## **Article**

# Precision QALYs, Precisely Unjust

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Abstract: Warwick Heale has recently defended the notion of individualized and personalized Quality-Adjusted Life Years (QALYs) in connection with health care resource allocation decisions. Ordinarily, QALYs are used to make allocation decisions at the population level. If a health care intervention costs £100,000 and generally yields only two years of survival, the cost per QALY gained will be £50,000, far in excess of the £30,000 limit per QALY judged an acceptable use of resources within the National Health Service in the United Kingdom. However, if we know with medical certainty that a patient will gain four extra years of life from that intervention, the cost per QALY will be £25,000. Heale argues fairness and social utility require such a patient to receive that treatment, even though all others in the cohort of that patient might be denied that treatment (and lose two years of potential life). Likewise, Heale argues that personal commitments of an individual (religious or otherwise), that determine how they value a life-year with some medical intervention, ought to be used to determine the value of a QALY for them. I argue that if Heale's proposals were put into practice, the result would often be greater injustice. In brief, requirements for the just allocation of health care resources are more complex than pure cost-effectiveness analysis would allow.

**Keywords:** health care justice; cost effectiveness; National Institute of Health and Clinical Excellence (NICE); individualized QALYs; personalized QALYs; utilitarianism; targeted cancer therapies

#### Introduction

Warwick Heale has recently defended the notion of individualized and personalized Ouality-Adjusted Life Years (OALYs). He sees this as a matter of justice, at least from a utilitarian point of view. Ordinarily, a QALY methodology is used to make allocation decisions at a population level.<sup>2</sup> Should we, for example, the National Health Service (NHS), invest more health care resources in treating cancer patients, or patients with heart disease, or patients with rheumatoid arthritis? The goal of a QALY analysis is to maximize the amount of health benefit achieved through some medical intervention at the lowest possible cost. If a drug that treats heart failure costs £10,000 per year and increases a patient's quality of life for that year from .4 to .8, and if a cancer drug costs £15,000 per year and increases a cancer patient's quality of life from .4 to .7, then a society with limited resources to treat unlimited needs ought to invest all the resources needed by those heart failure patients before investing resources in those cancer patients.<sup>3</sup> This maximizes social utility. We can readily imagine that healthy individuals concerned about the efficient use of their tax dollars would endorse this as a just outcome since they would not know whether they might have cancer or heart disease in the future.

The ethical issue for Heale in the above scenario is that the QALY methodology is about averages of cost and benefit for some defined *group*. Individuals who might achieve far more benefit at a lower cost per QALY in the group are lost in the average. Their well-being (it seems) does not count. Heale sees that as unjust *from that same utilitarian perspective*. If one of our cancer patients above needs only half as much of that drug to improve her quality of life from .4 to .8, then more utility is achieved at a lower cost than for the average heart patient above. Heale's basic

argument is that it would be unjust to prefer, in terms of resource allocation, all those heart patients before assisting this superior cancer patient. This is the core reason why he wishes to defend individualized QALYs in some range of clinical circumstances. He writes: "Only if we do this [individualize QALYs], can we maximize utility and give the patient a fair opportunity to benefit." In addition to defending individualized QALYs, Heale wants to defend personalized QALYs, that is, a QALY that reflects a personal valuation of the quality of different health states. Heale sees failure to respect such personalized valuations in the context of resource allocation as a matter of justice as well. I shall argue, however, that if Heale's proposals were put into practice, the result would often be greater, not less, injustice with regard to health care resource allocation. In brief, requirements for the just allocation of health care resources are more complex than pure cost-effectiveness analysis would allow.

#### Individualization: A Critical Assessment

The NHS relies upon the National Institute for Health and Clinical Excellence (NICE) to make judgments about the cost-effectiveness of new medical treatments. NICE, strictly speaking, does not have an official limit for what it will judge to be a cost-effective intervention. However, its decisions seem to reflect an upper limit of about £30,000 per QALY gained.<sup>7</sup> For the sake of argument, we will accept that as a reasonable limit. Heale asks us to imagine some life-prolonging intervention that cost £100,000 and that yielded on average two extra years of life expectancy of reasonable quality. Obviously, that technology exceeds our £30,000 per QALY limit. However, if physicians can confidently predict that certain patients will gain four extra years of life, then the cost per QALY for those patients is reduced to £25,000, which is well within the limit. If they are denied access to that technology at NHS expense because the average cost of the technology is twice that, Heale concludes they have been treated unjustly. More specifically, those patients, he contends, would have been denied their fair share of limited health care resources. In addition, the NHS would have failed to maximize utility.

## Heart Transplants and Cost-effectiveness

Heale's conclusion has a certain intuitive appeal, especially if we think of a high cost medical intervention with variable outcomes, such as a heart transplant. If a heart transplant costs \$400,000 in the United States, and if we take \$50,000 as a reasonable cost for a QALY, then 55% of these patients will survive for ten years at a cost per QALY of \$40,000. We also know that about 30% of these patients will survive less than five years.<sup>8</sup> These patients clearly fail Heale's QALY criteria. However, if we imagine that the deaths of all in that 30% cohort come as a complete surprise to everyone, then those individuals would have as much a right to that transplant as anyone else. Predictive ignorance would trump stingy compassion. However, patients in end-stage heart failure older than 55, or ventilator dependent prior to the transplant, or receiving a heart from an older individual are much more likely to be in the 30% cohort that would survive less than five years.<sup>9</sup> A cold-blooded, hard-hearted, friendless utilitarian might be ethically and psychologically comfortable informing such patients anticipating a transplant that they would be denied a transplant because they were confidently predicted to survive less than

five years, and hence, their survival would not be worth it from a societal point of view. However, I must believe that utilitarians with a normal sense of compassion would blanch at the thought of carrying out such a judgment.

## Heart Transplants and Veils of Ignorance

Heale may deserve philosophic praise for being a perfectly consistent utilitarian, but that consistency is ethically painful and problematic in a number of contexts. Recall that heart transplants represent an absolutely scarce medical good. In the United States, only about 2500 hearts become available each year for transplantation while many thousands of additional patients in heart failure need that transplant for survival (but will die prematurely). What criteria should be used to make just allocation decisions regarding these hearts? Should individualized cost-effectiveness be the dominant or exclusive criterion?

If a patient will die without a heart transplant in the next two months, but has some life-threatening co-morbidity that almost certainly will limit life expectancy to one year, even with a heart transplant, I suspect most would agree that it would be morally permissible (not unjust) to deny that patient a heart transplant. However, I would be surprised if the dominant reason given for that judgment were that it was not cost-effective. Instead, I could imagine individuals in good health behind a real world "veil of ignorance" about their own future health needs agreeing to a transplant rule that would exclude from the transplant list individuals who would gain less than two years from a heart transplant. They would understand that a future possible version of their self in heart failure might have either a prospect of survival of less than two years with a transplant or more than ten years. Their thinking might be that it was ethically preferable to save many more years than many fewer years. Thoughts about cost-effectiveness would be beside the point.

This last point would be clearer if we modify the thought experiment and compare survival of four or five years with survival of ten years or more. Ethical intuitions seem to shift in this latter scenario, as some empirical research by Peter Ubel has shown. Additional survival of "only" four to five years with a heart transplant is clearly not cost-effective (or even seven years with a \$50,000 limit per QALY), but four to five years will be seen by most individuals as an ethically significant gain in life expectancy. Hence, most individuals would not accept as "just enough" any rule that would exclude such individuals from the transplant list. Cost-effectiveness per QALY in this situation should be regarded as being ethically irrelevant.

## Heart Transplants and a Normal Life Expectancy

Consider another scenario. We have two patients with equal urgency for a heart transplant. One patient is an especially vigorous 75-year old (apart from bacteria-induced heart failure) whose physicians are virtually certain will gain at least ten extra years of life with a transplant. The other patient is 57 years old with a comorbid condition such that he would likely gain only seven extra years with a heart transplant. Our first patient would clearly satisfy Heale's cost per QALY criterion; our second patient would not. Only one heart is available for transplantation. We could do our "veil of ignorance" thought experiment. I could imagine two

conclusions that most would regard as ethically acceptable from behind that veil of ignorance. We might accept a coin flip to determine who got the heart. Alternatively, we might simply note that our second patient has not had the opportunity to achieve a normal life expectancy, and therefore, he has the strongest just claim. The conclusion we would likely not accept is that the 75-year old gets the heart because that yields the most cost-effective outcome. This suggests an ethical problem with individualized QALYs.

Here is another scenario. Imagine that we have two 60-year old patients who both need a heart transplant. Both are equally likely to be among the 70% who achieve 10-year survival. However, one of them is blind (or one of them is paraplegic); the other has no quality of life health deficiencies. In either case, we will attribute to our person with disabilities .7 as their societally-judged QALY (though this attribution itself is problematic). Our 60-year old in good health would have a cost per QALY gained of \$40,000, but our patient with either of those disabling conditions would have a cost per QALY gained of \$57,000 (which exceeds the societal limit of \$50,000) and would seem to exclude him *individually* as a candidate for the transplant for Heale. However, this is exactly the conclusion that has generated enormous ethical criticism of QALY methodology.<sup>12</sup>

## Being NICE: Cancer Therapies and QALYs

How should we think about these targeted cancer therapies from a QALY perspective, either overall or individualized? The basic problem is that most of these targeted therapies cost \$100,000 to \$200,000 or more, for a course of treatment for metastatic cancer granting an additional year of life. None of these drugs are curative. Gains in life expectancy are typically measurable in weeks or months, not years. All of them will fail the QALY cost-effectiveness test. The practical implication of that conclusion is that no one with metastatic cancer should receive these drugs at social expense outside a clinical trial. Perhaps that is an ethically correct conclusion, though this is not current practice in the US, the UK, or the European Union.

In the UK, NICE is responsible for assessing these targeted cancer therapies, in part from a cost-effectiveness perspective, to determine whether they will be covered by the NHS. Many of these drugs are approved for specific indications, though they fail the usual cost-effectiveness guideline. This is because NICE takes account of social values as well as cost-effectiveness. More specifically, NICE has created an "end of life" premium, according to which the NHS will pay for these targeted cancer therapies for patients with metastatic disease so long as physicians are confident these patients will gain at least three extra months of life (even though this is clearly not cost-effective). NICE sees this exception as respect for a widely endorsed social value (even though economists might dissent).<sup>14</sup> Perhaps philosophers should dissent as well. 15 It is not clear how that social value should be named. It could be "compassion for the medically least well-off" (because these patients are terminally ill), or it could be a presumptive obligation to provide a "last chance therapy," or it could be a "duty to rescue." There is no need now to settle this naming issue. What is important to note is that something more than cost-effectiveness is relevant to making fair allocation decisions. In addition, it is a social value, not something individualized.

With that "end of life" premium in mind, we note that NICE has approved for specific indications about two-thirds of these targeted cancer therapies for NHS funding. Still, that approval does not necessarily imply that all metastatic cancer patients needing those drugs for some specific indication will receive those drugs. That decision is up to the commissioning groups who must live with a fixed budget. A particular commissioning group might decide not to fund nivolumab for patients with Stage IV non-small-cell lung cancer for whom there might be a median gain in life expectancy of four to five months. However, a small number of these patients will be "super responders." They will gain extra years of life from access to one of these targeted therapies. Should they have a strong just claim to these drugs because of the very substantial gains in life expectancy they will receive?

### Cancer and the Super Responder Problem

At present, few biomarkers have been discovered that would reliably identify these super responders before treatment initiation. However, research is ongoing with this goal in mind. <sup>16</sup> Presumably, Heale would endorse this research because this would individualize allocation decisions in a way that would yield what he would regard as a more just outcome. However, unlike our heart transplant example, which has one large fixed cost upfront, these cancer drugs have very high monthly costs (\$10,000 or more per month) which continue to add up for almost as long as that patient survives. If a patient with a heart transplant gains ten extra years of life, the cost per QALY will be about \$40,000. If a cancer drug costs \$156,000 per year of treatment, every year of life gained will cost \$156,000.

If a commissioning group in the UK responsible for meeting the health care needs of tens of thousands of its members had ten such super responders in a year, this would be a very large hit on a fixed budget. If a commissioning group had forty patients with the same metastatic cancer whose predicted survival gain was only three months, that would have the same budgetary impact as our ten prior patients in the space of a year. Are these outcomes ethically equivalent so far as health care justice is concerned? From a cost-effectiveness perspective, they are equivalent. More precisely, both alternatives exceed by three times what would be regarded as a reasonable cost per QALY for NICE. In other words, none of these patients should be provided these drugs at social expense. However, the implied outcome would strike many as ethically awkward or indecent, given the number of life-years that would be foregone by the super responders.

It is one thing to have a cohort of metastatic cancer patients and know that somewhere in that cohort a few individuals would be super responders if given access to this drug. We have no way to identify them individually. We deny the drug to the entire cohort. We regret the lost life-years for the super responders. On the other hand, if we can identify the super responders before treatment initiation, we would have to look someone in the face and say to them, "We have a drug that will give you several extra years of life, but we cannot provide it to you at NHS expense; we are going to allow you to die." This scenario would strike most people as indecent and uncaring. Heale's proposal to individualize care for reasons of justice seems like an apt compassionate response. However, Heale is clear that individualizing decisions must still stay within the upper bounds of a QALY, which means he would allow our potential super responding cancer patients to

die rather than gain those extra years of life. This is what a consistent utilitarian needs to conclude, but it is not a conclusion that most people would accept as ethically reasonable because high quality life-years are being sacrificed unnecessarily.

## Individualized QALYs: Some Ethical Incongruities

Heale asks us to imagine some expensive life-prolonging drug whose dosing is weight-dependent. For the average 70 kg person the drug will be cost-effective. For a 55kg person this drug is even more cost-effective since she needs less of it. However, for a 90 kg person the drug would not be cost-effective (since he needs more of it), though for all three individuals the same degree of benefit could be expected. The 90 kg person is not a poor responder. Heale himself concedes that "having a policy not to treat the heavy, costly patient (with high individualized cost) may seem unpalatable even if such a policy would maximize utility." Nevertheless, he is willing to endorse such a policy with "some discomfort."

Heale tries to dismiss the discomfort with a very abstract argument. In brief, he argues that we do this all the time at the population level with QALYs. One population group is approved to receive some treatment that for them is cost-effective while another population group has some unfavorable characteristic that results in their being denied that treatment, because they have a different subtype of that disease. The most obvious way to interpret this argument is that the disfavored group has a different genetic feature (or some other physiological feature) that will likely render the intervention ineffective or marginally effective, and consequently, not cost-effective. However, that does not address the weight issue where the drug is *equally effective*, no matter the weight of the patient. That equal effectiveness is the ethically relevant consideration that ought to generate ethical discomfort, even for a committed utilitarian.<sup>18</sup>

#### Personalized QALYs: A Critical Assessment

Heale wants to defend in some range of circumstances both individualized QALYs and *personalized* QALYs. His claims in this latter regard also need critical assessment. He writes, "If we do not personalize QALYs, we assume that each person's quality valuation of health states is the same, but this is not the case." Again, his basic claim is that personalizing QALYs in some range of cases results in the more just allocation of health resources because this increases overall utility. I argue, to the contrary, that the subjectiveness this would necessarily involve will yield less just outcomes.

#### Personalized QALYs: The Subjectivity Challenge

Heale gives the example of a concert violinist, perhaps world-renowned, who severely injures the fourth finger on his left hand in some sort of accident. The same injury could occur to my fourth finger as well. A relatively simple surgery will restore basic functionality to that finger. No one would question that the surgery was cost-effective. However, that simple surgery will not restore the very fine sensitivity required for that violinist to play at the level of excellence he had achieved. He would judge that his quality of life would be reduced by 50% if he

loses exquisite sensitivity in that fourth finger. I will embellish the scenario by saying a \$200,000 surgery will achieve the desired level of superior functionality. Imagine that adds twenty years to his career. That yields a cost per QALY gained of \$20,000, well within our QALY benchmark. Heale contends the violinist has a just claim to that surgery. However, there are at least two reasons for disputing that judgment.

Ronald Dworkin would ask whether this was a matter of "expensive taste." <sup>20</sup> If resources were relatively scarce for purchasing food for a population, individuals who were accustomed to steak and caviar and fine wines would have no just claim to extra resources needed to satisfy those tastes. They would only have a just claim to food nutritious enough and in enough quantity to sustain their health. Commissioning groups in the UK have fixed budgets to meet the health needs of a defined population. If other health needs of that defined population can be met effectively for a fraction of the cost per QALY associated with that elegant surgery, that is where justice would require those resources be allocated.

Norman Daniels offers another sort of argument.<sup>21</sup> His basic contention with respect to health care justice is that we have a just claim to whatever health care resources might be needed to restore us to the "normal opportunity range" of our society. Hence, if someone has been in a terrible automobile accident and is now a quadriplegic, we might be obligated (as a matter of justice) to provide the rehabilitation and computer-assisted technology that would allow that individual to participate to the maximal extent possible in the normal opportunity range of our society. That cost could be \$750,000. The violinist, however, is asking to be restored to a degree of functionality that far exceeds the normal opportunity range in our society. Consequently, from Daniels' perspective, he does not have a just claim to those resources, even though they only represent 25% of the resources required by our quadriplegic whose care, depending upon predicted life expectancy, might fail Heale's personalized cost-effectiveness test.

#### Personalized QALYs and Religious Claims

Heale gives another example of a personalized QALY that he argues ought to be respected. He mentions the case of a Jehovah's Witness patient in need of a blood transfusion to save her life. She refuses the transfusion (very inexpensive) because her life would have no worth at all from her religious perspective if she were to accept that transfusion. His point, which I endorse, is that we ought to respect her choice. However, this does not get at the issue of the just allocation of health care resources.

A number of years ago a medical resident brought a case to me of a 26-year old Jehovah's Witness woman with an ectopic pregnancy. Such pregnancies must be surgically removed to save a woman's life. However, a substantial risk of bleeding exists. The surgeon explained this to the patient who absolutely refused a transfusion if it were to become necessary. She did begin to bleed out during the surgery. The surgeon respected her choice but did not want to allow her to die. Consequently, he chemically paralyzed her and administered an extraordinarily expensive clotting drug that saved her life. She needed ICU care for two weeks and was uninsured. The cost of her care was more than \$100,000 from the hospital's charity care budget. She had not requested that intervention. Still, it did save her life without violating her religious commitments. Did she have a just *personalized* claim to those resources?

We can assume she would survive at least another forty years, which yields a cost per QALY of \$2500, very far below our QALY limit. It strikes me as obvious that Heale would endorse her just claim to this very expensive resource. Again, she did not demand this resource as her right. However, we can imagine her exclaiming to her entire religious community about her good fortune, thereby creating the expectation that everyone in her community could request and expect a similar accommodation. I contend this would not be a just expectation.

Members of her community would have a just claim if they either all agreed to take up a collection to cover the relevant costs for any member of their community in a similar situation, or else they purchased some sort of special rider to private health insurance plans (assuming an insurance company were willing to offer such a rider). However, Jehovah's Witness patients would not have a right to health care resources needed to satisfy their personal religious beliefs as opposed to health needs that they shared with everyone else in the insurance pool.

## Personalized Medicine and Informed Consent

Heale contends that the informed consent process permits all manner of personalized health choices to make just claims on the health care system so long as those claims are within our cost-effectiveness limits. However, those personalized choices are all about medically necessary health needs and relevant medical options for meeting those needs. Some women may elect to have a C-section "for reasons of convenience," as opposed to a less expensive vaginal delivery. Perhaps such choices should be respected as a matter of autonomy, but it is ethically controversial that the additional costs related to that choice represent just claims to social resources, even if such a choice is cost-effective.

To be clear, religious belief is not what is at issue in the Jehovah's Witness case. Individuals might have all manner of other health-related beliefs that could make cost-effective but unjust claims on shared health care resources. Consider, for example, the case of patients who are apotemnophiliacs.<sup>23</sup> These are individuals who want to have several of their limbs surgically removed because they feel those limbs are not really part of them. They see their "real selves" as amputees in a way analogous to the feelings transgendered individuals have about being in a body with the wrong gender. They claim that they are miserable with these "excess limbs." They might rate their current quality of life as .5. If they have the surgery, they become very happy and would now rate their quality of life as 1.0. If the surgery costs \$20,000, it would clearly be cost-effective and justified from a utilitarian perspective. However, it is far from obvious that this represents a just personalized claim to social health care resources.

A similar situation exists for hyper-anxious individuals who fear that every headache they have might be a brain tumor. They may want an MRI scan of their brain every six months and, no doubt, they will be much happier with a negative outcome. However, they still would have no just claim to those resources, even though from Heale's personalized perspective this use of resources would be cost-effective and satisfy his utilitarian criterion. This sort of example can be multiplied thousands of times over. The basic ethical problem is that such demands are subjective and arbitrary, and therefore, unjust. This is essentially either another version of the "expensive tastes" problem to which Dworkin has called our attention or the "irrelevant utilities" problem of Frances Kamm.<sup>24</sup> If such demands

were taken seriously in the context of fixed health care budgets, they would unjustly crowd out objective higher priority health needs. That such demands could be met cost effectively would be ethically irrelevant.

## Can QALYs Meet the Clinical Exceptionality Challenge?

What prompted Heale to write this essay? He calls attention to situations in which NICE has recommended to the NHS that some medical intervention not be funded for some defined population of patients. Individuals might be denied that treatment by some commissioning group for that reason. Nevertheless, they would still have the right to file an Individual Funding Request (IFR) claiming "clinical exceptionality." The request would be filed with the IFR panel. However, Heale points out that there is no mandated ethical framework for judging the "clinical exceptionality" of any particular request. Heale sees his proposal in this essay as providing the necessary and appropriate ethical framework. However, applying the QALY methodology Heale has in mind is not as simple and straightforward as he believes.

## Weighing QALYs: Fat Phobia Justified?

Recall our earlier discussion of drugs administered on a weight-related basis. Imagine a situation in which a patient is started on such a drug. The drug is life-preserving but not curative. At her current weight the drug is cost-effective. However, a major side effect of the drug for most patients is weight gain after about three years. That will mean they will need more of the drug to compensate for the weight gain if the life-preserving effect of the drug is to be maintained. At that point, the drug is no longer cost-effective in QALY terms. Keep in mind that Heale is committed to *individualized* judgments of cost-effectiveness.

This patient will need to be on this drug for the rest of her life, which her physician confidently believes will be at least ten years. Here are the ethically awkward options Heale must face. If we know from the beginning that this drug will no longer be cost-effective for this patient after three years, would we be ethically justified in denying her the drug right then (and allow her to die)? She could then file an IFR. What should the IFR committee decide, following Heale? The committee could allow her to have access to the drug at NHS expense for three years, then deny it to her (and allow her to die) after the third year. The committee could "average" the cost-effectiveness numbers for the first three years with the following two years (as long as that remained within the cost-effectiveness limit), then deny her the drug thereafter (and allow her to die). All three options are ethically repugnant, because the drug would effectively prolong for her a good quality life for at least ten years. This should make clear that individualized cost-effectiveness judgments are ethically problematic, at least in some range of circumstances.

#### Individualized QALYs: More Ethical Awkwardness

Heale considers a number of challenges to his view in the latter portions of his essay. He imagines a critic calling attention to some number of patients whose care (as individuals) will not be cost-effective but who will be "sheltered" by the averages typically used with QALYs. The critic expresses concern that they will be

"called out" and denied the care they need because, as individuals, their care would not be cost-effective. This would be part of the ethical cost of "saving" other individuals on the other side of the cost-effective divide whose care would be cost-effective, except that they are trapped by the QALY average, which means they are denied that care. Heale's assuring response is that only these latter individuals would have the opportunity to file an IFR and to be saved from the life-threatening "theoretical average" they are under. The IFR committee, he adds, would not be looking for cost-ineffective individual free riders in the other group.

Heale seems ethically comfortable with this conclusion. He should not be. This result, from his own perspective, would be neither fair nor protective of social utility. Those "hidden" cost-ineffective individuals are taking advantage of resources to which they have no right from Heale's perspective. To be sure, this is not something those individuals themselves are doing. Still, a basic principle of fairness is that like cases should be treated alike. If Heale is vigorously trying to save patients whose care would be cost-effective from insensitive QALY guidelines that would deny them that care (contrary to both equity and social utility), then consistency requires equally vigorous effort to deny those other patients the care they would otherwise receive that would be cost-ineffective (and contrary to both equity and social utility). This is what Heale's arguments require him to do, though I suspect most people would find such an effort ethically repugnant.

#### Conclusion

Heale's overall argument is essentially internally conflicted. Heale is a critic of current IFR committees because they have no objective, *quantifiable* basis for making their decisions. Heale sees his use of QALYs and cost-effectiveness methods as resolving that deficiency for *individuals*. However, he also wants to *personalize* judgments regarding just claims on health care resources. Those judgments are neither objective nor rigorously quantifiable. On the contrary, they threaten to corrupt the just distribution of health care resources because of their potential arbitrariness and subjectivity. In conclusion, Heale may be trying to align his ethical views with precision medicine and its emphasis on personalized, individualized therapies. In the final analysis, however, his precision QALYs are precisely unjust.<sup>26</sup>

#### Notes

- Heale W. Individualised and personalised QALYs in exceptional treatment decisions. Journal of Medical Ethics 2016;42:665–71.
- Soares MO. Is the QALY deaf, dumb and blind to equity? NICE's considerations over equity. British Medical Bulletin 2012;101:17–31.
- 3. In the United States, that QALY figure is often put at \$50,000. Some researchers believe that figure is too low and should be set at \$100,000. In either case, neither of these numbers has any "official" standing. One reference point that might reasonably be used is the \$88,000 per patient per year we now (2017) spend to support a patient on dialysis through the Medicare End-Stage Renal Dialysis program. In essence, the implied argument is that if we are willing to fund through taxes this level of support for dialysis patients, then we ought (for justice reasons) to be willing to fund effective life-prolonging efforts for other disease processes at this same level.
- 4. Lakdawalla DN, Romley JA, Sanchez Y, Maclean JR, Penrod JR, Philipson T. How cancer patients value hope and the implications for cost-effectiveness assessments of high-cost cancer therapies. *Health Affairs* 2012;31(4):676–82.
- 5. See note 1, Heale 2016, at 665.

- 6. Advocates for a QALY methodology generally imagine that QALYs would be imputed on the basis of some set of objectively-measurable criteria. This is the focal point of a very large literature within which much is disputed. We need to put aside those disputes, given our objectives in this essay. See Schwartz S, Richardson J, Glasziou PP. Quality-adjusted life years: Origins, measurements, applications, objections. Australian Journal of Public Health 1993;17(3):272–8.
- 7. See note 2, Soares 2012, at 27.
- 8. Wilhelm MJ. Long-term outcome following heart transplantation: Current perspective. *Journal of Thoracic Disease* 2015;7:549–51.
- Kilic A. Younger patients more likely to live at least ten years after heart transplant. Annals of Thoracic Surgery 2012;93:699–704.
- 10. One notable exception to this last statement would be John Harris, a strict egalitarian. See Harris J. *The Value of Life: An Introduction to Medical Ethics*. London: Routledge & Kegan Paul; 1985:87–111.
- 11. Ubel PA. *Pricing Life: Why It's Time for Health Care Rationing*. Cambridge, MA: MIT Press; 2000: 67–95
- 12. See Harris J. QALYfying the value of life. *Journal of Medical Ethics* 1987;13:117–23. More recently, see Campbell SM, Stromondo JA. The complicated relationship of disability and well-being. *Kennedy Institute of Ethics Journal* 2017;27:151–84.
- 13. Peppercorn J. Financial toxicity and societal costs of cancer care: Distinct problems require distinct solutions. *The Oncologist* 2017;22:123–5. The phrase "targeted cancer therapies" refers to drugs that target specific "driver" mutations of a cancer, such as BRAF (colon cancer or melanoma) or EGFR mutations (lung cancer), with the intent of disabling that cancer by disabling its driver.
- 14. See note 2, Soares 2012.
- 15. Cookson contends that this end-of-life premium cannot be given a coherent ethical justification. He considers and refutes ten possible justifications that various writers have offered. See Cookson R. Can the NICE "end-of-life premium" be given a coherent ethical justification? *Journal of Health Politics, Policy and Law* 2013;38:1131–50.
- Prasad V, Vandross A. Characteristics of exceptional or super responders to cancer drugs. Mayo Clinic Proceedings 2015;90:1639–49.
- 17. See note 1, Heale 2016, at 670.
- 18. Heale may not have noted that 59% of adults in the UK are overweight or obese. See Yang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. *Lancet* 2011;378:815–25.
- 19. See note 1, Heale 2016, at 666.
- Dworkin R. Sovereign Virtue: The Theory and Practice of Equality. Cambridge, MA: Harvard University Press; 2000:11–64.
- 21. Daniels N. Just Health Care. Cambridge, UK: Cambridge University Press; 1985.
- 22. Fleck LM. Case study: My conscience, your money. Hastings Center Report, 1995;25(3):28-9.
- 23. Henig RM. At war with their bodies, they seek to sever limbs. *New York Times* (22 Mar 2005); available at https://www.nytimes.com/2005/03/22/health/psychology/at-war-with-their-bodies-they-seek-to-sever-limbs.html (last accessed 1 Sept 2018).
- Kamm F M. Morality, Mortality: Death and Whom to Save From It. New York, NY: Oxford University Press; 1993:144–64.
- 25. See note 1, Heale 2016, at 671.
- 26. No doubt, bedside rationing decisions (at the level of individual patients) must be made and made fairly. However, my own view is that multiple justice-relevant considerations should be used to justify such decisions, not just cost-effectiveness in relation to QALYs. See Fleck LM. Controlling health care costs: Just cost effectiveness or "just" cost effectiveness? Cambridge Quarterly of Healthcare Ethics 2018; 27(2):271–83.