

Health Informatics 3.0 and other Increasingly Dispersed Technologies Require Even Greater Trust: Promoting Safe Evidence-based Health Informatics

Contribution of the IMIA Working Group on Technology Assessment & Quality Development in Health Informatics

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Summary

Background: Health informatics is generally less committed to a scientific evidence-based approach than any other area of health science, which is an unsound position. Introducing the new Web 3.0 paradigms into health IT applications can unleash a further great potential, able to integrate and distribute data from multiple sources. The counter side is that it makes the user and the patient evermore dependent on the 'black box' of the system, and the re-use of the data remote from the author and initial context. Thus anticipatory consideration of uses, and proactive analysis of evidence of effects, are imperative, as only when a clinical technology can be proven to be trustworthy and safe should it be implemented widely - as is the case with other health technologies.

Objectives: To argue for promoting evidence-based health informatics as systems become more powerful and pro-active yet more dispersed and remote; and evaluation as the means of generating the necessary scientific evidence base. To present ongoing IMIA and EFMI initiatives in this field.

Methods: Critical overview of recent developments in health informatics evaluation, alongside the precedents of other health technologies, summarising current initiatives and the new challenges presented by Health Informatics 3.0.

Results: Web 3.0 should be taken as an opportunity to move health informatics from being largely unaccountable to one of being an ethical and responsible science-based domain. Recent and planned activities of the EFMI and IMIA working groups have significantly progressed key initiatives.

Conclusions: Concurrent with the emergence of Web 3.0 as a means of new-generation diffuse health information systems comes an increasing need for an evidence-based culture in health informatics.

Keywords

Health informatics, evaluation, Web 3.0, risk, business ethics

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Introduction

As health informatics applications offer tremendous opportunities to improve health care there is an increasing political urge to implement available IT solutions, examples being [1-5]. These systems are designed to support health care workers in their information processing and exchange by efficient access to and sharing of patient data (e.g. electronic records, telemedicine applications, remote monitoring), in providing efficient care (e.g. order sets in order entry), and filtering and interpreting patient data and reducing error rates (e.g. decision support) and in reusing (clinical) data for other purposes (e.g. research, auditing and billing). Having initially been discrete application systems, with interoperability rapidly developing, a new generation of systems will be Internet based and virtual.

The Internet has evolved from static and centrally-provided content (Web 1.0) to dynamic and community-driven content (Web 2.0) and is gradually moving towards Web 3.0, which is characterised in particular by semantic tagging, personalization, localization and context-based filtering of information and thereby combining and enriching information from multiple sources. Defining

Web 3.0 in greater detail is in itself difficult due to its emergent and groundbreaking nature, but both the editorial and a leading article in this Yearbook consider this in some detail [6,7]. Web 3.0 offers new paradigms of information management, whose introduction into health IT applications can unleash great potential. There may be pressure to exploit these paradigms in health care before there is full understanding of all the issues – especially risks, controls, impact, and optimisation of use.

Primarily through semantic tagging linked to data management functions Web 3.0, and thus its applications categorised as Health Informatics 3.0, open up new potentials and horizons for which only the limits of imaginative thinking are the boundary, but for which feasibility, ethics and acceptability may be the limiting factors. This semantic tagging can be of 'things', but also of items such as a patient clinical value, diagnostic result, or action. These tagged items can then be delivered 'intelligently' either proactively or reactively to someone else with an interest, whether concerning that patient or that condition. But it may also include, for example, tagging of orders and their means of implementation, such as blood transfusions, prescribed pharmaceuticals, or implanted devices. As it

is an emergent technology it is not easy to find mature examples, but they could range from telling a lead clinician new information about one of his/her patients, through to more profound public health analysis or product or disease surveillance. Because the potential is so wide-ranging and capable of crossing current conceptual boundaries, both appropriate control (and evaluation) become all the more challenging, but important. Without scientific knowledge of what happens, and its effect on all stakeholders, arguments for deployment and its benefits can only be hypothetical, and guarantees of control of potential adverse effects can only be aspirational.

Health Informatics 3.0 should be able to integrate multiple information sources such as clinical data, laboratory data, literature, guidelines and so on, based on semantic tags, and for instance linking with clinical pathways or archetypes. For and through these applications the role and influence of the users becomes elevated. This comes at the time when the paradigm shift ongoing in health care from hospital and organisation-centric health care to citizen-centred care is being actively pursued, making citizen-centric domiciliary-based health and wellness systems the actively sought informatics tools. Moreover, this vision is one of multi-agent coordinated care, in which citizens are active participants in their own health and care - in prevention, healthy life style, treatment of illness and follow-up. All this justified seeking of citizen-centred integration and co-ownership means that Health Informatics 3.0 may be seized upon as a new and potentially invaluable tool, but the transcending of old boundaries and the lack of experience of the new applications means new risks and unexpected effects, that without a systematic evaluation process adverse effects will only be discovered after they have happened, and similarly optimal use will only be discovered anecdotally.

The counter side of this uncharted path mixing development and ownership is that it makes the user (clinician and pa-

tient) evermore dependent on the enigmatic and impenetrable 'black box' of the informatics system [8]. In healthcare there are already concerns amongst clinicians as users, and patients, increasingly not only as subject of the medical record but also as user of healthcare applications, as to 'letting go' of the paper records, or the simple computer file which they can understand. This is legitimate, insofar as only when a clinical technology can be proven to be trustworthy should those treating - or being treated - use it, though unfortunately health informatics has perpetuated an extended honeymoon period within which it has considered itself exempt from this full rigour considered mandatory for other health technologies. Furthermore, the more data that are connected, the more increasingly derived and complex data are created. Given semantic tagging and context dependency, how much needs to be made explicit by the data generator or by the system, to give both accountability and also context as a determinant of meaning, without creating inhibiting complexity? Only evaluated experience will show how to ensure that the proper context and presentation for information are defined. The potential risks of virtual service orientated architectures in health informatics have already been flagged up [9], though apparently little followed through in practical impact.

Even for more simple health IT applications ample examples exist in which the use of IT in health care causes hazards and problems - either due to context and use such as in [10,11] or to malfunction, examples being [12,13]. For more complex Health Informatics 3.0 systems the risks for these hazards and problems are likely to be even larger, due to the deeper dependence on technical specifications and actions, which may not fully accommodate the health need and all the possible variations of circumstance, and which may not be fully understood or trusted by patients or health professionals each with so much at stake. Additionally, the ubiquitous and pervasive technologies applied to implement these systems are

frequently likely to be proactive, and cannot be controlled in the same way as traditional health IT systems, meaning also that privacy and security issues become elevated, requiring new solutions, both conceptually and technically.

There are many regulations for all other kinds of health care interventions which influence the patients' treatment and thereby patients' outcome. For example the Food and Drug Administration in the United States, the European Medicines Agency and national regulatory bodies in each Member State, and similar arrangements in many other countries globally prescribe strict regulations on the pre-clinical and clinical trials which must precede the release for human use of medicinal products, and the post-release surveillance which must continue in place to identify any iatrogenic effects under particular circumstances. Similarly, Medical Devices including implants are strictly controlled in human use by national (and European) regulatory mechanisms, which include both pre-release and post-marketing surveillance requirements. New treatment methods, such as specific minimally invasive techniques, are less formally regulated, but there is still a powerful hidden sanction in that it would be considered unethical, and an issue of professional liability, if a clinician applied a technique which he or she had not properly assessed for that specific clinical context from the evidence available, and for which they had not adequately been prepared and trained. Pursuant to this, from an early stage an evaluation and evidence base and culture was developed for these technologies, as reported for example in [14,15].

By stark contrast there is a lack of such regulations for validation or authorisation of health informatics (HI) interventions. Though strict data protection principles apply to these underpinned by legislation, there is no prior assessment of these aspects, nor validation of the core functionality or observation of the effects in use and on healthcare practice. The only new exception is that software dedicated to a

medical device or to be used for a diagnostic or therapeutic function (itself an imprecise definition), is now included under the European Medical Devices regulations [16]. Given the increasing commitment to health informatics, and that almost all HI interventions are disruptive in that they disrupt long-operated clinical procedures and their underpinning thought processes, and also are very likely to render ineffective and redundant previous manually-based systems and controls, it is more than ever imperative to assess the impact of that investment on not only the quality and effectiveness of care delivery, but also on the organisations where the IT application is broadly installed and on the way health care professionals practice [17, 18, 19]. Modern healthcare should be evidence-based, and there is no reason for informatics to be exempt – particularly given its black box nature and disruptive properties, yet with the health of patients and the practice of professionals directly at stake, as shown by the review in [11].

Once these evaluations are performed it is important to share the results of these with all direct stakeholders but also with external interested parties who might learn from these evaluations. In many circumstances reports of such evaluations are of limited evidential value because essential information is not properly communicated through scientific or professional media – possibly because scientific standards are missing, because of an informatics culture of never admitting sub-optimalism or ‘failure’ (including on the part of policy makers who have had to argue for a specific IT investment) [18], or because of lack of commitment to wider societal learning in the informatics and managerial communities.

This paper briefly outlines the political and ethical imperative of undertaking evaluation of Web 3.0 IT applications in health, as well as giving an overview of the activities of the IMIA working group on Health Technology Assessment and Quality development and the EFMI working group Assess-

ment on Health Information Systems in order to reach evidence based health informatics.

An Evidence-based Approach in Health Informatics

Self-evidently, policy-making in any aspect of health should be evidence-based. As was postulated in a British Medical Journal editorial nearly two decades ago: "... at a time when ministers are arguing that medicine should be evidence based, is it not reasonable to suggest that this should also apply to health policy?" [20] A modest but sound literature on this has built up; see for instance [21-23]. However, using an evidence-based approach to policy is still not the rule, and regrettably this is particularly the case for health informatics (or e-Health) policy and investment decisions.

Health informatics applications are unquestionably science-based, as they are grounded in computer and computing science including software engineering, communication sciences, and behavioural and social sciences. A core logic of applying science in societal responsible situations is that it should be applied scientifically – it is an unacceptable paradox to suggest that an application or intervention based on applied science should be deployed according to motivations that have no scientific basis, nor any regard for risk. Any form of health informatics technology (HIT) inherently has aspects which themselves should raise warning signals that indicate that a thorough risk review and sound evidence-base is needed to validate the application: such systems interpose in practitioner-based interactions with or for the patient; they are disruptive to existing well-established practices; their totality is unlikely to be seen and thus validated by any one individual; there is seldom an established community of practice nor a body of experience; and quality assurance processes are seldom devised and implemented prospectively. Even when

the apparent benefits are clear, it is a brave and potentially irresponsible decision to replace existing procedures with virtual ones on trust without the surety that they will operate without failure or unanticipated detrimental effects. And as has been shown, detrimental effects, up to and including patient deaths, can occur [11]. Yet unlike patients or clinicians, those who promote or implement new health informatics systems put neither their own lives nor their livelihoods at risk.

A further challenge is that health informatics systems as currently set up are fast-moving due to the frequent implementation of updates and innovations. This will apply to the most leading edge applications, such as Web 3.0. In these environments, one may even not be aware of any system update since they take place somewhere else than where data were captured and used. But this too has become a culture that is accepted by default. Clinical pharmacology is another science with constant development of knowledge, both on the chemistry and pharmacodynamics, but also with continued development of the evidence base from surveillance, reporting of side-effects, and behavioural understanding. Yet it would be seen as totally inappropriate to licence and use a pharmaceutical therapy which was then continually adjusted and updated, and with the outcome of a trial being the licensing of an as yet not finalised variant – no, the adjustment and testing must be completed in advance, and except for urgent problems, adjustment is a paced and reflective matter. Thus the current accepted tendency in health informatics to market ‘vapour ware’ (a version not yet completed let alone tested), albeit based on the good though misplaced intentions of the latest being the best, is difficult to defend.

Business ethics, though gaining recognition elsewhere, and indeed with a dedicated journal and institute [24,25], are seldom talked of in the health informatics sector. But ethics permeate other areas of healthcare, and it is difficult to accept that health informatics should be exempt. In particular health

informatics systems need scrutiny because they affect patient lives, and they affect professionals' practice, the two central features of healthcare, and one of the four core principles of health ethics is that of *'non nocere'* – not to harm [26]. No health information system can be said to pass this principle unless it has been evaluated in practice, in its current version. And linked to this, the Precautionary Principle would suggest that unless an application of any kind has been proven to be beneficial, or at very least not harmful, it should not be used. As demonstrated earlier, some health information systems have been proved in retrospect to be harmful only once damage has been done, and few applications are rigorously tested as meeting the Precautionary Principle, yet there is still reluctance to take an evidence-based approach.

One important recent initiative is that the American Medical Informatics Association (AMIA) set up a Task Force on HIT Vendor Values, which has reported recently and been accepted by the AMIA Board [27]. This has recommended that patient safety should be of over-riding value, that patient safety should feature large in contracts, that all parties should collaborate on the adoption of best practice, and that there should be published standards of corporate conduct. However, though welcome, this appears to fall short of considering the ethical processes within companies, or indeed to insist on evidence-based implementation. (Unfortunately, the full AMIA Board position paper seems not to be readily available in the public domain.)

Such issues are all the more pertinent given the also recent publication of a deep evaluation report into a multi-site system implementation which indicated a supplier approach which was not soundly user- and purchaser-orientated, with quick fix or cover-over solutions not against the culture [28]. While such attitudes cannot be considered the norm, they must be more rigorously guarded against and considered unacceptable.

Thus it is important to take Web 3.0, the latest development of informatics power, as an opportunity as well as a need to move health informatics from its position of being largely unaccountable, based on it being acceptable to supply or implement systems with positive intentions but no effective proof of benefit (nor of the absence of unintended adverse effects) to one of being an ethical and responsible science-based domain within health. Web 3.0 marks a milestone as it creates a dependence on a virtual 'black box' situation, but furthermore one where no specific supplier nor system can be clearly identified as responsible for the management of data and operation of processes crossing all organisational boundaries. Moreover, with the use of 'cloud' computing, there is not a physical platform which can be identified, nor physically controlled in the same way as an older mainframe installation [9]. With Web 3.0 there has to be strong trust on the correct identification and tagging of data items, as well as their attribution and linkages, and their effects on security and privacy – putting onus both on the system's veracity as well as on the operating user. Currently the basis of that trust is not proven, nor is it required to be.

EFMI and IMIA Moves to Strengthen and Promote Evaluation

Hitherto, evaluation has been identified as a Cinderella in the health science world [29]. However, coordinated by the EFMI (European Federation of Medical Informatics) Working Group "Assessment of Health Information Systems" (<http://iig.umit.at/efmi>), and the IMIA (International Medical Informatics Association) Working Group "Technology Assessment and Quality Development in Health Informatics" (<http://www.imia.org>), a range of activities has been conducted in the last years to promote the idea and approaches to health IT evalua-

tion. These processes can accommodate any form of Health Informatics development and application.

In 2003, an Exploratory Workshop on "New Approaches to the Systematic Evaluation of Health Information Systems", funded by the European Science Foundation (ESF), took place in Innsbruck, Austria. The results of this workshop have been summarized in the Declaration of Innsbruck [19]. This declaration emphasized the ethical obligation for evaluation and the complexity of evaluation, and gave recommendations for future work. This workshop was the starting point and foundation for several international activities, including workshops and tutorials during Medinfo, MIE, AMIA and other health informatics conferences. Out of the Innsbruck Declaration's twelve elements, the present paper emphasises that two key ones (ethics, and evidence base imperatives) still need promoting, while good progress has been made on many others (as exemplified by the actions and achievements reported later). Consequently, though the barriers facing evaluation have diminished, there are still challenges ahead, not least with application in practice to inform and lead policy, and with the advent of new technologies and applications such as Health Informatics 3.0 and their breach of former boundaries and constraints.

In 2004, the web-based database EVALDB (<http://evaldb.umit.at>) was launched [30]. This database comprises at the moment around 1,500 indexed abstracts of health IT evaluation between 1980 and 2010. The database can be used to find health IT evaluation studies, offering query options including search for publication data, type of evaluation system, or evaluation method. EVALDB contributes to a more transparent and easy accessible evidence-base of health informatics. The database is available for free and is updated bi-annually.

In 2005, a website called "Bad Health Informatics can Kill" (accessible via the Bad Health Informatics link at <http://iig.umit.at/efmi>) was launched that col-

lects published examples where health IT caused or contributed to patient harm or process disruption. This website contains at the moment 38 cases – this is almost certain to be a serious under-estimation because of the factors militating against publicity of such events. (A site recording wider adverse effects of health IT systems is <http://www.ischool.drexel.edu/faculty/ssilverstein/cases/?loc=cases>), while <http://catless.ncl.ac.uk/Risks/> through its search function identifies medical and health risks.)

In 2009, the STARE-HI guidelines (Statement on reporting of evaluation studies in health informatics) were published [31]. These guidelines resulted from a need identified at the Innsbruck meeting, and describe items that should be included in a health IT evaluation paper. In the meantime, STARE-HI has been adopted by the IMIA General Assembly as an official IMIA document, is endorsed by the EFMI Board and the AMIA special interest group on evaluation and referenced in the guideline for authors by the journals *Methods of Information in Medicine* and *Applied Clinical Informatics*. An explanation paper for STARE-HI that gives detailed instructions and examples is in preparation. STARE-HI has been used to develop special guidelines for conference health IT evaluation papers. These guidelines are accepted to be published in 2011 [32].

A further and extensive piece of work being undertaken under EFMI and IMIA auspices is the preparation of comprehensive generic guidelines on Good Evaluation Practice in Health Informatics (GEP-HI). These too will be published in 2011. They describe the steps to be performed, and the issues to be considered, during planning and performing a health IT evaluation study, and emphasise the importance of evaluating not just the physical system, but its organisational context and the interests of stakeholders. Both STARE-HI and GEP-HI guidelines have been spread to the interested community via several conference workshops, tutorials, publications and e-mail lists.

Other Important Evaluation and Evidence-promoting Initiatives in Health Informatics

Besides the activities of the EFMI and IMIA working groups on health IT evaluation and the recent AMIA Taskforce on HIT Vendor Values [27], several other groups also launched activities concerning evaluation HIT. We summarize a few of them below to highlight the diversity of the issues to be addressed, and the solutions proposed.

In February 2009 first steps were taken in Kuala Lumpur towards the creation of an "Alliance for Clinical Excellence" (ACE), a not-for-profit global organisation to promote ethical evidence-based health informatics through establishing an evidence-based philosophy for health IT. This alliance spans academia, government, health authorities and health service providers, and the health informatics industry, with each of the four sectors being seen as equal partners with a common interest. Founding participants came from within the Asia Pacific region, but interest has quickly spread. ACE now has participants from Singapore, Hong Kong, Australia, New Zealand, Europe and North America, and a core group is working on developing a global structure, formal objectives, and public profile, and incorporation as a legal entity under Singaporean law. The position of ACE is that "Driven by the need for transparency and ethical responsibility towards the Healthcare Industry globally, [it] ... aims at synchronizing global efforts for the development of evidence-based tools and guidelines as a framework to optimize the cost-benefit equation of IT deployment in Healthcare."

Arising from a European Commission goal to facilitate more objective selection and use of telemedicine, a Model for ASsessment of Telemedicine applications (MAST) has been developed in an EU-funded project *Method-Telemed* with the purpose of giving advice to users on what are the preceding considerations before an evaluation

study can be started, and to list aspects of telemedicine evaluation [33]. A MAST toolkit is being developed to support the selection of evaluation criteria.

For the AHRQ National Resource Center, Cusack et al. have developed an evaluation on toolkit Health Information Technology to provide step-by-step guidance for developing evaluation plans for health information technology projects [34]. The toolkit assists evaluators to define the goals for evaluation, what is important to stakeholders, what needs to be measured to satisfy stakeholders, what is realistic and feasible to measure, and how to measure these items. Examples are presented with suggested evaluation methodologies for each. The toolkit is thus very useful from the methodological point of view and it can be applied within the GEP-HI framework, but it does not give guidelines for the evaluation project itself, how to manage it, how to carry out the project, or how to complete and report the study, and thus details only part of the GEP-HI coverage.

Thus the processes, standards, and necessary role of evaluation in health informatics technology and its applications are being progressed, through IMIA and EFMI as well as by other key bodies. The need for them increases exponentially with the proliferation and the deepening of HIT applications, linked to both the ethical and the safety aspects. Moreover, the urgency of their becoming more systematically and rigorously used is underscored not only by the recognition that HIT systems can cause harm [11,12,13], but also by growing evidence that claims for systems are frequently not supported by robust evidence [35].

Making Health Informatics 3.0 a Safe Virtual Place

With a truly virtual approach as Web 3.0 can be considered, there needs to be development of matching virtual governance and audit processes. This

can only be built up with knowledge built on a scientific evidence base, as would be expected with any other health intervention, most of which are far more concrete. This is not to question in any way the potential benefits to health care and thus to patients and practitioners of Web 3.0 or any other health informatics application, but simply to say that given their power and increasingly intangible operation, they should operate to the same scientific principles to establish their optimally safe use as any other health intervention.

New responsibility and liability issues arise. Who is accountable for presentation of the data in their new context? Is this entirely a downstream product liability, since it can no longer be the responsibility of the data's source, usually a healthcare professional? Another issue is the tracing of usage of data, requiring a clear line of responsibility for a follow up in case of upstream correction of erroneous data. Much responsibility must lie on the providers of the front-end portal which links to preselected software services, or has selection criteria for discovering them in real time, thus determining the overall functionality and its fitness for purpose and reliability.

However, in promising a new paradigm of benefits, Health Informatics 3.0 by definition brings a new paradigm of risks, from errors within the 'virtual black box' to breaches of privacy very remote from the original data capture. Thus Health Informatics 3.0 needs to be subjected, both generically and at the application or initiative level, to rigorous evaluation pre-release, based on the planned use context and environment. This must be evaluation of the service as presented to the end user, and cannot be an add-on or afterthought, but an essential prerequisite to ethical use of increasingly virtual and ephemeral health informatics applications. Given the higher order risks (and benefits), this could be a milestone opportunity for health informatics and HIT to move to an ethical scientific position – the countervailing threat be-

ing increasing public and professional suspicion and distrust if and when adverse and unexpected issues arise.

At the same time, the process of evaluation of Health Informatics 3.0 systems itself raises new challenges. Not least, with tagged items transmitted to 'interested' parties, through dispersed systems, the concepts of 'stakeholder' and 'user community' themselves become dispersed and nebulous, being link-defined and transient, and also not bounded by organisational or geographical boundaries. The data subject if a person is still an entity, but the concept of data subject or owner is more difficult for things, whilst transactions have by definition two or more equal subjects. The concept of 'user' – someone who uses data – is significantly different from that of recipient, who may not use what comes to them, and indeed may find the data unwanted, unsuitable, or otherwise unhelpful. In short, evaluation processes themselves will have to be revised to accommodate the new need.

Of course, even sound systems cannot guarantee safe usage. User training is vital, both generically on the use of electronic systems in healthcare, as strongly advocated and specified by IMIA [36], and provided by initiatives such as with the European Computer Driving Licence (ECDL) Health module [37, 38], the AMIA 10x10 initiative [39], or the American nursing Technology Informatics Guiding Education Reform (TIGER) initiative [40], and subsequently with training on use of the specific application. This latter can be challenging with distributed virtual systems, as some remote users may be accidental parties. But ensuring sound proven systems is a prerequisite to enabling safe and effective use.

Similarly, identification of problems and adverse effects once a system is exposed to a volume of use, often in varying situations, is important as is now being recognised by the US Federal Drug Administration [27]. Surveillance and incident reporting, requiring open and impartial communication of putative faults, their logging and analy-

sis, are necessary but still rare, whereas they should become the norm, and are required under the EU directive [16], and they may become even more significant given the innovative nature of Health Informatics 3.0. These are forms of quality assurance and consumer protection that apply in the pharmaceutical and other scientific applications in health, so should be considered the appropriate culture for health informatics too.

Surveillance and reporting complement formative evaluation and piloting, by capturing systematically post-release new knowledge. But these factors do not diminish the importance of that initial evaluation to ensure a safe system in the first place, and subsequent evaluation of system effects and side effects in practice.

Conclusion

Concurrent with the emergence of Web 3.0 as a means of diffuse new-generation health informatics systems to support health comes an increasing need for a set of activities to promote and facilitate evaluation and thereby evidence-based health informatics, together with development of contexts and education for safe usage. This is timely, and indeed overdue. As systems become more powerful but less linked to traditional manual processes, it is vital for health informatics to move to become an evidence-based health science. In the last decade several initiatives and activities were started to develop this evidence base, not least by IMIA and EFMI groups, but future research is needed to extend these and make them applicable to the new generation health informatics systems. This understanding and culture of evidence-based informed implementation must be embraced by policy makers (including politicians) as both logical and ethically imperative.

People from all disciplines and from all over the world who are involved in evaluation of health informatics are heartily welcomed to join the Working

Group „Assessment of Health Information Systems“ of EFMI and the Working Group „Technology Assessment and Quality Development in Health Informatics“ of IMIA either by joining the mailing list, or attending workshops or business meetings during conferences in order to realize this. The promoters of Health Informatics 3.0 innovations are encouraged to link with these communities so as to enable mutually recognised scientific evaluation processes leading to the development of a robust and defensible evidence base.

References

1. Commission of the European Communities. COM 356: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making health care better for European citizens: An action plan for a European e-Health Area (COM (2004) 356, Brussels; 2004.
2. European Commission: ICT for Health & i2010 - Transforming the European healthcare landscape - Towards a strategy for ICT for Health, June 2006 http://europa.eu.int/information_society/activities/health/docs/publications/ictforhealth-and-i2010-final.pdf. Luxembourg: Office for Official Publications of the European Communities; 2006.
3. European Commission. Database of European eHealth priorities and strategies; <http://www.ehealth-era.org/database/database.html> (accessed 29 March 2011)
4. United States Congress. American Recovery and Reinvestment Act of 2009; United States Government Printing Office, Washington DC; 2009
5. Sittig DF, Classen DC. Safe electronic health record use requires a comprehensive monitoring and evaluation framework. *JAMA* 2010 Feb 3; 303(5):450-1.
6. Kalra D. Health informatics 3.0. *Yearb Med Inform* 2011;8-14.
7. Kulikowski C, Geissbuhler A. Towards Health Informatics 3.0. Editorial. *Yearb Med Inform* 2011:6-7.
8. Grémy F, Bonnin M. Evaluation of Automatic Health Information Systems - What and How? In: van Gennip EMSJ, Talmon JL, editors. *Assessment and Evaluation of Information Technologies in Medicine*, Amsterdam: IOS Press; 1995. p. 9-20.
9. Nadkari PK, Miller RA. Service-oriented Architecture in Medical Software: Promises and Perils; *J Am Med Inform Assoc* 2007;14:244-6.
10. Han YY, Carcillo JA, Venkataraman ST et al. Unexpected increased mortality alter implementation of a commercially sold computerized physicians order entry system. *Pediatrics* 2005;116(6):1506-12.
11. Ammenwerth E, Shaw NT. Bad health informatics can kill - is evaluation the answer? *Methods Inf Med* 2005;44(1):1-3.
12. Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL. Role of computerized physician order entry systems in facilitating medication errors. *JAMA* 2005 Mar 9;293(10):1197-203.
13. Eslami S, Abu-Hanna A, de Keizer NF, de Jonge E. Errors associated with applying decision support by suggesting default doses for aminoglycosides. *Drug Saf* 2006;29(9):803-9.
14. Banta HD. Introduction. Minimally Invasive Therapy in five European Countries: Diffusion, Effectiveness and Cost-effectiveness; *Health Policy* 1993 Jan;23(1-2):1-5.
15. Banta HD, Vondeling H. Diffusion of Minimally Invasive Therapy in Europe; *Health Policy* 1993 Jan;23(1-2):125-33.
16. European Union Guideline on Medical Devices MEDDEV. 2.7.1 Rev.3 December 2009.
17. Rigby M. Health Informatics as a Tool to Improve Quality in Non-acute Care - New Opportunities and a Matching Need for a New Evaluation Paradigm; *Int J Med Inform* 1999; 56: 141-150.
18. Rigby M. Evaluation: 16 Powerful Reasons Why Not to Do It - And 6 Over-Riding Imperatives. In: Patel V, Rogers R, Haux R, editors. *Medinfo 2001: Proceedings of the 10th. World Congress on Medical Informatics*, Amsterdam: IOS Press; 2001. p.1198-202.
19. Ammenwerth E, Brender J, Nykanen P, Prokosch HU, Rigby M, Talmon J. Visions and strategies to improve evaluation of health information systems. Reflections and lessons based on the HIS-EVAL workshop in Innsbruck. *Int J Med Inform* 2004;73(6):479-91.
20. Ham C, Hunter DJ, Robinson R. Evidence-based Policy. *BMJ* 1995;310:71.
21. Lohr KN, Eleazer K, Mauskopf J. Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines. *Health Policy* 1998 Oct; 46(1):1-19.
22. Walshe K, Rundall TG. Evidence-based Management: From Theory to Practice in Health Care. *The Milbank Quarterly* 2001;79:429-57.
23. Gray JAM. Evidence-based Healthcare: How to make Health Policy and Management Decisions. 2nd ed. Edinburgh: Churchill Livingstone; 2001
24. <http://business-ethics.com/> (accessed 4 January 2011)
25. <http://www.ibe.org.uk/> (accessed 4 January 2011)
26. Beauchamp T, Childress JF. *Principles of Biomedical Ethics*. 6th ed. New York: Oxford University Press; 2009.
27. Goodman KW *et al.* Challenges in Ethics, Safety, Best Practices, and Oversight Regarding HIT Vendors, their Customers, and Patients: a Report of an AMIA Special Task Force (AMIA Board Position Paper); *J Am Med Inform Assoc* 2011 Jan 1;18(1):77-81.
28. Patrick, J. A Study of a Health Enterprise Information System. School of Information Technologies, University of Sydney. Technical Report TR673, 2011, pp 190.
29. Rigby M. Evaluation - the Cinderella Science of ICT in Health. In: Kulikowski C, Haux R, editors. *IMIA Yearbook of Medical Informatics 2006*. Stuttgart: Schattauer; 2006: 114-20.
30. Ammenwerth E, de Keizer N. An inventory of evaluation studies of information technology in health care trends in evaluation research 1982-2002. *Methods Inf Med* 2005;44(1):44-56. Erratum in: *Methods Inf Med* 2005; 44(3): III.
31. Talmon J, Ammenwerth E, Brender J, de Keizer N, Nykanen P, Rigby M. STARE-HI - Statement on reporting of evaluation studies in Health Informatics. *Int J Med Inform* 2009;78(1):1-9.
32. de Keizer N, Talmon J, Ammenwerth E, Brender J, Rigby M, Nykanen P. Systematic prioritization of the STARE-HI reporting items to facilitate application to short conference papers on health informatics evaluation. *Methods Inf Med* 2011 Mar 4;50(3). [Epub ahead of print]
33. Kidholm K, Bowes A, Dyrehauge S, Granström Ekeland A, Flottorp SA, Kvistgaard Jensen L, Duedal Pedersen C, Rasmussen J. The MAST Manual. MAST-Model for assessment of telemedicine. <http://www.epractice.eu/en/library/315610> (accessed 22 Nov. 2010).
34. Cusack CM, Byrne C, Hook JM, McGowan J, Poon EG, Zafar A. Health information technology evaluation toolkit: 2009 Update (Prepared for the AHRQ National Resource Center for Health Information Technology under Contract No. 290-04-0016.) AHRQ publication No. 09-0083-EF. Rockville, MD: Agency for Healthcare Research and Quality. June 2009, www.ahrq.gov (accessed 15 Nov. 2010).
35. Black AD, Car J, Pagliari C, Anandan C, Cresswell K, et al. 2011 The Impact of eHealth on the Quality and Safety of Health Care: A Systematic Overview. *PLoS Med* 8(1) 2011: e1000387. doi:10.1371/journal.pmed.1000387.
36. Mantas J, Ammenwerth E, Demiris G, Hasman A, Haux R, Hersh W, Hovenga E, Lun KC, Marin H, Martin-Sanchez F, Wright G. Recommendations of the International Medical Informatics Association (IMIA) on Education in Biomedical and Health Informatics <<http://www.schattauer.de/en/magazine/subject-areas/journals-a-z/methods/contents/archive/issue/1053/manuscript/12538/show.html>>. IMIA White Paper. *Methods of Information in Medicine* 2010;49 (2):1 - 16.
37. European Computer Driving Licence Foundation. ECDL/ICDL Module 11; at <http://www.ecdl.org/programmes/index.jsp?p=108&n=764> (accessed 6 April 2011)
38. Rigby MJ, Hulm C, Detmer D, Buccollero L. Enabling the Safe and Effective Implementation of Health Informatics Systems - Validating and Rolling Out the ECDL/ICDL Health Supplement; in KA Kuhn, JR Warren, and T-Y Leong: *MEDINFO 2007 - Proceedings of the 12th World Congress on Health (Medical) Informatics: Building Sustainable Health Systems*, 1347-51.
39. American Medical Informatics Association. Training Health Care Professionals to Serve as Local Informatics Leaders and Champions, at www.amia.org/10x10 (accessed 6 April 2011)
40. Technology Informatics Guiding Education Reform at www.tigersummit.com (accessed 6 April 2011).

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