Finding, Appraising and Interpreting the Evidence of Health IT

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Abstract. Evidence-based health informatics can be described as a scientific approach to meeting the multiplicity of tasks involved in the development, implementation and sustainability of health information technologies (IT). The practice of evidence-based health informatics incorporates methods to help find, appraise and utilise research-based knowledge. The aim of this contribution is to describe the steps of finding, appraising and interpreting the evidence of health IT. It lists major sources of literature in the health field, and highlights a number of considerations for undertaking reviews, drawing on some key landmark reviews that have helped to shape the health informatics discipline. It also considers key issues highlighted by these reviews particularly in regard to the validity of findings, their generalisability and their impact on patient outcomes. The contribution also provides suggestions for tackling the challenge of potential publication bias, and how to deal with heterogeneous findings.

Keywords. Evidence-Based Medicine; Evaluation Studies; Information Systems; Medical Informatics; Research Methodology.

1. Introduction

Evidence-based health informatics can be described as a scientific approach to meeting the multiplicity of tasks involved in the development, implementation and sustainability of health information technologies (IT) [1]. The practice of evidence-based health informatics incorporates methods to help find, appraise and utilise research-based knowledge by using the most current literature sources, ranging from large established databases through to government reviews, consultancy reports and industry appraisals. This can encompass a variety of different review methods including: personal searches of the literature; traditional literature reviews, which provide an overview of the literature without necessarily focusing on outcomes; scoping reviews that assess the scope of existing literature; expert reviews where an expert or group of experts makes a judgement call on an issue related to the literature; realist reviews which concentrate on generating generalisable theories, and meta-systematic reviews involving reviews of systematic reviews.

In and of themselves, all forms of literature reviews can be conceived of as a means to make sense of a (usually large) body of literature. The distinguishing feature

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of a systematic review, however, lies in its comprehensiveness and its adoption of formal approaches and transparency leading to its ability to be reproduced [2].

Systematic reviews are thus required to comply with rigorous methods as a means of identifying, appraising and synthesising all the studies relevant to the research question(s) at hand [3]. Generally, this means providing answers about the effectiveness of a healthcare intervention. Systematic reviews can be adopted for a variety of other reasons, including the investigation of the feasibility of an intervention, its appropriateness or even to identify evidence about consumer experiences. Systematic reviews have been used to examine many aspects of the impact of health IT on different areas of the clinical care process (e.g., medications, incidents, preventative care) employing a range of metrics such as care quality, provider productivity, user satisfaction and information quality [4].

The aim of this contribution is to describe the steps of finding, appraising and interpreting the evidence of health IT, and the context in which they may be employed. These steps include:

- Formulating the study question.
- Developing a search strategy.
- Finding the evidence.
- Tackling publication bias.
- Organising the evidence.
- Critically appraising the evidence.
- Being sensitive and aware of context.
- Interpreting the evidence.

2. Formulating the study question

The first thing that a clinician, policy maker, health informatician or researcher needs to consider before undertaking a review is what type of review is required. Systematic reviews of randomised controlled trials are considered to be the highest level of evidence (Level I) [5], but this does not mean a systematic review is always the most suitable instrument for the topic area. There are many factors to consider. It is usually worthwhile undertaking a systematic review of a health IT system when there is a lack of clarity about its effectiveness or impact. Or it may be necessary to ascertain what the evidence is revealing about the system. Sometimes, there may be a lot of existing research without clear answers about its effect on patient outcome, clinical performance or about its broader benefits. A systematic review can also be used to obtain an overall picture of the existing evidence and its quality in order to direct future research efforts.

Guides about how to undertake a review of the literature emphasise the importance of arriving at a suitable question. Petticrew and Roberts [3] offer some helpful questions to guide the decision-making process: i) Does this review really need to be carried out? ii) Does anyone want the question answered? iii) Who will benefit from the results [3]?

The formulation of a question involves a decision about the problem or issue under investigation. Is the question about the quality of the health IT application (e.g., its

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functionality, performance or responsiveness); its utilisation (e.g., user perception, ease-of-use or user experience); or about its benefits (e.g., appropriateness, health outcomes or efficiency). Identifying and appreciating the multiple perspectives involved (e.g., clinicians, health IT vendors, patients, healthcare managers) is also important for arriving at an appropriate question to guide the literature search.

3. Developing a search strategy

Finding the relevant literature necessary to answer the research question is a crucial part of a successful systematic review. Search strategies are required to be as specific as possible in order to maximise the identification of all relevant evidence. The task of undertaking a robust search strategy begins with ensuring that all the different components of the research question are incorporated into the search strategy. Many researchers begin the process by identifying some key papers that meet the inclusion criteria for review. This can help to identify common subject terms and keywords to be incorporated as part of the full search [6].

Scientific and methodological rigour requires the clear and transparent reporting of the methods used to undertake the search. This allows the search to be replicated and updated at another point in time. It is important to report items such as how the evidence was found (e.g., the databases used to find the relevant literature as discussed further below), the dates of the search period and when it was undertaken, the search terms used (e.g., the Medical Subject Headings [MeSH] terms – a controlled vocabulary thesaurus using various levels of specificity [7]), the electronic search strategy, alongside a flow diagram that accounts for all the available references. There are a number of guides and appraisal tools (discussed further below) which provide valuable information about how to deal with different types of evidence (e.g., qualitative or quantitative) across diverse scientific disciplines.

The quality of the search strategy will depend heavily on the accuracy, precision and completeness of the completed tasks. A 2006 study by Sampson and McGowan [8] of the types of errors in reviews identified a range of search errors including:

- Spelling error (e.g., misspelled search operator).
- Missed spelling variant or truncation errors (e.g., failure to accommodate for multiple spellings of the word ‘randomised’).
- Logical operator error (e.g., mistakes using the logical operators “AND” or “OR”).
- Missed MeSH terms (e.g., where a relevant MeSH term was not used).
- Search strategy was not adapted to suit differing databases [8].

4. Finding the evidence

CENTRAL (The Cochrane Central Register of Controlled Trials), MEDLINE and EMBASE are widely recognised as the most valuable sources of literature in the health field [6]. Normally researchers are expected to have considered more than one database. For instance, although MEDLINE is a highly-utilised database that covers biomedical literature, there are many journals (including some in the health informatics and allied health fields) that may not be indexed in MEDLINE and are more likely to be found in
databases such as the Cumulative Index of Nursing and Allied Health Literature (CINAHL) or the Institution of Engineering and “Inspec” database. Table 1 provides a selected list of some of the most widely used databases relevant to health informatics.

Table 1. Selected list of widely-used literature databases.

<table>
<thead>
<tr>
<th>Database</th>
<th>Description</th>
<th>Website</th>
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<tbody>
<tr>
<td>BIOSIS</td>
<td>Biological and biomedical sciences that includes journal articles along with meeting and conference reports, books and patents.</td>
<td><a href="http://scientific.thomsonreuters.com/products/bp">http://scientific.thomsonreuters.com/products/bp</a></td>
</tr>
<tr>
<td>Campbell Collaboration</td>
<td>A library of systematic reviews in the areas of education, criminal justice and social welfare.</td>
<td><a href="http://www.campbellcollaboration.org">http://www.campbellcollaboration.org</a></td>
</tr>
<tr>
<td>Cochrane Central Register of Controlled Trials (CCRCT)</td>
<td>Part of the Cochrane Library, includes details of published articles taken from bibliographic databases (notably MEDLINE and EMBASE), and other published and unpublished sources.</td>
<td><a href="http://apps1.jhspih.edu/cochrane/central.htm">http://apps1.jhspih.edu/cochrane/central.htm</a></td>
</tr>
<tr>
<td>Cochrane Database of Systematic Reviews (CDSR)</td>
<td>Includes systematic reviews and protocols.</td>
<td><a href="http://www.cochrane.org">http://www.cochrane.org</a></td>
</tr>
<tr>
<td>Human-Computer Interaction Resources</td>
<td>Human-Computer Interaction is a discipline concerned with the design, evaluation and implementation of interactive computing systems.</td>
<td><a href="http://www.hcibib.org/">http://www.hcibib.org/</a></td>
</tr>
<tr>
<td>Cumulative Index of Nursing and Allied Health Literature (CINAHL)</td>
<td>Nursing and allied health disciplines such as occupational therapy, emergency services, and social services.</td>
<td><a href="http://www.ebscohost.com/cinahl">http://www.ebscohost.com/cinahl</a></td>
</tr>
<tr>
<td>Database of Abstracts of Reviews of Effects (DARE)</td>
<td>A database published by the Centre for Reviews and Dissemination. Also part of the Cochrane Library.</td>
<td><a href="http://www.crd.york.ac.uk/crdweb">http://www.crd.york.ac.uk/crdweb</a></td>
</tr>
<tr>
<td>Embase</td>
<td>An international pharmacological and biomedical database</td>
<td><a href="http://www.embase.com">http://www.embase.com</a></td>
</tr>
<tr>
<td>IET Inspec</td>
<td>Created by the Institution of Engineering and Technology that provides indexing to a wide range of scientific and engineering papers including computing and information technology.</td>
<td><a href="http://www.theiet.org/resources/inspec/">http://www.theiet.org/resources/inspec/</a></td>
</tr>
<tr>
<td>MEDLINE</td>
<td>A general medical database accessed through service providers such as Ovid or PubMed.</td>
<td><a href="http://www.ncbi.nlm.nih.gov/sites/entrez/?db=pubmed">http://www.ncbi.nlm.nih.gov/sites/entrez/?db=pubmed</a></td>
</tr>
<tr>
<td>Science Citation Index/Science Citation Index Expanded</td>
<td>Articles from approximately 6,000 major scientific, technical and medical journals and links them to the articles in which they have been cited (a feature known as cited reference searching).</td>
<td><a href="http://wokinfo.com/">http://wokinfo.com/</a></td>
</tr>
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There are a large number of additional international or specialty databases which either contain evidence themselves (e.g., the Evaluation Database, EvalDB, as a specialist resource specific to the field of evaluation in health informatics) or that are helpful for developing and undertaking a robust search strategy (e.g., EQUATOR). Table 2 provides a selected list of these websites.
Table 2. Valuable websites to aid the planning and undertaking of an evidence search.

<table>
<thead>
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<th>Website</th>
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<tr>
<td><strong>Bandolier</strong> – Bandolier aims to summarise results research studies in a clear concise way. Searches PubMed and the Cochrane Library each month to identify recently published systematic reviews and meta-analyses. <a href="http://www.medicine.ox.ac.uk/bandolier/">http://www.medicine.ox.ac.uk/bandolier/</a></td>
</tr>
<tr>
<td><strong>Evaluation Database</strong> – web-based inventory of evaluation studies in medical informatics (EvalDB) EvalDB contains references and structured information of health IT evaluation studies and is part of a collaboration between the European Federation of Medical Informatics Working Group on “Evaluation in Health Information Systems” and the International Medical Informatics Association Working Group on “Technology Assessment and Quality Development in Health Informatics” <a href="https://evaldb.umit.at/">https://evaldb.umit.at/</a></td>
</tr>
<tr>
<td><strong>The EQUATOR Network</strong>: Enhancing the Quality and Transparency of health Research provides useful guidelines and toolkits for authors of systematic reviews <a href="http://www.equator-network.org">www.equator-network.org</a></td>
</tr>
<tr>
<td><strong>The Health InterNetwork access to Research Initiative (HINARI)</strong> HINARI provides access to a number of databases including The Cochrane Library and nearly 4,000 major journals for healthcare professionals in local, not-for-profit institutions in over 100 low-income countries.[6] <a href="http://www.who.int/hinari/en/">www.who.int/hinari/en/</a></td>
</tr>
<tr>
<td><strong>The McMaster Health Knowledge Refinery</strong> encompasses a collection of projects of the Health Information Research Unit (HiRU) related to the retrieval, appraisal, classification, organisation, dissemination and uptake of health care evidence <a href="http://hiru.mcmaster.ca/hiru/HIRU_McMaster_HKR.aspx">http://hiru.mcmaster.ca/hiru/HIRU_McMaster_HKR.aspx</a></td>
</tr>
</tbody>
</table>

5. Tackling publication bias

Publication bias is caused by the publication or non-publication of research findings, depending on the nature and direction of the results [9]. It is often associated with the failure to include “grey literature,” or literature that has not been formally published in sources like a book or a journal [6]. The existence of publication bias can affect the validity of the findings and their application as guidelines and best-practice protocols [10]. There are a number of factors that can contribute to publication bias, including pressure from vendors, managers or publishers to publish only positive findings, or even a lack of commitment to the effort to generate a robust evidence base [11]. The issue is important for health informatics [12]. In 2005 the authors of a US Agency for Healthcare Research and Quality (AHRQ)-funded systematic review of the costs and benefits of health IT highlighted the absence of research evidence about how health IT is used, the individuals who are using it, and the environment in which it is used [13]. This absence can have a major effect on the applicability, generalisability and usability of the existing evidence base to broader audiences.

There are many potential sources of publication bias that can weaken or threaten the validity of systematic reviews. One of these relates to database bias where relevant journals are not indexed. Another potential source of bias may occur with conference abstracts which contain only truncated information that may be misleading when compared with full publications [10]. There is also potential for language bias when non-English language studies are excluded, and time-lag bias if publication of relevant findings are delayed because of a failure to get published [14]. The issue of publication bias is hence integrally bound up with key ethical imperatives related to the safety, usability and cost effectiveness of health IT [11].

There has been a growing awareness of the problems associated with publication bias [10]. In line with advice offered by many critical appraisal tools, many journals
now expect authors to undertake rigorous measures to locate research evidence and to include an assessment of the extent of publication bias in their systematic review [15]. One of these methods involves hand-searching – the manual examination (page-by-page) of journal issues, conference proceedings and relevant research literature. This is an important part of the search strategy because there may be relevant findings not included in the electronic database, or even if they are included, they may be difficult to find because they do not contain relevant search terms in their titles and abstracts [6]. This is a problem often encountered in health informatics, which is still a relatively new and developing research discipline with a rapidly evolving vocabulary of concepts, terms, and applications [16].

Other ways to locate grey literature include contacting authors/institutions of key studies, and searching the Internet (e.g., Google Scholar) for dissertations, conference proceedings or reports. Publication bias in meta-analysis can be examined using funnel plots, a simple graphic test involving a scatter plot of the effect estimates against sample size (or function of sample size) [9]. The results should normally show a symmetrical scatter of points around the total overall estimated effect (see Figure 1). If the scatter of points is skewed and asymmetrical in shape, there may be a bias, even though it may not be possible to identify which biases are present [14].

![Figure 1. An example of a funnel plot with a symmetrical scatter of points around the total overall estimated effect.](image)

The OPEN Project (Overcome failure to Publish nEGative fiNdings) Consortium has suggested the establishment of a public register which lists all healthcare trials prior to their commencement. This is an idea aimed at detecting and dealing with publication bias [17], and also making research evidence accessible to a wider public. The trial registry idea has had particular resonance in the health informatics field because of its potential to enhance the quality and transparency of health informatics research [18].
6. Organising the evidence

One way to appraise and interpret findings from search results is to present the relevant findings in a table. The process of tabulating the evidence involves identifying logical categories that describe the studies, and then analysing the findings within each of these categories. There is no definitive approach to choosing a set of meaningful categories other than ensuring that they are related to the research question. For instance, a systematic review of the impact of electronic ordering in Emergency Departments may categorise evidence according to the type of electronic order studied, (e.g., laboratory, medical imaging, etc. [19]); according to the different types of study design (e.g., randomised controlled trial, case-control study, etc.); or by outcome (e.g., adverse events rates, drug dosing etc.) [20].

A decision also needs to be made about the characteristics of the findings. This should include an assessment of the heterogeneity of the findings so as to ascertain whether or not the studies are comparable in terms of population, intervention, study characteristics and primary outcomes of interest, and whether a meta-analysis is possible or necessary. There are advantages to undertaking meta-analysis including: increased statistical power of results, increased precision for the estimation of the effect of the health IT system, and the ability to explore difference between studies and groups of studies to investigate potential causes and effects [3]. Conversely a meta-analysis may not be suitable when the studies in a systematic review include different hypotheses and measures. In such cases it may be unwise to make conclusions based on inappropriate aggregations across sub-groups, as this may lead to an incorrect conclusion about the benefit (or otherwise) of the system. Different findings may be due to a range of reasons such as the variances in the products themselves, their implementation and their use in different care settings [21].

7. Critically appraising the evidence

Critical appraisal of all the relevant studies is a key component of evidence reviews. It is important to consider the quality of the evidence, its validity and the degree to which the studies are free from study bias.

Common types of study bias in health informatics can come from differences in the comparison groups (allocation bias), or as a consequence of systematic differences in those involved in the study (selection bias). It is also important to consider the impact of other, extraneous or unintended factors on the study (e.g., contamination or confounders). Research studies are expected to provide an adequate sample size to have the ability (statistical power) to detect significant differences between the comparison groups. A lack of a significant effect could be due to the study lacking sufficient numbers rather than the failure of the health IT system. It is also important to consider the independence of participants – a lack of independence is known as the

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clustering effect (e.g., when participants are from the same GP practice or community group).

Health informatics researchers additionally need to carefully consider the integrity of the health IT implementation, including the independence of the researcher evaluating the system (i.e., is the researcher also the designer of the system?). They should also consider whether the failure or ineffectiveness of a health IT system may have been a consequence of the incomplete delivery and implementation of the system – this type of evaluation error has been described as a Type III error [22].

The validity of the conclusions drawn from systematic reviews depends on the quality of the systematic reviews. In 2012 Weir et al. assessed the quality of 13 systematic reviews of the impact of computerised provider order entry systems on clinical outcomes. The authors noted the wide variability in the quality and scope of the reviews. While some content areas including the reporting of search strategies, selection of articles, and description of original studies were robust, others like the diversity of primary studies and the assessment of the scientific quality of studies were less strong [23]. There is wide and growing range of reporting aids, frameworks and critical appraisal tools which can be used to enhance the quality of research and aid the task of critical appraisal. Within the health informatics field the Good Evaluation Practice guideline for Health Informatics (GEP-HI) provides a systematic approach to the design and execution of evaluation studies and the building of a stronger health informatics evidence base [24]. This is supplemented by the Statement on Reporting of Evaluation Studies in Health Informatics (STARE-HI), which was published in 2009 [25] and has been endorsed by the International Medical Informatics Association (IMIA) and the European Federation of Medical Informatics (EFMI) as a guideline for the reporting of evaluation studies [1].

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines provide a system for rating the quality of evidence in systematic reviews and the strength of recommendations in guidelines. The GRADE working group website www.gradeworkinggroup.org/index.htm provides a comprehensive toolkit [26]. Other tools which researchers can utilise include instruments that perform an appraisal (e.g., Assessment of Multiple Systematic Reviews [AMSTAR] [27]); provide a reporting checklist (e.g., Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA] [28] and Critical Appraisal Skills Program [CASP][29]); or a reporting standard (e.g., Meta-Analysis of Observational Studies in Epidemiology [MOOSE] [30]). These instruments vary according to the type of study they target. Instruments for meta-analyses include MOOSE and PRISMA; for qualitative research systematic reviews there is STARLITE (Sampling strategy, Type of study, Approaches, Range of years, Limits, Inclusion and exclusions, Terms used, Electronic sources) [31] and for systematic reviews there is AMSTAR.

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5 See also: P. Nykänen et al., Quality of health IT evaluations, in: ibid.
6 See also: E. Ammenwerth et al., Publishing health IT evaluation studies, in: ibid.
8. Being sensitive and aware of context

Context can be defined as a set of factors or attributes that can affect a health IT implementation. This may include the organisation’s leadership, mission, climate or learning environment [32]. The task of designing, implementing and sustaining health IT systems is complex. It involves a lot of people (often across many settings), who are required to coordinate the storage, management, analysis and display of large amounts of mostly heterogeneous information [33]. In 2011, the US Committee on Patient Safety and Health Information Technology, Institute of Medicine, warned against viewing health IT as a single product which is expected to lead inevitably to improved health care. Rather health IT should be understood as a collection of hardware and software working in conjunction with people, processes, and workflow [21].

Existing reviews of health informatics research have commented on the scarcity of information about contextual domains such as the size, location, academic status and the implementation components of the intervention [34]. The reason contextual information is not always reported is that many implementations are reviewed as if they were the “solution” which if shown to work in one situation will also work elsewhere. Many health informatics researchers have embraced elements from a social science approach to systematic reviews, recommending that the traditional Population, Intervention, Comparison, Outcomes (PICO) approach to undertaking systematic reviews should now become PICO(C) by including a “C” for context [3].

For instance, Shekelle and Goldzweig’s systematic review of the costs and benefits of health information technology published in 2009 included a valuable list of categories for data extraction, which identified factors related to the health IT system’s implementation strategy, its penetration, interoperability and sustainability and even its financial context (e.g., managed care or capitation) and long-term cost issues [13]. Such contextual information can improve our understanding about how to maximise value from health IT and deal with any potential negative effects.

9. Interpreting the evidence

There are some basic considerations which contribute to a robust interpretation of the results and the appraisal of the quality of the evidence. This can begin with an assessment of the overial strength of the evidence, particularly its consistency and validity. It is also important to consider the integrity and applicability of the evidence, as this constitutes an important part of processing the evidence and the resulting recommendations. This may include an assessment of the reach of the system, its sustainability and effectiveness.

In their overview of eHealth and its impact on the quality and safety of healthcare, Car, Black et al. concluded that the volume of research publications in health informatics was poorly collated and of variable quality, which made it difficult to synthesise and interpret [16]. Theoretical approaches can play a valuable part in the interpretation of findings by providing an analytical frame of reference or schema for understanding the significance of research findings. In health informatics, some researchers employ socio-technical theoretical approaches to help analyse and interpret the complex interrelationships between technology (e.g., software, hardware), people
Another area of expanding interest is the role of IT as an enabler of *patient-centred care, care coordination* and *shared decision-making*. Despite the enthusiasm about health IT’s potential contribution, the evidence up to now has not been conclusive [35]. In some part, this may be due to the failure to adequately explore how electronic systems (e.g., patient portals and personal health records) actually contribute to better patient care [36, 37]. This situation points to the need to explore how greater access to information and evidence, and communication with health care providers can contribute to improved patient care.

10. Conclusion

For many years now, there has been an ongoing concern within the health informatics community, that despite the massive increase in the research literature dedicated to the evaluation of health IT, understanding of how it can be translated into better and more effective health care is still variable [34]. Evidence-based health informatics, with its focus on methodological rigour and transparency, provides an effective means for enhancing the quality of care to meet the needs of patients, clinicians, health care administrators and policy makers, now and into the future.

Recommended further readings


Food for thought

1. How do flaws in search strategy (e.g., databases used, search script) affect the validity and robustness of a health informatics systematic review?
2. Do you think that health informatics has been, or is being affected by publication bias?

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3. What methods can be employed to address publication bias?

4. What possible effect does the context and setting of a health IT system have on the external validity of a study?

References


Studies in Health Technology and Informatics

Title Details

Title: Studies in Health Technology and Informatics
ISSN: 0926-9630
Publisher: IOS Press
Country: Netherlands
Status: Active
Start Year: 1992
Frequency: Irregular
Latest Volume / Issue: vol 170, [2011]
Language of Text: Text in: English
Refereed: Yes
Abstracted / Indexed: Yes
Serial Type: Monographic series
Content Type: Academic / Scholarly
Format: Print
Website: http://www.iospress.nl/html/shti.php
Description: Publishes papers and studies dealing with the impact of technological developments and information sciences on health care and health policy, particularly in Europe.

Subject Classifications

Additional Title Details

Publisher & Ordering Details

Price Data

Online Availability

Other Availability