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Next Steps in Evaluation and Evidence – from Generic to Context-Related

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Abstract. Introduction: E-health systems are increasingly important and widespread, but their selection and implementation are still frequently based on belief, rather than scientific evidence, and adverse effects are not systematically addressed. Progress is being made in promoting generic evaluation methodologies as a source of scientific evidence, but effort is now needed to consider methods for special situations. **Method:** Review of five evaluation contexts - national e-health plans, telemedicine, Health Informatics 3.0, usability and economics. **Conclusion:** Identification of requirements for approaches to be developed in these five settings.

Keywords: Health Informatics; evaluation; evidence; policy; usability; economics

1. Introduction

Health information systems harnessing computing, software, automated sensing, and telecommunication technologies offer considerable opportunities to improve health and health care, but are seldom fully exploited. There is an increasing political urge to adopt Information Technology (IT) solutions in health, assuming automatic benefits. European policies call for progress, including national plans and road maps [1].

However, progress in investment and in uptake has been slow, and there is both professional apathy in many cases, and public concern about loss of sensitivity or confidentiality. Other areas of health care science and investment rightly are evidence-based. Pressure rightly is increasing for policy decisions in health to be also evidence-based, as shown in [2,3]. But health informatics as both a discipline and a supplier community, and proponents of Information and Communication Technology (ICT) based health information systems, still fight shy of this. Too often decisions are made on the basis of hope, expectation of economic benefits, or promise of systems not yet developed, and these expectations often do not materialize. Conversely, errors or poor

design can lead to rejection, poor levels of benefits, impediment to professional practice and care delivery, or patient harm or death, as reported in [4,5,6,7], while robust evidence of benefits is sparse [8].

Key to improving this situation is development of a robust scientific evidence base, the main source of which will be rigorous scientific evaluation. Recent activities of the EFMI and IMIA working groups on evaluation and health technology assessment go a considerable way to developing the appropriate principles and tools, an important one of which is the reporting guideline STAtement on Reporting of Evaluation studies in Health Informatics (STARE-HI), adopted by IMIA, and endorsed by EFMI and the AMIA special interest group on evaluation [9]. Other EFMI and IMIA initiatives include a web-based database of health IT evaluation studies, a website with examples of health IT that harmed patients, and guidelines for planning, performing and reporting health IT evaluations (GEP-HI) - see [10].

1.1. Strengths and Weaknesses of Genericism

All these activities have concentrated on a generic approach applicable to any type of application. This is in principle legitimate, and as core aspects of evaluation such as defining objectives and ensuring analysis of stakeholder interests apply to all systems. However there can also be weaknesses in this approach. Certain types of application, or particular dimensions of use, can require specific approaches and tools. The plan of the EFMI and IMIA working groups is to examine the issues of developing and supporting such focused interest. This paper seeks to identify the issues needing consideration in the special situation of National E-Health Plans, Telemedicine, Health Informatics 3.0 (Web 3.0) systems, Usability Studies and Economic Analysis.

2. Expert Review of Special Issues

In order to present an informed view of the next stage of evaluation study development, the next sections give an overview of core issues, and in some cases current work. Each has been drafted from an expert viewpoint, but (for reasons of space and time) is an overview rather than a formal systematic review, and only key references are cited.

2.1. National E-Heath Plans

Most EU Member States are now drafting e-health plans, for intrinsic reasons and to comply with European goals [1]. However, the plan should not be an end in itself, and both the outcomes and the effects should be assessed. Most States are becoming aware that there is an urgent need for (continuous) evaluation activities, both to better control policy progress and to learn from challenges and experiences, but documented comprehensive frameworks defining the necessary evidence to manage different stages of national plan implementation are still few. A sound model comes from Finland, where the legislation of 2007 stipulated that a National electronic Health Information System (KanTa) [11] is to be built. The Social Affairs and Health Committee of the Parliament required an action to *monitor and assess the implementation of national e-health services with a view to providing timely support to the different actors involved.* An evaluation planning project (KaTRI), launched in November 2008 as a joint venture between the Ministry of Social Affairs and Health and the National Institute for Health

and Welfare (THL), drafted a framework to support implementation of the plan and monitor its progress and outcome [12,13]. From literature in 2009, Australia, Canada and the UK were found to have documented national e-Health evaluation frameworks, which were used as a reference to draft the GEP-HI-compatible Finnish framework.

The Finnish framework was used as a case in an MIE 2009 workshop to reflect on core issues and challenges in large-scale evaluation for supporting system development, implementation and impact assessment. The discussions were then used in refinement of the methodology-based definition of core concepts and variables to be monitored. A refined methodology was published at Medinfo 2010 [13], and some results gained by measuring the baseline situation in eTelemed 2011 [14]. In Medinfo 2010 a question was raised on an international dataset on monitoring National eHealth solutions, and a workshop is being planned in collaboration with Danish, Swedish and Austrian experts on further elaboration of this idea. These are early steps along a promising path.

2.2. Telemedicine (including Pervasive and Ubiquitous Systems)

Telemedicine is an important and developing area of health informatics applications. However, it has some aspects which make it distinct from other health information systems. These differences fall naturally from the nature of telemedicine systems, namely that they cross boundaries and distance, and that there are two sets of users, who may not know one another, and may have little affinity. The remote user may be a partner health professional, such as when a second opinion or guidance on a diagnosis is sought; they may be a different type of health professional, as when a nurse-led casualty service is supported by a parent trauma unit; or (increasingly) the remote user may be the patient, either being monitored passively or as an active care participant. Organisationally telemedicine is different, too – it is seldom deployed within one organisation, but usually crosses organisational and geographical boundaries, and increasingly international borders, making the identification of a user community and corporate responsibility almost impossible [15]. Further, the behavioural issues are different, particularly when patients are the remote users. These affect both patients as users, who may comply partially or poorly, and clinicians whose practice may change. Some of the issues of responsibility and evaluation have been highlighted [16,17]. They are also recognized internationally as ISO TC215 is developing a technical specification for quality criteria for telehealth. Already one important proposal to modify the STARE-HI principles to apply to telemedicine has been published [18].

2.3. Health Informatics 3.0 and other Virtual Systems

Web 3.0 and thus Health Informatics 3.0 offer new paradigms of health information system, based on semantic tagging – of things, data values, encounters, or actions. Tagging and accumulation may include, for example, diseases and their occurrence, clinical orders and their means of implementation, prescribed pharmaceuticals, or implanted devices. As the data can be delivered to another person or organization with an interest in the data subject, the systems are largely virtual. Furthermore there is not a single physical system, and the use of cloud computing gives another dimension to virtuality. Health Informatics 3.0 should be able to integrate multiple information sources such as clinical data, laboratory data, and model clinical pathways. This comes at the time when the desire to move health care from hospital and organisation-centric health care to home-based care is a policy priority.

In promising a new pattern of systems and activity, Health Informatics 3.0 thus brings a new paradigm of risks, from errors within the virtual system to changes of user perception and behavior. However, the evaluation of Health Informatics 3.0 systems raises new challenges. The concepts of 'stakeholder' and 'user community' become nebulous, as there is no physically defined user population, and like telemedicine is also not bounded by organizational or geographical boundaries. The concept of active user is different from that of unanticipated recipient. The virtue of the new virtual systems is that they break previous constraints, but in being outside traditional controls, the evaluation issues and methods need to be rethought too.

2.4. Usability Studies

Specifically for health technologies the EU requires usability evaluation of all medical devices. These obligations may be extended to any "software […] intended [...] to be used specifically for diagnosis and/or therapeutic purposes" [directive 2007/47/EC]. The recommended way to fulfil this is to adopt a user-centred design cycle of the product and to document both the methods applied and the outcomes of the usability studies. Alternatively, it is possible to perform a summative usability evaluation once the product is ready to go to market, to check there is no major risk of usage errors.

Fundamentally, usability studies are integrated in the (re-)design cycle of products and therefore serve mainly formative evaluation purposes. Their main objective is to find the usability flaws of the product and of its user interface and to propose solutions to fix the problems. Several iterations and discussions / negotiations with the vendors / designers of the product might be necessary to get a usable and safe product. Guidelines such as GEP-HI, organized in sequential phases, may have some limitations in supporting such constructive evaluation. Moreover, Health IT evaluation studies aim at establishing evidence regarding the impact of systems in use, while usability studies aim at optimizing the application. Finally, usability studies benefit from a number of standards (e.g. ISO 13407) structuring their methodological approach. Therefore, evaluation guidelines may require adaptation to integrate more closely with usability.

Nonetheless, the use of guidelines such as GEP-HI looks promising in informing usability studies. A recent usability study applied GEP-HI phases 1 and 2 and could identify the following benefits: (i) clarification of the information need, which led to a slightly extended scenario for usability tests; (ii) strong involvement of the designers and vendors of the product; (iii) early clarification and consensus about usability goals; (iv) shortened iterations and re-engineering cycles, and (v) better contract basis.

2.5. Economic Analyses

Economics are crucial in responsible health management. However, the economics of health informatics applications has been under-addressed. Many advocates expect electronic systems to reduce costs, but though they eliminate some processes, or improve quality, they much less frequently reduce spending. Quality improvements do not yield cash, and increases in throughput may actually increase spending. The situation is further complicated by the fact that significant studies showing positive return on investment in e-health have computed societal gains [19] – this is laudable, but societal gains do not pay running costs nor reimburse the system operator.

Costing methods should identify implementation costs (including training and process re-engineering), operating costs (including maintenance), and savings, but also

wider impacts including quality improvement and risk reduction, and additional costs such as increased activity. But in the same way that service industries such as banking and civil aviation recognise that effective informatics systems are key to core business success, the health sector needs means of identifying and funding net enterprise value.

3. Discussion

Time is overdue for health informatics to move to being a science-based health technology, implemented according to robust evidence. The EFMI and IMIA groups have progressed well generic evaluation methods to enable generation of such evidence. The next important steps needed are production of targeted methods for specific aspects.

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