The QALY is ableist – on the unethical implications of health states worse than dead

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Abstract

A long-standing criticism of the QALY has been that it discriminates against people in poor health. Calculated as the product of the length and the (health-related) quality life, extending the lives of individuals who have severe underlying health problems, gains fewer QALYs than extending the lives of individuals who are 'more healthy'. Proponents of the QALY counter that this reflects the preferences of the general public and constitutes an efficient allocation of resources.

A pivotal issue that, so far, has not been considered by proponents from any side of the debate is that some health states are considered worse than dead - all else being the equal, extending the lives of individuals who live in such states gains fewer QALYs than not extending them. The implications are dramatic, and should be considered unacceptable for two reasons.

Firstly, 'negative QALYs' neither adequately reflect the preferences of the general public, nor of the individuals who live in 'worse than dead states'. Instead, they are based on a questionable, and probably misconstrued concept of utilities in the QALY model.

Secondly, while there may be much reasonable disagreement over the relative value of different health outcomes, no individual should ever be considered to be unworthy of living. This would clearly be incompatible with the norms and values of a liberal democratic society. However, in this paper, I demonstrate that using states worse than dead, in economic evaluations, to value the changes in individuals' survival times, and distributing health care resources accordingly, implies exactly such a discriminatory value judgement.

I argue that a non-negative value should be assigned to all human lives (that is to their survival times), and explore how the QALY model can be improved, to abolish the currently implied abhorrent value judgments about people living with severe health conditions.

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1 Introduction

The QALY is sometimes considered the 'gold standard' for measuring and valuing health in economic evaluations (Lipscomb et al., 2009). First proposed in 1968 (Klarman et al., 1968), it is now being widely used to inform societal decisions about the allocation of health care resources (MacKillop & Sheard, 2018). But despite its success, the QALY is not without limitations. One major and long-standing line of critique has been that the QALY discriminates against people with disabilities and chronic conditions (Harris, 1987) [1] : all else being equal, extending the the lives of individuals with disabilities or underlying health conditions gains fewer QALYs than extending the lives of people without disability or health problems. Several authors have argued that this is unjust, and that all life-years should be of equal value, regardless of the health state the receiving person is in (Pearson, 2019; Ubel et al., 2000; Singer, et al., 1995).

Proponents of the QALY framework counter that the allocation of finite health care resources will inevitably involve trade-offs. Since people are generally willing to give up some lifetime for gains in health-related quality of life (HRQoL), it is argued that, by implication, one additional life-year in poor health is of lower value than one additional life-year in perfect health. From a utilitarian perspective, it might then seem rational to discriminate based on individuals' HRQoL, in order to allocate resources most efficiently (Beckstead & Ord, 2015; Cubbon, 1991; Ubel, et al., 1999; Williams, 1987).

One pivotal issue that has thus far not been considered in this debate, is that HRQoL can not only be low, but also negative: health states that are

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[1]The debate on whether or not the QALY is ableist is by no means new, but it has recently seen a resurgence of interest, as the Institute for Clinical and Economic Review, a private, nonprofit organization in the US, considered adopting the QALY metric. They received heavy criticism from various interest groups and the National Council on Disability (Neumann 2009; Pearson, 2019).

considered worse than dead (SWD) get assigned negative values. Accordingly, treatments that extend the lives of individuals who live in those SWD (without improving their HRQoL) generate negative QALYs.

This paper investigates the significant implications of the concept of SWD. It is argued that the value judgment implicit in SWD is unethical, and it is shown how SWD may lead to a systematic undervaluation of life-extending treatments in almost any patient group. I thus propose that SWD should not be used in economic evaluations to value changes in individuals' lengths of life. Different alternatives to adapt the QALY framework and their practical challenges are discussed.

2 Background

2.1 Key concepts and methods

An understanding of the technical aspects of the QALY framework will be necessary to appreciate the significance of SWD and the ramifications of their use in economic evaluations. It will therefore be useful to revisit some of the key concepts and methods.

The QALY is used as a measure of health in economic evaluations. It is the arithmetic product of survival time and HRQoL. HRQoL, in turn, is determined by the health state an individual is living in. This means, 'measuring' QALYs usually involves two components: firstly, a descriptive system of (mutually exclusive) health states; and secondly, a social value set to map each health state to a (social) HRQoL[2] value (Whitehead & Ali, 2010).

There are many different health classification and valuation systems (e.g. EQ-5D 3L/5L, SF-6D, HUI, etc) (Brazier et al., 2017, p.147-197). A common

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[2]I use the terms 'HRQoL' and '(health state) utilities' interchangeably, and sometimes refer to them as 'social values'.

approach to derive HRQoL values for states in these systems, is to survey a group of individuals, elicit their health preferences through the Standard Gamble (SG) or the time trade-off (TTO) method, and to fit a statistical model to estimate a social value set – below, we will describe the TTO, but the principles equally apply to the SG method.

2.2 The time trade-off method

The TTO method is used to elicit individuals' preferences over health states. Preference intensities are expressed in terms of utilities, measured on a scale that is anchored at full health, which is assigned a value of 1, and dead, which is assigned a value of 0. To determine the HRQoL of any other health state i, individuals are asked to choose between living t years in state i (and then be dead), and $t - k$ (with $k \leq 0$) years in a state of full health,(and then be dead). By guiding the individual through a series of choices, in which the value of k is adaptively increased or decreased, a point is identified, at which the individual is indifferent between the two alternatives. The value of $\frac{(t-K)}{t}$ at the point of indifference is then assumed to reflect the individual's utility, or HRQoL, of state i (Attema et al, 2013; Torrance, 1976). See Figure 1 for an example. Subsequently, utility values are aggregated across individuals, in order to derive a social preference function (which is also called a social value set), which assigns (social) HRQoL values to all health states.

2.3 Negative health state utilities for SWD

If an individual prefers zero years in full health, i.e. immediate death, over ten years in state i, it is inferred that state i must be worse than dead. The individual is then presented with a different task[3]. They are asked to choose between 10 years in perfect health, followed by 10 more years in state

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[3]The setup and technique of eliciting preferences for SWD varies across different protocols. Here we consider the EQ-5D 5L valuation study protocol, which uses the 'composite TTO method' (Attema et al, 2013, Oppe et al., 2016).
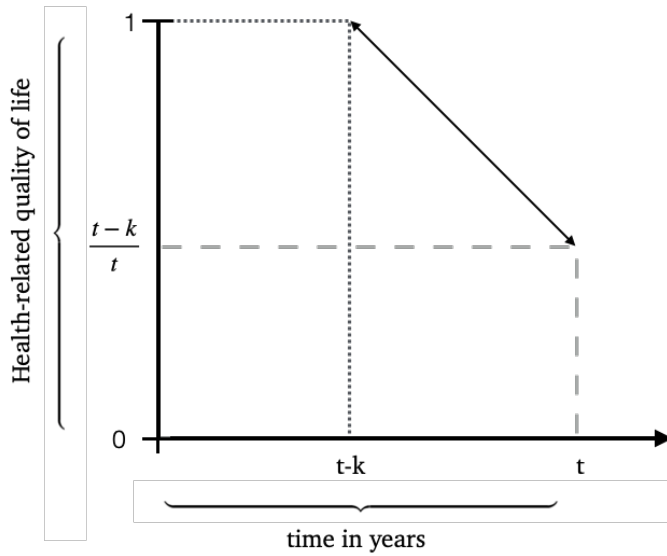
Figure 1: Figure 1. Time trade-off method for states better than dead (adapted from Torrance, (1971)). **Example:** Being indifferent between 10 years in some state i and 6 years in full health, yields a utility of $\frac{10-4}{10} = 0.6$. This means, for any given amount of time, being in state i is assumed to provide 60% of the utility of being in full health.

i (and then be dead), or $10 - k$ years in full health (and then be dead). Put plainly, participants are asked how much (healthy) life time they are willing to forgo, to avoid spending ten years in state i. If, for example, an individual is indifferent between 10 years in full health followed by 10 years in state i, and 8 years in full health, it is inferred that state i has a HRQoL of -0.2 (Attema et al, 2013; Oppe et al., 2016; Tilling et al., 2010).

It might be interesting to point out that the theoretical basis for negative utilities, assigned to SWD, is not well defined, as they seem qualitatively different from their positive counterparts. While positive utilities are measured as a proportion of utilities derived from full health, with an upper limit of one, negative values reflect actual preference intensities. Although the TTO design presented above restricts negative values to have a lower limit of -1 (individuals cannot forgo more than $k = 10$ years)[4], in theory, values can range to minus infinity (Tilling et al., 2010).

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[4]In a previous TTO protocol, HRQoL could take values of up to -39, which caused major problems in the estimation of the UK social EQ-5D 3L tariff. The low negative values caused the majority of health states to have negative social values. To resolve this issue, negative values are commonly transformed to have a lower limit of -1, even though this limit is set completely arbitrarily and without any conceptual justification (de Charro et al., 2005; Tilling et al., 2010).

2.4 SWD in the context of the UK EQ-5D 3L system

To provide some context, we may consider the situation in the UK, where NICE currently uses the UK social EQ-5D 3L tariff as a reference case in economic evaluations (NICE, 2019). The social value set is based on the preferences of around 3,000 individuals who were broadly representative of the UK society in 1993 (MVH, 1995). The EQ-5D 3L system consists of 243 health states. In the UK social tariff, 84 (34.6%) of those are SWD, with HRQoL values ranging from -0.001 to -0.594 (Dolan, 1997)[5]. To give an example of a SWD, being confined to bed and having extreme pain or discomfort, but no problems with self-care, usual activities, and anxiety or depression has a HRQoL value of -0.050 (MVH Group, 1995, Dolan, 1997). The prevalence of SWD in the English population is about 5.1%, i.e. one in twenty adults lives in a health state that is considered to be worse than dead (own analysis of HSE, 2017). Economic evaluations usually consider selected patient population, in which the prevalence of SWD can obviously be much higher (Mulhern, et al., 2018).

2.5 Preferences sources and perspectives

It is essential for the argument of this paper, to note that social health state values are generally based on the preferences of the general public. These values do not, and are not supposed to, reflect how a particular individual *experiences* a certain health state. Instead, members of the general public – some of which may have little or no experience with poor health – are asked to imagine having certain health problems and then to state their preferences over these hypothetical health states (Brazier et al., 2018, Versteegh & Brouwer, 2016). Afterwards, individuals' preferences are aggregated into a single social welfare function, which is used to value everyone's health states

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[5]It may be interesting to note that the proportion of negative states in the EQ-5D 3L system differs widely across countries. For Japan, only 6 (2.5%) states have negative values, with a minimum of -0.111 (Tsuchiya et al., 2002), while for Singapore, there are 144 (59.3%) negative states with a minimum of -0.769 (Luo et al., 2014).

(Weinstein et al., 2009). Units of HRQoL and/or QALYs thus do not reflect the preferences of any particular individual, and they should not be confused with measures of individual utility or self-assessed health.

3   The (un)ethical implications of SWD on the individual level

The complexity of modern health economic evaluations makes it difficult to examine their implicit value judgments (Klonschinki, 2016). To develop an intuition for the ethical implications of SWD, it will thus be useful to make some simplifications. We will begin with a motivating example, in which the new treatment only extends survival time, and has no effect on HRQoL; it is cost-free, and the decision is to be made for just one individual. This seemingly trivial case will be used to discuss the potential conflict between individual and social preferences, and to outline general guiding principles. The complexity of the example will then be gradually increased, maintaining, at each step, that the principles still apply.

The aim is to demonstrate the the conclusions derived from the simple example hold even for much more complex health economic evaluations in the real world, where treatments usually affect both, the length, as well as the HRQoL of patients; where decisions are made for large populations; where the incremental cost-effectiveness ratio may not be the only relevant decision criterion; and where models may be based on highly aggregated data from multiple sources, which makes it impossible to identify any particular person who is being discriminated against.

3.1   Motivating example I

Suppose Alice has a severe health condition, and, according to some valuation system (based on the preferences of the general public), her health state

has a HRQoL of -0.1[6]. With no special treatment (alternative A), she will be able to live 10 years in her current state before she dies. Now, suppose a new life-extending treatment (alternative B) becomes available, which prolongs Alice's life by 10 more years (without changing the underlying health condition or her HRQoL), and further suppose that the new treatment does not incur any additional costs.

An economic evaluation of the two alternatives will come to the conclusion that the new treatment generates -1 QALY at no cost (see below). This means, alternative B is not only not cost-effective, but it is dominated by A.

$$\Delta Q_B = \frac{c_B - c_A}{s_B * q_B - s_A * q_A} = \frac{0}{(-0.1) * 20 - (-0.1) * 10} = \frac{0}{-1} \rightarrow \text{dominated}$$

ΔQ = incremental cost-effectiveness ratio; c = costs; q = HRQoL; s = survival time; subscripts A and B indicate the respective alternatives.

What is more, assuming a threshold of £20,000 per QALY, the new treatment would need to save more than £20,000, before it would begin to have a positive incremental net monetary benefit (McCabe et al., 2008). Based on these cost-effectiveness estimates, the recommendation would unmistakably be not to provide the new treatment to Alice.

3.2 Appraising the appraisal I

The outcome of the economic appraisal of alternatives A and B seems striking. The new treatment would extend Alice's survival time by ten years, it is available at no extra cost, and Alice might be desperate to receive the treatment, yet, society considers Alice's health state to be worse than dead, and based on this evaluation, the treatment is withhold from her.

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[6]To give a comparison, in the UK social EQ-5D 3L tariff, a value of -0.108 is assigned to state '33222', defined as being confined to bed, unable to wash or dress one-self, having some problems with daily activities, moderate pain/discomfort, and being moderately anxious/depressed (MVH Group, 1995).

It seems obvious that, in this simple example, the value judgment implicit in SWD is unethical. The negative HRQoL suggests that Alice's health state is worse than dead – but maybe not for her. As a matter of fact, Alice herself might well enjoy life (Bernfort et al., 2018). Even if her health state causes severe suffering, there might be numerous other good reasons for her to seek life-extending treatment (faith, meaning, family, etc). It should be self-evident that it is not for society to decide whether or not Alice's life is worth living. To do so would be a blatant violation of her autonomy. Alice alone should have sovereignty about this question (Chang, 2000; Farsides & Dunlop, 2001; Harris, 2003). If she is willing to receive the life-saving treatment, society seems to have no right to deny its provision.

It is important to note that, at this point, we only consider the case in which the new treatment is available at no extra costs. If the treatment were more costly than no treatment, the question if, and if so, how much additional resources society should be willing to spend to save Alice is a separate issue. Any money spent on Alice cannot be spend elsewhere, and so society may legitimately decide that saving Alice is not the most efficient use of resources. In the example above, however, we assumed that the only potential costs of the new treatment may fall on Alice, in the form of negative QALYs. But if Alice were keen to receive the new treatment, one may wonder, who would lose what exactly from her living ten years longer?

3.3 SWD and the conflict of individual and social preferences

I believe that some misconceptions about the preferences that underlie the QALY, and confusion about the distinction between individual and (assumed) social preferences are at the heart of the problem. In this section, I will elaborate on four key points, that should be considered in this context.

1. The QALY is supposed to reflect the health preferences of the general public, which differ considerably from patients' individual preferences;

As stated above, social health state values, such as the UK social EQ-5D 3L tariff, usually reflect the general public's preferences over hypothetical health states (Weinstein et al., 2009). There is no reason to assume that these values correspond to patients' individual evaluations of their own situations. In fact, a study by Burström et al. (2013) found that when social value sets are estimated based on patients' preferences, the resulting values differ considerably. Using the TTO method, they asked about 45,000 Swedish citizens to value the EQ-5D 3L health state they are currently in. From the data, they estimated an experience-based social value set. The most striking result was that the value set had no negative values: the objectively worst health state ('33333') was valued at 0.340. For comparison, the UK general public assigned this state a value of -0.594 (Dolan, 1997; MVH Group, 1995).

Even without the empirical evidence, solely on theoretical grounds, it can be argued that individuals who receive life-extending treatments do not consider their health state worse than dead. After all, medical interventions are only being offered. The individual can usually decide whether or not they want to receive it.[7] If they prefer 'being dead' over staying alive in their health state, they can refuse to take the treatment and/or choose to stop the treatment at any time (Harris, 2003). Assuming that patients are not generally misled about the effects of medical interventions, it is the act of choosing to take up life-extending treatments that – by definition – assigns a positive utility

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[7]It should be acknowledged that there can be situations, in which the individual is not able to make their own decisions (e.g. young children, unconscious patients, etc). But even then, decisions ought to be made on the individual's behalf ('what would they have decided?'). A general social welfare function does not seem to be useful for this and should be considered irrelevant.

value to their health states. Generating negative QALYs by offering life-saving treatments may thus be a paradox in itself.

2. In general, it may be justified to use public preferences as the basis for the allocation of health care resources in society;

Despite the differences in perspectives between the general public and patients, preferences from members of the general public may still play pivotal role in health policy. This may be justified, if, for example, the health care system is publicly financed. It could then be argued that members of the public, 'the tax payers', should have some say in how resources are being allocated. In addition to such democratic considerations, utilitarian ethics may also legitimize the unequal distribution of health care resources: while it may be arguable whether it is legitimate to use HRQoL as a relevant criterion, considering the lives of some individuals (socially) more valuable than others, and allocating health care resources accordingly, does not seem a priori objectionable (Versteegh & Brouwer, 2016; Weinstein et al., 2009). Notwithstanding, none of these arguments can be used to justify the existence of SWD in the current QALY framework.

3. With respect to SWD, QALY scores are misspecified and members of the general public would probably consider their preferences being misrepresented;

If HRQoL values are supposed to reflect the social preference for the allocation of health care resources, they are falsely constructed and clearly misspecified. Participants in health valuation studies are not actually asked how they prefer resources to be allocated, but to imagine being in a particular health state themselves. However, translating this one type of preferences into another may not be permitted – especially when it comes to SWD. Some people might say that they would rather prefer to be dead, than to be con-

fined to bed (Rubin et al., 2016). Yet, the very same people may well consider their preferences being grossly misrepresented, if they led to the evaluation that the lives of people who are confined to bed are not worth living, and that life-extending treatments should not be offered to them. They may rightly object that this is just not what they meant. At closer inspection, it seems rather absurd to assume that the general public in the UK would consider the lives of individuals in poor health states – i.e. about one in twenty adults (HSE, 2017) – not only not worth saving, but also unworthy of living. Yet, this is exactly what the use of SWD in economic evaluations implies.[8]

> 4. Even if some parts of the general public actually had preferences that are consistent with SWD and the QALY implications, a liberal, democratic society should discard and ignore such preferences.

Even if some individuals had such appalling preferences and preferred some other individuals to die earlier rather than later, those preferences should be deemed irrelevant. While everyone has, of course, the right to consider their own life in a certain health state to be worse than dead and to refuse life-extending treatments, considering someone else's life in a certain health state worse than dead is morally a completely different issue. To then also prefer that life-extending treatments are withheld from certain (other) individuals, because one prefers them to be dead, would undoubtedly be reprehensible[9] –

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[8]In many liberal democratic societies access to health care is considered a basic human right. Even convicted murderers and terrorists have (free) access to life-extending treatments.

[9]It may be instructive to consider a deterrent historical example. In Nazi Germany, people with mental and/or physical disabilities were deemed of no use to society and even considered a threat. They were referred to as 'unwertes Leben' (= Life unworthy of living) and money spent on their care were considered a waste of resources. Between 1939 and 1945, Nazi physicians implemented a 'Euthanasia program'. Intentionally framed as 'mercy killings' for those deemed incurably sick, it resulted in the systematic mass murder of hundreds of thousands of adults and children with disabilities (Mostert, 2002).

it may constitute, what is called, an 'objectionable preference' (Chang, 2000; Klonschinki, 2016).

Liberal democratic societies have moral constraints and laws that set boundaries for the realisation of preferences. The domain of preferences is commonly restricted to protect individual rights, for example. Certain types of preferences, say for sexism, racism, genocide, or tyranny, are being discarded as objectionable and ignored in societal decision-making: it just does not matter how many people prefer that health care is only provided to people of a certain ethnicity or how strong their preferences are. Such views are not taken into account. This means, even if some some individuals preferred that (other) individuals in SWD do not get access to life-extending treatments, their preferences should be considered objectionable and be discarded.

3.4 Intermediate conclusion

From the simple example given above and the subsequent discussion, I conclude that it should be considered illegitimate for society to deem the lives of certain individuals not worth living. Only the individual themselves may consider their lives to be worse than dead. This means, all else being equal, society never ought to prefer individuals to die earlier, rather than later (unless this coincides with the individual's own preferences). This means, extending the life of any individual by some amount of time should generate at least zero QALYs and shortening the life of any individual by some amount of time should gain at most zero QALYs respectively. While one may also argue that human life has an intrinsic, positive value, assigning a non-negative value to all human life time should be considered a minimal ethical constraint for society (Franklin, 2016).

4 The (un)ethical implications of SWD on the group level

So far, we have only considered economic evaluations of treatments for specific individuals. Yet, in the real world, decisions are, of course, made for groups. To ths end, HRQoL values are aggregated, across many different individuals and over time, into 'disease state utilities'. These disease state utilities usually represent the average HRQoL of a group of patients with some disease (e.g. 'pre-progression' and 'post-progression' in lung cancer; 'mild', 'moderate', and 'severe' in COPD, etc).

For a group, in which all members lived in SWD, the arguments we used on the individual level seem to be directly transferable: If we maintain that society should provide life-extending treatment for any individual in a SWD, given that the treatment is available at zero (additional) costs, it follows that society should do the same for a whole group of individuals in SWD. What is more, even though the logical connection may not be immediately apparent, SWD can also have significant implications for individuals who live states that are better than dead (SBD), and for treatments that are not available at no extra cost. To demonstrate this point, we will slightly expand the simple example from above.

4.1 Motivating example II

Suppose Alice, Bob, and Claire are a group of patients with some chronic disease D. They are all in different health states, with HRQoL values of ˘0.1, +0.2, and +0.4, respectively. The average HRQoL for disease D is then given by $\frac{-0.1, +0.2+0.4}{3} = 0.167$.

4.2 The (indirect) effect of SWD on average utility scores

This evaluation is problematic, because the average HRQoL reflects a mixture of Bob's and Claire's positive, and Alice's negative HRQoL. If we maintain that society may not deem individuals' lives unworthy of living, reducing the

willingness to pay for an additional life year in that group proportional to Alice's negative HRQoL, is illegitimate. The notion of 'negative QALYs' is unethical, regardless of whether they occur on the individual- or aggregate group-level. The implied value judgment is exactly the same. To reiterate this crucial point, an economic evaluation that uses the average utility value of 0.167 to value changes in the survival times of patients with disease D, is making societal decisions as if Alice's life were considered unworthy of living, as if society prefers her to die earlier rather than later. t.

Maintaining that society should assign a non-negative value to all human life time, I argue that the use of SWD to value changes in life times should be abandoned. Accordingly, one additional life-year in patients with disease D should yield at least $\frac{0 \ + \ 0.4 \ +0.2}{3} =$ 0.2 QALYs. Now we can see how the provided example becomes relevant for life-extending treatments that are not available for free: with the initial (unethical) HRQoL estimate for disease D patients, and still assuming a threshold of £20,000, society would be willing to spend $0.167 * £20,000 =£3,333$ per additional life-year. When a non-negative value is assigned to all life-years, and the disease state utility of disease D patients is increase to (at least) 0.2, society would be willing to spend $£20,000 * 0.2 = £4,000$ per additional life-year - this is 20% higher than the original figure.

What this result suggests is that traditional health economic evaluations may systematically underestimate the value of any life extending medical intervention that does not fully resolve the underlying impairment or disability. Applying the minimal ethical constraint would increase the disease state utilities in many areas. Evidently, some patient groups may be more affected by this than others, depending on the prevalence and magnitude of SWD.

Furthermore, it seems conceivable that some life-extending treatment exist, say for disease D, that is currently not being considered cost-effective, but would be considered cost-effective, if the minimal ethical constraint were applied. Through this mechanism, SWD do not only discriminate against individuals who live in SWD themselves, but also against anyone who is in the same disease group: Bob and Claire would be disadvantaged, if society decides not to provide some life-extending treatment for disease D patients, only because of the impact that Alice's SWD had on the group's average utility value.

4.3 Using SWD to value changes in individuals' health states

Up until now, we have discussed the ethical issues with SWD in the context of treatments that only affect people's survival times. Before we proceed to explore potential solutions, we also have to consider treatments that affect HRQoL.

Preserving HRQoL differences between SWD seem desirable and necessary to determine whether living in SWD i is better or worse than living in another state j. As long as survival times are held constant, those evaluations also do not seem problematic. They only reflect relative preferences over different health states, and do no involve any judgment about the value of additional (or lost) life-years. This means, for the assessment of treatments that only affect HRQoL, but not survival time, the use of SWD do not imply discriminatory value judgements. On the contrary, moving someone from a SWD to full health for one year even generates more than one QALY[10]. This means, while SWD should not be used to to value changes in survival times, their use to value changes in HRQoL seem unproblematic. This leaves open how

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[10]In the EQ-5D 3L for the UK, moving from the worst ('33333') to the best state ('11111') for one year generates (1 - (-0.594) = 1.594 QALYs.

changes in HRQoL during gained life-years should be valued – this question will be addressed in the next section.

5 Alternative solutions

I have argued that using SWD to value changes in survival time is unethical, and that the current QALY framework should to be adapted. Broadly speaking, there are two different types of solutions to this problem: either the preference elicitation methods need to be altered, so that negative HRQoL values are not produced, or the QALY arithmetic needs to be adjusted, so that QALYs cannot be negative, even if negative HRQoL values exist.

5.1 Whose preferences and what kinds of preferences?

To solve the problems around SWD, one could elicit health state preferences from a different source, or use a different perspective in the elicitation, so that the resulting social value sets simply do not contain any SWD. In particular, preferences could be elicited from individuals who experience those health states themselves. As explained above, experienced utilities differ from hypothetical utilities in many respects, including that they give considerably higher values and usually do not contain negative HRQoL values (Burström et al., 2014; Versteegh & Brouwer, 2016, Brazier et al., 2018). Alternatively, if the preferences over hypothetical health states are elicited from members of the general public, one could ask the individuals to imagine someone else being in that state, rather than asking them to imagine being in the states themselves. This method is also likely to produce higher, and non-negative values. The Person trade-off (PTO) method may also be considered in this context (Nord, 1995) – assuming that the purpose of social value sets is to incorporate the view of the general public into societal decision making, one could argue that PTO preferences more accurately reflect social preferences

for the allocation of resources in the health care systems (Weinstein et al., 2009).

5.2   The QALY arithmetic and its alternatives

The QALY arithmetic is depicted in Figure 2. It offers a simple, but internally consistent framework for valuing changes in the quality and quantity of life. The QALY is computed as the product of survival time and HRQoL. Accordingly, for each box A-E in Figure 2, the QALY is given by its geometric area, defined by the product of time t and HRQoL q (e.g. For box A: $Q_A = t_A * q_A$).
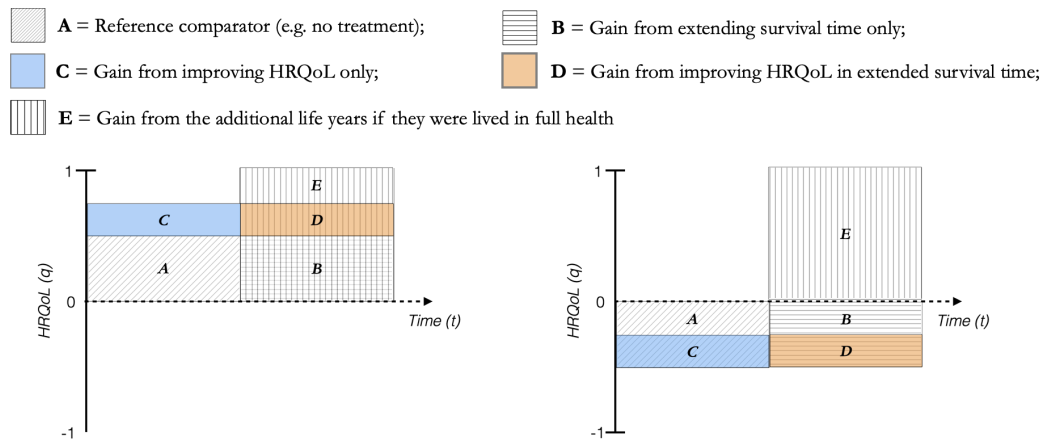

Figure 2: The left figure shows the QALY framework as it is usually presented; and the right is the corresponding figure for SWD. Note that for states better than dead, areas B and D overlay area E, and that for SWD, area C overlays area A, and area D overlays area B. Adapted from Basu et al., 2020.

If we take area A as the base comparator (e.g. no treatment), area B gives the incremental QALY gain (or loss) from additional life years, area C the gain from HRQoL improvements, and area D the gain from HRQoL improvements in additional life years. The incremental QALY gain from a treatment, which improves survival time and HRQoL is given by: $\Delta Q = B + C + D$

To retain the principles of the QALY frameworks, but ensure that a non-negative value is assigned to all additional life-years, there are broadly three

possible approaches, which will be briefly described: 1) assign a value of zero to any additional life-year in a SWD (minimal constraint approach); 2) assign a value of one to any additional life-year in a SWD or SBD (Equal Value of Life); or 3) assign different, but strictly positive values to additional life years in a SWD or SBD, depending on the HRQoL (Health Years in Total).

5.2.1. Minimal constraint

As a minimal ethical constraint approach (MCA), we define that all additional life-years have a value of at least zero, while all other aspects of the QALY arithmetic are kept:

$$\Delta Q_{MCA}(B, C, D) = \begin{cases} \text{B+C+D} & \text{if B+D} \geq 0, \\ \text{C} & \text{if B+D} < 0, \end{cases}$$

Inadvertently, this framework yields perplexing results. Setting the value of any additional (or lost) life-year in a SWD to zero, implies indifference between any amount of additional (or lost) life-years in any SWD: t additional years in any SWD i is equivalent to $t + k$ additional years in any SWD j, for any k, including $k = -t$, i.e. immediate death. This means, the evaluation is unresponsive towards changes in survival time, as well as changes in HRQoL during gained life-years. At the same time, however, a small change in HRQoL during the reference survival time (areas $A + C$) outweighs any change in life-years in SWD: increasing the HRQoL by any amount m, with $m > 0$, yields more QALYs than gaining t more years in any SWD.

5.2.2. Equal Value of Life

The Equal Value of Life (EVL) approach was proposed by Nord et al. (1999), as part of a broader initiative to incorporate fairness and equity concerns into the QALY. They argue that HRQoL weights should only be used to value changes in health states – any life year gained, however, "should count as

one [QALY] and no less than one" (Nord el at., 1999). QALY gains from additional life years are thus not given by area $B \pm C$, but area E:

$$\Delta Q_{EVL}(B, C, D) = C + E$$

In contrast to the MCA, the EVL is responsive to gains in lifetime, but it remains unresponsive to changes in HRQoL during additional life time. For the latter, the EVL does not even differentiate between the worst SWD and full health, or any other SBD: $t + k$ additional life years in any SWD or SBD i yield more QALYs than t additional years in any SWD or SBD j, for $k > 0$.

5.2.3. Health Years in Total

Basu et al. (2020) recently proposed the Health Years in Total (HYT) framework, which aims to integrate EVL and the QALY approach. It uses a weight of 1 QALY for every life year gained, but also takes into account HRQoL changes that occur during those additional life years:

$$\Delta Q_{HYT}(B, C, D) = C + D + E$$

In effect, the HYT is responsive towards changes in both, HRQoL and life time. Although SWD are not explicitly mentioned by Basu et al. (2020), their approach also ensures that additional life years always have a non-negative value (as long as SWD have a lower limit of -1). More specifically, the HYT has the following characteristics: Firstly, all else being equal, more life years are better than fewer ($(t + k) * i > t * i$, if $k > 0$), i.e. time in any state is better than dead. Secondly, higher HRQoL is preferred over lower ($t * i > t * j$, if $i > j$). And finally, gains in lifetime are traded-off against gains in HRQoL ($t * i > (t + k) * j$, if $i > j + k$).

5.3 Choosing a method

It is not within the scope of this paper to provide an exhaustive list of possible alternatives, nor to prescribe any particular method. The examples given above shall only demonstrate that there are different approaches one could take to ensure that SWD are not used to value changes in life time in economic evaluations – each comes with its benefits and challenges.

As a practical solution, the QALY arithmetic can be adjusted, so that it can only produce non-negative or positive values by design. However, all three methods presented above (MCA, EVL, and HYT) add something 'extra' to the social welfare function, a liberal constraint, which is neither derived from TTO preference data, nor based on any other empirical estimate, but set by some decision-maker, based on theoretical arguments. Whether this kind of paternalistic approach is considered legitimate and/or desirable depends on one's normative position. At any rate, imposing rules for non-negative or positive HRQoL values post hoc will distort the QALY's otherwise consistent trade-off between units of quality and units of quantity of life.

Alternatively, changing the perspective or the source of preferences in health valuation studies (e.g. using patients' instead of the general public's preferences) may solve the problem of SWD, without the need to revise the arithmetic of the QALY framework. But such a change would also require additional theoretical justification, as it would involve a major shift in the normative position of health economic evaluations.

6   Discussion and further considerations

Based on the premise that social preferences are to be constrained by ethical norms and individual rights, I have argued that SWD should not be used in health economic evaluations to value changes in individuals' survival times.

Liberal democratic societies may not attempt to decide whose lives are worth living, and whose are not. Instead, it seems imperative to maintain that all additional life-years have, at least, a non-negative social value.

The position outlined in this paper does not appear to be controversial: while there may be reasonable disagreement over the relative value of life-years gained in one group (e.g. individuals with underlying health conditions) compared to another (e.g. individuals with none), additional life-years should never be considered a loss for society by and in themselves. Yet, this is exactly what SWD imply, if they are used to value changes in people's survival times. It therefore seems striking how widely and uncritically SWD have been, and are being used in health economic evaluations (e.g. Sharma & Stano 2010). It can only be attributed to the complexity of economic modelling, which may (up untill now) have concealed the implicit value judgments, that there has not been an outrage from the general public, patient advocacy groups, or health economists.

While I advocate for abolishing the use of SWD in health economic evaluations, I do not intend to prescribe any particular approach to do so. I proposed one approach, the MCA, to adapt the QALY arithmetic, but also outlined its limitations, and acknowledged that, depending on one's normative position, assigning a non-negative value to human life-years may seem insufficient. The EVL and the HYT represent two alternative approaches that go further than the MCA in that they assign positive values to all life-years – the EVL maintains that every additional (or lost) life-year has the same value, while the HYT also takes into account gains from HRQoL during additional life-years (Basu et al., 2020; Nord et al., 1990). Alternatively, if the QALY arithmetic is to be kept, the problem of SWD could also be avoided by eliciting preferences from a different source (e.g. patients) or by using a different perspective (e.g. third-person) in the elicitation. In addition, there

may be other methods, not mentioned in this paper, which may achieve the same goal (Franklin, 2017). This is to say, there are multiple approaches for avoiding the use of SWD in health economic evaluations. The question, which approach is most appropriate, cannot be answered in isolation, but must be guided by a normative theory of the valuation of health. In the current absence of a widely accepted, coherent theoretical framework, more conceptual research seem to be required.

Given that health economic evaluations are ultimately supposed to inform societal decision making, health economists should ensure that the methods that are being used in economic evaluations of health interventions reflect the norms and values of society as a whole. This requires entering into a meaningful and sustained dialog with citizens, policy makers, and other stakeholders. Future conceptual research might also benefit from a closer consideration of the relevant literature in other fields (sociology, social choice, democratic theory, etc) and broad, interdisciplinary collaborations.

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