Evidence-based Health Informatics: How Do We Know What We Know?

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Summary

Background: Health IT is expected to have a positive impact on the quality and efficiency of health care. But reports on negative impact and patient harm continue to emerge. The obligation of health informatics is to make sure that health IT solutions provide as much benefit with as few negative side effects as possible. To achieve this, health informatics as a discipline must be able to learn, both from its successes as well as from its failures.

Objectives: To present motivation, vision, and history of evidence-based health informatics, and to discuss achievements, challenges, and needs for action.

Methods: Reflections on scientific literature and on own experiences.

Results: Eight challenges on the way towards evidence-based health informatics are identified and discussed: quality of studies; publication bias; reporting quality; availability of publications; systematic reviews and meta-analysis; training of health IT evaluation experts; translation of evidence into health practice; and post-market surveillance. Identified needs for action comprise: establish health IT study registers; increase the quality of publications; develop a taxonomy for health IT systems; improve indexing of published health IT evaluation papers; move from meta-analysis to meta-summaries; include health IT evaluation competencies in curricula; develop evidence-based implementation frameworks; and establish post-marketing surveillance for health IT.

Conclusions: There has been some progress, but evidence-based health informatics is still in its infancy. Building evidence in health informatics is our obligation if we consider medical informatics a scientific discipline.

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1. Motivation: Need for Evidence

Health IT has been introduced and used in health care settings for many years now, trusting that it will increase the quality and efficiency of health care. And in fact, numerous studies and reports have shown that health IT can be associated with an increase in quality, efficiency, and safety [1, 2]. But then reports of failed implementations and negative impact of health IT started to appear – first rather sporadically [3], in the last few years in an increasing and somewhat frightening number [4 – 6].

We must bear in mind that every new technology – such as the Internet, mobile phones, nuclear energy, or modern transportation – is meant to provide benefits, but may also lead to new problems both for the individual and for society as a whole. Health IT seems to be no exception here. Consequently, many health informatics associations have adopted codes of professional and ethical conduct. For example, AMIA's "Code of Professional and Ethical Conduct" states that "members … should be mindful and respectful of the social or public-health implications of their work" and "members … should recognize technical and ethical limitations" [7].

Modern health care is not thinkable without health IT [8], especially when taking into account the exploding amount of health information generated by more and more elaborate diagnostic and therapeutic technology, the growing need for communication and cooperation between different health care professional groups and health care institutions when treating multi-morbid patients in an aging population, and the challenge of providing high-quality care in times of economic crisis. The obligation for health informatics is to respond to these challenges and to provide efficient and effective health IT solutions, with as much benefit and as little negative side effects as possible. To achieve this, health informatics as a discipline must be able to learn, both from its successes as well as from its failures.

Learning is an individual process, but can also be a process within academic disciplines as a whole. Learning within health informatics includes collecting experiences, best practices, anecdotes, evaluation reports, and scientific study results. All this forms a (virtual) professional knowledge base that can help to generate scientifically valid evidence that helps to advance the field of health informatics. However, many recent reviews on the impact of health IT have found that this available (published)

evidence is astonishingly limited for many types of health IT, for manifold reasons. Thus, health informatics seems not as evidence-based as it should be. Missing evidence does not mean that health IT is without value, but it means that decisions on health IT development and implementation are based on "what we think makes sense, what we can afford, what vendors recommend…" [9] – and not on scientific evidence.

The objective of this paper is to present the idea and the challenges of evidence-based health informatics. First, the idea of evidence-based medicine is discussed, and the vision and history of evidence-based health informatics is presented. The generation of evidence by evaluation is then put forward in light of the life cycle of health IT. Then, achievements and challenges on the path towards evidence-based health informatics are discussed, and need for action is identified.

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2. The Vision of Evidence-based Health Informatics

To understand evidence-based health informatics, it is helpful to have a look at the history and motivation of evidence-based medicine.

The origins of evidence-based medicine can be traced back to the 19th century [10]. Nowadays, the most influential definition of evidence-based medicine stems from David Sackett: "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. … [It] means integrating individual clinical expertise with the best available external clinical evidence from systematic research" [10]. This definition focuses on individual patient-oriented decision-making, in contrast to another branch of evidence-based medicine that focuses on the effectiveness of population-based interventions. Sackett stresses that neither the external evidence nor the individual clinical exper-

tise alone is enough for clinical decision-making, but "good doctors use both" [10].

Health informatics strives to improve health care through technical (often socio-technical) interventions. Along these lines, it needs to provide evidence for the efficiency and effectiveness of its interventions, as discussed above. In analogy to evidence-based medicine, evidence-based health informatics can thus be defined as the conscientious, explicit, and judicious use of current best evidence to support a decision with regard to IT use in health care [11].

These "decisions" can be, for example, decisions on whether to introduce a certain type of health IT system or not, how to choose among alternative health IT systems, how to customize its user interface, how to introduce it into the clinical workflow, or how to train it. Some of these decisions will need evidence on efficiency and effectiveness of a health IT intervention; we call this "summative evidence". For example: Does a CPOE (computerized physician order entry) system lead to a decrease in medication errors? Does a PACS (picture archiving and communication system) reduce the turnaround time of radiological images? Which form of alert presentation is best to increase guideline adoption? But evidence-based health informatics is not only focused on efficiency and effectiveness: Evidence is also needed to answer questions such as "What is the best implementation strategy?" or "How can unintended consequences be avoided?" We can call this "formative evidence". This type of evidence helps to improve health IT systems.

The term "current best evidence" implies that scientific findings are needed – and not marketing promises, hopes, or assumptions [9]. Scientific evidence is typically built on results from well-designed systematic evaluation studies or systematic reviews. However, in analogy to evidence-based medicine, we have to add to the definition that evidence-based health informatics also means integrating individual health IT expertise with the best available external evidence from systematic research [11]. This addition is important. It is not realistic that health IT guidelines can be developed which, when followed, will be

able to assure that a health IT implementation or health IT operation is effective and efficient and without side effects.

Instead, health IT interventions are socio-technical interventions [10, 11] in a complex and quite specific health care environment. Health IT typically only indirectly affects the patient by influencing clinical processes and clinical decision-making in a vivid health care environment. This health care environment is characterized by complex, interconnected, and often sparsely standardized processes where various health care professionals have to cooperate in their specific roles, with complex legal and ethical issues, and with patients and their families as recipients and co-builders of care with their specific demands, fears, and emotions. As this clinical context is unique, each health IT implementation also is unique [9]. Organizational and cultural context is thus crucial for the success, failure, and impact of health IT and needs to be taken into account when applying external evidence.

To summarize these thoughts, we want to slightly update the original definition of evidence-based health informatics [11] as follows:

Evidence-based health informatics is the conscientious, explicit, and judicious use of current best evidence to support a decision with regard to the selection, implementation, and use of health IT. It means integrating individual health IT expertise with the best available external evidence from systematic research, taking into account the organizational and cultural context of patient care.

The available "current best evidence" is sometimes also denoted "evidence base". The evidence base of a scientific field is the (virtual) collection of available best evidence.

3. History of Evidence-based Health Informatics

While the term "evidence-based health informatics" has only appeared recently, the understanding that health IT has to be systematically evaluated is quite old. First evaluation studies were already published in the 1970s (e.g. [12, 13], see also the over-

views in [14] or [15]). An attempt to classify health IT evaluation studies was published in the 1980s [16]. In the 1990s, a more systematic scientific discussion on health IT evaluation started that is reflected e.g. in working conferences of the International Medical Informatics Association (IMIA) in Montpellier (1990), Leiden (1994), and Helsinki (1999) (17). In the following years, books on health IT started to appear [18–24], health IT evaluation was included in many health IT evaluation curricula, health informatics associations (such as IMIA, EFMI, AMIA) started working groups on health IT evaluation [25], and health IT evaluation is now a regular topic at major health informatics conferences.

Overall, the number of scientific publications in health informatics has been increasing since the mid-1990s (▶Figure 1). Even more strongly, the number of systematic reviews in health informatics has been increasing since 2005 [25]. The number of published health IT evaluation studies is more difficult to spot. A detailed analysis on 1,035 health IT evaluation studies published between 1982 and 2002 showed that an increasing number of evaluation studies had been published since 1995, with around 120 published each year in 2001 and 2002 [15].

The term "evidence-based health informatics" was first used at McMaster University in the mid-1990s [26]. The term was used here to name information resources to support evidence-based medicine, which is not in line with the definition of evidence-based health informatics in this paper.

One of the first persons to clearly formulate the need for an evidence base to health informatics was Michael Rigby who wrote in 2001: "Information systems … are no different from any other health system in needing to be evidence-based." [27]. The already cited definition of evidence-based health informatics was published in 2007 [11]. In 2010, IMIA included the topic "evaluation and evidence-based health in-

formatics" in its revised recommendations on health informatics education [28]. In 2013, the IMIA Yearbook of Medical Informatics 2013 chose as it annual topic "evidence-based health informatics" [29] and so made this term recognized worldwide.

3. Evidence and Life Cycle of Health IT

Evidence is generated, as discussed before, by systematic research based on formative or summative evaluation studies. Depending on the life cycle of health IT, evaluation studies have to answer different questions and thus focus on different issues and produce different types of evidence.

The following list gives a short, and clearly incomplete, list of possible evaluation questions and methods that can be applied to generate related evidence:
- Development phase: What are the user needs? (needs assessment); Is the soft-
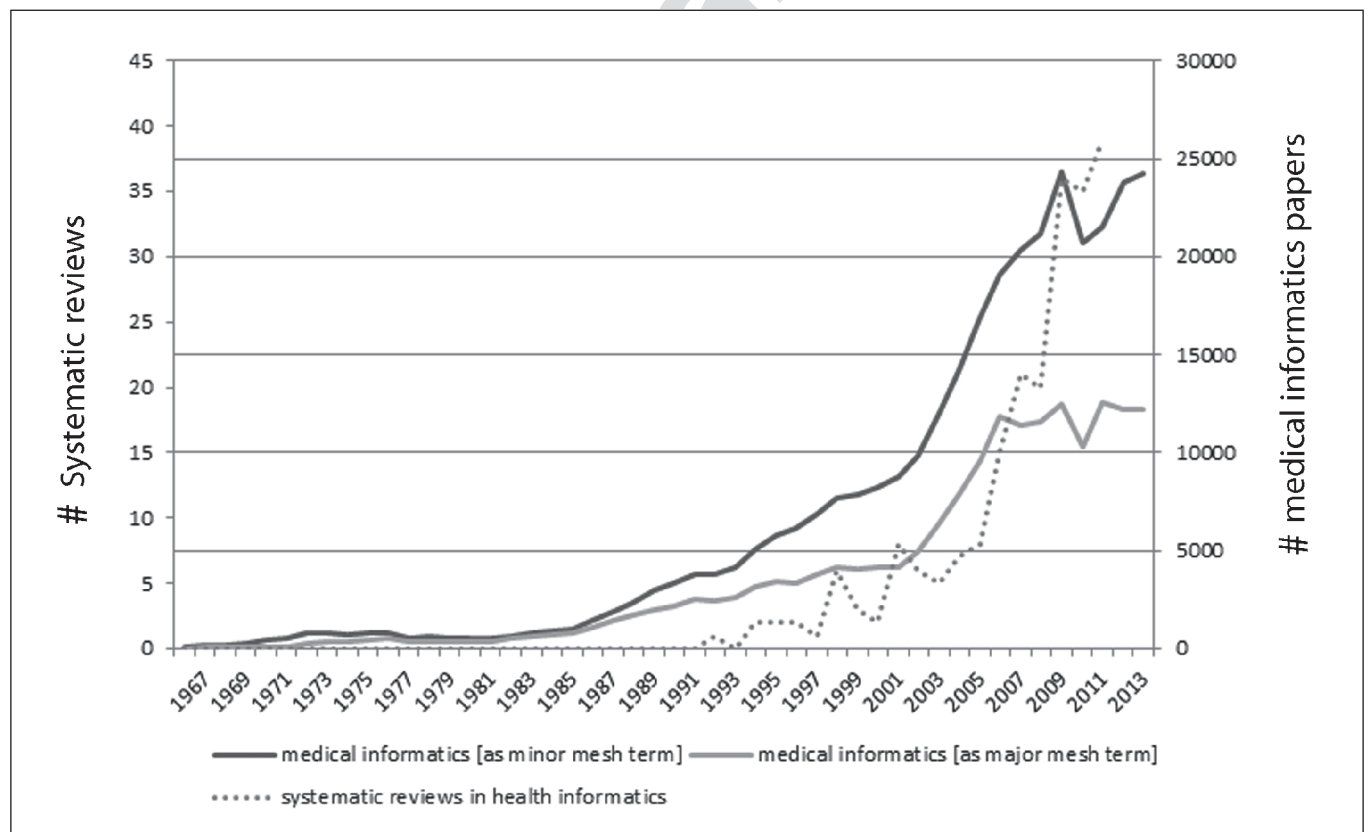
Figure 1 Number of medical informatics publications (identified by minor or major MeSH term "medical informatics" in PubMed) for the period 1966–2013. In addition, the number of systematic reviews in medical informatics is presented as identified by a query described in more detail in [25].

ware and hardware free of errors? (test runs); Was the software built as defined in the requirements? (verification); Was the software built as wanted by the users? (validation); Will the software work in practice? (simulation studies).

- Pilots and early use: Is the technical quality adequate? (performance measurements); Is the software user-friendly? (usability tests); Is the software sufficiently integrated in the clinical processes? (observations); Does the software work as intended? (interviews).
- Routine use: Is the software adopted as intended? (usage pattern analysis, documentation analysis); Are the users satisfied? (user survey); Is the software cost-effective? (cost analysis); Does the software create errors? (error report analysis); What is the impact of the software on efficiency, appropriateness, organization, or outcome quality of care? (experimental or quasi-experimental studies).

This list clearly indicates that there is not just "one" evaluation for a given health IT system. A recent analysis of all 1,818 studies in a health IT evaluation database [30] found that around one-third of the health IT studies addressed the impact of health IT on appropriateness of care, and one-fifth addressed the impact on efficiency on work processes or user satisfaction, respectively (▶ Figure 2). It is striking that "impact on outcome quality of patient care", which is the most important outcome seen from the point of view of patients, is only ranked fifth. The reason may be that health IT often only indirectly affects the outcome of patient care, unlike many medical interventions.

Dependent on the state within the life cycle, on the type of system, and on the questions that need to be answered, different evaluation studies with different methods will be conducted. It is therefore quite obvious that the full range of quantitative and qualitative evaluation methods that are available, e.g. from biostatistics, epidemiology, social science, psychology, or health care management, can and must be used. From this point of view, any discussion on the "best" evaluation approaches seems somehow misleading.

Each of these individual studies will generate evidence that helps to improve the health IT system or its implementation (formative evidence), or to justify it and decide on its future (summative evidence). This evidence, however, is of primary interest for the health care organization in which the health IT system is being implemented or operated. We can thus call it "in-house evidence". To be able to generate evidence that can help *other* health care organizations in taking decisions on a health IT system, we have to aggregate this "in-house evidence". This is typically done in the form of systematic reviews and meta-analysis – we will come back to this later on.

4. Towards Evidence-based Health Informatics

Now let's have a look at what has already been achieved and what is missing. To make progress towards evidence-based
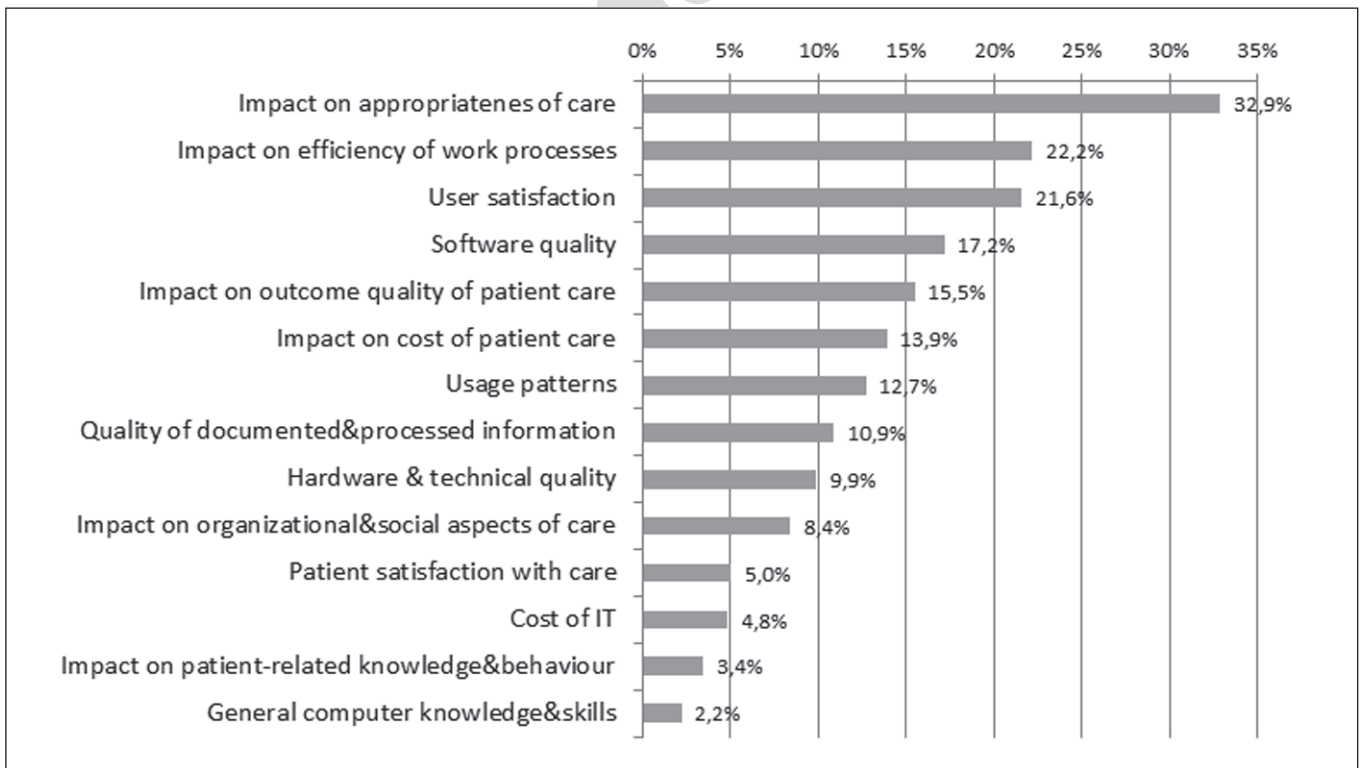
Figure 2 Analysis of the type of addressed evaluation questions of 1,818 health IT evaluation papers published between 1982 and 2014 and contained in the health IT evaluation database [30]. One paper may address more than one evaluation question.

health informatics, we obviously need well-designed evaluation studies. These studies need to be published and they need to be locatable for others. They need to be aggregated in the form of systematic reviews and meta-analysis. To achieve all this, we need well-trained health informatics specialists. Available evidence then needs to be translated into practice. In addition to studies, we need ad-hoc adverse event reporting systems. We will now have a look at these aspects in detail.

4.1 Challenge 1: Quality of Evaluation Studies

Conducting a well-designed evaluation study on health IT has been reported to be challenging [31]. As discussed before, we are dealing with complex socio-technical interventions [32]. This makes it difficult to control all relevant contextual factors in a controlled or even randomized study design [33]. Health IT is implemented in a steadily changing clinical environment and is itself affected by changes [34], leading to the problem of a moving target. Different stakeholders often define the "success" of health IT differently [35]. Too many evaluation questions may be of interest (see the life cycle discussion above), only few can be tackled in one study, or evaluation questions may change during the study [35]. In addition, health IT evaluation has to be seen as a "multi-perspective and multi-method" task [33], and formative and summative evaluation approaches from different scientific fields need to be carefully selected, combined, and thoroughly applied, taking into account the partly conflicting underlying theoretical or philosophical assumptions [36, 37]. This all makes planning an evaluation study quite challenging [9, 31, 32].

To respond to this complexity and to increase the internal validity of health IT evaluation studies, several guidelines have been developed. Already Krobock in 1984 [16], Grémy and Degoulet in 1993 [38], Kaplan in 1995 [39], and Heathfield in 1997 [35] proposed frameworks for evaluation questions or evaluation phases. These frameworks can be seen as a first approach towards health IT evaluation guidelines. A well-established health IT evaluation

guideline was published in 2009 by the Agency for Healthcare Research and Quality (AHRQ) as an "evaluation toolkit" [40]. This toolkit offers step-by-step guidance for developing a health IT evaluation plan. This guideline ends with describing how to write an evaluation plan. This toolkit is frequently used and regularly updated. To further support health IT evaluators, AHRQ has published helpful resources such as an overview on evaluation measures and survey instruments on its website.

However, we found that not only planning an evaluation study, but also conducting the study is challenging and needs to be supported as well. Therefore, in 2011, the EFMI and IMIA working groups on health IT evaluation published the GEP-HI guideline, a guideline for good evaluation practice in health informatics [41]. This GEP-HI guideline builds on earlier guidelines (including AHRQ), but extends them by also considering the phases of conducting and finalizing an evaluation study.

If we take all these available health IT evaluation guidelines, and also consider the already mentioned health IT evaluation textbooks, it seems that quite some guidance to conduct high-quality health IT evaluation studies is already available. Now they need to be applied.

4.2 Challenge 2: Publication Bias

The next step needed for evidence-based health informatics is to make the "in-house evidence" that is generated by "local" evaluation studies available to others. The first step is to publish. In a survey of 136 health IT researchers, we found that a large proportion of health IT evaluation studies, even when being conducted in academic settings, never get published [11]. In this survey, mostly "no time" was given as the reason for non-publication, but political reasons were also mentioned.

When studies with negative findings are not published due to political reasons, this is called publication bias. Publication bias is a problem well known in medical research [42] and also seems to be a problem in health informatics [43], even when the exact amount of the problem is not known. The Han paper [4] was a laudable excep-

tion from the rule that negative studies are not published.

But the question remains: How can we motivate researchers to publish their evaluation results, even when the results are negative or inconclusive? In the medical sciences, clinical trial registries requiring all trials to be registered have been introduced, but they have been only partly successfully [44]. These registries do not guarantee publications of the finalized trial, but at least allow an estimate of the problem of publication bias, and they allow other researchers to identify and contact potentially interesting clinical trials even when their results are not published in the end. Thus, establishing a health IT evaluation study registry is something that we as a community should initiate. Individual journals have already suggested this [45], but all major health informatics journals would have to agree that they only accept trials for publication that have been registered previously. The registry itself should be maintained by an independent and international health informatics organization.

4.3 Challenge 3: Reporting Quality of Evaluation Studies

When an evaluation study is published, this publication will be read and used by others to support decisions to be made. The study publication needs to be of sufficiently high quality to support this. However, many review authors found – despite a rigorous peer-review process before publication – that many study publications suffer from insufficient quality [33, 46 – 48]). Problems include, among other things: incomplete description of both the technical and the organizational dimension of the health IT interventions; incomplete description of the clinical and organizational setting; incomplete description of the methods or tools used; overoptimistic or uncritical presentation of results; or incomplete discussion of limitations. An analysis on the quality of health IT evaluation papers in the last 15 years showed that their quality remains low [48]. This incomplete information in study publications makes it difficult to use and generalize the evidence of the study.

This problem is well-known in the medical sciences, and several publication guidelines have been developed in the last few years for clinical trials, including CONSORT for reporting of randomized controlled trials [49], STARD for reporting of diagnostic studies [50], STROBE for reporting of observational studies [51], or PRISMA for systematic reviews [52]. Due to the rising number of publication guidelines in the medical sciences, the EQUATOR network was launched in 2006 [53]. On its website, EQUATOR collects available guidelines and makes them easily accessible. In October 2014, the website already contained 224 publication guidelines. Many of these guidelines are also of relevance for health IT evaluation publications.

However, we found that health IT evaluation publications have specific attributes which are not fully covered by these guidelines, such as the thorough description of the socio-technical intervention. Therefore, in 2009, the STARE-HI guidelines [54] were published. They build on available publication guidelines, but extend them to health IT evaluation publications. STARE-HI has been adopted by major health informatics journals (e.g. Methods Inf Med, Int J Med Inform), by EFMI and IMIA, and it has been included in the EQUATOR network as well. An elaboration paper is also available [55].

Overall, it seems that for any type of health IT evaluation study, good publication guidelines are available. Now let's hope these guidelines are used by authors of research papers, so that the quality of health IT evaluation publication will increase. Examples from the medical sciences show that guidelines alone may not be sufficient to improve publication quality; the evidence is mixed regarding this question [42–44]. Additional activities such as training may be needed – this will be discussed later on.

4.4 Challenge 4: Identification of Published Evaluation Studies

Evidence from published evaluation studies can only be used by others when these publications are locatable in reference database or other sources. This is not al-

ways easy, as evaluation studies are often not indexed with appropriate keywords – in PubMed, for example, there is no specific MeSH term for health IT evaluation studies. MeSH terms are in general considered too unspecific for the growing field of health informatics [56]. Therefore, some institutions have decided to offer their own databases with health IT evaluation study publications. For example, AHRQ offers a collection on literature about health IT costs and benefits, containing around 630 papers [57]. And, hosted by UMIT, the EFMI Working Group on Assessment of Health Information Systems offers a database of more than 1,800 health IT evaluation papers [30]. Both databases allow a systematic search, e.g. based on type of evaluated system, type of study, clinical setting, or outcome criteria. Both databases seem to be well-accepted in the community; the UMIT database, for example, is accessed up to 200 times per month.

However, maintaining this type of database is time-consuming, and the databases tend to be outdated quite soon. It would be much better if major reference databases such as PubMed allowed more specific indexing for health IT evaluation studies. Indexes should allow specifying the fact that a paper presents a health IT evaluation study, and to name at least the type of evaluated information system. If this were possible, additional health IT study databases would no longer be needed.

To facilitate indexing, a taxonomy to describe the type of the evaluated system is needed. Recent standardization efforts [58] as well as ongoing terminology discussions [59] can be used as a basis for this. A taxonomy would help to cluster and reuse evidence around certain types of health IT systems, and would thus support evidence-based health informatics.

4.5 Challenge 5: Need for Systematic Reviews and Meta-analysis

As discussed before, local evidence needs to be aggregated to serve as evidence in other, comparable clinical settings. In evidence-based medicine, this is typically done in the form of systematic reviews. According to the Cochrane Collaboration,

"a systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view towards minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made" [60]. Systematic reviews are frequently published in health informatics [61–64], and the number of systematic reviews per year seems to be increasing [15].

A systematic review may include a meta-analysis. A meta-analysis "is the use of statistical methods to summarize the results of independent studies" [60]. A meta-analysis combines the measured effect from all studies analysed in a systematic review to come up with a quantitative estimate of the effect. Meta-analyses in health informatics seem to be less frequent (e.g. [65–67]). What could be the reasons? A meta-analysis is often not feasible when dealing with health IT evaluation studies: Included studies are often quite heterogeneous regarding clinical setting and type and functionality of the evaluated system, making a summary of effects not feasible [46]. In addition, health IT evaluation studies often do not use a randomized approach, but rather a quasi-experimental approach. The quality of evidence here is considered not sufficient for inclusion in a meta-analysis. Nevertheless, meta-analyses seem to be a very straightforward way of collecting evidence from homogeneous evaluation studies. They also allow investigations of possible publication bias by generation of a funnel plot [68]. Health informatics should strive to do more meta-analyses as soon as sufficient comparable and high-quality (randomized) studies are available for a given question.

However, we must be aware that a meta-analysis is only feasible for questions related to the impact of health IT and that it is only able to integrate quantitative studies. For evidence regarding other questions such as success criteria or reasons for acceptance or non-acceptance of a system, or for evidence from qualitative studies, reviews also integrating qualitative evidence are needed. This qualitative evidence also contributes to evidence-based medical informatics. Health informatics should thus

start to exploit available methodologies from health service research for integrating qualitative evidence such as meta-synthesis [69] and for integrating quantitative and qualitative evidence such as meta-summary [70].

4.6 Challenge 6: Training of Health IT Evaluation

The previously discussed challenges make it clear that, for making progress towards evidence-based health informatics, well-trained health IT evaluation experts are needed. These may have a background in medical informatics, but also in other disciplines such as medicine, nursing, social sciences, health economics, or psychology, depending on the evaluation questions and the methodology used. All persons that take over responsibilities regarding selection, implementation, and use of health IT should have sufficient knowledge about health informatics and health IT evaluation.

For health informatics specialists, the International Medical Informatics Association (IMIA) recommends that health IT evaluation form part of the health informatics core curriculum [71]. In particular, these recommendations state that "evaluation and assessment of information systems, including study design, selection and triangulation of methods, outcome and impact evaluation, economic evaluation, unintended consequences, systematic reviews and meta-analysis, evidence-based health informatics" should be taught in health informatics curricula. Several textbooks already exist that cover at least some of these issues [22–24].

However, a detailed curriculum for health IT evaluation does not exist yet. Therefore, the working groups on health IT evaluation of EFMI, IMIA and AMIA have launched an initiative to develop recommendations for health IT evaluation [72]. These recommendations will describe the content of health IT evaluation courses in dependence to the intended level of expertise to be achieved.

4.7 Challenge 7: Translation of Evidence into Practice

Collecting and disseminating high-quality evidence does not guarantee its uptake in practice. For example, a large randomized study demonstrated the effectiveness of electronic alerts to prevent thromboembolism [73] – nevertheless, this type of alert is still not in routine use in a larger number of hospitals. Or, despite available evidence that CPOE systems may reduce medication errors and preventable adverse drug events [46, 74], their adoption rate remains low. Reasons may be manifold, including expectations of unintended and even harmful consequences [75, 76], and a less favourable local organizational and cultural context [77].

This problem of missing uptake of evidence holds true for health care in general. Despite the availability of scientific evidence and evidence-based clinical guidelines, large variations in clinical care exist [78], and many patients receive sub-optimal or even harmful care [79].

To overcome this problem, it has thus been argued that implementation of clinical evidence itself needs to be evidence-based, and that strategies for changing practice need to be developed and summarized in evidence-based implementation frameworks [78, 80]. This also needs to be done for health informatics interventions: We need evidence-based implementation frameworks describing how to implement health IT systems in clinical practice. Theses frameworks need to be based on theoretical and practical knowledge about change management and behaviour change both on an individual and organizational level. For this, we especially need formative evidence, often coming from qualitative oriented trials.

4.8 Challenge 8: Post-market Surveillance

Until now, we have discussed evidence-based health informatics from the point of view of evaluation studies and systematic reviews. However, this is not the only way important evidence can be generated. When we look at drug development, phase I–III studies can be compared to the health IT evaluation studies discussed before. But we also need phase IV studies – post-market surveillance, describing the routine monitoring of side effects after a product is put onto the market. Post-market surveillance is established standard for medical devices.

Databases such as MAUDE [81] allow vendors and users to report on near-misses and adverse events related to a drug or a medical device. Some of these reports are also related to health IT, and interesting analyses on the number and type of reported adverse events have been conducted based on this information [82]. However, only part of health IT is regulated as a medical device, and thus these databases only contain a fraction of adverse events related to health IT. We therefore urgently need specific types of reporting database for health IT related adverse events. For example, health care organizations may offer a health IT adverse event reporting system for their users, to collect and analyse adverse events. Best practice examples are already available [83]. An analysis of these reports can give important insights into sources of errors and into approaches to improve the safety of health IT.

5. Need for Action

Based on the challenges described above, the following need for action can be summarized to make progress towards evidence-based health informatics:
- teach and train the application of health IT good evaluation practice guidelines and publication guidelines;
- introduce health IT evaluation training in health informatics curricula;
- teach the foundations of health informatics and health IT evaluation to clinical professionals;
- provide incentives for publishing high-quality, yet negative health IT evaluation studies;
- develop a taxonomy for health IT systems;
- establish a health IT evaluation study register and make registration mandatory for peer-reviewed publication of evaluation results;

- update the PubMed MeSH term regarding adequate health IT evaluation terms;
- provide incentives for publishing qualitative reviews, systematic reviews, meta-analysis, and meta-summaries on health IT;
- develop evidence-based implementation frameworks for various types of health IT systems; and
- establish health IT adverse event reporting systems on national levels.

6. Discussion

As stated before, evidence-based health informatics is based on well-designed, published, and locatable evaluation studies that are aggregated in systematic reviews and meta-analysis. To achieve all this, we need well-trained health informatics specialists. In addition, we need adverse event reporting systems for post-marketing surveillance of health IT. We have discussed these issues in more detail and have identified need for action, including establishing health IT study registries, increasing the quality of publications, improving indexing of published health IT evaluation papers, moving from meta-analysis to meta-summaries, including health IT evaluation competencies in health informatics curricula, developing evidence-based implementation guidelines, and establishing post-marketing surveillance for health IT (not only for medical devices).

It seems that we are making progress [84]. The number of systematic reviews on health IT has been increasing in the last few years (▶ Figure 1), and health IT evaluation has been included in health IT curricula recommendations. The term "evidence-based health informatics" was topic of the IMIA Yearbook 2013, promoting this concept worldwide. The regulation around the Medical Device Directives in Europe forces companies to put more emphasis on usability and clinical evaluation. And the rising concerns on hazards and patient harm associated with health IT [75, 85 – 88] is clearly supporting this trend. The quality of health IT contributes to patient safety and best possible care. Health IT evaluation is strongly needed to support and guarantee this.

But the taken path is not easy. Comparable to the resistance against the movement of evidence-based medicine, there also is reluctance to perform high-quality and independent evaluation of health IT [9, 27]. Other professional areas such as aviation may show us how to systematically detect errors and learn from them (89), even when differences between these areas are obvious [90].

Theory and practice of health IT evaluation seem to be pushed forward mostly by academics, as health IT practitioners and health developers were often found to be reluctant [27], including being "too busy writing the next line of code" [91]. By putting more emphasis on health IT evaluation in health informatics curricula, motivation and understanding on the need and methodology of health IT evaluation will hopefully rise outside the academic environment. The curricula recommendations that are currently being worked on by EFMI, IMIA and AMIA working groups [72] thus appear to be a timely and urgent initiative.

The increasing complexity of interconnected health IT, socio-technical information systems, interlinked organizational issues, and increasing legal regulations increase the complexity of health IT and call for more comprehensive evaluation studies and approaches and for equally well-trained health IT evaluators. Only high-quality evidence will lead to higher confidence and trust in health IT instead of unfulfillable promises and marketing slogans. Medical informatics is a scientific discipline [92], and so we have to "combat hype with science" [93]. As Christian Lovis emphasizes: "Building evidence in our field is no longer an option. It is a necessity and an obligation" [84].

This paper claims that evidence-based health informatics contributes to high-quality patient care and patient safety. The critical reader will immediately respond that this is a claim that still needs to be evaluated. And this is absolutely correct. As recent discussions on clinical guidelines show [94], evidence-based guidelines may also be wrong. An evaluation of the impact of evidence-based health informatics is thus needed.

7. Conclusion

Evidence-based medicine now has a history dating back to 1972, when Archie Cochran published "Effectiveness and Efficiency" [95] describing the lack of evidence for many clinical practices. Evidence-based health informatics is much younger – offering an interesting professional perspective for young health IT experts and health IT evaluators in the years to come.

References

1. Jones SS, Rudin RS, Perry T, Shekelle PG. Health information technology: an updated systematic review with a focus on meaningful use. Ann Intern Med 2014; 160 (1): 48–54.
2. Institute of Medicine. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, D.C.: The National Academic Press; 2011.
3. Dowling AF, Jr. Do hospital staff interfere with computer system implementation? Health Care Manage Rev 1980; 5 (4): 23–32.
4. Han YY, Carcillo JA, Venkataraman ST, Clark RS, Watson RS, Nguyen TC, et al. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. Pediatrics 2005; 116 (6): 1506 –1512.
5. Magrabi F, Ong MS, Runciman W, Coiera E. Patient safety problems associated with heathcare information technology: an analysis of adverse events reported to the US Food and Drug Administration. AMIA Annu Symp Proc 2011; 2011: 853–857.
6. ECRI Institute. Deep Dive: Health Information Technology. 2012 [accessed Jan 14, 2015]; Available from: http://www.healthit.gov/facas/sites/faca/files/STF_Deep_Dive_Health_Information_Technology_2014-06-13.pdf
7. Goodman KW, Adams S, Berner ES, Embi PJ, Hsiung R, Hurdle J, et al. AMIA's code of professional and ethical conduct. J Am Med Inform Assoc 2013; 20 (1): 141–143.
8. Haux R. Medical informatics: past, present, future. Int J Med Inform 2010; 79 (9): 599– 610.

9. Koppel R. Is healthcare information technology based on evidence? Yearb Med Inform 2013; 8 (1): 7–12.

10. Sackett D, Rosenberg W, Gray J, Haynes R, Richardson S. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312 (7023): 71–72.

11. Ammenwerth E, de Keizer N. A viewpoint on evidence-based health informatics, based on a pilot survey on evaluation studies in health care informatics. J Am Med Inform Assoc 2007; 14 (3): 368–371.

12. Ware GO, Park MK. Evaluation of search time for two computerized information retrieval systems at the University of Georgia. J Chem Doc 1972; 12 (4): 224–227.

13. McFarlane AH, Norman GR. A medical care information system: evaluation of changing patterns of primary care. Med Care 1972; 10 (6): 481–487.

14. van der Loo R. Overview of Published Assessment and Evaluation Studies. In: van Gennip EMSJ, Talmon JS, editors. Assessment and evaluation of information technologies. Amsterdam: IOS Press; 1995. pp 261–282.

15. Ammenwerth E, de Keizer N. An inventory of evaluation studies of information technology in health care: Trends in evaluation research 1982 – 2002. Methods Inf Med 2005; 44: 44–56.

16. Krobock JR. A taxonomy: hospital information systems evaluation methodologies. J Med Syst 1984; 8 (5): 419–429.

17. Gremy F. Hardware, software, peopleware, subjectivity. A philosophical promenade. Methods Inf Med 2005; 44 (3): 352–358.

18. Flagle C, Grémy F, Perry S, editors. Assessment of Medical Informatics Technology Joint Working Conference Montpellier du 22 au 26 octobre 1990. Rennes: Éditions ENSP; 1991.

19. Anderson JG, Aydin CE, Jay SJ, editors. Evaluating Health Care Information Systems – Methods and Applications. London, New Delhi: Sage Publications; 1994.

20. van Gennip E, Talmon J, editors. Assessment and evaluation of information technologies in medicine. Amsterdam: IOS Press; 1995.

21. Lorenzi NM, Riley RT. Managing Change: An Overview. J Am Med Inform Assoc 2000; 7 (2): 116–124.

22. Anderson J, Aydin C, editors. Evaluating the Organizational Impact of Healthcare Information Systems. New York: Springer; 2005.

23. Friedman C, Wyatt JC. Evaluation Methods in Medical Informatics. 2nd ed. New York: Springer; 2006.

24. Brender J. Handbook of evaluation methods for health informatics. Burlington, MA: Elsevier Academic Press; 2006.

25. Rigby M, Ammenwerth E, Beuscart-Zephir M, Brender J, Hyppönen H, Melia S, et al. Evidence Based Health Informatics: 10 years of efforts to promote the principle. Yearb Med Inform 2013; 8 (1): 34–46.

26. Haynes RB, Hayward RS, Jadad AR, Sebaldt RJ. Evidence based health informatics: an overview of the Health Information Research Unit at McMaster University. Leadersh Health Serv 1996; 5 (3): 41–44.

27. Rigby M. Evaluation: 16 Powerful Reasons Why Not to Do It – And 6 Over-Riding Imperatives. In: Patel V, Rogers R, Haux R, editors. Proceedings of the 10th World Congress on Medical Informatics (Medinfo 2001). Amsterdam: IOS Press; 2001. pp 1198–1202.

28. Mantas J, Ammenwerth E, Demiris G, Hasman A, Haux R, Hersh W, et al. Recommendations of the International Medical Informatics Association (IMIA) on Education in Biomedical and Health Informatics. First Revision. Methods Inf Med 2010; 49 (2): 105–120.

29. Seroussi B, Jaulent MC, Lehmann CU. Looking for the evidence: value of health informatics. Editorial. Yearb Med Inform 2013; 8 (1): 4–6.

30. UMIT, EFMI WG Eval. Health IT Evaluation Database. 2014 [accessed Jan 14, 2015]. Available from: http://evaldb.umit.at

31. Ammenwerth E, Gräber S, Herrmann G, Bürkle T, König J. Evaluation of Health Information Systems – Problems and Challenges. Int J Med Inform 2003; 71 (2–3): 125–135.

32. Heathfield H, Buchan I. Current evaluations of information technology in health care are often inadequate. BMJ 1996; 313 (7063): 1008.

33. Heathfield H, Pitty D, Hanka R. Evaluating information technology in health care: barriers and challenges. BMJ 1998; 316: 1959–1961.

34. Kaplan B, Duchon D. Combining qualitative and quantitative approaches in information systems research: a case study. MIS Quarterly 1988; 12 (4): 571–586.

35. Heathfield H, Peel V, Hudson P, Kay S, Mackay L, Marley T, et al. Evaluating Large Scale Health Information Systems: From Practice Towards Theory. In: Masys D, editor. AMIA Annual Fall Symposium. Philadelphia: Hanley & Belfus; 1997. pp 116–120.

36. Sim J, Sharp K. A critical appraisal of the role of triangulation in nursing research. Int J Nurs Stud 1998; 35 (1–2): 23–31.

37. Barbour RS. Mixing qualitative methods: quality assurance or qualitative quagmire? Qual Health Res 1998; 8 (3): 352–361.

38. Grémy F, Degoulet P. Assessment of health information technology: which questions for which systems? Proposal for a taxonomy. Med Inform 1993; 18 (3): 185–193.

39. Kaplan B. An Evaluation Model for Clinical Information Systems: Clinical Imaging Systems. In: Greenes R, Peterson H, Protti D, editors. Medinfo 95 – Proceedings of the 8th World Congress on Medical Informatics. Amsterdam: North Holland; 1995. p 1087.

40. AHRQ. Ageny for Healthcare Research and Quality: AHRQ Evaluation Toolkit. 2009 [accessed Jan 14, 2015]. Available from: http://healthit. ahrq.gov/health-it-tools-and-resources/health-it-evaluation-toolkit-and-evaluation-measures-quick-reference

41. Nykanen P, Brender J, Talmon J, de Keizer N, Rigby M, Beuscart-Zephir MC, et al. Guideline for Good Evaluation Practice in Health Informatics (GEP-HI). Int J Med Inform 2011; 80: 815–827.

42. Malicki M, Marusic A, Consortium O. Is there a solution to publication bias? Researchers call for changes in dissemination of clinical research results. J Clin Epidemiol 2014; 67 (10): 1103–1110.

43. Friedman C, Wyatt J. Publication bias in Medical Informatics. J Am Med Inform Assoc 2001; 8 (2): 189–191.

44. Wager E, Williams P, Consortium of Project Overcome failure to Publish Negative Findings. "Hardly worth the effort?" Medical journals' policies and their editors' and publishers' views on trial registration and publication bias: quantitative and qualitative study. BMJ 2013; 347: f5248.

45. Eysenbach G. Tackling publication bias and selective reporting in health informatics research: register your eHealth trials in the International eHealth Studies Registry. J Med Internet Res 2004; 6 (3): e35.

46. Ammenwerth E, Schnell-Inderst P, Siebert U. Vision and challenges of Evidence-Based Health Informatics: a case study of a CPOE meta-analysis. Int J Med Inform 2010; 79 (4): e83–8.

47. Peute LW, Driest KF, Marcilly R, Bras Da Costa S, Beuscart-Zephir MC, Jaspers MW. A framework for reporting on human factor/usability studies of health information technologies. Stud Health Technol Inform 2013; 194: 54–60.

48. de Keizer NF, Ammenwerth E. The quality of evidence in health informatics: how did the quality of healthcare IT evaluation publications develop from 1982 to 2005? Int J Med Inform 2008; 77 (1): 41–49.

49. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340: c332.

50. Bossuyt PM, Reitsma J, Bruns D, Gatsonis C, Glasziou P, Irwig L, et al. Towards Complete and Accurate Reporting of Studies of Diagnostic Accuracy: The STARD Initiative. Ann Int Med 2003; 138 (1): 40–44.

51. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet 2007; 370 (9596): 1453–1457.

52. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Int J Surg 2010; 8 (5): 336–341.

53. EQUATOR. The Equator Network: Enhancing the Quality and Transparency of Health Research. 2014 [accessed Jan 14, 2015]. Available from: www. equator-network.org/

54. Talmon J, Ammenwerth A, Brender J, de Keizer N, Nykänen P, Rigby M. STARE-HI – Statement on Reporting of Evaluation Studies in Health Informatics. Int J Med Inform 2009; 78 (1): 1–9.

55. Brender J, Talmon J, de Keizer N, Nykanen P, Rigby M, Ammenwerth E. STARE-HI – Statement on Reporting of Evaluation Studies in Health Informatics: explanation and elaboration. Appl Clin Inform 2013; 4 (3): 331–358.

56. Dixon BE, Zafar A, McGowan JJ. Development of a taxonomy for health information technology. Stud Health Technol Inform 2007; 129 (Pt 1): 616–620.

57. AHRQ. Agency for Healthcare Research and Quality: Health IT Costs and Benefit Database. 2009 [accessed Jan 14, 2015]. Available from: http:// healthit.ahrq.gov/health-it-tools-and-resources/ health-it-costs-and-benefits-database

58. ISO. ISO/TR 14639:2012: Health informatics – Capacity-based eHealth architecture roadmap; 2012.

59. Cravens GD, Dixon BE, Zafar A, McGowan JJ. A health information technology glossary for novices. AMIA Annu Symp Proc; 2008. p 917.
60. Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. 2011 [accessed Jan 14, 2015]. Available from: http://www.cochrane-handbook.org
61. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review. J Am Med Inform Assoc 2008; 15 (5): 585–600.
62. Bright TJ, Wong A, Dhurjati R, Bristow E, Bastian L, Coeytaux RR, et al. Effect of clinical decision-support systems: a systematic review. Ann Intern Med 2012; 157 (1): 29–43.
63. Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med 2006; 144 (10): 742–752.
64. Vervloet M, Linn AJ, van Weert JC, de Bakker DH, Bouvy ML, van Dijk L. The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature. J Am Med Inform Assoc 2012; 19 (5): 696–704.
65. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials. Bmj 2004; 329 (7458): 145.
66. Shea S, DuMouchel W, Bahamonde L. A meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting. J Am Med Inform Assoc 1996; 3 (6): 399–409.
67. Walton R, Dovey S, Harvey E, Frreemantle N. Computer support for determining drug dose: systematic review and meta-analysis. BMJ 1999; 318: 984–990.
68. Mavridis D, Salanti G. How to assess publication bias: funnel plot, trim-and-fill method and selection models. Evid Based Ment Health 2014; 17 (1): 30.
69. Jones ML. Application of systematic review methods to qualitative research: practical issues. J Adv Nurs 2004; 48 (3): 271–278.
70. Sandelowski M, Barroso J, Voils CI. Using qualitative metasummary to synthesize qualitative and quantitative descriptive findings. Res Nurs Health 2007; 30 (1): 99–111.

71. Mantas J, Ammenwerth E, Demiris G, Hasman A, Haux R, Hersh W, et al. Recommendations of the International Medical Informatics Association (IMIA) on Education in Biomedical and Health Informatics. First Revision. Methods Inf Med 2010; 49 (2): 105–120.
72. Ammenwerth E, Craven C, Georgiou A, Mantas J. Health IT Evaluation in Health Informatics Curricula: International Overview and Recommendations. Workshop at Medical Informatics Europa (MIE2014), 1.9.2014, Istanbul 2014 [accessed Jan 14, 2015]. Available from: http://person.hst.aau.dk/ska/MIE2014/WorkshopsAndPanels/W03_ID_472.pdf
73. Kucher N, Koo S, Quiroz R, Cooper JM, Paterno MD, Soukonnikov B, et al. Electronic alerts to prevent venous thromboembolism among hospitalized patients. N Engl J Med 2005; 352 (10): 969–977.
74. Cresswell KM, Bates DW, Williams R, Morrison Z, Slee A, Coleman J, et al. Evaluation of medium-term consequences of implementing commercial computerized physician order entry and clinical decision support prescribing systems in two 'early adopter' hospitals. J Am Med Inform Assoc 2014; 21 (e2): e194–202.
75. Eslami S, Abu-Hanna A, de Keizer NF, de Jonge E. Errors associated with applying decision support by suggesting default doses for aminoglycosides. Drug Saf 2006; 29 (9): 803–809.
76. Ash JS, Sittig DF, Dykstra R, Campbell E, Guappone K. The unintended consequences of computerized provider order entry: findings from a mixed methods exploration. Int J Med Inform 2009; 78 (Suppl 1): S69–76.
77. Durieux P. Electronic medical alerts--so simple, so complex. N Engl J Med 2005; 352 (10): 1034–1036.
78. Gross PA, Greenfield S, Cretin S, Ferguson J, Grimshaw J, Grol R, et al. Optimal methods for guideline implementation: conclusions from Leeds Castle meeting. Med Care 2001; 39 (8 Suppl 2): II85–92.
79. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003; 362 (9391): 1225–1230.
80. Grol R, Grimshaw J. Evidence-based implementation of evidence-based medicine. Jt Comm J Qual Improv 1999; 25 (10): 503–513.
81. FDA. MAUDE – Manufacturer and User Facility Device Experience Database. 2014 [accessed Jan 14, 2015]. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

82. Magrabi F, Ong MS, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. J Am Med Inform Assoc 2012; 19 (1): 45–53.
83. Meeks DW, Smith MW, Taylor L, Sittig DF, Scott JM, Singh H. An analysis of electronic health record-related patient safety concerns. J Am Med Inform Assoc 2014; 21 (6): 1053–1059.
84. Lovis C. Evidence-based Biomedical Informatics. The Long Way from Pioneer to Science. Yearb Med Inform 2013; 8 (1): 47–50.
85. Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. J Am Med Inform Assoc 2004; 11 (2): 104–112.
86. Campbell EM, Sittig DF, Ash JS, Guappone KP, Dykstra RH. Types of Unintended Consequences Related to Computerized Provider Order Entry. J Am Med Inform Assoc 2006; 13 (5): 547–556.
87. van der Sijs H, Kowlesar R, Aarts J, Berg M, Vulto A, van Gelder T. Unintended consequences of reducing QT-alert overload in a computerized physician order entry system. Eur J Clin Pharmacol 2009; 65 (9): 919–925.
88. Kushniruk AW, Triola MM, Borycki EM, Stein B, Kannry JL. Technology induced error and usability: the relationship between usability problems and prescription errors when using a handheld application. Int J Med Inform 2005; 74 (7–8): 519–526.
89. Low DK, Reed MA, Geiduschek JM, Martin LD. Striving for a zero-error patient surgical journey through adoption of aviation-style challenge and response flow checklists: a quality improvement project. Paediatr Anaesth 2013; 23 (7): 571–578.
90. Randell R. Medicine and aviation: a review of the comparison. Methods Inf Med 2003; 42 (4): 433–436.
91. Sullivan F. What is health informatics? J Health Serv Res Policy 2001; 6 (4): 251–254.
92. Uckert F, Ammenwerth E, Dujat C, Grant A, Haux R, Hein A, et al. Past and next 10 years of medical informatics. J Med Syst 2014; 38 (7): 74.
93. Hoyt R. Evidence-based health informatics: Replacing hype with science. 2013 [accessed Jan 14, 2015]. Available from: https://prezi.com/zsbc329–25db/evidence-based-health-informatics
94. Godlee F. How guidelines can fail us. BMJ 2014; 349: g5448.
95. Cochrane A. Effectiveness and Efficiency: Random Reflections on Health Services. London: Nuffield Provincial Hospitals Trust; 1972.