Evaluation of informatics systems: beyond RCTs and beyond the hospital

Harold Lehmannm,1 Lucila Onno-Machado2

The current focus and funding of health information technology forces the informatics research community to ask many questions. A key one is: Are we providing policy makers the evidence they need to make the best decisions? Corollary to this question are two more: Are we using the best methods? Are we looking for evidence in all the right places?

Liu and Wyatt1 present their perspective on the critical role of randomized clinical trials (RCTs) in the assessment of clinical information systems. The authors briefly review the sources of skepticism that claim that RCT-based evaluation is not useful in evaluating health information systems due to ethical and technical grounds. Liu and Wyatt present counter-arguments to make a compelling case that clinical information systems can be very influential in determining clinical outcomes, so they should be subject to the same rigorous evaluation standards as other types of clinical interventions, such as medications and procedures. Regardless of design, justification of the match between purpose and design is paramount.

*JAMIA* agrees that RCTs are the preferred standard for evaluation in general, but it is not appropriate in all circumstances. As Liu and Wyatt point out, RCTs, which are often expensive, are appropriate for the evaluation of systems that expose added risk to subjects or that are associated with high costs. However, the growing field of comparative effectiveness research helps our thinking beyond RCTs and is directly relevant, not only because informatics systems often provide the data for those studies. Thus, leading comparative effectiveness research researchers provide guidance on when non-RCT designs are appropriate.2 For example, “To evaluate real-world applicability... to study multiple treatment paradigms simultaneously...to understand current practices...where trials have not been or cannot be performed...when treatment adherence differs...when providers have different training...” Each of these items applies when evaluating informatics systems: such systems can embody multiple interventions (eg, think of the many decision support options employed); baseline studies prior to implementation help us to understand current practice; trials have rarely been performed, especially of commercial systems; adherence, in terms of adoption, varies greatly within an institution; and training for HIT systems is notoriously variegated.

Thus, while many reports that are based on RCTs have appeared in the journal recently, other reports evaluate system features that may not expose patients, clinicians, or healthcare workers to added risk and are relatively inexpensive to implement. These studies are important for documenting the impact of a clinical information system in clinical outcomes and/or processes and for guiding subsequent system development. These reports may ultimately influence decision makers to implement certain system features at their sites.

More examples of studies not based on RCT designs appear in this issue, such as quantitative evaluations of clinical decision support interventions for appropriate test ordering in primary care and for timely discontinuation of antibiotics after surgery. Arguably, these interventions did not impose added risk to patients and were relatively inexpensive when compared to the cost of implementing a whole clinical information system. In these circumstances, other study designs may be appropriate.

Similarly, *JAMIA* publishes qualitative evaluations and reports of studies that employ methodologies designed to model behavioral and social systems and does not restrict its publications to quantitative evaluations or studies that utilize methodologies designed to model physical systems. Therefore, *JAMIA* ignores the perceived dichotomy between “soft” versus “hard” sciences. The field of health and biomedical informatics is diverse and each study is unique; thus, it is important to understand what is most appropriate for a particular investigation and to avoid a priori rule-in or rule-out of particular methodologies.

Beyond correct methodologies, we must study at the right level of organization. *JAMIA* is encouraging the submission of articles in all areas addressed in AMIA’s strategic realignment,3 especially those that have been relatively under-represented in the journal. At the opposite extreme of hospital-based informatics is public health informatics.

Although computer systems have been used since 1958, when Illinois used IBM tabulation equipment for vital statistics,4 the self-consciousness of public health informatics (PHI) as a field is relatively new as evidenced by the 2001 Spring AMIA meeting,5 the 2003 publication of the PHI textbook,6 and the funding for syndromic surveillance in the mid-2000s by the CDC Centers for Excellence in Public Health Informatics and the Department of Homeland Security.

In addition to being relatively new, the scope of PHI is also broad. In the spirit of evidence-based inquiry, we reviewed *JAMIA*’s publications in this area, mapping article titles to PHI topics and to the 10 Essential Public Health Services.7 Of 275 articles (of all sorts) published in 2008–2010, 51 (19%) were directly related to public health and addressed only four of the functions identified by the Essential Public Health Services (see next page).

IS 19% TOO BIG? TOO SMALL?

Consider some of the functions not on the list. “Mobilize community partnerships and action to identify and solve health problems” does seem to be an epiphenomenon of health information exchange activities, but we have not published research that addresses community mobilization head on. “Enforce laws and regulations that protect health and ensure safety” is perhaps represented by articles on privacy, but those articles mostly address the technology of deidentification.
Meanwhile, education of public health professionals makes no appearance. Even the functions that do appear on the list are not well-represented. While “consumer health” is on the list, most of the articles deal with personal health records, and not the public health function of “inform, educate, and empower people about health issues.” Certainly more research exists about informatics and developing countries or rural domestic areas beyond a couple of articles. The same goes for each of the other areas.

The final two functions—evaluating the “effectiveness, accessibility, and quality of personal and population-based health services” and “research for new insights and innovative solutions to health problems”—are part of every JAMIA submission, but return us to the question of research methods.

The broad scope of PHI means that there should be a wide range of topics that JAMIA will publish, for example, health messaging; uses of mobile technologies in developing countries; decision support for public health practice; emergent behavior of social networks and their effect on public health. We plan to issue a call for papers soon, which will address these under-represented areas in the journal.

With both appropriate methodology and proper level of analysis, the best evidence will be reproducible and generalizable to different settings. Therefore, JAMIA requests that authors thoroughly justify study design choices, submit data and code as appropriate for peer-review and for potential inclusion in online appendices, and discuss study limitations explicitly. We have broadened the scope of the journal to encompass all areas of biomedical and health informatics and look forward to receiving submissions which represent research, applications, reviews, and perspectives in all areas. Our collective contributions can have a large impact in healthcare in the USA and abroad.

**REFERENCES**