



Guideline for good evaluation practice in health informatics (GEP-HI)

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ABSTRACT

Objective: Development of a good practice guideline to plan and perform scientifically robust evaluation studies in health informatics.

Methods: Issues to be addressed in evaluation studies were identified and guidance drafted based on the evaluation literature and on experiences by key players. Successive drafts of the guideline were discussed in several rounds by an increasing number of experts during conferences and by e-mail. At a fairly early point the guideline was put up for comments on the web.

Results: Sixty issues were identified that are of potential relevance for planning, implementation and execution of an evaluation study in the health informatics domain. These issues cover all phases of an evaluation study: Preliminary outline, study design, operationalization of methods, project planning, execution and completion of the evaluation study. Issues of risk management and project control as well as reporting and publication of the evaluation results are also addressed.

Conclusion: A comprehensive list of issues is presented as a guideline for good evaluation practice in health informatics (GEP-HI). The strengths and weaknesses of the guideline are discussed. Application of this guideline will support better handling of an evaluation study, potentially leading to a higher quality of evaluation studies. This guideline is an important step towards building stronger evidence and thus to progress towards evidence-based health informatics.

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1. Introduction

Development and use of health informatics applications offer tremendous opportunities to improve health care, its delivery and outcomes. There is an increasing political urge to implement available information technology (IT) solutions, as discussed by Refs. [1–4]. However, there are also hazards and

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problems related to the use of IT in health care, for example IT may be inappropriately specified, unreliable, user-unfriendly or the organization may not be properly prepared to adopt IT within the clinical work flows and processes, as shown by Ref. [5]. Health IT may also be ill-functioning, for example inducing medical errors by presenting faulty displays of the electronic health records, see Ref. [6], or having negative impacts on the outcome of care in a specialised care unit, as documented by Ref. [7]. The effectiveness of health IT is still limited and inconsistent, across a wide range of fields, as reviewed by Ref. [8]. In the primary care the only benefits reliably documented on health information exchange were those on efficiency, including improved access to test results and other data from outside the practice, and decreased staff time for handling referrals and claims processing. Barriers included cost, privacy and liability concerns, organizational characteristics, and technical barriers, see Ref. [9]. This situation calls for evaluation to provide robust evidence about the impacts and actual efficiency, quality, and safety gains of health IT that can be achieved.

Evaluation is the means to assess the quality, value, effects and impacts of IT in the health care environment, as stated by Refs. [10,11]. Evaluation is defined as the “act of measuring or exploring properties of a health information system (in planning, development, implementation, or operation), the result of which informs a decision to be made concerning that system in a specific context” [[12], p. 480]. The white paper [13] suggests extensive and systematic pre-implementation evaluation studies to inform difficult decisions prior to starting any programme initiative as well as post-implementation evaluation studies. The present contribution provides a guideline for conducting health IT evaluations. It goes beyond pre- and post-impact evaluation to support evaluation studies in general, formative as well as summative studies. Formative evaluation is performed throughout the systems lifecycle and it provides information for improving the system under development. Summative evaluation is focused on assessing the effect or outcome of the evaluation object at a certain point of time after implementation [14].

The exploratory workshop HIS-EVAL by European Science Foundation (ESF) was instrumental in identifying the state of affairs with respect to evaluation of health IT applications and in defining the necessary steps to further evaluations [12]. An important result from the workshop was the Declaration of Innsbruck [15] summarizing the importance of evaluation as:

“Health information systems are intended to improve the functioning of health professionals and organizations in managing health and delivering healthcare. 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 information systems”.

Reflective deliberations at the HIS-EVAL workshop led to the conclusion of a need for two guidelines: One for struc-

tured reporting of evaluation studies (STARE-HI¹) and one for good practice for planning and execution of evaluation studies (GEP-HI). The STARE-HI statement is finalized and published in Ref. [16]. It is endorsed by the board of the European Federation of Medical Informatics (EFMI) and adopted as an official document by the International Medical Informatics Association (IMIA), and is cited by the Equator network for good reporting of health informatics studies [17]. The present paper describes the GEP-HI guideline as well as its development process.

1.1. Background

The current state of evaluation studies was explored in a review of problems and pitfalls [[11], pp. 243–323] resulting in a listing of several biases one should be aware of when designing and executing an evaluation study. These biases may result in incorrect results, wrong interpretations and under- or over-estimation of the findings. In the review [11] many examples were found for most of the identified biases while it was difficult to find publications on high quality studies that properly addressed all of these potential biases. The conclusion is that evaluation of health IT is more than the deployment of a collection of methods, it is both a discipline and a specialty, and requires an overarching objectives-led design and operational management. Evaluation can be compared with health technology assessment (HTA), but HTA is based on a pre-defined formal framework and usually has a summative nature using general evaluation methods and approaches, often quantitative in nature, see Ref. [18]. Reviews of the health IT evaluations commissioned for the IMIA Yearbook showed the importance of evaluation, the challenges, and the currently very limited response, both in recognising integrated methodologies and in endorsing the importance of robust studies, as argued by Refs. [19,20].

The need to develop and publish a guideline was identified in the health IT evaluation domain concurrent with the GEP-HI guideline development. In a literature review on discourses, dimensions and methods of health IT evaluation the conclusion was that the identified evaluation frameworks differed in terms of generality, specificity, timing related to system development phases and theoretical underpinning, see Ref. [21]. GEP-HI adds to this knowledge by presenting a guideline for design and execution of an evaluation study.

A Model for ASsessment of Telemedicine applications (MAST) was developed in an EU-project Metho-Telemed to give advice to users on what to consider before an evaluation study. The MAST-model lists aspects of telemedicine evaluation within seven domains of outcomes: Health problem and characteristics of the application, safety, clinical effectiveness, patient perspectives, economic aspects, organizational aspects and socio-cultural, ethical and legal aspects, see Ref. [22]. It is planned as a toolkit, a checklist of issues that need to be considered in evaluation. MAST is based on a HTA approach and focuses on telemedicine systems, not on health IT generally. In contrast, this GEP-HI guideline is wider and applicable to evaluation of health IT in general. Additionally, MAST does

¹ Abbreviation for “STatement on Reporting of Evaluation studies in Health Informatics”.

not consider the execution and management of an evaluation project.

Cusack et al. developed for the US Agency for Healthcare Research and Quality (AHRQ) a toolkit to provide step-by-step guidance for developing evaluation plans for health IT projects [23]. The toolkit assists evaluators in defining 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 methods for each item. The toolkit is very useful from the methodological point of view and it can be applied within the GEP-HI guideline. The toolkit does not, however, give guidance on the evaluation project itself, how to manage it, how to carry out the project, or how to complete and report the study. Thus it details only part of the GEP-HI guideline.

Life cycle frameworks for evaluation have been proposed for example by Catwell and Sheikh [24] and Clarke et al. [25]. These are focused on how to evaluate health IT interventions while being designed, developed and deployed. These schematic models are formative and relate evaluation to the phases of the system development. The frameworks propose various evaluation measures and checkpoints during the system phases. The lifecycle evaluation frameworks are valuable tools to monitor the development process and the deployment of a new system. The frameworks do not, however, give guidance for the planning and execution of an evaluation project, and do not support evaluation as an independent activity.

Additional reports on various approaches and frameworks on evaluation are published, for example in Refs. [26–31]. These frameworks can be applied together with the over-arching GEP-HI guideline as they provide support for methodical choices but do not deal with the overall design and execution of an evaluation study as do the GEP-HI guideline.

1.2. Objective of the guideline

The objective of the GEP-HI guideline is to give advice on how to design and carry out evaluation studies in various health IT contexts. The guideline aims to be general and practical, and to provide evaluators with a set of structured principles for good evaluation practice. The principles are inspired by the best evaluation practices as implicitly and explicitly described in the literature. In the guideline we point at issues and list recommendations on how to design evaluation studies, how to make methodological choices, how to conduct studies, and how to define evaluation criteria at specific phases of the health IT applications' life cycle.

2. Method

The method applied to develop GEP-HI guideline was a consensus-seeking process within the community of health IT evaluation experts. The primary authors of GEP-HI, all were participants of the ESF HIS-EVAL Workshop (see Ref. [15]) and active in the EFMI and IMIA working groups dealing with evaluation of health IT applications and HTA; and they all have long experience in planning and conducting evaluation studies [see for example Refs. [5,11,12,16,19,20,25,30,32,33,36,38]]. The

starting point for the guideline development was the existing knowledge, experience and literature on evaluation studies, methodologies, guidelines development, codes of ethics and good implementation practices. In particular the following recent review material, encyclopaedias and textbooks provided the foundation for preparation of the guideline: [11,12,16,32–38].

An initial list of important items was drafted based on the literature analysis as well as on the experiences of the authors. The guideline also took inspiration from other types of guidelines within health informatics and medical research, such as guidelines cited by the Equator Network [17], the Agree Collaboration [39], the CONSORT statement [40–42], the QUOROM statement [43], the STARD statement [44], the STROBE [45] and an extension of the CONSORT [46]. Overviews of the various guidelines are published in Refs. [17,47].

At regular intervals, the GEP-HI guideline was presented and/or submitted for discussion among an increasing number of evaluation experts through EFMI's EVAL-working group mailing list, see Ref. [48]. This mailing list includes a comprehensive list of people with expertise in evaluation (340 in total as per December 2010) ranging from evaluation experts to healthcare practitioners, and coming from universities and health organizations, from industries, and elsewhere. Initial ideas for the guideline were presented and discussed in workshops during the World Congress on Medical Informatics (MEDINFO) in 2004, and Medical Informatics Europe (MIE) in 2005 and 2006 congresses. Feedback was collected in these workshops to inform the core team for further elaboration of the guideline. The guideline items were not formally rated or balloted, but agreements were achieved during consensus discussions in working sessions and by emails. A first full draft of the guideline was presented at MEDINFO in 2007 and elaborated further at workshops in MIE 2008 and MIE 2009 as well as at a dedicated Amsterdam working conference in 2008 juxtaposing GEP-HI with the needs of usability evaluation studies. The close-to-final version of GEP-HI was presented in a workshop in MEDINFO 2010 for discussion and led to further feedback included in this current version.

3. GEP-HI guideline for evaluation STUDIES

This GEP-HI guideline presents the essential aspects and activities to be taken into account in the design and execution of an evaluation study, including the study's management. The specific methods to be used are not explicitly mentioned. It is up to the users of the guideline to identify which method is applicable in their specific concrete situation, for instance by means of the latest edition of handbooks and textbooks like Refs. [11,35,49–54], and other relevant literature such as Refs. [21,31,37,38,55] as well as websites collecting evaluation studies [48]. The use of models and theories in methodological implementation is strongly recommended.

The guideline is divided into parts corresponding to the phases of an evaluation study (Fig. 1). The theoretical background for the study phases is analogous to a traditional approach in information systems development models, here presented in a cascade fashion. Implementation may equally well be seen as an iterative spiral because the topics are in

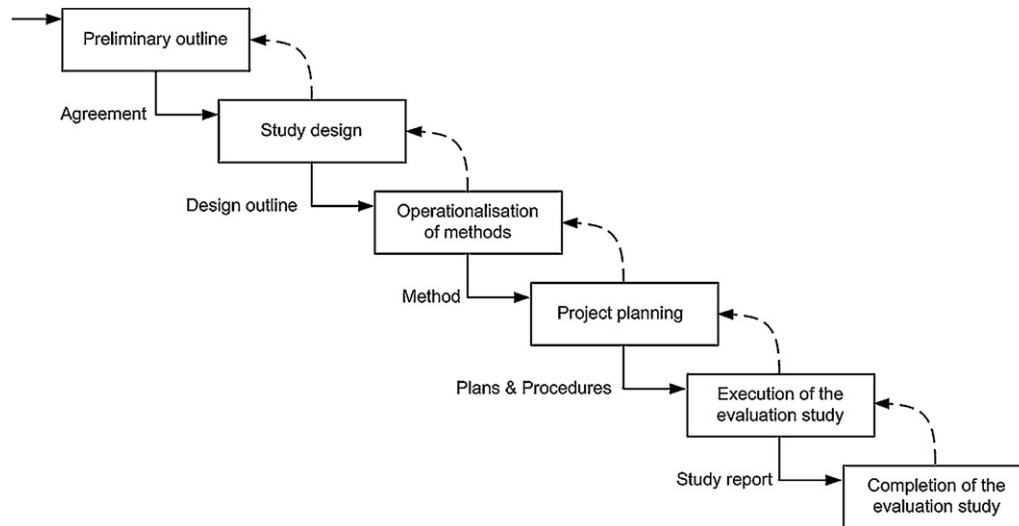


Fig. 1 – Phases of the GEP-HI guideline.

general repeated in depth or breadth to achieve progress during all phases, and because of the feedback loops urging to revisit earlier phases when new aspects, additional information, or changes in context appear. The phases include items that are coherent and meaningful components for the given phase. The phases in GEP-HI guideline are:

- *Preliminary outline* presenting the purpose of the study and the first ideas on why, for whom, and how the evaluation should take place,
- *Study design* clarifying the design issues for the evaluation study,
- *Operationalization*² of methods making the methodological approach and methods concrete and compliant with the system type, the organization and the information need,
- *Project planning* developing plans and procedures for the evaluation project,
- *Execution of the evaluation study* accomplishing the designed evaluation study,
- *Completion of the evaluation study* reporting, accounting, archiving of evaluation study results, finalization of outstanding issues and formal closure of the evaluation study.

The phases and their related issues are described one by one in more detail in the following sections according to the overview in Table 1.

3.1. Preliminary outline

This phase describes the purpose of the evaluation and the evaluation question, the primary hypothesis stimulating or initiating the study, and the subsequent explorative activities to establish its feasibility and relevance. This phase is the strategic planning level and it forms the basis for the entire study.

The evaluator should get acquainted with the prior research and evaluation studies that address similar topics as the study at hand to get an overview of the approaches and to learn from previous work. The following articles and textbooks provide good background [10-12,16,19-21,30,31,35,38].

During the preliminary outline phase the following items should be addressed:

- *Purpose of the study*: Establish the purpose of the study, the preliminary hypothesis reflecting the information need. As stated in the Declaration of Innsbruck [15]: “Evaluation of IT in health care only has a value when there is a purpose, i.e. there is a question to be answered, for example improvement of knowledge and generation of insight from a scientific perspective, or making informed decisions about design, procurement, development or routine operation of a health information system”. Establishing the purpose and the preliminary hypothesis is relevant, as these will guide almost all of the study design decisions and will secure that the results obtained are clear and relevant to those who will be involved in the decision or affected by it.
- *Primary audience*: Identify the recipients, readers and users of the evaluation results.
- *Identification of the study funding party(ies)*: Identify the payers, funders of the evaluation. They may, for instance, be the evaluators, their employer, a system development project, a university, a company, a health care organization or institution, an external research foundation, or a governmental organization. It should be noted from the beginning what potential bias the given funder may create, explicitly or unintentionally, and hence what measures need to be taken demonstrably to minimize such bias.
- *First identification of stakeholders*: Identify, broadly, who are the stakeholders in this evaluation study. By ‘stakeholders’ we mean the interest groups such as IT developers, users in this or in another organization, management, policy makers, healthcare funding bodies, patients, and so on, all those who may be directly or indirectly affected by the study itself,

² The act of making the method operational (ready for use) for its specific purpose and context.

Table 1 – The phases and items of the GEP-HI guideline.

Phase no	Phase	Items of the phase
1	Preliminary outline	<ul style="list-style-type: none"> - Purpose of the study - Primary audience - Identification of the study – funding party(ies) - First identification of stakeholders - Identification of required expertise - The organizational and user context of the evaluation study - Object of evaluation, type of health IT - First exploration of evaluation methods to be used - Ethical and legal issues - Budget - Preliminary permissions for publication - Result of preliminary outline - Formal acceptance to proceed to the next phase
2	Study design	<ul style="list-style-type: none"> - Detailed rationale and objectives for the study - Key evaluation issues, questions, indicators - Stakeholder analysis/Social Network analysis - Study methods - Organizational context, the study setting - Technical setting, the type of health IT - Participants from the organization - Project timeline - Material and practical resources - Establishment of the study team - Risk analysis and quality management - Budget - Ethical and legal issues - Strategy for reporting and disseminating the results - Result of study design - Formal acceptance to proceed to the next phase
3	Operationalization of methods	<ul style="list-style-type: none"> - Study type - Approach - Assumptions and feasibility assessment - Frame of reference - Timing - Justification of the methodological approach - Expertise - Outcome measures - Avoiding Bias - Quality control on data (measures) - Participants - Ethical and legal issues - Result of operationalization of methods - Approval of operationalization of methods
4	Project planning	<ul style="list-style-type: none"> - Project management - Study flow - Evaluation activity mapping - Quality management - Risk management - Recruitment of necessary staff - Inform all relevant stakeholders - Result of project planning - Approval of project planning
5	Execution of the evaluation study	<ul style="list-style-type: none"> - Undertake the study, collect data and interpret observations - Quality control of findings and observation of changes - Continuous project management, quality and risk management - Regular reports - Final result of execution of the evaluation study

by its anticipated outcome, by the system being evaluated, or by future implementations/revisions.

- *Identification of required expertise*: Identify the required evaluation expertise dependent on the type and scope of the

study. In some cases it may be necessary to involve an experienced evaluator or an external consultant, e.g. a statistician, either as a partner, as a discussant/mentor, as an actor or as actual participant in the study. It is important

that the neutrality of evaluators is already established at this early phase, and evaluators should preferably be impartial in relation to the object of evaluation. If they are not neutral and independent, it should be made clear from the beginning what kind of relations they have and what measures are taken to minimize the potential resulting bias.

- *Organizational and user context of the evaluation study*: Outline a preliminary picture of the organizational context where the evaluation study will be performed. Describe roughly the organization (unit/department, and the type of care provider and health system) and the user types that will be involved in the evaluation study.
- *Object of evaluation, type of health IT*: Prepare a first description of the object of the study, i.e. description of the system, application, method or service to be evaluated. It is important to present which features of the system are in focus at the evaluation.
- *First exploration of evaluation methods to be used*: At this stage it is important to develop an overview of applicable and suitable methods to serve the purpose, given the context and the conditions of the study. Selection of methods is to be based on the study purpose and objectives, the study type (for example objective or subjective, summative or formative) and the information need (quantitative or qualitative, objective or subjective, prognostic or diagnostic, etc.). To search for available methods see for example the review in Ref. [11].
- *Ethical and legal issues*: Seek informal advice on which legal and ethical aspects need to be considered and solved, examples are:
 - The ethical and legal aspects related to patient data access and usage (data privacy and confidentiality)? How will anonymity of confidential patient (and end user) data be handled? Are patient and/or staff consents necessary? Is it mandatory to get approval from ethical committees or similar bodies?
 - Are there any conflicts of interest or likely issues or restrictions, publication-wise, financially, or personally, or by a particular stakeholder that needs to be taken into account upfront?
 - How are the intellectual property rights (IPR) to be managed? Will IPR in terms of business secrets impact the study execution and/or reporting?
- *Budget*: Outline a draft budget, or alternative budgets, based on the purpose, objectives, scope and the desired depth of the study, and the list of applicable methods. The budget should present the estimates of the needed resources.
- *Preliminary permissions for publication*: Ask always the appropriate authority(ies) for permission to publish the results before a study starts, thus ensuring right to report the study results. The main goal is to be able to present the study results openly without pressure from any of the stakeholder groups, and if there are publication constraints, for instance from a sponsor, you need to know those conditions for publication in detail.
- *Result of the preliminary outline phase*: Document the result as an outline report that presents a draft design of the study, including description of the study purpose, preliminary hypothesis and information need, the evaluation object, the system under study and its organizational

environment, the aspects of interest in evaluation, publication constraints, the draft budget and the resources and co-operation needed. The outline document should also indicate whether the outlined study is feasible from the perspectives of stakeholders, funding parties and the organizational and user contexts.

- *Formal acceptance to proceed to the next phase*: Present the outline report for political or administrative bodies within the information system's organizational environment, for the sponsor of the study, and for staff/professional committees and/or ethics committees. Which bodies to approach depends on who has to authorise these kinds of decisions as well as on which party could potentially influence the execution of later phases of the evaluation study.

3.2. Study design

This phase builds the foundation for developing the detailed project plan. During the study design phase the following items should be addressed:

- *Detailed rationale and objectives for the study*: Formulate the rationale for the study and reasons to carry out the study, and describe the detailed study objectives.
- *Key evaluation issues, questions, indicators*: Describe the key issues, main questions and evaluation criteria or indicators to be addressed in the evaluation. Are there any desirable secondary evaluation questions? Make sure that the list of key issues corresponds to the study objectives.
- *Stakeholder analysis/social network analysis*: Elaborate the stakeholder analysis while addressing both the formal and informal aspects of the organization to get the full picture of the stakeholders, their relations, and their possible support or resistance.
- *Study methods*: Make a shortlist of methods for the study, for example with which methods it is possible to acquire the data and information necessary to provide the answers to the key evaluation questions. Get acquainted with the assumptions and perspectives behind these candidate methods, the validity of methods and how easy or difficult they are to use.
- *Organizational context, the study setting*: Develop a more detailed description of the organizational context where the evaluation study will be carried out. Important issues to consider are the kinds of organizational units that will be involved, their type and size and their roles and tasks in the evaluation study. The implementation of IT systems in an organization usually impacts the distribution of tasks between healthcare professionals, the communication and cooperation procedures, and the distribution of information across individual minds and tangible supports. Moreover, the quality and completeness of the training process also has an impact on the resulting work situation. Unfortunately those intermediary (hidden) variables are usually not controlled and their impact on the results of the evaluation study not taken into account. As a result, a given IT system implemented in similar organizations may end up generating fundamentally different work systems as far as collective and individual cognitive and work processes are concerned. Depending on the type of IT application under

evaluation, the description of the organizational context may need to be completed by a human factors (HF) based analysis of the work system to be able to identify the relevant HF intermediary variables and their potential impact on the results of the evaluation study.

- *Technical setting, the type of health IT*: Prepare a description of the evaluation object, system, application, service or method to be evaluated covering sufficient system details, system type and phase of development, and any other aspects of interest. It is recommended that trainers and users of the health IT system under study verify the technical description. This is to ensure the right level of understanding by all involved parties. Describe also how the object of study fits within the larger health IT environment of the organization or unit, and where relevant within the wider health sector.
- *Participants from the organization*: Describe the participants to be recruited from the organization, system users and other health professionals. Describe their roles and tasks in the organization and in the study, and the arrangements and permissions needed to have these participants involved in the evaluation study, and how potential bias will be mitigated.
- *Project timeline*: Outline one or more alternative schedules, and calendars, for the project duration, project events and milestones.
- *Material and practical resources*: Describe what is needed in the health care organization and what are the materials and resources that need to be brought in by the evaluation team.
- *Establishment of the study team*: Identify the person-related resources and the personal competencies and powers that are needed from the organizational environment and what is available from external sources. Identify and appoint members of the team to carry out the evaluation study. Make clear that evaluators must be impartial and unbiased in relation to the object of the evaluation. If not transparently achievable, describe their relations and what measures are taken to minimize the risk that these relations influence the outcome of the study.
- *Risk analysis and quality management*: List elements that comprise significant risks such as potential changes in key personnel, potential unexpected events in the study environment, ongoing adaptation of the IT application, process changes, potential failures of the health IT system installation and other systems being installed during the study period. Prepare a preliminary quality management plan that describes the organization of the project, roles and responsibilities of the participants, control actions and tools for monitoring the progress and for reporting.
- *Budget*: Refine the budget of the study to the necessary level of detail based on the current study design, estimated participants and resources and planned scope and study duration. Take into account that some variants depended on the methods to be chosen.
- *Ethical and legal issues*: Pay attention to legal and ethical issues. Data protection, security and privacy principles and laws must be obeyed. Some study types may require legal registration, e.g. registration in a clinical trial registry. Ethical issues are related to consents needed to manage confidential patient (and possibly practitioner and organiza-

tion) data and permissions from the organization to involve users (nurses, doctors) in the study. Further, formulate a strategy, policy and principles for how to handle problematic issues that may be identified or observed during the project period – examples may be procedures for how to deal with observation of human errors, observed adverse events, and similar events that will expose individuals or the organization. It is advisable to engage an Ethical or Internal Review Board (IRB) at this stage to identify potential barriers that should be dealt with in the final study plan.

- *Strategy for reporting and disseminating results*: Pay attention to the following two issues: (i) How the results of the study will be communicated locally to the various study stakeholders; and (ii) how the study results will be reported and disseminated in the public domain. These should be encapsulated and shared in a communication strategy. For reporting, define the reporting schedule with the type, scope and contents of the reports. Use the STARE-HI reporting principles for the definition of the report content [16]. Specify the target audience, the responsible authors, the strategy for handling ethical issues in reporting, the other publication and dissemination means, for example scientific journals, conference papers, reports, presentations, web-based publications, etc. Define whether any approval is needed and clarify what acknowledgements and disclaimers should be used in various publication types.
- *Result of the study design phase*: Document the study design as a first evaluation study plan, which forms a basis to achieve an agreement with the appropriate decision-making authorities and a commitment as regards to the organization's engagement and resources.
- *Formal acceptance to proceed to the next phase*: Seek formal acceptance from the necessary stakeholders in order to proceed with evaluation planning.

3.3. Operationalization of methods

This phase deals with the selection of appropriate methods to answer the evaluation questions in accordance with the study context and setting, the physical and financial resources and the objectives of the study. It is essential to consult textbooks and handbooks on evaluation methods, since there are many potential impediments to the desired level of quality, accuracy and precision of the outcome. Examples of relevant textbooks, handbooks and articles in this respect are Refs. [11,21,23,35,37,49–54].

3.3.1. Methodological aspects

The following methodological aspects should be addressed:³

³ 'Methodology' signifies "the science of methods". In functional terms it is concerned with the knowledge of how to prepare and use methods in some context [11], pp. 13–14]. A 'method' is a formal description of the procedures involved to accomplish an actual task, based on a well-defined theory and a set of coherent and consistent techniques, tools and principles for organizing it.

- *Study type*: Specify in detail the characteristics of this evaluation study, for example quantitative or qualitative, subjective or objective, formative or summative.
- *Approach*: Make an informed choice on the approach and methods. Describe in detail the selected methodological approach(es) (for example observational, case-study, action research, conceptual research, empirical study).
- *Assumptions*: Specific approaches may imply various assumptions – for example on their scope, specificity and application range, on the results' interpretation or on the data set. Identify the consequences of these assumptions and consider how they may affect the study outcomes.
- *Frames of reference*: Specify the frame of reference for the interpretation of the findings of the study. In some evaluation approaches, the establishment of a frame of reference is an integrated feature of the method/methodology, such as in before-and-after studies and controlled studies. For other methods requiring a frame of reference, this may be compiled from several sources, for example from the organization's pre-implementation work flow and performance, but also from standards, normative rules and laws, from theoretical optimal values and generally accepted good practices or guidelines, or from specific study objectives. Explore if the frame of reference already exists, and if so, how was it established, where/what is it derived from, is it reliable? Consider if it is applicable in this situation, or is there a risk that it may have a regressive bias by being based on previous technologies and their related safeguards.
- *Timing*: Explore if the planned time schedule for evaluation is in agreement with other plans in the health care organization and in the research organization. Consider also if the timing is adequate for measuring as intended, for example are there enough users with adequate experience available?
- *Justification of the methodological approach*: Justify that the methodological approach is feasible for the study and its context and that it complies with the objectives of the study. Confirm that this approach allows adequate measurement of all relevant aspects with sufficient confidence for the study purpose.

3.3.2. Methodical aspects

The following items should be addressed with respect to the methodical aspects:

- *Expertise*: Identify whether relevant professional competencies for applying the selected methods are available for the study. If not, identify the actions to be taken to acquire the necessary expertise.
- *Outcome measures, evaluation criteria*: Identify which specific measures and evaluation criteria will provide the answers to the information need and study objectives, and identify which specific methods for data acquisition/elicitation and data analysis are needed. Define the threshold values, success/failure levels for the evaluation criteria. Examples of methods are interviews, questionnaires, observations, surveys, log file analysis, document analysis. Specify how the data collection is planned, i.e. methods, setting, types and number of cases needed for the study. When appropriate,

HF measures should be added to other outcome measures and evaluation criteria.

- *Avoiding bias*: Consider whether using specific methods might yield differential response rates, or promotion of specific views or interests; identify what measures could be introduced to prevent or minimize such risk, see for instance Ref. [11].
- *Quality control on data (measures)*: Explore whether the actual measures have been tested as regards to syntactic and semantic validity, whether the calculations are working properly, and whether the questionnaires have been tested for validity, etc. Identify what means can be taken to ensure that the collected data suffice for the purpose.
- *Participants*: Identify which participants (evaluators/observers, patients/clients, and/or staff participants) are involved and when, which specific stakeholder groups or organizational units, skill types, and specific individuals are essential or necessary or useful for the study. Identify for which tasks and for what purposes they are involved, and how the participation is organized. The inclusion and exclusion criteria should be explicitly and comprehensibly defined for the participants that are to be included in the study. Communicate information on the study to the users and other study participants and stakeholders.
- *Ethical and legal issues*: Prepare all practical details, such as necessary approvals, consents and permissions, dedicated forms, etc.
- *Result of operationalization of methods*: Document the methodological and methodical aspects of the study. The plan should include sufficient details to serve as a protocol for the project planning and execution phases of the study.
- *Approval of operationalization of methods*: Seek approval from the relevant stakeholders to proceed to the detailed study plan.

3.4. Project planning

During this phase a detailed project plan is developed. The following items should be addressed:

- *Project management*: Establish a project management plan according to the size and complexity of the evaluation study and the organization's preferences as regards the project management model, values and principles. Use dedicated tools and approaches for management. Define a quality management strategy and related action plan. Define a communication strategy and a dissemination and publication strategy and related action plans and responsibilities. Identify means and tools for conflict resolution. Identify mechanisms for incorporation of lessons learned and identify mechanisms for interim corrections of the project plan and handling of ethical and legal issues.
- *Study flow*: Identify the start-criteria, end-criteria and success-criteria for each activity, periods, interventions, participation, and reporting deadlines. Specify milestones in order to be able to monitor and control the progress of the evaluation study.
- *Evaluation activity mapping*: Divide evaluation tasks into activities and sub-activities, map them on to a time table and put named resources and responsibilities to them.

Identify dependencies between the activities. Make a path analysis to identify the critical path(s) and activities. Match all activities with responsible activity managers, allocated personnel, affiliated experts/scientists and third party actors. Establish a budget monitoring and mitigation strategy.

- *Quality management*: Elaborate further the preliminary quality management plan according to the preferred quality management model and principles, for example ISO 9000 standards can be applied.
- *Risk management*: Elaborate a list of significant risks and reassess them with respect to likelihood of occurrence, with relevant measures for monitoring, means for remedy and anticipated impacts of risks. Some risks may relate to the organization or the system under study, others may relate to the evaluation itself such as loss of key personnel or failures/induced biases of the data collection methods. Specify a mitigation strategy and potential means and corrective actions in case a given risk manifests. Nominate the person in charge of each risk factor. Identify also risks related to confidentiality and conflict of interest principles, processes, and sanctions.
- *Recruitment of necessary staff*: Specify what types of competencies are needed, such as statistical, organizational insights, cognitive/psychological competences, sociological, etc., and necessary training. Employ the project team. Ensure the evaluators' neutrality and their commitment to confidentiality of data within the studied system as well as of the analyses and pre-publication findings.
- *Inform all relevant stakeholders*: Inform all relevant stakeholders sufficiently about the study and about all relevant aspects, but in such a way that the behaviour or performance of the participants will not be changed due to the fact that they know they are observed (the Hawthorne effect).
- *Result of project planning phase*: Document the project plan with incorporated project management tools.
- *Approval of project planning*: Present the project plan to relevant stakeholders to seek approval to proceed for the study implementation.

3.5. Execution of the evaluation study

Now the evaluation study can be executed. During the study execution, however, a situation may arise where the study design has to be redefined due to unforeseen events or conditions and then the study plan has to be modified accordingly.

When executing the evaluation study the following items should be addressed:

- *Undertake the study, collect data and interpret observations*: Implement the prescribed methods for the study. Adherence to the methodological and methodical agreements is important. Verify the assumptions by means of the data, and interpret the resulting findings. It is necessary to analyse and identify the causal relations behind unexpected events and unexpected observations, in order to secure that none of these will interfere with the conclusion.
- *Quality control of findings and observation of changes*: Implement the quality management plan to its finest detail. Organizations, people, processes, and contexts may change

as a function of time and opportunities. Any such changes with a potential to affect the study need to be documented.

- *Continuous project management, quality and risk management*: Implement continuous management and control of the project. Evaluation studies are often large and formal projects, and they may take a long time and involve a large group of personnel.
- *Regular reports*: Prepare and deliver regular reports to the relevant parties and stakeholders.
- *Final result of execution of the evaluation study phase*: Prepare a final report for the commissioner of the study summarizing the main information on objectives, the setting, the conditions, the method, the outcome data and information and the results and conclusions.

3.6. Completion of the evaluation study

In this phase the study should be reported and made public for the benefit of similar studies and the potential future users of similar systems, as recommended by the Declaration of Innsbruck [15]. Reporting also supports development of reflective practice, learning from professional experiences.

During the completion phase the following items should be addressed:

- *Accounting*: Prepare and deliver accounts when external funds were acquired and/or specific demands exist with respect to accounting.
- *Archiving*: Keep the data and other collected materials of the study in storage, and accessible to others if and when needed for later follow-on analyses. Archiving has to follow the local and national legislation, regulations and good practices on archiving and disclosure of medical and/or research data. If privileged types of data were acquired, for example extracts from medical records, regulations for these must be followed.
- *Reports and publications*: Produce the project's operational reports and publications. They may be of many types and potentially for many recipients. Detailed recommendations on writing reports and publications are elaborated more fully in the STARE-HI statement [16]. See also appropriate guidance for the authorship in Ref. [56] and for ethical and moral aspects of publication in Ref. [57].

4. Discussion

This guideline for good evaluation practice in health informatics was developed to support evaluators, health care professionals, decision makers and other health IT stakeholders in design, planning and execution of an evaluation study. The guideline gives support and advice on what to do and on aspects needing attention at each evaluation phase. Existing methodological textbooks will give the details of which methods to apply and how.

The guideline has been developed through an informal consensus-seeking process in the community of health IT evaluation experts, and it was put regularly into open discussion through the HISEVAL website and many conference workshops. The final list of items was achieved through

informal discussions and feedback; no formal rating or balancing has been applied for the items. The timeline for this guideline development has been long, from 2004 until 2010, and this made it possible to collect wide feedback and elaborate revised versions for further discussion.

The purpose of this guideline is to raise the level of quality of evaluation studies through careful planning, and thus contribute to the accumulation of the scientific evidence base for health informatics.

4.1. Applicability of the GEP-HI guideline

This guideline can be applied to any health IT evaluation study, either a small scale or a large scale study, and irrespective of whether the object of study is an IT application or a method like nursing classification or data security practice. The guideline is applicable at various phases of a health IT project, starting from design and development, over application or system implementation and installation, and ending with the study of effects and impacts in routine use.

This GEP-HI guideline can be used for different types of health IT evaluation studies such as feasibility, effectiveness, efficiency and impact evaluation. In small or circumscribed evaluation studies not all phases of the guideline may be needed. The user should consider in each situation which phases are necessary and relevant for the design and execution of the given study. However, it is recommended that even if all the guideline items are not documented, they should be considered during the design and the reason for non-inclusion documented.

For health informatics usability evaluation studies there are specific conditions due to legal regulations, such as the European Commission's prescription of usability evaluation of all medical devices applying for CE marking. This prescription could be extended to health IT applications used for medical diagnosis and therapeutic purposes. Moreover, usability studies rely on specific standards and usability heuristics applied as frames of reference in usability evaluation studies [see Refs. [58–62]]. Economic evaluation has also specific conditions that need to be considered due to the approaches and methods required to measure economic aspects [see Refs. [55,63]]. These domains require a topical technical specificity. GEP-HI provides a generic guideline, therefore, for certain types of highly standardized studies such as RCTs, the GEP-HI guideline can be complemented with specific guidelines such as the CONSORT statement (see for example Refs. [42,44,45,47]).

4.2. Strengths and weaknesses of the guideline

The present guideline was intentionally made as general as possible and with an awareness of cultural aspects. Fortunately, the consensus approach involving experts from all over the world gave some assurance that global diversity will not hinder appropriate application of the present guideline. In different cultural environments the evaluation study principles are likely to be the same, but the actual study design could be influenced by the local cultural preferences, however, no major conflicts could be expected.

The rigor of this GEP-HI guideline may initially bring some minor additional costs and other additional resource usage

to the evaluation study, but should ensure higher quality, reduced risks, and higher utility to the general health IT and health community through production of stronger evidence. Potential organizational barriers to apply the guideline may arise as some organizations may find it somewhat threatening to expose their practices to a robust methodology and open scrutiny. However, thorough approaches for evaluation are necessary to fulfil the ethical imperative (see Ref. [15]) and to collect reliable information on the health IT intervention in order to make decisions.

The strength of the guideline is that it forces the user to go through a checklist of relevant issues that might otherwise only act informally as tacit knowledge, or even be overlooked. This systematic approach will increase the likelihood of an outcome with the desired level of accuracy and precision and hence an increased effectiveness, and additionally encourage the adoption of a scientifically valid approach in an evaluation study.

4.3. Further development and validation of GEP-HI guideline

Further development and assessment of the validity, clarity and completeness of the guideline will take place through its application and use, through pilot health IT evaluations and by peer reviews in panels of evaluation experts.

5. Conclusions

A comprehensive lifecycle of phases has been developed, strengthened by world-wide iteration, to plan and execute health IT evaluations effectively. The phases contain some 60 detailed items, which are presented in relation to the evaluation study phases. When designers and executors of evaluation studies address these items, the plan, structure, objectives and results of the studies will become more robust and consequently the studies contribute an important step towards evidence-based health informatics.

Authors' contributions

This GEP-HI work has been a shared activity of EFMI's Working Group EVAL and IMIA's Working Group on Technology Assessment and Quality Development. The idea of this standard/guideline contribution crystallised during the ESF working conference 2003 in Innsbruck, organized by E Ammenwerth and attended – among others – by J Brender, P Nykänen, M Rigby, and J Talmon. P Nykänen and J Brender drafted a first list of issues, while in later versions P Nykänen and J Brender together as the responsible coordinators integrated the various contributions and further completed and refined the successive versions of the manuscript. E Ammenwerth, J Talmon, N de Keizer, M Rigby and MC Beuscart-Zephir contributed actively by critically assessing the items and their descriptions, making suggestions for directions and expansion, as well as contributed to the writing of the various versions of the document. All authors have read and approved this final version.

Summary points

What was already known on the topic

- Health IT applications are widely used to achieve benefits and improvements in health care practices. However, there are problems and hazards related to adoption of health IT applications for clinical use.
- The significance and volume of health IT applications in clinical practice calls for a need to evaluate health IT applications to collect evidence on their efficiency, effectiveness and impacts.
- Evaluation of health IT is a discipline and a specialty that requires good practices for design, execution and management of evaluation studies.
- The need to develop an evaluation guideline has been identified and guidelines to develop guidelines have matured.

What this study added to our knowledge

- The GEP-HI guideline adds on to existing evaluation approaches and guidelines by providing guidance for systematic design, execution and management of an evaluation study.
- The GEP-HI guideline is applicable to different types of health informatics evaluation studies independent on whether the object of the study is an IT application, or a method, a service or a practice.
- The GEP-HI guideline may serve as a basis for developing guidelines for specific niches, like usability evaluation studies.

Conflict of interests

P Nykänen and J Brender are co-chairs of the EFMI working group on Evaluation (EVAL) that has E Ammenwerth as the chairperson. N de Keizer is the chairperson of IMIA's working group on Technology Assessment and Quality Development. J Talmon has been chair of this IMIA working group till May 2008, and J Brender was his co-chair until the end of 2007. Besides this all authors have positions as university employed researchers with no commercial interests and no conflicting interests financially or otherwise in relation to the GEP-HI guidelines.

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