

Evidence-based primary care ethics

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Evidence-based primary care ethics

Penultimate version

Roger Newham and Andrew Papanikitas

# Introduction

‘Evidence Based Medicine’ is often quoted as ‘The conscientious, explicit, and judicious use of the current best evidence in making decisions about the medical care of the individual patients’.[[1]](#endnote-1) This has been extrapolated to ‘The conscientious and judicious use of the best evidence relevant to the care and prognosis of the patient to promote better informed and better justified ethical decision making.’[[2]](#endnote-2) The two statements can perhaps be essentially read as saying the same thing. It seems odd that if one is committed to using the best available evidence in the everyday setting, one might not use it in ethically difficult circumstances. Both statements, however, seem to imply that where evidence supports a treatment as the ‘best’ available clinicians should favour it, and moreover should not recommend any treatment that the evidence does not support. This simplistic approach trades on leaving the notion of evidence somewhat vague. For example, should the term ‘evidence’ include both the normative and the empirical, or to put it another way, ethical or moral ‘arguments, reasons and values’ and 'facts'. In this chapter we will discuss what might constitute an evidence-base for primary care ethics and what might constitute its use for the process of ethical decision-making. We will reflect on the forms of evidence that make up 'ethics' in practice. We will consider some of the ways in which quantitative and qualitative empirical research claims to inform healthcare ethics, two ways of 'systematically' reviewing literature for worthwhile healthcare ethics content and an account that combines the normative and empirical as a single methodological research approach. We do not propose to solve the problems of disputed ethical language, modes of reasoning and conclusions. However, using a case and examples relevant to primary healthcare, we aim to make the reader aware of those disputes, and to foster a critical and reflexive approach to healthcare ethics.

# The forms of evidence on which ethical decisions in practice might depend

The evidence-base which appears to be common in UK primary healthcare education is similar to that which informs undergraduate medical education. We have initially interpreted 'evidence' very broadly here as that on which ethical deliberation and action might depend.

* Philosophies of practice
* Philosophical ethical framework
* Authoritative statements/guidelines/the law
* Empirical work: Surveys, quantitative research, qualitative research, systematic reviews of quantitative studies, systematic reviews of qualitative studies
* Religion and culture
* Political Ideology
* Stories of how clinical cases were managed including personal reflective accounts

Consider which of these you would count as evidence. One divide may be that normative (knowledge that informs how we ought to act, or moral values) and the empirical (knowledge that tells us what is, or ‘facts’) are different and distinct. Another division may be that within the empirical on the type of research which a ‘fact’ is based and on the quality or rigour of the studies. Or another division for a possible divide between what counts as evidence could be between practicality and justification.[[3]](#endnote-3) Practicality highlights the need for a focus on actual practice such as influencing the behaviour of actual patients (or broader policy concerns) and justification highlights their legitimisation.

In her text, ‘Evidence based medicine – a critical reader’ Ridsdale[[4]](#endnote-4) addresses medical ethics in general practice by offering two common scenarios, and applying personal experience, communication skills, the law and Beauchamp and Childress’ Four Principles method as made popular in the UK by Gillon.[[5]](#endnote-5) She acknowledges the major influence of outcomes-based ethics and duty-based ethics. If we applied her rationale to a hypothetical question raised by one of the author’s urban colleagues it might look like this.

A 24 year old politics, philosophy and economics student attends your GP clinic. He tells you that back home in USA he saw a doctor (speciality unspecified) for concentration problems during his first degree. The doctor diagnosed him with attention deficit hyperactivity disorder, for which he has since purchased methylphenidate by mail order. He would like to be prescribed this medication.

The Ridsdale method invites the reader to ask: How do I ensure good communication, what do I know about my legal liabilities, how do I apply beneficence, non-maleficence, autonomy and justice to analyse the problem?

Ridsdale focuses on the four principles, but in practice clinicians may be exposed to an *ethical smorgasbord*.

* Medical School: Four Principles of Autonomy, Beneficence, Non-Maleficence and Justice
* Postgraduate Education: Virtues (Professionalism) and Duties (e.g. laws and, professional guidelines such as from the General Medical Council in the UK)
* Politically: A contractarian language of rights and obligations
* Evidence-based medicine and healthcare resource allocation *as often used*: emphasis on utilitarian/consequentialist thinking

This paints a confusing picture, and different clinicians may favour synthesised principles, one or more grand theories, or reject all of the above in favour of combinations of narrative, the law and common sense.

The list below covers the issues on which BMA members have most frequently sought advice from the BMA Ethics Department in 2009-2010:

1. Under what circumstances can confidential health information be disclosed?
2. Who can apply for access to a patient's health records?
3. What should a doctor do when they have child protection concerns about a patient?
4. How much information should patients be given in order for consent to treatment to be valid?
5. What should a doctor do if they are asked by a terminally ill patient to write a medical report to use abroad for assisted dying?
6. Does a patient have a right to see a medical report written about them?
7. Under the Mental Capacity Act 2005, when is a person judged to lack capacity?
8. How and when, can a doctor broach the subject of private treatment with NHS patients?
9. Are GPs able to register asylum seekers and refused asylum seekers?
10. What is the BMA's position on organ donation?

This list does not however tell us with certainty which issues are common, but those which were the commonest to result in requests for advice to one particular advice service for one undifferentiated profession in one country at one point in time. The list appears to be focussed mainly on issues with medicolegal ramifications. And yet these issues or concerns are all pertinent to primary care reflecting the differing and potentially conflicting types of evidence GPs and others in primary healthcare may need to be aware of and use in their differing roles. Such evidence includes empirical facts, underlying or ‘hidden’ values such as respect for individual patient autonomy, public health aspects of primary care and resource allocation involved in commissioning.[[6]](#endnote-6) The many types of evidence need to be combined with the normative moral philosophical analysis. [[7]](#endnote-7)

# Empirical Ethics

Empirical ethics may be defined as

…research strategies in ethics that aims to combine the collection and analysis of empirical data with moral philosophical analysis. These research strategies are generally undertaken to shed light on issues in practical ethics: that is, the endeavour to make normative claims about practical situations.[[8]](#endnote-8)

Sociologists in particular have offered a critique of empirical ethics or bioethics: (where bioethics is understood as being concerned with issues in applied ethics such as practical issues in primary healthcare but with philosophical analysis being in some sense primary).[[9]](#endnote-9)

* Philosophical bioethics lacks a sense of context, as evidenced by unrealistic thought experiments and complex jargon
* Sociologists are better than philosophers at identifying injustice and understanding the imperfections of the real world
* Ethics is just another way in which those who are in power oppress those who are not[[10]](#endnote-10)

For their part, moral philosophers have offered critiques of empirical methods for ethics by distinguishing facts from values or for drawing normative conclusions from non-normative premises (alone). [[11]](#endnote-11) The fact-value distinction is well-discussed in medical ethics.[[12]](#endnote-12)

Thus both philosophical normative evidence and empirical evidence must be critically considered when considering evidence based medicine and its use in evidence based ethics.

# Evidence based medicine and Ethics

Traditionally evidence based medicine has been taught in terms of a hierarchy of evidence. In this hierarchy, systematic reviews (which assess the quality of available randomised and controlled trials (RCTs)) and meta-analyses (which combine the data from multiple RCTs) is the best kind of evidence being ‘maximally informed and minimally biased’.[[13]](#endnote-13) By contrast case reports and personal experience is the lowest form of evidence. If there is a clear population, intervention, comparison and outcome (PICO), then an RCT may well be appropriate. Indeed there have been calls for government policy to make more use of PICO and RCTs in testing new and existing policy. This may challenge untested political ideology as a source for policy if that policy does not work or is shown to cause harm.[[14]](#endnote-14) If the ideal of best evidence consists of RCTs or other quantitative research methodology then for the most part explicit use of values and moral values is limited with the ideal perhaps being value free (at least with regards to justification); the focus being on physiological outcomes of or as treatment effects. But the evidence base as empirical research can and perhaps should come from other disciplines for example from the social sciences of psychology, sociology and anthropology which (like the non-empirical as law, religion and moral philosophy understood as practical ethics) needs applying to the particular case.

The inclusion of other, non RCT, types of empirical research as evidence is especially relevant for evidence based ethics in primary care because patients often present (at least in the first instance) with ‘non-specific symptoms that may be related to complex social and psychological factors as well as physical pathology’.[[15]](#endnote-15) Such social and psychological factors lead to another important ‘outcome’ of medicine or healthcare that of quality of care. Quality may include patient satisfaction with treatment or care leading to patients and those around them flourishing more generally; hence the importance of qualitative methods as evidence particularly when patients present to their GP with problems around coping with their conditions (*ibid*.). Primary care disciplines such as general practice (and its worldwide equivalents) involves both the science and art in an especially integrated fashion with some claiming anecdote, patient stories and personal experience though classified as ‘lower levels’ of evidence having an equally valid contribution to make to decision making.[[16]](#endnote-16)

In a sense the use of RCTs and meta-analysis does have an ethical underpinning when thinking about (physical) benefits and harms to patients and the need to avoid bias in deciding what these are or the risk of them. But as mentioned above, perhaps especially in primary care, the external validity of such trials may often be problematic. However there is a growing body of literature suggesting that systematic reviews of non-empirical research are required as evidence in evidence based ethics to help GPs and policy makers avoid ethical bias.[[17]](#endnote-17) [[18]](#endnote-18)

McCullough *et al* propose that a systematic review of clinical ethics literature should address a population, intervention, comparison and outcome (PICO) like regular systematic reviews. Unlike regular systematic reviews they should end with a moral outcome rather than a physical one. For example such a question might sound like, “In university students who claim to have a prior diagnosis of attention-deficit hyperactivity disorder, is prescription by a general practitioner of drugs which may also be used as cognitive enhancers, rather than referral to a psychiatric specialist, ethically justifiable?” McCullough *et al* assign numerical scores to papers based on the quality of the reasoning and each paper’s net conclusion.[[19]](#endnote-19)

Sofaer and Strech propose that a systematic review of reasons address the empirical question of what reasons have been given for the ethical question and has conceptual analysis applied post review.[[20]](#endnote-20) This might generate a different kind of question. “What are the reasons for and against the prescription of cognitive-enhancing medications to university students by general practitioners?” They suggest searching multiple types of database and coding (grouping under a descriptive heading) the eligible literature in terms of reasons mentioned in passages of text and reason types. Reasons that occur in multiple publications are thematically 'stronger' but this does not necessitate what ought to be done, merely what the more usual reasons considered in the literature are. Their approach appears in essence to be a form of thematic analysis of reasons. They add that a table of characteristics of included publications allows reviewers to assess the state of the field and identify gaps. The rationale for such reviews is to make reasons available to policy makers and decision makers and this plausibly will include academics, educators and practitioners in primary care in order to improve decision making.

So what amongst the many empirical methods (as well as non-empirical, political or theological approaches) is to be counted as evidence and why it should be so counted has been and remains contested. It has been suggested that until this is clarified then the very idea of evidence based ethics ought to be put on hold, especially since the evidence in ethics is often of a qualitative nature thus compounding problems about quality.[[21]](#endnote-21) Others have also claimed that evidence-based ethics ought to be put on hold for the reason that it is actually incompatible with (bio)ethics normative mandate.[[22]](#endnote-22) However two forms of evidence have recently offered promise: systematic reviews of reasons and development of a ‘narrow’ account of fully integrated empirical ethics.

# Recent evidence

Empirical disciplines do not explicitly claim to justify how people ought to behave or what people ought to do ethically speaking. This is traditionally the province of philosophical ethics which seeks justification of the particular practices via authority as binding universally independently of any particular standpoint or context; although this account of ethics is often seen as contentious in sociological research[[23]](#endnote-23) and in some philosophical literature.[[24]](#endnote-24) [[25]](#endnote-25) [[26]](#endnote-26) If there were agreement as to what counts as evidence or ‘best’ evidence for primary care ethics, which there currently is not, a further and related issue is the use that is made of it. How is the philosophical theoretical account of normativity ‘combined’ with the empirical and other types of evidence for evidence based *ethics* or empirical ethics?

Evidence-based ethics has largely focussed on empirical bioethics, though ‘reason based reviews’ are also developing, in the sense that the evidence is a synthesis of facts that ‘inform’ moral decision-making, thus seemingly, leaving the answer quite vague. Empirical evidence (and some form of ‘mother wit’ or intelligence) has always informed ethical deliberation but unless the empirical determines the ethical the problem of the integration between the empirical and the ethically normative for evidence based ethics remains.[[27]](#endnote-27) [[28]](#endnote-28)

Two types of strategies seem common. Davies *et al* carried out a systematic review of methodologies that used both empirical research and philosophical analysis that aimed at drawing normative conclusions; not just descriptions of data to support factual premises or just philosophical analysis regarding moral authority but an ‘integrative’ approach. The results found two broad poles, ‘dialogical’ and ‘consultative’. Roughly the dialogical approach involves getting a shared understanding and normative *consensus* on a discrete problem. The consultative approach uses an external thinker who analyses the data and then independently develops normative conclusions based on theoretical coherence. Others recommend similar approaches as ‘pragmatic’ where evidence is thought to be neutral in regards to people’s explicit values which, in our multi-cultural and liberal democratic times, seems to afford a way of consensus.[[29]](#endnote-29) A dialogical approach in the case of our example might ask how the ethics of treating students with cognitive enhancing medications emerges from qualitative research involving clinicians and patients. A consultative approach might gather relevant qualitative and quantitative data and pass them to a philosopher who would produce a reasoned judgement on the ethics of treating students with cognitive enhancing medications.

This still raises three important questions as to the use of evidence in evidence based (bio)ethics for normative justification. 1) The justificatory question as to how moral justification can be found through coherence or consensus. 2) The analytic process used; notably where the priority should lie between the thinker, theory or stakeholders. 3) The kind of conclusion that is sought; general or particular.[[30]](#endnote-30)

The second strategy is more radical than the rest in that it attempts to combine empirical findings (‘is’ data) with normative (‘ought’ arguments) as ‘new methodological practices’ rather than coherence between two separate research methods.[[31]](#endnote-31) Briefly Dunn et al claim that the empirical research ought to inform normative argument and that the normative arguments ought to influence research to shape (for instance) individuals’ attitudes and experiences. This is not meant to be the method of wide reflective equilibrium[[32]](#endnote-32) or other coherentist accounts that are cyclical.[[33]](#endnote-33) These, they claim, are problematic as accounts of how such integration is achieved in research. Rather they suggest new strategies aimed to be *practically convincing* and based on similarity to social scientific research for *methodological* development in empirical ethics (seen as synonymous as evidence-based medical ethics). It is different from social scientific methods in its integration of normative philosophical theory. It differs from more contextualised and from pragmatic approaches that call for metaethical revision -for example about the importance of general features of agents for moral authority. They call for a new generation of ethicists skilled in both empirical and philosophical methods.

# Conclusion

Primary healthcare offers a rich testing ground for evidence-based ethics, partly because evidence-based medicine is already nuanced in this context – a hierarchy of evidence with an RCT at the top does not adequately answer the questions that need answering. Practice in primary healthcare is not exclusively technology or even physiology dependent and many decisions and interventions defy statistical analysis. Extrapolating from Sackett's seminal definition of evidence based medicine, evidence based ethics is the conscientious and judicious use of the best evidence concerning the care and prognosis of the individual patient in making ethical decisions.[[34]](#endnote-34) The key issue is the ethical responsibility of a healthcare professional to make use of good ‘evidence’ in ethical decision-making. What is to count as evidence is usually understood as an empirical matter both quantitative and qualitative though other sorts of ‘evidence’ may need to be somehow included. Concerns have arisen as to the quality of such evidence especially of a non RCT type though the claim that only those things which may be counted (such as in an RCT) are ‘true’ has been hotly debated. ‘Empirical’ evidence-based ethics seems to imply that it has straddled the divide between the seemingly distinct empirical facts and normative philosophical ethics and moral values. Again the literature is characterised by debate. Perhaps the best that can be offered in terms of justification and academic consensus in terms of ‘evidence’ is the offering of ‘is’ data and well-curated ‘ought’ arguments, as in Sofaer and Strech systematic review of reasons. We do not present these questions as unsettled to unleash a form of postmodern ethical existentialism but to make some simple points: a reflexive practitioner or policymaker may consider how a good decision is made.

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