Individualised and personalised QALYs in exceptional treatment decisions

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ABSTRACT
Quality-adjusted life years (QALYs) are used to determine how to allocate resources to health programmes or to treatments within those programmes in order to gain maximum utility from those limited, shared healthcare resources. However, if we use those same population-based QALYs when faced with individual treatment decisions we may act unjustly in relation to that individual or in relation to the wider population. A treatment with a population-based incremental cost-effectiveness ratio beyond our willingness to pay threshold may be denied to a patient even if, for that particular patient, the QALYs gained for the cost would fall within that threshold. When considering individual cases, it is proposed that we should take an individualised approach to the cost of treatment and response to treatment (‘individualised QALYs’) and a personalised approach to the valuation of health states (‘personalised QALYs’). Only if we do this, can we maximise utility and give the patient a fair opportunity to benefit. Individualised and personalised QALYs also allow us to express patient choice and religious treatment preferences in terms of utility. Individualised and personalised QALYs are explored in the context of individual funding requests in the National Health Service. In preference to the concept of ‘clinical exceptionality’, individualised and personalised QALYs provide the potential for better and more consistent decisions and improved utility. Rather than treating unequal patients as if they were equal, individualised and personalised QALYs promote fair and unequal access to resources for some of our most unequal patients. Potential challenges are also considered.

INTRODUCTION
While the health economist or policy maker may focus on determining the most effective treatments for a population, it is inevitably not an amorphous collective population that feels the effect of such policies, but individual members of that population who may find that a treatment that could benefit them not made available. In focusing on maximising utility for the population, there may be insufficient attention paid to individual utility.

Debates about quality-adjusted life years (QALYs) have sometimes made reference to their potential role in relation to treatment decisions for individual patients. In some cases, this has been included as one category of possible uses of QALYs, but one that has then remained relatively undeveloped. In other cases, the conclusion has been drawn that using QALYs for individual patient treatment decisions is ethically questionable or impractical. However, doctors continue to experience the consequences of QALY-based policies in their interactions with individual patients and the desire to use QALYs in these circumstances refuses to go away completely. In this article, I consider how QALYs could be used in the National Health Service (NHS) in relation to requests for ‘exceptional’ patients to access treatments that are generally not approved for state provision. These decisions present us with a practical opportunity (or perhaps even a requirement) to develop QALY assessments for individual patients or to use QALYs as a conceptual tool to improve individual decision making.

INDIVIDUALISATION
Individualised QALYs
In practice, QALY cost-effectiveness assessments are based on population-level information: the average benefit of the treatment compared with its average cost. While this may be an effective way of making macro resource allocation decisions—deciding which health programmes or which treatments to support—we should not generalise from population averages to individuals. I use the term ‘individualised QALY’ to describe a QALY assessment that takes account of the benefits of treatment for a specific individual.

QALYs measure the accumulated net benefit of treatment rather than short-term response to treatment. However, for many treatments degree of response is a predictor of longer-term benefit (and in even more cases, lack of response is a predictor of poor QALY benefit). As it would take years to assess long-term accumulated benefit, I will focus on scenarios where response is a good proxy.

Policy makers will not approve certain treatments for state provision based on average QALY gains for the cost even though some individual patients may have above-average gains for below-average cost. For such patients, an individualised QALY assessment may actually fall within our willingness to pay (WTP) threshold and, I argue that such patients should be able to access the generally prohibited treatment.

The distribution of benefits of treatment can vary widely and, as I will discuss later, I am particularly interested in cases at the edges of that distribution. A patient who achieves double the average survival time will have half the cost per QALY. If that treatment is not approved for the general population because it costs £50 000 to gain a QALY (and our WTP is perhaps £30 000 per QALY); for the exceptional patient costing £25 000 per QALY it would be unjust to refuse the treatment. Otherwise, we will support other treatments for other patients that are no more cost-effective—and our exceptional patient would be unfairly denied his or her

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fair share of our limited healthcare resources; and we would fail to maximise utility.

However, an individualised QALY assessment is only useful if it can be done before treatment commences or at an early stage of treatment. It is not very helpful to identify after the end of treatment that the patient had an unusually good response to treatment; we need predictors of good response. Sometimes there are genetic or physiological markers that are associated with a particularly good response. In other cases, the response can be identified at an early stage of treatment and a decision can then be taken to continue or cease treatment. At whatever stage it is possible to estimate individualised QALYs, such an assessment would help us to maximise utility.

**Individualised cost**

Better than average response to treatment is one aspect of individualisation, but there may also be average response to treatment for below-average cost. Often response and cost can overlap: if a patient responds unusually well this may be less costly—a shorter course of treatment, lower drug dose or less intensive treatment. We could choose to assess the individualised response or the individualised cost and, in either case, the result might justify treatment. However, in some cases, the cost can be considered independently.

There are cases where reduced cost of treatment is straightforward to quantify, for example, drugs with dose dependent on the surface area or weight of the patient. In calculating average QALY benefits, the cost for a theoretical standard patient is used. If this standard patient is assumed to weigh 70 kg, then the 55 kg patient’s drug cost will be 21% lower. If we were to individualise the cost per QALY, we might bring a treatment that is generally above our WTP to within that limit; and in such a case, the individualised treatment cost would be known before the commencement of treatment.

Without individualised QALYs, we treat unequal people as if they are equal. Patients who have high costs or a poor response will consume a disproportionately high share of shared resources compared with patients who have lower costs or a better response to treatment. It is unfair to the wider population to treat the patient with a poor individualised QALY and it is unfair to the patient with the unusually good individualised QALY not to offer treatment.

**Individualised incremental cost-effectiveness**

Having discussed individualised response and individualised cost, there is another aspect to individualisation that is particularly significant in relation to patients who respond poorly to standard treatment.

The incremental cost-effectiveness ratio (ICER) is used to compare treatments so that while two treatments may both fall within a WTP threshold, only the most cost-effective treatment will be supported. The QALY ICER is affected by the cost-effectiveness of the treatment with which we are concerned and by the cost-effectiveness of the alternative treatments.

Until now I appear to have condemned patients with a poor response to the withdrawal of treatment, but the individualised approach may offer hope for such patients. For the poor-responding patient, the QALY ICER of the standard treatment may fall outside our WTP. However, that could mean that the QALY ICER of a more expensive treatment that would normally be deemed to offer relatively poor value for money might, in relation to that patient, be regarded as a cost-effective option.

There is a challenge to be faced in relation to obtaining precise individualised cost and QALY data, particularly in advance of treatment or early in treatment. This may be possible where cost is clearly identifiable or where response is measurable and is a good predictor of longer-term prognosis. In such instances, cost per QALY would not have to be recalculated from scratch—one could adjust the standard calculation for the individual patient. To do this, it would be necessary for National Institute for Health and Care Excellence (NICE) to publish the full cost and QALY calculation. This would allow the individual data on predicted cost or predicted outcome to be inserted in place of the population-based data. Without this, a broad estimate of the impact of the individual data on cost or QALYs may still be possible and we may find that this less precise assessment would be sufficient as we only need to determine on which side of our WTP threshold an individual case would fall—precision beyond this is unnecessary. Even beyond this, there may be value in using individualisation as a conceptual tool to support decision making, as will be discussed later.

**PERSONALISATION**

**Personalised QALYs**

Personalised QALYs similarly respond to the criticism of the application to individuals of population-wide QALY calculations, but instead of considering the costs and responses of individuals to treatment, I use the term ‘personalised QALY’ to describe a QALY that reflects a personal valuation of the quality of different health states.

If we do not personalise QALYs, we assume that each person’s quality valuation of health states is the same, but this is not the case. In some instances, these differences relate to an inconsistency in quality valuation at different times because of changes in perspective. However, people will also genuinely value states of health differently and, in order to maximise utility, we should allow for a personalised weighting of those health states to be reflected in a QALY ICER assessment. I draw a distinction between individualised and personalised QALYs because individualised QALYs are objectively verifiable—response to treatment and cost of treatment for the individual can be known; whereas personalised QALYs are difficult to assess and I will address this later.

For illustrative purposes, the loss of the fourth finger of the left hand would not be deemed to have a significant impact on quality of life under population-wide QALY assessments, but for a concert violinist whose career and personal pleasure is dependent on this finger, the quality weighting for life years without this finger might be significantly lower and therefore the QALY benefit of treatment to preserve that finger would be significantly greater than the population-based QALY would suggest. Similarly, hearing impairment might have a greater adverse impact on quality of life for the violinist than the population average.

Musicianship may not sound significant enough to use as a reason to personalise QALYs; we might think that a true personalised weighting should be related to more fundamental functions or activities of everyday life. As an example, the EQ-5D model includes, ‘mobility, self-care, usual activities, pain/discomfort and anxiety/depression’. We might expect less variation in people’s quality valuations of such basic functions, but there would still be some variation and this should be reflected in personalised QALYs; some functions would be more significant for some people than for others. Furthermore, the ‘usual activities’ dimension does include ‘work, study, housework, leisure activities’ and this would generate significant variation in cases such as that of my violinist. We should not prevent an individual
accessing a particular treatment because the population average quality valuation is different from their own.

**Personalised QALYs and patient choice**

It could be argued that personalised QALY assessments operate in a crude way at the doctor–patient interface when discussing treatment choices: patients will take decisions on whether to accept or continue treatment, given their personal views of the impact on quality of life. For example, there are a variety of treatment options for prostate cancer: open, laparoscopic or robotic prostatectomy; external radiotherapy or brachytherapy; active surveillance, chemotherapy and hormone therapy. If we were only interested in population-based utility, we would allow the stage of disease and likelihood of progression to determine the treatment according to the QALY ICERs. However, these treatment options also have different risks to varying degrees, such as urinary incontinence, difficulties in passing urine, faecal incontinence and impotence. Patients have different views on the relative importance of these and we allow these views to have an influence on the selection of treatment against the strict interests of population-based QALY utility. We may conventionally regard this simply as an example of patient autonomy, but we could also regard patient treatment choices as crude personalised quality assessments. The difference between respecting patient choice and a personalised QALY assessment is that we cannot quantify a threshold for permissible choice and link it to utility. If, however, we were to convert a treatment preference to a formal personalised QALY assessment, by revaluing the QALY for each treatment according to the patient’s individual valuation of health states, we could link patient choice to utility. We would allow patients to choose a treatment according to personalised QALYs only if the resulting QALY ICER was within our WTP. A patient with a very low personalised quality weighting for impotence might fairly access resources to support that valuation and receive a treatment that minimises the risk of their unfavoured outcome, whereas a patient with less concern about impotence, but a very low personalised quality weighting for faecal incontinence would be able to access a different treatment. However, some preferences might have insufficient personalised weighting to meet the WTP threshold and in such cases, treatment should not be approved simply on the grounds of ‘choice’.

Personalisation of QALYs provides us with a justification for respecting patient choice within a principle of utility maximisation. Otherwise, we would

1. reject patient choice because it compromises utility;
2. develop an indemonstrable rule-utilitarian justification by, for example, proposing that utility is maximised in the long term if we respect patient choice as this creates a system where patients engage better with healthcare;
3. add an additional, unquantifiable principle of ‘respect patient choice’ to our utility principle when making treatment decisions. Re-describing ‘patient choice’ as ‘personalised QALYs’ allows us to offer choice and maximise utility without having to invoke another principle. It also has the advantage of allowing us to distinguish between patient choice that should determine treatment (where the personalised QALY ICER is within the general WTP) and choice that we consider insufficient (where the personalised QALY ICER is outside the WTP).

The calculation of personalised QALYs is more difficult than the calculation of individualised QALYs. However, as noted previously, a less precise assessment might be sufficient as we only need to determine on which side of our WTP threshold an individual case would fall. There may also be value in using personalisation as a conceptual tool to support decision making, as will be discussed later.

**Personalised QALYs and religiously motivated treatment preferences**

An interesting category of personalised QALY relates to objections to treatment on religious grounds. In such cases, the personalised quality weighting may not relate to the health state achieved by treatment, but to the quality disadvantage of the treatment itself. Years gained by a treatment that contravenes a religious prohibition will have a lower personalised quality weighting than those gained by a treatment that is compatible with the patient’s religious views.

I will illustrate this with the case of a Jehovah’s Witness wishing to avoid blood transfusion. The reason for selecting this example is that even where there are clear prohibitions in other religions, such as a ban on accepting porcine-origin medicines, most religions allow such prohibitions to be set to one side in cases of dire necessity or to save a human life. It is sometimes even the case that strict adherence to the normal rules in life and death cases is itself regarded as wrong. For the Jehovah’s Witness, however, there is no exception to be made in a case of dire necessity.

If we ask a Jehovah’s Witness to personalise QALYs, we would find that the years of life gained by blood transfusion would have a zero quality weighting—the patient’s personalised valuation would be to choose no years of life over any years of life gained by such treatment. A treatment that avoids blood transfusion would therefore have a significant personalised QALY ICER advantage.

A patient with no religious objection to blood transfusion and a personalised QALY valuation in line with the population average should be given blood transfusion in preference to more expensive alternative treatments. However, for the Jehovah’s Witness an outcome following blood transfusion would be valued at zero personalised QALYs (or possibly a negative value—a state worse than death) and the next most cost-effective treatment should be provided as long as the QALY ICER is within our WTP. In calculating this, we do not give the Jehovah’s Witness patient any additional quality weighting for the benefits of the non-transfusion treatment. The difference between the Jehovah’s Witness patient and the ‘other’ patient is not in the personalised QALY valuation associated with the religiously acceptable treatment, it is in the valuation associated with the unacceptable treatment and therefore the QALY ICER that the acceptable treatment gives relative to that unacceptable treatment.

This example treats the religious objection as so fundamental that for a Jehovah’s Witness a life lived after a blood transfusion would have no value. There may be many years of life with a rewarding job, warm family relationships, great charitable deeds and so on, but we would apparently be saying that for the patient this life would have no value. This would be better explained as attributing a positive value to those life years, but overriding this in our personalised QALY assessment with a negative value attributed to the means by which those years were obtained. While this may seem remarkable to someone from outside this faith, this is, in effect, the position of the Jehovah’s Witness patient who refuses a transfusion, accepting the risk that he or she may die without treatment.

This Jehovah’s Witness example has an extreme effect on the QALY of the standard treatment; in most other circumstances, personalised QALY valuations would result in much smaller shifts in overall QALYs ICERs. I am not promoting the interests.
of Jehovah’s Witnesses or any other groups above those of anyone else. I argue that all of us should be entitled to have our personalised quality valuations recognised and that to do so actually supports utility maximisation. We should all be entitled to support from our shared healthcare system according to our personalised QALYs, not find our access denied because we are unequal and value things unequally. Therefore, the personalised QALY approach gives an ethical justification for respecting the Jehovah’s Witness’ religious views and provides reassurance for patients of other faiths or no faith that this is fair in that they could expect their own quality valuations to be similarly considered. In this manner, the personalised QALY approach is different in principle than saying that for the Jehovah’s Witness transfusion is a treatment option that is not available—using the latter construct, we would need to be able to defend to other patients why this was something special that we would take into account, but if we consider this as a personalised QALY we allow a common principle to apply to all patients.

Without personalised QALYs, the consequentialist response to a Jehovah’s Witness’s request for a religiously acceptable treatment would be to refuse that request if it would result in lower utility for the cost. This response could be moderated if we accept that utility alone is insufficient to determine treatment selection, but we would then have to introduce unquantifiable ‘respect for religion’ as an additional principle. Personalised QALYs enable us to justify some religious treatment choices on grounds of utility maximisation without needing to introduce another principle.

INDIVIDUAL FUNDING REQUESTS IN THE NHS

Individualised and personalised QALYs have most relevance where individual decisions to treat or not to treat are to be made, and the population-based QALY assessment shows the treatment to be close to the WTP (either above or below). NICE is responsible for assessing the clinical utility and cost-effectiveness of treatments for use in the NHS in England. The key determinant of these decisions is QALY-based incremental cost-effectiveness with a WTP of about £30 000 per QALY and this is used across all health conditions. However, if NICE has not yet considered a particular treatment or even if it has recommended that the treatment is not provided, an individual patient may still request that treatment. A blanket ban on a treatment is not permitted; instead, the legal position is that patient—by NHS commissioning organisations via ‘individual funding requests’ (IFR) panels. There are two broad categories of case that these panels are asked to consider:

- Some conditions are deemed to have an insufficiently high clinical priority, such as cosmetic conditions, and no treatments are routinely provided for these.
- Some conditions do have a sufficient clinical priority to justify treatment, but the cost of a particular treatment may be very high compared with the benefit, such as drugs that may extend the life of a patient with cancer by a few weeks at exceptionally high cost.

These decisions will often have life-changing or life-limiting consequences for the affected patients and can be difficult for all concerned. A doctor may disagree with the policy in general or in relation to the circumstances of a particular patient. Furthermore, doctors and patients are often left dissatisfied by a refusal to approve funding, convinced that the process is designed to avoid spending money however good the case for treatment. IFR panels and policy makers are rightly keen to ensure that they avoid the special pleading of an individual case leading to the spending of limited healthcare resources on one patient to the detriment of the wider population, but much as we owe it to the wider population to fairly distribute healthcare resources, we also owe individual patients a fair assessment so that they have the opportunity to access their share.

Clinical exceptionality and utility

There is no mandated ethical framework for IFR panels, but in general to be approved for funding the case will have to demonstrate ‘clinical exceptionality’ which is defined by NHS England as, ‘when a clinician believes that their patient is clearly different to other patients with the same condition or where their patient might benefit from the treatment in a different way to other patients’. There is, however, no suggested, quantifiable degree of difference that would lead to a case being approved. Furthermore, the concept of clinical exceptionality has no connection with cost-effectiveness and does not allow for the setting of any rational limits on resource consumption in the individual case. Any case that is approved creates the risk of consumption of an inequitable share of resources, risking a motivation to err on the side of refusing treatment.

To the extent that IFR panels consider cost-effectiveness, they rely on the published QALY data for the treatment as background information against which the vague question of clinical exceptionality for that individual can be considered. This can lead to a presumption that the treatment offers poor utility for everyone. In using population-based QALYs as the measure of utility of the treatment, we treat unequal patients as if they are equal to the average patient, yet IFR cases are some of our most exceptional and unequal patients: these are the patients for whom the standard treatment should not be used or has failed; the patients with very unusual circumstances; the patients with conditions that can only be treated by novel therapies; the patients with rare conditions. I believe that justice is served if we treat them unequally as befits their unequal circumstances and that can be done if we consider individualised and personalised QALYs. As these patients may not have responded well to standard treatment, we should consider individualised and personalised QALYs in relation to the standard treatment as well as the requested treatment because of the effect on incremental cost-effectiveness. As population-based QALYs will have been used by NICE as a key determinant of a recommendation that a treatment should not routinely be provided, one could argue that it is possible to use individualised and personalised QALYs in IFR cases and even that we are required to do so in order to use the same tool in the individual case that led to that treatment being made unavailable in the first place.

IFR decisions sometimes almost take individualised and personalised QALYs into account in a general sense without using these terms—if a patient is likely to respond well to treatment or the standard treatment cannot be tolerated the case may be approved. However, as there is no attempt to calculate individualised or personalised QALYs, utility will be poorly served in cases where treatment is approved despite the exceptionality of the case being insufficient to bring the QALY ICER to within our WTP; and equally poorly served in cases where treatment is refused despite an exceptionally good individualised or personalised QALY ICER.

In ostensibly ‘cosmetic’ cases, IFR panels sometimes approve treatment if the patient’s anxiety about his or her appearance has led to psychological problems that have themselves become sufficient to require treatment. One could regard this as either a
crude personalised QALY assessment where the quality valuation of the health state that will result from treatment is exceptionally high, or as a crude individualised QALY assessment where additional QALYs are derived from the treatment if the psychological distress is alleviated. However, IFR panels do not frame their decision making in this way and, unlike a true personalised or individualised QALY, it is difficult to give this a sense of proportion—how much distress is necessary before utility is maximised by approving the treatment request?

It is as if IFR policy makers have been grasping for individualised and personalised QALYs, but not quite finding them and so have relied on less useful concepts instead. The NHS England definition of clinical exceptionality quoted previously, ‘when a clinician believes that their patient is clearly different to other patients with the same condition or where their patient might benefit from the treatment in a different way to other patients’ could be interpreted as an expression of individualised and personalised QALYs. NHS England illustrate ‘clinical exceptionality’ with the following example, ‘... dental implants are not routinely offered by the NHS, however if a patient could not use their arms due to a disability and needed dental implants to hold a pen so they could write, this might be considered an exceptional case’. This could be seen as an attempt to articulate an individualised QALY (greater health gain as a result of treatment than the average patient) or a personalised QALY (a higher valuation of the ability to grip with ones teeth), but in an unsophisticated way that does not allow an easy comparison with other scenarios and does not provide something quantifiable to support an approval or refusal to treat.

Impact of IFR decisions on the wider population
If we consider the impact on total healthcare resources, an IFR approval for a single individual may appear defensible. The macro resource allocation policy decision has been generally applied, securing resources for the population as a whole and the impact on the wider population of treatment for an individual patient is minimal. However, unless we are confident that utility is furthered by the individual decision, then even a minimal impact on the wider population would be a poor use of resources. Individualised and personalised QALYs offer a way to give us that confidence. This would even be true if IFR decisions that go against the policy are made in significant numbers. For some treatments, the distribution of individualised or personalised QALYs could result in many cases being within the WTP and approving these would offer the affected patients access to resources on an equivalent basis to that applied to others.

The effect of such an approach would be to provide more treatments that are currently not approved for state provision and therefore to incur additional cost. To maintain affordable provision for the population, the state might therefore have to reduce its WTP threshold, although this could only require a very small adjustment. The theoretical consequence that this would result in fewer treatments being approved for general provision might not come to pass: currently pharmaceutical companies endeavour to bring the cost of expensive treatments to just within the NICE WTP threshold, for example, via ‘patient access schemes’, and a desire to secure access to the state healthcare market might drive a marginal reduction in prices to correspond to the marginal reduction in the WTP threshold.

Practical applicability
I am not proposing that, we should consider individualised and personalised QALYs for all patients. The majority of patients will have individualised and personalised QALY ICERs sufficiently close to the average that they would remain on the same side of the WTP threshold as the population-based calculations. Individualised and personalised QALYs are of most significance to patients at either end of the distribution of cost, response or quality valuation for whom ignoring individualised and personalised QALY ICER would lead to high utility treatment being denied or low utility treatment being approved. We do not need to establish a stifling bureaucracy of individualised and personalised QALY ICER assessments for every treatment for every patient, but we should have a system that considers this for exceptional cases.

Such a system might encourage many more people with a remote chance of benefit to seek IFR approval. As long as this was managed efficiently and effectively, I regard this as the acceptable cost of a more just system.

It would be possible to adjust a published population QALY ICER to reflect individualised QALYs where individualised cost is predictable, such as when the drug dose is dependent on size or weight or where there is a good reason to anticipate an unusually straightforward operation or short hospital stay. Similarly, we might be able to identify a good predictor of response that allows an adjusted QALY to be calculated. Revising the QALY ICER for a patient for whom the standard treatment was ineffective should also be possible. However, I recognise the complexities of QALY calculations and that sufficient comparable information on the population calculation and the individual cost or response would often be unavailable. Personalised QALYs present even greater practical difficulties: there would have to be the time and expertise to perform the calculations; the weightings would have to be validated in some way, such as assessing them a number of times at intervals; and most problematically, a patient applying for a particular treatment to be funded would be likely to skew his/her responses to make it more likely that the desired treatment was approved. To take notice of these exaggerated valuations would be to damage utility rather than support it, by drawing resources away from the other patients who were not making special pleading.

However, IFR panels do not need to be able to accurately calculate individualised or personalised QALY ICERs in order to use these concepts to support their decisions, they can be used as a decision-making framework to more methodically consider an individual case. The panel can ask whether individualisation or personalisation could reasonably be considered to be sufficient to affect a decision. Instead of asking, ‘Does this case demonstrate “clinical exceptionality”?’, panels should consider, Do the circumstances of the case suggest lower individualised cost, better individualised response or a higher personalised quality valuation of sufficient magnitude to move the standard QALY ICER from outside the willingness to pay threshold to within it; or could high cost, poor response or low quality valuation in relation to the standard treatment reasonably be anticipated to lead to a favourable ICER for the proposed alternative treatment?

Individualised or personalised QALY considerations could be applied to almost all IFR cases that I have encountered. Even just using these approaches as a conceptual framework should improve decision making and support utility and equity. We would also give a better justification for a life-changing refusal to approve treatment than simply asserting that, ‘the Panel did not conclude that clinical exceptionality had been demonstrated in this case’.
INDIVIDUALISED AND PERSONALISED QALYS BEYOND THE NHS
The same principles should apply in any health system that uses a single QALY model, a range of condition-specific QALY models or any similar measures of cost-effectiveness. Any such system should adapt measures of utility to individual patient circumstances whatever the legal framework around patient rights for individual case consideration. Utility can only be maximised if individualised and personalised QALY ICERs are taken into account—otherwise the policy that purports to maximise utility for the population will not deliver its stated aims; and patients will be subject to unjust denial of treatment.

CHALLENGES
I will not consider general challenges to the ethics of using QALYs. That debate can continue elsewhere and I will make the assumption that it is desirable to maximise utility and that QALYs are accepted as a good tool for macro resource allocation. However, I am interested in the particular challenges that are presented by individualised or personalised QALYs.

Misuse of QALYs?
It could be argued that to even attempt to use QALYs for individual patient decisions is wrong—QALYs were designed for macro resource allocation and we are simply misusing them when considering the individual case. However, a ‘population’ is just an aggregation of individual people and it is those people who feel the effects of population-based QALY assessments. As the policies that result in a treatment being generally unavailable have been built on QALY ICER assessments, it is surely necessary to consider individualised or personalised QALYs when challenging those policies in the individual case.

Individualised or personalised refusals to treat
In general, I have described individualised and personalised QALYs as providing an opportunity to secure treatment that would otherwise be refused. Although I have mentioned the opposite scenario, I have focused less on using individualised or personalised QALYs to justify a refusal to treat. If the good responder should be given treatment, should the poor responder not be refused treatment? If the 55 kg patient should be given treatment, should the 90 kg patient not be refused treatment? Even if refusing to treat a poor responder (with poor individualised QALYs) might be accepted, having a policy not to treat the heavy, costly patient (with high individualised cost) may seem unacceptable even if such a policy would maximise utility. I accept that this is problematic—while I wish to see utility maximised, I retain some discomfort about a purely consequentialist approach to treatment decisions. However, we should note that this difficulty is not unique to individualised or personalised QALYs. Under a system of population-based QALYs, we will approve a particular treatment for a group of patients while refusing a treatment for another group, with the groups perhaps distinguished only by certain subtypes of disease. Individualised and personalised QALYs are a refinement that makes this discrimination less unjust in potentially permitting treatment for a patient with the unfavoured subtype, but favourable individual factors. If that would also result in a refusal to treat the patient with the favoured subtype but with unfavourable individual factors then, if our intention is purely to maximise utility, we should accept this.

One reason that I have focused more on promoting access to treatment is because I am particularly interested in IFR cases. In such cases, we can view the decision that is being made as follows:
- Decision 1: A treatment is deemed not to be cost-effective for the population. Therefore, this treatment will not be made available.
- An individual patient requests this treatment.
- Decision 2: The IFR panel must consider whether there are circumstances about this case that justify overturning the population policy.

Described in this way, no treatment is actually prevented by the IFR panel as the treatment has already been prohibited in advance via the population policy (Decision 1). The default position following Decision 1 is that the patient will not be treated. A decision to approve treatment (Decision 2) is then a decision to overturn the population-wide policy in this particular instance. In deciding the case, the IFR panel does not deny treatment; instead, it gives an opportunity for the individual case to be approved. It is because of my interest in IFR cases that I envisage that, in practice, individualised and personalised QALYs offer more opportunity to extend access to treatment than to restrict access—no patient who benefits from the population policy, but who has poor individual factors would apply to the IFR panel to have treatment denied.

Withdrawal of treatment
A doctor would currently be obliged to cease a treatment that had no beneficial effect, but if individualised and personalised QALYs were generally adopted, a doctor might be more frequently challenged to cease a treatment that was effective for the wider population of patients with the condition, but not effective enough for the particular patient with a less good response. In such a scenario, the treatment might clearly produce more good than harm and might even be the only treatment option, but an individualised QALY assessment would conclude that it was outside our WTP. Scenarios already exist where health policy makers determine that a treatment should only be continued if response exceeds certain levels, so this ethical challenge is not unique to individualised QALYs. However, I do accept that the frequency and difficulty of such cases would be increased.

Treatment in order to assess individualised response
If we supported treatment for patients with an unusually good response, we could encourage doctors to try treatments which would have poor population-based QALY ICERs with the intention of ceasing treatment for the poor-responding majority and continuing treatment for an unusually good responding tiny minority. While it may be possible that this would maximise utility if doctors were universally prepared to cease treatment at an early stage for poor responders, it is likely that this would result in significant waste of healthcare resources. In general, policy makers would prevent this by determining that the treatment should not be generally available and doctors’ own ethical codes would often prevent treatment with only remote chances of benefit.

A similar challenge is that patients who could pay for treatment outside the state system and therefore demonstrate that they were unusually good responders with good individualised QALY ICERs could then justify treatment within the state system; and thereby gain privileged access to treatment (and an unfair share of resources) that would be denied to those who could not afford to have their response assessed. The extent to which this is a problem will depend on the exact arrangements in any particular healthcare system, but it is likely that this is a
challenge that already exists—although adoption of individualised QALYs might make such cases more frequent.

**Making QALYs too powerful**

I am proclaiming that one positive attribute of individualised and personalised QALYs is that they enable us to apply degrees of utility to patient choice and religious treatment preferences. However, this means that QALYs, which already hold great influence in the NHS, would gain even greater power. While the committed consequentialist might celebrate that we could produce even greater utility for our limited resources, others will be concerned that we are allowing even less space for other ethical principles to influence our treatment decisions. In the NHS where QALYs hold the influence that they do, I conclude that we should argue for fair access to treatment for individual patients on the territory that we and they inhabit. The more clearly that we can demonstrate that treatment for the individual patient will maximise QALY utility, the greater the chance of securing treatment that would otherwise be denied because of the population-based QALY policy. In practical terms, it matters little whether we are wholly comfortable with utility-based treatment decisions—we have to work within that system.

**Valuing one person above another**

In relation to personalised QALYs, we might be seen to favour one person above another for reasons related neither to clinical factors nor to considerations of justice, but to factors that should be morally irrelevant. It is generally accepted that it is unethical to value people differently—we should not value one person above another due to their personal circumstances. We should not allow the mother of a disabled child, the charity worker or the wounded soldier to argue that their social circumstances make them more worthy of treatment, however much this may pull at our heart strings. But personalised QALYs do not do this—they value health states and not individuals. The religious person is not saying that their religion gives them additional worth to be taken into account, they are saying that their beliefs affect the value of the health state delivered by different treatments. The health state is worth more to one person than another, it is not that their beliefs or preferences make the person worth more. If social factors have clinical implications (e.g., lifestyle choices affecting chances of successful treatment), then they should be taken into account, not because they affect individual worth, but because they become indirect clinical factors, affecting the response to treatment and the individualised quality and quantity of life years gained.

**CONCLUSION**

Individualised and personalised QALYs allow us to apply a consistent WTP to different patients with very different individual circumstances, to treat them all fairly and maximise utility. These principles even allow us to unite utility with ethical considerations that apply at the level of the individual patient, such as patient choice and respect for religious treatment preferences. We are also able to distinguish between preferences that have sufficient weight to justify treatment and those that do not. In the context of IFR cases, individualised and personalised QALYs offer the potential for better and more consistent treatment decisions than those based on clinical exceptionality. There may be wider ethical and practical implications than those I have addressed here, but if we accept QALYs we should be prepared to take an individualised and personalised approach rather than deny treatment to a real individual patient because he or she differs from a theoretical average patient.

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 Individualised and personalised QALYs in exceptional treatment decisions

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