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QALY MAXIMIZATION AND PEOPLE'S PREFERENCES

After Paul Dolan ET AL

In cost-utility analysis, the numbers of quality-adjusted life years (QALYs) gained are aggregated according to the sum-ranking (or QALY maximization) rule. This required that the social value from health improvements is a simple product of gains in quality of life, length of life and the number of persons treated. The results from a systematic review of the literature suggest that QALY maximization is descriptively flawed. Rather than being linear in quality and length of life, it would seem that social value diminishes in marginal increments of both. And rather than being neutral to the characteristics of people other than their propensity to generate QALYs, the social value of a health improvements seems to be higher if the person has worse lifetime health prospects and higher if that person has dependents. In addition, there is a desire to reduce inequalities in health. However, there are some uncertainties surrounding the results, particularly in relation to what might be affecting the responses, and there is the need for more studies of the general public that attempt to highlight the relative importance of various key factors.

Cost-utility analysis (CUA) seeks to provide health care policy-makers with information on the health benefits associated with alternative resource allocation decisions. Health benefits in CUA are measured in terms of the number of quality-adjusted life years (QALYs) gained. The QALY is a combination of the value of the health states and their duration, and every QALY is equivalent to one year of life in full health. In CUA, the numbers of QALYs gained are aggregated across individual patients according to the sum-ranking (or QALY maximization) rule. This required that the social value from health improvements is a simple product of gains in quality of life, length of life and the number of persons treated.

In this paper, we consider the results of a methodological review of the literature concerning the de facto standard in CUA that the sole objective of health care is to maximize the number of QALYs gained, irrespective of who those QALYs go to and how they are distributed across society. The objective of the review is to search for studies where different ways in which the descriptive validity of this de facto standard is examined. We then seek to draw some general patterns that emerge from the data and to suggest where future research efforts might be directed. In what follows, we describe the basis of QALY maximization and present the questions addressed in the review. Next we describe the literature search and some descriptive data on the papers reviewed. Subsequent sections open with the theoretical literature on each item, and then report the evidence from the review. Finally, we discuss some of the problems with interpreting the results and the implications of the results for future empirical research. In the simplest case, with no uncertainty and no changes in health over time, and individual's health gain from treatment, QALY_G, can be represented as

$$\text{QALY}_G = T_1Q_1 - T_0Q_0$$

where T is the number of years, Q represents health state values, and the subscripts 1 and 0 represents health with and without treatment, respectively.

Discussion

This review has shown that an increasing number of studies are looking at the descriptive validity of the QALY maximization rule. In relation to *the linear additivity of quality and length of life*, there seems to be a diminishing marginal social value associated with changes in both Q and T. However, very few of the studies have properly controlled for the possibility that people's preferences may have been contaminated by the belief that there is a diminishing marginal value to incremental health benefits. Some studies focusing on quality of life, like that of Nord and Dolan, have explicitly told respondents that the more severely ill patients will gain less benefit from treatment than the less severely ill patients, but more could be done in future studies to get respondents to really appreciate the interval properties of health state valuation scales. For example, respondents could be asked to identify two treatments that they consider to bring about the same individual benefit but which start and finish at different points on the valuation range. Only then would they be asked to consider the social value of these treatments. This is somewhat similar to the design adopted by Doland and Green. In a similar way, studies that have looked at the linear additivity of life years might have been contaminated by decreasing marginal utility of life years, and possibly even by positive time preference. So, again, future studies should first seek to establish that the duration of individual benefits are considered identical before proceeding to the evaluation of social benefits.

In relation to *the value of life years at different ages*, there have been some studies that suggest that all ages should be treated equally but the majority of the empirical evidence is supportive of giving lesser weight to older people. Whilst perceived differences in productivity across age groups alone are unlikely to have explained the results in these studies, it is often difficult to tell how much of the preference for the young is due to the benefits to the young being greater (or being perceived to be greater) and how much is due to the young having lived for less time. The former explanation is consistent with the QALY maximization rule while the latter is consistent with the 'fair innings' arguments. One possible way to do control for health benefits might be to ask respondents to compare different ages when the benefits do differ, and then to ask them the same question when the benefits are the same; in this way, the difference between what they are being asked to do and what they might naturally do (i.e. answer in a way consistent with the first question) is made explicit.

Regarding the *importance of other characteristics,* there is some evidence to support the view that people who are considered to be responsible for their ill health should be given lower priority, but this is never a majority view, and it is certainly an issue that generates much controversy. There is a greater consensus, insofar as there is majority support, for the idea that we should discriminate in favour of those with dependants. The evidence pertaining to peoples' preferences about *inequalities in health* suggests that there is a clear preference for reducing inequalities in health when they are described according to socio-economic status, but no real desire to when they are described according to gender. Finally, in terms of the questions addressed in this review, there is evidence that people are not indifferent concerning *the distribution of a fixed benefit*. Generally, they prefer to disperse benefits as widely as possible but, if the benefits going to any one individual are considered to be too small, they prefer to concentrate benefits amongst fewer people instead. The possibility of threshold effects - where health benefits and/or the final level of health are considered to be too small to give priority to - seem to be pervasive amongst many of the studies reported here (e.g. also in relation to the linearity additivity of *Q* and *T*), and so it really is important that empirical research is directed at this issue.

Overall, many empirical studies have been undertaken to look at the societal value of health gains. Most of these studies have used relatively small samples and, to enhance the policy usefulness of the results, we would welcome more large-scale general population studies. However, given that people's preferences are partly constructed during the process of elicitation, such studies must also make some attempts to 'get behind the numbers' so that we can be much clearer than hitherto about what preferences are the result of concerns for equity and what are the results of extraneous factors. It has not been possible from this review to draw any real conclusions about the weight given to these considerations relative to one another. This is because respondents have typically been asked to weigh only one factor at a time against health gain and have rarely been asked to consider more than one factor simultaneously. Moreover, very few studies have actually tried to estimate weights for those factors that a simple QALY maximization rule might be traded-off against. Therefore, our main recommendation would be for a coherent research programme that attempted to provide some very general conclusions about the relative importance of various key factors and then perhaps to elicit some general weights for them.

BECOMING A CYBORG: SOME ETHICAL AND LEGAL IMPLICATIONS OF ICT IMPLANTS

(Information and Communication Technology)

A common complaint about ethics is it does not keep up with technology. Implicit in the remark is the suggestion that ethics could keep up with technology if only ethicists, policy-makers, legislators, clergy, or perhaps people in general would think about ethics more. To an extent this suggestion is correct. We should do our best to anticipate technological change and put policies in place to accommodate it. But ultimately ethics will always lag behind. We cannot foresee all technological changes and consequences accurately or precisely. We possess well-established ethical concepts and principles, but application of ethics requires interpretation and analysis of situations as well as knowledge of concepts and principles. When new technology generates novel situations, as it usually does we need to access fresh what we should do. Hence, we should expect that setting ethical and legal polices for ICT implants will be a dynamic enterprise. We can and should begin to frame such policies, but we must remind ourselves that the job will be ongoing. I expect ICT implants to be an evolving growth industry that will require the generation and reevaluation of ethical and legal policies for decades, if not centuries, to come, we are now only beginning on what will be a long journey.

What is special about ICT implants as opposed to implants in general or to genetic manipulation? The answer lies at what is the heart of information communications technology – the computer. Computers whether they be massive machines or nanochips are in principle universal machines. They are logically malleable both syntactically and semantically. We can alter their programs and we can redefine what their states represent. Although there are well known logical limits to computers, practically speaking the limits of their application depend largely on our imaginations. Implanting ICT devices will give humans functionality well beyond what they currently have or could ever have through traditional transplants or genetic manipulations. ICT implants provide us with colossal opportunities for improved and novel capabilities. But, they will also be a continual source of policy vacuums.

What difference does it make if the ICT occurs inside the body or outside? Isn't ICT the same wherever it occurs? The difference is that psychologically and socially we typically take out bodies as defining our boundaries as persons. We base many of our customs and laws on this assumption. As an example, consider a situation in which a patient requests a doctor to turn off a pacemaker located outside the patient's body. Such a request is generally regarded as a refusal of treatment and doctors in the United States are obligated to follow the patient's request. This is regarded as allowing the patient to die, but not killing the patient which is illegal in the US. But now suppose the pacemaker is located inside the patient's body and he makes the same request. Is a doctor obliged to follow the patient's request? Should shifting the pacemaker from outside the patient to inside the patient make an ethical or legal difference?

What ethical principles should we follow when considering whether to allow ICT implants? Most people agree that ICT implants used for therapeutic purposes are acceptable. Hundreds of thousands of people have had cardiac pacemakers or defibrillators implanted. Significant progress is being made in developing bionic eyes. Interestingly, there has been some reluctance among some in the deaf community toward cochlear implants. This illustrates that a device that is taken to be therapeutic by some may be regarded as enhancing by others. In fact, often devices that are the therapeutic have some enhancing aspects. An implant that picks up a paralyzed patient's brain pattern may allow him to operate a computer, but it also gives him the unusual capacity to manipulate physical objects in the world by merely using his though patterns.

Beyond therapeutic applications, I wish to argue that a principle of autonomy should give people a broad choice of ICT implants, even those that are clearly enhancing. But the principle of autonomy does not override all considerations. Considerations which may trump autonomy are health, duty (for example, the duty of a parent), privacy, control, and fairness.

BRAIN IMPLANTS SCIENTIFIC OVERVIEW AND ETHICAL ASPECTS

Neurosurgery is familiar with brain and peripheral implants at the level of the spinal cord and nerves.

Nerve trunk stimulation is on study for paraplegic patients (SUAW project: stand-up and walk) with some promising results. Vagus nerve stimulation (VNS) in intractable epilepsy is commonly used. VNS is also starting in treatment-resistant depressions. Spinal cord stimulation is daily used for peripheral pain relief. Some experimental studies have been conducted for getting advantage of the sympathetic effect of spinal cord stimulation in lower limbs arteriopathies. Those implants don't raise big ethical controversies.

Brain stimulation may be made through cortical stimulation (at the surface of the brain) or through deep brain stimulation with implanted electrodes. Electrodes at the surface of the brain are used for recording electrical activity in refractory epilepsy with the aim to localize the epileptic focus that could be treated by neurosurgery. They are also used for brain stimulation in the treatment of severe chronic pain so as for the localization of the motor strip during neurosurgical procedures ineloquent areas of the brain. Those activities don't raise much ethical debate.

But when we enter the field of deep brain stimulation we open a delicate window, not for Parkinson disease, but for other indications. For Parkinson disease, it is evident that, in the present time, deep brain electrodes into the subthalamic nucleus with selective stimulation offer the best choice for those patients who have no relief from medical treatment. A few years ago, we had great hope in fetal cells grafting that was stopped because of few long-lasting results. But the expectation to get other cells (stemcells for example) in the future remains a great hope since with deep brain stimulation, we treat the symptoms but not the illness itself that could be repaired by cell transplantation. But, when implanting those electrodes in the deep thalamus, some colleagues have observed, by hazard a positive effect on obesity. In the present time, no date have been published but that could be a very important scientific and ethical topic.

What is on the way in the present time is long-term electrical capsular stimulation in patients with obsessive-compulsive disorder. Psychoneurosurgery has been performed in the past for several psychiatric disorders like schizophrenia, depression, anxiety, OCD for the main indications. The procedure was prefrontal leucotomy. The often unacceptable side effects of this treatment and the advent of psychotropic drugs, led to waning enthusiasm for psychosurgery. By the way, ethics became more and more important in our daily life and leucotomy is no more acceptable in the present time. Unfortunately, the prognosis of treatment-resistant affective disorders and OCD are quite poor, so these patients and their families are burdened with extreme emotional and psychic costs, as well as marked suicide risks. Therefore there has recently been a renaissance of interest in surgical approaches to psychiatric disease with new targets like the cingulum, limbic lobe or the anterior limb of the internal capsule and techniques (stereotactic capsulotomy, Gamma Knife capsulotomy or long-term electrical capsular stimulation). These procedures required a severe ethical control. One should also take advantage of modern neuroimaging in the definition of the pathoanatomic basis of mental disorders. The interest in deep brain stimulation is the reversible effect which is very important in psychomodulation. New minimally invasive or non invasive procedures based on functional imaging and an improved knowledge of psychiatric disease may use neuroaugmentive or transplantation methods. These new methods may change the attitude of governments, psychiatrists, third-party payers, and society which still equate psychoneurosurgery with the destructive procedures of the past. Randomized blinded prospective studies across European centers using standardized assessments tools should be encouraged. Furthermore, one should also focus in the future on studies which could protect the society against criminal pedophilia and sexual disorders of people relaxed from jails. That cannot be made without strong ethical guidelines.

Nerve trunk stimulation and Spinal cord stimulation are not a source of big ethical debate as opposed to Brain stimulation either through cortical or deep brain electrodes. Cortical electrodes are used for epilepsy recording in the preoperative planning. Cortical stimulation is routinely used for the localizaton of motor strip during neurosurgery in eloquent areas or as a treatment for chronic pain relief with implanted electrodes at the surface of the brain. But the main brain implants we should discuss to day are deep brain stimulation for Parkinson diseases and almost other indications like Obsessive-Compulsive Disorder (OCD) and perhaps in Obesity and in some sexual delinquents.

Those aspects raise ethical debate.

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