

# Evolving Health IT Systems Evaluation: The Convergence of Health Informatics and HTA

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**Abstract.** The credibility and reliability of health IT systems as a means of achieving changes towards safer and cost-effective care have been questioned for over two decades due to the lack of methodologically strong evidence. As national level adoption and implementation of health IT are becoming widespread across the EU and globally, but are also being offset by adverse reports, the demands for evidence become more pronounced and the stakes higher. The adaptation of HTA (health technology assessment) methodology as a means to address gaps in health IT evidence production has been proposed repeatedly and tested in the field of telemedicine services. HTA has in many ways run a course parallel to that of health IT, while in certain respects attaining more clear achievements. This contribution investigates aspects of a bilaterally beneficial relation between the two disciplines using three lines of exploration: the methodological goodness-of-fit between health IT evaluation and HTA; the solutions each has proposed to the problem of producing high quality evidence in reduced amount of time; and the way each has addressed the strengthened role and position of patients. The analysis demonstrates areas of convergence between health IT and HTA. It also highlights topics which would need to be jointly addressed in the process, such as innovative and high quality data collection and analysis, inclusion of patient reported outcomes and patient safety, and transferability and generalizability of findings. In closing, it takes a glimpse of the challenges emerging as a result of the progress at the cross-roads of medicine, science and technology.

**Keywords.** Medical informatics, biomedical technology assessment, outcome and process assessment, healthcare, policy.

## 1. Introduction

*“Information technologies (IT) are often put forward as important instruments to improve quality and efficiency in health care. However, the evidence is lacking of the specific contribution of these technologies to outcome and efficiency improvement. ... A major cause for lack of evidence of effectiveness is the methodological difficulties in establishing this evidence. ... What is needed in this area is consensus on methods and criteria to be applied in assessment, similar as in e.g. evaluation of drugs or diagnostic devices. This consensus is needed both for the industry, as well as for the IT users, at various levels” [1].*

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These words could have been written today, but surprisingly they are already twenty years old. High hopes and expectations have been placed on health IT as a major driver of changes that would make healthcare practices and systems better and safer, in an efficient and cost-effective manner. With financial pressures rising, populations and work forces both aging but also becoming increasingly mobile, the need for validated, proven and transferrable health IT solutions becomes an imperative, particularly from the perspective of decision makers. Meanwhile, Health Technology Assessment (HTA), although relatively young as a discipline, has established its position as a methodology for high quality, research-based evidence generation. In turn, such evidence forms the basis supporting the decisions necessary for ensuring health system sustainability. Could HTA hold the key to improving the quality, reliability and cost-effectiveness of health IT?

Until now, the subject has been approached on the basis of what health IT could and should learn from HTA, particularly in order to be able to produce robust and convincing evidence of its worth. The additional dimension this contribution aims to bring to the existing discourse is the complementary side of the image, i.e. what HTA can gain from health IT and what are the requirements for this to be achieved. In other words, the contribution approaches the subject of discipline synergy as a mutually beneficial process, with a particular emphasis on methodological issues.

After a short introduction covering the evolution of the health IT domain (section 2), we will explore the following three questions:

- *How good is the fit between the two disciplines? (section 3)*

We explore the question of degree of fitness through a review of selected HTA studies of key health IT applications, in order to demonstrate the messages which have emerged through the application of HTA methodology. Conversely, the experiences gained and lessons learned through the large scale testing of the Model for the Assessment of Telemedicine (MAST model) [2] in several EU-funded projects provide indications on health IT's experiences with HTA approaches – MAST being the first concrete instrument to result from adaptation of HTA methodology instruments to telemedicine evaluation.

- *How have the two disciplines addressed the challenge of quick production of high quality evidence? (section 4)*

Technology and change are deeply intertwined and as choices amongst interventions increase and resources diminish policy makers demand reliable evidence within a shorter turn-around cycle. We go further into methodological perspectives by examining examples of the instruments each of the two fields has developed and proposed in order to address the problem of rapid delivery of quality evidence.

- *How have HTA and health IT related to the role of patients? (section 5)*

Making the patient a (potentially equal) partner in the production of evidence goes hand in hand with the trend of patients taking a central role in the definition and implementation of their care plans. The efforts undertaken earlier in each of the two fields are raised to a different dimension of prospects and challenges brought about by the possibilities of own data production and analysis facilitated by latest technologies such as health apps and sensors.

Finally, we will sum up the conclusions to be drawn from the parallel and intersecting course of the two fields so far and attempt to look at future developments, including drawing up a list of proposed work topics for those interested and motivated to explore further the synergies between health IT and HTA.

## 2. Setting the scene

### 2.1. Definitions of the health IT domains and their evolutions

Health IT, just as any area of activity relying heavily on technology, is in a constant state of change, which is also reflected in the abundance of definitions over time. The scientific discipline and corresponding term of Medical Informatics dates back to the 1970 and was seen as belonging to the area of applied informatics research [3]. According to van Bommel, *“medical informatics comprises the theoretical and practical aspects of information processing and communication, based on knowledge and experience derived from processes in medicine and health care”*. [4]

The expansion to the more general term ‘Health Informatics’ reflects the need to capture the increasingly multidisciplinary practice of medicine, as well as the growing interest in a universal approach to health and well-being. The concept of eHealth – a newer arrival – was if not born, at least strongly supported by policy making such as the European Commission’s hallmark eHealth Action Plan of 2004 [5]. The scientific community also invested considerable energy in demarcating the field, with a series of articles published on eHealth definitions about a decade ago and the exploration still ongoing [6].

Following the drive of technology evolution through mobile devices, we are living already in the mHealth era [7]<sup>2</sup>, which presents some interesting new features, namely the increased practical ability to focus on individuals rather than organisations, decentralization and ubiquity [8].

It is important to also take a look at the definitions related to telemedicine, since it has partly been a distinct field all along, as well as the first concrete test-bed for HTA methodology application in IT. Taking once again the view of the policy makers, we see the European Commission understanding the element of distance between patients and healthcare professionals as the defining feature of telemedicine and telemonitoring [9]. From the UK then we have the emergence of two related, but still distinct terms: “Telehealth” and “Telecare” [10]. What differentiates telehealth from telemedicine is its inclusion of preventive, promotive and curative aspects. Telecare on the other hand is rather close to telemonitoring if viewed specifically in the context of home care, but including wider daily living aspects.

### 2.2. The imperative of evidence

*“The major finding from reviewing the empirical evidence – which is of variable quality ... is that there is very limited rigorous evidence demonstrating that these technologies actually improve either the quality or safety of healthcare.”* [11]

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<sup>2</sup> See also: B. Vallespin et al., Ensuring evidence-based safe and effective mHealth applications, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

Other than the fact that it is a persistently recurrent finding, why is the lack of evidence on health IT a major problem? A large part of the answer is to be found in the implications of health policy making, particularly on the EU-level, where eHealth uptake has been consistently promoted. The 2004 eHealth Action Plan has been followed by a series of ministerial conferences and decisions (e.g. Communication on Telemedicine & large scale pilots, eHealth Task force report Redesigning Health 2020 etc.) and more recently the new eHealth Action Plan until 2020 [5, 9, 12, 13].

The general and increasingly stronger trend is the transition from hospital-based care to extramural care with shortened periods of hospitalization, combined with the increased transfer of responsibility to the patient/citizen. The degree of collaborative work and the variety of actors involved to realize these plans essentially make health IT an indispensable tool [14]. Moreover, the advent of cross-border care brings along new demands and challenges or expands old ones to a new scale [15]; either way the solutions are unimaginable without health IT.

However, the fact that these policy and practice shifts towards a dependency on health IT are being espoused without evidence of its supporting quality or safety of healthcare is alarming – hope-based policy is no substitute for evidence-based policy and would not be tolerated in other aspects of health practice. Promoting the use and integration of technologies cannot be done without simultaneously preventing or mitigating the accompanying risks, such as diversion of valuable resources or causing actual harm. Reflecting these concerns, the WHO saw the ‘rigorous evaluation of eHealth’ as a necessary requirement and among the recommendations and identified action items [16] listed the following priorities:

- Identify and adapt, where necessary, robust and relevant tools for the evaluation of eHealth;
- Develop simple and pragmatic tools to enable decision makers to review and select eHealth systems, based on appropriate evaluation-generated evidence of impact, and potential for scalability and sustainability;
- Develop principles and recommended practices to evaluate and assess eHealth, with a view to increasing transparency, accountability and integrity.

A similar approach can be seen in the eHealth Stakeholder Group statement concerning telemedicine: *“Benefit and added value of telemedicine services should be systematically monitored and evaluated to allow for justified inclusion into guideline supported clinical practice.”* [17]

In the quest for robust evidence and methods to obtain it, it is easy to see why HTA is a good candidate source. According to the HTA Glossary [18], Health Technology Assessment has been defined as follows:

*“The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.”*

The glossary further notes that *“HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods”*.

The discipline focuses on the assessment of individual health technologies in a manner useful to decision makers, combined with the adoption of a global perspective: ensuring that the medical, social, ethical, and economic implications of the development, diffusion, and integrated use of technologies are addressed. On the other

hand, the technologies usually being the subject of HTA analysis are different in nature from health IT. In the view of many, eHealth/health IT applications are socio-technical systems.<sup>3</sup> There is a constant interplay between the technology and human/social factors in the environment of implementation, which brings about changes in all involved (systems, humans, organizations, services). Further, health IT systems are usually a combination of technologies and services, or a means supporting innovative service provision. Essentially, before progressing with proclaiming HTA as the method of preference in health-IT evaluation we need to address the first of our questions.

### **3. How good is the fit between the two disciplines?**

We shall begin with exploring how well the HTA approach transfers to a domain with the features of health IT. Through utilizing Ohtanen [19], an online database of HTA reports maintained by THL [20], we have selected among the featured health IT/eHealth related HTA studies examples focusing on popular and promising health IT applications, such as: early warning and handover systems, Computerized Physician Order Entry (CPOE), medication management, and treatment of psychiatric disorders. The main focus is on the findings and conclusions of the studies, in order to gain insight on what they have revealed for health IT applications and their developers and how well they have addressed socio-technical matters.

#### *3.1. Health technology assessment of the use of information technology for early warning and clinical handover systems*

The study conducted by the Irish Health Information and Quality Authority (HIQA) [21] examined clinical and cost-effectiveness of IT for early warning and clinical handover systems. It used the methodology of a systematic literature review. In addition, benefits and investment requirements were estimated and key themes for effective robust implementation were outlined. The results indicated the presence of some evidence that implementation of electronic early warning systems has contributed to reduced mortality rates. However, the quality of studies on the clinical effectiveness of these systems was hampered by poor study design, small sample size and unspecified follow-up, while cost-effectiveness data was minimal. Due to the significant differences in the models of healthcare provision between the US and Ireland the ability to generalize return-on-investment findings to the Irish context was deemed rather uncertain.

On the socio-technical aspect, the review found clinicians' perception of improved patient safety to be positive, due to better handover communication processes. However, a face-to-face element to clinical handover was identified as an important part of patient care. The review also underlined the importance of strong leadership and adequate staff training levels<sup>4</sup> and pointed out the significant capital investment

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<sup>3</sup> See also: B. Kaplan, Evaluation of people and organizational Issues – Sociotechnical ethnographic evaluation, in: E. Ammenwerth, M. Rigby (eds.), *Evidence-Based Health Informatics*, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

<sup>4</sup> See also: E. Hovenga et al., Learning, training and teaching of health IT and its evidence for informaticians and clinical practice, in: E. Ammenwerth, M. Rigby (eds.), *Evidence-Based Health Informatics*, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

required for implementation. The study recommended that in order to maximize the effectiveness of implementation, the employment of human factors analysis would be instrumental in creating work environments supportive of productivity, while minimizing risks to patient safety.<sup>5</sup>

### 3.2. Medication management and IT

The objective of the study by McKibbin et al. [22] was to review the evidence on the impact of health IT on all phases of the medication management process (prescribing and ordering, order communication, dispensing, administration and monitoring as well as education and reconciliation), to identify the gaps in the literature and to make recommendations for future research.

Most included studies evaluated changes in process and outcomes of use, usability, and knowledge, skills, and attitudes. Most showed moderate to substantial improvement with implementation of IT-enabled medication management. Although the field of IT-enabled medication management is well-studied, a closer examination of the literature showed that the evidence is not uniform across phases of medication management, groups of people involved, or types of medication management. The application of health IT to medication management was assessed as having the potential to improve processes; however, shortage of clinical and economics studies and limited understanding of sustainability issues were also identified.

With regard to socio-technical parameters, the study showed that physicians were more often the subject of evaluation than other participants. Even though other health care professionals, patients, and families have an important role to play they are not studied as thoroughly as physicians. These non-physicians groups often value different aspects of IT-enabled medication management, have diverse needs, and use systems differently.

### 3.3. Computerized Physician Order Entry – effectiveness and efficiency of electronic medication ordering with decision support systems

Prescription is an important step within medication management, and health IT in the form of Computerized Physician Order Entry/Clinical Decision Support Systems (CPOE/CDSS) has been specifically designed to support it. The study [23] examined the effects CPOE/CDSS on medication errors. The study found that CPOE/CDSS systems are able to reduce the rate of errors when ordering medications.<sup>6</sup> However, using the data available, it could not be assessed conclusively to what extent CPOE systems or the reduction of medication errors has an impact on the Adverse Drug Event (ADE) rate – a clinically more relevant element - or on mortality. Regarding the cost-benefit-ratio from the hospital perspective, the two qualitatively best economic studies arrived at contradictory conclusions. A positive cost-benefit-ratio for any individual hospital cannot therefore be assumed, particularly as the results cannot be generalized.

Prospective, systematic multi-centre evaluation studies with clear methodology which include an analysis of the user-friendliness and of social and technical aspects of

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<sup>5</sup> See also: F. Magrabi et al., Health IT for patient safety and improving the safety of health IT, in: *ibid.*

<sup>6</sup> See also: H. Seidling et al., Evaluating the impact of health IT for medication safety, in: E. Ammenwerth, M. Rigby (eds.), *Evidence-Based Health Informatics*, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

the system are needed. A detailed description of the system used and of the hospital evaluated is essential. If possible, costs and cost effects should be surveyed and documented transparently. The authors noted that a quantitative evaluation of the economic effects of implementing a CPOE/CDSS system in (all) hospitals in a large country would be too far-fetched: the reliability of study results regarding relevant endpoints was found to be still limited. Conclusions in regard to another context are only possible when data presentation is highly transparent, enabling local assessment of transferability of evidence. Structured interviews at selected hospitals with and without CPOE/CDSS systems would generate important input and help to assess the need for further research.

### *3.4. Telehealth Services for the Treatment of Psychiatric Issues: Clinical Effectiveness, Safety, and Guidelines*

The study conducted by the Canadian Agency for Drugs and Technologies in Health [24] analyzed the reported clinical effectiveness and safety of tele-psychiatry. It accepted for inclusion seven studies in total, including two systematic literature reviews, two randomized controlled trials and three clinical practice guidelines. One of the two analyzed systematic reviews reported that very few studies have examined the effectiveness of tele-psychiatry in improving the outcomes for patients or clients. Therefore, although positive outcomes have been reported for the management of depression, post-traumatic stress disorder, bulimia nervosa and psychosis, the evidence was not enough to support strong conclusions about effectiveness. Tele-psychiatry may be comparably effective and safe; and may be a feasible alternative for making tele-mental health services available in resource constrained settings.

On the socio-technical dimensions, the study places emphasis on two issues, in order to promote effective management of emergency situations when providing tele-mental healthcare services: a) ensuring that both patients and staff at the point of care are familiar with emergency protocols and procedures specific to each of the tele-psychiatry services and environments in which care is provided, and b) that staff have had appropriate training on the procedures and techniques.

### *3.5. MAST model: adapting HTA methodology to health IT*

Having explored the view of health IT from the HTA perspective, now we reverse our observation angle. We review the experiences from the application of the MAST model [25] – the first tangible tool born out of an effort to adapt HTA methodology to the needs of a health IT area. MAST was developed in the context of an EU-funded project (MethoTelemed) [26] that aimed at developing an evaluation framework for telemedicine applications, based on the principles of the HTA Core Model [27]. Its creators have described it as “*A multidisciplinary process that summarizes and evaluates information about the clinical, economic, organizational and socio-ethical issues related to the use of telemedicine, in a systematic, unbiased and robust manner*” [27].

The first large scale testing and validation of the MAST model took place in the context of the Renewing Health project, a study of telemedicine services covering almost 7,000 patients across nine EU regions [28]. The study also utilized know-how of the UK National Health Service Whole System Demonstrator project, in assessing patients’ perceptions with the same 22-question questionnaire [29]. From the

experiences reported on the methodological aspects of assessment [30] it is important to note some key points:

- Economic aspects are difficult to assess in a transferrable manner because of their dependence on a deep knowledge of the organisation of healthcare and reimbursement systems at the location of implementation.
- Organizational aspects are affected by the availability of technology or skills to master the technology which in turn might differ across countries;.
- The main problem within transferability of assessments is the general lack of interest within the field, leading to limited dedicated local resources. There is no strong tradition within the field of transferability or generalisability on methodology or reporting.
- Even though MAST can produce useful information for assessing a telemedicine application, its applicability is limited when it comes to evaluating a new, immature application [31].

The overall impression of applying MAST, based on the questionnaire answers of the 11 cluster or pilot leaders in the Renewing Health project, was that it is a valuable framework. Challenges included problems in obtaining scientific and rigorous knowledge from local sites, as well as assessment of ethical and legal aspects. Both the legal framework as well as the perception on the delimitation between legal and ethical issues, appeared to vary across countries/regions. A practical proposal to address the latter problem is explicitness and transparency, by means e.g. of a description of the legislative references and how they were met in the context of each specific project.

Additional value generated by the Renewing Health application of MAST has been the accompanying guidance documentation generated (concerning data collection, analysis and reporting of results) as well as the expertise attained locally [32]. Following Renewing Health, various national and international telemedicine studies in Europe, some of them still ongoing, have proceeded to use MAST as the framework for assessment. Of particular interest is the extension and adaptation of the model to cover aspects of social and healthcare integration (such as in the projects SmartCare and CareWell) [33, 34], as well as the application of the MAST model in accordance with methodologies of the HTA field (recommendations of the International Society for Pharmacoeconomics and Outcomes Research Good Research Practice Task Force on Prospective Observational Studies and the STROBE statement) [35].

#### **4. How have the two disciplines addressed the challenge of quick production of high quality evidence?**

Change is a typical feature of the evolution phase of a health IT, as defined by Brender [36], according to whom the evolution phase starts when *“the complete IT solution has achieved reasonable stability (with regard to faults and adaptation) of operations and when actual new developments or major revisions are being started”*. Generally in the field of health IT, innovation and speed are desirable properties, giving rise to continuously changing technologies.

As a result, any form of evaluation and assessment activity has often been perceived as a hindering factor. Even more so, HTA methodology traditionally comes into play only after a technology has matured enough and evidence has been gathered

that can inform decision making. How feasible is it to align these needs and traditions in the best way in order to achieve the desired development and implementation of evidence-based health IT? Can the newly developed Rapid Assessment methodology of HTA provide a solution to the challenge of evolving systems evaluations? What respective trends can be detected on the side of health informatics?

Let us begin by taking a look at what Rapid Assessment HTA methodology is about. Rapid Relative Effectiveness Assessments (REAs) are assessments of a specific technology within a limited time frame in comparison with one or more relevant alternative interventions. (Relative) effectiveness focuses on events occurring under the usual circumstances of health care practice, as opposed to (relative) efficacy, where observations are produced under ideal circumstances [37]. A REA covers generic research questions (i.e. issues) considered most relevant for four different applications each focusing on the assessment of specific types or uses of health technologies: pharmaceuticals, diagnostic technologies, medical and surgical interventions and screening technologies

The first published version (V3.0) of the HTA Core Model® for Rapid Relative Effectiveness Assessment (abbreviated as ‘Model for Rapid REA’) was developed for pharmaceuticals only with the intention to produce a rapid assessment within a limited timeline [38]. The driver was EU countries’ legal obligations in assessment of technologies or for the purposes of pending coverage decisions. The latest version of the Model (V4.1) (public consultation of which has been recently completed) has been extended to cover also applications for medical and surgical interventions, and for screening and diagnostic technologies. The aims are three-fold: to improve the applicability of HTA information in other (e.g. national or regional) HTA projects, to enable actual collaboration between HTA agencies by providing a common framework for the production of rapid Relativeness Effectiveness Assessments, and to avoid duplication of work.

The ‘Model for Rapid REA’ is based on the HTA Core Model® [27]. But where the Core Model® organizes study-relevant information into nine domains, the Model for rapid REA – in search of time savings – covers only the first four domains<sup>7</sup> and within these domains only a subset of issues. In addition, and because the objective is to share commonly required elements of information, only information that is considered both important and transferable is collected.

The remaining five domains (i.e. on costs, ethical, legal, social and organizational issues) are excluded as highly context-dependent topics and hence areas of limited transferability. Instead, a checklist is supplied for a quick assessment of possible relevant issues emerging in these domains which would be justifiable to address. Relevant assessment elements from these four domains may be selected from the HTA Core Model®. Pre-established problems/issues, with regard to ethical, organisational, social and legal aspects, which are common to the technology to be assessed and its comparator(s) will, as a rule, not be addressed, as it is not to be expected that the addition of a new technology will lead to changes. To date, several studies have been published based on the application of the REA Model [39, 40].

The attempt to speed up the evaluation process is visible also on the side of health informatics, although the context and driving forces partly differ. Both demonstrative examples come from the United States, where political will and its translation to

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<sup>7</sup> Description and technical characteristics of technology (TEC), health problem and current use of the technology (CUR), clinical effectiveness (EFF) and safety (SAF).

legislation have lately been boosting the wide-scale implementation of EHR (Electronic Health Record) systems. Time pressures, combined with the high-speed change of the implementation environment, generate the need for new approaches to evaluation. It is also perceived that more rapid evaluation will also increase relevance and thus make the translation of results into policy and practice more likely.

Drawing on the tradition of anthropology and its mixed-method approaches to evaluation<sup>8</sup>, McMullen et al. [41] developed a rapid assessment methodology for clinical information systems, intended to be flexible enough as to address the needs and characteristics of different healthcare practice settings. Application of the method in the assessment of clinical decision support systems has provided already interesting results, by making explicit critical areas of unanimity and even more so difference of opinions among vendors and users (on usability, training, metrics, interoperability, product use, and legal issues) [42].

Glasgow and colleagues on the other hand [43] have investigated the possibilities offered by implementation science approaches, selecting four candidate models (the Evidence Integration Triangle; the Expanded Chronic Care Model; the Health Literate Care Model; and Reach Effectiveness Adoption Implementation Maintenance model RE-AIM) and applied their methodology in several studies [44, 45]. The authors have acknowledged the potential for applying HTA approaches to rapid evaluation of health information systems and have also drawn attention to the need for a stronger role of patients in health information systems evaluations, by making concrete proposals for the incorporation of patient-reported outcomes in electronic health records [46]. The latter brings us to our next topic, the role of the patient in HTA and health IT evaluation approaches.

## 5. How have HTA and health IT related to the role of patients?

Health IT developers and scientists as well as the HTA community have each in their own ways approached the subject of the patient taking up a different, more defining and determining role in modern healthcare delivery. As mentioned earlier, increased responsibility of patients for their care has also become an essential component of many healthcare policies. It is therefore relevant to explore whether there is a shared view and vision of the role of the patient between the two communities, identify what has been done in practice to achieve it and what could be the next steps.

Health informatics has had a long and difficult road in establishing successful relationships with health IT end users who, in most cases have been healthcare professionals, rather than patients [47]. The attention to patients and their needs, as well as the consideration of possible means for better engaging them has been constantly on the rise for over a decade<sup>9</sup>, nevertheless the focus is still more on the design rather than the evaluation side of health IT. And when it does come to

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<sup>8</sup> See also: P.J. Scott et al., Mixed methods: a paradigm for holistic evaluation of health information system, in: E. Ammenwerth, M. Rigby (eds.), *Evidence-Based Health Informatics*, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

<sup>9</sup> See also: L.L. Novak et al., Realizing the potential of patient engagement: Designing IT to support health in everyday life, in: E. Ammenwerth, M. Rigby (eds.), *Evidence-Based Health Informatics*, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

evaluation, there is still some way to go in order to see results of health informatics applications use on the level of patient (relevant) outcomes [48].

The trend is however there [49] and this could be yet another input area from HTA to health IT: the engagement of patients through patient reported outcomes. Systems built by eHealth researchers and developers should take into account the accumulated experience and available tools on the side of the HTA community, as well as existing information on types of data required [50].

The complexity and challenge of accepting and engaging patients as equal stakeholders, essentially a major paradigm shift, is demonstrated by the fact that, in spite of the consistent and long-term commitment of HTA researchers to ensure the representation of patient priorities, a lot remains to be done. A 2010 report [51] targeted at clarifying the views of patients and their organisations towards HTA, as well as the understanding of various stakeholders, concluded that “*patients are ignorant about HTA, and regard the process as complex, and often beyond their comprehension*”. Greater involvement, more transparency and heavier patient influence are among the desired changes.

## **6. Working towards synergy**

Having come full circle, we can now review the key messages that have emerged in answer to the three questions which guided us in this journey.

### *6.1 Goodness of fit between the two disciplines*

The concern as to whether HTA can address successfully the socio-technical dimension of health IT at least at first instance would not seem completely justified; HTA studies have explicitly brought forward socio-technical dimensions in which health IT implementations could and should invest more and have also proposed the means for doing that. Nevertheless, that is not to say that there are no differences in the type of technologies which have traditionally formed the bulk of work for each discipline. In that respect, the disambiguation of each field’s targeted technology characteristics, the identification of its particularities and a harmonized means of describing it, also constitute an area where further work will be required in order to bring HTA and (evidence-based) health informatics closer together.

The application of HTA to health IT systems keeps returning to the need for improvement of quality and reporting of studies. The good news is that tools to support the task are available [52, 53] and the challenge remains to ensure their uptake and implementation among health IT researchers.

### *6.2 Addressing the balance of speed and quality in production of high quality evidence*

Both disciplines have explored methods for rapid evidence generation, while preserving high quality standards. Experiences from their application have pinpointed transferability and generalizability of findings as challenges shared by both domains. Transferability was found to be one of the weak areas in the validation of MAST and it is an area that HTA REAs have addressed by trying to avoid the inclusion, if possible, of the most controversial assessment domains such as those of ethical and legal aspects.

Transferrable and more generally applicable results constitute such key potential benefits of coordinated evaluation that they still deserve thorough analysis and investigation. In addition to being tested, the REA proposed approach of selective inclusion can also be considered. Ethical principles do also have universal dimensions, codes of conduct have been internationally agreed at least for some areas of activity, legal frameworks can be developed and managed on the international level and organizational issues present also internationally. Moreover, flagging up of key ‘hot spot’ issues which will need to be addressed within the local context of health system, law, and ethics of health care delivery will be helpful, since the solutions can only be found locally.

Overall, the areas of comparative efficacy and effectiveness assessment, in their traditional but even more so in their rapid form, also constitute a meeting point for HTA and health IT – the shared interest being the collection of relevant data. At the core of the data collection process are EHRs – Electronic Health Record Systems. Relative efficacy and the ‘ideal’ use circumstances of clinical trials have constituted the focus of many research and development health informatics projects [54-56]. The other major source of observational data is patient registries appropriately termed as the “goldmine” of healthcare [57] – a recognition of the value engrained in extensive collections of curated longitudinal patient data. Paradoxically perhaps, but largely due to historical reasons, a major limitation of registries is the currently low uptake and utilization of IT in standard operations. In the EU context the problem is being addressed on several complimentary levels though a collaborative effort of the European Commission and several Members States (the PARENT Joint Action) [58], aiming at ensuring high quality and interoperable electronic registry data. Moreover, collaboration with the EU HTA community has begun, in an effort to clarify and address the data needs of HTA from electronic patient data collection systems [59].

### 6.3 The role of patients in evaluation

Focusing attention on the preferences, experiences and perceptions of patients is one of the important pathways in the future development of both disciplines, including among others the incorporation and utilization of patient reported data as part of regular data collection and analysis processes both in healthcare services, as well as in statistics and research [50, 60, 61]. In addition to the action points raised earlier, yet another area of particular interest from the perspective of patients is that of safety, where HTA and health IT should also seek synergies and build jointly on their existing achievements.<sup>10</sup>

The Safety (SAF) domain of the HTA Core Model covers “...*the direct and indirect harms of a technology for patients and staff and how to reduce the risk of harms. There is usually a spectrum of known and unknown harms, which can be intended or unintended, of different seriousness, and dose or time dependent*”. In the context of health IT, the element of safety can be viewed from at least two different sides:

- a. development of systems for recognition and identification of patient harm;

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<sup>10</sup> See also: F. Magrabi et al., Health IT for patient safety and improving the safety of health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

- b. follow up of the safety profile of health IT applications themselves, an area that presents its own set of challenges. Nevertheless, steps are being taken such as the Health IT Safety Roadmap in the US and the focus on engagement of patient as partners of patient safety initiatives [62, 63].

## 7. Emerging Challenges

As technology keeps evolving, new challenges lie ahead when seeking synergies between health IT and HTA. Two such upcoming areas are direct to consumer digital health technologies, and modelling tools for personalized medicine.

The former, part of the mHealth area, are suffering from the same shortage of meaningful outcomes and means for quality control as many other health IT applications before them [64] (see also *Chapter 20: Ensuring evidence-based safe and effective mHealth applications*). In addition, technologies such as health and well-being apps have a very rapid development and evolution cycle, combined with very localized implementation setting [65]. Applying or extending HTA methodology to cover this domain will not be an easy task. On the other hand, there are once more gains expected for both sides: it is in seeking clinically meaningful endpoints that HTA turns to direct data collection from the patient rather than relying on the interpretation of clinicians regarding the degree of success in treatment outcomes. mHealth opens new routes precisely for that sort of data gathering.

While the science and practice of medicine move towards personalized, preventive and integrative solutions, also the methodology of assessing health technologies will have to keep abreast with these developments [66]. As researchers involved in the Virtual Physiological Human project have discussed, the application of HTA in a field based on predictive computer modeling will need to take into account two additional elements: a) the technology's possibility to revolutionize currently applied clinical guidelines; b) the extension of the assessment to Research and Technology Development (RTD) policymaking, i.e. decisions made during the development of the technology itself. The proposed solution is based on the introduction of technology readiness levels throughout its lifecycle.

Taking stock of the broader landscape, health IT evaluation stands to benefit from a consolidation and through it possibly better uptake of robust methodology. HTA, even though an equally multi-disciplinary field, has successfully aligned the various approaches to the area of study and worked consistently towards a unified view and application of methodology on an international scale, albeit respecting national differences. HTA agencies and units operating world-wide on regional and national levels already provide a more concrete structure and operational framework for coordination of activities. Health informatics on the other hand is still very much either a business or an academic undertaking. The move into policy and established organizational forms such as national competence eHealth centers in several EU countries is a relatively recent development. The successful coupling between the academic and the policy world is still a challenge to be answered. Academic organisations and communities need to focus their efforts and initiatives on establishing communication and collaboration channels to policy makers. Promoting the objective of robust quality and policy-relevant evidence for health IT is a step in the right direction.

## Recommended further readings

1. Geissbühler A, How Can eHealth Help Fix Broken Health Systems? *Methods Inf Med* **50** (2011), 297–298.
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## Food for thought

1. What means would you propose for enhancing the uptake of methodological standards to improve the quality of the available health IT evidence such as GEP-HI<sup>11</sup> and STARE-HI<sup>12</sup>?
2. What opportunities and challenges do you see emerging for health IT and HTA through their application to integrated care environments?
3. What is your view on the HTA REA Model approach to evaluation items of limited transferability (see sections 4 & 6.2. of this contribution)? Do you find the argumentations in favor of exclusion valid or not and why? What other ways of addressing transferability challenges can you come up with or have already encountered?
4. How do you understand patient engagement in health IT evaluation? How are you addressing it in the project(s) you are currently involved with?

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