

EMBEDDING ETHICS IN QALYs

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1. INTRODUCTION

Psychoanalysis is an impossible profession and sometimes it's more difficult than other times.

Same is true of the ethics of allocation of and access to healthcare resources, especially very expensive ones.

Deciding on the ethics of allocation of and access to scarce healthcare resources is an impossible task and sometimes it's more difficult than other times.

QALYs raise ethical issues because they are concerned with the allocation of and access to healthcare resources.

So, how do we decide what is ethical and what is not?

Basically by asking a series of questions and trying to include as many as possible of the right questions.

2. "DOING ETHICS"

So, let me briefly describe the **broad structure**

we use to try to make good ethical decisions.

Need to look at both **principles and process**.

Basically **two bases for finding ethics**:

Principle based
Cf. Utilitarian

Principle based or deontological ethicists:

Is it **inherently wrong**?

If so, doing good is not a justification:
the ends do not justify the means.

Utilitarian ethicists start by asking:

Do benefits and potential benefits
outweigh the risks and harms?

If yes, conduct seen as ethical
despite its risks and harms:

Ends justify means.

Whichever base one uses, very briefly, ethical analysis involves the following steps:

i). Identify all **ethically relevant facts**.

Good facts are necessary for good ethics.

But what constitutes **facts re:**

QALYs,
situations that involve QALYs,
and how those **facts are used**?

Statistical facts are statistically true for a **class of persons**,
not true for any given **individual**.

How are QALYs **assessed**?

Judging “quality of life” can be controversial ethically

Is the **method of assessment** ethical?

Is the **range of facts** taken into account ethical?

Too narrow?

Too broad?

How are “facts” **used**?

How do physicians **decide in practice**?

Role of evidence based medicine

Cf. primary obligation of personal care

In order to obtain patients’ **informed consent** must physicians disclose treatments that are not funded because they did not reach the QALY cost-effectiveness threshold for those patients?

ii). **Identify all the values** relevant to those facts.

Respect for life, respect for individuals’ autonomy and self-determination, relieving suffering, saving lives, advancing science, saving costs to healthcare system, justice and so on.

iii). **Identify any conflicts of values.**

No conflict and all values can be honoured then no ethical problem

Conflict, for example, between prolonging life and limiting cost to the healthcare system

iv). **Prioritize conflicting values.**

Disagree on priorities.

Patient or family wants to give priority to providing **all possible life-prolonging treatment**, hospital or healthcare funder wants to **limit costs**

v). **Ethically justify the priority adopted.**

Respect for life most important value and **failure to provide treatment is to disrespect life**

Refusing treatment because of cost puts a **price on human life**
- not worth more than a certain amount

But is there a difference between putting a price on treatment and putting a price on life?

Respect for the individual’s **autonomy and self-determination**

Cf.

Justice indicates treatment should not be provided; rather resources should be used elsewhere for other patients.

Is a QALY assessment an ethical justification?

If yes, by itself or only with other justifications present?

3. ETHICAL DECISION MAKING PROCESS

i) Who decides on QALYs?

ii) Using which criteria?

i) Who exercises discretion?

Public consultation

Physicians

Patients

Committees

Regulatory bodies

Insurers

Governments

Are they appropriate persons or bodies ethically?

Are they subject to the same limitations
they impose on others?

Consider politicians and their families

- should be limited to using the same healthcare
system they choose for other citizens.

Committee agrees to decision no one individual would take.

Is the exercise of the discretion safeguarded?

Avoiding conflict of interest

“Physician gatekeepers”

“positive” gate-keeping

“negative” gatekeeping

“de facto” gate-keeping

- physicians allocate approx 80 percent healthcare resources

Guardian moral syndrome cf. commercial moral syndrome.
Problem of mixed ethical system – pharmaceutical industry.

ii) Using which criteria – that is, on what basis?

QALYs are cost effectiveness/health economics based.
Here's what ethicist Daniel Sulmasy has to say about cost-effectiveness assessment:

“CEA is not a morally neutral way to make allocation decisions. It is not rationality itself. Rather, it represents a particular view about the rational that **prizes efficiency over fidelity and outcome over process. It assumes one can commensurate everything that human beings value in monetary terms.** As MacIntyre states, CEA has the argumentative form of utilitarianism. ...

Skepticism about the ethics of CEA does not entail skepticism about the usefulness of engaging in formal decision analysis for individual patients, the value of outcomes, or the value of efficiency. A critic of CEA might very well believe that consequences count, but hold that **other things in addition to the net cost-effectiveness ratio ought to be considered** to determine the right and just decision. ...

As Rawls has remarked, “utilitarianism does not take seriously the distinction between persons.”

Daniel Sulmasy

Physician decides what treatment to offer an individual
- personal identification with the individual
Cf. decide for a group what treatment to offer - QALYs

It is not ethical to bring the resource question to bear at the individual level as a primary consideration.

Is it not ethical not to bring the resource question to bear at the collective level – justice requires it.

Not either/or situation or choice of decision-making process:
need both individual and collective decision-making
i.e. art and science of medicine.

Sulmasy suggests common sense (classically, “art”) deals with individuals and CEA with the science of medicine.

To ensure ethics need to use all our “human ways of knowing”

Recent talk of "cost effectiveness"

Cf. "comparative effectiveness"

probably to avoid the word “cost” which raises
alarm and activates moral intuitions re the
ethics governing the decision making

Amount cut-off

Cap \$50,000 (not adjusted for inflation)

per quality adjusted life year

cf. legal cap on damages for pain and suffering
adjusted for inflation

Is QALY amount arbitrary?

Basis for choosing it?

Can limit be ethically justified?

Features of decision making that can make a limit seem
more or less ethical can be manipulated.

4. IMPACT OF FEATURES OF THE DECISION-MAKING PROCESS

Features of decision-making process can affect how we see a
decision, including ethically

Yacht lost at sea cf. level crossing accidents

Hidden decision-making, hidden decision makers,

indirect impact on important values and so on.

Putting a price on life affects important shared values

But to repeat a question asked before, can we put a price on treatment without putting a price on life?

5. BASIC PRESUMPTIONS

Although we don't always recognize it, all of our decision making always starts from a **basic presumption and the basic presumption chosen can affect the decision outcome, because when we are in equal doubt as to the ethically correct decision the basic presumption governs.**

What is the **ethical choice of basic presumption?**

That depends on who should have **burden of proof** with respect to either **gaining or denying access to treatment.**

Four basic presumptions:

i) **“No”.**

The drug will not be made available.

ii) **“No, unless...”**

The drug will not be made available, unless...

This presumption makes the frugal choice the default position

iii) **“Yes, but...”**

The drug will be made available, but not if...

This presumption makes the generous choice the default position.

iv) **“Yes”**

The drug will be made available.

The person relying on the exception – the “unless” or the “but” has the burden of proof of the exception.

So in cases of equal doubt as to whether an exception applies, the patient will get the drug under a “yes, but” basic presumption, but will be refused it, in exactly the same circumstances, under a “no, unless” basic presumption.

If basic presumption used is “no”, can argue that ethically must provide for an unless,
that is, an exception in individual cases.

This links to whether, ethically, decision-making should be based on objective criteria or subjective ones, or both.

6. OBJECTIVITY cf. SUBJECTIVITY

Often assume former more ethical, but is it?

How do we make decisions about ethics?

Recent articles in Nature:

“The Moral Brain” – emotional component in good moral decision-making.

People with damage to their emotional centres could not make good moral decisions.

Damage to frontal cortex – “overly utilitarian decisions”

Again, not an either/or situation

need both types of assessment for good ethics in allocation of and access to treatment

To repeat, **to ensure ethics need to use all our “human ways of knowing”**

And **physicians’ primary obligations of personal care** to each patient as compared with their secondary obligations to other patients and society to conserve healthcare resources mean we need both kinds of assessment.

UK seems to have recognized this in their latest approach:

The National Institute for Health and Clinical Excellence (NICE) has asked its appraisal committees to consider “survival benefits” when evaluating end-of-life medicines that fail to successfully pass the institute's cost-effectiveness evaluation, that is,

to look further than the basic health-economics model and give greater consideration to survival benefits when evaluating end-of-life medicines.

But only for patient's not expected to live more 24 months, where the treatment will extend life by at least 3 months, and the patient population is small.

Criticisms have been that this approach could involve arbitrary decision making. That means some safeguards are needed if decisions are to be ethical. One such safeguard, is avoiding conflict of interest.

7. LEVELS OF DOING ETHICS

Micro	individual
Meso	institutional
Macro	societal
Mega	global

Conflict between levels

QALYs function at the institutional and societal levels and can be in conflict with rights of patients and obligations of physicians at the individual level.

8. JUSTICE

Unfairness of QALYs to certain groups
- terminally ill and disabled people

This is probably another reason the UK approach makes a subjective exception
“no, unless...”

Discrimination

People with rare diseases have argued that they are discriminated against re treatment development.

The UK “small population” criterion for access brings forward the opposite claim: that where a drug would be widely used it might be

too expensive to make it available and, in the interests of fairness, no one would get it.

I've had an experience in this regard: I sat on a COHTA committee to decide who should get cardiac assist devices (around \$55,000 each). The committee decided to fund 50 a year and leave it at that. First come first served can be the most ethical way to proceed (but people find it hard to accept) and the larger question is how to ethically justify the 50 limit.

9. MAJOR FUTURE ISSUES FOR ETHICS

Major future issues for ethics:

- Complexity
- Uncertainty
- Potentiality

QALYs has them all.