Cost-value Analysis in Health Care: Making Sense out of QALYs


Eric Nord’s book is required reading for all those interested in resource allocation. It is largely a book on health economics, but the importance of the issues discussed and the clarity of this book mean that it is relevant to all those involved in resource allocation.

One of the more common objections to QALYs (Quality Adjusted Life Years) is that they focus on maximising the benefit produced by health care without paying attention to other factors relevant to allocation. One of the basic theses of Nord’s book is that there is something right about this line of criticism and he sets out to correct cost-effectiveness studies by building into them societal concerns for the way in which health care resources are distributed. In chapter four he argues that the standard approach to QALYs is inconsistent with two major societal concerns about fairness. First it violates the strength with which people wish to give priority to the severely ill over the less severely ill at the expense of the total amount of health produced. Second, QALYs overlook the societal concern to allow people to realise their potential for health, whether this is big or small. Reasons such as these mean that “...to rank projects in terms of costs-per-QALY as often as not may tend to distort resource allocation decisions rather than to inform them” (page xx). He proposes that the utility values used in cost-effectiveness equations be generated from representative sampling of persons who have received treatment.

One of the really interesting differences between Nord’s approach and that of the QALY concerns the appropriateness of trade-offs between gains in quality of life and length of life. If QALYs are interpreted as measures of psychophysical quantities, then such a trade-off exists by definition, but when we follow Nord’s suggestion and go for individual valuations it becomes an empirical question whether people really are prepared to make such quality/quantity trade-offs under all circumstances. He argues that there is evidence for individuals not being prepared to make such trade-offs when services lead to minor functional improvements and when patients face life-saving procedures.

As Nord points out, most people who use QALYs want them to be applicable across the whole range of health care interventions, so for example they are used to look at the relative cost-per-QALY of hip replacements and heart transplants and conclusions are drawn about where money ought to be spent. QALYs focus on maximising health benefits to individuals and fairness seems to require more of us than that, QALYs need to be based upon the societal value of health care programmes. In chapter six Nord sets out “the person trade-off technique”, which he advocates for ascertaining societal preferences.

Empirically this will work by researchers specifying the characteristics of outcomes of different kinds and asking a representative sample to express the number of people obtaining one kind of outcome that they would regard as equivalent to a given number of people obtaining another outcome.

While I think this is an excellent book, and I recommend it highly, I have two worries about Nord’s approach. First, when thinking about the crucial question of how we can best allocate health resources it is tempting to think that it must be done on the basis of a theory of allocation that can provide us with the definitive answer. Nord thinks there may be something inherently misleading about allocating treatments on the basis of QALYs alone (a very plausible belief). However, many people who actually make decisions about how resources are to be distributed use QALYS, but only as one tool in a process of deciding about what will be funded. A good allocation decision should involve careful deliberation about a number of relevant factors, for example, how urgent the treatment is, and whether the group suffers a disability also, as well as attention to cost-effectiveness. So Nord may be right to argue that the standard QALY is not sufficient for making the right decisions about allocation but I am optimistic that those making these decisions do not make them on the basis of QALY alone.

Second, I am still concerned about what it is we are measuring when we discover individuals’ preferences via the direct person trade-off technique. The assumption seems to be that there is nothing more to ascertaining fairness than getting an accurate picture of what people in general believe about various allocations. Arguing about fairness and justice is a complicated matter and it may well be that people have ill-considered or unjustifiable beliefs about what this amounts to. Furthermore there is no single theory of justice that everyone accepts. Once we assume we have a tool that incorporates societal concerns about fairness then presumably we have the magic key that will unlock resource allocation decisions for us. An advantage of the present situation is that if our health authority makes an allocation decision that we think is unfair or unjust we can apply pressure on them to explain why they think this a just decision. Inevitably when they do this they implicitly or explicitly use one conception of justice or another, but this is something for which they must take responsibility and for which they can accept criticism.

JOHN McMILLAN
Ethox and University College
University of Oxford

www.jmedethics.com
Ethics in Medical Research: A Handbook of Good Practice


Research ethics is a very exciting field at the moment. Important public debate is continuing at national and international levels, concerning the proposed revisions to the Declaration of Helsinki and the Council for the International Organisation of Medical Sciences (CIOMS) guidelines, the proposed European clinical trials directive and the recent Good Clinical Practice guidelines. There is also debate about obtaining, using and storing genetic, and tissue, samples. This ferment has resulted in a wealth of guidelines and learned articles, but as yet there are few useful and up-to-date book-length discussions of the field. This is partly due to the increasing diversity of types of research (including research design), and the variety of the contexts of research (the hospital-based clinical trial is arguably no longer typical of medical research). However, it is also to do with what such a book is supposed to do. Recent works like Baruch Brody’s Ethics of Biomedical Research (OUP, 1998) give, in effect, an analytical commentary on the international guidelines; the classic work by Robert Levine (Ethics and Regulation of Clinical Research, Yale University Press, 1988) gives a philosophical justification for the consensus position that grew up around research ethics in the 1980s, following the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research’s report, (the Belmont Report, 1978), and Don Evans and Martyn Evans seek to link the theory of research ethics to the practice of research ethics review in their A Decent Proposal (John Wiley and Sons, 1996). The new (or even established) researcher or member of a research ethics committee, as distinct from the research ethics specialist, is thus faced with a rather unhelpful literature. A handbook is needed to give them a briefing on the main issues that concern them, to suggest approaches to these issues, and to lay out a framework for analysing research protocols in order to make reasonable and responsible decisions about them. Trevor Smith’s book seeks to be that handbook.

This book covers an impressive range of topics, from epidemiology to xenotransplantation. It is clearly written. Perhaps reading it from cover to cover is not to be advised, as there is no “narrative” (handbooks normally don’t aim at plot!), but as a work to be dipped into it fits the bill. In general, its treatment of the topics it covers is fair and reliable, and for this alone it can be recommended to research ethics committee members.

None the less, this work has its weaknesses. There are good chapters on audit and post-approval monitoring, but these reflect only one solution to these problems, and need more context and discussion. Analytically, this is a work of no great depth, since it concentrates on the pragmatics of review—what questions to ask, and what sorts of answer to look for. This is probably acceptable for clinical trials, in that we are now relatively sophisticated and stable in our collective understanding of this kind of research, at least where the research takes place in the UK. In some of the other areas covered, this degree of simplicity may be misleading. The chapter on xenotransplantation, for instance, is so brief that it cannot reasonably cover the topic or the issues around it in a way that does justice to this highly controversial issue. If a topic like xenotransplantation or gene therapy is to be covered, there is a good case for giving more analytic examination of the issues, in order to account for the lack of consensus, and perhaps to assist the development of one.

There is a general difficulty throughout the book, which Dr Smith makes a number of attempts to resolve. How far should “research ethics review” be attempting to give substantive “ethical” judgments (for example, is embryo research moral or immoral in itself, notwithstanding the consent and licensing arrangements?) This next problem bedevils the research review process itself (it is no failure of Dr Smith’s): is a research ethics committee a bioethics committee, a regulatory committee, a peer review, or something else again? Or, to put it another way, can a research ethics committee restrict itself to consideration of the ethics of process, or must it consider also substantive ethics? It is no criticism of Dr Smith that he does not resolve this problem; his book only makes clear how pressing this difficulty actually is.

Some features of this book will make it vulnerable to change (in particular the chapters on fast-changing areas of medicine, such as genetics, and of the law, such as data protection and personal medical information). None the less, this book will be a useful tool for members of research ethics committees, and researchers planning their projects. Dr Smith is to be congratulated on reducing so much to manageable proportions.

RICHARD E ASHCROFT
Department of Primary Health Care and General Practice, Imperial College, London

Organ Transplants from Executed Prisoners


In Organ Transplants from Executed Prisoners, Louis Palmer proposes alleviating the urgent shortage of organs for transplantation by requiring condemned felons to donate their vital organs after execution. The book proceeds as follows.

In his first chapter Palmer reviews the development of the quasi-property rights relating to the bodies of the dead, including the right to dispose of one’s own body by means of a will and the right of relatives to bury it. In the second chapter, The Market for Human Body Parts, he goes on to review the current American laws restricting the sale of body parts in order to show that death-sentence removal might be permissible within established principles of law. A C MacDonald has recently provided a good review of the legal restrictions placed upon access to organs of the deceased in which he points out that despite the fact that a large pool of potential donors exists, legislators and the public have consistently and severely restricted access to them—with good justification.

In a most remarkable sequence in the same chapter, Palmer goes on to note that in China, where organs are taken from executed prisoners: “The frequency and volume of executions are traced directly to an international black market in human body parts”. This is a telling argument against such practices. Nevertheless, Palmer continues to argue for required organ
removal from executed prisoners—presumably only somebody else’s government can abuse power!

In chapter three, Removing Transplantable Organs of Capital Felons, Palmer argues, in the light of the previous two chapters, for the moral appropriateness of capital punishment and of required organ donation.

The problem with this kind of argument of course is that, even if one accepts capital punishment, it is only appropriate if used in a perfectly fair and accurate fashion. But no system can guarantee this. The present American system certainly cannot and is fraught with error as documented by the exoneration of thirteen (!) prisoners scheduled for execution in the State of Illinois and the recent suspension of executions in that state.2

In the fourth chapter Palmer develops a quasi-scholarly constitutional justification for his organ procurement scheme. And in The Need for a New Method of Execution he argues self-referentially that “Execution by anaesthesia-induced brain-death would prevent destruction of transplantable organs” (page 71), and that this method of execution should therefore be adopted. This too is highly controversial. For whilst it is well known that deep anaesthesia can reversibly mimic brain death it is not the same state. Physicians are always careful to determine brain death in the absence of anaesthetic influence. Thus, while physicians can painlessly remove the heart and other internal organs from an anaesthetised person, that would be unacceptable: an execution performed by physicians. It would have nothing to do with brain death.

In the final chapter Palmer returns to the theme of chapter three and attacks the unfairness of capital punishment—in my view, he should have started and stopped here. Americans have had enough difficulty trying to get capital punishment “right” without introducing issues of secondary gain into the execution process.

Let me present my biases. Major organ transplantation effectively prevents premature death, albeit imperfectly with an expensive technology still under development. Increasing the organ supply is not as important as improving the technology and decreasing the costs of transplantation. But in the pursuit of this important goal we must not trample on other strong moral or medical considerations. Palmer’s arguments for the required use of organ transplants from executed prisoners must be rejected. They wish away centuries of governmental abuse of power. They assume that we can achieve perfect justice in capital punishment—an assumption all experience belies. They treat prisoners differently from others and make prisoners more exposed in their vulnerability, not protected. Finally, they require intimate physician participation in the act of execution.

References
2 Folsheid, Dominique, professor of philosophy at the University of Maine-la-Valle. Whereas Byk is more positive in his approach towards bioethics, Folsheid regards it not simply as “une imposture”, but—yes—as a “monster”.

Byk writes: “Bioethics does not explain and does not categorize the phenomena. It analyses and discusses them, it confronts them with our knowledge as well as with our faith. It trains us to exercise freedom and responsibility, we who are ethically incomplete precisely because ethics is part of our history and our perspective. They urge us to ask ourselves: What are the consequences of our actions? What is the right thing to do? What is the good? What is the bad? What is the just? What is the unjust? What is the right relationship between people and their environment? And in the spirit of perennial questions of ethics—what is good for whom and to what end? What is the purpose of our actions? What is the purpose of our lives? What is the purpose of our society?”

To Byk, bioethics—a field in which he has been a professional expert—is not a branch of study in any traditional way, like biology, sociology or philosophy. His experience underwrites his ability to analyse the nature of the expertise required, an expertise which he keeps at an ironic distance. He sees the ethics committee, so frequently appealed to as the last resort, as the melting pot of several existing orders, whose standardised product is consensus. The expert is the one who knows how to produce the product sought. And, after all, is the product so very bad? Byk ends on a more positive note than Mémethue.

Dominique Folsheid, on the other hand, is positively horrified. Folsheid saluted bioethics in its coming from across the Atlantic, as though it was the salvation of academic philosophy, and in particular of ethics. Welcoming what he thought to be a carrier pigeon, he woke up to having opened his arms to a bat—a chimera with wings like a dove and fur like a rat. Aye, the creature would flap its wings in proof of spirituality—it was after all “ethics”—and display its fur too, to convince “the inhabitants of the american caves” that it was, like them, delightfully beastly—it was “bio-” as well. It would refuse to determine itself as either an ethics of biology or a biology of ethics and remain unclassifiable as anything else but a living claim to be what it in fact comes to devour.
The dramatic language of Folsheid produces a brilliant piece of sarcasm, weird enough to become a classic in—oh well—bioethics.

The politicians Bernard Sellier and Christine Boutin both contribute their perspective on “bioethics”. Actors in the process which, against their will, have made “bioethics” a part of the Code Civil, their keen retrospective criticism also allows us to look forward. The frustration which comes across as a violent appeal must point in the direction opposite to the controlled pluralistic ideology of “la pensée unique”, which makes of bioethics the new framework of a totalitarian populism. The contributions of Jean-Francois Poisson, Michel Schooyans and Lucien Israël reinforce the impression of a book against “bioethics”. But what alternative is offered? Beyond polemics, it is both simpler and more complex than bioethics: it is ethics. METTE LEBECH National University of Ireland, Maynooth, Co Kildare, Ireland

The Nazi War on Cancer


It is interesting, that with the notable exception of the Cologne-based geneticist Benno Müller-Hill, German historians of medicine have not bothered a great deal with looking into German medical history during the Third Reich. We owe Pennsylvania State University’s Robert N Proctor a great deal of gratitude for uncovering this history, and for making it accessible in a highly readable format. Proctor has established himself rapidly as the pre-eminent US American historian of medicine inevitably corrupts scientific inquiry in some fundamental sense. However, it is also important to recognise that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

The politicians Bernard Sellier and Christine Boutin both contribute their perspective on “bioethics”. Actors in the process which, against their will, have made “bioethics” a part of the Code Civil, their keen retrospective criticism also allows us to look forward. The frustration which comes across as a violent appeal must point in the direction opposite to the controlled pluralistic ideology of “la pensée unique”, which makes of bioethics the new framework of a totalitarian populism. The contributions of Jean-Francois Poisson, Michel Schooyans and Lucien Israël reinforce the impression of a book against “bioethics”. But what alternative is offered? Beyond polemics, it is both simpler and more complex than bioethics: it is ethics. METTE LEBECH National University of Ireland, Maynooth, Co Kildare, Ireland

The Nazi War on Cancer


It is interesting, that with the notable exception of the Cologne-based geneticist Benno Müller-Hill, German historians of medicine have not bothered a great deal with looking into German medical history during the Third Reich. We owe Pennsylvania State University’s Robert N Proctor a great deal of gratitude for uncovering this history, and for making it accessible in a highly readable format. Proctor has established himself rapidly as the pre-eminent US American historian of medicine inevitably corrupts scientific inquiry in some fundamental sense. However, it is also important to recognise that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.

It is widely accepted today that ideologically corrupted inquiries can still yield scientifically sound research and research results. As Proctor says: “Nazi inspired research was often idiotic, but not always” (page 257).

One last point Proctor makes is that the Nazi regime’s leading figures ran bitter campaigns against smoking. The regime also established progressive occupational health policies designed to reduce the number of cancers caused by occupational exposure to asbestos, radium and uranium and other carcinogenic materials. The politicians Bernard Sellier and Christine Boutin also fight each other both with regard to the “right” direction of public and occupational health policies.