Introducing guidelines for good evaluation practice in health informatics

Pirkko NYKÄNEN[a1], Jytte BRENDER[b], Elske AMMENWERTH[c] Jan TALMON[d], Nicolette de KEIZER[e], Michael RIGBY[f]

[a]*Department of Computer Sciences, University of Tampere, Tampere, Finland*
[b]*Aalborg University, Department of Health Science and Technology and Virtual Center for Health Informatics, Aalborg, Denmark*
[c]*UMIT – University for Health Sciences, Medical Informatics and Technology, Hall in Tyrol, Austria*
[d]*School for Public Health and Primary Care: Caphri, Maastricht University, Maastricht, The Netherlands*
[e]*Dept Medical Informatics, Academic Medical Center, Amsterdam, The Netherlands*
[f]*School of Public Policy and Professional Practice, Keele University, Keele, UK*

Abstract. Good evaluation practice guidelines have been developed through a consensus making process by a core team and the health informatics community. A set of 60 issues has been identified that is relevant for planning, implementation and execution of an evaluation study in the health informatics domain. These issues cover all phases of an evaluation study: Study exploration, first study design, operationalisation of methods, detailed study design, execution and finalisation of an evaluation study. Issues of risk management and project control are also addressed in the guidelines. Through application of these guidelines the general validity and generalisability of evaluation studies are likely to be increased, since these guidelines aim at avoiding a number of omissions, pitfalls and risks.

Keywords. Health informatics, Guidelines, Study Design, Evaluation

1. Introduction

The Health Informatics Systems Evaluation (HIS-EVAL) Exploratory Workshop funded by the European Science Foundation (ESF) resulted in the Declaration of Innsbruck that summarizes the importance of evaluation in these words: "Health information systems are intended to improve the functioning of health professionals and organizations in managing health and delivering health care. Given the significance of this type of intervention, and the intended beneficial effect on patients and professionals, it is morally imperative to ensure that the optimum results are achieved and any unanticipated outcomes identified. The necessary process is evaluation and this should be considered an essential adjunct to design and implementation of health information systems" [1, p. 487].

Reflective deliberations at the HIS-EVAL workshop have led to the development of two guidelines: STARE-HI for reporting of evaluation studies and GEP-HI for good practices for planning and execution of evaluation studies. The STARE-HI guidelines

---

[1] Corresponding author: Pirkko.Nykanen@uta.fi, PO Box 607, University of Tampere

are finalized and published [2]. The Good Evaluation Practice Guidelines (GEP-HI) are presented and discussed in this workshop.

1.1. Guidelines objectives and methods of development

The objective of the GEP-HI guidelines is to present the grounding principles and issues for good evaluation practice for health informatics applications. The guidelines list and discuss those issues that are relevant for health informatics evaluation studies. The issues are organized according the phases of the project life-cycle. The guidelines can be used by health care professionals, health informatics professionals, decision makers, and other health IT stakeholders. They can not only be used to plan and execute evaluation studies of health informatics applications, but also by those who will use the results of such studies by providing guidance on the critical issues that affect the quality and validity of such studies. However, since these guidelines are not a cookbook on which methods to apply in the context of specific evaluation studies, we assume that the target audience has the required methodological knowledge – or at least has access to such knowledge – as well as some evaluation or project management expertise. The essential message is that application of these guidelines requires a professional approach: an evaluator should be able to assess which parts of the guidelines are applicable and where the context requires deviation. This is comparable to the role of clinical guidelines which have to be translated into specific protocols dependent on the setting in which they are implemented.

These guidelines aim to be general and practical and to provide evaluators, users and health professionals with a set of structured, comprehensive and understandable rules for good evaluation practices. They are grounded on a stringency corresponding to scientific principles and inspired by the best practice of evaluation as implicitly described in the literature. Over time, the guidelines will be adapted and refined based on feedback from practical experience with the guidelines by their users worldwide. The guidelines list the criteria and aspects on how to design evaluation studies, how to select methodologies, how to conduct studies both in quantitative and qualitative terms, and how to define evaluation criteria at specific phases of the health informatics application's design, development, adoption, implementation and installation. The guidelines cover the issues which need to be considered at each evaluation phase and to design and manage the evaluation study.

The method used to develop GEP-HI was a consensus-making process in the community of health informatics evaluation experts. The starting point of the guideline development was the existing knowledge and experience – that is, existing literature and published materials on evaluation studies, methodologies, evaluation experiences, guidelines development, codes of ethics and good implementation practices. In particular the following recent review material, encyclopaedias and textbooks guided this development: [1, 3, 4, 5, 6, 7]. A core group of authors developed a draft of GEP-HI guidelines. This draft – and subsequent versions – were published on the website of the EVAL working group of EFMI and presented at MIE and MEDINFO workshops to collect comments and suggestions. These comments have then been used to refine the drafts.

1.2. The phases in the GEP_HI guidelines

GEP-HI guidelines present aspects and activities to take into account at the various phases of the design, implementation, execution and finalization of an evaluation study.

Methods to be used at each phase and links between specific information needs and such methods will only exceptionally be mentioned in the guidelines. It is up to the reader to identify which method is applicable in the situation by means of the latest edition of handbooks like [5], textbooks like [4, 8, 9, 10, 11], and other central literature like [3, 6, 7, 12, 13], as well as websites collecting evaluation studies such as http://evaldb.umit.at or specific reporting guidelines like http://www.equator-network.org/. These GEP-HI good practice guidelines are designed to provide the overview of what to do and in which sequence – that is, as a checklist, while the textbooks provide the technical and methodological details of how to do it.

The phases of the guidelines are:

1. Study exploration focusing on the starting question of the evaluation study,
2. First study design focusing on the preliminary design of the evaluation study,
3. Operationalisation of methods focusing on making the design and evaluation methods concrete and compliant with the organizational setting and the information need, while taking into account the known pitfalls and perils,
4. Detailed study plan and project plan focusing on providing plans and procedures detailed to the level necessary for the specific study,
5. Evaluation study implementation focusing on activities related to the actual accomplishment of the designed evaluation study,
6. Project control and risk management focusing on the good project management practices specifically for an evaluation study,
7. Finalisation of the evaluation study focusing on accounting, archiving of materials, and reporting of evaluation studies in terms of the STARE-HI guidelines.

The GEP-HI paper presenting the latest update of the guidelines is available at http://iig.umit.at/efmi

1.3. Conclusion and further development of the guidelines

A comprehensive list of 60 issues relevant for properly developing, executing and finalizing health informatics evaluation studies is elaborated on in the GEP-HI guidelines. These issues are presented in relation to various phases of an evaluation study. The issues cover various aspects, such as the real information need, the context of the study, the identification of stakeholders, risk and project management, financial aspects, ethical and legal issues, global and detailed study design, identification and management of biases etc. When these issues are properly dealt with in evaluation studies, their general validity and generalisability is likely to be increased, since a number of potential omissions, pitfalls and risks will be actively identified and dealt with. As a consequence the improved quality and validity of individual studies will strengthen the evidence base of health informatics and in the end lead to improved validity of meta-analyses of health informatics applications.

With these Good Evaluation Practice guidelines for Health Informatics (GEP-HI) we hope to inspire evaluators from the earliest possible point onwards, namely starting at the study exploration phase to be aware of potential omissions, pitfalls and biases in the design, the planning and execution of an evaluation study. These guidelines present the knowledge in a form that is easy to follow and to take into account at planning and execution of an evaluation study, yet without the overwhelming scenario-specific alternative details that would turn the guidelines into an encyclopaedic 'cook book'. The present guidelines serve to get the overview of **what** to do and in which sequence – that is, as a checklist; while the textbooks may provide the details of the **how** to do it.

Further development and validation of the guidelines will be done by users of the guidelines in real evaluation studies. Feedback and input from those who apply the guidelines will be collected continuously by the EFMI and IMIA working groups and by EFMI WG Eval website and mailing list.

2. Outline of the workshop

The objectives of <u>the Good Evaluation Practice guidelines</u> workshop are to present the guidelines, their objectives, development and contents and to demonstrate them in a case study. The participants are invited to critically assess the value of GEP-HI and thereby contribute to the continuous refinement of the guidelines.

Workshop moderator: Michael Rigby
<u>Presentations:</u>
- Importance of robust evaluation evidence base: Elske Ammenwerth, Michael Rigby
- Good evaluation practice guidelines – objectives, development, contents: Pirkko Nykänen
- A walk-through of the key guidelines issues: Jytte Brender
- Interactive session: Case study example: a guideline based Decision Support System (DSS) for cardiac rehabilitation: Nicolet de Keizer, Jan Talmon
- Summary and conclusions: Michael Rigby

Who should attend: Informatics researchers, health informaticians, researchers, system designers, stakeholder health professionals, policy makers.

Goal: Participants will learn in theory as well as by a practical example on evaluation study planning, on what issues to consider and how to carry out the study. They will also learn to understand the importance of evaluation.

Prerequisites: none, although some evaluation experience will help.

This GEP_HI work is a shared activity of EFMI's Working Group EVAL and IMIA's Working Group on Technology Assessment and Quality Development.

References

[1] 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.

[2] Talmon J, Ammenwerth E, Brender J, de Keizer N, Nykänen P, Rigby M. STARE-HI - Statement on Reporting of Evaluation Studies in Health Informatics. Int J Med Inform 2009, 78 (1), 1-9.

[3] Kaplan B, Shaw N. Future directions in evaluations research: People, organisational and social issues. Meth Inf Med 2004, 43, 215-231.

[4] Friedman CF, Wyatt J. Evaluation methods in medical informatics. Second edition. Springer Verlag, New York, 2006.

[5] Brender J. Handbook of Evaluation Methods for Health Informatics. Academic Press, New York, 2006.

[6] Westbrook JI, Braithwaite J, Georgiou A, Ampt A, Creswick N, Coiera E, Iedema R. Multimethod evaluation of information and communication technologies in health in the context of wicked problems and sociotechnical theory. J Am Med Inform Assoc 2007, 14, 746-755.

[7] Yusof MM, Papazafeiropoulou A, Paul RJ, Stergioulas K. Investigating evaluation frameworks for health information systems. Int J Med Inform 2008, 77, 377-385.

[8] Quinn Patton M. Qualitative Research & Evaluation Methods, 3rd Edition. Sage Publications, Thousand Oaks, 2002.

[9] Davidson EJ. Evaluation Methodology Basics, the Nuts and Bolts of Sound Evaluation. Sage Publications, Thousand Oaks, 2005.

[10] Fink A. Evaluation Fundamentals, Insights into the Outcomes, Effectiveness and Quality of Health Programs. Sage Publications, Thousand Oaks, 2005.

[11] Owen JM. Program Evaluation, Forms and Approaches, 3rd edition. The Guilford Press, New York, 2007.

[12] Ammenwerth E, de Keizer N. An inventory of evaluation studies of information technology in health care trends in evaluation research 1982-2002. Meth Inf Med 2005, 44 (1), 44-56.

[13] Vimarlund V, Olve N-G. Economic analyses for ICT in elderly healthcare: Questions and challenges. Health Informatics Journal 2005, 11 (4), 309-321.

Equator Network. Reporting Guidelines, http://www.equator-network.org/ (visited 06-12-2007).