Evaluation and Evidence: Applying guidelines for health IT evaluation in developed and developing countries

Nicolette de Keizer, Michael Rigby, Elske Ammenwerth, Pirkko Nykänen, Hamish Fraser, Tom Oluoch

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Health informatics systems intend to improve quality of care

- Some health informatics systems disrupt current processes and work practices
  - Unintended events and unintended side effects
  - E.g. a CDSS on CD4-testing in HIV patients:
    - Not used because of lack of electric power
    - Not used because time-consuming
    - Not used because of disagreement with guideline
    - More focus on CD4-testing resulted in improved CD4 testing but also increased unnecessary testing -> higher costs
Evidence Based Health Informatics

- Implementation need to be based on evidence not simply on aspiration or promises
- To provide evidence it is necessary to evaluate systems in practice to assess the overall effects, costs and outcomes
  - Setting is important

Evidence Based Health Informatics

- Importance:
  - Theme of this year’s IMIA’s yearbook
  - WHO Bellagio meeting in 2011
  - Collaboration between IMIA and WHO to promote and practice an evidence-based approach, especially in developing countries
Work of EFMI and IMIA WG

- To reach Evidence Based Health Informatics
  - GEP-HI
    - generic principles of health informatics evaluation;
  - STARE-HI
    - a standard for reporting results from an evaluation study;
  - EVALDB
    - a database of evaluation studies;

Objective of this Workshop

- Share generic principles of health informatics evaluation
  - Developed and developing countries
- Case study from a developing country
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The IMIA work in Context

Michael Rigby and Siobhan Melia
Principles and Plurality

- IMIA work is consensus- and evidence-driven
- Other evaluation innovators have worked in other settings
- Many different services and settings are covered by health informatics.
- Value in looking at other methodologies alongside GEP-HI.

Yusof et al – HOT-fit

- 2008
- Focuses on three dimensions:
  - Human
  - Organisation
  - Technology
- Assesses how the application ‘fits’ the local need
Yusof et al – HOT-fit

- The three dimensions are important
- Accommodates the importance of context, not least level of development
- Each of the three dimensions is itself multi-dimensional
- Challenges:
  - metrics and analysis
  - Assessment of ‘fit’
- Compatible with GEP-HI, within method selection

AHRQ Evaluation Toolkit

- 2009
- United States Agency for Health Research and Quality
- Evaluation Toolkit developed to provide step-by-step guidance for developing evaluation plans for health information technology projects
AHRQ Evaluation Toolkit

- Assists evaluators to define
  - the goals for evaluation
  - what is important to stakeholders
  - what needs to be measured to satisfy stakeholders
  - what is realistic and feasible to measure
  - how to measure these items
- Methods, but not study management
- Compatible with GEP-HI, within method selection

Model for ASsesment of Telemedicine (MAST)

- Currently finalising / validating
- Result of European Commission project
- Purpose is to describe effectiveness and contribution to quality of care of telemedicine applications
- And to produce a basis for decision making
- So far applied to real time telecare and telemonitoring only
Model for ASsesment of Telemedicine (MAST)

- Preceding analysis, then –
- Assessment against seven categories:
  - Health Problem and characteristics of the application
  - Safety
  - Clinical effectiveness
  - Patient perspectives
  - Economic aspects
  - Organisational aspects
  - Socio-cultural, ethical, legal aspects
- Potential for transferability

Model for ASsesment of Telemedicine (MAST)

- Follows an HTA format, so familiar to policy makers
- Does not cover management of evaluation
- Strong interest in influencing policy makers
Socio-Technical Approach – STAT-HI

- 2010
- Seeks to address need for socio-technical approach (early writers - Lorenzi; Berg; Ash)
- Not yet widely used
- Claims compatibility with GEP-HI.

Summary

- There have been a number of conceptual models for Health Informatics evaluation
- Mainly created in developed world, but generic
- Each has strengths and weaknesses
- Only GEP-HI takes full cycle including evaluation project management
- Core objectives:
  - seeking evidence
  - making evidence available where needed
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Using the Guideline for Good Evaluation Practice in Health Informatics (GEP-HI) for Success

P Nykänen, J Brender
The guideline provides
- guidance for systematic design, execution and management of an evaluation study in health informatics domain
- 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.
- has been developed through consensus seeking process by evaluation experts and by collecting feedback from the health informatics community in workshops and through evaluation mailing list.
GEP-HI guideline

1. Preliminary outline
   – Starting question
2. Study design
   – Preliminary design
3. Operationalisation of methods
   – Methodological approach, methodical aspects
4. Project planning
   – Detailed planning
5. Execution of the evaluation study
   – Accomplishment of the planned evaluation study
6. Completion of the evaluation study
   – Accounting, archiving, reporting of evaluation study results

**Phase 1: Preliminary outline**

- THE key issue
- Identify those who directly or indirectly will be affected by the study itself, by its anticipated outcome, or by the system that is being evaluated

1.1 The information need
1.2 Primary audience
1.3 Identification of the study funding party (ies)
1.4 The organisational context of the evaluation study
1.5 Identification of stakeholders
1.6 Identification of required expertise
1.7 A first sketch of the health care setting
1.8 First exploration of evaluation methods to be used
1.9 Ethical, moral and legal issues
1.10 Budget
1.11 Exploring the restrictions of study execution and publication
1.12 Result of Study Exploration
1.13 Formal acceptance to proceed to the next phase

The selected methods have to be tightly correlated with the information need and its qualities and the study objectives, taking the study setting constraints into account.

Which issues are relevant?

What are the restrictions?
Phase 2: Study design

2.1 Elaboration of the detailed rationale and objectives for the study
2.2 Key evaluation issues/questions
2.3 Budget
2.4 Establishment of the study team
2.5 Stakeholder analysis/Social Network analysis
2.6 Study methods
2.7 Organisational setting, the study context
2.8 Technical setting, the study context
2.9 Participants from the organisational setting
2.10 Material and practical preparations
2.11 Time and timing
2.12 Risk analysis
2.13 Ethical, moral and legal issues
2.14 Strategy for reporting and disseminating the results
2.15 Result of Study Design
2.16 Formal acceptance to proceed to the next phase

Get a rich picture of Who’s Who, and their potential motives
Get a rich picture of the organisation
Place the planned activities in a calendar
Data protection and security principles and laws need to be obeyed. Have a strategy, policy and principles been formulated for how to handle problematic issues?
Seek approval to go on as now planned

Phase 3: Operationalisation of methods

3.1 Study type
3.2 Approach
3.3 Assumptions
3.4 Pitfalls and perils
3.5 Expertise
3.6 Frame of reference
3.7 Timing
3.8 Justification of the methodological approach
3.9 Quality Control on data (measures)
3.10 Participants
3.11 Study flow
3.12 Result of Operationalisation of Methods
3.13 Ethical, moral and legal issues
3.14 Approval of Operationalisation of Methods

quantitative versus qualitative, subjective versus objective, formative versus summative, etc
Limitations of the methods (scope, accuracy, specificity, applic. range)? Of the hidden assumptions?
Which candidates in your set-up?
Which? How to get it? Can you get it?
Get approvals, consents and permissions, prepare dedicated forms, etc.

GEP-HI Good evaluation practice guideline MEDINFO2013 Workshop
### Phase 4: Project planning

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<td>Evaluation activity mapping</td>
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<td>4.7</td>
<td>Result of Project Planning</td>
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<td>4.8</td>
<td>Approval of Project Planning</td>
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**GEP-HI Good evaluation practice guideline MEDINFO2013 Workshop**

### Phase 5: Execution of the evaluation study

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<th>5.1</th>
<th>Establishment of the frame of reference</th>
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<tbody>
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<td>Undertake the study and collect data</td>
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<td>5.3</td>
<td>Quality control of findings</td>
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<td>5.4</td>
<td>Interpretation of observations</td>
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<td>5.5</td>
<td>Observation of changes</td>
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<td>5.6</td>
<td>Continuous project management, quality management</td>
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<td>5.7</td>
<td>Regular reports</td>
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<td>5.8</td>
<td>Final result of Evaluation Study Implementation</td>
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**GEP-HI Good evaluation practice guideline MEDINFO2013 Workshop**
### Phase 6: Completion of the evaluation study

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<th>6.1</th>
<th>Reports and publications</th>
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<td>Reporting scope</td>
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<td>Ethical and moral aspects</td>
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<td>6.8</td>
<td>Preparation of reports/publications</td>
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- ... if accountings of finances are needed
- ICMJE: In order of substantial intellectual contributions
- For publicly available evaluation reports use the STARE-HI guidelines

**Nykänen P, Brender J, Talmon J, deKeizer N, Rigby M, Beuscart-Zephir MC, Ammenwerth E,**

**Guideline for good evaluation practice in health informatics**  
*Int J Medical Informatics* 2011; 80: 815-827

Available also at:  
iig.umi.at/efmi
Challenges in Finding the Evidence

*How do we know what we know?*

Prof. Dr. Elske Ammenwerth, UMIT, Hall in Tirol
EFMI WG on Assessment of Health Information Systems

[http://iig.umit.at/efmi](http://iig.umit.at/efmi)
Motivation

- While conducting systematic reviews on health IT impact, we found that important information was missing in many study papers, e.g.,
  - Details of the health IT
  - Clinical context, clinical processes
  - Patterns of IT usage

Ammenwerth E, Schnell-Inderst P, Siebert U.
Vision and Challenges of Evidence-Based Health Informatics.
Int J Med Inform 2010; 79: e83-e88

STARE-HI-Guidelines

- Guideline on how to structure a publication of an health IT evaluation study
- Recommended by journals, e.g., Methods Inf Med, Int J Med Inform and ACI

[Image of STARE-HI-Guidelines]
STARE-HI-Guidelines Elaboration

• Additional paper with examples and explanations just published in ACI, July-24th

Health IT Evaluation Database

• [http://evaldb.umit.at](http://evaldb.umit.at)
  – Contains around 1,800 abstract of health IT evaluation papers

• All papers are classified and searchable, e.g. according to
  – Type of system
  – Clinical setting
  – Evaluation methods
  – Evaluation criteria
Health IT Evaluation Database

• Only < 2% of evaluation studies come from developing countries

• Need for more health IT evaluation studies in this special context!
IMIA/EFMI WG

- For more information on the work of the IMIA WG and EFMI WG on health IT evaluation:

  [http://iig.umit.at/efmi](http://iig.umit.at/efmi)

  Or contact [elske.ammenwerth@umit.at](mailto:elske.ammenwerth@umit.at)

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Call to Action on Global eHealth Evaluation

Dr Hamish Fraser
Assistant Professor, Division of Global Health Equity, Brigham and Womens Hospital and Harvard Medical School

Senior Advisor in Medical Informatics, Partners In Health

Call to Action on Global eHealth Evaluation

Consensus Statement of the WHO Global eHealth Evaluation Meeting,
Bellagio, September 2011

“To improve health and reduce health inequalities, rigorous evaluation of eHealth is necessary to generate evidence and promote the appropriate integration and use of technologies.”
Impact of eHealth

Used appropriately, eHealth has the potential to catalyze, support and monitor health improvements at scale, and to accelerate achievement of national and global development goals, including the United Nations Millennium Development Goals.

If used improperly, eHealth may divert valuable resources and even cause harm.
Core Principles

1) Core principles underlie the structure, content, and delivery of an eHealth system independent of the rapidly changing technology used.

2) High quality data collection, communication and use are central to the benefits of eHealth systems.

3) Evaluating eHealth both demonstrates its impact and fosters a culture that values evidence and uses it to inform improvements in eHealth deployments.

Core Principles

4) To ensure the greatest benefit from eHealth and enhance sustainability and scale, eHealth evaluations should recognize and address the needs of all key constituencies.

5) Evidence is needed to demonstrate costs and benefits of eHealth implementations, and maximize eHealth’s beneficial impact on health system performance and population health.
Core Principles

6) The value of a complete evaluation program is enhanced through research that is attuned to the differing requirements throughout the life-course of the project, whether at needs assessment, pilot-, facility level-, regional and national scale-up stages.

7) Independent and objective outcome-focused evaluation represents the ideal of impact evaluation.

Core Principles

8) Country alignment and commitment to a clear eHealth vision, plan, and evaluation strategy is essential.

9) Improving the eHealth evidence base requires more than increased numbers of studies but also improved quality of eHealth research studies.
Bellagio Call to Action

- Develop repository of tools, studies, frameworks, teaching materials
  - mHealth Alliance HUB
  - mHealth Evidence
- Refine frameworks – GEP-HI, PRISM, KDS, and others
- Create training courses on evaluation in developing countries
  - MIT-Harvard Course
- Advocate to funders to require evaluation in eHealth projects
Barriers to evaluation

• Not seen as a priority
  – “eHealth is just infrastructure”
  – Not aware of the challenges in effective use/impact
  – Uptake or usage is the only measure of interest
  – More important to “get implementation done”

• Not sure how to do it
  – Think all studies must be big and expensive
  – Not familiar with range of evaluation methods
  – Studies that are done are poor quality

• Threatened
  – Don’t want to look bad...

• Need resources/prioritization from funders

Conclusions

• Large investment in Global eHealth to date - $Billions!!

• Particular need to monitor day to day system performance and activity

• Measuring impact of eHealth, what are the alternatives and control groups?

• How role of e/mHealth differs in resource poor environments
Plan of action

- Study the real needs of healthcare/patients
- Build great software tools
- Rigorously optimize those tools in the field
- Evaluate their impact and costs – initial and long term

*Poor data wastes everyone’s time and money!*

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Medinfo 2013 Copenhagen 21/08/2013 54
Evaluating Health Information Systems in Developing Countries

Tom Oluoch
US Centers for Disease Control and Prevention
Division of Global HIV/AIDS – Kenya

Medinfo Conference
August 20-23, 2013

Outline

- Introduction
  - Implementing EMRs in developing countries and in Kenya
  - Need for evidence-based investment in EMRs and CDSS
- Methods
  - Guidelines for Good Evaluation Practices in Health Informatics
- Results
  - Some selected applications of GEPHI
  - Lessons learnt and challenges
- Conclusion
  - Appropriateness and applicability of GEPHI in evaluations in developing countries
Introduction (i)

- EMRs have been shown to improve quality of care.
- Majority of the evaluations have been conducted in developed countries.
- Recent systematic review on evaluation of EMR-based CDSS in developing countries showed only 12 studies published.
- Need for evaluations due to unique challenges in developing countries:
  - Weak infrastructure (erratic power supply, poor Internet connectivity, inadequate computers)
  - Low ICT literacy among health workers, Policies, etc.
  - Managing chronic conditions (e.g. HIV) require managing complex longitudinal data

Introduction (ii)

- It is essential that future investments on eHealth projects in developing countries are guided by evidence of what works and what does not.
- Need for well designed, executed and documented evaluations in developing countries (inc. Kenya).
- CDC-Kenya in collaboration with the Kenya Medical Research Institute (KEMRI) have developed evaluation protocols guided by the GEP-HI principles.
- Some evaluations supervised by the University of Amsterdam.
Evaluation Questions

- Do EMRs+CDSS improve HIV care?
- Does SNOMED CT based recording of opportunistic infections improve quality of registration and quality of HIV care?

Guidelines for Good Evaluation Practices in Health Informatics (GEPHI)

- Provides guidelines for planning and implementing evaluation studies in health informatics
- Consists of 5 iterative phases:
  - Preliminary outline
  - First study design
  - Operationalization of methods
  - Detailed study plan & project plan
  - Evaluation study implementation
Preliminary Outline

Information need: Do EMRs+CDSS improve HIV care?

Context: Clinical decision support in rural HIV clinics

Restrictions: Restriction on use of PEPFAR funds for rigorous scientific studies.

Budget: Budget discussed with KEMRI/CDC leadership. Studies to ride on existing EMR scale-up.

Sponsor: KEMRI and CDC, using PEPFAR resources

Ethical, moral and legal issues: Institutional ethical regulations referenced

First study design

Study constraints
- Design restrictions
- Infrastructure
- Low ICT literacy

Organizational and technical settings
- Participating clinics
- Computer locations

Participants
- Investigators & roles
- Clinicians
- Data team
- Programmers

Risk analysis
- Patients
- Institutions

Reporting
- Dissemination plan
- Audiences (local, national, global)
**Operationalization of methods**

- **Approach**
  - Operational research incorporating service delivery and evaluation

- **Assumptions**
  - Guidelines used uniformly

- **Outcome measures**
  - Initially broad (e.g. quality of care)
  - Refined to specific and measurable

- **Study flow**
  - Study flow designed to replicate regular work flow

---

**Detailed Study Plan and Project Plan**

- **Project management**
  - Defined project mgmt structure
  - Resources & timelines

- **Communication strategy**
  - Channels of comm.
  - Among study team
  - Feedback to sponsors
  - Progress reports

- **Risk management**
  - Mitigation of risks
  - Procedures for responding to adverse events
  - Contact persons

- **Roles of participants**
  - Revised list of investigators
  - Redefined roles
Evaluation Study Implementation

Observe changes:
- Changes were documented and minor adjustments made (no violation of protocol)

Continue project mgt:
- Review progress against pre-set timelines and milestones

Interpret observations:
- Interpret events and take action

Regular reports:
- Progress reports to sponsors
- IRB report for continuation

CDSS Study

- To evaluate the alert-based CDSS on its effectiveness to:
  - Timely order CD4 according to Kenya MOH and WHO guideline
  - Timely initiation of ART according to the Kenya MOH and WHO guideline
- Study sites: 20 HIV clinics in Siaya county
- Design: Prospective, Comparative
  - 10 sites with EMR+CDSS
  - 10 sites with EMR only
- Current status:
  - Data collection in final stages
  - Preliminary data review in progress
- Dissemination
  - 2 manuscripts on baseline data in IRB clearance
  - Additional manuscripts planned on the prospective study
  - All manuscripts will be based on STARE-HI
SNOMED CT study

- To determine whether SNOMED CT based registration of OIs improves:
  - Data quality
  - Accuracy of WHO staging
  - Appropriate ART initiation based on WHO staging

- Study site: A Teaching and Referral Hospital's Maternal & Child Health clinic, western Kenya

- Design: Pre-post, with an external control

- Current status:
  - Data collection yet to start
  - System design and development

Lessons learnt

- GEP-HI is very elaborate and comprehensive.

- Components are iterative and some happen in parallel. Practical implementation may not always follow the order in which steps are listed in GEP-HI.

- We omitted steps that were not critical for our studies (e.g. identification of sponsor and social network analysis).

- Although some of the steps are repeated in several phases, we were able to complete them in a single phase, while others took several iterations to complete.

- Working with more than one IRB, sponsor or collaborator may require modification of some steps.
Conclusion

- GEPHI acts as an important checklist for key activities in evaluation studies, from protocol development to pre-publication stages. We found it practical in our resource-limited setting in a developing country.

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