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Evaluating informatics applications—some alternative approaches: theory, social interactionism, and call for methodological pluralism

Bonnie Kaplan *

Center for Medical Informatics, Yale University School of Medicine, New Haven, CT, USA

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Abstract

A review of evaluation literature concerning CDSSs indicates that randomized controlled clinical trials (RCTs) are the ‘gold standard’ for evaluation. While this approach is excellent for studying system or clinical performance, it is not well suited to answering questions concerning whether systems will be used or how they will be used. Because lack of use of CDSS has been of concern for some years, other evaluation research designs are needed to address those issues. This paper critiques RCT and experimental evaluation approaches and presents alternative approaches to evaluation that address questions outside the scope of the usual RCT and experimental designs. A wide range of literature is summarized to illustrate the value of evaluations that take into account social, organizational, professional, and other contextual considerations. Many of these studies go beyond the usual measures of systems performance or physicians’ behavior by focusing on ‘fit’ of the system with other aspects of professional and organizational life. Because there is little explicit theory that informs many evaluations, the paper then reviews CDSS evaluations informed by social science theories. Lastly, it proposes a theoretical social science base of social interactionism. An example of such an approach is given. It involves a CDSS in psychiatry and is based on Kaplan’s 4Cs, which focus on communication, control, care, and context. Although the example is a CDSS, the evaluation approach also is useful for clinical guideline implementation of and other medical informatics applications. Similarly, although the discussion is about social interactionism, the more important point is the need to broaden evaluation through a variety of methods and approaches that investigate social, cultural, organizational, cognitive, and other contextual concerns. Methodological pluralism and a variety of research questions can increase understanding of many influences concerning informatics applications development and deployment. © 2001 Published by Elsevier Science Ireland Ltd.

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* Corresponding author. Kaplan Associates, 59 Morris Street, Hamden, CT 06517, USA. Tel.: +1-203-777-9089; fax: +1-203-777-9089.

E-mail address: bonnie.kaplan@yale.edu (B. Kaplan).

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1. Introduction

Informatics researchers and practitioners have been developing systems to support clinical care and decision making for a half century. Information technologies now are a standard fixture in clinical settings. Nevertheless, there is a general consensus that a variety of systems for clinical decision support are little used, even though their potential benefits have been demonstrated repeatedly [1]. A review of evaluations concerning clinical decision support systems (CDSSs) indicates that these studies are done in a way that precludes findings useful for understanding why CDSSs may or may not be effective. This omission could result in making less informed decisions about these technologies and, by extension, other medical informatics applications. The review reports that most studies use an experimental or randomized controlled clinical trials design (RCT) to assess system performance or to focus on changes in clinical performance that could affect patient care. Few studies involve field tests of the CDSS and almost none use a naturalistic design in clinical settings with real patients. Most focus on physicians rather than other clinical users or patients. In addition, there is little theoretical discussion, although papers are permeated by a rationalist perspective that excludes contextual issues related to how and why systems are used. Further, CDSS evaluation studies appear to be insulated from evaluations of other medical informatics applications [1].

Although RCTs and other experimental designs are excellent for assessing system performance or specific changes in clinical practice behaviors, some authors have pointed out that these methods are not well suited for studying other research questions. Consequently, other approaches have been developed: simulation, usability testing, cognitive

studies, record and playback techniques, network analysis, ethnography, and social interactionism among them. However, when these are used under controlled conditions, it can be difficult to investigate a variety of human, contextual, and cultural factors that affect system acceptance in actual use. Further, a focus on pre-specified outcome measures precludes examining processes of actual system use during daily activities [2].

This paper builds on that literature review [1] to argue for expanding evaluation approaches to enable increased understanding of the many influences concerning informatics applications development and deployment so that we can improve these processes and their connection with patient care. The paper draws on a wide range of literature that was identified through a combination of manual and automated literature searches as described in [1]. Although the literature is from fields that often remain separated, here it is linked to illustrate the need for evaluation designs that go beyond RCTs and experiments, that focus on a variety of individuals and on organizational concerns rather than primarily on physicians' behavior, and that are informed by evaluations in many areas of medical and health informatics. To further these aims, the paper discusses evaluations that take into account social, organizational, professional, and other contextual considerations. It also proposes: (1) a theoretical base for evaluation; and (2) methodological pluralism in evaluation that incorporates both multiple methods and also addresses a variety of evaluation issues. The paper suggests a social interactionist approach that draws on social science theory, incorporates multiple methods, and addresses a variety of evaluation issues. This approach is illustrated by an example of a CDSS evaluation in psychiatry. The example is based on Kaplan's 4Cs, which focus on communication, control, care, and

context [3,4]. Although the discussion concerns CDSSs, a social interactionist approach is useful when evaluating clinical practice guideline implementation or other medical informatics applications.

2. Limitations of RCT/experimental evaluation approaches

Although RCTs are the ‘gold standard’ of clinical research, this hierarchy of research design is not adhered to in other scientific disciplines and recently has been questioned in medicine [5,6]. With respect to CDSS, as early as 1987, Lundsgaarde reported that evaluations of expert systems often ignored context, such as culture, organization, and work life. He observed that this lack might help explain why so few systems have moved from laboratory to clinic [7]. A few years later, Forsythe and Buchanan, noting the tendency to evaluate systems performance, argued for extending the methodological repertoire in particular by proposing approaches so as to include social and contextual issues crucial to user acceptance. They pointed out that, unlike in evaluating drugs, users’ opinions of reactions to computer systems make a difference in whether or not a system will have an effect [8]. Heathfield and Wyatt’s 1993 paper stated similar concerns [9]. Despite their plea for change, their observation remains true that evaluators tend to carefully examine structure and function, but not impact on users and their clinical problem. Heathfield and colleagues made the point again in 1998 [10]. Patel and colleagues have often called for broadening evaluation, in their case advocating cognitive approaches [2,11]; Berg and colleagues have been advocating a sociological approach that employs sociocultural analyses and socio-technical design [12–14]; Lau and Hayward

provided an excellent example of the value of action research [15]; and Anderson and colleagues have advocated social interactionism in their various publications [16,17]. All these authors noted both the need to focus on systems as they actually are used in health care settings and also the limitations of studies with pre-specified dependent measures for identifying unanticipated consequences or emergent effects that may be enduring [18].

The fact that these claims and criticisms have been made repeatedly indicates a problem that still has not been addressed [1]¹. This gap in the CDSS literature is long-standing, even though concern over lack of system use has been voiced repeatedly for the past 50 years [20]. It reflects a similar trend in evaluation in other areas of informatics. Concern with such contextual questions as power, culture, group relationships, work routines, stakeholders, professional values, social networks, institutional organization, and judgement elude quantitative and RCT-type evaluation approaches [21]. Even where applications are evaluated in practice, often they omit such key information as descriptions of the setting in which they occurred [22]. The primacy of experimental and RCT approaches perhaps is why current understanding of influences on system success is limited. Because reviews (and perhaps publication preferences [1,23]) often exclude evaluations done any other way, they omit studies that may focus on user, organizational, socio-cultural, or other contextual issues, and in-

¹ Because few systems are in routine use, some argue that it can be quite difficult to evaluate them in real settings, or to determine how effective they may be [19]. However, such evaluations need to occur for systems that have not yet reached this stage. Although this may limit how evaluations are conducted, it would be possible, and even desirable, to evaluate systems in actual use before they are implemented for routine use.

stead print evaluations that decontextualize the system under study.

The CDSS literature seems insulated from studies and methodologies for investigating research questions pertaining to a variety of related reasons for why clinicians may or may not use CDSSs or change their clinical practice behaviors. The emphasis on RCTs has underlying assumptions that do not address users' perceptions of a system, the meaning system use has for users, and whether or not they will adopt it into routine practice [8]. Such studies are difficult to do within a RCT design.

Moreover, RCTs or experiments may not provide decision makers with enough scope or detail [10]. Further, it has been argued that it is impractical and difficult to generalize from randomized trials [24], for example, whether CDSS trials in large practices or in-patient settings generalize to small ambulatory practices [25]. Heathfield et al. point out that randomized controlled clinical trials are not practical for multi-site evaluation studies with multiple stakeholders and multi-disciplinary evaluation teams. As they report, evaluation against objectives is not straightforward and it is difficult to determine (and to know how to determine) what the most important evaluation questions are. They found that the focus of their evaluation of computer-based patient records constantly had to be reconsidered as new hypotheses emerged during the project. Evaluation objectives, too, changed as a site's understanding deepened [26]. These difficulties contravene assumptions of experimental designs for testing hypotheses.

3. The need for an alternative

Thus, it appears as though the standards of RCTs and other experimental approaches,

while excellent for measuring clinical behavior changes or system performance, may be resulting in an impoverished understanding of issues pertaining to system use. Whether or not an informatics system works depends upon social and cognitive processes as well as on technological ones [27]. Because RCT and experimental evaluation approaches do not include social, organizational, cultural, cognitive, or contextual issues, they cannot answer key questions: Why are the outcomes that are studied as they are, and what might be done to affect outcomes? What influences whether CDSSs will have the desired effect? Why do clinicians use or not use CDSSs, or any other informatics application?

It is well recognized that evaluation methods and questions depend upon both system development phase and purpose of the evaluation [22,28–30]. Because RCT and experimental designs are not well suited for investigating why performance changes occur or systems are used, some have called for making it a priority 'to develop richer understanding of the effects of [system] benefits in health care and to develop new evaluation methods that help us to understand the process of implementing it' [24]. It is increasingly recognized that organizational and behavioral issues, clinical context, cognitive factors, and methods of development and dissemination are involved in informatics applications' uses and effects [19,22,31–34].

Some CDSSs may include clinical practice guidelines. There are parallels between what has happened with CDSSs and with compliance with clinical guidelines [35,36], whether or not part of a CDSS: 'few are routinely used, as they do not address physicians' real needs, are perceived as threats to physician autonomy, and are not generally evaluated before introduction' [9]. There are few studies that consider more than one barrier to guideline adherence, so it becomes less likely that

implementation can be successful because often several barriers operate together. Further, a theoretical approach may help explain the variety of barriers and which strategies may be successful in different settings, and, therefore, possibly help target interventions to specific barriers [37], but such an approach is lacking. Consequently, as Davis and Taylor-Vaisey claim, ‘The adoption of any innovation or the dissemination of new medical knowledge should be considered in a holistic, contextual manner’ [38]. As with CDSS, then, ‘pervasive evidence’ that [guidelines] rarely lead directly to changes in medical practice’ suggests that attention to social and behavioral considerations is needed. Hence, Mittman et al. observe [39]:

Guideline dissemination and implementation policies and intervention approaches must take into account existing patterns of social interaction and influence and must be carefully designed to meet the characteristics of target clinicians and practice settings. Patterns of influence and interaction vary widely across specialties, practice settings, and other situational variables, and successful application of social influence approaches requires conforming to the specific characteristics and context of the local setting.

Thus, they advocate an approach that:

emphasizes such influences as shared beliefs and assumptions, group norms, organizational culture, and related behavioral factors, as well as acknowledging economic considerations and other related influences on behavior.

Similarly, Woolf et al. write [40]:

When clinicians already know the infor-

mation contained in guidelines, those concerned with improving quality should redirect their efforts to identify the specific barriers, beyond knowledge, that stand in the way of behaviour change.

Especially because CDSSs may contain practice guidelines, both for CDSS and guidelines, then, the scope of evaluation needs to be extended beyond RCT-inspired designs so as to examine these other concerns. New perspectives are emerging in evaluation which emphasize the need for multi-perspective, multi-method studies that focus on a variety of professional, organizational, and behavioral issues [3,4,10]. Where experimental or RCT evidence of CDSS effectiveness is either equivocal or negative, without understanding the reasons for such results, information is lacking that may help in building better systems or in preventing decisions that may result in abandoning technologies that could potentially be useful [10].

4. An alternative approach to evaluation

4.1. ‘Fit’

The CDSS literature seems not to be informed by studies of other systems, such as hospital information systems (HISs), computer based patient records (CPRs), or ancillary care systems (e.g. laboratory, radiology) that, like studies of guideline compliance, could provide useful insights into issues that may be relevant to acceptance and use of CDSSs.[1] One area that has received some attention when considering acceptance or rejection of CDSSs, or, any clinical information system, may be broadly categorized as ‘fit.’

There are a variety of dimensions to ‘fit,’ drawn from considering both the CDSS

literature as well as other areas of medical informatics. Some authors discuss fit with work flow [41–43] or clinicians' level of expertise [42], while others put these together into a model of fit between the information technology and user [31,44]; some emphasize fit, or compatibility, with values and professional norms [45,46]; institutional setting [47]; communication patterns [48]; organizational culture [49]; and cognitive processes [50]. Matching technology and information needs, and the fit between health care operations and technology, also are important, as was found for a successful CDSSs in ambulatory medical record implementations [51], as is the fit between technology, clinical work, and organization [52]. This kind of fit includes characteristics of the system, the user, and the operating model under which the system is used [53]. Southon et al. attribute the failure of several large systems used in public health to problems of fit among key components of the organization, such as organizational structure, strategy, management, people's skills, and technology [54].

Heathfield and Wyatt attribute CDSS problems to 'a failure to appreciate the nature of decision problems and a mismatch in motivations between developers and users' [9]. Differences between developer and clinician goals [32,55,56] as well as between different physicians, administrators, developers, and patients [57,58] have been noted by others as well. Cultural 'fit', or compatibility, therefore, is important [59,60]. As Kaplan's research suggests, reasons for physicians' reluctance to use CDSSs include a poor fit between CDSS developers' goals and physicians' cultural values, in that physicians may consider these technologies: (1) as detrimental to developing the doctor-patient relationship; (2) as undermining their professional status as diagnostician and architect of patient management; (3) as subverting the art of medical

practice; and (4) as interfering with professional autonomy. For them, there may be little perceived benefit to using a CDSS. At the same time, other physicians may consider these technologies as enhancing their capabilities by providing information necessary for clinical decision making, thereby improving the scientific practice of medicine and enabling better patient care. Physicians have been willing users when computer information systems are compatible with their professional values and norms, provide benefits they consider important, and conform to their work patterns [41,45], all dimensions of 'fit.'

These and other aspects of 'fit' are illustrated and discussed beautifully by Sicotte and colleagues in their report of a multi-method multiple case study of CPR system implementation in four hospitals, one part of which involved feedback to physicians [43,61,62]. Based on interviews, focus groups, observations, and secondary documented sources, they describe the history of a project that medical and nursing staff boycotted. Nevertheless, they say, user-resistance was not the problem. Instead, they explain how the complexities of fitting care processes and information processes caused the main problems. The project team made few concessions from their original vision of the CPR. They focused on an automated patient history for physician use, rather than on functions that physicians thought would facilitate their work [61]. For nurses, the new system ended up being 'highly normative as it tried to impose a new reality, producing uniformity and predictability in thought and behavior pattern of nurses'. Consequently, the new system caused 'information overload and standardization, clerical task load increase, work organization rigidity, and expert autonomy negation' [43], much as reported by Massaro in his classic description of the

problems house staff experienced during implementation of a hospital information system [49]. These findings could be relevant to Sicotte et al.'s report of another aspect of the study pertaining to CDSS: providing feedback did not affect physician practice profiles [61].

The notion of 'fit' runs in both causal directions. While the degree to which an information system fits other aspects of organizational life is crucial, so, too, is the degree to which the system embodies appropriate models of work routines, management assumptions, patient care philosophies, and users' conceptions of their needs. As indicated in the example from Sicotte, the boycotted CPR was based on particular views of physicians' needs and of nursing practice.

Ways in which instruments and artifacts incorporate values, norms, representations of work, and assumptions about usability have been discussed in both the social studies of science literature and computer science literature, notably by Suchman [63], and, specifically, in the human-computer interaction (HCI) literature [64]. Carrol and Campbell argue that '*artifacts embody implicit theories of HCI*' and implicit psychological theories ([64], emphasis in original), while Dillon provides a view of systems as 'artifacts of theories' that combines and extends both cognitive psychological models of users as information processors and sociological models of users as social beings [65].

Similar perspectives have appeared in medical informatics literature, for example, in Forsythe's discussion of how a system for educating patients about headache embodies physicians' ideas of what patients should want to know instead of embodying patients' concerns that surfaced in an ethnographic study [57]. Covvey uses the idea of system as artifact of theory to discuss why systems in health care have not provided the decision

support that might have been expected for managers. Reminiscent of Suchman's claim that systems incorporate assumptions about work to be done with it [63], Covvey points out that a system is never only a system, but contains cognitive models of how people work and think. Consequently, he argues that system functions and human work processes must be addressed together. Implementation of a new system requires changes in process, and may run counter to existing work practices [66]. Because software encodes a model of end users do their work, some work processes will be enabled while others may become more difficult.

Attempts are under way to extend design principles and approaches into the argument that software embodies work. These efforts concern more closely linking work design and software design, including attempts to model work according to users' views [63,67]. This requires understanding users' goals, roles, tasks, and how they think about their work [67]. Different groups of users may have different conceptions of their work, even if they are ostensibly doing the same work, as Kaplan and Duchon found for clinical laboratory technologists, all using the same system within the same laboratories [68].

'Fit,' then, is useful for understanding implementation issues surrounding a particular system, why the same system may be viewed differently by different users [69], and also why it may be implemented more successfully in one setting than in another [58,70]. 'Fit' also links evaluation and design, as recognized by some of the authors of CDSS evaluations [71–75]. As the above discussion illustrates, different dimensions of fit are related and interweave in complex ways when a system is introduced. Further, an evaluation tradition focusing primarily on physicians ignores other clinicians and the relationships among them, as well as ignoring other con-

texts and individuals who may potentially use or be affected by an information system. Evaluation methods and theory both need to take account of these interrelationships. A theoretical grounding for ‘fit’ would be useful, as it would for evaluation in general.

4.2. Theoretical bases in social and behavioral science

As illustrated by the discussion of fit, and, as several have observed: ‘Sociologic, cultural, and financial issues have as much to do with the success or failure of a system as do technological aspects’ [76] because ‘information technologies are embedded within a complex social and organisational context’ [24]. A theoretical base that recognizes the importance of such issues is needed. There is little reference in the CDSS literature to studies that draw on theory for understanding the many issues that arise in developing, implementing, and using CDSSs [1].

Such a base may be found in social science [34]. As Grémy and Bonin noted [32], medical informatics is essentially a human activity and raises questions of what it means to be human, so that applications should be evaluated using the ‘human’, or social, sciences rather than imposing a computer-like model on human and organizational thought and behavior. They consider failure of so many medical informatics applications, including expert systems, as indication of the need for a new philosophy and advice from social scientists, with evaluation taking a sociological approach. There has been a thread of evaluations informed by theoretical work in the social and behavioral sciences for some time [34]. Earlier examples of this work are contained in [77]. This thread occasionally appears in the CDSS literature. For example, nine of the 27 CDSS studies reviewed in a literature review of CDSS evaluations em-

ployed qualitative methods [1], indicative of a broader approach to evaluation than the RCT model. A few papers identified in the search done for that review provided a more manifest theoretical social sciences basis. These papers are discussed further here.

In the CDSS literature, one such approach is related to Carrol and Campbell’s work at the IBM T.J. Watson Research Center’s User Interface Institute, where they, like Patel [2,11], advocate using psychology to analyze tasks and user interfaces. They propound the idea that HCI should be understood as ‘an ecology of tasks and artifacts’ [64]. Carrol and Campbell draw on Suchman’s argument that artifacts cannot be understood independently from how they are used in actual practice. Suchman’s influential study of situated action [78], and later other studies and theoretical contributions clearly related to her continuing concern with how systems incorporate representations of work, result from her experiences as an anthropologist serving as a principal scientist and manager of the Work Practice and Technology area at Xerox Palo Alto Research Center [63]. In one paper discussing different philosophies of systems design, Lipscombe draws on this theoretical background to argue for systems that extend the physician rather than provide an ‘artificial’ medical colleague [79]. In a paper published a few years later, Musen gives an impassioned argument for situated cognition, reminding us that ‘knowledge can never be decontextualized—for example, as a self-contained expert system,’ because knowledge ‘is situated in particular social and physical systems’ and ‘emerges in the context of interactions with other people and with the environment’ [80]. This theme is apparent, too, in a special issue of *Artificial Intelligence in Medicine* [81]. Authors in this AIM issue draw on Scandinavian participatory design approaches [82] and on the writings of Wino-

grad and Flores [83]—works little cited by the medical informatics community—as well as on Suchman [63].

In a related approach, Berg's work, suggestive of influence from actor-network theory, which was developed among sociologists of science by Latour [84], is explicitly informed by sociotechnical theory as presented in information systems literature. In its early formulation, in sociotechnical theory, a change in technology, people, task, or structure is seen to result in adjustments by the other three components in order to maintain organizational stability [85]. Berg focuses on work practices and how individuals, tools, documents, and machines are cooperative elements in emergent networks that make work practices function smoothly [12]. He sees information as contextual by nature, entangled with the work done to gather it [13]. In his extensive field study of two CDSSs [86], de Dombal's abdominal pain system and Emerson and Wyatt's ACORN chest pain advisor, Berg argues that neither the environment nor the system itself is stable. His descriptions make it apparent that there is something of a co-evolution of the environment and the system. Users adjust their work routines to a system just as they adjust system use to their work environments. In the process, each changes the other. This is similar to others' arguments that clinical work, the organization, and the information and communication technologies change each other [52], though Berg's analysis is subtle and complex in seeing the technology, the work, and the clinicians as interwoven agents of change.

Berg's analysis also suggests (though he does not state it in these terms) that the way an application is used (and whether it will be used at all) is influenced by the beliefs, values, practices, and norms of those who are supposed to use it (an example of 'fit'), and that these beliefs, values, practices, and

norms evolve along with the use of a system over time [86]. This could be an example of a phenomenon noted by Patel and Kaufman in their study of a diabetic clinic: '... integration of systems into clinical settings fundamentally change not only how physicians view their daily work practice but also the very process of medical reasoning itself' [87].

In a similar vein, Sicotte and his colleagues studied how feedback affected physicians' practice patterns. In a paper on the medical records implementation context of their investigation, they argue for studying the interplay between structural characteristics of a technology, as anticipated by designers and the project team, and those that emerge from human interaction. As they explain: 'technology is physically constructed by actors working in a given social context. It is socially constructed by actors through the different meanings they attach to it and the various features they emphasize and use' [62]. These studies indicate that introducing technology has effects that cannot be anticipated and that users (or potential users) may react in complex ways. As has been pointed out, evaluation studies, therefore, need to be designed to investigate these unforeseeable effects [3,4,26,45,88].

Another base found in the CDSS literature draws on Classic Diffusion [of Innovation] Theory, as developed by the communications scholar, Rogers [89]. This theory underlies much of the evaluation research by Anderson et al. [17], and social network analyses of the acceptance and diffusion of medical information systems, e.g. [90]. Some of the above CDSS studies confirm its applicability to CDSSs, although those authors do not mention it. Davis and Taylor-Vaisey recognize its applicability to the adoption of clinical practice guidelines [38], while Lee and Cooper's recommendations for how to implement clinical guidelines overlap with Classic Diffusion

Theory, though they do not explicitly use it [91]. Their recommendations fit the general tenets of Classic Diffusion Theory: adoption of an innovation depends on: (1) whether users consider its potential use beneficial; (2) how the innovation is communicated along social networks over time; (3) what information sources are used to communicate about the innovation at each stage of adoption; and (4) compatibility of the innovation with adopters' beliefs, values, practices, and norms, i.e. various dimensions of 'fit' described above. Kaplan et al.'s study of a psychiatric expert system was influenced by this theory and employed an ethnographic approach [73]. Weaver draws explicitly on the theory to discuss barriers to the diffusion of Weed's Problem Knowledge Coupler (PKC) in terms of communication channels, awareness of the innovation, compatibility with how clinical problems generally are solved, and resources required for development and diffusion. He also addresses organizational effects and impacts. His conclusion: social factors, rather than benefits to patient care or the merits of the particular CDSS, hinder the PKC's deployment [92].

5. Social interactionist theory

Situated action or cognition, actor-network theory, sociotechnical theory, constructionist approaches, and Classic Diffusion Theory each provide theoretical bases that could inform informatics studies, as could ethnography, cognitive studies, and theories of artifacts as embedded models of psychological theories. These theoretical bases have in common that they are, in some way or another, social interactionist approaches [3,17,93,94], and a number of the researchers cited have social science degrees. Unlike more common research strategies reported in the

medical informatics literature, which take an approach based on a rational perspective and objectivist orientation [1], these studies instead use a social influence or social interactionist approach that takes account of the kinds of social, political, cultural, historical, institutional, cognitive, and other contextual constituents of the change process [39,94,95].

In a social interactionist approach to evaluating medical informatics applications, how the technology is used and what changes occur are thought to result from complex social interactions. Because users may modify information systems during design, implementation, and use, they are viewed as active participants in what occurs. The way a technology is designed, implemented, and used, then, is influenced by individuals' and groups' objectives, preferences, work demands, professional status, communication patterns, and social networks [4]. Characteristics of the technology, of the developers and potential users, and of the organizations into which they are introduced, are seen to interact with each other and may themselves change through these interactions. The participants, the setting, and the technology are treated as dynamic emergent processes rather than as variables that can be held constant, and causality is seen to be multi-directional rather than uni-directional. Social interactionist evaluation involves studying social, political, organizational, and related processes as they unfold over time [17,96]. Researchers draw on theories of change and social science theories to investigate these interrelationships. They also may use an interpretivist approach and study what meanings individuals ascribe to the technologies and processes under study, which requires using qualitative approaches [12,97]. Kaplan has suggested guidelines for doing such studies: (1) focus on a variety of concerns; (2) use multiple methods; (3) be modifiable in study design; (4)

employ longitudinal study designs; and (5) conduct formative as well as summative evaluations [3,4].

These newer approaches to evaluation have been developed in order to assess why and how a CDSS—or any informatics application—is (or is not) used [3,4]. They provide a way of examining what the above analyses of CDSSs suggest: that medical computer systems do not stand by themselves, and that user acceptance is a dynamic, interactive, and iterative process, the details of which play out differently in different specific situations or contexts.

6. Example

Drawing on this social interactionist tradition, Kaplan's 4Cs evaluation framework is based both on a social interactionist theoretical perspective and on empirical evaluation research studies of a variety of medical and health informatics applications. It can be used for studying and influencing processes of design, implementation, adoption, and use in natural settings where a clinical application is introduced. The framework calls attention to four of the many interrelated areas when conducting an evaluation: communication, care, control, and context [3,4]. As an illustrative example, a study of a CDSS in routine use in a psychiatric hospital [73] is re-analyzed using the 4Cs framework.

A Computer Evaluation and Monitoring System (CEMS) was developed and used routinely at a psychiatric hospital. CEMS issued alerts when standard clinical practices were not followed (e.g. when medication orders did not seem consistent with diagnosis), or when laboratory results indicated the presence of abnormalities. CEMS also checked symptoms and diagnosis for consistency. The evaluation was ethnographic in that it investi-

gated how the different individuals at the hospital viewed CEMS. The research involved interviewing clinicians from all patient care areas, including attending physicians, nurses, all resident physicians, and other clinical staff. In addition, observations were conducted at training sessions and of routine clinical use of the CDSS. The evaluation was done under the auspices of Quality Assurance, the individuals responsible for initial system development and its continued use.

6.1. Communication

CEMS communicated with clinicians both on-line and through printed reports. Alerts were available on-line for clinicians to review at any time, and so that clinicians could enter information to resolve the alert. In addition, CEMS produced two reports. One listed alerts that had not been resolved. Physicians who supervised psychiatry residents and non-physician clinicians received reports of their own and their supervisees' alerts. The other report was a list of diagnoses that did not match symptoms, according to standard psychiatric diagnostic criteria.

Physicians said that they did not consider these CEMS outputs particularly helpful to them. Although they said that they regularly checked their alerts, they also said that they rarely got new information from them. They explained that they already had known about the situation and usually saw no need to change treatment decisions. They also considered the diagnosis reports not very useful. They received them sometimes as late as weeks after the patient had been discharged. Thus, they reported, CEMS did not communicate information that affected how they treated patients.

Clinicians tended to indicate that CEMS served administrative purposes more than clinical ones. This suggests an additional

communications issue. Quality Assurance, which had mandated system use, valued the documentation provided by CEMS, although they presented the system in terms of its benefits to clinicians and patient care. How system benefits were communicated, then, was important at this hospital, and relates to all 4Cs.

6.2. *Care*

Because clinicians did not think they got much benefit from CEMS outputs, they reported little effect of CEMS on their practice or patient care. Quality Assurance, on the other hand, considered that CEMS improved patient care. Thus, clinical staff and Quality Assurance staff differed in whether they thought that the increased documentation and cross-checking that CEMS provided did improve patient care. It may have been problematic to actually use data collected through CEMS to test whether various quality measures improved. For example, clinicians were observed to tell each other to simply enter symptoms that were required by diagnostic criteria, so as to be able to work around system constraints.

6.3. *Control*

The different perceptions of system benefits between clinical staff and Quality Assurance staff point to a sense of difference between clinical administrative goals. They also suggest differences between each of these groups and system developers. System developers, including those who were involved from Quality Assurance, presented CEMS as having resulted from a participatory design process. Nevertheless, physicians complained about the cumbersome checklists and menus rather than a graphical user interface. They were observed to have difficulty remembering

commands and understanding what data or keystrokes needed to be entered for different screens. In addition, they found it time-consuming to enter patient information, a difficulty that was compounded because there were few terminals and they were placed inconveniently. Some said they came in early or stayed late simply to get terminal access.

Parallel to the question of whom CEMS benefited, there was an issue of how decisions were made in terms of system design, terminal placement, and system benefits. All these issues suggest that there were tensions between administrative, clinical, and system staff that pertained to control. Attitudes towards CEMS and how it was used were affected by where individuals' considered control to be vested. Residents, for example, felt there was little choice about using CEMS. These control issues were related to contextual issues as well.

6.4. *Context*

The psychiatric hospital recently had been an independent institution. They had a proud history and excellent reputation. They also had pioneered the use of computers in psychiatric practice as early as the 1960s. Everyone involved in the study spoke of changes and difficulties now that they had become part of a university teaching hospital and also were experiencing staffing cutbacks. They were feeling pressured by the demands of managed care and concomitant documentation requirements. CEMS was part of all these changes, in so far as clinicians were concerned, and just one more way that life had become more difficult for them. Everyone recognized that CEMS was part of the new managed care environment, and, as such, for clinicians, it also was a symbol of increasing administrative control and loss of their independent clinical tradition.

6.5. Discussion

This example illustrates how the 4Cs framework may be used to analyze evaluation findings. Moreover, it points to the importance of designing evaluation studies that take into account such important social, contextual, and organizational issues as communication, care, control, and context, while also leaving open the possibility of surfacing unanticipated issues. That this CDSS was one of the few in actual clinical use is a noteworthy achievement. The study was concerned with how this was achieved and what effects this had. Rather than employing an experimental or RCT approach and solely quantitative methods, the study used ethnographic interviews and observations to investigate what this CDSS meant to the individuals involved. Had the evaluation been limited to a more usual design, some of the important issues of data quality, system usefulness, control issues, and potential impact of all these on patient care may not have been examined. Study design was based on a social interactionist theory and both data collection and data analysis were interpretative. The results provide insight into reasons for the kinds of reactions individuals have to CDSSs.

7. Conclusion

The long history of difficulties in achieving clinical use of some kinds of clinical informatics applications, such as CDSSs and clinical guidelines, suggests a need for deeper understanding of reasons for this recurring pattern. When staff revolt or boycott new hospital information systems where they are required to do order entry [49,61,98]; when users sabotage systems [99]; when despite years of effort it has been notoriously difficult to get physicians to use clinical

guidelines; when CDSSs are not used despite repeated demonstrations of their accuracy, clearly more is needed than additional exhortations or carefully designed demonstrations. Basing evaluations primarily on an experimental or clinical trials approach answers different research questions from ones concerning the interplay of contextual, organizational, and personal influences that affect whether or not any information system actually is used. Moreover, when RCT-type evaluations indicate equivocal outcomes, more information is needed so as to understand the reasons for such results. Without this information, it is difficult to improve design and implementation approaches, or to make informed decisions about whether to continue developing potentially useful technologies.

That this point has been made before indicates a problem that still needs addressing. Unless evaluation approaches include social, organizational, cultural, cognitive, and contextual issues, they cannot answer key questions about why clinicians use or do not use an informatics application. It is time to heed the repeated calls from respected members of the medical informatics community to develop alternative, theoretically grounded, empirically based approaches to studying these complex issues while systems are used as part of routine clinical practice. Otherwise, the understanding of why informatics applications may or may not be effective will continue to be lacking, resulting in inability to make informed decisions about these technologies and other strategies for improving patient care.

This paper suggests a social interactionist approach that draws on social science theory, incorporates multiple methods (including both qualitative and quantitative methods), and addresses a variety of evaluation issues. Even though focussed here on CDSS, the approach is generally applicable both for in-

formatics and for clinical practice guidelines implementation. Most importantly, although one approach is advocated here, methodological pluralism is needed to develop a rich and deep understanding of medical system implementation and use. A pluralistic orientation that considers a multiplicity of research questions through a variety of methods would contribute to making studies not only rigorous, but also relevant to clinical practice, and help systems have a better chance of actually improving patient care.

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