 Evaluation: salvation or nemesis of medical informatics?

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Abstract

The currently prevailing paradigms of evaluation in medical/health informatics are reviewed. Some problems with application of the objectivist approach to the evaluation of real—rather than simulated—(health) information systems are identified. The rigorous application of the objectivist approach, which was developed for laboratory experiments, is difficult to adapt to the evaluation of information systems in a practical real-world environment because such systems tend to be complex, changing rapidly over time, and often existing in a variety of variants. Practical and epistemological reasons for the consequent shortcomings of the objectivist approach are detailed. It is argued that insistence on the application of the objectivist principles to real information systems may hamper rather than advance insights and progress because of this. Alternatives in the form of the subjectivist approach and extensions to both the objectivist and subjectivist approaches that circumvent the identified problems are summarized. The need to include systems engineering approaches in, and to further extend, the evaluation methodology is pointed out. © 2002 Published by Elsevier Science Ltd.

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1. Introduction

Medical or Health Informatics\(^1\) [1] is not a discipline for which a homogeneous notion has been achieved. Criticisms include that it lacks a coherent theoretical and methodological basis. The efforts to remedy this situation include efforts to improve the strength of evaluations in medical informatics. For instance, the inaugural issue of the Journal of the American Medical Informatics Association in

\(^1\)The terms “medical informatics” and “health informatics” are used interchangeably here. They denote “the field that concerns itself with the cognitive, information processing, and communication tasks of medical practice, education, and research, including the information science and the technology to support these tasks” (according to [1]). The adjective “medical” in this definition is used to denote all issues related to health care and not just the domain of physicians or surgeons.

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1994 contained a paper [2] which argued that evaluation must be part of research and development in Medical Informatics in order to warrant support from public funds. Most research councils seem to share this principle. Obviously, the conviction that evaluation is not only mandatory from the point of view of accountability, but also a prerequisite to progress is widely shared. It also makes intuitive sense.

On the other hand, one may wonder as to what of the current information technology would be available, had it been required to pass through the needle’s eye of proof of efficacy. Much of what we currently use evolved through a serendipitous process resembling natural selection, driven largely by market forces. Examples include the word processor with which this paper is written, as well as the operating system that runs it.

The issue is that evaluation is not only a sufficient prerequisite for progress but also that it may not be even a necessary one. The issue is that, if done inappropriately, evaluation may inhibit progress. I will try to show this in order to make a case for considerate comprehensive evaluation that suits the purpose of enhancing insights and hence progress in medical informatics. To this end, I argue that considerate and sensitive, and above all innovative approaches are necessary.

2. A prevailing paradigm of evaluation in medical informatics

The current status of evaluation methodologies in medical informatics is characterized by some key publications. A textbook by Anderson et al. [3], published in 1994, gives a considerate well-selected spectrum of methodological approaches and a number of case examples on the basis of a thorough literature review up to 1993. It is an edited multi-authored collection of articles. Another text, published by Friedman and Wyatt [4] presents a more focused and homogeneous view. It characterizes a currently prevailing paradigm of evaluation in medical informatics [5]. The following discussion will, therefore, be based predominantly on this widely referenced text.

One of the merits of the Friedman and Wyatt [4] text is to use the distinction of ‘objectivist’ and ‘subjectivist’ approaches, according to House [6] instead of the more common ‘quantitative’ and ‘qualitative’ methods. The reason is that qualitative and quantitative measurements are desirable in both approaches and that the more important distinction is on achieving objectivity or exploiting subjectivity in the investigation of its nature. Therefore, I will also use this distinction.

2.1. The objectivist approach

The objectivist approach is based on a number of assumptions. It assumes that a valid model of the world exists and is known, and that a knowledge of its components allows us to explain the whole. The approach is, therefore, reductionist. It further assumes that truths exist and can be measured as attributes of the components of the model. If the attributes cannot be measured directly, they can be inferred reliably and validly, e.g., from human judgement.

Measurement of such characteristics is based on procedures grounded in measurement theory which yield data expressed on a variety of scales, such as cardinal, ordinal, nominal or existential, depending on the goals of measurement and the characteristics under investigation. Achievement of objectivity and the elimination of subjectivity are the primary concerns. Objectively established truths in the form of the measured characteristics of components of the model are used deductively
to understand the truth of complex systems made up of these components. This approach stems from
the experimental laboratory environment. It is well suited to the investigation of artificial systems
and biological sub-systems such as tissues and organs. It has been successfully adapted to the more
complex world of studying human beings and human populations.

The objectivist approach proceeds according to the following well-defined steps [4]:

1. Define the study question.
2. Define the system under investigation.
3. Select measurement methods and instruments or develop them through a cycle of measurement
   studies.
4. Design demonstration study.
5. Conduct demonstration study.
6. Analyze and report results.

A closer look at each of the first four of these steps shows, however, that it is difficult to fit these
approaches to the very complex world of the assessment of information systems with automated
components.2

Such information systems are complex technical artifacts, which are grafted onto the cognitive
processes of humans and their social interactions. Their crucial component is software, which is a
different type of artifact than a physical device, such as a prosthesis, or a drug. Unlike these artifacts,
software typically exists in multiple versions and is in a constant process of evolution and change.
These and other characteristics pose problems with the selection of study questions, the definition
of the system under study, and the selection measurement methodology and instruments.

2.1.1. Definition of study questions

The definition of study questions for the evaluation of information systems hinges on the identifi-
cation of appropriate stakeholders. Potential groups include not only the researchers involved in the
evaluation, but the producers of the system, their customers, the systems’ users, accrediting agencies,
system engineers charged with maintaining them, etc. The selection is therefore not easy and may
result in oversight of important questions or the selection of irrelevant ones. Even if the stakehold-
ers are validly determined, the validity of the selected study questions depends on the ability to
answer them, and hence on the availability of instruments that are able to measure the necessary
characteristics, and the availability of skilled personnel to use them.

A further determining issue is the availability of resources to answer the selected questions. A
large number of interesting questions can be answered if time and money are not an issue. Since
both are typically very limited, the questions selected may be the easy rather than the important
ones.

2.1.2. Definition of system under investigation

The definition of the system under investigation is similarly subject to arbitrary vagaries. Au-
tomated information systems are not built into a vacuum. They replace and complement existing
information systems. There is a close interaction between an automated system, which is presumably

2 The term “information system” is used comprehensively to include data processing as well as knowledge-based
applications. Much of the argumentation is based on information systems for management support, however.
under investigation, and its environment. We are not evaluating the characteristics of a device. We are evaluating the characteristics of a dynamic process, a process of adaptation of a new information system component with an existing information system. It is not uncommon that the efficacy of the conventional information system remains substantially improved even if the automated components are removed. The definition of the boundary of the system under study is therefore not easy. Last but not least, the definition of the system under investigation is also determined by the selection of questions to be answered and hence by the availability of methods to answer them.

2.1.3. Selection or development of measurement methods

As stated already, availability of measurement methods and instruments impact the preceding two steps and would ideally have to be answered before them. In practice, it is approached iteratively. However, the available monetary, personnel and time resources have profound impact on the selection of methods. If methods have to be developed, an iterative loop of measurement studies results, in order to produce reliable and valid measurement instruments. The ability to produce these hinges further on the availability of test environments and test systems that are sufficiently close to the real systems under study without being identical to it, because that would obviously introduce a host of artificial effects.

Measurement studies are time consuming and resource intensive. To conduct them may not allow achieving results in the real demonstration study in time for them to be relevant. Results achieved too late are in practice as bad as wrong results. For all these reasons, the temptation is great to resort to available methods, i.e., to methods which have resulted from conscientious measurement studies conducted by others, and for which the essential characteristics such as reliability and validity are assumed to be known. It may suffice to state that the available instruments often do not address the questions, which are most pressing from the perspective of one or the other or even all of the stakeholders in the evaluation studies. How else could it be that questions like the correlation between the self-reported “computer literacy” or “attitude towards computers” and the mode of use of a particular system are so prevalent in the literature? [7].

2.1.4. Design of a demonstration study

The demonstration study, the evaluation proper, comes in several forms:

- Descriptive study,
- correlation study, and
- comparison study.

The descriptive study consists only of dependent variables, which are measured on a variety of scales and analyzed with descriptive statistics. In correlation studies, the patterns of association between two or more variables are analyzed using correlation or regression techniques without attributing the cause and effect. This is only possible in comparison studies. Comparison studies consist of two objects, or one object in two states, one of which is subjected to an intervention, in our case the use of an information system. The intervention is determined by a hypothesis stated at the outset of the study. The effect of the intervention on one or more dependent variables is then determined.

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3 This assumption is in itself deserving some discussion, which we will leave aside here, however.
The randomized controlled trial design is frequently considered the epitome of the comparison study, because it ensures utmost objectivity. My argument though is that this objectivity comes at a tremendous cost when applied to the evaluation of information systems in the manner devised for controlled trials with physical interventions.

2.2. Critique of the objectivist approach

It may be obvious by now that the objectivist approach has serious drawbacks for the evaluation of information systems, in general, and in health care. These include practical and epistemological ones.

2.2.1. Practical drawbacks

Practical drawbacks include the resource requirements of funds, time and personnel. Even if we assume that important questions concerning an adequately delimited system have been identified, and valid measurement instruments are available to answer them, the approach still requires compromises of a nature that are likely to produce other artifacts which decrease the value of achieving objectivity. An example is the need to insulate an intervention group from a control group in a comparison study so that carry-over effects are avoided.

Take, for example, the introduction of an evidence-based information system for the treatment of defined disorders. For one, it is hard to ensure achievement of the insulation of the professionals who are given advice from the evidence-based system. Monitoring the degree of insulation increases the complexity of the investigation, and hence, its resource requirements. In the absence of control over the achievement of insulation, the results may be as flawed as with lack of objectivity. But more importantly, it may neither be necessary nor proper to conduct the evaluation in an RCT fashion. It is difficult to justify the resources required for the introduction of information systems if they do not achieve a substantial effect. As a consequence, one should not expect minor incremental improvements from their introduction. In this respect, the introduction of information systems is different from the testing for instance of drugs. Contrary to the situation, such as in oncology, where even slight improvements achieved from a new measure are desirable, such slight improvements would not justify the organizational upheaval and expense that the introduction of an information system engenders. On the other hand, if major effects are to be expected in the first place, it is not necessary to conduct a comparison study of the RCT type. It is also ethically problematic to conduct a comparison study, and withhold an intervention from a control group that can be expected to benefit substantially from it.

Another example is the impossibility, in many cases, of fitting a large number, let alone a randomly selected number of recipients with an information system under investigation. Rather one has often to work with small convenience samples of highly motivated early adopters, who are not typical for the general population. Since there is often no alternative, the question is not how to achieve a large representative sample, but how to arrive at valid insights despite the flaws of the sample for objectivist requirements.

Another problem is the effect of the research instrumentation on the study questions. As indicated already, timeliness of results is in conflict with the need to judiciously select research questions, measurement instruments and the system under study. Hence, easy questions are more likely pursued than difficult ones, which however may be the important ones.
Also, the systems under study are often so complex and expensive that it is simply impossible to introduce them into selected objects. It is not possible to randomly select hospitals and to fit them with a complex hospital information system in order to study its effects. Nonetheless, evaluation of hospital information systems is necessary in order to make design, development, purchase or management decisions. We are challenged therefore to make evaluation possible.

2.2.2. Epistemological problems

In addition to these practical concerns, there are epistemological ones: the rigidity of the approach which requires research questions, if not hypotheses, to be formulated at the outset of the demonstration study locks the investigator in. New questions arising during the study cannot be pursued. As a consequence, the scope of insights that are possible is limited by the decision made at the outset of the study. Questions relevant at the end of the study may not have been asked, let alone answered.

The approach also assumes that the system under investigation and its environment remain static. Typically, these assumptions are unrealistic. Information technology not only changes rapidly itself, but also effects constant changes of culture, values, legal context, and is affected by them. The recommendation is, of course, to “freeze” the system under study [2], i.e., to render static what is not. The recommendation amounts to the request to arrest progress—in support of progress! On the one hand, it is difficult because even if one can cease and desist the modifications of the component under development, one usually has very little control of this kind over the environmental components affected by the system. In addition, one risks that the system thus tested is woefully behind the state of the art by the time testing is done.

Then, there are numerous problems with the external validity of the results of such studies. The environments of information systems usually differ in many ways. Study subjects often differ significantly between a study environment and the environment to which the results of the study are to be applied, e.g., across institutional, provincial, national, or continental boundaries. And such simple factors as the location and accessibility of computers have often a greater effect on the efficacy of an information system than the information provided by the system. Finally, we have so far tremendous problems with defining such fundamental concepts as information, information need, etc., and hence with our ability to measure them validly [8,9].

Also, the complexity and dynamic properties of information systems make it hard to maintain the reductionist approach. We are not dealing with simple physical artifacts that consist of a finite number of components, which can be characterized relatively easily—and for the intended purposes completely. We are also not dealing with more complex biological systems, which, however, have been around for some millions of years without much change, and have been studied systematically for some four hundred years, and on which we can hope to continuously increase our knowledge. We are dealing with software, with artifacts that exist for a short time, and often in many clones and variants, and change constantly. We simply cannot hope to have the time to accumulate enough knowledge to understand them completely from an understanding of their components.

In summary, the practical difficulties with conducting objectivist studies in the manner recommended in [4] for the evaluation of information systems make it difficult to conduct such studies in the first place. They further affect the validity of the questions asked, the systems studied and the methods employed to such an extent as to obviate the value of the objectivity achieved. With
strict adherence to the objectivist approaches as developed for the laboratory environment, we risk investigating sub-aspects of little importance. We risk that our results are overtaken by the evolutions outside our control. We risk that our studies are not only perceived as irrelevant, but that they are irrelevant. I, therefore, argue that if we adhere too rigidly to the objectivist paradigm, we may not do our discipline a favor. Luckily there are alternatives. Friedman and Wyatt [4] describe subjectivist approaches as an alternative, which I will go into next. But extensions of both approaches are needed. There are numerous examples, well represented in [3]. I will point to a few further ones below.

2.3. The subjectivist approach

In view of the problems of the objectivist approach, which are clearly seen and described in singular, dispassionate completeness and detailed by Friedman and Wyatt [4], it is surprising that these authors introduce the subjectivist approach almost apologetically as an alternative. “The subjectivist approaches... address the problem of evaluation from a different set of premises... that may be unfamiliar or perhaps even discomfiting to some readers” ([4], p. 205). What is introduced in this manner is an approach that rather than trying to eliminate subjectivity, tries to take full, considerate advantage of it. It is devoted to finding out [4]:

- what people really want or need to know,
- through a description of system, environment and effects as perceived by people,
- on the basis of careful, sensitive, detailed observation that takes full advantage of subjectivity,
- using inductive reasoning for understanding of the world.

There are a number of different subjectivist approaches, but the one most often referred to in the context of system evaluation is the ethnographic approach, developed by anthropologists in order to understand cultures foreign to their own. It is closely related to the ethological approach developed for understanding animal behaviors.

Fundamentally, the ethnographic variant of the subjectivist approach consists of an identification of theses and questions based on results of initial observations and interrogations, which are then pursued iteratively, with increasing detail and adjustment of the direction of pursuit. If necessary and possible, proof of specific questions concerning sub-aspects can then be addressed using the objectivist approach [10,11].

The following procedure is recommended [4]: The themes and questions to be pursued should form the subject of a contract. Subsequently, researchers typically immerse themselves in the system under study and start with data collection based on their own or their associates’ observation, the results of conversations and interviews, or the analysis of documents, etc. The observations, which may include automated data collection from automated systems for descriptive characterization, are then progressively refined through cross-checking with the subjects under study and further detailing. Concurrently, explanations are formulated, in the light of existing or newly developed theories.

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4 The subjectivist paradigm is also prevalent in the Total Quality Management/Continuous Quality Improvement (TQM/CQI) approaches [10,11], despite the fundamentally objectivist orientation of this community.
The approach is holistic, and explains the world inductively from accepted observations. Its advantages include flexibility in the adjustment to changes, be it in the questions raised by stakeholders or by influences on the system under study. A thorough, detailed analysis of complex representations of few cases replaces the analysis of masses of data, often of limited scope and quality, from a large number of cases. The approach is thorough and rigorous, and the need for artificial constraining conditions is limited.

The subjectivist approach can be very economical. The pursuit of insights can be adjusted to the necessary degree of certainty and detail. As soon as this is achieved, the study is completed, rather than when a process following a predetermined design is finished. This can make it time efficient.

Finally, the approach forms a good basis for the design of objectivist studies, which, thereby, can become more specific, better focused and hence more economic. Rather than viewing the subjectivist approach apologetically as a complement to the objectivist one, it might better be seen as a mandatory prerequisite to objectivist studies. A case example might serve to illustrate the contrast:

In the early Eighties, we were consulting a professional association of pharmacists in Germany. This association had maintained an information service on drug-related questions for pharmacists, who in Germany operate overwhelmingly as private entrepreneurs in community-based pharmacies. Originally this service was provided by telephone and based on a continuously updated card file. The updating was eventually computerized, and the Medline-type interface developed to query the computer-based database. As a next step, it was considered to offer this computer-based information service to pharmacists [12]. At this stage the system had supposedly reached the stage of a “turn key” system ready to be rolled out to its end users. We were asked to assess the value of this information service to pharmacists [13].

According to the objectivist approach one could have developed a number of research questions concerning the acceptability of the user interface, the information service, its timeliness, cost, etc. Subsequently, one could have defined a random sample of pharmacies, installed the information system, educated staff in its use and done a descriptive or even a comparison study after developing or adopting appropriate measurement methodology. This type of study might have taken several years and cost in the order of hundreds of thousands of dollars.

We went a different route for various reasons. These included:

- availability of funds,
- time frame for the generation of results,
- the desire to avoid unnecessary invasion of the professional environment, and
- our knowledge that the existing user interface was less than adequate for occasional users.

Our approach was compatible with the subjectivist paradigm. We started by casually talking to a number of pharmacists, about a scenario, which purposely assumed the existence of an intuitive, easily usable interface, and a system that would reliably yield the desired information. During these initial conversations, we found that despite the optimistic features of our scenario, there was

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5 This would make it compatible with the intention of [2].
very limited enthusiasm for the information service, and
an apparent gradient from pharmacies in the city core, where one was able to imagine some benefits for the service, to village pharmacies where the idea was rejected outright.

On the basis of this insight, we switched to a small, defined objectivist study. We developed an interview guide and trained an interviewer who then visited a number of pharmacies selected according to their location in city centers, suburban and rural areas. The subsequent systematic assessment of the results of the interviews confirmed the gradient from city centers to rural areas and revealed its reason: anonymous client—provider relationship with high propensity for foreigners needing unusual drugs in the cities, long standing personal relations and stable routine in the villages. It also confirmed the lack of desire for the service for reasons of lack of resources and financial reward for the investment of the information system, the resources required for training, and the searches themselves. The whole investigation took a few months, cost the equivalent of a few thousand dollars and resulted in pivotal insights for the further development of the information resource:

- the need to work on the interface and complementary functionality of such a system, and
- the advisability to start with the information service in city centers.

This case was selected because it can be summarized briefly, and because it proves that the approach is not new. We did many other similar evaluations [14]. Our experiences make us suggest that the subjectivist approach deserves a guiding role in the evaluation of health information systems rather than that of an exceptional complement for the objectivist approach. It can serve to focus objectivist approaches and as a consequence to reduce resource requirements, as well as the need for artificial constraining conditions.

3. Methodological extensions

The text by Anderson et al. [3] represents a fair methodologic variety. But the methodological armamentarium desirable for health informatics is basically open-ended. Some methods such as the vast systems engineering methodology are not covered in the text. New methods will yet have to be devised, such as to overcome the shortcomings of the objectivist approaches, or to assess cognitive impacts of information systems, or to develop a better grasp of such concepts as information and information need.

The case illustration given above is an example of both needs. The evolutionary properties may have to be accounted for even in a product considered ‘ready’. And particularly when developing automated components in the first place, this development has to be guided by constant evaluation [2]. Automated information systems are fundamentally software artifacts. They are created in a software-engineering context [2,15,16]. Software systems typically evolve from individual components into complex systems. Testing cannot, therefore, be only concerned with the final product, but has to cover the early stages. In this respect, there are analogies to the production and assembly of complex, material systems such as cars, airplanes, and production plants. One difference of software systems from material artifacts is that they are not subject to material limitations and deterioration and can be reproduced at almost no cost in very high quantities. A more substantial difference,
particularly in this context, is that they are highly dependent on their environment, easily changed and corrupted and do usually exist in multiple versions of multiple clones. Therefore, the engineering and testing principles developed for material artifacts do not apply identically, and the knowledge of software engineering theory and methodology is essential in evaluating medical informatics. And so is the research for the advancement of such theory and methodology.

This need was clearly perceived by Stead et al. in their publication on the need for evaluation in health informatics projects [2]. In fact, they structured their recommendations according to the phases of the software-engineering life cycle and caution that complex evaluations be deferred to mature stages of the information systems. Just like [3,4], they did not, however, offer references to the vast literature of evaluation in software engineering [15,16] without which evaluation in health informatics can hardly be considered complete.

Once considered ready for the intended application, the software products become part of the complex socio-cultural systems and have to be evaluated in the context of those. This is where the principles addressed in the publications by Anderson et al. [3], and Friedman and Wyatt [4] come to bear. While the latter text emphasizes the objectivist approaches, the former presents a wider methodological spectrum, one that includes sociologic and economic approaches, and even a reference to simulation methodologies. It is, however, perhaps even more important to realize that we are not dealing with a closed system of evaluation approaches. We will continue to need to invest in the development of new and innovative methods to complement the existing ones.

Patel and colleagues [17] provide a good example of quantitative approaches in fundamentally subjectivist research. It is also a seminal contribution for evaluation in health informatics, making the relation between users’ cognitive structures and the information systems they use amenable to the evaluator and presentable to others. The effects on the improvement of a complex information system are well documented [17].

Our own work [14] crossed the boundaries of subjectivist and objectivist approaches and aimed at compensating the drawbacks of the latter by resorting to computer simulation. This approach uses data collected from selected real systems to build computer models, which represent the crucial characteristics of these systems. On this basis, one can then explore the effects of the introduction of information systems on their environment in objectivist manner without incurring the cost, the problems of biased samples and limited collaboration that ails this approach in real-world experiments.

We have analyzed the complex effects of computer-based practice management systems on the practices of physicians [18,19] and dentists [20] in this fashion. We were facing the typical challenge of working with highly motivated early adopters. So we resorted to descriptive investigations, starting in the subjectivist manner and complementing our findings with the results of targeted objectivist investigations. Based on the results, we built computer models of the typical practices. Then we simulated the operation of these practices under various conditions, such as with and without computer use.

These investigations allowed us to show in one instance that even though some computer-based procedures take more time than the conventional practices they replace, the overall work load in the practice was reduced by approximately one-third [18]. This was a strong argument in favor of the introduction of the investigated office management systems at the time.

In another instance, McDaniel in our group simulated the support of an entire province in Canada [21] with his previously developed message exchange system [22]. In this case, we were able to show that the cheap, secure and reliable system was only used to about one-quarter of its capacity when
supporting the message exchange requirements between practices, hospitals, pharmacies, laboratories and health agencies in an entire province. This kind of insight is important because successful introduction of information systems hinges on their ability to scale up and to respond to an increase of the use of the information service over previous levels, that usually follow system adoption.

In both instances, we avoided the monetary and time expense, as well as the hassle for all involved, of introducing these experimental systems into complex environments. At the same time, we were able to answer questions regarding the effects of such introductions in considerable detail, with good control over validity and in a very short time frame (in each case less than a year) in a fundamentally objectivist manner. But more importantly, we had rather elegantly circumvented the shortcomings of the objectivist approach, even without abandoning the objectivist paradigm. We were able to come to generalizable insights despite working with small, severely biased samples. We also did it on a very limited budget.

4. Conclusion

In summary, recent methodological extensions of the evaluation methodology in medical/health informatics include making the subjectivist approach quantifiable and circumventing the unrealistic requirements of the objectivist approach in order to achieve evaluations that “increase what is learned”. Other extensions of the evaluation methodology are necessary and will doubtlessly follow. It is therefore neither necessary nor advisable to adhere only to the objectivist approach as developed for clinical trials, and to consider comparison studies modeled after the RCT as the pinnacle of evaluation in health informatics. If we do, we may hamper progress in health informatics rather than fostering it.

5. Summary

Approaches recommended for evaluation of information systems in health are reviewed. In particular, the objectivist and subjectivist approaches are summarized to some extent. The drawbacks of the objectivist approaches that can be compensated by subjectivist methods are identified. The need for a considerate expansion of the evaluation methodology, one that includes systems engineering approaches in the early phases of systems development, and that extends to an assessment of cognitive and social effects in the operational phases is advocated.

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References

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