Chapter 1 The importance of addressing outcomes of evidence-based practice

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Key learning points

- Most of us reside in countries where healthcare resources are finite but healthcare costs and demands are increasing.
- Health service funders, providers, and policy makers need to ensure interventions associated with evidence of shorter- and longer-term clinical and cost-effectiveness are implemented. This is often hindered by a lack of information on what comprises a "good" or a "bad" outcome from the perspectives of relevant stakeholders.
- Use of evidence-based practice (EBP) is assumed to lead to better health outcomes; however, it is clear that use of tools such as guidelines, protocols, and pathways may not lead to anticipated benefits if all relevant outcomes, including process outcomes, are not considered from the outset.
- Despite the development of models and theoretical frameworks to support EBP, implementation remains a complex undertaking. Interventions to support the use of EBP need to reflect context, culture, and facilitation.
- Approaches to derive and evaluate outcomes need to be undertaken with the same level of rigor as other interventions and procedures that the EBP movement focuses on.

Introduction

In this chapter, the background to the development of the book is outlined as are some of the reasons why we felt it was timely and appropriate to bring together a text which focuses on the outcomes of implementation of evidence-based practice (EBP). Experts in the field of knowledge translation and EBP invited to contribute chapters to the book were asked to consider how to determine if outcomes of EBP in their areas of expertise were efficacious, how efficacy could be measured, and how to ascertain if the outcomes of interest were the most important from the perspectives of relevant stakeholders. As described by Ian Graham and colleagues in Chapter 2, outcomes of EBP could include change in behavior demonstrating use of evidence in practice and impact of use on outcomes such as better health and more effective use of healthcare resources.

Why are outcomes of EBP important?

We hope that by reading the chapters and following the perspectives presented by the authors that the need to accord equal priority to the outcomes of implementation as with all other steps to support the use of research in practice will become apparent. Most of us live in countries where healthcare resources are finite, an issue whether our healthcare is largely funded through our taxes or private insurance schemes. Some readers will reside in countries where healthcare systems face an unprecedented increase in the burden of ill health arising from chronic, non-communicable diseases-for example as a consequence of the epidemic of obesity or an aging population. Others will reside in countries which face epidemics of disease including TB, HIV/AIDS, persistent high maternal and infant mortality and morbidity, or where poor or fractured infrastructure cannot support an effective healthcare system. For those living in developed countries, while there have been unprecedented advances in healthcare technology and year on year increases in healthcare funding from government, the increase in resources has not been matched by improvements in health. This is most evident in the US, where it is estimated that healthcare costs for 2009 were \$2.7 trillion, the highest level of healthcare spend anywhere in the world, yet life expectancy is lower than in many other developed and middle-income countries indicating large discrepancies between healthcare costs and outcomes (Institute of Medicine 2009). We also have healthcare systems where despite a plethora of technology, gaps remain in the quality of data to accurately inform and compare the outcomes of care. In the UK, efforts to gauge whether investment in healthcare following the election of a Labour government in 1997 had resulted in improved health outcomes were hampered by constraints in measures of quality and need for better measures of output and outcome extending beyond hospital episode data (Lakhani et al. 2005).

The development of EBP

For the last two decades, in response to some of the reasons outlined above, greater emphasis has been placed on the need to provide healthcare informed by evidence of effectiveness, the premise being that use of evidence will optimize health outcomes for the service user and maximize use of finite healthcare resources. The main drivers for EBP have come from political and policy initiatives which also instigated the establishment of organizations to develop guidance to inform healthcare such as the National Institute for Health and Clinical Effectiveness (NICE) in England and Wales, the Scottish Intercollegiate Guideline Network, and the US Agency for Healthcare Research and Quality. The remit of a national body such as NICE is to make recommendations for care based on best evidence of clinical and cost-effectiveness. Suites of guidelines to inform a range of acute and chronic physical and psychological health conditions and appraisals of innovations in technology and pharmacology have been developed and published by NICE which aim to standardize patient care, reduce variation in health outcomes, discourage use of interventions with no proven efficacy, and encourage systematic assessment of patient outcomes. The National Institute for Health Research which funds research to inform National Health Service (NHS) care in England requires studies funded across all of its programs to provide evidence of clinical and cost-effectiveness.

The role of NICE in the synthesis and dissemination of evidence to prioritize healthcare interventions has generated criticism that it promotes rationing in healthcare (Maynard et al. 2004), an issue with implications for determining how outcome measures are derived to elicit benefit and from whose perspective. As Maynard and colleagues (2004) write "...rationing is the inevitable corollary of prioritization, and NICE must fully inform rationing in the NHS," the issue being not *whether* but *how* to ration (p. 227). In the UK,

publication of NICE guidance which does not support the use of a particular drug or therapy because the evidence reviewed did not indicate clinical or cost-effectiveness has frequently been challenged by industry (Mavnard & Bloor 2009), service user charities, and in media reports of an individual's experience of being refused treatment which did not comply with NICE recommendations. Recent NICE recommendations which generated criticism about its role include restrictions on use of the drugs for people with early stage Alzheimer's disease, restrictions to fertility treatments, and use of drugs to treat kidney cancer. In some instances, the Department of Health was forced to reverse the original NICE recommendation to deflect public criticism, for example the use of Herceptin for women with early stage breast cancer (Lancet 2005). Nevertheless, this is an interesting juxtaposition-whose outcomes should receive the highest priority when decisions about healthcare interventions and optimal use of finite resources are made? That certain treatments may make a difference to someone's quality of life will not influence recommendation for use across the NHS if the evidence assessed does not demonstrate clinical or cost-effectiveness at thresholds set by NICE. The recent introduction of "top up" fees to enable patients to bypass NICE recommendations and purchase drugs not recommended for NHS use reflects the power of today's informed healthcare consumer (Gubb 2008). Although only likely to be utilized by a small group of people, as Maynard and Bloor (2009) propose, this raises issues about the role of NICE and regulation of the pharmaceutical industry; how drug prices should be determined; and how, if at all, to deal differently with rare or end-of-life conditions when making resource allocation decisions in healthcare. It also introduces the issue of consumers opting to purchase interventions which they view as likely to provide a better outcome which could include aspects of physical and/or psychological health and/or well-being.

The development of strategies to encourage use of evidence to inform decisions about healthcare was stimulated initially by what has been referred to as a "movement" for evidence-based medicine (EBM). One of the first people to propose that medical care should be informed by evidence of effectiveness was Archie Cochrane, whose book *Effectiveness and Efficiency: Random Reflections on Health Services* was published in 1972. Cochrane also advocated that this approach should be applied to education, social work, criminology, and social policy (Cochrane 1972). The work of Archie

Cochrane triggered groups such as those led by Gordon Guyatt and David Sackett to develop methods to synthesize and critique evidence to support decisions in clinical practice. In the late 1970s and 1980s, Ian Chalmers at the National Perinatal Epidemiology Unit in Oxford pioneered the methodology to systematically review the evidence related to effective care in pregnancy and childbirth. Building on this work, the Cochrane Centre was established in 1992 and was crucial for the spread of EBM, which in turn stimulated revisions to healthcare education and training, policy development, publication of new journals, and establishment of academic centers. Principles of EBM have subsequently been applied to support the commissioning of healthcare services, recommendations for pharmacology treatments, surgical interventions, diagnostic tests, and medical devices. Of note is that although attention has been paid to the use of measures of "outcome," limited attention has been paid to the definition or consequences of a "good" or "poor" outcome. Reviewers for the Cochrane Pregnancy and Childbirth group define an outcome as an "adverse health event" (Hofmeyr et al. 2008). In a Cochrane review, data from meta-analyses of relevant trials will be presented in a forest plot with the beneficial effect of an intervention presented to the left of the "no effect" line and a harmful effect to the right of the line. This is an extremely useful way to present outcomes of pooled data, but it is one part of the picture if we are to ensure that outcomes are the most relevant for all concerned. Further exploration of outcomes is required in order that consequences beyond implementation can be considered from a range of perspectives, an important stage in the continuum of research use.

What is evidence?

There is ongoing debate as to the definition of "evidence" and what counts as evidence, although it seems consensus has been reached that evidence can come from a number of sources and not just the findings of randomized controlled trials (RCTs). A recent position paper from Sigma Theta Tau describes research evidence as:

methodologically sound, clinically relevant research about the effectiveness and safety of interventions, the accuracy and precision of assessment measures, the power of prognostic markers, the

strength of causal relationships, the cost-effectiveness of nursing interventions, and the meaning of illness or patient experiences.

(Sigma Theta Tau International 2005–2007, Research and Scholarship Advisory Committee Position Statement 2008, p. 57)

In a 1996 commentary in the British Medical Journal, Sackett et al. (1996) defined EBM as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients," and stressed the need for the clinician to use evidence along with their expertise and judgment to make decisions which also reflected the choice of the individual patient. A later British Medical Journal commentary reiterated that evidence alone should not be the main driver to change practice and that preferences and values needed to be explicit in clinical decision making (Guyatt et al. 2004). Of note is that the authors highlighted that the biggest future challenge for EBM was knowledge translation (Guvatt et al. 2004). The need to synthesize evidence for use by busy clinicians, to place evidence in a "hierarchy" with the most robust evidence at the top of the hierarchy and acknowledgment that evidence can come from a number of external sources continues to be emphasized (Bellomo and Bagshaw 2006).

When reading any literature which refers to use of evidence, it is apparent that a number of terms have been used to describe the process which include EBM, EBP, evidence-based clinical decision making and evidence-informed practice. The term *evidence-based practice* is more commonly used to describe evidence use by nurses, midwives, and members of the allied health professions (Sigma Theta Tau International Position Statement 2008).

Throughout this book, we refer to EBP in line with the following definition:

the process of shared decision making between practitioner, patient, and others significant to them based on research evidence, the patient's experiences and preferences, clinical expertise or know-how, and other available robust sources of information.

(Rycroft-Malone et al. 2004)

As we have already indicated, an outcome could reflect behavior change at the individual, team, or organizational level, an improvement in individual health status or better use of healthcare resources. The increase in access to electronic bibliographic databases, such as the Cochrane Library of Systematic Reviews, and dissemination strategies originally adopted by groups such as NICE, professional organizations, and healthcare providers were viewed as ways to increase clinician awareness of research, with an assumption that the use of research evidence would spontaneously occur and improved health patient outcomes would follow. Studies of dissemination and implementation strategies found that few were effective (Grimshaw et al. 2004). Grimshaw and colleagues (2004) undertook a systematic review of the effectiveness and efficiency of guideline dissemination and implementation strategies. Studies were selected for inclusion if they were RCTs, controlled clinical trials, controlled before and after studies, and interrupted time series. A total of 235 studies which looked at 309 comparisons met inclusion criteria. Overall study quality was poor. Multifaceted interventions were addressed in 73% of the comparisons. The majority of comparisons which reported dichotomous outcome data (87%) found some differences in outcomes with considerable variation in observed effects both within and across interventions. Single interventions which were commonly evaluated included reminders, dissemination of educational materials and audit and feedback. The majority of studies only reported costs of treatment, and only 25 studies reported costs of guideline development, dissemination or implementation although data presented in most cases was of low quality and not suitable for extraction for the review. In conclusion, the authors recommended that decision makers needed to use considerable judgment when making decisions about how best to use limited resources to maximum population health.

Models and frameworks to support research use

A number of models and theoretical frameworks to support research use in practice have been developed—for example, the IOWA model (Titler et al. 2001), the PARiHS framework (Kitson et al. 1998) and the Ottawa Model (Graham & Logan 2004) which are described further in Chapter 3 of this book and are the focus of Book 1 of this series (Rycroft-Malone & Bucknall, 2010). It is now appreciated that implementation is complex, multifaceted, and multilayered and interventions need to be able to reflect and take account of context, culture, and facilitation to support and sustain research use. Despite the development of frameworks and models as Helfrich and colleagues (2009) highlight with respect to PARiHS, there is as yet no pool of validated measures to operationalize the constructs defined in the framework. Work in this area is ongoing, as is other work to support research use including tools to assess the extent to which an organization is ready to adopt change. An example of this is the organization readiness to change assessment (ORCA) instrument developed by the Veterans Health Administration (VHA) Quality Enhancement Research Initiative for Ischemic Heart Disease (Helfrich et al. 2009). Although still in the developmental stage, this could be a useful approach for future implementation strategies.

Why is it important to measure/evaluate the impact of EBP?

As illustrated in the following chapters that describe examples ranging from evaluation of outcomes of wound care interventions, cardiac care interventions, and the perspectives of service users, the importance of evaluating the outcomes of use of evidence is essential. The need to submit the evaluation of outcomes to the same level of rigor as other interventions and procedures that the EBP movement focuses on is also apparent.

There are many examples in clinical practice of interventions introduced on assumption of benefit rather than evaluation of impact on a range of outcomes from the perspectives of the relevant stakeholders. In maternity care, universal roll-out of interventions such as routine perineal shaving and enemas at the onset of labor, separation of mothers and babies after birth to prevent infection, and routine use of episiotomy occurred with no supporting evidence that immediate or longer-term outcomes were better-it was assumed that they would be. When these interventions were eventually subjected to rigorous evaluation more often than not there were no differences in outcomes or indications of potential harm (Basevi & Lavender 2008; Carroli & Mignini 2008; Reveiz et al. 2007; Widstrom et al. 1990). The Term Breech Trial (Hannah et al. 2000) provides a useful example of why longer-term outcomes from different stakeholders' perspectives need to be considered and evaluated before universal change in practice takes place.

A small proportion of women (around 2-3%) will have a baby which presents at term in a breech presentation and studies which

had previously considered which mode of birth was optimal for the baby and for the woman had been inconclusive due to methodological issues and small sample sizes. In certain cases, for example if it was a footling breech or if the baby was large, planned cesarean section (CS) had been considered safer than planned vaginal birth. The Term Breech Trial was designed to provide the ultimate answer to the mode of birth debate, with the proviso that study centers would have clinicians with the expertise to support vaginal breech births. The trial took place in 121 centers in 26 countries and recruited over 2,000 women. Women and their babies were initially followed up to 6 weeks post-birth. Primary study outcomes included perinatal and neonatal mortality or serious neonatal morbidity and maternal mortality or serious maternal morbidity. At 6 weeks, perinatal and neonatal mortality and morbidity were significantly lower among the planned CS group (17 of 1039 [1.6%] versus 52 of 1039 [5.0%]; relative risk 0.33 [95% CI 0.19–0.56]; p < 0.0001). There were no differences in any of the maternal outcomes. The trial was stopped early due to a higher event rate than expected. The authors concluded that planned CS was better than planned vaginal birth. Trial results were fast-tracked for publication by The Lancet (Hannah et al. 2000) despite need for caution raised by one peer reviewer because of concerns about the impact on practice of differential findings and implications this could have for maternity care in both developed and developing countries (Bewley & Shennan 2007).

Contrary to the usually slow uptake of research findings, in this case, the trial rapidly changed practice in many countries, with planned CS rates rising steeply following publication of the trial (Alexandersson et al. 2005; Caravol et al. 2007; Molkenboer et al. 2003). In England, planned elective CS is now the preferred mode of birth for women with a diagnosed breech baby at term (Department of Health 2008). Debate about the findings of the Term Breech Trial has continued particularly following publication of a two-year planned follow-up of women and babies, which showed no differences in outcomes between the study groups (Whyte et al. 2004). Criticisms of the original trial included lack of adherence to the study protocol, variation in standards of care between trial centers, inadequate methods of fetal assessment, and recruitment of women during active labor when they may not have had a chance to properly consider participation (Glezerman 2006). That women were not supported to birth in upright positions which could have increased the likelihood of a vaginal birth was also criticized (Gyte & Frolich 2001).

Criticisms have been refuted by the trial team who defended their position that this was a peer reviewed trial evaluated in a number of countries and that criticisms in the main reflected the prior beliefs of clinicians (Ross & Hannah 2006).

The worldwide impact of study findings and rapid implementation of its findings into practice has already had an unplanned outcome on the erosion of clinical skills to support vaginal breech birth (Glezerman 2006). As such it is important to consider if immediate and longer-term outcomes and reporting in response to queries raised should have been assessed prior to publication, and if the trial outcomes were the most appropriate for all relevant stakeholders. Practice changed globally based on publication of immediate outcomes, despite criticisms that study results may have been subject to bias due to problems with the trial protocol (Glezerman 2006); however, the longer-term (2 year) outcomes showed no difference (Whyte et al. 2004) which may have been a more reassuring finding for clinicians and for women, posing the issue of which outcomes at which time point should be used to inform practice? In terms of how women were reassured, we would also have to consider the basis for outcomes on which obstetricians defined their expertise in supporting vaginal breech birth and whether outcomes would have differed if midwives had also been involved. The other moot point here is the prior beliefs of those most likely to be implementing change and those likely to be the recipients of the change, and whether an RCT was the most appropriate research method to use given the vagaries of maternity practice context, policy, and culture across the globe (Kotaska 2004). The trial which aimed to provide the definitive answer has changed practice when perhaps it should not have done, given the concerns about the protocol and the presentation and interpretation of outcomes. What is clear is that this trial could never be repeated due to change in routine practice and loss of clinical skills.

Why do interventions of unproven benefit continue to be implemented?

Although considerable resource has been directed to improving health, implementation of best practice continues to be haphazard. It has been estimated by researchers in The Netherlands and the US that 30–45% of patients do not receive care based on research

evidence and that around a quarter of patients receive care which they do not require or which is potentially harmful (McGlynn et al. 2003; Schuster et al. 1998). Audits and national surveys of practice have found that interventions which could improve patient outcomes have not been universally implemented despite evidence of effectiveness—for example, statins in patients who have suffered a cerebral vascular accident (LaRosa et al. 1999) and one-to-one support for women in labor (Redshaw et al. 2007).

One main barrier is that studies rarely address all aspects of a "full-cycle" evidence implementation strategy either because funding is tailored to short-term follow-up only or as evidenced by the Term Breech Trial (Hannah et al. 2000), publication of short-term outcomes inform a change in practice which is difficult to reverse if longer-term outcomes suggest this may not have been necessary. Work to understand how and why the Term Breech Trial changed practice so rapidly when other interventions of proven benefit continue to be implemented piecemeal should be undertaken as this could illustrate how and in what circumstances individual clinicians use evidence, what value they place on the evidence and the influence of their prior beliefs.

Barriers to changing practice in line with evidence of effectiveness can take many forms, including lack of resource for, and poor attention to, dissemination and implementation strategies as illustrated by Grimshaw et al. (2004). Barriers to change could also include lack of necessary equipment or a health providers' reluctance to purchase new equipment due to other competing priorities, use of local pathways or protocols which do not accord with national recommendations, lack of appropriate clinical skills, and low patient adherence with recommended management (Straus et al. 2009). More often than not, challenges to achieving change will occur at different levels and at different points across an organization. Cheater and colleagues (2005) undertook a Cochrane review of tailored interventions to overcome barriers to change and considered effects on professional practice and healthcare outcomes. The objectives of the review were to assess the effectiveness of strategies tailored to address specific, identified barriers to change in professional performance. To meet the objectives, two comparisons were considered: (1) an intervention tailored to address identified barriers to change compared with no intervention or an intervention(s) not tailored to the barriers and (2) an intervention targeted at both individual and social or organizational barriers compared with interventions targeted at only individual barriers.

Fifteen studies were included in the review. The reviewers were unable to identify which barriers were valid, which were the most important, if all barriers had been identified and if they had been addressed by the intervention chosen. The effectiveness of tailored interventions to address barriers to change remains uncertain and further research which also considers process outcomes is required.

As poor interprofessional collaboration and communication could hinder the delivery of health services and patient care, another Cochrane review considered the effects of practice-based interventions on professional practice and healthcare outcomes (Zwarenstein et al. 2009). Five studies were included in the review; data from which suggested that interprofessional interventions could improve healthcare processes and outcomes, but the small number of studies, issues with how collaboration was conceptualized and measured and heterogeneity of interventions and settings meant it was difficult to draw conclusions about the key elements of interprofessional collaboration and its effectiveness.

If we are to ensure approaches to assess the impact and outcomes of EBP are accorded equal priority with the development of methods, theories and frameworks to support the synthesis, critique, and implementation of evidence, it is clear that we need to consider strategic approaches to define what we mean by an "outcome" from the outset of planning an intervention in practice. Davies and Nutley (2008) suggest the following strategic considerations; are we interested in organizational or individual impacts?; who are our key audiences and why do they want information assessing research use and impacts?; will any use and impact assessment be primarily for *learning* (when examinations of process may also need to be emphasized), or will the assessment be primarily to enable *judgments* to be made (requiring examinations of output and outcomes to be emphasized)?

Majumdar (2009) discusses a series of case examples to elicit why some studies are successful in changing practice. Based on the case examples, he found that the studies which were successful had the following in common:

- Addressed a common and clinically important problem,
- Evaluated well-designed interventions,
- Had adequate sample sizes,
- Used reasonable and robust analytic plans,
- Delivered valid results,
- Were published in high-impact general medical journals.

There is a clear need to ensure that if the results of an intervention lead to better outcomes, if they are to be replicated elsewhere *all* components of the intervention must be applied, sufficient details of the intervention have to be available to support those charged with implementation and better descriptions of what a clinically significant outcome would entail would need to be decided at the planning stage.

The importance of outcomes in policy and politics

Our healthcare systems are subject to the vagaries and fluctuations of political and policy change; a priority for policy in one year may well change the following year. In some cases, change is implemented because of a political motive to garner the populist vote and although this may have an evidence base, the longer-term impacts may not have been fully considered. As referred to earlier with respect to the recommendations of NICE, we also have to be mindful of the powerful role that consumers and industry can play in reversing an unpopular decision about a healthcare intervention, if there are political repercussions for the government of the day.

During recent years we have seen increased reference to the need for evidence-based policy (Department of Health 1999), although many studies continue to assess outcome from an individual perspective (Davies & Nutley 2008). In 1999, a paper from the English Department of Health outlined plans for significant reform of how the UK government would work, which included that policy making would be informed through "better use of evidence and research in policy making and better focus on policies that will deliver long term goals" and would be a continuous learning process (Department of Health 1999, p. 17).

Bodies that fund research, particularly in health and social care are increasingly likely to tailor funding priorities to accord with government policy to increase the usefulness of the research output. This in turn is focussing attention on to how to increase the impact of the research output (Nutley 2003). As Nutley (2003) writes, while there is developing evidence of how to increase impacts of research use on the individual practitioner we know little about the effectiveness of strategies aimed at promoting use of evidence by policy makers. The role of organizations such as the Cochrane and Campbell Collaborations are essential to promote robust research evidence for use by a range of stakeholders, including policy makers. However, active dissemination of findings does not mean that review findings will be reflected in policy directives in the way originally intended by research teams.

What is required now is more methodological work to know when, where, and how to assess the outcomes of use of research. From a policy perspective, dialog is necessary to ascertain if interest is in actual or potential outcomes, given that policy makers may be more interested in immediate recommendations for change due to the political impetus rather than awaiting the longer-term impacts. The outcomes of primary or secondary evidence when used by policy makers are also likely to be subject to integration with other forms of research, knowledge, and expert opinion as well as shifting priorities at government level.

Conclusion

Throughout the following chapters, authors describe different approaches to capturing data on a range of outcomes. These include specific healthcare service and practice outcomes relevant to the topic of interest, the economic and resource impact of EBP as viewed from the perspective of relevant stakeholders and need to ensure the outcomes a research team consider important are actually a priority from the perspective of the intended target user group. Whichever approach is used, whether quantitative or qualitative, the practical issue of how to evaluate the outcome of EBP in practice has to be addressed. This not only has to reflect an appropriate measure, it also requires consideration of when the outcome should be captured, from whose perspective and implications for future use. We should also pay more attention to process outcomes which could provide information on the influence of context and culture on research use.

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