

SYMPOSIUM ON EVIDENCE BASED MEDICINE

Ethics of evidence based medicine in the primary care setting

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Evidence based medicine has had an increasing impact on primary care over the last few years. In the UK it has influenced the development of guidelines and quality standards for clinical practice and the allocation of resources for drug treatments and other interventions. It has informed the thinking around patient involvement in decision making with the concept of evidence based patient choice. There are, however, concerns among primary care clinicians that evidence based medicine is not always relevant to primary care and that undue emphasis placed on it can lead to conflict with a clinician's duty of care and respect for patient autonomy. In this paper we consider the impact of evidence based medicine on primary care, and the ethical implications of its increasing prominence for clinicians and managers in primary care.

Primary care does not sit so easily within the paradigm of evidence based medicine as secondary or tertiary care. As the first point of contact with the health care service for most patients, the primary care practitioner is often faced with non-specific symptoms that may be related to complex social and psychological factors as well as physical pathology. A consultation or illness episode in primary care is part of a continuum of health care provision, often provided by the same practitioner over many years. There is a greater degree of diagnostic uncertainty than in secondary care, investigations and treatments are often low technology, and relevant outcome measures can be difficult to define. Therefore it is likely that most decisions in primary care are not evidence based, if we mean by evidence based that decisions are based on the results of randomised controlled trials (RCTs) or other quantitative research methodology. Indeed, until the mid 1990s it was generally assumed that most medical practice in both primary and secondary care was not based on evidence.¹ In 1996, however, Gill *et al* concluded from a retrospective study in one general practice that 30% of interventions were based on evidence from RCTs and 81% of interventions were based on either RCTs or "convincing non-experimental evidence".² This followed a similar study in a secondary care setting by Ellis *et al* that had similar findings.³ It was not clear in the general practice study exactly what constituted convincing non-experimental evidence beyond the consensus opinion of a group of general practitioners, or whether the RCT evidence cited was relevant to a general practice population. Thus there are still questions to be answered about what is meant by evidence based practice in primary care. Concerns about generalisability of evidence to primary care settings, the disregard of evidence other than that from empirical, predominantly quantitative, research, and the impact of evidence on physician and patient behaviour, particularly in the context of continuing care, may also suggest there are moral as well as practical issues to be considered in the practice of evidence based medicine in primary care. A recent UK study into the feasibility of evidence based patient choice as a model for general practice found that general practitioners (GPs) articulated concerns that reflect some of these issues.⁴ These included concerns over the lack of evidence for some conditions, the scarcity of evidence derived from the patient's perspective, the strict

exclusion criteria of RCTs, and contradictory guidelines which had the potential to limit patient choice. Other studies have had similar findings.^{5–7} In this paper we will consider the ethical issues raised by evidence based medicine in the context of primary care under three headings: individual autonomy and informed patient choice; the public health role of primary care; and distributive justice in commissioning care.

SHARING THE EVIDENCE: RESPECT FOR AUTONOMY AND INFORMED PATIENT CHOICE

The move away from paternalism in Western health care to a focus on patient autonomy, informed consent, and shared decision making has been accompanied by increased patient access to information about treatments, and consumerist trends in society. There is a growing public expectation that patients will be fully informed about their illness and the options for treatment, and fully involved in decisions about their health care. The idea of the paternalistic physician making decisions about diagnosis, investigation, and treatment in the patient's best interests, and the patient accepting these decisions without question, is no longer tenable.⁸ Even in general practice, (or family medicine) where there is a tradition of the trusted family physician, there is now an expectation that patients will be consulted and informed at every stage of the health care process.⁹ Thus, evidence based practice must include the use of evidence in the discussion between practitioner and patient as well as the use of evidence in informing clinical judgment. If the autonomy of patients is to be respected, they must be given information that enables them to make choices that are consistent with how they wish to live their life. Evidence based medicine would seem to be a powerful force for enhancing patient autonomy. In order to make autonomous decisions, however, patients need to be able to understand and evaluate the evidence as it relates to them and their particular situation. One of the criticisms of evidence based medicine in the primary care setting is that many of the data are from clinical trials based in secondary or tertiary care, carried out on highly selected patients according to strict exclusion criteria. Results from such trials may produce convincing evidence that is highly persuasive to both practitioners and patients making decisions about care. The impact of convincing

results in controlled clinical trials may, however, be attenuated when the treatment or intervention is applied to a broader group of patients in a primary care setting, where multiple pathology may be common and adherence to treatment regimens is less than in a controlled trial. An honest assessment of how well the intervention will work in the reality of primary care will be more relevant to the patient considering treatment. This may become possible with more primary care based research both in terms of research participant population and type of condition studied. The hierarchy of evidence currently used in evidence based medicine may, however, cause further problems for the primary care practitioner wishing to facilitate an informed decision about health care on the part of his or her patient. Randomised controlled trials are seen as the gold standard for evidence in health care. Other research methods such as observational studies and qualitative research carry less weight when evidence is evaluated to inform individual practice or guidelines. Randomised controlled trials are often not appropriate, however, for answering research questions in primary care. The complexity of disease presentation and management interventions in primary care means that it may not be feasible to conduct a high quality RCT for many conditions. Most RCTs use outcome measures that have been designed to be easily quantifiable and amenable to statistical analysis. This is so even when more patient relevant outcome measures such as disability scales and quality of life measurements are used. When these approaches are used in primary care the results are often disappointing because other, non-quantifiable, factors come into play, which affect either the intervention or the outcome measures.¹⁰ These other factors will have even greater impact when the evidence based intervention is rolled out for implementation in everyday clinical care. Research which provides evidence that is relevant to primary care practice will require a number of different research methods, and the importance of these different methods needs to be recognised in the use of evidence to inform patients in primary care. Qualitative research that informs the development of RCTs or provides an alternative or complementary approach to answering the specific research question is becoming recognised as a valuable component of research in primary care.¹¹ Thus future research has the potential for producing evidence that is more relevant to the reality of primary care and to the individual patient making health care decisions in the primary care setting.

Of equal importance to the production of high quality, relevant evidence to inform patients is the presentation of such evidence in a way that the patient can understand. Results of research published in medical journals are not always easy for clinicians to interpret and systematic reviews may present conflicting results. Presentation of headline results without interpretation, or provision of complex statistical information, can result in confusion or lack of understanding on the part of both practitioners and patients. The use of relative rather than absolute risk reductions in reporting research results may mislead patients if it is not placed in the context of their current level of risk.¹² This will not enhance patient autonomy.

The appropriate presentation of research evidence to patients to enable them to make decisions about their health care enhances their autonomy only if they can use that information in conjunction with other information that is more specific to them as an individual, and then evaluate all the information to make their decision. Research evidence is evidence about populations of patients rather than individuals. Significant risk reduction at a population level may not be so important for an individual when weighed

against other considerations in that individual's life. Evidence that a particular treatment is not effective in a given patient population may not convince a specific patient who has experienced personal benefit from the treatment. A parallel development to evidence based medicine in recent years has been that of "patient centred medicine". This could be considered the antithesis of evidence based medicine, particularly if the concept of patient centred medicine as the opposite of disease centred medicine is used.¹³ Patient centred medicine has a humanistic, biopsychosocial perspective and focuses on the practitioner's understanding of the patient's true reason for the encounter, and the patient's real needs and wishes.¹⁴ It is difficult to see how a primary care practitioner could truly respect a patient's autonomy without taking this into account. The practitioner/patient relationship in primary care often spans many years of a patient's life and involves the shared experience of multiple illness episodes, some minor, some major. Consideration of the individual patient's background, beliefs, and long term wishes is fundamental to managing their lifetime experience of health and disease in this context. This is less so in secondary care where practitioner/patient encounters are more likely to centre around discrete illness episodes of limited duration, or to be of limited time. The importance of the patient's particular influence and perspective on the disease process has long been a focus of writing and teaching in primary care.^{15 16} This is based on a recognition of the patient as an autonomous individual. Evidence based medicine should contribute to patient centred care but not override it. If biomedical research evidence takes its place with other forms of evidence such as patient experience and clinical judgment, patient autonomy should be enhanced. There is a danger, however, that in their enthusiasm for evidence based medicine clinicians may replace the paternalistic mantra of "doctor knows best" with the paternalistic mantra of "the evidence knows best".

We have so far assumed that the enhancement of patient autonomy by the appropriate use of evidence based medicine in the provision of information to patients is a good thing. An interesting consequence of empowering patients to make their own health care decisions, or to actively share in the decision making process, is that patients will then have some responsibility for the consequences of their decisions. All research findings have an element of uncertainty in terms of their application to individual patients. A success rate of 70% for a treatment means a failure rate of 30%. In making a decision to try a particular treatment one accepts that the treatment may fail and that there may be side effects. If patients expect and are expected to make these decisions, then the burden of responsibility for accepting the uncertainty will also fall on them. It is unclear whether the transfer of this uncertainty from clinician to patient will be of benefit or harm.

THE PUBLIC HEALTH ROLE OF PRIMARY CARE: USING EVIDENCE TO MAXIMISE WELFARE

Clinicians in primary care have an important public health role, both in terms of disease prevention and disease management. In the UK, the restructuring of the health service has placed public health firmly within the primary care setting by incorporating public health into the responsibilities of primary care trusts (PCTs). Primary care trusts are responsible for commissioning and providing health care for their constituent populations and thus need to have a strong commitment to public health. Both doctors and nurses in primary care have traditionally been closely involved in the delivery of public health interventions such as immunisation and screening programmes. More recently, the national

service frameworks for coronary heart disease and diabetes have been aimed not only at improving the quality of care for individual patients with these conditions, but also at reducing the population morbidity and mortality arising from them. The use of evidence based medicine to inform public health measures should raise fewer problems in terms of relevance of evidence than in the area of individual patient care. The health benefit being sought in public health is at the population level, and research evidence relates to a defined population. However, although the outcome of a public health intervention is measured at a population level, the intervention is often delivered in individual patient consultations. Recently it has been recognised that patients have not always been given the information they need to enable them to make a decision about some aspects of health care that are aimed at population level disease control. Cervical and breast screening have been the focus of studies on enhancing informed choice for women enrolled into the screening programmes.¹⁷ The high profile debate in the UK about triple vaccine for measles, mumps, and rubella (MMR) brings into sharp relief the conflict between the usual practice of active persuasion of parents to have their children immunised, and individual parent choice. The debate has tended to focus on the quality of evidence for a link between the vaccine and autism, but it also raises the issue of balancing population risk against individual risk even when the evidence base is accepted. If there is strong evidence that a vaccination programme is effective in reducing the population risk of disease, but the risk to an individual of developing the disease is small and there is also a small risk to an individual of suffering a side effect of the vaccination, then simply relying on the evidence may not achieve the desired public health outcome. Individuals may weigh the individual risks differently from the population risk and therefore refuse to participate in programmes even if the evidence shows a large population benefit. Increasing availability of evidence to patients could jeopardise some public health measures. Perhaps we then need to consider the limits to individual autonomy in the context of public health.

A longstanding feature of UK primary care, or more specifically general practice in the UK, has been the linkage of financial payment to the delivery of clinical care in the form of target setting. Since 1990 general practitioners have been paid for achieving target childhood immunisation rates and cervical cytology rates. Financial incentives have also been linked to prescribing targets which, although often claimed to be related to quality markers in prescribing, are more likely to be linked to cost containment.¹⁸ An imminent new contract for GPs will include quality payments that will be linked to the targets set by the national service frameworks—for example, the number of patients at risk of ischaemic heart disease who have been prescribed statins, or are on other recommended medication. The National Institute for Clinical Excellence (NICE) has recently issued a range of guidelines for clinical care of specified conditions, and it would seem likely that compliance with these guidelines may be linked to quality payments in the future. The quality markers to be used are justified on the grounds that they are based on good evidence. The NICE guidelines are also evidence based. This of course begs the questions of what evidence has been used to inform the guidelines, and what are its quality and relevance to primary care, as already discussed. Assuming, however, that the guidelines or quality indicators meet these criteria, their linkage to financial incentives could still raise ethical concerns. The imposition of uniformity of care by guidelines has been criticised on moral grounds because of reduction in practitioner autonomy and potential coercive paternalism.¹⁹ Coercive paternalism is even

more likely if failure to achieve targets or comply with guidelines is associated with a loss of income for the clinician. Evidence based guidelines and targets may result in restricted choices of treatment being offered to the patient, but in the absence of clinician incentives the patient can refuse the recommended options. In a recent study of 97 patients with atrial fibrillation—for example, by eliciting preferences and performing decision analysis—the number of prescriptions for warfarin desired by these patients was reduced by 40%; whereas management guidelines which ignored patients' preferences recommended treatment for a higher proportion of patients.²⁰

If, however, clinicians know their income will be increased if the patient complies with the recommended treatment, they could alter their consultation behaviour to make it more likely that the patient would comply. This does not have to be by overt coercion or bullying. Recent research has shown that the way in which information is presented to patients can alter their decisions.²¹ The aim of performance targets and guidelines is to improve the quality of patient care, thus benefiting the patient and reducing unnecessary harm, a morally desirable outcome. If, however, they are linked to incentives or penalties that have a potential adverse effect on a clinician's personal interests, and if they are based on evidence that can never be completely appropriate to an individual patient in an individual clinical setting, they may precipitate a serious conflict of interest for the clinician. The financial or other gain does not have to be realised by the individual clinician. Financial benefit to the practice that will benefit other patients, or financial penalty that will adversely affect the practice's ability to improve patient care generally, will cause a similar conflict of interest.

Of course clinicians may consider that their duty of care to their patients will override any personal interest and that financial incentives do not alter their clinical practice. This may be asking rather a lot of clinicians, and there is anecdotal evidence of GPs in the UK removing patients from their list because they refuse to have their children immunised. Whether financial incentives actually make a significant difference to clinicians' behaviour may not be the main issue. It is the perception by patients that their doctor is influenced to advise a certain course of action, or to restrict information about options, because of his or her own personal gain that leads to a breakdown of trust in the doctor/patient relationship. The issue of MMR vaccination illustrates this point. Prior to the concern about the MMR vaccine causing autism, most patients were unaware that their GPs were paid for achieving target vaccination rates. As the debate about MMR continued, parents became concerned that their GP was persuading or pressuring them into having their child immunised without fully addressing their concerns. The argument was that GPs were accepting the establishment, evidence based view. When it became more widely realised that the MMR vaccination was included in GP targets and associated with financial payment, the distrust of GPs as patient advocate, or partner, was increased. Many GPs were so concerned about the potential damage to their relationship with their patients that a motion was passed at the annual conference of the British Medical Association, calling for an end to target payments for childhood immunisation.

THE INFLUENCE OF EVIDENCE ON PRIORITY SETTING IN PRIMARY CARE: DISTRIBUTIVE JUSTICE

Primary care trusts now have responsibility for commissioning secondary and tertiary care for their patient population as well as for providing and commissioning primary care services. In a situation of restricted resources, rationing, or

prioritisation, must occur. In a study currently being conducted on the ethical issues facing PCTs by one of us, the process of prioritising health care services in the commissioning process was seen as the major ethical dilemma for the managers and clinicians within the PCT executive. The presence of evidence of clinical and cost effectiveness is a major factor for PCTs in decision making around priority setting. The large body of research evidence on secondary and tertiary care interventions is now accompanied by evidence from an increasing number of studies focusing on primary care interventions. Already we have data to support an increasing number of treatments for acute and chronic diseases, and for interventions to prevent or delay the onset of some diseases, derived from primary care—for example, the treatment of atrial fibrillation to prevent stroke, and the management of hypertensive and lipid disorders to reduce the risk of myocardial infarction.^{22–24} Evidence also now exists which questions the effectiveness of some treatments that have traditionally been used in primary care—for example, the use of antibiotics for viral infections.^{25–26} National guidelines and targets, such as those from the National Institute of Clinical Excellence, which also influence the commissioning decisions of PCTs rely on evidence from research studies for their authority. A superficial assessment of the process of allocation of limited resources may conclude that using evidence of effectiveness and efficiency as the standard for judging all health care interventions would be fair. Each intervention would be judged by the same standard, and cost inefficiencies would be minimised, enabling more interventions to be commissioned. This assessment does not, however, take into account the inequality in availability of evidence, or of appropriate research, across different diseases and treatment options. Medical research, particularly the “gold standard” RCT, is much more common in the area of drug interventions. This is partly because the pharmaceutical industry is a major source of research funding. Other interventions, including the more complex interventions often required in primary care, are less likely to have received the attention of well funded research, and thus less likely to have robust evidence of clinical and cost effectiveness. If PCTs prioritise allocation of resources to those interventions that are supported by good quality evidence, some groups of patients will be disadvantaged. Evidence based medicine would increase inequity between these groups.

Implementation of evidence based medicine is aimed at individual clinical decision making or service provision at a population level for specific diseases. It does not address inequities in health status resulting from factors other than disease, such as ethnicity and social class. It is possible that inequity could be increased by implementation of evidence based medicine if these more complex determinants of health are not considered. Mortality rates for heart disease are greater in some ethnic minorities and social groups, but the evidence based guidelines for the primary prevention of coronary heart disease do not include ethnicity or socioeconomic status as risk factors.²⁷ Applying the guidelines across the whole population may lead to greater inequity between these groups. Primary care trusts are expected to deliver health care sensitive to the needs of their local population, and reducing inequity is regarded as an important goal. This may not be consistent with decisions based only on evidence of effectiveness and efficiency.

CONCLUSION

Evidence based medicine has the potential to improve patient care, prevent harm, and promote patient autonomy. As it is currently understood and practised, however, its focus is on

research evidence mainly from RCTs and other quantitative methodologies, while ignoring other forms of evidence such as patient experience and clinical judgment. The complexity of disease presentation and management in primary care does not fit easily into the parameters of this limited view of evidence based medicine, and if this is not recognised there is a danger that patient autonomy and good patient care may be diminished. The appropriate use of good research evidence to inform patient care must be encouraged, but its elevation to a position of overriding importance, particularly if associated with incentives to clinicians for its implementation, gives rise to ethical concerns in relation to both individual autonomy and distributive justice.

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