Key Issues in Selected Articles on Evidence Based Medicine

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Abstract

EBM (evidence based medicine) is an application of knowledge management, appraising clinical studies critically and considering their applicability in clinical work. To discover current EBM issues, this paper presents an analysis of recent published articles. Issues identified include: Benefits of using EBM; Need for and possible lack of accuracy in available evidence; Difficulty of relating RCT (randomised clinical trial) evidence to clinical practice and to the individual patient; Potential for conflict with the experience of the practitioner; Lack of time and lack of understanding for full use of EBM; Need for improved training in the use of EBM; Need to constantly update and expand the available evidence.

Keywords
evidence based medicine, EBM, issues, knowledge management, KM

Introduction

EBM (evidence based medicine) is a methodology for appraising clinical studies critically and considering their applicability in clinical work. It is the careful and explicit application of current best evidence in making decisions about the care of individual patients. (Pitkala, Mantyranta, Strandberg, Makela, & al, 2000) It is a knowledge management system that uses library documents and meta-analyses to manage an increasing volume of clinical knowledge.

There are four distinct steps to EBM: (1) formulate clear clinical questions from a patient’s problem; (2) search the literature for relevant articles; (3) evaluate the evidence for its validity and usefulness; (4) apply useful findings in clinical practice. (Leung & Whitty, 2000) The second and third steps are supported by a large body of literature in which all available randomised clinical trials (RCTs) are evaluated and the overall results summarised. Thus an EBM report will provide best evidence that is based on all of the available trials.

The second and third steps may also be seen as a potential application for knowledge management: The information gained from evaluation of all available RCTs is made available in order to support the clinical knowledge and experience of clinicians.

Effective EBM depends on clinician access to facilities such as the Cochrane electronic database of systematic reviews of RCTs and the online Medline library. At the same time, patients and other interested parties may also access the CochraneConsumer database, with
its plain English summaries of the results found in the Cochrane library. These databases and libraries are repositories of knowledge on patient diagnosis and interventions.

EBM is an important topic for medical researchers, clinicians and consumers. As an application of knowledge management it is also of interest to information systems researchers and practitioners. This paper provides an introduction to current issues in EBM, with the issues presented within a framework that is drawn from knowledge management.

**Methodology**

The analysis is based on 45 articles from the ProQuest (ABI/Inform) online library. The search was for all articles containing the exact phrase "evidence based medicine" in the article title, citation or abstract. Related topics such as evidence based health, management and practice were not selected. The search was limited to peer reviewed journals although each article was not necessarily peer reviewed. In order to identify "current" issues, only journals from 1999 to February 2003 were searched.

A similar search of Expanded Academic ASAP returned 515 articles. Emerald Library showed two articles. Medline had several thousand articles on "evidence based medicine". (A second search of Medline – to confirm the exact number of hits – failed due to the university library server failing during the search. The risk of loss of contact with online libraries is an issue which is, surprisingly, not mentioned in the 45 articles being analysed. Access to an EBM library is dependent on ICT – information communications and technology – yet continued access to ICT is apparently taken for granted.)

The search results were necessarily biased by the type of journal included in ProQuest. For example, the "case study experience" versus "RCT evidence" debate appears to be stronger in specialist medical journals than in general ProQuest journals. The overall ProQuest emphasis is on business and management related journals rather than specialist medical. This suits my own requirements, for an information systems rather than medical view of EBM.

Having identified 45 articles referring to EBM, the articles were coded according to a published taxonomy for knowledge management articles (Lethbridge, 2002). This provides a simple grouping based on grounded theory research methodology. The categories are listed in Table 1 and their relationships shown in Figure 1.

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<thead>
<tr>
<th>Groups</th>
<th>Categories</th>
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<tbody>
<tr>
<td>Cause</td>
<td>Knowledge, Technology, Individuals, Organisation, Strategy</td>
</tr>
<tr>
<td>Context</td>
<td>Managers, Culture, System, Scope</td>
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<tr>
<td>Situation</td>
<td>Environment, Organisation, Strategy</td>
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<tr>
<td>Action</td>
<td>Environment, Organisation, Process, System</td>
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<tr>
<td>Consequence</td>
<td>Individual, Operational, Strategic, Knowledge Management</td>
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*Table 1 Categories for EBM Articles*
Figure 1 Relationship of EBM Article Categories

Discussion

The 45 articles provided 73 codes, where each article could match one or more categories. The codes are summarised in Figure 2. From the figure it is clear that there are concentrations of articles in "Cause-Knowledge" and "Action-Process". There are also quite a few articles that discuss the "Consequences" of EBM, across the various categories.

Figure 2 Summary of Categories
The "Cause-Knowledge" category concerns knowledge itself – its existence, its value, the need for knowledge to be effectively managed or protected. Several articles discuss the quality, accuracy and relevance of the information provided by the EBM analyses. Others challenge the value – or otherwise – of EBM. There is a healthy debate between supporters of EBM and those who favour case-based medicine, with its strong dependence on knowledge and experience of the individual clinician. For some, EBM supports the financial management of large numbers of patients, while case-based medicine is more suited to the needs of the individual patient.

The concentration of "Action-Process" articles is explained in part by a regular series of articles (eight of the 45) that provide practical examples of the application of EBM. (See Phillips, 2001 and others by the same author.) Without these there would still be twelve EBM case studies, a reasonably large number. A dedicated medical library such as Medline, or the Cochrane Library itself, would provide an even larger proportion of articles documenting the actual processes of EBM.

The articles matching categories of "Consequence" of EBM discuss a broad range of issues. At the "Individual" level there are questions of current level of knowledge of EBM amongst clinicians and means of raising that level of knowledge, others consider the impact of EBM on individual clinicians and patients. Several articles take a strategic view of EBM, including further application of existing analyses and extension of EBM into further fields of medicine.

The articles were also categorised in a simpler fashion, into book reviews, discussion of EBM issues, EBM case studies and humour. In this analysis, each article was only allowed to fall into one category. The results are shown in Figure 3.

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tr>
<td>Book reviews</td>
<td>9</td>
</tr>
<tr>
<td>Discussion of EBM</td>
<td>19</td>
</tr>
<tr>
<td>EBM case studies</td>
<td>14</td>
</tr>
<tr>
<td>Humour</td>
<td>3</td>
</tr>
</tbody>
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*Figure 3 Analysis by Type*

The most common category for this analysis is the discussion of issues related to EBM. Case studies are the next most common. Again, a dedicated medical library could contain a larger proportion of actual EBM case studies and analyses. The particular focus of the ProQuest library could preclude a number of the more technical journals and articles.

The high proportion of book reviews (20% of all articles) is rather surprising. One possible explanation is, that EBM is a well-established but still developing field. New EBM books are being published and are of interest to readers of the journals. One book, for example, guides the reader in the interpretation of an EBM report. Another only mentions EBM as having been written about twenty years earlier, before the term "evidence based medicine" was coined.

Finally, there are three articles classified as "Humour". These articles are, presumably, not peer reviewed. One is published anonymously. Nevertheless, each one makes a valid statement regarding EBM. Each of the three "Humour" articles could just as accurately be classified as being a discussion of EBM issues.
Detailed Analysis

This section takes a category-by-category, brief look at the issues discussed in the articles. A secondary intention of the section is to show, by example, the meaning of the categories within the knowledge management / EBM taxonomy.

Cause: Knowledge

Cause-Knowledge: Knowledge itself – its existence, its value, the need for knowledge to be effectively managed or protected – has driven the development of a knowledge management system.

There is recognition that the large body of existing medical knowledge would be more effective if it were organised and made available to clinicians. (This is the key justification for EBM.) Making knowledge available needs to be through standard analyses and a centralised library of results. "This database is a major resource in Evidence Based Medicine (EBM) – one of the fastest growing areas of medical interest. CDSR [the Cochrane EBM database] is a collaborative effort of researchers, healthcare professionals, consumers, and others who share an interest in generating reliable up-to-date evidence relevant to the prevention, treatment, and rehabilitation of particular health problems such as stroke, drug treatment, medical strategies and residual disabilities." (Anonymous, 2001)

The quality of the stored information is a key issue in the success of EBM. (The Cochrane Library, for example, has strict standards to ensure quality and accuracy.) The more accurate the information, the more effective will be EBM. "There is increased recognition that clinical practice benefits from research evidence of the most effective treatments. However, the strength of evidence based clinical decisions will depend on the quality and relevance of the evidence and on its interpretation." (Barnes, Stein, & Rosenberg, 1999) "... It presents short summaries or original material from medical research papers... Sometimes the original presentation is flawed, and the reader is asked to suggest improvements..." (Ridout, 2001)

Increased rigour of data collection may also be an issue, for older data. "Although the quality of data in this review is good, it is important to be conscious of the limitations of the data available. Many of the data are from the early 1980s, before the rigour of evidence based medicine and peer review that is now in place in medical journals..." (Spence, 2002)

Large scale RCTs (randomised clinical trials) are an essential part of EBM. Many articles raise the issue of the relevance of RCT results to the exact situation of an individual patient. The clinician, the patient and the patient's environment all influence the preferred intervention in any single clinical situation. "... the benefits of many clinical interventions have been demonstrated in controlled clinical trials, small to negligible effects tend to be found when they are tested in 'real world' settings... good clinical treatment is individualised for the child and family, compatible with the clinician's style, intuitive, and attentive to the relationship with the child and family." (Barnes et al., 1999)

Caplan considers the quality of the stored knowledge in terms of its relevance to the individual patient. The issue is less the accuracy of the evidence and more the complexity of reality: RCTs test a limited set of variables, the individual patient is inextricably linked with a vast array of known and unknown variables. "The almost religious zeal for cloaking all decisions under the banner of evidence based conceals the real problem – that is, what is the evidence? Does it apply to the individual patient being treated? What is the context in which the evidence was gathered and it will be applied?" (Caplan, 2001) It is quite possible that the clinician's and patient's views of an intervention may differ from that of the published
evidence: "This paper tries to bridge gaps between a patient's and doctor's narratives and the evidence." (Reis, Hermoni, Livingstone, & Borkan, 2002) A possible reason for this is the complexity, the number of variables, when any one patient is being considered. "Unfortunately, medicine delivered by recipe is rarely free of trouble, and clinical judgment is required. What are the grey areas?" (Savage & Channer, 2002)

On the one hand, EBM is being challenged for its accuracy and its relevance: "Almost inevitably there has been a backlash with challenges made to the reliability and applicability for the individual of evidence based on randomised controlled trials and overviews." (Eden, 2000) On the other hand, both duty of care and the threat of litigation demand use of the most justifiable methods: "... evidence based medicine is undoubtedly here to stay. We do owe it to our patients to optimise favourable outcomes and minimise toxicity. It might also just help to keep us out of the courts!" (Eden, 2000) In terms of duty of care, Phillips states the case for acting only after examination of all available knowledge: "It is commonly believed that a trial is justified if the clinician honestly does not know whether a study's treatment is likely to be beneficial for the patient in front of them (equipoise). This position can only really be achieved after a thorough systematic review of any existing literature on the subject." (Phillips, 2002) If strong evidence is not available then new trials are required.

A basic issue of EBM is that an RCT may apply to one situation but not to another. Something as simple as a non-standard definition may cause difficulties. "I think part of the difficulty I had with this book is that the US definition of dysfunctional bleeding differs from that used in the UK... if readers are not aware of the different definitions they may find the discussion confusing." (Lumsden, 2000)

Deliberately false information provides a further issue. The more a clinician depends on RCTs rather than personal knowledge and experience, the more important it is that the recorded results are accurate and honest. "... one of the reasons a piece of research which is not original might be undertaken is that one simply does not believe the results in published papers, despite their apparently impeccable methodology; there are enough examples of fraudulent work in the literature for one not to be overly coy about mentioning this as a possibility." (Moseley, 2001) "Evidence based medicine is the holy grail of medical practice – well, that is what some of us think. Remember, however, the dangers of meta-analysis, and even 'quality sources' must be treated with some suspicion. Dark forces such as publication bias, pharmaceutical vested interest, incomplete search databases, and publication fraud are at work. Remember the first rule of medicine: 'Do no harm.'" (Spence, 2002)

There are still challenges in the accumulation of accurate knowledge for EBM. Nevertheless, the direction appears to have been set. "The principal justification for EBM is the quest for relevant and reliable evidence to demonstrate effectiveness, or relative effectiveness, so that practitioners offer only effective, or most effective therapies... The combined effects of institutionalised provision, budget limitations, an ever expanding armoury of potentially effective clinical interventions, a possibly expanding expressed demand for health care and a rapidly expanding supply of information, provides more than sufficient justification for systematic appraisal of the accumulating evidence." (West, 2000)

**Action: Process**

**Action-Process:** Actual operation of – use of – the knowledge management system.

The actual process of EBM is a major topic for journal articles, with 20 out of 45 presenting or discussing the EBM process. Eight of the 20 were from a series of practical articles by the
one author. Of the remainder, the key issues were, EBM examples, pointers to sources of clinical evidence, and discussions of EBM methods.

A typical EBM paper presents analysis of disease and treatment based on RCTs. The following examples have not been simplified for this paper: Understanding an EBM "process" paper does require an understanding of the medical terms being used. These quotes demonstrate the specialist nature of the required vocabulary.

"The tumour control of acoustic neuroma after radiosurgery is 91% at five years with a 17% risk of VIIth and a 45% risk of VIIIth neuropathy at five years. Radiosurgery has been advocated for patients with other benign tumours. Early results suggest a recurrence rate of small benign meningiomas of > 10% at five years with a 6% risk of neurological toxicity… On present evidence single fraction radiosurgery for brain tumours is associated with higher toxicity than is seen with fractionated irradiation, so far without the reassurance of long term efficacy." (Brada & Cruikshank, 1999)

The EBM analyses are very specific in their area of application. As discussed earlier, this tends to restrict their relevance to the "real" patient with a complex range of interacting symptoms and environment. For example: "… evidence based treatment, antithrombotic treatment in atrial fibrillation…" (Howitt & Armstrong, 1999) "We searched Medline between December 1999 and May 2000 with the keywords atrial fibrillation (paroxysmal), tetralogy of [Fallot], atrial arrhythmia, anticoagulation, primary care, family medicine, general practice, and ambulatory medicine…" (Reis et al., 2002) "… determine, using a literature search, whether patient age influences the outcome of surgical reconstruction of a torn anterior cruciate ligament…" (Sloane, Brazier, Murphy, & Collins, 2002) "Application of evidence based medicine with continuous auditing of practice could lead to a decrease in caesarean section rate…" (Wasef, 2000)

The second theme of "Process" papers is the guide to sources of evidence. The article by Brown indicates the importance attached to current knowledge: "… a helpful and functional evidence based medicine page … A nice touch is a subdirectory of sites that have been appraised in the last month." (Brown, 2001)

The third theme used EBM methods in related areas, explained methods, or discussed training in the methods. For example: "… In the early stages of the project, we constructed questions in the format used in evidence based medicine (population, intervention, comparison, and outcome)…” (Greenhalgh, Toon, Russell, Wong, & et-al, 2003) "The success of evidence based medicine has led to pressure to make medical education more evidence based. Greenhalgh and colleagues tested the transferability of these principles when developing a postgraduate course." (Greenhalgh et al., 2003)

**Consequence**

The final major grouping of papers was in the "Consequence" group. This covered the consequences of EBM in four categories: individual, operational, strategic and knowledge management. Each of these is discussed below.

- **Individual:** The effect of the knowledge management system on individuals.

A major issue for the individual is the preference of EBM over individual clinician expertise: "Thou shalt treat all patients according to the EBM cookbook, without concern for local circumstances, patients' preferences, or clinical judgment… Thou shalt reward with a bounty any medical student who denounces specialists who use expressions such as 'in my experience'…” (Anonymous, 2002) This article (and the more seriously presented versions of
The same view) are balanced by the need for individual clinicians to be able to use EBM: "General practitioners and paediatricians, who may not have substantial training in child mental health, will look in part to published work when planning treatment or referral. There is increased recognition that clinical practice benefits from research evidence of the most effective treatments." (Barnes et al., 1999)

The effect of EBM on individual patients is also considered: "Debate is needed about the merit of open access to expensive treatments for many people to identify the few who gain marginal benefit. An evidence based approach can conflict with perceptions of fair access by patients and carers..." (Doyle, 2001)

Several articles raise the issue of understanding of EBM concepts versus the ability to apply the results in practice. "To practise evidence based medicine, clinicians need to understand and use terms such as 'relative risk reduction,' 'absolute risk reduction,' and 'number needed to treat.'" (Young, Glasziou, & Ward, 2002) "The authors recognise that people who cannot demonstrate knowledge in a potentially intimidating academic environment may be more successful at using knowledge in real life. The ability to explain a term may not be the kind of knowledge required of general practitioners." (Woodcock, Greenley, & Barton, 2002) Bear in mind that the "term" referred to is related to RCTs and statistical analysis rather than to traditional, hands-on medicine.

There are more general concerns with the general implementation of EBM. "Evidence based medicine is fashionable and, at face value, a simple concept that should be self evidently desirable. In practice, it is a rapidly changing and complex field driven by information technology. This handbook attempts to bridge the gap between the sunny uplands of what is desirable and the realities of trying to provide evidence based primary care at the coal face of general practice." (Hannay, 2000)

- **Operational**: The knowledge management system is used as a part of day-to-day operations of the organisation.

Michel and Johnson see the need to integrate EBM into surgical practice: "If surgeons want to develop a health policy agenda that emphasises patient care issues above providers' or payers' interests, they should also enhance education programmes, improve continuing objective assessment of the way surgery is performed, face moral issues raised by innovation, and assume an increased leadership role in sound critical evaluation of non-validated new techniques. They should no longer consider EBM as a weapon turned against the surgical profession, but rather see it as a tool that may provide some answers to chronically unresolved questions in the evolving art of surgery." (Michel & Johnson, 2002)

In a review of a new book, Moseley raises the issue of the time available for full use of EBM: "Compared to the medical academic, a clinician has little time to search the EBM literature for each and every patient... this slim paperback [includes] two chapters which orientate the reader on why and how to keep abreast of the medical literature, including its electronic forms, nine on various aspects of reading papers, and one on implementing evidence based data. All necessary skills for the medical academic, of course, or for someone approaching a little aired but thorny issue. However ... it is difficult to picture the general practitioner, medical registrar, or even less the tyro casualty officer, asking the patient to wait while he or she boots the computer and searches the medical literature, starting with a couple of systematic reviews and delving into an article published in Revista Medica Espanola, for example, only to do the same during the next consultation and, possibly, repeating the process next week, as an important new contribution may have appeared." (Moseley, 2001)
• **Strategic:** Knowledge management becomes a part of strategic planning for the organisation, or, the article discusses the effects on knowledge or information strategies.

An article by Doyle was cited above as dealing with the consequences of EBM on the individual patient. The same article extends this issue to the need for high-level strategies to deal with potential inequities: "This conflict [fair access to EBM by patients and carers] poses a challenge to independent local advisory forums proposed under the NSW plan. Since blanket bans on access to treatments are legally indefensible, the process of decision making must be reasonable and transparent." (Doyle, 2001)

Isaacs and Fitzgerald anticipate an issue for the future, as use of EBM becomes more prevalent. "Clinical decisions should, as far as possible, be evidence based. So runs the current clinical dogma. We are urged to lump all the relevant randomised controlled trials into one giant meta-analysis and come out with a combined odds ratio for all decisions. Physicians, surgeons, nurses are doing it; soon even the lawyers will be using evidence based practice. But what if there is no evidence on which to base a clinical decision?" (Isaacs & Fitzgerald, 1999) As EBM extends its coverage, those areas not yet covered will come under increasing pressure to match the defensibility of EBM.

Tomlin et al see a need for an approach to EBM that is more compatible with those who are expected to use it: "The findings suggest that the central assumptions of the evidence based medicine paradigm may not be shared by many general practitioners, making its application in general practice problematic. The promotion of effective care in general practice requires a broader vision and a more pragmatic approach which takes account of practitioners' concerns and is compatible with the complex nature of their work." (Tomlin, Humphrey, & Rogers, 1999)

West raises the issue of a continuing need to continue and expand the effective coverage of EBM: "The combined effects of institutionalised provision, budget limitations, an ever expanding armoury of potentially effective clinical interventions, a possibly expanding expressed demand for health care and a rapidly expanding supply of information, provides more than sufficient justification for systematic appraisal of the accumulating evidence." (West, 2000)

Research in Australia points to the need for further education in the practice of EBM: "Medical education in Australia has largely not prepared general practitioners for evidence based medicine. Remediation is crucial if they are to understand research findings on which clinical practice ought to be based and avoid pitfalls such as 'framing effect.' Little rigorous research has been conducted to identify effective educational strategies for clinicians." (Young et al., 2002)

• **Knowledge Management:** The article discusses consequences in terms of the overall effects on knowledge management across organisations in general.

Some of the articles discuss the consequences of application of EBM on the way in which the knowledge itself (the evidence) must be gathered. There are issues with the data: "The main advantages of systematic reviews lie with their rationale and scientific rigour, evaluating all the relevant evidence and not simply a convenient sample. The disadvantages arise mainly from their practice, that they are not sufficiently scientific and may not all be sufficiently rigorous, and their consequences." (West, 2000) These issues must be dealt with through more effective gathering and presentation of the data: "The challenge for those working in evidence based medicine is to provide summaries of the evidence in a variety of formats that reflect the range of skills of users of evidence, using innovative methods of presentation."
These should be arranged hierarchically so that those with interest and skills can drill down to find detail. This transparency is the best safeguard to ensure against bias in pre-appraised summaries. More and better training may not be amiss either. (Woodcock et al., 2002)

**Conclusions**

Clearly identified articles on "evidence based medicine" (EBM) were analysed, using a knowledge management set of categories, in order to identify current issues in EBM. The majority of papers were found to be within the categories of: Cause-Knowledge, Action-Process and Consequence. Within these areas, a number of issues were identified. The issues are summarised below.

There is recognition that the large body of existing medical knowledge would be more effective if it were organised and made available to clinicians. This needs to be done through standard analyses and a centralised library of results: through the methods of EBM. Both duty of care and the threat of litigation demand use of the most justifiable clinical methods and interventions.

RCT results may not be directly relevant to the exact situation of an individual patient. The clinician, the patient and the patient's environment all influence the preferred intervention in any single clinical situation. The issue is less the accuracy of the evidence and more the complexity of reality: RCTs test a limited set of variables, the individual patient is inextricably linked with a vast array of known and unknown variables. Use of the best available evidence may seem to be an "obvious" requirement; The fact that individual patient complexity is seen as a limiting issue does indicate that there is the need for more work. The work may be either extending the evidence, or convincing the skeptics.

A related issue is the preference of EBM over individual clinician expertise: This downgrades the importance of individual clinician experience, yet the clinician is the one who deals directly with each patient. Again, the validity of this issue may be questioned. It is, however, a perceived and published issue.

There is also an issue with the time required for full and effective use of EBM: EBM needs to be integrated into surgical and clinical practice, yet the practicing clinician may not have the necessary time.

The quality of the stored information is a key issue in the success of EBM. The more accurate the information, the more effective will be EBM. The more a clinician depends on EBM rather than personal knowledge and experience, the more important it is that the recorded results are accurate and honest.

Deliberately false information is a part of the issue of data accuracy.

The need for effective training in the methods of EBM is raised as an issue. There is a need for an approach to EBM that is more compatible with those who are expected to use it, and a need for further education in the practice of EBM. A related issue is the need to present EBM results in a fashion that may be clearly understood by its users.

As the coverage of EBM is extended, there must be strategies to ensure that its benefits are available to all patients. Both Cochrane Library and CochraneConsumer are available to Australians. Yet the contents are still limited when compared to the total scope of medical practice. With increased dependence on EBM, quality, currency and coverage of data must also be maintained.
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