The first issue of the Journal of the American Medical Informatics Association (JAMIA) included a paper that proposed a framework for design of applied medical informatics projects and the evaluative studies that are part of them. A fundamental concept was that innovation in medical informatics takes place through sequential stages of system development. The first stage is specification, followed by component development, combination of components into a system, integration of the system into the environment, and, finally, routine use. The level of evaluation should be tuned to the stage of development. For example, problem definition and bench testing are appropriate during the specification stage. Field and validity testing become possible as components are combined into a system. Evaluation of efficacy is not practical until the system is integrated into the environment.

As a follow-up to this initial paper, I have re-read the 39 manuscripts describing original investigations or research that have been published in the first two volumes of JAMIA. I classified each according to the developmental stage of the work being reported and the level of evaluation employed. One goal was to get a feel for how well reports that had passed peer review fit into the proposed framework. Since the initial paper did not include examples, a second goal was to provide now an index for representative work based on the stage of development and level of evaluation. The brief citations that follow identify each article by the volume of JAMIA in which it appeared and its starting page number [see the box for author(s) and title].

Fifteen papers reported work in the specification stage of development. Several strategies were used for problem-definition-level evaluations. Test sets of patient records [1:61, 395, 404] and a sample guideline [2:238] were used to categorize the information that must be represented or located to perform a task. Non-case-based examples [2:4, 323] were used to explain models for representing clinical data. Surveys [1:381, 2:374] were utilized to identify computer literacy and attitudes. The bench-testing level of evaluation was also utilized at the specification stage of development. One or more cases [1:218, 249, 2:19, 116] were used to test a model for representing clinical data. A secondary analysis of cases [2:160] was used to demonstrate the utility of a framework for characterizing system use [2:160]. One guideline was incorporated into a clinical system [2:316] to explore the problems of such an application. Two sample implementations were used to demonstrate the feasibility of a framework for representing information sources [2:383].

Eight papers reported work in the component-development stage of development. Each of these involved the bench testing level of evaluation. The use of natural-language processors to map clinical text into a structured database [1:142, 161] was tested through comparison of recall and precision of queries of a resultant demonstration database with those of experts using the source text. The adequacy of a schema for representing data from chest x-ray reports was tested via manual verification of structured data from one of these processors against a subset of the source documents [1:233]. A set of standard terms for representation of nursing care was pilot-tested by showing consistency among terms selected by three coders [1:175]. A test set of cases was used to evaluate variation in model factors [1:272]. A search strategy was tested against manual review of a subset of journals [1:447]. A speech interface was evaluated by
contrasting two grammars [2:36] and by comparison of the recognizer with a hidden experimenter [2:46].

Ten papers reported work at the stage of development in which components were combined into a system. The majority involved the bench-testing level of evaluation. Performances of expert search [1:51] and diagnostic [1:127] systems with test cases were compared with those of human experts. Test cases were used to test multiple search interfaces against each other [1:285] and to compare content captured through a computer interface with that captured in a manual note [2:365]. Databases of case abstracts were used to train and test systems to predict risk
STEAD, Matching Evaluation of Projects to Stage of Development

[1:439] and length of stay [1:459]. A simulator was demonstrated by modeling two solutions for a test environment [2:220]. The report of the features of a client-server clinical record system together with benchmarks of performance [1:186] represents a field-test level of evaluation of work at this stage of development. Evaluation of computerized concurrent review with manual review in a crossed, blocked design is an example of a validation-level evaluation [1:339]. The evaluation of the utility of database assistance through a longitudinal study of two cohorts is an example of an efficacy-level evaluation.

Six papers reported systems that were at the stage of routine use. The majority had the character of the field-trial level of evaluation [1:35, 2:102, 307] in that they reported what worked and lessons learned. A comparison of knowledge-base disease profiles before and after update [2:297] is a validation-level evaluation. Another assessed impact through a survey to assess system utility [1:428] as perceived by different user groups. A randomized trial of the effect of providing a length-of-stay reminder is an example of an efficacy-level evaluation for work at this stage [2:58].

This placement of papers into categories represents one person's opinion and it is not precise. Most papers fit into the framework cleanly. An exception involved a case [2:36] where the methods were placed in one paper with the formal evaluation appearing in a companion paper. The papers grouped as field trials of systems in routine use [1:35, 2:102, 307] might be better characterized as something other than research studies since their focus is upon methods.

This review of medical informatics research published in JAMIA indicates that the majority of effort is being devoted to projects involving the early stages of system development. Accordingly, most evaluation focuses upon need assessment and bench testing. This finding may represent sampling error in that validity and efficacy studies are likely to be accepted by less specialized biomedical journals. Nonetheless, we need a balance of research at each stage of development.\(^2\) In particular, we need more controlled trials.\(^3\)

The field of medical informatics will not gain widespread credibility until more innovations reach the level of maturity that permits researchers to document their efficacy through use in practice. As those studies become possible, a significant percentage should be published in an informatics journal, where they are most likely to reach people who need to be encouraged to do similar studies. The rest should go to very general biomedical journals, where they reach a large audience that needs to be aware of innovations that are ready for general use.

WILLIAM W. STEAD, MD

References


Correspondence and reprints: William W. Stead, MD, The Annette and Irwin Eskind Biomedical Library, Vanderbilt University Medical Center, Nashville, TN 37232-8340. e-mail: bill.stead@mcmail.vanderbilt.edu

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