A multi-dimensional model of clinical utility

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Abstract

Clinical utility is an increasingly used concept in health care, but one that lacks an agreed formal definition or conceptualization. In this article, I show that the term is commonly used as a synonym for studies of clinical effectiveness and/or economic evaluations and argue that further factors relating to everyday working practice should be included under its auspices. I go on to develop a multi-dimensional model that outlines four factors in practitioners’ judgements about clinical utility: appropriateness, accessibility, practicability, and acceptability.

Keywords: clinical adoption, clinical utility, innovation, work practice

What is clinical utility?

Utility literally means usefulness; so clinical utility could mean the usefulness of an intervention for, or in, clinical practice. Utility is also associated with utilitarianism—that is, the ethical doctrine of achieving the greatest good for the greatest number. In this sense, a clinical outcome, judgement, or practice might be justified according to a balance of benefits and drawbacks. Pertinent questions for judgements about clinical utility would thus be (i) what are the components of usefulness, benefits, and drawbacks; (ii) how might we define and measure these factors; (iii) how should they be weighed against one another; and (iv) usefulness and relative benefit for whom? To begin the task of answering some of these difficult questions, I will explore what is, and what should be, included under the auspices of the term clinical utility. I will explain how the concept is commonly used and present two studies that have extended the concept beyond this common usage.

Clinical utility in common usage

Clinical utility is a much-used and increasingly popular term in health care literature. A key word search of clinical utility on the ISI Web of Science bibliographic database returned 1023 hits on ‘paper titles’ alone since 1995 (‘science citation index’ and ‘social science citation index’, ‘all languages’, ‘all documents’, undertaken on 17 May 2005). It first appeared in academic papers in 1961, and its use has increased ever since (see Figure 1, generated using the above search parameters). Although the appearance of a term in the titles of academic papers is a crude measure, these data demonstrate how its use has flourished.

Despite its widespread use, I was unable to trace a formal definition. This does not mean, however, that there is a lack of consensus on how the term is being used. On the contrary, there appears to be a widespread view about how to judge clinical utility that indicates what the term is being employed to mean. Papers that profess to judge ‘the clinical utility of x, y or z’ commonly present data on the effectiveness of an intervention, sometimes accompanied by a health economic evaluation. Thus, the term appears to be used as a synonym for describing evaluations of clinical effectiveness and/or economic evaluations. The extent of this commonplace usage can be demonstrated by briefly considering the remit of studies of clinical effectiveness and economic evaluations.

Ashcroft [1] writes that judgements about the clinical effectiveness of medical interventions are a routine aspect of biomedical science and a particular goal for the science of clinical trials. In clinical trials, an intervention is usually judged as effective in relation to its primary purpose [2]. Results are commonly judged in terms of ‘outcome measures’; as Ashcroft [1] explains, these may include ‘objective endpoints’, ‘which demonstrate or measure capacities of the therapeutic agent’ (such as a biomedical test or life years saved), and ‘preference endpoints’, which report patient preferences [such as ‘quality-adjusted life-years’ (QALYs)] (p. 231). Such measures may be specific to an intervention (e.g. how far a measure of cholesterol is lowered by a drug treatment) or generic (e.g. gains in ‘life-years’ or QALYs).

Health economic evaluations do not appear to directly measure anything called clinical utility (the term does not
feature in the subject index of a selection of recent textbooks. Nevertheless, economic evaluations are central to judgements about clinical utility because they provide information to help answer difficult questions about the allocation of scarce resources or about choices between competing options. To do this, health economists measure ‘costs’ in relation to outcomes. As Gray [2] explains, costs are the resources that are involved in an intervention (e.g. products, staff, space, and sometimes the future resource implications of decisions or the cost consequences for patients, family, and society). A ‘cost–benefit’ analysis asks whether costs are greater than benefits to ascertain if an objective is worthwhile and compares alternative options to establish the most efficient way of attaining that outcome. Economists do measure something called utility in a ‘cost–utility’ analysis, but this is actually just a variant of cost-effectiveness that relies on measures of the preferences (or utilities) of patients (e.g. QALYs) [3].

As these brief outlines demonstrate, the label clinical utility is used to describe work that judges aspects of clinical effectiveness which can be measured using ‘objective’ or ‘preference’ outcome measures. It is also used in relation to economic evaluations of costs, benefits, effectiveness, and preferences. In this routine usage, the concept of clinical utility can be seen to include elements of whether the clinical outcomes of an intervention are effective and whether its implementation offers an economically efficient solution to a health care problem. Clearly, both such assessments provide information that is central to making health care decisions. As I will now show, however, there is an additional element that should be accounted for in judgements of clinical utility.

Work practice

Findings from research on ‘clinical adoption’ (i.e. factors that affect the adoption of innovation into routine practice) support the idea that work practice should be considered as a key component in judgements about clinical utility. Studies have demonstrated that practitioners purposefully incorporate or resist changes to their everyday routines. The needs and motivations of practitioners are central in decisions to adopt new techniques or technologies [4,5], and such decisions are influenced by the contexts within which people work [6–9]. This relationship between individuals and their immediate working contexts has now become a focus for research [10–14]. These enquiries are beginning to map how everyday decisions about the usefulness, benefits, and drawbacks (i.e. the clinical utility) of a potential change to practice are influenced by practitioners’ current work routine and their working context.

I was able to identify only two articles that overtly explored the concept of clinical utility, and work practice was a crucial feature in each. In the field of occupational therapy in Canada, Polgar et al. set out to evaluate the clinical utility of an ‘assessment scale’ [15]. They define clinical utility as ‘[...] the ease and efficiency of use of an assessment, and the relevance and meaningfulness, clinically, of the information that it provides’ (unnumbered, emphasis added). As such, their evaluation involved considering questions about the impact of an intervention on routine work and clinical practice. Their study shows the types of concerns that some practitioners have when they consider the utility of an intervention (see Table 1).

Issues about effectiveness (e.g. the value of information gained) and economics (e.g. costs of products, staff, space and so on) are accompanied by ‘work practice’ considerations about the quality, clarity and availability of materials, training and professional boundaries, the needs of clients, relevance of information and so on.

In the field of psychiatry in the United States, First et al. [16] discuss the clinical utility of the reference manual used by practitioners (the ‘Diagnostic and Statistical Manual of Mental Disorders’ or DSM). In 2003, Kendell and Jablensky [17] had stated that the utility of a diagnostic concept is the ‘information it provides about outcome, treatment response and etiology’ (p. 4). First et al. [16] argued that this definition ‘[...] ignores some of the DSM’s more important clinical uses (e.g., communication of clinical information)’ (p. 947). They propose a broader definition: ‘[c]linical utility is the extent to which DSM assists clinical decision-makers in fulfilling the various clinical functions of a psychiatric classification system’ (p. 947). Routine work is again central to this definition, with the focus on the performance of clinical roles and duties such as diagnosis, communication, and providing care. In contrast to the Canadian occupational therapy example (which included more mundane work-practice issues), First et al. [16] considered that ‘practical but non-clinical concerns’ are ‘excluded from the concept of clinical utility’ (p. 947).

In these explicit considerations of clinical utility, concerns about effectiveness and economics are joined by matters of work practice. In its broadest sense, work practice includes everyday matters that may affect feasibility; in a more narrow perspective, the focus is on professional duties. Health economists, in their calculation of costs, can address some matters relating to feasibility (e.g. space, time, and resources). However,
matters relating to work practice could be regarded much more broadly (e.g. fulfillment of roles, the practicability or accessibility of particular resources or the acceptability of an intervention to practitioners, or even their clients/patients).

**Judging clinical utility**

To address the question ‘how should we judge clinical utility?’, I now outline a multi-dimensional model of clinical utility (a heuristic device that may be useful for researchers and decision makers). I will then reflect on some key challenges for using such a model in health care decision-making.

**Conceptualizing clinical utility**

Clinical utility can be conceptualized as a multi-dimensional judgement about the usefulness, benefits, and drawbacks of an intervention. For a practitioner, a judgement about the clinical utility of a new technology or technique might involve asking: Is the innovation appropriate, accessible, practicable, and acceptable? A model of clinical utility that includes these four components is summarized in Table 2 and will now be discussed.

In the model, questions about an intervention being ‘appropriate’ encompass crucial information its effectiveness. In relation to an innovation, for example, this would be based on health outcomes data from clinical trials. In addition to this, however, a practitioner is also likely to make assessments about the appropriateness of an innovation based on its ‘relevance’. These judgements about relevance can introduce elements of work practice into their assessments of potential clinical utility. For example, practitioners may question how an innovation ‘fits’ into the existing treatment process, if it is likely to cause disruption to the current organization of work or patient-care pathways and how meaningful the intervention could be in the broader context of clinical decision-making.

Economic considerations are included under the ‘accessible’ component in the model. Formal evidence of an intervention’s resource implications is likely to be important in a practitioner’s judgement about its clinical utility. An additional element that should be accounted for, however, is the practical issue of ‘procurement’. This may relate to questions such as the availability of new technologies in the market place or managing relationships with suppliers (including, e.g. potential problems about the quality of materials or training and technical support). Other procurement issues may arise in relation to working practices and organizational contexts, specifically financial and accounting processes. These can include the everyday duties involved in managing budgets, the processes of commissioning new goods or services, or dealing with the issues surrounding an organization’s internal accounting procedures (e.g. establishing whose budget pays for what or ensuring that training or technical support is appropriate and available).

The component of ‘practicability’ is focused on working practice, particularly the relationship between an innovation and the practitioners’ specific needs and capabilities. With respect to needs, it is necessary to address questions about the functionality of an innovation and also its suitability in a particular working context. If the innovation was a new technological artefact, for example, questions of functionality would

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**Table 1** Polgar, Reg, and Barlow’s elements of clinical utility

<table>
<thead>
<tr>
<th>Core element</th>
<th>Criteria to consider</th>
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<tbody>
<tr>
<td>Ease of use</td>
<td>Availability and price, complete and clear instructions for use (both for the clinician and for the client), materials and methods required for use specified or provided, spatial or location requirements clear and accessible</td>
</tr>
<tr>
<td>Time</td>
<td>Time required and any effects of timing on reliability and validity</td>
</tr>
<tr>
<td>Training and qualifications</td>
<td>Professional, knowledge, or ability boundaries on use, training or learning requirements, availability of training (or manuals)</td>
</tr>
<tr>
<td>Format</td>
<td>Acceptability to the client, role of client and their capabilities considered, acceptability to the clinician</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Ease of interpretation of outcome, availability or necessity of IT support, requirement for interpretation by others, training or qualifications required for interpretation</td>
</tr>
<tr>
<td>Meaning and relevance of information obtained</td>
<td>Information gained from interpretation, use of that information in the clinic, ability to respond to clinical change, factors that may compromise the use of the information</td>
</tr>
</tbody>
</table>
be ‘is it complete and in working order?’, whereas questions of suitability would be ‘does it do what we need it to do in actual everyday situations?’ Aside from the functionality and suitability of the innovation, it is also necessary to address questions about the practitioners’ skills and capabilities. This would include issues surrounding training and professional qualifications, such as the adequacy of current levels and potential future needs. The provision of skills and training could itself be influenced by practical or organizational matters. For example, managers may encounter problems in releasing staff for training due to workloads, there may be tensions between professional groupings over the boundaries of their expertise, or disputes may arise between employers and employees about acceptable work practice.

The final component in the multi-dimensional model questions whether an intervention is ‘acceptable’ to practitioners (and others). Although the ethical or societal implications of many interventions are negligible, in some instances, it may be necessary to consider whether practitioners have moral objections to an innovation. In terms of clinical utility, a practitioners’ willingness to use an innovation may be affected by their moral concerns (or if they perceive that their patients/clients or others in society have concerns). With potentially contentious developments, it may be prudent to consult with the wider public, relevant civil and political groups, and the patients/clients (and their families and/or carers) that are most affected. Practitioners’ judgements about utility could also be influenced by the more mundane factors that can affect their ability to achieve concordance. In this respect, exploring the views of patients and carers about service delivery could identify potential rifts between the practices or expectations of recipients and providers.

It is important to reiterate that practitioners’ judgements about innovations are made in relation to existing rules, norms, and practices (both formal and tacit) and that these relate to the contexts in which they work [6–14]. For the purpose of understanding clinical utility, it may be beneficial to consider [...] the role of norms and practices at three levels.

Challenges: acceptance, evidence, and synthesis

In the remainder of this discussion, I consider several challenges facing multi-dimensional clinical utility. There is no argument that the established and rigorously validated measures of health outcomes (e.g. clinical effectiveness and economic evaluations) are centrally important to decisions about clinical utility. A concept of clinical utility that is wholly

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**Table 2** Summary of the dimensions of clinical utility

<table>
<thead>
<tr>
<th>Component</th>
<th>Aspects</th>
<th>Issues that might be considered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate</td>
<td>Effective Relevant</td>
<td>Existence of formal evidence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Impact on existing treatment process</td>
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<tr>
<td></td>
<td></td>
<td>Disruptions to current work or care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Importance for clinical decision-making</td>
</tr>
<tr>
<td>Accessible</td>
<td>Resource implications</td>
<td>Costs and cost-effectiveness</td>
</tr>
<tr>
<td></td>
<td>Procurement</td>
<td>Availability, supply, and quality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Navigating finance processes (e.g. budgets, commissioning, and internal accounting)</td>
</tr>
<tr>
<td>Practicable</td>
<td>Functional Suitable</td>
<td>Are the materials, methods, or instructions complete and working?</td>
</tr>
<tr>
<td></td>
<td>Training or knowledge</td>
<td>Do the materials, methods, or instructions perform their tasks <em>in situ?</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adequacy of current levels and potential future needs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Need to re-negotiate professional or work-practice boundaries</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Everyday constraints on training</td>
</tr>
<tr>
<td>Acceptable</td>
<td>To clinician</td>
<td>Ethical, legal, social, or psychological concerns that may affect practice</td>
</tr>
<tr>
<td></td>
<td>To clients (including</td>
<td>Ethical, legal, social, or psychological concerns that may affect treatment process</td>
</tr>
<tr>
<td></td>
<td>families and/or carers)</td>
<td>Preferences about service delivery</td>
</tr>
<tr>
<td></td>
<td>To society (public or</td>
<td>Ethical, legal, social, or psychological concerns that may affect acceptance</td>
</tr>
<tr>
<td></td>
<td>stakeholder groups)</td>
<td></td>
</tr>
</tbody>
</table>

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...
reduced to such measures, however, will fail to evaluate all the judgements that practitioners make in deciding whether they actually want to utilize an innovation or alter their practice. In a multi-dimensional model of clinical utility, it is possible to account for the influences of everyday working practice, including the opinions of the people who might be affected by the change. The first challenge, however, will be to convince the biomedical science and policy communities of the value of a multi-dimensional model and the importance of its additional components.

A second, related challenge concerns evidence. Clinical trials and health economics research already provide data for key aspects of clinical utility, and social science could help to generate additional evidence. (First et al. [16] outline some possibilities with respect to their concern with performance of clinical roles.) The key challenge will be gathering valid and generalizable evidence about the aspects and components of the multi-dimensional model that currently receive least attention. It will be necessary to find ways to generate valid data about the role and influence of tacit clinical and working knowledge on practitioners’ judgements (such as how disruptions to everyday routine or resistance from patients affect practitioners’ thinking about the benefits or drawbacks of an innovation). Also, as some of the factors that influence practitioners’ judgements are context bound, assessments of clinical utility would need to account for the localized or particular knowledge and experience of different practitioners (or groups of practitioners). It could, however, be asked: What would be the value of these context-specific evaluations for practitioners and decision makers who are elsewhere?

To generate valid measurements of how tacit clinical knowledge or mundane working practice influences practitioners’ judgements about clinical utility, it would be necessary to look beyond overt ‘rational choices’. Although health economists can and do generate evidence of practitioners’ preferences for treatment options, it may prove difficult to quantify the role and influence of tacit and mundane factors. Qualitative social science methodologies could play an important role in addressing such research questions, using methods such as interviewing, documentary analysis, and observation [18–21]. With respect to clinical utility, qualitative research could be designed to explore questions such as why practitioners think and act as they do and how they create and sustain their everyday clinical and working practices. Furthermore, the viewpoints of practitioners (about the nature and adequacy of existing practice and the potential benefits and drawbacks of an innovation) could be investigated to reveal the grounds on which practitioners themselves are judging clinical utility.

It should be noted, however, that although qualitative approaches may be at least a partial solution to the problem of researching the everyday factors, they could actually compound the problem of generalizability. Qualitative studies rarely aim to use inferential statistics to generalize study findings to other populations [22] but rely on what Williams [23,24] terms ‘moderatum generalizations’ (in the sense that they should be carefully limited to reflect the logic of the research design and the context of the study). Although a qualitative approach might be a useful and necessary element of a multi-dimensional study of clinical utility, such ‘moderatum generalizations’ might not suffice for practitioners and health care policy makers who need to justify their decision about clinical practice or resource allocation. As such, there are at least three ways for integrating the beneficial qualitative aspects into a research process that has greater generalizability.

The first is to adopt an ‘evidence-based’ approach, that is, to assess the reliability and validity of individual qualitative studies of clinical utility by comparing them with existing knowledge base. There is, for example, a wealth of research about innovation and change in health care that has been systematically reviewed by Greenhalgh et al. [25]. Secondly, where a more specific comparison is necessary, the qualitative aspects of a multi-dimensional study of clinical utility could be designed as comparative multicentre, even multinational, research. A third option is to develop mixed method research design or even multi- or inter-disciplinary studies. Qualitative work can be preliminary, where a small number of interviews or an observational study is used as an ‘exploratory’ tool to discover key factors or influences that are then explored using quantitative work. Alternatively, qualitative approaches can be used after quantitative studies, to explore why respondents answered in the manner that they did.

The next challenge I consider is the synthesis between the different components in the model. The multi-dimensional model of clinical utility represents the four components as ‘discrete’ entities, although it should be recalled that the model is a heuristic device, and care should be taken to avoid simplistic reification. It could be useful, however, to consider how the components (and the aspects within the components) might interact and overlap with one another. It is reasonable to assume that in everyday life, practitioners are unlikely to think in a disconnected fashion and might instead weigh different dimensions and aspects of utility against one another (e.g. the value added by gaining information from a diagnostic test against the logistics of undertaking the testing process). Practitioners’ judgements about clinical utility may actually be a great deal more ‘fuzzy’ than is implied by the multi-dimensional model.

To comment on these matters with more certainty, however, requires further evidence. The actual interaction of multiple influences on practitioners’ decisions about clinical utility is a matter for empirical enquiry. Such research can build on recent studies of clinical adoption, which have shown how evidence alone may not be sufficient to change practice and that practitioners’ decisions can be framed by personal experience and the opinions or experiences of close colleagues [10–14]. Future research questions could include (i) do some aspects or components of clinical utility have priority over others and why; (ii) how do practitioners synthesize different types of knowledge (e.g. formal evidence, tacit understandings, routine practice, moral or political views, personal experience, and so on) in their decisions; (iii) what are the sources of conflict, and how is consensus reached; and (iv) how do existing norms and practices influence decision-making?
A final challenge to note with respect to synthesis is the cross-disciplinary nature of studying practitioners’ decision of clinical utility. The various aspects of a multi-dimensional study could be separated out and distributed to academics with the required specialist expertise. There could, however, be difficulties in this approach, particularly when it comes to collating the disparate data and negotiating or making judgements on any disputed findings in the final report. An alternative option would be to bring together the academic specialists into a multi-disciplinary team, or inter-disciplinary research project, that could produce its own integrated findings. Although this approach may enjoy some benefits in terms of coherence, there may be management and organizational challenges with respect to developing and maintaining a working team.

Conclusion

Practitioners make multi-dimensional decisions about the usefulness, benefits, and drawbacks of potential changes to their practice. In formal academic publications, analyses of these decisions appear to have been largely reduced to questions of effectiveness and/or cost-effectiveness. This narrow conceptualization of clinical utility ignores many subtle but important influences on practitioners’ decisions, including their working environment, their everyday routines, their accumulated clinical knowledge, their views and opinions, and so on. To address this shortfall, I presented a model of practitioners’ decisions about clinical utility with four components (appropriate, accessible, practicable, and acceptable) and emphasized that utility judgements should be viewed in the light of existing rules, norms, and practices. This multi-dimensional model of clinical utility offers health care decision makers an opportunity to evaluate proposed changes to practice in a thorough and accurate manner.

References


Accepted for publication 21 July 2006