*Evidence-Based Health Informatics*
*E. Ammenwerth and M. Rigby (Eds.)*


*doi:10.3233/978-1-61499-635-4-3*

# The Need for Evidence in Health Informatics

Michael RIGBY[a,1] and Elske AMMENWERTH[b]
[a] *Keele University, Keele, Staffordshire, ST5 5BG, U.K.*
[b] *UMIT – University for Health Sciences, Medical Informatics, Hall in Tirol, Austria*

**Abstract.** While the use of health IT applications has increased rapidly over past decades, this does not compare strongly with other business sectors. Both reluctance to invest in, and lack of demand to use IT systems may in part be due to lack of robust evidence as to proven benefits. At the same time, the health IT sector has lagged behind other health technology areas in working to, and being expected to work to, robust evidence standards showing benefit and also avoidance of harm. Exacerbating this, limited availability of evidence has perpetuated this misplaced comfort in use of aspiration and expectation rather than evidence in driving investment in health IT applications. Reference back to the core principles drawn from influential thinkers shows the essential centrality of the need for evidence of safety and effectiveness, and for its use relevantly related to context.

**Keywords.** Health IT, health informatics, evidence, decision making, effectiveness, safety.

## 1. Introduction – the Exponential Growth of Information in Health and Society

It is self-evidently true that information is key to health care – information about the patient; information about treatment options; information about the ongoing care (and prevention) processes; and if we are to achieve improvement through critical learning, information on outcomes. But each of these information components within healthcare is also expanding exponentially, at individual patient level and at societal level, as care becomes more accessible; as patients as consumers become more knowledgeable and have increasing expectations; as treatments become more sophisticated and fine-tuned; as diagnostic technologies become more advanced and in themselves information rich (including digitisation of images and videos as well as documents); and as healthcare delivery becomes increasingly closely managed and coordinated among specialised health care providers.

It is also self-evident that all sectors of industry, commerce and civil society are increasingly using information technology to collect, store, and process information, but then go much further not only to create added value and deeper knowledge from that information. They have moved more fundamentally to a new paradigm of activity as a result of the fast, reliable and generally low cost of these processes. This is

[1] Corresponding author: Prof. Dr. Michael Rigby, Emeritus Professor of Health Information Strategy, School of Social Science and Public Policy, Keele University, UK, c/o Lavender Hill, 6 Carrighill Lower, Calverstown, Kilcullen, Co. Kildare, Ireland, m.j.rigby@keele.ac.uk.

conspicuous across the full range of societal activity, from computerised 'fly by wire' aircraft to social interaction of teenagers though social media; from computer-aided design to consumer on-line shopping; and from teleconferencing to electronic news media.

In that transition over past decades the question of 'can we computerise that process?' has been inverted to 'how do we optimise the business (or social) process?'. It was half a century ago, in 1964, that Marshall McLuhan wrote '*The Medium is the Message'* – not a slogan, though it could well have been, but an essay in his book on media and their effects on man and society. [1] The core concept was that the medium (in our case computers and related data management) change the societal expectation and processes such that the new medium defines both the service and consumer behaviour. A good example is in the hospitality and leisure industries – for many people the process of booking a holiday or a business trip is now progressed by checking web sites in real time to see what is available, where and when – a process totally different from previous processes of looking at brochures and then instructing an agent to make a booking within defined parameters, then paying by cheque. Yet the hotel itself, the stay, and the leisure and business activities are essentially unchanged. The medium (real time comparator sites and hotel web pages) creates the way the consumer thinks and acts, and in particular opens up new horizons of choice and of optimising decisions such as availing of offers, as well as speed, ease, and personal control of selection.

This has led many commercial sectors to totally redesign business processes, including (but by no means restricted to) the services they offer, and how they interface with the public. For instance, civil aviation has reshaped from a model based on travel agents and check-in desks to a model based on consumer searching and booking flights, checking in and selecting the seat of their choice, and with many other added value options such as choosing in-flight meals. The older methods of booking and checking in are still available for customers not comfortable with digital options, or for those with special situations such as cancelled flight and missed connections.

## 2. The Cause and Effects of Innate Conservatism

By contrast to the general commercial world, or to general consumer behaviours, in healthcare there have been few major changes in core service approaches and processes. There has not been the same handover to the consumer or user of core interface processes as has occurred in banking and insurance, in civil aviation, or in retail purchasing. Overall, healthcare has continued with its traditional processes, and seen information and communication technology (ICT) as an enabler of those.

To a large degree this is because of the special nature of health services, and in particular their special fixed assets of hospitals, diagnostic facilities, and the sensitive and complex role of the health sector, and the highly specialist staff. But many of the features claimed to be unique are not in fact so. Civil aviation systems are clearly life critical. Banking is highly personal.

Two strong underlying factors are the lack of clear strategic investment decisions, and lack of evidence, and these interlink. Those making health IT investments have a dearth of reliable and robust evidence available and accessible to them, and often have to rely on material from elsewhere and earlier systems, interlaced with vendor or industry sector promises, and a general feeling that investment in modern systems

ought to be worthwhile. Even a decision to invest, inevitably in the face of competition for other reasoned claims on development funds, can be difficult to justify, and any subsequent call for tenders may be less than perfectly constructed in terms of obtaining the most appropriate solution.

But this lack of evidence is in many ways caused by the reluctance to evaluate systems after implementation [2], and by likely publication bias against disappointing results. Policy makers may be reluctant to have less than optimal results broadcast, and vendors have an interest in protecting their products, and indeed the sector, against directly or indirectly adverse publicity. So, with the pressure on resources, it is natural not to seek to invest in, or enable, thorough rigorous analysis. However, this is both selfish and short-sighted, as it is a roadblock to policy makers making future optimally informed investment decisions.

Thus where evidence to support rational and wise strategic and investment decisions is needed, it is missing because of reluctance by others. This has all the makings of a downward spiral, if investment decisions are hampered by lack of scientifically grounded knowledge. And in turn, this leaves the field susceptible to unmoderated influence from the hopes of advocates and promises of suppliers, which however well-intentioned are unlikely to be as grounded as validated evidence.

## 3. Scientific Evidence and Health Informatics – addressing the aversion

This is an anomalous situation for the health sector, which in all other respects is firmly grounded in evidence, and in not making patient-related intervention changes without rigorous independent appraisal of the evidence. This applies, for instance, to pharmaceuticals, to changes to treatment regime, to prosthetic devices, or to patient-specific forms of health technology.

Yet all health IT systems affect patients. Some applications, such as decision support systems, do this in a very direct way; others such as computerised physician order entry or electronic prescribing do so by being a key part of the clinical process; but even scheduling systems and recall systems have patient effects through being tools which are depended upon to organise care, and which if malfunctioning or incorrectly operated will deprive patients of intended clinical interventions. Through such errors harm can be caused to patients, even up to death, as has been documented [3, 4, and e.g. 5, 6].

### *3.1. The Inappropriately Low Expectations*

It is now an anomaly that health IT systems do not have to submit to the standards of science, evidence, and probity expected of all other health sciences and technologies. Not only are there the risks of direct harm, but even safe but inefficient or ineffective systems are detrimental to patients by diverting resources, or by adding to the burdens of clinicians

Given that health IT is safety critical, directly and indirectly affecting patients as indicated above, this low expectation is difficult to justify but is being perpetrated widely. For instance, the International Society for Quality in Health Care (ISQua), with a proclaimed mission of “Inspiring, promoting and supporting continuous improvement in the quality and safety of healthcare worldwide”, held in summer 2015 what was entitled their “ISQua Education's Global Debate for 2015” on the subject “Health

Information Technology is already improving healthcare safety and current regulation around it is sufficient" [7]. For a serious global body to think that health IT can be considered homogenously, for all its safety aspects to be linked to regulation, and for the four debaters to be drawn from just the USA, UK and Australia, would indicate how low are expectations of a true evidence-based approach to considering health IT – even when addressing the key issue of patient safety.

In the modern healthcare setting the Cochrane Collaboration is seen as the must-go-to source of robust evidence. However, as Urquhart and Currell show elsewhere in this volume[2] the evidence there is very sparse. Health Informatics primarily falls into the Effective Practice and Organisation of Care (EPOC) category, and there are very few robust systematic studies. This is of concern, given the role, application spread, and global ubiquity of health IT.

### *3.2. Risks to Patients and Practitioners*

The introduction of change is desirable if this is known to be a positive move, and in simpler settings the decision maker and the user will each be able to assess the problem, the proposed solution, and the intended benefit, and be able to assess reasonably confidently that risks will be controlled and benefits achieved. However, as computing became more powerful this made health informatics more challenging. In 1995 François Grémy was one of the first to point out that the computer in clinical systems was now becoming a 'black box' whose contents and thus whose functioning the clinician could not know in detail, and thus whose effects (s)he could not know. Grémy therefore argued the need for evaluation of this new construct of informatics applications, and for this to be by class of complexity of application which would require not just health technology assessment skills but also human and psychological sciences, and social science [8].

Such an approach once technology becomes too advanced for the individual practitioner, or policy maker, to see in totality is important for maintaining the Precautionary Principle, which is European Commission policy, and assumed as a default position elsewhere, namely that change should not be made until it can be assured that it will not have harmful effects [9,10]. First and foremost, this is to protect the patient against adverse outcomes of new technologies, with patient safety always being a high priority in any health system. But secondly, it has to be remembered that the causing of harm by using a system, even one provided by their employing organisation, could be seen as a breach of their duty of care by a health professional and thus render them liable to disciplinary action, even up to the point of losing their licence to practice.

### *3.3. International Moves to Promote Evidence*

To recognise this need to move to an evidence culture, the European Federation for Medical Informatics (EFMI) set up an Evaluation Working Group, and the International Medical Informatics Association (IMIA) a Working Group on Technology Assessment & Quality Development. In this context, in order to stimulate

[2] C. Urquhart et al., Systematic reviews and meta-analysis of health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

further action, an expert European workshop was convened in Innsbruck in 2004, funded by the European Science Foundation as this was seen as the development of a new application of scientific study [11]. This workshop created an action plan, much of which has been achieved. Meanwhile, in the USA the Agency for Health Research and Quality (AHRQ) also has addressed the issue [12].

As this momentum developed, in 2013 IMIA took Evidence-based Health Informatics as the theme for its Yearbook of Medical Informatics [13]. This incorporated many papers on the theme of creating appropriate evidence, as well as a scene-setting paper on the decade of work to move towards a more evidence-based culture in the sector and to promote the concept and principles of Evidence-based Health Informatics [13].

The World Health Organisation has established a Global Observatory for E-Health, which seeks to promote effective sue of information technologies [14]. However, this operates primarily at the level of advising on national systems, undertaking useful periodic global surveys, and producing updated E-Health Atlases and collations of national policies. This is important at the national policy and infrastructure level, but is not an application evidence source.

In 2011 the WHO joined the Rockefeller Foundation in convening a workshop in Bellagio, Italy with the title "Ehealth, Evaluation, Evidence", whose purpose was based on the credo "To improve health and reduce health inequalities, rigorous evaluation of eHealth is necessary to generate evidence and promote the appropriate integration and use of technologies." [15]. This workshop built on an earlier initiative with Archbishop Desmond Tutu to initiate an eHealth Call to Action, and this time initiated a Call to Action on Global eHealth Evaluation. This meeting agreed nine Principles, including "5. Evidence is needed to demonstrate costs and benefits of eHealth implementations, and maximize eHealth's beneficial impact on health system performance and population health" and "9. Improving the eHealth evidence base requires more than increased numbers of studies but also improved quality of eHealth research studies." These are welcome principles, but the Nine Recommendations for action seem not to have had significant overall impact or follow-through.

On a more practical note, the IMIA and the European Federation of Medical Informatics (EFMI) have linked through their relevant working groups to sponsor an Inventory of Health IT Evaluation Studies and Systematic Reviews [16]. This repository was created to help researchers to identify studies that have been conducted in defined settings, and now contains approaching 2,000 references to published evaluation studies and reviews of evaluation studies of health information systems. However, it is voluntarily maintained and depends on studies being published.

## 4. The Limited but increasing Volume of Activity

Evaluation studies of health IT have been conducted and have been published since the early 1970s, and thus since the emergence of medical informatics as an individual discipline, but the numbers were small. Only in the mid 1990s did the number of published health IT evaluation studies start to rise steadily, with around 1% of all medical informatics papers in the year 2000 being evaluation papers [16].

Systematic reviews represent the building of the evidence base of a scientific field. In health informatics, as a recent analysis shows, a larger number of systematic reviews only started to appear after 2005 [17]. This 10-years lag behind in systematic reviews

can be explained by the time needed to build up reviews on published studies. At the moment, around 30 systematic reviews related to health IT are being published annually, with a clearly increasing trend in number. This leads to a slowly, but steadily growing evidence base of health informatics.

## 5. Getting Decision-makers to Expect and Use Evidence

While one serious problem is that the healthcare sector is accepting of the fact that health IT investment decisions are made based on a lower standard of evidence than rightly is applied in all other areas of healthcare, including pharmaceuticals and medical devices, the corollary is that many decisions are made on inadequate evidence. Often this is at a political level, or at a national level by generic policy makers rather than informatics experts – who themselves have inadequate data to draw on. Two examples show the span of depth given to such decisions.

At the one extreme, it has already been reported that the huge policy decision to create a universal electronic health record system for the NHS in England was made by Tony Blair as Prime Minister in a meeting lasting under two hours, and devoid of health informaticians or sound evidence [18, 19]. At the other extreme, many countries have set up mechanisms which may have taken years to collect and assimilate evidence, which then runs the risk of being out of date. Evidence needs to be constantly refreshed, and so also do policies. The intransigence of informatics innovators to application of new evidence, resulting in their opposing updated versions of their vision, has been documented [20], and is even more likely at institutional level.

Thus creation of, availability and use of evidence for decision-making in health IT have both a pull and push effect, both of which are weak [21, 22]. There should be an expectation from policy makers at all levels to be able to get comprehensive, robust evidence on health IT matters as they would for any other type of health decision, and to be willing to invest in its creation through policy or research channels. It thus needs stronger demand to stimulate the process, and the funding, of evaluation and of evidence publication. At the same time the health informatics community needs to raise its game, to be much more rigorous in generating an evidence culture and processes, to enable supply of good evidence and the establishment of its position as a serious partner alongside the other health sciences and related production sectors. This was also recognised by the WHO-Rockefeller Bellagio event, whose very relevant concluding recommendation was to: “Create a multi-stakeholder web-based platform for constructive sharing, publication and learning from successes and failures. Include a registry of eHealth evaluation studies and results, and a repository of evidence-based eHealth best principles and practices”[16]. Neither the push nor the pull have so far been strong enough to see this implemented, though in global terms the cost would be small and the potential payback large.

## 6. Returning to Visionaries and distilling Core Principles

While this contribution extols the need for robust evidence, and an evidence culture, there is equally a need for moderation and focus. Because health IT has many aspects, each of which has many stakeholders, and many dimensions from safety to cost-benefit, and then each must be seen in both the national health system and the local context,

there is a real risk of moving eventually toward an overload of evidence and issues. This can lead to the situation of 'paralysis by analysis', and the perfect becoming the enemy of the good – which is a stage too far beyond the current lack of knowledge in many cases about what is good. It may therefore be sound to return to core principles, and the insight of key thought leaders.

### *6.1. Hippocrates*

Hippocrates first and foremost gave us the dictum *non nocere* – do no harm. That should be a key tenet – yet too often it is conveniently passed over. However, Hippocrates did not just bring ethical principles to healthcare – he brought the principle of systematic record keeping which underpins current thinking and delivery in healthcare, and of subsequent analysis to create new knowledge [23]. While clearly Hippocrates was not talking of computers, he was instilling the importance of recording full evidence as the source of robust and reliable knowledge to inform future actions. Within this, he emphasised the importance of patient outcomes as the prime consideration and currency. This indicates that when implementing health IT full records should be kept of the actual effects, particularly on outcomes, so as to form the basis of analysis and shared learning.

Despite the fact that, as explained earlier, we do know that health IT can do harm, and frequently we choose not to enquire too deeply, either before implementation as to the effects of the application approach, or after implementation concerning the system in operation, that 'blind eye' approach is not defensible. In effect policy-makers and sections of the supplier industry are acting unethically by Hippocrates' standards by not protecting against possibly (or actually) causing harm.

### *6.2. George Boole*

Our second key thought leader is George Boole, a largely self-educated man who moved from being a teacher in Lincolnshire in 1849 to be founding Professor of Mathematics at the newly-established and thus somewhat independent-minded Queen's College Cork, now University College Cork. Boole is often held up as the founder of computing, which indirectly means that he was instrumental in medical informatics. Of course, he had no concept of computers, and incidentally might well have views on our cause since he died young as a result of his caring wife insisting on a non-evidence based treatment for a severe winter chill.

However, Boole's underlying mission was to systematise thought [24]. One core concept included the differentiation between 'OR' and 'AND'. In the ever increasing complexity of evidence, including the evidence related to health IT applications, this central differentiation between effects that are mutually exclusive (including the opportunity cost of commitment of resources of investment and time), and those which may be accumulative (particularly unintended as well as intended outcomes) is important. As decision-making and underpinning analysis continue the tendency to increasing complexity, refining them back by simple rule will help clarify the options, and frame the consequences in format closer to summated net effects, thereby increasing clarity and accountability.

### *6.3. Archie Cochrane*

Whereas Boole's advanced thinking has been simplified to its core, our next visionary, Archie Cochrane, has had his simple ideas turned into an industry, with increasing complexity but arguably with a deviation for his core clarity. While the gold standard developed by the Cochrane Collaboration is the double blind RCT – which is so hard to achieve in health IT implementations, and which in clinical fields is remote from the reality of comorbidity and local treatment contexts – Cochrane's starting points were quite different. Cochrane's first peer reviewed scientific paper was not set in purposefully constructed controlled trail settings, but in prisoner of war camps in wartime Germany [25] – not exactly ideal conditions, but yielding evidence from observation, and the first of four studies from those settings. By 1951 he was publishing epidemiological analysis from the applied Medical Research Council Unit in South Wales that he was to make so effective, starting with [26]. The later, reflective main opus of Cochrane gives us the core concepts in its title – *Effectiveness and Efficiency* [27]. These objectives, rather than an elusive complex method, and recognition of the challenges of very real worlds, should be taken as Cochrane's core insights for us.

### *6.4. Evidence in the Real World Context*

Thus from these three thought leaders we understand the importance of evidence based approaches; contemporaneous recording of all aspects a situation and interventions; looking at the real world and at context; the importance of patient outcomes as the most important currency; systematizing our thinking to be most effective; and above all of looking at avoiding doing harm while looking for optimal effectiveness and efficiency. In the modern field of using health IT to harness a new science in the service of health and healthcare, these key principles point to the importance of Evidence-based Health Informatics (EBHI) as the essential route to take.

Yet this should be followed in a balanced and reflective way, not as the unthinking applications of a formula or rule set. From the paradigm of Evidence-based Medicine, both Sackett as a core early protagonist, and Greenhalgh as a modern informed commentator, have emphasized that the evidence is a tool to be applied informedly [28, 29]. Context, and application, are vital and are key essentials or professionalism.

## 7. The Motivation for this Book

This dearth of good evidence in the face of the need for it has provided the impetus for this book. It is clear that the communities of policy makers, informaticians, system suppliers, and healthcare and other users, are poorly served by the shortage of effective objective evidence in health informatics, by the limited volume of activity and publishing and by the lack of readily available evidence sources.

It is important for all in the health sector to realise and recognise the importance of evidence, what aspects it should cover, how it should be obtained, and thus how to assess it. Health informaticians, and users of health IT systems, should be no exceptions to this. The inclusion of all domains of healthcare, and the many aspects to be considered, are intended to give a comprehensive overview and source of understanding.

## 8. Discussion and Conclusion

There are increasing expectations that healthcare, and activities to support the health of the population, will be based on good science, safely applied in an equitable and efficient way. Health IT is one of the newest sciences, is in parallel with the major use of ICTs in most sectors of societal endeavour both commercial and social, and is assumed to be harmless. However, more informed assessment shows the falseness of these assumptions. Health IT can be well applied and strongly beneficial, but applications can also be badly conceived or applied; resources can be wasted; staff and patients can be disadvantaged; and actual harm and death can result.

The use of robust evidence drawn impartially from evaluation and from objective observational studies, and informedly applied in the local context, is the essential methodology for policy makes of all types and levels. This book seeks to put forward the types and sources of evidence applicable to each type of situation, how to create and to source that evidence, and the dimensions to be taken into account in making health IT decisions in any situation. We hope that it will result in better decisions, and thus in better health for populations.

## Recommended further readings

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## Food for thought

1. Are we confident, from scientific evidence, that our planned approach, application or implementation will do no harm?
2. Are health IT implementations monitored to assess their effects, not least on patient outcomes?
3. Have the real health IT investment alternatives been identified, and their anticipated cumulative effects (within the organisation, and more widely), been assessed based on sound analysis?
4. Subsequently, have these predictions of outcomes been verified, and can they be improved?

5. Have the application impacts been assessed in terms of (a) is the health IT intervention effective?; and (b) is it efficient?; based on robust analysis in the real world setting and context?

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