



Good Evaluation Practice in Health Informatics – GEP-HI

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AMIA 2009 Workshop Proposal

Good Evaluation Practice in Health Informatics – GEP-HI

This workshop is sponsored by the AMIA Evaluation WG

Abstract: Several authors have presented text books that provide guidance on the selection of study designs and methods for evaluation studies in health informatics. They often indicate some of the methodological pitfalls (and related biases) that may exist. Nevertheless, researchers are still asking for guidance on how to do evaluation studies in practice. Many of the questions are not related to the methods to use, but to how to get a proper definition and profile of the evaluation project, such that the results can inform a decision to be made. To address this problem and need, members of the AMIA, EFMI and IMIA working groups on evaluation have developed GEP-HI: Guidelines for Good Evaluation Practice in Health Informatics.

The objective of this workshop is to briefly present those guidelines and to discuss with the participants a few case studies to demonstrate what problems may arise and how GEP-HI could guide the planning, design and execution of a Health Informatics Evaluation study. GEP-HI can be applied broadly including, but not restricted to evaluations during the development, implementation and post-marketing surveillance of EHRs, PHRs, CPOE, clinical databases, NLP systems for clinical use etc. Participants are encouraged to familiarize themselves with GEP-HI that is available at <http://iig.umat.at/efmi/>.

Keywords (MeSH): Guidelines, Health Informatics, Evaluation

Duration: workshop
Level: introductory

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1. Description and topical outline of workshop

Evaluation of health informatics (HI) applications is an ethical imperative. Because of the potential effect that such applications have on the quality of care, they should be evaluated as thoroughly as any other medical intervention. There are however major differences compared to new drugs and other medical interventions because HI applications often have an impact on the organization and the way health care professionals provide their service. This impact on people and organizations make that the approaches used for the evaluation of other medical interventions provide too restricted a view. For example usability studies can address whether the HI application provides a safe environment that can smoothly be integrated in the process of care provision.

Besides this need to assess HI applications from a health care perspective, there is also a political and economic need to evaluate HI applications. Major investments are being made in the health care sector worldwide. In several countries HI infrastructures are being developed that support the exchange of health care information with the objective to improve the quality of the health care delivered and to reduce avoidable errors.

Given this complexity there is a need for guidance for the design and execution of evaluation studies of HI applications. Members of the evaluation working groups of AMIA, IMIA and EFMI have contributed to the development of such guidelines, which are currently known as GEP-HI.

The objective of this workshop is to present the principles of GEP-HI and to demonstrate how to apply these guidelines using one or more case studies. The participants of the workshop will be actively engaged in this process. Not only will

participants apply the GEP-HI guidelines in the case studies, but the rationale of the principles of GEP-HI will be discussed and feedback from the audience will be solicited to inform the ongoing refinement of the guidelines.. The a selection of the following issues will be discussed organized according to the various phases of an evaluation study, dependent on the interests of the audience, and how the case studies develop in the interaction.

A. Preparation phase

- Defining the information need
- The context of the evaluation study
- Identification of stakeholders
- A global draft of the approach, including the setting, the possible methods
- An outline of the kind of results one can expect given the proposed approach
- Initial budget estimates
- Ethical and legal issues
- Identification of restrictions on the execution of the study and the publication of results

B. First study design

- Elaboration of rationale for study, formally define the evaluation issues and questions
- Elaborate the stakeholder analysis, study the social network
- Elaborate the organizational setting and technical setting of the evaluation study,
- Define expectations on participation of the various stakeholders (including management support, study participants, access to environment etc)
- Elaborate the methods to be used, the timing of the study and the associated resources needed
- Risk analysis
- Strategy on reporting

C. Operationalisation of Methods:

- Specify methods to be used in detail, including a description of the known pitfalls and perils, the required skills
- Define a frame of reference for the interpretation of results (e.g. establishment of a baseline measurement prior to intervention, an overview of what is already known on the topic etc)
- Define the outcome measures in detail
- Specify the quality control of the data/measures
- Detail the study flow
- Address the ethical and legal issues, including Internal Review Board (IRB) approval when needed

D. Detailed project plan

- Define project structure and project management
- Establish quality and risk management
- Define communication strategy
- Define additional required staff

E. Evaluation Study Implementation

- Establish the frame of reference
- Observation of changes
- Quality control
- Interpretation of observations
- Project, quality and risk management
- Reporting

F. Final evaluation Phase

- Reporting and publications (cf STARE-HI)
- Archiving of observations, reports etc.
- Debriefing

2. Attendee background

Basic knowledge on evaluation of health informatics applications.

3. Presentation format

The presenters will use slide-based presentations. Participants are encouraged to prepare themselves by reading downloading and reading the GEP-HI guidelines from the EFMI WG website. Furthermore, cases will be discussed in an interactive way with the audience to stimulate discussion on the guidelines and the approaches that can be taken.

4. Learning Objectives

After the workshop, participants will be able to:

- Appreciate the need for a project based approach for evaluation studies in health informatics
- Understand the criticality of the scope of the study
- Understand potential risks
- Appreciate the ethical aspects of evaluation studies in health informatics
- Understand the relevancy of including all stakeholders involved in the use of a health informatics application.

5. Required Equipment

No special equipment, other than the presenters' laptops will be required.

6. Classification

Practice-oriented and educational.

7. Brief Biographies of the presenter(s)

Jan Talmon, PhD, is Associate Professor in Medical Informatics at the University of Maastricht, The Netherlands. He has been active as a researcher in the field of medical informatics for more than 30 years. He has been a supervisor of several PhD students and in that capacity has been involved in several evaluation studies of prototype systems in both laboratory and practice settings. He is editor of the International Journal of Medical Informatics and reviewer for several Medical Informatics journals and conferences. He is co-author of the Declaration of Innsbruck that led to the development of GEP-HI and the accompanying guideline for reporting of evaluation studies STARE-HI. Together with Elske Ammenwerth he led the development team of STARE-HI. He is an active participant in the development of GEP-HI.

Marie-Catherine BEUSCART-ZEPHIR worked for 15 years as assistant and assistant-professor at the Faculty of Psychology of Lille where she specialized in cognitive psychology and problem solving. In 1995, she moved as a senior researcher to the Medical Informatics Laboratory (CERIM) at the Faculty of Medicine (University of Lille2) where she developed researches in the domain of Ergonomics and Cognitive Psychology for the Healthcare domain. MC Beuscart-Zéphir is the founder (2001) and present manager of the Evalab, a usability lab supported by the University Hospital of Lille, the Faculty of Medicine of Lille and the Region Nord-Pas-de-Calais. Evalab is dedicated to the analysis, evaluation and optimization of Information Technologies and Informatics/Telematics solutions for Healthcare. As such, Evalab is accredited by the French ministry of health. MC Beuscart-Zéphir is an active participant in the adaptation of GEP-HI to Human factors studies for Health Informatics

Dr. Peter L. Elkin is a Professor of Medicine at the Mount Sinai School of Medicine. He is the Center Director of Biomedical Informatics and the Vice-President of Mount Sinai hospital for Biomedical and Translational Informatics. He received his Bachelor of Science from Union College and his M.D. from New York Medical College. He did his Internal Medicine residency at the Lahey Clinic and his NIH/NLM sponsored fellowship in Medical Informatics at Harvard Medical School and the Massachusetts General Hospital. Dr. Elkin has been working in Biomedical Informatics since 1981 and has been actively researching health data representation since 1987. He is the primary author of the American National Standards Institute's (ANSI) national standard on Quality Indicators for Controlled Health Vocabularies ASTM E2087, which has also been approved by ISO TC 215 as a Technical Specification (TS17117). He chairs the OASIS International Healthcare Continuum and served as a co-chair of Health and Human Service's HITSP Technical Committee on Population Health. Dr. Elkin served as the co-chair of the AHIC Transition Planning Group. Dr. Elkin is a Master of the American College of Physicians and the American College of Medical Informatics. Dr. Elkin chairs the International Medical Informatics Associations Working Group on Human Factors Engineering for Health Informatics. He was awarded the Mayo Department of Medicine's Laureate Award for 2005. Dr. Elkin is the index recipient of the Homer R. Warner award for outstanding contribution to the field of Medical Informatics.