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

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Summary

This article is part of a For-Discussion-Section of *Methods of Information in Medicine* about the paper "Evidence-based Health Informatics: How Do We Know What We Know?" written by Elske Ammenwerth [1]. It is introduced by an editorial. This article contains the combined commentaries invited to independently comment on the Ammenwerth paper. In subsequent issues the discussion can continue through letters to the editor.

With these comments on the paper "Evidence-based Health Informatics: How do we know what we know?", written by Elske Ammenwerth [1], the journal seeks to stimulate a broad discussion on the challenges of evaluating information processing and information technology in health care. An international group of experts has been invited by the editor of Methods to comment on this paper. Each of the invited commentaries forms one section of this paper.

1. Comment by N. Al-Shorbaji

1.1 Introduction

The Fifty-eighth World Health Assembly (WHA) in May 2005 discussed eHealth for the first time in the history of the Organization. The Assembly issued its resolution on eHealth (WHA58.28) which described eHealth as "the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research" [2]. That discussion constituted the recognition of the Organization and its Member States of eHealth as one of its technical programmes. Since that date eHealth programmes were formally established in WHO/HQ and its six Regional Offices. The current Programme Budget (2014/2015) [3] which was approved by the WHA in May 2013 and the next biennium Programme Budget, (2016/2017) [4] which was discussed and approved by the WHA in May 2015 include eHealth as one of the programme areas under health systems. The WHA in its 66th session in May 2013 discussed eHealth standardization and evaluation. The Assembly adopted a resolution (WHA66.24) [5] which reiterated the importance of eHealth and recalling the previous WHA resolution on eHealth of 2005 mentioned above. The 2013 resolution stated in its preamble that "Emphasizing that scientific evaluation of the impact on health care outcomes of health information systems based on information and communication technologies is necessary to justify strong investment in such technologies for health; and that "Highlighting the need for national eHealth strategies to be developed and implemented, in order to provide the necessary context for the implementation of eHealth and health data standards, and in order that countries undertake regular, scientific evaluation" requested the Director-General of WHO "to provide guidance and technical support, as appropriate, to facilitate the coherent and reproducible evaluation of information and communication technologies in health interventions, including a database of measurable impacts and outcome indicators".

WHO Global eHealth Evaluation Meeting held in Bellagio, Italy in 2011 [6] issued a call to action which stated that "to improve health and reduce health inequalities, rigorous evaluation of eHealth is necessary to generate evidence and promote the ap-

propriate integration and use of technologies".

WHO and the International Medical Informatics Association (IMIA) published a special theme issue of the Bulletin of the World Health Organization (May 2013) [7]. This theme issue highlights what has been learnt from eHealth projects throughout the world in terms of feasibility, acceptance and impact on processes and concluded that "The recipe may seem familiar and replicable, but the proof is in the pudding, in the clear demonstration that eHealth can result in economic benefits and improve health outcomes. Programme evaluators and implementers face the challenge of generating such evidence, a prerequisite for the widespread adoption of eHealth" [8].

WHO and its member states and partners have demonstrated commitment to evaluation and to creating the evidence-base for eHealth. This commitment has been translated into a number of actions as elaborated above and through the work of the Organization in countries and in project implementation. Monitoring and evaluation is an integral part of the work of the WHO which aims at improving performance, accountability and learning.

The paper (Evidence-based Health informatics: how do we know what we know) has provided an excellent overview of the issues surrounding evaluation of health informatics activities and projects. It also provided a vision and set of challenges to evaluation of health informatics. The call for action towards the end of the paper also provided an excellent basis for interested institutions to go forward in a collaborative manner.

1.2 The Issues

Commenting on this paper is not meant to criticise any of its parts or any parts of the literature cited in the paper. It is meant to shed further light on the issue from another perspective considering the experience of WHO in supporting eHealth planning and implementation and the commitment the Organization and its Governing Bodies have expressed to support eHealth. Taken the above into consideration, I would like to share the following points:

1. The paper did not present a definition or scope of what health informatics really means and/or covers. The way the term is used gives the impression that it's about care delivery to patients (individual care). If this is the case then this doesn't represent all what information and communication technology (ICT) can potentially offer to improve health outcomes, including health education, palliative care, access to literature, etc. The WHA definition of eHealth provides a comprehensive framework of the area of work and can be used as a basis to establish a knowledge domain. Looking into the other terms and concepts such as medical informatics, clinical informatics, public health informatics, consumer informatics, telemedicine, telehealth, Health IT, etc. makes health informatics, as a concept, look short of being inclusive of all these. The issue is not the terminology, as such. The issue is the huge diversity of activities and projects that may fall under this umbrella term or that. This makes evaluation much more difficult and complicated. Evaluating a health web site on the Internet is, for sure, different form evaluating an electronic health record system or a hospital management information system or a public health campaign using mobile technology. They all contribute, supposedly, to improving the health of people (public or individual health), but in different ways. Therefore, call to action in the paper to develop a taxonomy of health IT system is important and should be taken forward in order to remove ambiguity and offer consistency in support of comparisons.

2. eHealth has been suffering from the "pilotitis" disease for a very long time. What we see in many counties is eHealth projects externally funded as pilots. These pilot projects extend from few months to few years. The pilot is supposed to provide a basis for learning and scaling up. These projects are evaluated, in some cases, but only as pilot projects and to get more funding to extend the pilot rather than to sustain and scale up. This type of evaluation has not resulted in learning and building the evidence as the conditions for imple-

mentation, monitoring and evaluation are not meant for that. Many pilots do not even include evaluation as part of their budgeting cycle. Worse than this when the activity is not a pilot it is run as a project to avoid legal barriers and to avoid accountability. The call to register evaluation and research activities can improve learning and build the evidence base.

3. Weak or absence of evaluation culture. The paper rightly cited evidence and provided recommendation for action regarding education and training of health informatics professionals on evaluation. The issue is not only the human capacity to evaluate or manage evaluation activities in eHealth. The issue goes much beyond that as the evaluation culture is either weak or does not exist. There is fear from evaluation because failure is not reportable. Major eHealth projects are externally funded, especially in low and middle income countries. These projects, in many cases, are not only funded by external donors, but also managed by the same. In other cases driven by the industry. These projects are not demand-driven. They offer solutions looking for problems. Evaluation becomes a cosmetics, nice to have and not a necessity. The fear from evaluation has resulted in complacency, lack of transparency and lack of accountability. Monitoring and evaluation is essential in project management. In the absence of accountability and willingness to learn, unlearn and share lessons and best practices, evaluation suffers.

4. The paper rightly mentioned in two locations that "Health IT interventions are socio-technical". This is true as eHealth is multidisciplinary by nature. It involves in addition to health scientists, researchers and practitioners (in a most generic sense) information and communication technology infrastructure experts, social scientists, behavioural scientists, psychologies, information science and management. Implementing an eHealth project successfully requires a multi-stakeholder approach and meaningful engagement by all these specialists. Outcomes of intervention by professionals from these different disci-

plines are measured in many different ways. Performance of computer hardware/software, network throughputs and amounts of data generated and exchanged cannot be measured in the same way as measuring the performance of a software based on acceptance by health practitioners or computer engineers or sales people. Let alone using evidence-based medicine methods to do the evaluation including randomized controlled (clinical) trials. Evaluation of health informatics projects and creating evidence have to be considered in a different way. A new methodology needs to be developed and adopted away from, but benefitting form, the (randomized) controlled trials model, which has been criticized by many anyway.

5. Evaluation of health IT or eHealth has been focussing on the economic value of IT applications in health and looking for the return on investment. The patient safety concerns have not been widely addressed, especially that health IT is not only related to patient care and clinical applications. eHealth has the potential to reduce cost, improve quality of services, empower communities and individuals and improve equity to access to health information and services. Applying the evidence-based model (clinical trials to generate and synthesise evidence (systematic reviews) when the "treatment" or the "intervention" is not targeting an individual becomes very risky. Similar situations are faced when building and synthesizing the evidence related to environmental health and health systems, as an example.

1.3 Conclusion

In conclusion, evaluation of health informatics, eHealth or health IT and building the evidence and knowledge base are prerequisites for proper and seamless integration of ICT in healthcare delivery. Healthcare is an information-intensive sector that requires deployment and use of the information and communication infrastructure in an efficient, cost-effective and safe manner. The proof is in the pudding.

2. Comment by L. Hanmer

The paper by Ammenwerth [1] reflects more than a decade of work focussed on evaluation of health information technology (HIT) applications, including the development of guidelines and other support mechanisms to encourage health informatics practitioners to evaluate their activities. The paper makes a strong and convincing argument for evidence-based health informatics, provides a comprehensive and very valuable overview of HIT evaluation activities and tools, and includes concrete proposals for improving HIT evaluation.

From the review of HIT evaluation activities as reflected in published literature, as befits an academic discipline, it is clear that there has been only limited reporting on evaluation experiences to date. As the author indicates, the limited published literature is likely to reflect a combination of lack of reporting on some evaluations which have been carried out, and lack of evaluations of HIT implementations. An additional reason for the limited number of identified evaluation studies could be a reflection of the challenge of defining the criteria to be used to identify evaluation studies in the published literature, given the wide range of HIT applications, and the differing frameworks used to inform evaluations of HIT implementations.

The issue of selection criteria is reflected in the fact that a 2012 scoping review of the impacts of eHealth on the outcomes of care in low- and middle-income countries by Piette et al. [9] is not included in the UMIT/EFMI Health IT evaluation database referenced by Ammenwerth [10]. This paper includes a review of primary health care applications, and refers to the need for further evaluation of the large-scale HIT implementations in multiple low- and middle-income countries. It has only very limited referencing in common with the Ammenwerth paper, reflecting the complementary rather than overlapping foci of the two reviews.

A recent evaluation of EHR implementation impact and contingency factors by Nguyen et al. published in 2014 (and therefore overlapping in time with the Ammenwerth presentation on which the paper is based) [11] uses models from the information systems (IS) success literature, modified for the HIT environment, as the framework for the review. The review covers a wide range of HIT evaluation studies, including primary health care applications and EHR implementations in multiple countries. Another 2014 paper by authors from several countries reports on a rigorous systematic review of the effectiveness of computerised decision support systems linked to EHRs [12]. Both of these papers have some overlap in referencing with the Ammenwerth paper, but also include multiple unique references, again reflecting differences in focus of the three reviews.

Since the UMIT/EFMI database [10] has not yet been updated for 2014, it is not clear whether the two reviews of HIT evaluation studies focussed on EHRs [11, 12] would have been included, based on current selection criteria for inclusion. It is worth noting that none of the papers [9], [11] and [12] refers to the comprehensive HIT evaluation and evaluation reporting guidelines GEP-HI and STARE-HI respectively, which could have been expected of review papers on the impact of HIT applications on outcomes of care, although each of these papers does follow a (different) defined method or framework.

These examples illustrate the fact that, in a wide field like health informatics, it is possible that available evidence is missed due to the wide range of topics, foci and implementation environments which could be included under the umbrella of evidence related to the (positive or negative) impact of HIT implementation. Existing guidelines such as GEP-HI and STARE-HI seem not to be used as widely as they could be, reflecting missed opportunities to ensure the completeness and rigour of HIT implementations, although other guidelines and frameworks could also be appropriate for use, depending on the focus of the HIT applications being evaluated. In future, meta-analyses of reviews of HIT implementation evaluations could provide the opportunity to reflect the full breadth of applications and application environments of HIT, as they affect the health services and systems which they support.

3. Comment by R. Hussein

The paper published in Methods – entitled "*Evidence-based Health Informatics: How do we know what we know*?" [1] – provides a comprehensive approach towards evidence-based health informatics. The identified challenges and the corresponding need of action will definitely address the problem of lacking of well-designed evaluation studied in health IT. To complete the picture, we will also need a *benchmark* to measure the progress of *evidence-based eHealth* while achieving its ultimate goals in tackling the health systems challenges. The current global interest of realizing the Universal Health Coverage (UHC) by 2030 qualifies UHC to be the optimal benchmark for the evidence-based practice of eHealth. Especially, the dedicated efforts of the international organizations – mainly, the World Health Organization (WHO), and the World Bank (WB) – have led to position UHC as one of the goals of the post-2015 development agenda [13].

UHC has been defined as "*the desired outcome of health system performance whereby all people who need health services (promotion, prevention, treatment, rehabilitation and palliation) receive them, without undue financial hardship*" that was committed to be achieved by all WHO member states by the year 2030 [14]. Accordingly, the framework for monitoring UHC progress – that will be a part of a comprehensive framework for monitoring national health system performance- categories the UHC measures and indicators into the following [15]:

1. Coverage of essential health services – in terms of relevance, quality and availability
2. Coverage of financial protection
3. Equity in coverage

Consequently, UHC requires efficient health systems in which eHealth can play an essential role in strengthening their functionalities [16], through:

i) connecting various health information systems, and
ii) providing the healthcare domain with telemedicine, mHealth and eLearning applications.

At the practical level, the evaluation study of the International Development Research Centre's (IDRC's) projects on the eHealth research portfolio in health systems- performed in Low- and Middle-Income Countries (LMICs) from 2005 to 2010 – stated that "*the majority of the program implementation and intervention evaluation focused on process improvement and its potential impact on health outcomes and overall quality of care*" [17]. Despite the challenges in measuring the influence of eHealth interventions to health status outcomes, the IDRC's eHealth projects have shown a number of significant outcomes covering the evidence contributing to potential outcomes, process outcomes, and health status outcomes [18].

In addition, recent publications have shown the potential of mHealth in i) strengthening health systems through utilizing 12 common mHealth applications [19], ii) prioritizing integrated mHealth strategies for UHC [20], and iii) Harnessing mHealth to overcome health system constraints and achieve UHC [21]. The described mHealth and ICT framework – developed by WHO, the Johns Hopkins University Global mHealth Initiative, the United Nations Children's Fund (UNICEF), and frog Design – mainly targets the reproductive, maternal, newborn and child health (RMNCH) in low settings. However, we still need to develop a generic framework for eHealth interventions in health systems to answer the following questions, utilizing a similar approach described in [21]:

- When should eHealth applications be applied within the health systems?
- What functions of the health systems are being strengthened?
- Which health constraints are being overcome?
- How are eHealth applications applied, i.e., identifying technology function, use, purpose?
- Where do eHealth applications interact with policymakers, healthcare providers, payors, and patients?
- To which extent would eHealth be able to realize UHC? This can be achieved through benchmarking the eHealth evidence indictors (either direct or proxy)

of strengthening the health systems against the UHC monitoring indicators.

Building on the proposed need for action described in [1], the health informatics curriculum should also reflect the need of better understanding of the role health systems in overcoming the global health challenges. This will necessitate addressing the different aspects affecting complex health systems, namely, the social, political, economic and environmental factors [6]. Moreover, future health informaticians should be able to evaluate eHealth evidence in health systems, monitor the progress toward UHC, and efficiently conduct health systems and policy research [22].

Furthermore, it is necessary to develop a portal for eHealth evaluation evidence that should be also maintained by an independent and international health informatics organization. Through this platform, best practices in eHealth implementation as well as eHealth evaluation guidelines can be shared worldwide. However, it is recommended to automate the entry process of the best practices to encourage the researchers to add their expertise in standardized-user friendly formats. Additionally, the evaluation guidelines should be automated and provided in an interactive mode to facilitate their understandability and adoption at global scale.

4. Comment by F. Magrabi

It is no longer a question about whether or not transformations of our healthcare delivery systems to improve quality and safety will involve information and communication technology, but rather how best those technologies can be harnessed to meet the needs of patients and clinicians. Evaluation is then central to designing and assessing the effects of these informatics interventions. In this paper Ammenwerth reviews progress towards improving the evidence base for informatics interventions – timely, because these interventions are integral to transformations of care delivery [1].

Ammenwerth, building on previous reviews, provide an up-to-date roadmap from her reflections on the literature and
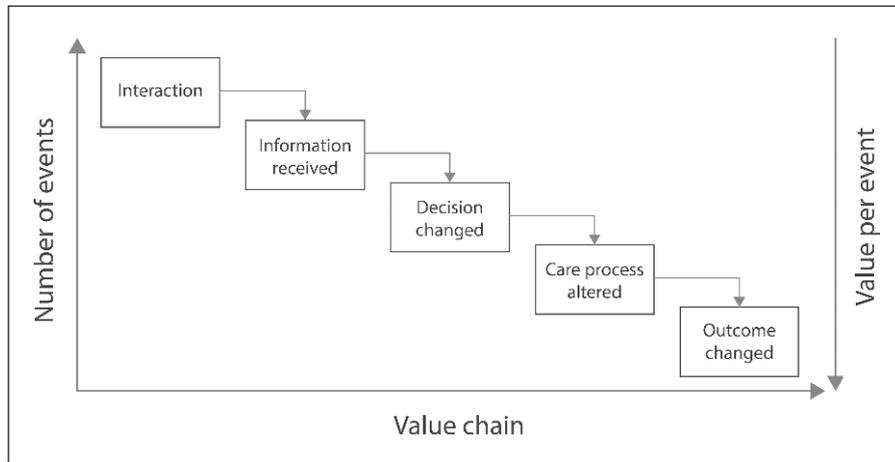
Figure 1   The information value chain: creating and accessing information may not always lead to a change in clinical processes and outcomes because there are many steps in the information value chain that links system use to final outcomes. At any step in the chain the expected utility can be calculated by combining event frequency with event value (or utility). The number of events is higher earlier in the value chain (from Coiera 2015) [25].

her own experiences. For novices, the paper provides an extensive list of references to textbooks and guidelines for designing, conducting and publishing evaluation studies. For those more expert there is a useful report card on international efforts currently underway to address a number of challenges previously discussed in the literature [23, 24].

These include initiatives to: improve the quality of evaluation studies; address publication bias; enhance reporting quality; facilitate easy access to publications; conduct systematic reviews and meta-analyses and develop an evaluation curriculum for informatics trainees. There are also two additional challenges presented, namely those relating to the translation of evidence into practice and post-market surveillance. These issues are by no means unique to health informatics but are shared with the broader discipline of medicine. The paper usefully calls attention to methodologies for synthesising qualitative research including meta-syntheses and meta-summaries.
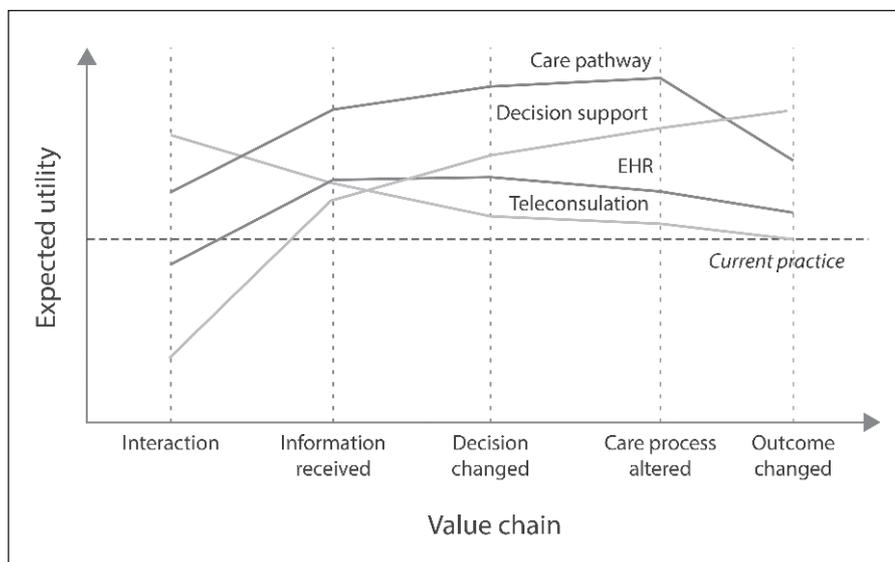

Figure 2   Hypothetical profiles of expected utility for informatics interventions at each step of the information value chain (from Coiera 2015) [25]

While current efforts will improve the conduct and reporting of evaluations this, in itself, is unlikely to generate more evidence about effects on patient outcomes. This is because, as Ammenwerth notes, many informatics interventions usually influence decision-making and care process, and any effects on patients are indirect. For instance, a patient portal may facilitate booking of appointments eliminating the need to call a primary care clinic. An evaluation of this system may show improved efficiency in the process of booking appointments, high utilisation and patient satisfaction but we might find that there is no significant change in patient outcomes. This may be because the portal has made no difference to the quality of care provided by the clinic, which is already very high. Limited evidence about outcomes may therefore indicate a more fundamental problem with our goals and expectations when designing and evaluating informatics interventions. Perhaps we need to reconsider our approach.

4.1 A New Decision-theory Based Framework

Coiera has recently proposed a new decision-theory based evaluation framework which offers a plausible way forward [25]. Informatics interventions are considered as a 'bundle' of technology, process and workflow changes. He asserts that an *information value chain* connects use of technology to final outcomes (▶ Figure 1). The chain is initiated when a user interacts with a system. A subset of these interactions will yield new information, and only some will lead to a changed decision, and only some decisions will see a change in the care process. Similarly, only a subset of process changes may have an impact on patient outcome. Evaluation can be undertaken at each step in the value chain. But, as we saw earlier, a good result at one step may not translate into a good result at the next i.e. improved efficiency in booking appointments via the portal may not have a significant effect on patient outcomes.

At each step in the value chain, the *value of information* is essentially the, "difference between the value of persisting with the present state of affairs and the value to us of

being able to embark on a new decision, influenced by new data". For new data to have a value, the information must be actionable in some way through changed decisions or outcomes. For example, it is possible to measure the value of a clinician interacting with an electronic health record to read the result of a patient's blood glucose test that leads to a change in the management of the patient's diabetes. The *expected utility* of this interaction is calculated using decision theory i.e. by combining *event frequency* (or probability) with *event value* (or utility).

As one progresses down the value chain there is an inherent asymmetry both in the *number of events* at each step and in the *value* of these events which needs to be taken into account when designing and evaluating interventions. For instance, the number of times the clinician interacts with the EHR is greater than the number of times that interaction leads to a changed decision. And not all changes in decisions will lead to better outcomes. In general, the number of events is usually higher earlier in the value chain, while the value of individual events tends to be higher further down the chain (▶ Figure 1). Using this approach Coiera proposes hypothetical profiles of the expected utility for a range of informatics interventions at each step of the information value chain (▶ Figure 2). For example, introduction of decision support can provide information that directly improves clinical outcomes. In contrast, teleconsultation might improve the quality of interactions but might not provide additional information over current practice that changes clinical decisions.

Compared to previous evaluation frameworks Coiera's approach considers informatics interventions at a more fundamental level, in terms of the information they provide and the many steps through which that information needs to transition before changing outcomes [26–28]. It is grounded in decision theory, which is foundational to our discipline of health informatics, and offers a simple yet extremely powerful way of quantifying the expected utility of the interventions we design and evaluate. Validity of this framework in term of the effectiveness for design and evaluation, and the ways in which it can be ap-

plied, at each step of the information value chain, are areas for further research.

4.2 Conclusion

Ammenwerth's timely review has highlighted an urgent need to reconsider our approach to evaluation which is critical to designing and evaluating informatics interventions. As she explains: evaluation directly supports decisions about interventions and so it seems highly reasonable to apply decision theory to the task.

5. Comment by A. Moen
Evidence for Next Practice

Building from sound evidence is an obvious responsibility and mission for any field. In such pursuits questions, intentions and chosen perspectives will distinguish contributions and shape the accumulating body of knowledge and experience that constitutes valid evidence for advancement of health informatics. I choose "information in medicine" to secure benefits for clinical practice, professional accountability and patient safety, as a starting point.

The societal mandates for health care with strong commitments to do no harm, and the dynamic features of the judgment based, formal and more informal, handling of information by patients, populations, health providers, or in health domains differentiate health IT from "commonplace" information systems. Driving our evolving field are efforts to articulate, represent, evaluate, aggregate and disseminate content; data, information, knowledge and wisdom, in our practices over time and for different purposes [29]. Professional, contextual, cultural and personal knowledge and expertise paint a complex picture of health care, and call for a variety of up-to-date resources for clinicians, patients and their appointed significant others, as well as managers and policy makers. This implies differentiating health IT support according to patient-specific, organization specific and domain-specific activities [30].

In the elaboration of "evidence-based health informatics" Ammenwerth [1] suggests sound evaluation studies as the major strategy moving forward. Evaluations of

existing health IT take us some way to document what happened in any sociotechnical system deploying Health IT. However, relying on "summative and formative" published evidence, from well-designed, published and locatable evaluations studies of Health IT and then aggregated in systematic reviews and meta-analysis [1, p.14], as key resources, leaves significant questions unanswered. Learning from discussions and experiences in evidence-based medicine [31] suggests that seeking foundation for well functioning, evidence-based Health IT is not a trivial or easy activity. Therefore, expanding the perspective and strategies to contribute inputs to "evidence-based health informatics" will be important as we move forward.

The dynamic nature of patient care, variety of treatment alternatives and specific experiences are hard to control, model or fully predict from an information science or computer use perspective. Studies of health IT interventions in fine-tuned, optimized socio-cultural health systems report on guidelines that does not always apply, and partial or too rigid regimes may actually end up detrimental to intended purpose(s). For example, the significance of learned intermediaries [32], adjusting and bending standards to achieve local relevance [33], or reports of unintended opportunity for harm to the safety of patients or professional accountability [34], illustrates such concern. Standardization efforts suggested by health IT experts could contradict patient autonomy and professional accountability to ensure personalized treatment and optimized care for specific health problems.

Therefore, *next practice* requires us to broaden our discussion of "evidence-based health informatics" as we search evidence, and embrace additional content and alternative perspectives. I believe we will be required to differentiate the evidence according to purpose of activities, and concurrently expand repertoires to support patient-specific, organization-specific or domain-specific activities. This implies questions and methods that elicit operating (often robust) strategies and mundane realities of everyday practices of professionals as well as patients and citizens. To do so, we could explicitly assess and document con-

tributions to smoother patient trajectories, for example if health IT lead to changes in time to treatment and required resources, safety, or quality of diagnostic work [35]. I would further argue that we could achieve more when such evidence is transformed for *design* and *planning*, not just presented as reports of implementation and evaluation of existing health IT. This could help mitigate a) evolving, ambiguous, and even contradicting professional knowledge, b) accumulated expertise across constituencies, c) articulate patient experiences, and d) techniques from information science, organizational and management science, or computer use.

Material from additional, still unanswered questions would broaden our evidence for Health IT since insights from design, planning and patient focused efficiency or effectiveness in clinical practice would attend to patient needs, professional differences, contextual cues and situational considerations. Furthermore, seeking methods to document health IT contributions to clinical processes and patient outcomes would complement current sociotechnical analyses, and help us do more "right things right' for patient engagement, professional commitment to personalized, high quality care, safety, and sound resource utilization. Going forward, this would encompass evidence to support the plethora of known, emerging and currently unknown activities in citizens', professionals' or policy makers' next practices and requirements to health IT.

6. Comment by L. A. Moura

I thank the editors for inviting me to comment on Professor Ammenwerth's "Evidence-based Health Informatics: How do we know what we know?". [1]. Let me make it clear that my comments are more motivated by my own experience as a devote health informatics practitioner and my passion for the theme, rather than a scientific approach that, I am sure, will be thoroughly provided by other colleagues.

I have been lucky enough to work on several aspects of "pure" Health and Biomedical Informatics, from designing and implementing devices and systems for im-

mediate clinical use to deploying large Health Information Systems in complex settings. More recently, I became involved in strategies for national and subnational eHealth programs. As such, I have tried to put together best practices that cover all aspects of health information systems deployment and assessment. In particular, I extensively learned from and see great value in the National eHealth Strategy Toolkit published by WHO and ITU [36] as it makes a systematic approach to designing and deploying such strategies.

The successful deployment of Health Information Systems, especially in complex environments, involves many more aspects than those usually covered as part of health informatics itself. Organizational aspects such as investment, strategy, policies, regulation and governance have proven to be key to the success or failure of such initiatives. It seems that, as a community, we are more prone to explain failures than thoroughly assess the overall environment before starting large projects.

Given the complexity of our field, the notion of "evidence" is often replaced by that of "best practice". Any large health informatics implementation project involves change management, project management (PMO), use of standards, training and other factors. Successful health informatics projects have used best practices to develop and manage subprojects for each of these aspects. However, even when those are properly taken into account, it is impossible to be completely sure that success will be attained.

It seems fair to say that health informatics is in its infancy, as a science. Not until recently have we started evaluating the uses of health informatics. Reports of unsuccessful projects in health informatics are obviously useful for us to learn what to avoid. However, in our field, success is clearly more difficult to identify than failure. Failure can happen at very early stages of a project. It suffices that just one out of several components fails. Success, however, needs a great deal of time to be recognized. When considering the impact of health informatics to patient treatment and outcomes, identifying success is certainly even more challenging, as years may be required to gather solid evidence of success. Getting

data to define a baseline before starting a health informatics project is often challenging, as systematic data collection is frequently the aim of the new initiative and thus data may not be available at the time of deployment. Because of that, we tend to measure partial results such as increases in productivity, in availability of services or in reach, as indicators of better health care delivery and, axiomatically, of better care and better health.

I agree with Elske that our community needs to create a proper framework for gathering and distributing information on evidence in health informatics. My understanding is that this needs to recognize the importance of the environment around each deployment. We need also to encourage serious research around the impact of the environment on success. It has been shown that innovation in strategies brings, in the long run, much more value than innovation in products or services [37]. In my view, this fits as a glove to health informatics. When dealing with large health informatics projects, we have learned to understand the need for infrastructure, capacity building and even change management, but we often overlook aspects such as governance, investment, will to change and emotional room for change, stakeholder analysis, policies and regulation. For health informatics to be closer to a science our community needs to embrace the challenge of considering all these aspects in our research.

As president of IMIA, I really hope we can promote an environment for this discussion to happen. I thank Professor Ammenwerth for her paper. It gives us motivation to carry on promoting this essential discussion.

7. Comment by H. A. Park

In the beginning, information technology (IT) in healthcare was introduced mostly by the hype from academia, the IT industry and government based on the assumptions, that health informatics applications reduce overall cost of healthcare, improve multiple inefficiencies in the healthcare system and improve the quality of healthcare, which in turn would improve patient safety. As use

of health informatics applications is becomming widespread, decision makers are seeking best evidence to justify their decision to introduce health informatics applications. Unfortunately, there is a lack of evidences because what, how, and when to measure benefits, of health informatics applications were not well defined.

Dr. Ammenwerth [1] discussed challenges and needs for action to build evidence to support a decision with regard to the selection, implementation, and use of health informatics applications from evaluation studies to systematic review and meta-analysis, and finally translation into practice. They are quality of evaluation studies; publication bias; reporting quality of evaluation studies; identifying published evaluation studies; systematic reviews and meta-analyses; training health IT evaluation experts; translating evidence into health practice; and post-market surveillance for unintended consequences.

Key to evidence-based health informatics is a good health information system that is accessible to the authorized users, provides accurate information, and is easy, flexible, and secure to use [38]. Information from a good information system should be understandable, relevant, complete, available, reliable, concise, and timely to the users [38]. However, the information

is not desirable if the solution is more costly than the problem. Thus, the cost of gathering data and processing it into information must be weighed against the benefits derived from using such information.

Dr. Ammenwerth introduced different types of studies to generate evidences for health informatics to for examples, formative or summative evaluation studies, and evaluation studies depending on the life cycle of health IT. There are a wide variety of measures available to evaluate the benefits of health information systems such as user adoption and attitude measures, clinical process measures, workflow impact measures, financial impact measures, and patient outcome measures. The success of health information system implementation can be evaluated by user satisfaction, time required to document the delivery of care, accuracy and completeness of documentation, monitoring the use of transcription services, verbal ordering, COPE by authorized providers, and secure messaging by patients over time [39]. However, evaluation measures to support a decision with regard to the selection, implementation, and use of health information systems should come from the pilots, early use phase, or routine use phase of the life cycle.

I would like to group the evaluation measures published in the literatures by the

key beneficiaries of healthcare IT (healthcare providers, patients, and administer /insurer), and the intended benefits of the health information applications (improve efficiency, improve quality of care, and reduce cost). These benefits sometimes can be mismatched between who pays for the health IT and who accrues benefits from the use of the health IT. One extreme example would be a hospital's implementation of a health IT system that averts readmission. In this case health IT decreases hospital revenues, even though the health IT implementation has a net cost-savings from a societal perspective. Thus, the benefits need to be considered from a different point of views.

The cost of implementing a health IT must be weighed against the benefits derived from using the information system. Implementing a health information system involves significant expenditures. Total costs for a health information system may include the investment to install the system, the costs of maintenance, and the "opportunity cost" for time lost by healthcare providers in learning to use the system and in adjusting patterns of work. Nonmonetary investment may also be an important factor in whether healthcare providers will be able to use the system effectively. One such potential cost in health IT is cost as-

Table 1   Evaluation measures by key beneficiaries and intended benefits

Beneficiaries	Efficiency	Quality of Care	Cost
Healthcare providers	• Number of duplicated or unnecessary diagnostics tests • Reduced use of radiological services	• Nurses' time spent on direct patient care • Percentage of alerts or reminders that resulted in desired action • Harmful drug interactions or allergic reactions to prescribed medicines, • Adherence to recommended-care guidelines	
Patients	• Number of unnecessary visits	• Length of stay • Medication error • Reduction in hospital-acquired complications and infections	
Administers/ Insurers	• Medication turnaround time in inpatient setting • Length of time required to process a lab test or diagnostic image • Prescribing patterns of cost-effective drugs • Prescribing patters of preferred or formulary medications • Increased capability to exchange information		• Administrative costs • Overall cost of providing healthcare • Cost of prescription drugs • Cost of diagnostic tests • Cost savings from shifting prescribing patterns toward generic drugs

sociated with protecting the patients' privacy. Health informatics applications are not desirable if the system implementation is more costly than the benefits.

Even though a health IT does not demonstrate its cost-effectiveness out right, there is a significant potential benefit of health IT that has been recognized recently. That is its role in research on the comparative effectiveness of medical treatments [40]. Health informatics applications generate a substantial amount of clinical data, including medications, laboratory test results, patient problems, allergies, notes, visits, and life style and health behavior items. Once patients' identifying information has been removed and the data have been standardized and assembled in a data repository, these clinical data can be used for research to generate evidence of medical treatments. The depth and breadth of the clinical big data could provide more-comprehensive information about the outcomes of medical treatments than has previously been available. Knowledge gained from the analysis of big data generated by the health informatics applications might not only help make the delivery of services more efficient but also improve the quality of health care leading to better outcomes for the patients.

Dr. Ammenwerth stated in her conclusions that evidence-based health informatics is in its infancy. I hope there will be more evaluations studies on the benefits, and overall impact of health information technology published in the near future, in order to help combat hype with science.

8. Comment by P. Scott

8.1 To Implement, or Not to Implement?

Ammenwerth [1] rightly highlights the disparity between aspirations and evidence. Political expectations and commercial assertions about the benefits of health information technology are typically derived anecdotally or ideologically rather than from scientifically reliable evidence [41]. Clearly, this cannot mean that ambitious innovation in health informatics should be stopped. It is neither reasonable nor necessary for every application to be

rigorously tested in every possible socio-technical context before being 'licensed' for use in the real world.

On the other hand, caution is required when information systems are used to make changes in processes of care. As with innovations in direct care, there are both optimistic and pessimistic approaches [42, 43]. The optimistic school of thought argues that promising interventions lacking definitive evidence may be judiciously implemented, subject to concurrent evaluation of quality, cost and context. This would seem to be a plausible analogy for a health informatics innovation – as long as there is a well-reasoned business case that articulates the rationale for expecting the intervention to deliver net benefits, and the methods by which the impact will be assessed [44].

There are several broader contextual factors that influence implementation practice. Unlike direct care, health information technology (apart from medical devices in the European Union) is an unregulated domain. There is no country that requires minimum qualifications or training for individuals to become health informatics practitioners. There is no legislation or regulation, other than the EU Medical Device Directive, that controls who can develop or sell what health IT products. There are best practice methodologies for project management and change management, but their adoption and the effectiveness of their implementation is subject to organizational policy and competence. Ammenwerth notes that individual health informatics professionals have ethical duties in the conduct of their work, but the relative anarchy of the domain hinders consistent adoption of good practice.

8.2 Evaluation Methodology

The first challenge that Ammenwerth identifies is the quality of evaluation studies. Arguably, most health informatics deployments would qualify as "complex interventions" [45]: they involve "several interacting components", are sensitive to local contextual factors, difficult to assess using experimental methods and often characterised by an opaque causal relationship

between the intervention and the outcomes [46]. The UK Medical Research Council's guidance on complex interventions has much to offer health informatics studies, such as the potential of cluster randomised trials (where the aim is to determine effectiveness, controlling for context [47]) and the need for theory-based process evaluation that exposes the mechanisms of change and their interaction with context and outcomes [48]. The widely adopted 'Theory of Change' is a specific approach to unpack the assumptions, rationale, preconditions, indicators and impacts of a change programme [49], and seems to offer a promising method for health informatics deployments. Perhaps the GEP-HI guideline [50] should be expanded to incorporate principles from these sources.

A further weakness of many health informatics studies, that Ammenwerth does not directly highlight but which is implicit in section 4.5, is the virtual absence of measurement studies to validate instruments and outcome measures [51, 52]. Without such standardisation, the reliable application of meta-analysis in health informatics remains an elusive goal.

As a final observation, it might be suggested that a 'lite' method could be proposed for projects that lack formal evaluation funding. This should become part of the business case development process, building on the 'benefits realisation' plan in project management terminology [53] How can the programme funders know their anticipated business benefits have happened (and not been outweighed by unintended consequences) unless they have some clear method of assessment? Health informatics as a discipline would benefit enormously if the implementation experience of every project were captured and shared. This need not be an onerous or expensive add-on to project costs, but proportionate to the expected return on investment. This is currently lost evidence, and we are poorer for that loss [54].

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