyze the seemingly contradictory findings of the Han and the Del Beccaro studies and to make recommendations for further research on implementing informatics systems.

Methods

To compare both papers, seven experts on CPOE systems from the United States and Europe commented on these papers, with special focus on the contradictory findings. These experts were selected based on their experience in the introduction and/or evaluation of CPOE systems.

Results – Expert Commentaries

The following section presents the expert commentaries, listed alphabetically by author’s last name.

Joan S. Ash, Oregon Health & Science University, Portland

After the Han et al. paper was published, several of us expressed, in another Pediatrics paper [11], our strong conviction that the CPOE system itself should not be blamed for any adverse outcomes, putting aside debate about the science of the research. The most important lesson to be learned from the Pittsburgh study is that a flawed implementation process, including some especially misguided policy changes, caused organizational distress and the potential for great harm. When the Del Beccaro et al. study appeared, it provided direct validation

of our thesis, because the same system, implemented differently, has succeeded at the Seattle site.

There is a growing body of literature featuring lessons learned from CPOE implementations. For example, my research team has been reporting for a number of years now that CPOE implementation success depends primarily on 1) time considerations (response time and user time), 2) meeting information needs (using order sets), 3) multidimensional integration (especially with workflow), 4) the existence of essential people (leaders and support staff, plus involved clinicians), 5) certain foundational underpinnings (e.g. trust between administrators and clinicians), and 6) improvement through evaluation and learning (paying attention to user feedback) [12-15]. The Pittsburgh hospital had issues surrounding all of these factors, while the Seattle hospital paid careful attention to them. We have also warned of unintended consequences such as more work for clinicians, unanticipated workflow and system mismatches, changes in communication patterns, emotional reactions, and new kinds of errors [16, 17], and again it appears that the implementation at Children’s Hospital of Pittsburgh experienced all of these. Fortunately, those at the Seattle children’s hospital had the benefit of learning from Pittsburgh’s experience. Now that the second study has been published, decision makers and implementers have the benefit of being able to look at both papers side by side, to compare them, and to truly grasp their dramatic lessons. Unfortunately, the media has shown little interest in the second paper, while the first paper caused quite a stir. We in informatics need to aggressively continue to get the message out that a thoughtful implementation process, which is dependent on adequate resources, is the most important criterion for success.

David W. Bates, Brigham and Women’s Hospital, Boston

The Han study and the Del Beccaro study have provoked considerable controversy in the informatics world. The backdrop to the Han study is that this group does research on outcomes of pediatric intensive care for

those who need special care, and many of them are transferred in from outside hospitals. When CPOE was implemented, the group noted that things appeared to slow down in the care of these children. They then used their database to assess whether or not mortality changed after they implemented CPOE. They found a 2.3-fold increase in their mortality rate for the period after CPOE implementation, for the specific group of children who were transferred in. They did not report the mortality rate for all children in the ICU, or for all patients in the hospital. In their paper, Han et al. made much of the contrast between their findings, and a report from another group in Pittsburgh suggested a fall in the adverse drug event (ADE) rate after CPOE implementation, but this latter report used self-report to determine what the ADE rate was, and because self-report only identifies only about one in 20 ADEs, this comparison is not really meaningful.

In contrast, Del Baccaro et al. implemented the same vendor’s CPOE application, also in a large pediatrics hospital in intensive care [10]. They also measured the impact on mortality, and found a trend in a positive direction. In contrast to the Pittsburgh experience, this group followed many of the best practices for CPOE implementation.

So how can these two disparate results be reconciled? There are several possible explanations. One is that there was some flaw with the Han study, and that the investigators did something like only report data for a specific period, or that a temporal trend could have occurred. But more likely is that the Pittsburgh implementation was done poorly, and that the increases in mortality that were found were related to delays in care that were introduced. Some of these related to CPOE but others did not, and it is interesting and instructive to examine them.

First, CPOE was implemented in the whole hospital over six days. This made it extremely challenging to make changes quickly. Second, order entry was not allowed until the patient had physically entered the hospital – obviously creating particular problems for this population. This is a policy decision not directly related to CPOE. Third, after CPOE implementation, all

Table 1 Comparative reliability of the two studies

Han et al.	Del Beccaro et al.
1) Retrospective study	1) Retrospective study
2) Unadjusted mortality rate is significantly higher in the "after CPOE" group: $p < .001$	2) No significant difference between "before" and "after" CPOE groups
3) 13 months before – 5 months after	3) 13 months before – 13 months after
4) Comparability of before/after CPOE groups: – Exhaustive list of clinical characteristics – The groups are statistically equivalent except for two clinical characteristics	4) Comparability of before/after CPOE groups: – More limited list of primary diagnoses – The groups are not comparable: they differ significantly on 6 out of 10 demographic and clinical characteristics. – The comparison of unadjusted mortality rates of the two groups is not valid
5) Multivariate logistic regression to adjust for confounding factors	5) No adjustment
6) Difference of adjusted mortality rates between the two groups remains significant	6) No adjustment.
7) Results remain identical when the comparison is limited to balanced periods	
8) Reliable statistical methodology	8) Limited statistical methodology

medications including the vasoactive drugs were placed in the central pharmacy. Fourth, the pharmacy was not allowed to process medication orders until after they were activated. Fifth, the decision was made to go live without most of the necessary order sets in place. The second through fifth issues might all have been addressed had implementation been slower, and had these issues been identified as important problems in a pilot study.

The single most important takeaway message from these studies is that implementing CPOE well is extremely important, and not just of academic interest. In particular, it is absolutely essential to pay close attention to the socio-technical aspects of implementation. These have been described [18, 19], but some of the specific keys are strong leadership and long-term commitment, creating a culture of innovation, excellent project management, attention to clinical processes, and maintaining a focus on quality and safety. Organizations that fail to do this do so at their peril. In particular, the clinical and administrative leadership need to be closely involved, and need to ensure that the necessary resources for a successful transition are made available. Overall, CPOE has a wide array of benefits, but

achieving them depends on using this tool effectively.

Marie-Catherine Beuscart-Zéphir, Alain Duhamel, Evalab, University Hospital of Lille

Han et al. and Del Beccaro et al. have performed two apparently similar studies leading to what looks like contradictory results. In this situation it is necessary to assess the reliability of both studies from a methodological and statistical point of view, to assess the comparability of the studies, and to identify the underlying variables that may account for the contradictory results. We will do so in the next paragraphs.

Reliability of the Studies

Table 1 summarizes the reliability of both studies. Both are retrospective ones. Then no causal relationship can be demonstrated between the "Group" variable (before/after CPOE) and the observed results. Such a demonstration would require a prospective study. In the Han et al. study unbalanced periods were analyzed. This could have in-

duced a bias, for example if there was a seasonal variability in the patients' clinical profiles. However, Han et al. compared their two populations using a set of the most important patients' clinical characteristics in pediatric ICU, and they found no statistical differences. On the contrary, although Del Beccaro et al. analyzed matching periods, their before/after groups proved to be different. As a consequence, in the Del Beccaro study, the comparison of unadjusted mortality rates of the before/after groups is not valid. Contrary to the Del Beccaro study, Han et al. controlled the potential confounding factors: these factors were introduced into a multivariate logistic regression, in order to provide adjusted odds ratio [20]. Adjusted mortality rates remained higher in the after-CPOE group. Finally, when Han et al. compared the mortality rates on two balanced periods, the resulting differences were close to that observed on the whole period.

Comparability of the Two Studies

Besides their differences in statistical reliability, Han and Del Beccaro studies are not actually comparable, because the study populations are very different, as Table 2 shows.

The conclusion is that the Del Beccaro study is NOT a replication of Han's study. Thus, the results of the Del Beccaro study cannot oppose Han's results.

Both studies being retrospective ones, they cannot demonstrate a causal relation between the installation of the CPOE and the observed mortality rates. Then we are left with a "reasonable suspicion" that the installation of a CPOE might have had a negative impact on mortality rate for a five-month period on a very specific population.

Identifying Underlying Qualitative Variables

Both papers try to identify underlying qualitative variables that could account for their results. These supposed causal variables appear to be mostly of human factors nature. Given the "reasonable suspicion" mentioned above, we focus here on Han's qualitative report. Looking at the authors' comments on their work situation, a human fac-

tors expert can identify several categories of problems (see Table 3), most of them being well known in the specialized literature (see references given in Table 3).

Unfortunately, the authors did not use proper human factors methods to analyze the problems and document their observations. Therefore, this qualitative analysis turns into a retrospective report of experience possibly biased by the personal perception and feelings of the authors.

As a consequence, the results of this qualitative analysis have limited validity: Objective systematic observation and quantification are missing for most of the problems addressed; and: A number of problems or positive points might have been overlooked.

Conclusion

Studies on the impact of CPOE installation on healthcare outcomes are urgently needed. These studies should combine prospective multi-center evaluations with qualitative human factors analyses including usability and socio-technical analysis and assessment. The methodological quality of such studies is of utmost importance if we want to rely on the results to improve the quality of the informatics systems, of the organization of work, and ultimately of the healthcare outcomes [24].

Peter L. Elkin, Mayo Clinic College of Medicine

The study by Han et al. was plagued with systems changes around the implementation of their CPOE solution which should remind us that the systems we implement are used by real people who bring to their tasks their own work habits, biases and expectations regarding how systems should perform and their own experience with prior systems. Inevitably these pre-conditions influence how systems are used and in so doing how effective and safe will be the use of these systems.

Human factors engineering is the field which deals with the usability of systems and processes [25]. In the article by Han et

Table 2 Comparability of the studies

Han et al.	Del Beccaro et al.
Age: (median) 9 months	Age: (mean) 87 months (10 times older)
Exclusively children transferred from other hospitals: n = 1942, before = 1394 after = 548	All admissions: n = 2533, before = 1232, after = 1301 Only 284 children transferred from other hospitals (before = 125, after = 159)

Table 3 Likely underlying causal qualitative variables

Problem category	Results presented by Han et al.	Method applied by Han et al.
Parameterisation	Poor: no order sets, conflicting rules	
Usability flaws (categorized according to [21])	<ul style="list-style-type: none"> – Workload: too many clicks, augmented time – Compatibility: wrong default doses – User Control, Error Prevention: default “stop order” mechanism without notification to physician 	Subjective assessment
Socio-technical issues	<ul style="list-style-type: none"> – Negative impact on cooperation between the members of the ICU team (cp. [22]) – Model of work implemented in the system not adapted to the actual work in a pediatric ICU (cp. [16, 23]) 	Subjective assessment, self observation
Organizational issues	<ul style="list-style-type: none"> – Changes in the work procedures: no more ward stock (dispensing), no more pre-ordering – Simultaneous implementation of other applications 	No modelling of the procedures and workflow
Safety issues	<ul style="list-style-type: none"> – Changes in the control of the medication process – Changes in the staff-to-patient ratio 	No modelling of the organization

al. published in Pediatrics in 2005, there were a host of human factors issues which, as shown by Del Beccaro in a later Pediatrics article in 2006, turned a safe implementation into an implementation that led to an increased rate of fatalities within their pediatric intensive care unit at the University of Pittsburgh.

All systems work in an environment and are influenced by the organizational and social issues. These issues are often expressed in part as the vision and mission of the organization. These factors create a social/cultural environment that emphasizes certain work patterns. Individual work units create subcultures which include embedded work patterns and workflows. Within these rich and complex environments each of us develops specific workflows and work habits based on our own experiences and backgrounds. When systems are implemented these human factors require close attention in order not to undo safety mechanisms that have been put into place over

time to provide best and safest practice for our patients.

Human factors issues that we identified in the implementation of the Pittsburgh system included: not allowing medication ordering prior to the patient's arrival at the hospital; a time-consuming process was required to enter an order (i.e. 1-2 minutes per order); order sets and order sentences (fully specified orders) specific to the ICU setting were not built into the system; nurses needed an additional step to activate orders prior to the pharmacy being able to work on filling the order; while the pharmacy was working on the patients order no further orders could be entered and the bandwidth was such that sometimes the computer screen appeared frozen.

Clearly, the system was not implemented in such a way as to take into account the workflows and human factors necessary to provide optimal patient care in this intensive setting. Other factors which jeopardized patient safety included moving the medi-

cations out of the ICU to the pharmacy, leading to a potential delay in certain treatments. In Del Beccaro et al. they described an implementation which obviated many of these human factors issues and were able to show that the implementation of the same system in a similar clinical setting did not lead to an increase in mortality.

In order to feel secure that when we implement systems we are not endangering our patients' safety, we must insist that all systems be subjected to formal usability testing. Usability testing is a method employed in the field of human factors engineering. A usability study evaluates how a particular process or product works for individuals [26]. Optimally one would test a population of individuals who are a sample of typical users of the type of process or product being tested. It should be stated clearly to participants that the purpose of the study is to evaluate the process or product and not the individual participant.[27] Usability sessions are videotaped from multiple angles (including the computer's screen image) and participants are encouraged to share their thoughts verbally as they progress through the scenarios provided ("think aloud")[28]. This helps to define the participants' behavior in terms of both their intentions and their actions [29].

To accomplish a valid study, one must follow a specific protocol and have multiple participants (typically 6-12) interact with the system using the same set of scenarios [30]. It is important that the design team be able to observe multiple participants if they are to become informed by the study. The scenarios should reflect the way the system being tested is actually going to be utilized [31]. The closer the study design can mimic the true end-user environment, the more validity the results of the study will have [32]. In this manner, developers ascertain characteristics of their application that are functional, need improvement, fit user expectations, miss expectations, fail to function, or are opportunities for development [33].

Human factors engineering in general and usability testing in specific are powerful tools to help medical informaticians protect patient safety as we implement and utilize CPOE systems.

Reed M. Gardner, University of Utah

I found the two articles about the failure and success of computerized physician order entry (CPOE) in the journal *Pediatrics* and the subsequent commentary in *Pediatrics* [9] and a flurry of responses and commentaries in other medical journals healthy and stimulating. It is clear to me that the CPOE technology and methodology is not yet mature enough to be assessed and judged as a kitchen refrigerator might be by the Consumer Union's Consumer Reports in the USA.

We as informaticists still have much to learn about how to design, build and perfect complex systems that interact with and assist in the process of providing optimal health care. Several years ago while we were developing the HELP System at LDS Hospital in Salt Lake City, UT, USA, I presented Tutorials at the American Medical Informatics Annual Meetings. One of my favorite slides said in effect: What we are doing is 90% social and political and only about 10% technology. I further illustrated this supposition by presenting how we had failed and succeeded in installing complex computerized decision support systems in the clinical setting. During this time we had the opportunity to work with clinical colleagues and optimize the systems we developed so that they fit into the workflow process and helped rather than hindered providing patient care. We were not always successful, but the teamwork effort of informaticists, physicians, nurses, therapists and clerks was crucial.

On a broader perspective I found it interesting that this learning process had been stimulated by the journal *Pediatrics*. I don't know if the pediatricians were the first ones brave enough to take on the challenge of optimizing CPOE or if it was a sign of our maturity – that we were still children in our understanding of how and what to do about CPOE!! In addition, I found that the ability to do electronic tracking and journal recall via electronic means was superb. From the comfort of my own office at home, I was able to use the marvelous retrieval tools provided by the National Library of Medicine

(NLM) and its excellent PubMed/Medline facilities and cross-referencing. Then, I was able to retrieve and read the relevant commentaries and articles quickly and easily. We are indeed into a "new era" of information access. Thanks to the NLM and the publishers for providing these remarkable tools!! To those who have and are continuing to publish their work in the field of CPOE, I salute them for helping us learn. Sometimes we must publish failures – they are the least fun and most painful to publish, but from them we can all learn. Finally, we as informatics must develop methods to better evaluate our work. The experimental methods and strategies we currently possess are inadequate. We MUST develop more comprehensive and innovative evaluation methodologies and apply them every time we implement a new informatics solution. Much work still needs to be done in this area.

Some publications that have recently appeared on the topic further illuminate the challenges and opportunities: we have to perfect CPOE [11, 34, 35].

Antoine Geissbuhler, Geneva University Hospitals

Implementing the same computer-based system in different settings using different strategies leads to different outcomes. This confirms what has been demonstrated in the information technology industry in general and in complex environments such as hospitals in particular: technology represents a relatively small fraction of the challenge when implementing information systems.

Information systems are not just computer-based systems. They encompass the whole flow of information amongst stakeholders, be it verbal, handwritten or electronic, formal or informal. The lack of recognition of this wide scope and inherent complexity usually leads to risky approaches, where computer-based systems are expected to drive institutional change rather than more modestly enabling it.

Given its profound impact on care production processes and its deep integration with many components of a hospital information system, CPOE implementation is

emblematic of these challenges. Several authors [13, 36] have highlighted pitfalls and success factors for such implementations, which are well illustrated by Han's and Del Beccaro's reports. These include end-users appropriation through proper governance of the project, efficient ergonomics through the localization of order sets, and adequate training and support of the users.

It has also been recognized that computer-based systems cannot be expected to enforce inapplicable rules, even if these are already in effect. In some situations, the implementation of such systems unveils the inability to follow rules, and, eventually, rules have to be changed, not to match the system's capabilities to implement them, but to match the institution's capabilities to follow them responsibly. A classical example with CPOE is the handling and formalization of "verbal" or "telephone" orders.

Considering the criticality of medical order management for the safety and efficiency of the care production process, it is crucial to monitor its performance, in particular when the process is altered through computerization. Immediate outcome measures are useful to document the level of appropriation and the impact on the focal process itself. More distant outcomes, even though they are more difficult to measure and prone to many confounders, are essential to follow as they usually reflect the level of achievement of institutional strategies to manage the quality and efficiency of care.

A complementary approach, which recognizes the multidisciplinary dimension and the institutional and departmental specificities of the care production processes, is to analyze failure modes, effects and criticality using structured methods [37]. This approach has been shown to increase the level of awareness of potential risks before the implementation, and can be used to identify and prioritize potential improvements.

Discussion

The **methodological comparability** of both studies is an issue that has been raised in

many commentaries. The argument in the Del Beccaro study suggests that their study was a replication of the Han study. However, Beuscart and Duhamel conclude in their comment that the Han and the Del Beccaro studies are not truly comparable. Although the same commercial CPOE application was evaluated in two different U.S. pediatric intensive care units, the organizational context and the selection of patient cases were different. In particular, the difference in patient case selection and also the limited study methodology of the Del Beccaro paper do not allow to directly compare the major findings, that is the change in mortality rates, of these two papers.

This leads us to the question: What can we then learn from both studies? There is one message that stands out in all commentaries: implementing a clinical informatics application in health care is a **socio-technical activity**: It not only involves making a technical artefact available in an organization, but also requires aligning the implementation of the technical artefact with the formal and informal organization and workflow in the clinical setting [38]. Ignoring the existing organizational workflows and social interactions in the redesign of clinical processes may have negative impacts on clinical outcomes as was demonstrated in the Han paper. The Han and the Del Beccaro papers reinforce earlier research findings that concluded that the same informatics application may be successful in one organization and may have negative effects in another organization [39]. Hence the application as such is not necessarily the deciding factor, but rather the implementation process may be much more important.

Given the importance of the implementation process, health informaticians should be as careful to avoid unwarranted scepticism from a negative trial involving an informatics solution as they should avoid unwarranted optimism from another, apparently contradictory positive trial result. There are a growing number of studies on both commercial and home-grown CPOE systems. Negative trials, such as that of Han, are often much more discussed (and often criticized) than are positive studies. However, the context of each study is very individual, given the many factors that influence

informatics implementation projects; therefore, the results reflect the individual situation and are not easily generalizable. Our challenge is to identify the factors that may contribute to successful implementations and the factors that may hamper a successful result. Each study, be it positive or negative, helps us to recognize those factors and hence contribute to the evidence base for health informatics [24]. So, our focus should not be "What did they do wrong? (They are to blame because ...)", but more **"What can we learn from a case?"** In fact, each study in its specific context may enlighten us on how to avoid negative consequences of implementing informatics technology in health care. Just as in experimental medicine, where it is imperative and ethical to report the effectiveness of experimental treatments in the literature, independent of their positive or negative effects, it is imperative and ethical to report on implementations of informatics applications in health organizations [22]. Therefore, we applaud Han et al. for the courage to report on the negative effects.

The study of Del Beccaro shed light on how a different implementation strategy can make a difference in outcome, but their own study design was too limited to permit comparison with the Han study. Yet, by highlighting how the implementation process can impact the success or failure of an informatics application and leading to strong reactions and discussions, they demonstrated their value and contribution to our **evidence base on the implementation of informatics applications** in health care, as did the earlier paper of Koppel [40] and the subsequent discussions of it. This evidence base is built on the collection of systematic scientific studies on factors for success and failure of implementation projects (such as [41]). We believe that a comprehensive evidence base will lead to clear implementation guidelines that are crucial for increasing the chance of successful implementations in practice [42].

It has often been argued that informatics systems in health care should be evaluated in **randomized controlled trials (RCT)**. The Han and the Del Beccaro studies are warning signs to us and show that the implementation process and the organizational

context of an informatics application is as pivotal as the implemented application itself for success. When we do not control for all confounding factors during the implementation, an RCT of a clinical informatics application is equivalent to doing an RCT with a generic drug, but leaving the decision on the route of administration, the total dose, as well as the dosage scheme up to the treating physician and still making a judgment about the efficacy (or effectiveness) of the drug.

The question is whether we really can **control the implementation process**. In medicine, we have observed that some treatments are effective in some patients and not in others. The varied genetic make-up of patients may account for the different results. Similarly, in health informatics some applications work in one environment and not in others. To use a potentially useful evolutionary metaphor, the “genetic make-up” of the organization plays a role in this respect, including the formal and informal workflows in the organizations and the established practices that typically counteract situations where things might go wrong. In other words, the organization’s “immune system” is a critical, though often underappreciated element that cannot be ignored. The introduction of an informatics system into an organization has analogies to implanting an artificial organ in a human: you either adapt the artificial organ to be accepted by the body or you suppress the rejection reaction by the immune system. The latter makes a human vulnerable to all kinds of infections and can lead to a seriously compromised person. Let’s avoid compromising our health system by forcing it to suddenly accept rigidly-designed informatics applications on the basis of narrowly defined, purely technological benefits. These systems may destabilize our health organizations if they are not properly adapted to humans and their organizational “immune systems” with the care, time, and constructive feedback that can lead to appropriate changes in design and implementation that really do improve health care outcomes in the long term.

Given the discussed importance of the implementation process and the organizational context, **well-trained health informaticians** may well be the “missing links”

between clinicians and technologists, who can help users in good underlying methods of assessment, as well as the critical training in information management and health informatics. Expert informaticians help users to better understand the complexity of informatics solutions and to take it into account when planning any informatics implementation, thus reducing frustration and increasing the chance of success. Recommendations for the education of health informaticians have long been in place [43]. Several bachelor and master programs in health informatics have been initiated in the last 30 years. There are strong collaborations currently on going to pursue best education of health informatics (e.g. <http://www.iphie.org> [44]); also shorter programs directed at clinicians, such as the AMIA 10 × 10 program (<http://www.amia.org/10x10>), promote quality training. As technology becomes more mature and pervasive, the courses need to emphasize good implementation practices as well as the pitfalls and perils of informatics implementation in the clinical setting. Formal training in the evaluation of informatics applications in clinical settings should be part of these Medical Informatics curricula [22].

A strong remark should be made regarding the negative reactions to the Han paper. We have argued that it is important to have these studies appear in the literature, even though they highlight the negative side of informatics in health care. The authors should be protected against the flurry of criticisms that have appeared in the popular press and in the scientific literature. The authors have reported on what can go wrong when insufficient attention is paid to existing, proven clinical practice, and when the implementation of an informatics application is made to “improve” the overall organizational efficiency and to which all have to adapt. Given the reactions in the popular press and the scientific literature, there is the risk that in the future **self-censorship** will keep the negative studies from being presented in the scientific literature, leading to a strong publication bias [45]. The position and future careers of authors should not be at risk because of negative study findings. We must learn from errors – mostly from our own errors! Since

patients’ lives may depend on our informatics applications and how they are implemented [46], we cannot accept self-censorship or avoid reporting of errors that others of our colleagues could also make.

Finally, we want to emphasize the need to promote **systematic evaluation studies** with strong methodologies for assessing the many socio-technical factors that influence the introduction of increasingly sophisticated computer technologies within complex human organizations. People within these organizations have the ability to resist [47], and certainly critically affect how a technology actually works, rather than how it was designed to work. Studies on introducing informatics technology in health care is best done prospectively, so promoting assessment criteria and statistically well-controlled study designs in a scientifically rigorous manner by unbiased and disinterested medical informatics organizations is important [24]. It might even help counteract the uncritical technology-driven adoption of systems as much as the often hypercritical retrospective commentary that arises when things go wrong with the implementation of a technology in the absence of properly designed prospective or retrospective studies.

Conclusion

Implementing informatics applications in health care is primarily a socio-technical activity. Each setting is unique in its combination of sociological, technical, organizational and human factors. However, each evaluation study (especially those with negative results) helps to clarify and to improve the evidence base of health informatics. Well-educated health informaticians, using systematically developed implementation guidelines that take into account the socio-technical issues, can increase the chance of successful implementations of health informatics applications. Rigorous assessment studies, based on evaluation guidelines, can support early detection and prevention of adverse events that may occur. While it is never possible to foresee all possible adverse effects prospec-

tively, good study design can help avoid reaching unwarranted conclusions from ignoring possible confounding effects retrospectively – thereby leading to constructive feedback for future study design and system implementation. All these activities contribute to the emergence of the evidence base of health informatics.

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