DROP DEAD

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Abstract

By convention, values for generic 'preference-based' measures of health are anchored at 1 = full health and 0 = dead. Consequently, stated preference methods used to value health states often involve consideration of the state 'dead' or 'death'. Using dead as an anchor implies that states worse than dead must be assigned negative values. Despite considerable efforts devoted to developing new methods, the need to identify negative values continues to cause fundamental problems; for example, there is no agreement on the lower bound for negative values. This paper challenges the assumption that anchoring health state values at 'dead = 0' is a necessary condition for values to be used in quality-adjusted life year (QALY) estimation.

We consider five propositions, using narrative reviews of the literature and conceptual explication of the problem: i) anchoring at 'dead' is not required by theories of scale measurement and utility; ii) calculating QALY gains does not require a distinction between states better than and worse than dead; iii) cost-effectiveness analysis does not require that 'dead' has a value relative to health states; iv) using 'dead' as an anchor causes problems that make valuation studies difficult to conduct and their results difficult to interpret; and v) there are alternative states to 'dead' that exhibit favourable properties for anchoring.

There is strong support for each proposition. Anchoring health state values at dead was an arbitrary choice made early in the development of health state valuation methods. While it is important that, for economic evaluation, dead should equal 0 and dead people should generate no QALYs, we show that anchoring at dead = 0 is not a necessary condition for this.

We conclude that anchoring 0 at dead is not a requirement of the theoretical foundations of health status measurement or of cost-utility analysis. The use of dead as an anchor is unnecessary and undesirable because of the methodological and conceptual issues it causes and because alternative approaches are feasible. There is a clear case for health economists to drop 'dead' from health state valuation tasks.

1 Introduction

It is conventional, in calculating quality-adjusted life years (QALYs) for cost-effectiveness analysis, to employ single-number summaries of health states derived from health measurement instruments such as the EQ-5D. These summaries are, conventionally, measured on a scale anchored at 0 and 1, where 1 means 'full health' and 0 means 'dead'. Some states may be considered worse than dead – a 'state worse than dead' (SWD) – and therefore assigned a negative value. In estimating values from a patient or general population, it is, therefore, necessary to use stated preference methods that are capable of eliciting both positive and negative values.

Defining 'dead' as a health state has long been recognised as problematic (Kind and Rosser, 1979; Macran and Kind, 2001). More recently, some researchers have questioned the role of 'dead' in health state valuations (Parkin, 2011; Augestad et al., 2013; Little et al., 2014; Bernfort et al., 2018). The requirement to anchor at dead – and to estimate values for SWDs – introduces considerable complexity to valuation studies. A key challenge is to achieve methodological consistency for states better than dead and SWDs. Unlike health states better than dead, which have an upper bound value of 1 for 'full health', there is no obvious lower bound to negative health state values. Moreover, the methods used to handle SWDs can have consequences for the estimated values for all states, not just SWDs. The challenges involved in eliciting values for SWDs have led to much research on this issue, none of which has produced a method that finds widespread approval.

Despite the importance of these matters for the development and use of value sets, a thorough exploration of the origins of and rationale for anchoring at dead has (to our knowledge) not been conducted. The aim of this paper is to make a case for avoiding the use of 'dead' in health state valuation. We start by considering the history of the use of 'dead' as an anchor and the reasons for its use. From this, we present a series of propositions that challenge the presumption that anchoring health state values at dead is the best approach. In each case, we consider the evidence relating to that proposition, drawing on foundational literature on health status measurement, extra-welfarism, and cost-effectiveness analysis. We conclude by briefly describing alternative ways in which health state values could be anchored.

The paper is specifically concerned with the estimation of values that are to be used to generate QALYs for use in economic evaluation. Later, we outline the required properties of values used for this purpose. We do not examine other uses of values (such as to provide a convenient single number summary of health states for population health studies or statistical analysis) because they do not impose the same requirements.

2 The role of ‘dead’ in health state valuation

The use of ‘dead’ in health state valuation arose from developments in three related areas: measurement of health through health status indicators; the valuation of health states; and the use of health state outcome measures in cost-effectiveness analysis, in particular QALYs.

The death of individuals is easy to observe and record, such that mortality statistics have been collected for centuries. The health status indicator movement of the 20th Century was aimed at obtaining data on more ambitious measures of health. However, as Goldsmith (1972) noted, despite the decline in popularity of mortality as a health indicator in the 1960s, “mortality is the only identifiable common denominator of health status and, thus, its value should not be categorically dismissed”. In one of the earliest examples of a health status index, Chiang (1965) equated death to a state of ill health. Sullivan (1966) referred to death as “a well-defined event with adequate operational referents for our purposes [while] morbidity, however, is a diffuse and general term which requires clarification”.

In an influential paper, Fanshel and Bush (1970) developed a valuation-based health state index (HSI) described in terms of function and dysfunction, based on a person’s ability to carry out activities of daily living (ADL). This included death, defined as a state of absolute dysfunction.

Fanshel and Bush described different methods for estimating weights for states of well-being and death, including ‘weighting through equivalence in time’, which is essentially what has become known as the time trade-off (TTO) method. Function measured by ADL cannot be less than zero (where there is no function), so there was no concept of health states that could be given a weight below zero. Fanshel and Bush also described a measure of outcome for use in cost-effectiveness analysis called ‘dysfunction-free years’, which has the same calculation basis as the change in QALYs used in cost-effectiveness analysis. For this method, the level of dysfunction is multiplied by its duration and summed for a population with and without a health care programme. The difference is a measure of the outcomes of the programme.

Torrance et al (1972) extended this by explicitly placing the weighting process for a health state indicator in the context of utility measurement, retaining the scale assumption that ‘the healthy state’ has a value of one and ‘the dead state’ has a value of zero. The measure of outcome for use in cost-utility analysis is the number of ‘healthy days’ generated, similar to ‘dysfunction-free years’ and effectively the same as changes in QALYs.

Torrance et al also suggested that there might be states that are worse than dead, which have negative utility values. This gives ‘dead’ an active role in the valuation of health states in addition to its passive role as one of the anchors of the scale on which values are measured. In effect, health states judged to be better than dead are valued by comparing the health state with the preferred state of being in full health; those worse than dead with the preferred state of being dead. It is, therefore, necessary to use different methods for states better than and worse than dead and to ask respondents in a valuation study to identify with which category they associate a state as part of the valuation exercise.

Allowing for SWDs has the consequence that the scale has anchors but no defined minimum value. When translated into QALY measurement, it introduces the concept of states that generate negative QALYs, for which being dead is a preferred state. The value of states that generate positive QALYs incorporates preferences for being alive rather than dead. It is therefore possible to generate more QALYs than there are life years by improving the health of a person in a very bad health state. Effectively, this changes the scale of the QALY metric and therefore the measurement of QALYs gained from different interventions.

We will argue that it is not necessary to define dead as an anchor in order to obtain relative weights for health states; that it is not necessary to distinguish between health states that are better than and worse than dead in order to calculate QALYs and QALY gains; and that it is not necessary for judging improvements in health to incorporate preferences for being alive. We further argue that the inclusion of dead in health state valuation causes methodological problems that have no satisfactory solution and that there are plausible alternatives which overcome those problems.

Although not the main point of this critique, it is important to note that the words used to describe 'dead' in valuation studies may matter. In early expositions of health state valuation methods, the terms 'dead' and 'death' were both used, sometimes interchangeably and sometimes with different meanings. In the English language, 'dead' always refers to a state, but 'death' is an ambiguous term that can mean either a state or an event. For example, an instruction in a valuation study such as "imagine living in this health state for 10 years, followed by death" suggests an event, but could mean a state. A 'state worse than death' would normally be regarded as the same thing as a 'state worse than dead'. 'Immediate death', which is commonly used in valuation studies, is most obviously interpreted as an event. While it is reasonable, for convenience sake, to assign the state 'dead' or 'death' a value of zero, this does not imply that 'death' as an event should also be valued at zero (Parkin, 2011). Our concern in this paper is with 'dead' as a state.

3 Anchoring health state values at 'dead' is not required by theories of scale measurement and utility

In cost-effectiveness analysis, it is necessary that the measure of changes in benefit – changes in QALYs – is quantified on a ratio scale; it has a true zero and the interval between adjacent scale points is the same for every point. A ratio scale has no negative values, but it is of course possible to have negative QALY gains. This is a different use of the word 'negative'; it describes a loss of QALYs measured on the same scale as a gain. It is similar to, for example, money, which has a true zero (no money) and equal intervals (€2 is twice as much as €1). There is no such thing as negative money, but it is possible to lose €2, say that this is twice as big an amount as a €1 gain, and conclude that the net loss would be €1.

QALYs do not need to be measured on a ratio scale for *changes* in QALYs to be on a ratio scale. All that is required is that QALYs should be measured on an interval scale; a scale which also has the same distance between scale points but has an arbitrary zero. An interval scale for QALYs implies that the difference between 2 QALYs and 4 QALYs is the same as that between 4 QALYs and 6 QALYs, but we cannot say that 6 QALYs are three times as big as 2 QALYs because this invokes an additional assumption about the relative value of zero. However, if we are interested in QALY changes, it is true that a gain of 4 QALYs (generated by a change from 2 QALYs to 6 QALYs) is twice as big as a gain of 2 QALYs (generated by a change from 2 QALYs to 4 QALYs or 4 QALYs to 6 QALYs).

Life years form a ratio scale, thus embodying the requirements of an interval scale. In order for QALYs to exhibit interval scale properties, the scale on which health state values are measured must satisfy interval scale properties. As we will argue, it is not necessary to use 'dead' to obtain health state values with interval properties.

The underlying axioms for the construction of a measurement scale that has interval properties are well-known. Such a scale will be unique up to a linear transformation; assigning an arbitrary value to any two points on the scale will enable all other points to be assigned a value. A key development for such scales was to define them in terms of a utility function that could give interval properties to its objects. Von Neumann and Morgenstern (1944) defined the objects of the function as states that have a probability of happening. They developed axioms that would enable the utilities for those states to be given a scale value, using the method of mathematical expectation, known as von Neumann-Morgenstern (vNM) utilities.

Expected utility theory assumes that if a person is indifferent between two uncertain states of the world, their expected values must be the same. It is, therefore, possible to derive a scale that depends both on the values attached to the objects of the utility function and to the probabilities of their occurrence. These uncertain states of the world were referred to as gambles, having two possible mutually exclusive outcomes. In practice, measuring a scale from identifying indifference between two gambles is difficult, so a simplification was suggested whereby one of the states of the world is a certainty; in effect a gamble with a probability of one that a particular object is achieved. This is the basis of the 'standard gamble' (SG) as a means of measuring health state utilities. Applied to health state valuation, the certain state is the health state that we wish to evaluate, which is compared with a gamble in which two other mutually exclusive health states occur with given probabilities. A key point is that none of these states must necessarily be 'dead'.

The resulting scale has the desired interval properties. A further simplification is used to make the calculation of scale values easier. It is mathematically convenient to define the value of the uncertain alternatives as one and zero because the value of any health state then corresponds to the probability of the alternative that is given the value one. However, the choice of which health states are given those values is arbitrary, with no effect on the interval properties of the index. Again, it is not necessary for the zero-valued alternative to be 'dead'.

The time trade-off (TTO) method was developed by Torrance et al (1972) to overcome difficulties found in practice with the SG method, relating to subjects' comprehension of probabilities. Nevertheless, it was intended to be a means by which vNM utilities could be estimated, via a mathematical function that would link TTO with SG estimates. The axioms of TTO scale values have been considered (Torrance, 1976; Buckingham and Devlin, 2006) but, to our knowledge, have never been fully stated. For the purpose of our discussion, it can be assumed that they are the same as those for vNM utilities. In this case, the objects are assigned a duration rather than a probability and it is assumed that when a person is indifferent between alternative states of the world – that is, combinations of health states with given durations – the sum of the values of the health states multiplied by the durations are the same.

The SG defines health state values relative to other health state values, and the choice of the health state which is assigned the value zero is arbitrary. However, in TTO, the health state values are conceived as fixed rather than relative, specifically the interval measured from the value zero. In the SG, calculations are simplified by the fact that probabilities are bounded between 0 and 1, but durations have no upper bound, so the TTO scale remains a function of two durations rather than one. The resulting scale, therefore, depends on the health state values and their durations.

For both the SG and the TTO, it would be possible to define any health state as representing zero. A convenient choice in both cases is to specify the best and worst possible states as 1 and 0, respectively, because this gives an interval scale for the index lying between 0 and 1. Yet, current practice is to assign the value 0 to dead or death and to allow negative numbers to represent the value of states considered to be worse than this.

Torrance et al (1972) did not discuss the rationale for assigning the value zero to any particular state. Initially, they asserted that "an adequate scale might range from 0 for death (with negative values assigned to fates 'worse than death', if they exist)". Later, they referred to the World Health Organization definition of health, where the worst state is 'total absence of function'. Next, they discuss utility measurement and say that:

> *"The measurement technique used produces a linear interval scale. For convenience, the healthy state (i=1) is arbitrarily assigned a value of one (h_i=1) and the dead state (i=n) a value of zero (h_n=0)."*

In their subsequent expositions of SG and TTO, death as a state is not referred to explicitly – the state that has the value zero being referred to as h_n. Death is, however, referred to as an event, which takes place after the time period during which a health state exists.

There is one important line of argument that some researchers have used to defend the use of 'dead' in health state valuation, building on the 'zero condition'. Simply put, this is the idea that health states are of equal value when duration is zero (Bleichrodt, Wakker and Johannesson, 1997; Miyamoto et al., 1998). Based on this notion, and in contrast to our reasoning set out above, Roudijk et al (2018) have argued that QALYs must be measured on a ratio scale. Their work implies that an essential assumption to achieve this is that dead should be valued at zero and that dead should therefore be used as a zero anchor in valuation studies. It is true that, if we require a QALY measure to compare absolute values, a ratio scale is needed. However, the principal uses of QALYs in practice – to estimate incremental QALY gains – require only a relative measure. The authors' arguments are in part based on the fact that a defined zero value for QALYs is essential and that being dead has, by definition, a value of zero QALYs. However, because the dead state involves no life years, it is not possible to place a separate value on the 'quality of life' generated in this state, or even to conceive of such a concept. As a result, it has no implications for the measurement of quality of life. Hence, the 'zero condition' provides a basis for asserting that dead must have a value of zero, but not that a zero anchor must be based on valuation of the 'dead' state. Below, we discuss further arguments relating to people's preferences and the convenience of using dead as an anchor.

Nothing in the theory of scale measurement or utility measurement requires the scale to be anchored with dead or death as zero. Though Torrance et al (1972) admitted that this was an arbitrary choice, no justification was given for that choice as opposed to alternatives such as the worst possible health state. More recent exposition has demonstrated the apparent convenience of 'dead' for scale measurement, with post hoc rationalisations for its use in the context of QALYs (Miyamoto et al., 1998; Roudijk, Donders and Stalmeier, 2018).

4 Calculating QALY gains does not require a distinction between states better than and worse than dead

Using 'dead' to provide one value on a continuum of health states, rather than a minimum value for an indicator, has the consequence that there is a distinction between states better than and worse than dead. The use of this distinction in research has generated a body of evidence that some people do identify some health states as being 'worse than dead'. This has practical consequences for how valuation methods are currently applied because different valuations of these are required for states in the two categories.

In section 6, we discuss some of the problems that this causes for health valuation methods, in terms of the difficulty of obtaining values for states worse than dead and the inconsistency that this may generate between the values attached to states in these two categories. In this section, we consider whether the empirical finding that some states are valued as 'worse than dead' suggests that it is necessary to make this distinction in the calculation of QALY gains (or losses).

The importance of identifying states as better or worse than dead may depend on whether it is viewed as acceptable for an intervention to promote death. If the aim of an intervention is to improve health, then it is of no consequence for the measurement of the value of the health gain if the initial health state was better or worse than dead. Moreover, it is irrelevant if the final outcome is better or worse than dead if the objective is to maximise QALYs.

The decision rules only differ if the implication of a person being in a SWD is that they should be allowed to die. In effect, this defines a 'minimum endurable health state'. In such cases, estimating the different values attached to different SWDs would be an irrelevance, since the magnitude of any change is irrelevant. Decisions in this context should surely be determined by ethical rather than economic considerations, such as a person's right to end their own life or a physician's moral duty.

A consequence of assigning negative values to SWDs is that health improvements for those with a SWD are in some circumstances valued more highly than for those who have a health state valued better than dead. In the extreme, an intervention which improved the health of a person with a SWD to a state as bad as being dead would be valued more highly than an intervention that restored to full health a person who initially had a health state as bad as being dead. It could be argued that there is a duty to prioritise those with a SWD over those in other health states and therefore to value their gains more highly. However, that argument applies to comparisons between any two initial health states; should the valuation of health improvements be greater for those with worse initial health states? It is not clear that states worse than dead are a special case for that argument.

5 Cost-effectiveness analysis does not require that 'dead' has a value relative to health states

Section 3 established that it is not necessary to use the state 'dead' to calculate a health indicator of the kind used to calculate QALYs, and Section 4 that it is not necessary to distinguish between states better than and worse than dead when measuring QALYs. Are there other reasons why 'dead' should be incorporated in a QALY measure?

It may be argued that, because death is a possible outcome of ill health and that delaying death is a key aim of health care, it is essential that we place a value on death. Moreover, this should be comparable to the value that we attach to health improvements that improve quality of life and enable comparable values to be attached to health care improvements that affect both mortality and morbidity. In addition, we have noted that studies have shown that some people do rate some health states to be worse than death, suggesting that they do state their preferences as if death forms a point on a continuum of values that is not necessarily at the bottom of the scale.

The key requirement for cost-effectiveness analysis is that the state of being dead must have a QALY value of zero by virtue of there being no life years in which to generate health or quality of life. Likewise, to be alive is a prerequisite for a state to hold value in terms of health or quality of life. Viewed in this way, 'dead' is not a health state. The fact that it is an outcome that needs to be included in assessments of ill health and health care does not mean that it is a health state that can be compared with health states among the living. In this respect, death is analytically (though not emotionally) similar to other possible outcomes of ill-health and health care, such as unemployment among adults or the loss of human capital through restriction of children's education.

If we were to describe dead as a health state in EQ-5D-5L terms, we might assess a dead person's health state profile as 55511 (not able to do anything but suffering from no pain or anxiety), but this state often has a higher value than zero in EQ-5D-5L value sets (Parkin, 2011).

More generally, the issue of what ought to be included in an assessment of QALYs can be addressed by reference to extra-welfarism (EW), which we interpret as supplementing utilities with other information. EW is the dominant theoretical foundation for health technology assessment (HTA) (Culyer, 1989). What guidance – if any – is provided by the EW approach regarding the role of anchoring at 0 using 'dead'?

EW arose from criticism by Sen (1980, 1985) of the reliance of applied welfare economics on utility. Sen regards utility as a fundamentally flawed basis for making social choices. He argued that consideration of the 'characteristics of people', including their 'functionings' and 'capabilities', is important in decision making, creating the possibility of a non-utility view of quality of life. Culyer (2012) describes the "health measurement movement (QALYs, health indices etc) as an example of this non-utility approach" (p.58).

Culyer (1990) identifies 'characteristics of people' as the objects of value within the extra-welfarist evaluative space, which could include characteristics relating to health or non-health aspects of life, such as 'being able to feed oneself' or 'being reassured'. Thus, EW offers loose guidance on what is to be included in the social welfare function and how it is to be measured. It does not prescribe health as the sole domain of interest; it does not prescribe that QALYs are the only way of measuring health; and it does not require that quality of life values obey theories of utility. The foundations of EW do not stipulate the use of health status indices with anchoring, let alone anchoring at dead = 0. Thus, there is no specific basis in EW for adopting 'dead' as an anchor for health state values and alternative anchors could be consistent with the conceptual framework.

Indeed, it could be argued that EW rejects 'dead' as an appropriate anchor for valuing health because society comprises no people who have the characteristic 'dead'. Characteristics of people are weakly defined by Sen and Culyer, but all examples relate to states that can be experienced, and it is not the case that the state 'dead' can be experienced by current members of society. Being dead therefore has no apparent meaningful relationship in value to other characteristics of people considered relevant within an extra-welfarist framework. Thus, anchoring at 'dead' could be interpreted as being inconsistent with extra-welfarism.

If social choices regarding health care are to be made within an extra-welfarist framework, we would not necessarily be interested only in health, and 'death' might be considered normatively relevant. Nevertheless, it is not a requirement of EW, and there is no conceptual basis in EW for selecting 'dead' as a relevant characteristic.

Extra-welfarism has also been interpreted as being synonymous with health maximisation (henceforth referred to as EW-HM), supplanting utility with health as the maximand. This is a common interpretation of the operational form of EW in HTA in the UK and elsewhere. In practice, EW-HM has been operationalised as QALY maximisation. A core feature of QALYs is that they facilitate trade-offs between interventions that improve quality of life and those that postpone death, implying importance to the value of 'dead'.

Here, we assert that QALYs need not use values anchored at 'dead', even if the state of 'dead' is assigned a value of zero in practice. This assertion invokes fundamental questions about the QALY and what it represents, which lie beyond the scope of this paper. For our purposes, it will suffice for us to recognise that QALYs could be bound at a lower extreme by a state that satisfies the zero-condition but bears no relation to the state 'dead'.

If we seek to maximise health, the positioning of 'dead' on a value scale with interval properties is, as we have demonstrated, of no consequence because the interval properties of the underlying scale remain unchanged. The value of 'dead' is of no consequence to the process of health maximisation and therefore not required as part of EW-HM. Health maximisation remains possible in trade-offs between interventions that extend life and interventions that improve quality of life because the value of life-extension lies entirely in the generation of QALYs and not in the postponement of death. The process of calculating QALYs does not require valuation of a 'dead' state, as being dead will yield zero QALYs irrespective of the choice of anchor.

As currently practised, QALYs combine information on health-related quality of life and total quantity of life. By incorporating length of life as a part of the health state valuation process, non-health considerations are necessarily invoked. By incorporating an un-nuanced definition of quantity of life (with reference to 'dead'), the boundaries of the EW-HM evaluative space are potentially undermined. While trade-offs between health states can be made based on the same set of health-related characteristics, trade-offs with death might be expected to be dominated by non-health sources of value.

If social choices regarding health care are to be made on a narrower interpretation of extra-welfarism as health maximisation, this suggests that any anchors should be defined exclusively in terms of health. Thus, the use of 'dead' is likely to undermine the boundaries of the evaluative space.

6 Using 'dead' as an anchor causes problems that make valuation studies difficult to conduct and their results difficult to interpret

We have established that anchoring health state values with the outcome state 'dead' is not required by its basis in health status measurement, its use in measuring QALYs, or by the extra-welfarist foundations of cost-effectiveness analysis. In this section, we look beyond matters of theory to consider whether 'dead' exhibits properties that make it unsuitable as an anchor in valuation studies. We further explore the historical literature to identify the basis for the use of 'dead' as an anchor in health state valuation and identify the extent to which this was linked to its properties as an anchor.

6.1 How is 'dead' currently used as an anchor?

In TTO, death is what follows each of the two 'lives' which are described. That is, life A is presented (a varying time in full health, followed by death) and compared with Life B (a fixed time in the health state to be evaluated, followed by death). If a respondent identifies a health state as worse than dead, the task can then switch to choosing between Life A and the alternative of 'immediate death' (Dolan et al., 1994). Early observations revealed that some respondents would refuse to prefer Life A to Life B for any length of time in full health. As a result, exercises were altered such that participants would first identify whether a state was better or worse than dead and then be provided with the appropriate task.

There are other variants of the TTO, such as lead and lag time, which allow both positive and negative values to be elicited using a single task (Devlin et al., 2013). By trading off more years of life in Life A than are experienced in the state to be evaluated in Life B, the participant reveals negative values without explicit mention of dead or death other than it being something that follows both scenarios. This leads to concerns that participants' responses might generate negative values without them realising that this implies the state was worse than dead. As a result, the EuroQol Group created a composite TTO for valuation of the EQ-5D, which comprises the conventional TTO for states pre-identified as better than dead and the lead time TTO for states worse than dead.

An alternative to the use of TTO is the discrete choice experiment (DCE), in which pairs of states can be evaluated without stating their duration or invoking any consideration of dead or death. However, in order to anchor these for use in QALYs, the experiment would have to be modified by including duration in the definition of states; or explicitly comparing the states with 'dead'; or by undertaking additional valuation methods such as the TTO (Norman, Mulhern and Viney, 2016) to provide a post hoc means of anchoring at dead.

6.2 Challenges arising from the current use of 'dead'

Evidence suggests that people are not always aware of the implications of the 'dead' state when completing valuation exercises, and that they may interpret the exercises in different ways. In one study, more than 40% of respondents were not aware that a TTO exercise with a 10-year timeframe implied a reduction in life expectancy (van Nooten et al., 2014).

While a deterioration in health can result in death, this does not mean that death can be defined simply as a loss of health. People have preferences about being alive or dead, and these could fall beyond the scope of health preferences. A person may prefer to die (or not die) for reasons separate from their health state. We might therefore expect preferences for 'dead' to be dominated by factors other than the value of health.

Sharma and Stano (2010) found that the level of health that a person considers to be equivalent to dead depends on the individual's health prognosis, probability of survival into the future, and rate of time preference. Attitudes towards euthanasia also explain differences in valuations (Augestad et al., 2013; Barry et al., 2018). These findings clearly show that the relationship of different health states to being dead does not depend on health preferences alone.

With respect to SWDs, it is unclear whether individuals who value some states as 'worse than dead' are actually asserting that the state is worse than 'dead' or worse than 'death' or 'dying', or some combination of all three, or a qualitative judgement about the severity of the state being evaluated (Devlin et al., 2013). This may be due to shortcomings in the presentation or interpretation of the 'dead' state by researchers. Nevertheless, there is evidence that people are confused by the meaning of SWDs (Al Sayah et al., 2016), and that SWDs undermine attempts to capture experience-based values (Bernfort et al., 2018).

There is also the question of what relative values for SWDs mean. Alan Williams (Williams, 2005) described the properties expected from a health state valuation scale as follows:

> *"When estimating life expectancy the convention is that dead is rated at zero and alive is rated at one. Since what we were doing was essentially saying that some people are more 'alive' than others, then we should be working with a scale in which dead = 0 and healthy = 1, and in which states of less than full health would be rated at less than one."*

This appears to give a rationale for quality-adjusting health states in that some people are 'more alive' than others, so that a health state valued at 0.5 means the person is 'half as alive' as a person in full health. But this does not help us to understand what a health state valued at -0.5 would mean. Evidence suggests that differences in value between SWDs are not meaningful (Gandhi, Rand and Luo, 2019). Yet, there is good reason to believe that there is a meaningful difference in value between states 55555 and 55551, for example. This implies that the scale cannot be bound by 'dead' but that current methods to capture values below zero are inadequate.

These difficulties in understanding the state of 'dead' in health state valuation give rise to a variety of methodological difficulties. Some of these can be clearly attributed to the use of a 'dead' state, while others might reasonably be expected to be exacerbated by it.

Sutherland et al (1983) carried out one of very few analyses of the effects of using 'dead' as an anchor in health state valuations. In their study, removing the 'dead' anchor influenced values. When adopting anchors based on alternative health states, defined by vignettes, valuations were systematically higher. They concluded that "health cannot be regarded as a continuum with death as its lower boundary". Nord (1991) cites a pilot study in which the removal of 'dead' from a valuation exercise produced a reduction in values. This was in relation to the best possible health state, so it is possible that the removal of 'dead' would allow for a more sensitive scale. Nord also highlights the effect, in Kaplan et al's (1979) Health Status Index, of including a reference to "half-way between being dead and being completely well". The result was a compression of valuations in the upper half of the scale. Nord concludes that:

> *"one single factor, namely differences in the treatment of the state 'dead', seems to explain a large part of the observed variation in health state valuation across instruments. The stronger the presence of this state as a reference state, the higher the values of all states of illness."*

Becker et al (2007) have argued that it may be rational for an individual at the end of life to prefer any and all states to death, regardless of quality of life. As death approaches, individuals' willingness to pay to avoid it could become limitless, because wealth only has value for those who are alive. For this and other reasons, including religious beliefs, some people might have lexicographic preferences in relation to death. The existence of lexicographic preferences undermines random utility theory, causing particular difficulties for DCEs (Flynn et al., 2008). The inclusion of a 'dead' state can also create a gap effect, whereby very few health states are valued as being proximate to 'dead' (Stalmeier et al., 2005).

Methodologically, there is no consensus on the best way to use the anchor 'dead = 0' in valuing health states. Different approaches yield substantially different data characteristics. The way in which the valuation task is conducted will affect the minimum value that a state worse than dead can take. In the influential Measurement and Valuation of Health study (MVH Group, 1995), and others that adopted its protocol, the minimum value of -39 was the result of adopting a time horizon of ten years (120 months) overall and the smallest amount of time that could be chosen of three months (117 / -3 = -39). Observing that this generated a scale for SWDs which, unlike that for other states, was not linear, SWD values were re-scaled so that the minimum possible MVH value was -1. This, presumably, reflects a view that the value scale should be of symmetrical length around zero, from 1 to -1. In the EQ-5D-5L value set for England study, censoring was applied such that values of -1 could represent values of -1 or below (Devlin et al., 2018). This is based on a view that the value scale does *not* need to be a symmetrical length around zero. Both approaches to determining the range of values are based on strong – but arbitrary and contradictory – judgements by researchers.

A further issue raised by the inclusion of a dead state – and the corresponding problematic observations described above – is that it results in more exclusions in valuation exercises. This is particularly troublesome where the valuation seeks to elicit societal preferences, in which case 36 of 66 valuation studies reviewed by Engel et al (2016) excluded responses deemed inappropriate because of their relationship (or lack thereof) with the dead state.

Including life and death in valuation exercises involves assumptions about preferences for life-extension and quality-improvement, and these assumptions have implications for resource allocation. Violations of the constant proportional trade-off (CPTO) assumption in the QALY model are well-documented. Various explanations have been posited, including loss aversion acting on life years and not health. In TTO and standard gamble exercises, individuals are asked to trade-off life – rather than just health – against health states. Removing any consideration of life years *per se* from health state valuations might reduce such problems.

Preference reversals have been found due to maximum endurable time for both TTO and standard gamble (Stalmeier, 2002). It is possible that these problems are caused – or exacerbated – by the consideration of death. Death has an inherent permanency that does not apply to any other health state considered in health state valuations. This would not apply to other health-irrelevant states such as coma or unconsciousness. Consideration of death therefore requires a very different thought process and invokes considerations of life expectancy. Subjective life expectancy (SLE) should not affect people's responses to health state valuations. However, SLE has been shown to bias the results of TTO exercises where the time frame is not SLE in patients (Heintz, Krol and Levin, 2013) and the public (van Nooten & Brouwer, 2004; van Nooten et al., 2009). Furthermore, evidence suggests that individuals' valuations of health states do not bear a linear relationship in the duration of life (Scalone et al., 2015), though it is not clear whether it is the valuation of health-related quality of life or the valuation of life itself that causes this.

Attaching a value to a dead state (rather than assuming it to be one manifestation of an absence of value) also creates ethical challenges. It isn't clear, for example, whether death should ever be a preferred outcome in societal decision making.

In sum, the use of 'dead' as an anchor in health state valuation does not seem to be based on any advantageous properties as an anchoring state. Rather, evidence shows that its use can create difficulties for all methods of health state valuation including TTO and DCE. These findings suggest that 'dead' is neither an ideal nor a suitable state for use as an anchor.

7 There are alternative states to 'dead' that exhibit favourable properties for anchoring

Kaplan and Ernst (1983) argued that – when it comes to anchors for health state valuation – it is important to have readily understood and well-defined reference states, and that death and complete health represent this. Part of the appeal of adopting 'dead' as an anchor is its apparent clarity and its consistency in meaning across individuals. But given the considerable challenges in eliciting values for states 'worse than dead', and the conceptual difficulties outlined above, it is worth exploring whether alternative approaches to anchoring are *empirically* possible.

Numerous reviews of utility values have found the chosen anchor to have a significant effect on the utility values reported in the population (e.g. Poku et al (2013)). Health state valuations are also sensitive to the inclusion of 'dead' in discrete choice experiments (Norman et al., 2014). Adopting an alternative lower anchor in health state valuation would therefore have implications for cost-effectiveness analysis.

To our knowledge, there is no guidance in the literature about the types of states that constitute good anchors for health state valuation and what their characteristics should be. It is beyond the scope of this paper to establish such criteria. However, to facilitate discussion, we posit the following as being desirable properties of a lower anchor for use in the context of cost-effectiveness analysis:

1. The anchor should be a 'state', such that it is exclusive from any other state at a given time.

2. The anchor should have meaning in duration, such that different durations in the state are distinguishable.

3. The anchor should be a health state, defined in terms relevant to the domain of health.

4. The anchor should be well-defined and easily understood by respondents.

5. The lower anchor state should be relatively 'bad'. That is, it should provide sufficient scale length that the values of most observed health states lie between the lower anchor and an upper anchor of 'full health'.

In light of these considerations, we briefly consider six alternative lower anchors: 1) worst health state imaginable, 2) worst health state defined by the descriptive system, 3) a state as bad as being dead, 4) unconsciousness, 5) sleep, and 6) minimum endurable quality of life. In each case, 'dead' plays no part in valuation but retains its place in evaluation studies as an outcome that generates zero QALYs. There is also no distinction between states better than and worse than dead. This is not to say that there will not be some health states that some individuals consider 'worse than dead'. Rather, it asserts that that fact is irrelevant to the process of health state valuation.

7.1 Worst health state imaginable

To adopt 'worst health state imaginable' as a lower anchor would require an additional health state to form part of the valuation study. The task would generate a scale that had no negative values, since respondents would by definition prefer this to any described health states or be indifferent between them.

Respondents may conceptualise the worst possible health state in different and unknown ways, which may introduce inequities to interpersonal comparisons and aggregation of these responses. This is potentially true for all possible anchors, including the existing states of 'dead', 'full health', or 'best possible health'.

7.2 Worst health state defined by the measure

A similar approach would be to specify the worst health state defined by a measure (e.g. 55555 on the EQ-5D-5L) as a lower anchor equal to zero. This approach would not require valuation of any states in addition to those routinely included in current valuation approaches. It would mean that values cannot be negative.

7.3 A state as bad as being dead

The aim of using a state 'as bad as being dead' would be to establish a direct conceptual link between the outcome 'dead' and health state outcomes. This state would be assigned by the construction of a value of zero to match the zero-value assigned by definition to dead. As with dead itself, this would generate negative values for some states. The merit of this approach is in the framing of the valuation task, avoiding biases caused by respondents' aversion to contemplating death and the refusal by some to accept trade-offs between health and death.

There have been experimental EQ-5D valuation studies that used the anchor 'a state of health as bad as being dead', for which the value was explicitly set at zero (Parkin, Devlin and Sharma, 2005; Chevalier, J et al., 2009). These studies used a direct estimation method, whereby survey respondents gave a numerical estimate of their value of EQ-5D health states, anchored by 1 = full health and 0 = 'a state as bad as being dead', with the possibility of directly assigning a negative value to states thought by the respondent to be 'worse than dead'. In both cases, this questionnaire generated values for EQ-5D health states similar to those using a standard visual analogue scale (VAS) valuation questionnaire, but increased the number of usable responses, as respondents were no longer required to value the state 'dead', which many refuse to do. The studies were small and only carried out in the context of VAS valuations, so it is not possible to derive implications for other valuation methods, except that respondents appeared to have no problems in dealing with the concept of 'a state as bad as being dead'.

7.4 Unconsciousness

The state of unconsciousness is in several respects similar to the state of 'dead'. Individuals probably do not have any meaningful experiential conception of health during time in this state. However, it is important to note that the state of being unconscious or in a coma can span a wide range of dissimilar chronic conditions from minimally unconscious, through to locked-in syndrome, with ongoing medical research on the extent to which, although unresponsive, these patients experience their state.

Similarly to the state of 'dead', unconsciousness (objectively) corresponds to an EQ-5D-5L profile of 55511. The principal difference between being dead and being unconscious is, of course, their manifestations in time. Dead is, by definition, permanent, while unconsciousness is not, as it can be followed either by a change to a greater or lower level of unconsciousness and, eventually, by death. In this respect, while 'dead' does not satisfy criteria (2) above, unconsciousness does. A key difficulty in using this in valuation studies is choosing the time periods that the respondent is required to consider. It would also require assumptions about deterioration in health whilst unconscious.

The EQ-5D's original set of health states included a state 'unconscious', which was valued using the same VAS and TTO methods applied to health states defined by the EQ-5D classification system. On average it was ranked higher than death, though in some groups it was associated with values that were less than zero (MVH Group, 1995). Estimation of the values for this state is not included in the protocol for valuation of the EQ-5D-5L but, as this state is independent of the classification system, the originally estimated values would only change because of changes to the study protocols or to people's values over time.

7.5 Sleep

The use of 'dead' as an anchor is especially problematic when trying to value health states over a short duration. In this case, 'dead' may necessitate a dramatic loss of life years that overshadows any differences in the value of health states. In a study valuing short-term health states, Buckingham et al (1996) characterised sleep as 'approximating oblivion' and used the state of sleep in place of 'death'.

The use of 'sleep' as an anchor state may represent a convenient and unproblematic approach in the valuation of health states over short durations, but it may not satisfy criteria (3) or (5) above, regarding it being sufficiently unfavourable as a health state and definable within the domain of health.

8 Conclusions

Anchoring health state values at dead was a choice made early in the development of health state valuation methods because of its origins in health measures that viewed health as a functional concept rather than quality of life, and because it appeared to be a practical solution to defining a scale with desirable properties. It has subsequently become the convention because the assumptions upon which it is based have not been fully explored and the possibility of alternative anchors has not been seriously considered.

Our review of the literature suggests that there is strong support for each of the six propositions stated in this paper. There is no requirement to anchor 0 at dead in the health measurement and health status utility literature that gave rise to the methods we use to value health states. There is no requirement to anchor 0 at dead in the theoretical foundations of extra-welfarism and health maximisation. While it is important that, for the purpose of economic evaluation, dead should be valued at 0 and dead people should generate no QALYs, using 'dead' to anchor valuations is not a necessary condition for this.

Anchoring 0 at dead creates substantial and entirely avoidable issues, not least of which is the challenge of meaningfully eliciting values less than zero, where our practices remain deeply problematic and inconsistent. Alternative ways of anchoring at 0 are possible and can be used to generate meaningful QALY estimates.

We therefore conclude that, in valuing health states, researchers should 'drop dead'.

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