



Quality of Life and Risk Conceptions in UK Healthcare Regulation: Towards a critical analysis

Matthias Benzer

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Regulation

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Quality of Life and Risk Conceptions in UK Healthcare Regulation

Towards a critical analysis

Matthias Benzer¹

Abstract

The paper outlines a way of gaining fresh perspectives on the functions of ‘quality of life’ (QOL) conceptions in the health sector. The first objective is to spotlight a seldom considered issue. The paper describes different uses of the QOL concept and different links between the categories of QOL and risk in the works of three UK health regulators: NICE, the CQC, and the GMC. It is suggested that closer investigations of the diversity of applications of QOL and associated risk conceptions in health regulation can throw new light on their role in contemporary health systems. The second objective is to provide signposts for critical examinations of this issue. The paper draws attention to three contextual factors – knowledge selection, value dimensions, and decisions on participation – which seem to shape, and may therefore elucidate, health regulators’ various operationalisations of QOL conceptions and connections between QOL and risk ideas.

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Introduction

'Nowadays, the concept of quality of life [QOL] is probably the most ... widely used theoretical framework for assessing' social 'living conditions'. In Europe, QOL conceptions have allegedly 'replaced the idea of wealth' as the primary social 'goal' (Berger-Schmitt 2002: 403). Particularly popular in Europe and North America (Singh 2007: 103), the term is increasingly employed worldwide (Glatzer 2004: 3-5). QOL research constitutes a reference point 'at all levels of political organization' (Michalos 2008: xv) and in numerous spheres of 'public life' (Rapley 2003: xiii). Today, QOL is most readily associated with healthcare. The concept's many applications include evaluations of the severity of medical conditions and of the impact of care, interventions, treatments, and drugs (Phillips 2006: 39-61; Rapley 2003: 139-66). In healthcare, QOL is often specified as 'health-related quality of life' (HRQOL). 'By volume of research ... health-related QOL studies exceed all other [QOL] topics' (Sirgy et al. 2006: 370).

This paper outlines ways of acquiring fresh perspectives on the QOL concept's healthcare applications. An introductory overview, Section 1 reviews work on the concept's emergence in social thought and healthcare, emerging links between QOL and risk ideas, and criticisms of the QOL concept's healthcare uses. Section 2 raises a seldom considered issue: it highlights different operations of the QOL concept and various links between QOL and risk conceptions in the works of three UK health regulators. Section 3 provides signposts for critical examinations of this issue: it adumbrates lines of inquiry into contextual factors which seem to shape and thus elucidate regulatory uses of QOL ideas.

Emergence and criticisms

QOL in social thought

'Quality of life' is a product of the recent history of social thought. First used in 1920, the term 'failed ... to strike a responsive chord and disappeared' for decades (Wood-Dauphinee 1999: 355). QOL conceptions started being applied in the 1960s, partly thanks to their dissemination by North American and European 'social indicator' movements (Armstrong and Caldwell 2004: 362; Noll 2004: 151-2; Rapley 2003: 3-25; Sirgy et al. 2006: 364-6, 377).

By the mid 1900s, it had become common to assess social progress by the 'material level of living', notably GNP (Rapley 2003: 4). Yet 'economic indicators' were increasingly seen as inadequate measures (Land 1983: 3; Sirgy et al. 2006: 365). The perception of 1960s-1970s societies as materially prosperous was weakening the consensus on 'economic growth' as their 'major goal' (Noll 2004: 152). Moreover, prosperous societies were facing quandaries to which growth provided limited answers (Galbraith

1964: 120). Finally, the “social costs” of economic growth’ (Noll 2004: 152-3; Rapley 2003: 6) and its components – especially technological innovation – attracted attention. Overpopulation and environmental problems were becoming key concerns (Armstrong and Caldwell 2004: 362; Wagar 1970: 1179-80). Growth indicators were deemed blind to the dilemma that economic and technological achievements had negative ‘side-effects’ (Land 1983: 3). These suspicions were not only articulated by social scientists. The UN had also started questioning purely economic evaluations of social life (Sirgy et al. 2006: 382), and the 1960s US administration encouraged public agencies to find ‘new measurements’ for ‘domestic social programs’ (Prutkin and Feinstein 2002: 83).

What economic indicators were said to neglect was ‘the quality of life’ (Land 1983: 3), particularly the ‘noxious physical and sociological by-products [of runaway growth] that threaten the very quality of our lives’ (Wagar 1970: 1180). The QOL category was presented as a device for ‘multidimensional’, ‘more complex’ approaches to social living conditions (Noll 2004: 153). QOL evaluations were supposed to reach beyond a society’s economic achievements to capture a wider array of aspects of collective and individual existence (Finn and Sarangi 2008: 1570). In 1964, the economist John K. Galbraith (1964: 120) declared ‘quality of life’ society’s ‘primary goal’, and US President Johnson stated that progress could no longer ‘be measured by ... our bank balance’, but ‘only ... by the quality of the lives our people lead’² (in Pais-Ribeiro 2004: 121). Calls for emancipating societies from ‘runaway growth’ and ‘deal[ing] with the quality of living’ (Wagar 1970: 1181-2) were getting louder. With the 1974 foundation of the journal *Social Indicators Research*, the ‘[p]ublication of social indicator and quality of life research began in earnest’ (Sirgy et al. 2006: 367).

The first QOL indicators included numerous ‘objective’ items: access to resources, public order, social mobility, education, weekly working hours etc. (Rapley 2003: 4-6, 10-11; see also Noll 2004: 156). Their precedence was subsequently challenged by ‘subjective’ indicators focused on individuals’ perceptions of their lives and circumstances: feeling safe, job satisfaction, contentment with relationships etc. (Land 1983: 4-5; Noll 2004: 157-8; Rapley 2003: 5; Sirgy et al. 2006: 344-50, 383). It was roughly in the mid 1970s that social indicators researchers, who had previously prioritised ‘objective phenomena’, began to engage more closely with subjective wellbeing (Prutkin and Feinstein 2002: 83). Soon after its emergence, the QOL concept thus already designated a conspicuously broad range of elements of existence. ‘In part, it was the very vagueness of quality of life’, argue critics, ‘that allowed it to be invoked as a common goal ... across ... different political programs’ (Armstrong and Caldwell 2004: 363; see also Finn and Sarangi 2008: 1570).

² The UK government is currently planning to complement GDP (*The Guardian* 2010a) with assessments of Britons’ ‘psychological and environmental wellbeing’ and ‘quality of life’ (2010b).

The historical perspective appears to reveal affinities between the QOL concept and the concept of risk which are rarely mentioned in the literature on either category. QOL scholars cite two developments of the 1960s–1970s as decisive for the growing preoccupation with QOL: the period’s self-perception as prosperous made any over-concern with wealth production appear anachronistic; and measuring social life purely by economic growth and technological progress was deemed negligent of their undesirable characteristics. This suggests two parallels between the emergence of the QOL concept and the rise of risk as a central idea of late 20th-century social life. Firstly, as Beck (1992: 19-20) argues, late modernity’s achievements in curbing traditional material needs have undermined the priority of scarcity and wealth production, allowing the production and distribution of risk to gain attention. Secondly, ‘reflexive modernity’ harbours the concern that modernisation and the development of productive forces for wealth creation have generated new threats. Insisting on advancing production and technological innovation occasions blindness to the risks they create. ‘*Risk may be defined as a systematic way of dealing with hazards and insecurities induced ... by modernization itself*’ (Beck 1992: 21).

Given the operationalisation of risk and QOL categories in ever more areas of social life, it is unsurprising that they have come to be used in conjunction. In the 1970s, economic growth was already criticised not only for its negative QOL implications and risks, but also for generating risks *to* QOL: ‘smog, rising crime rates ... and vanishing species’ posed ‘threats to the quality of life’ (Wagar 1970: 1180). Such arguments may have inspired Douglas and Wildavsky’s famous 1983 distinction between ‘risk takers’ and the ‘risk-averse’. For the latter, ‘unbridled economic growth has hurt the natural environment and human life ... The advantages of quantitative growth ... have to be sacrificed to improve the quality of life’ (Douglas and Wildavsky 1983: 67). Seed and Lloyd pinpoint connections between QOL and risk conceptions established in the 1990s. The UK’s BSE crisis³ showed that intensive farming, which had increased the quantity of agricultural output, had also created serious hazards. These hazards were perceived as risks to QOL. ‘A prime role of government is ... protecting the quality of people’s lives, with which the quality of farming methods is linked’ (Seed and Lloyd 1997: 46). More generally, as ‘personal protection’ came to be seen as a ‘value consistent with quality of life’, QOL debates raised questions about ‘threats to personal safety’.⁴ While some argued that QOL hinged on eliminating the threats, others emphasised ‘relative risk’, ‘turn[ing] an argument about quality of life in terms of absolute values ... into a relativist approach based on quantifiable risk’ (1997: 44-5). In the 21st century, QOL researchers themselves are affirming the links between the two categories. The 2003 conference of the International Society for Quality-of-Life Studies centred on ‘[c]hallenges for quality of life’, notably the ‘threats, dangers and risks ... which – if they are taken into account by

³ On risk in the context of the BSE crisis, see van Zwanenberg and Millstone (2005).

⁴ Protecting people, especially vulnerable groups, from risks in ‘the personal social services’, for instance, was ‘directly related to quality of life values’ (Seed and Lloyd 1997: 114).

individuals or governments – could be reduced or avoided’ (Glatzer 2004: 4). One of the key questions engaging the 2006 conference was: ‘How best to evaluate quality of life ... in a time when humankind faces escalating risks and uncertainties – some of its own making’ (Møller and Huschka 2009: 1, see also 5).

QOL in healthcare

Precursors to present-day health-related QOL research have been located in the first half of the last century. Between the 1930s and 1960s, health scientists were already studying the ramifications of health conditions for non-biological dimensions of life: ability to perform basic activities, independence, need for assistance, time in bed etc. (Prutkin and Feinstein 2002: 80-2). The WHO’s 1948 extended definition of health as ‘a state of complete physical, mental, and social well being’ (in Prutkin and Feinstein 2002: 82) is often cited as a stimulus of attention to ‘psychological, social, and economic’ aspects of illness (Sirgy et al. 2006: 400-1). Yet the term ‘quality of life’ itself ‘seems to have entered the medical literature in ... 1966’. It gained currency in the 1970s, once the first assessment devices ‘specifically aimed at’ HRQOL had ‘appeared’ (Prutkin and Feinstein 2002: 85). Wood-Dauphinee reports that the US National Library of Medicine included ‘quality of life’ as a Medical Subject Headings keyword in 1977. Before 1974, it contained 40 references to QOL, compared with over 10,000 between 1986-1994. In the 1970s, medical research started shifting from purely ‘clinical laboratory indicators of illness’ towards evaluating HRQOL (Wood-Dauphinee 1999: 355-6).

The driving forces behind the QOL concept’s introduction into healthcare remain under discussion. ‘The main justification [*sic*]’ for its ‘widespread use ... is that it gives a much needed voice to the patient’s perspective in the face of the traditional dominance of “biological” ... outcomes’ (Armstrong and Caldwell 2004: 361). Health professionals and scientists of the 1960s were asked to rethink their conceptions of patients as mere bodies with material properties (length of life, blood pressure etc.) and to treat patients as multifaceted beings with psychological and social attributes (preferences, emotions, relationships, roles). QOL considerations were deemed ‘salutary’ (Levine 1987: 4) for expanding the medical perspective accordingly. They highlighted the consequences of health stimuli for non-biological yet equally important dimensions of complex lives (Seed and Lloyd 1997: 20).

However, many scholars doubt that the desire to ‘humanise’ medicine constituted the determining factor. Some argue that ‘ambivalence towards technological progress’ – not unlike social scientists’ ambivalence towards growth and innovation – ‘provided the crucible for quality of life to be forged’ (Armstrong and Caldwell 2004: 365). This argument is reconcilable with the view that humanising healthcare was important, but the emphasis is different. Post-war medicine had produced numerous technologies to improve longevity and biological attributes (Levine 1987: 4; Sirgy et al. 2006: 400). Yet

the longer lives made possible by technology were frequently found to be pestered by disability, chronic disease, and perpetual suffering: renal dialysis, for instance, ensured survival only at the cost of considerably lowering survivors' life satisfaction compared with healthy individuals (Armstrong and Caldwell 2004: 363-4). Assessments of healthcare with reference to survival rates were criticised for concealing the downsides of technologically prolonged lives. In the 1970s, health professionals and researchers came to suspect that treatments, drugs and care services should be assessed more comprehensively: in view of their effects not only on life quantity and physical aspects, but also on wellbeing and the quality of the life years gained, e.g. on their desirability for those receiving them (Armstrong and Caldwell 2004: 364-7; Sirgy et al. 2006: 351).

Some scholars additionally underline growing worries over constraints on health resources (Levine 1987: 4; cf. Seed and Lloyd 1997: 109-10). Limited finances demand sharper identifications of newly available technologies that really justify investment. Discriminating assessments of the consequences of treatments for life quantity and quality are said to promise better informed funding decisions (e.g. NICE 2010).

On many historical accounts, the QOL concept entered healthcare because it offered an innovative solution to material healthcare problems. Yet its emergence in health has also been scrutinised more critically. Following Foucault's (2003) archaeology, Armstrong et al. (2007) highlight developments within 20th-century medical thought. In the 1800s, medics started reading patient-reported symptoms and signs on the body as manifestations of underlying illnesses. Illnesses were conceived physiologically as pathological lesions deep inside the body. In the 1900s, vis-à-vis patients' 'distorted' symptom reports, doctors began to read reported symptoms additionally as expressions of patients' mental state. Simultaneously, psychiatrists were championing questionnaires as instruments for establishing patient-reported symptoms to uncover mental health. Soon, questionnaires for recording symptoms experienced by patients were employed in other medical areas, but for observing the severity of physiological ill-health (Armstrong et al. 2007: 570-3). Before long, questionnaires contained several experiential items, e.g. speech or motor function. This stimulated attention to patients' subjective perspective of health. Yet a disease's 'pathological severity' was 'found to be often poorly related to the symptoms and disability as experienced by the patient': this suggested a distinction between a disease's severity in physiological terms and in terms of dimensions such as 'activities of daily living' (Armstrong et al. 2007: 574). Physiologically distinct diseases could now be compared and classified with regards to their implications for life dimensions represented by subjective symptoms. Various 'distal symptoms', further removed from physiology, manifested the severity of illness in respect of its impact on everyday personal and social life. Healthcare in the 1970s drew on QOL ideas in order to capture the multitude of newly emerging distal symptoms in one measuring instrument of quality of life (Armstrong et al. 2007: 576-8).

Scholars working with the idea of ‘governmentality’ offer further critical perspectives on the QOL concept’s healthcare uses. During its emergence in 1960s social thought, the QOL category chiefly summarised objective social wellbeing factors (availability of resources, security etc.). The concern with subjective wellbeing seems to have developed slightly later (Finn and Sarangi 2008: 1568-9; Land 1983: 4-5; Noll 2004: 157; Rapley 2003: 4-5, 10, 14). In healthcare, by contrast, QOL at least included ‘the patient’s point of view’ from very early on. HRQOL scales of the 1970s already determined QOL as subjective health preferences and perceptions (Wood-Dauphinee 1999: 355-6; cf. Sirgy et al. 2006: 404-6). Although objective QOL measures are still widely applied, the 1980s witnessed growing interest in subjective QOL across public domains. Drawing on the works of Peter Miller and Nikolas Rose, Rapley (2003: 8-14; 121-38), Rapley and Ridgway (1998), and Finn and Sarangi (2008) link this development to the 1980s’ neo-liberal enterprise culture and right-of-centre market-endorsing ideology. According to the corporatist, managerialist discourse of the time, the individual constituted an enterprising self who was responsible for, and aspired to, her or his fulfilment. Humans were seen as consumers with personal preferences seeking contentment through choice. This coincided with a stronger accent on the ‘quality’ of commercial and public services consumed by individuals.⁵ In this discursive environment, the notion of QOL as dependent on subjective perceptions of life acquired greater legitimacy.⁶ Since the health sector had long emphasised QOL qua subjective health satisfaction, these discursive conditions may be seen to have been particularly conducive to the construct’s healthcare applications.

Endeavours to link the category of QOL with risk conceptions can also be identified in the health sector. Contemporary health systems are increasingly drawing on risk ideas to manage healthcare (Alaszewski 2005: 315). The *World Health Report 2002* (WHO 2002a) underlines the growing importance of not only tackling disease and injury, but also identifying, assessing and reducing threats to health for preventing disease. ‘Risk assessment estimates burden of disease resulting from different risk factors’ (WHO 2002a: 11). This means estimating for each risk factor: the amount of disease and injury in a population attributable to it; and the respective diseases’ and injuries’ ramifications for longevity and quality of life. The ‘impact of each risk factor should be assessed in terms of ... loss of quality of life as well as loss of life years’ (WHO 2002a: 12, see also 7-9). As in other areas, here the two categories represent risks *to* quality of life.⁷

⁵ The present UK government plans to measure QOL in view of ‘objective’ circumstances (e.g. ‘how much recycling gets done’) as well as ‘subjective wellbeing’ and ‘happiness’ (BBC 2010; *The Guardian* 2010b).

⁶ ‘Equipped with autonomy, responsibility and ostensible freedom, the subjects of neoliberalism are increasingly encouraged to self-actualize through a completeness of physical and mental health – one that is thought to be discoverable through acts of choice, consumption and programs of empowerment that are meant to give one’s life meaning and improve overall QOL’ (Finn and Sarangi 2008: 1570-1).

⁷ The WHO’s quantitative approach to risks of disease burden qua risks to longevity and QOL employs the widely debated DALY (disability-adjusted life years) ‘currency’ (WHO 2002a: 12; see also Murray 1994; Murray and Lopez 1996: esp. 296-324; Sassi 2006).

Various connections between the two concepts are also emerging from more specific healthcare areas, as Finn and Sarangi's (2008) study of Indian HIV/AIDS-related NGOs shows. The authors frame these NGOs' QOL discourse as a 'neoliberal mode of governance' at a distance. The HIV positive individual is conceptualised as responsible for attaining better QOL through choosing self-enhancing behaviours and lifestyles and through self-sufficient, self-motivated enterprise (as opposed to 'relying on welfare and waiting to die'). This self-disciplining endeavour is supported by 'right' – viz. 'expert' – knowledge of health, health-related (notably sexual) activities, and life satisfaction as well as 'techniques of empowerment' (Finn and Sarangi 2008: 1572-77). The authors underline that the 'marginalized groups' in question 'are simultaneously defined as "risky"'. This heightens the QOL discourse's 'moral legitimacy to intervene in (sub)-cultural populations' and 'mak[e] them accountable to civilizing processes' (Finn and Sarangi 2008: 1574). Reuter (2007) also diagnoses the 'responsibilisation' of individuals in the current health field. Her argument emerges from analyses of medical malpractice suits filed by parents of children born with severely impairing Tay-Sachs disease. Following Nikolas Rose, Reuter (2007: 237–48) examines these cases in the context of a contemporary 'bio-politics of risk': the individual subject is increasingly obliged to undergo genetic testing and gain knowledge about its chances of transmitting Tay-Sachs to offspring. Knowledge about genetics is supposed to inform reproductive decisions about whether or not to give birth to children with Tay-Sachs, whose QOL – conceived above all in relation to functionality – is frequently deemed less preferable than not being born at all (Reuter 2007: 248-53).

In 1987, Levine (1987: 4) warned that health professionals might eventually 'sloganiz[e]' and grow 'bore[d]' of QOL. The latter vision lacked foresight. The WHO (2003: 4) recently reasserted: 'Quality of life ... must be a priority. A focus on ... life expectancy can obscure the fact that a longer life is not necessarily a blessing if it is burdened with disability, disease, dependency, or abuse'. In healthcare, the QOL concept is used more extensively than ever for evaluating the impact of health products, services, and conditions on people's overall – rather than merely biological – being. There is little consensus on what drove QOL's rise as a central healthcare idea. Yet it is difficult to avoid the suspicion that the concept's immense scope – or vagueness – which makes it applicable to a variety of problems, contributes to its ongoing popularity:

Quality of life is 'an individual's perception of his or her position in life in the context of the culture and value system where they live, and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept, incorporating in a complex way a person's physical health, psychological state, level of independence, social relationships, personal beliefs and relationship to salient features in the environment' (WHO 2002b: 13).

Controversies

The QOL concept's rise as an ostensible solution to scientific, medical, and policy predicaments has been accompanied by methodological and severe moral philosophical criticisms of its healthcare applications.

Operationalising HRQOL constructs involves attempts to represent life's quality numerically. Critics highlight the 'apparent contradiction' in translating judgements of *qualities* into measurements of *quantities*. Moreover, they underscore the dependence of any numerical treatment of QOL upon its definition (Arnesen and Norheim 2003: 84). While much medical QOL research accepts the imperative to define QOL before measuring and quantifying it (Rapley 2003: 64), 'a single definition of HRQL remains illusive' (Wood-Dauphinee 1999: 356; see also Prutkin and Feinstein 2002: 80). Firstly, many QOL studies provide no definition (Arnesen and Norheim 2003: 84; Pais-Ribeiro 2004: 122). Secondly, there is no consensus on what QOL means. The literature contains many different definitions (Pais-Ribeiro 2004: 123; Rapley 2003: 64), variously emphasising: 'general health status, functional capacity, emotional status, level of well-being, life satisfaction, happiness, intellectual level, pain, nausea and vomiting, level of symptoms, fatigue, sexual functioning, social activity, memory level, financial status, and job status' (Prutkin and Feinstein 2002: 79). Thirdly, QOL is often defined by a precariously wide range of parameters. The construct's 'breadth' (Wood-Dauphinee 1999: 356) has been a lingering issue. According to one definition, HRQOL concerns: 'emotional well-being; spirituality; sexuality; social functioning; family life; occupational functioning; communication; eating; functional ability; physical status; treatment satisfaction; self-esteem; stigma; body image; future orientation; global ratings of health or life satisfaction' (Phillips 2006: 42). Finally, definitions of QOL occasionally draw on (other) vague categories: happiness, life-satisfaction, and freedom from want; or 'general mood' (NICE 2010), 'ability to perform the activities of daily life', and 'freedom from pain and mental disturbance' (NICE 2009a). The QOL concept's breadth and vagueness may have facilitated its dissemination in different fields and disciplines, but the methodological obstacles to defining QOL simultaneously affect its quantification in each context.

The ethical implications of HRQOL ideas have generated particularly heated discussions. Evaluating medical interventions purely by their capacity to prolong life coheres with the assumption that all human lives are equally valuable: lives extended by the same amount of time are equally desirable outcomes, regardless of specific characteristics. Assessments of interventions by their effects on life quantity and quality may be seen as challenging that assumption: lives prolonged by the same amount have different values if they have different QOL characteristics (cf. Pais-Ribeiro 2004: 123; Phillips 2006: 47). This resonates with several moral puzzles.

Scarce resources are often said to force health systems to decide against funding some technically available interventions. It is also seldom disputed that treatments prolonging life do not always improve its quality, let alone to the same extent (Harris 1987: 117; NICE 2010; Schlander 2007: 3). As critics like Harris (1987, 1995, 1996, 2005a, 2005b; Hope 1996; Phillips 2006: 47; Quigley 2007) have repeatedly argued, when such claims govern resource distribution, conflicts can arise. For example, where a life of higher quality is deemed more valuable, the claims could be taken to mean that whenever health services can only afford one of two equally expensive treatments for two patient populations with different conditions but the same potential to gain x number of extra life years from their respective treatment, scarce resources should be spent on treating the population with the potential to gain from its treatment x years of more improved quality. Such allocation strategies are condemned for disadvantaging individuals whose health, disability or age burden them with comparatively lower predicted QOL gain per expenditure unit. Groups with specific health or demographic attributes are – effectively because of these attributes – systematically classed as less worthy of investment, and their lives as less worthy of improvement or extension.

The opening pages of a 1990 book by a leading British HRQOL scholar announced a closely related problem:

There are ... states of life ... worse than death ... [F]ew people accept the ‘life-at-any-cost’ philosophy assumed by many doctors ... Whether the mere preservation of life is worthwhile in terms of its quality for the individual or ... its monetary value to society ... is a contentious issue (Fallowfield 1990: 16-18; see also Seed and Lloyd 1997: 20).

Some controversies surrounding QOL in healthcare centre on the practice of placing states of living on quality scales whereby being dead can be preferable to an exceptionally poor quality life (Brazier et al. 2007: 83-92; Macran and Kind 2001). The WHO’s statement that an existence affected by disability need not be a blessing circumscribes this practice. Time spent in ‘irremediably severe pain’ or ‘irrevocable ... deterioration’ (Overall 2003: 99) is frequently described as less desirable than not living. Expressed numerically, health states are placed on QOL scales ranging from 1 (best possible health) via 0 (equivalent with being dead) to negative values (NICE 2010). From this perspective, it may be seen as defensible to withhold life-saving resources from dying patients who, albeit potentially gaining lifetime from treatment, have no prospect of minimal QOL involving ‘continuing enjoyment or benefit’ (Howarth and Leaman 2001: 374). Thus QOL conceptions might facilitate ethically thorny decisions in favour of euthanasia or assisted dying.

QOL and risk conceptions in UK healthcare regulation: three cases

Since its emergence in health systems, the notion of quality of life has become one of the health sector's most prominent and most controversial ideas. This underscores the urgency of critical inquiries into its contemporary healthcare applications. Given the concept's pervasiveness, it seems advisable to frame such inquiries – initially at least – as case studies of operationalisations of QOL conceptions in specific healthcare areas (e.g. Finn and Sarangi 2008; Rapley and Ridgeway 1998; Reuter 2007). Social researchers have conducted fewer studies of this kind than the QOL concept's status in healthcare might lead one to expect. The role of QOL in health *regulation* constitutes one worthwhile topic of investigation.

UK healthcare regulatory organisations are increasingly drawing on QOL ideas. The National Institute for Health and Clinical Excellence is well known for its work on QOL, but other institutions, including the Care Quality Commission and the General Medical Council, are also using the term. Moreover, these organisations are using QOL conceptions in association with risk categories. Yet different regulators operationalise such conceptions in different ways. This section describes various operations of the QOL concept and connections between QOL and risk categories in the works of the three regulators. Closer examinations of these diverse applications can shed new light on QOL ideas in the health sector.

National Institute for Health and Clinical Excellence (NICE)

Set up in 1999 as an NHS Special Health Authority, NICE offers guidance on the 'clinical and cost effectiveness of ... health technologies' to the English and Welsh NHS (NICE 2008a: 4; see also 2008b: 17-19). NICE aims to support investment in pharmaceuticals and treatments that provide 'good value for money' (NICE 2010; see also Schlander 2007: 3-8).

The QOL concept is part of NICE's (2010) standard method. NICE uses it to expand assessments and comparisons of health technologies: it seeks to evaluate health stimuli in view of their effects not only on lifetime, but also on the quality of lifetime for those receiving it (NICE 2008b: 17).

Although one treatment might help someone live longer, it might also have serious side effects. (For example, it might make them feel sick ...). Another treatment might not help someone ... live as long, but ... improve their quality of life while they are alive (for example, by reducing their pain or disability) (NICE 2010).

NICE operationalises QOL conceptions to reach beyond objective medical outcomes, notably mortality and physiology. HRQOL includes 'a person's physical, mental and

social wellbeing; not merely the absence of disease' (NICE 2008a: 71). It involves 'level of pain', 'mobility', and 'general mood' (NICE 2010). NICE's preferred device for establishing patients' descriptions of health outcomes is the EQ-5D (Dolan et al. 2009; NICE 2008a: 38-9), a standardised, generic instrument for framing the QOL implications of health states. Patients describe their health in relation to five key QOL dimensions: mobility, ability to self-care, ability to undertake usual activities, pain/discomfort, and anxiety/depression (EuroQol Group 2010).

NICE assesses technologies quantitatively: in view of how many years of lifetime and quanta of life quality they yield. It aims to guide strategic resource spending on treatments which show the best balance in terms of costs on the one hand and added number of life years and quanta of QOL on the other (NICE 2010). Such quantitative evaluations require a unit which incorporates both outcomes and presents them in one figure. Units of this kind are described as HALYs (health-adjusted life years). Their most commonly used version is the QALY (quality-adjusted life year) (Gold et al. 2002; Sassi 2006). NICE (2010) uses QALYs for articulating 'how many extra months or years of life of a reasonable quality a person might gain as a result of treatment'. The temporal component is expressed in number of years lived in the corresponding health state. Its QOL component is established by ranking this health state – as described in relation to the aforementioned five QOL dimensions – on a scale (usually between 1 and values slightly below 0) of quality weights. An outcome's QALY value is calculated by multiplying the number of years lived in this health state by the quality weight this state has scored. Health interventions are evaluated numerically with regards to how many QALYs – incorporating life years and their quality weight – they promise to generate. If a standard treatment has been adding 1 year in a state weighted as 0.3 QOL, whereas a new treatment adds two years weighted as 0.4, the new treatment adds 0.5 QALYs (NICE 2010; see also Dolan 1998; Dolan et al. 2009; Gold et al. 2002; Sassi 2006). 'Generally', NICE (2010) does not consider a treatment 'cost effective' if it 'costs more than £20,000–30,000 per QALY'.

NICE's application of the QOL concept is affinitive with risk assessment in the health sector. As mentioned, risk assessment frequently focuses on threats posed by technological innovations which otherwise have desirable effects on human life. 'The "new genetics", for example, raises the *possibility* of some very novel risks ... alongside the promise of new benefits' (Calman et al. 1999: 107; see also Alaszewski 2005: 315). Secondly, risk categories inform evaluations of potential harmful effects in endeavours to control the future (Hutter 2010: 4-5). Similarly, NICE assesses products of medical, pharmaceutical, and health technological development which promise positive effects on survival in order to evaluate their potential future negative effects on aspects of human life summarised as its quality. NICE (2010) combines considerations of longevity and QOL partly because '[a]lthough one treatment might help someone live longer, it might also ... put them at risk of other illnesses or leave them permanently disabled' – and thus threaten their life quality.

Care Quality Commission (CQC)

Since April 2009, the CQC has been operating as England's 'independent regulator of ... health and adult social care' (CQC 2010a). It seeks to ensure that 'care ... meets essential standards of quality and safety' and to 'encourage ... improvements' of care (CQC 2010b: 6). Prima vista, NICE's and the CQC's applications of the QOL concept differ in that NICE employs this concept more frequently, is more explicit about its systematic function in NICE technology assessment, and conveys more clearly which dimensions QOL incorporates. Yet documents show that QOL and related concepts are important to CQC regulation.⁸

A central component of CQC work is regulating care providers. Among its six markers of 'high quality care' is promoting '[i]ndependence and wellbeing'. This means 'helping people ... achieve the best possible health and quality of life, and optimum independence' (CQC 2010f: 21-2). Here, wellbeing appears to be the more general category, comprising both health and QOL.⁹ This mode of employing the terms is not highly unusual.¹⁰ Crucially, when CQC documents on the regulation of care provision mention wellbeing – which they mention more frequently than QOL – QOL is also at issue.

The Commission's chief concern is care providers' fulfilment of 'essential standards of quality and safety'. The standards are 'focused on outcomes' and on 'views and experiences' of service users (CQC 2010b: 6). The standards comprise six outcome areas, which contain 28 'outcomes that we expect people using a service will experience when the provider is meeting the essential standards' (CQC 2010b: 7). Each outcome is based on a regulation in either the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 or the Care Quality Commission (Registration) Regulations 2009 (CQC 2010b: 6, 10-11). When a provider delivers – and people using its services experience – an outcome, the provider can be said to comply with the corresponding regulation (2010b: 8). The CQC also offers prompts which help providers meet essential standards by

⁸ Until recently, the CQC (2010c, 2010d) evaluated adult social care commissioning against standards of 'improved health and wellbeing', 'improved quality of life', and 'economic well-being'. New regulatory approaches in this area are currently being developed (CQC 2010e).

⁹ CQC (2010d) assessments of adult social care commissioning treated wellbeing and QOL as overlapping outcomes.

¹⁰ There are no prescriptions for employing the concepts. In health, 'well-being, QOL, and health-related QOL are ... often used interchangeably' (Sirgy et al. 2006: 401). 'QOL is ... widely deployed as ... shorthand ... for the collective well-being of human groups and ... as a summary description of the particulars of individual lives' (Rapley 2003: 63). In many contexts, QOL is more general: 'components of subjective well-being' are added to 'subjective and objective "physical well-being": ... feeling healthy and fit and having the ... physical competence to perform ... social roles. This is *in addition* to the "medical" components ... defined in terms of *satisfaction*'; together, these elements characterise QOL (2006: 41-2).

delivering outcomes. Prompts are non-binding, but might be referred to during compliance assessment (CQC 2010b: 9; 2010g: 6).

‘The focus of the regulations is on the safety and wellbeing of people who use services’ (CQC 2010b: 33). Yet only a handful of essential outcomes and prompts are defined with explicit reference to wellbeing. The prompt for delivering outcome 4 – ‘care and welfare of people who use services’ (CQC 2010b: 62) – is that care ‘[m]aintains [users’] welfare and promotes their wellbeing by taking account of all their needs, including: physical, mental, social, personal relationships, emotional, daytime activity’ (CQC 2010b: 64). Outcome area III (outcomes 7–11) is defined as ‘safeguarding and safety’. Providers must ensure that users, workers, and visitors of care institutions ‘are as safe as they can be and that risks are managed’ (CQC 2010b: 91). Outcome 7 is ‘safeguarding people who use services from abuse’ (CQC 2010b: 92). The CQC’s overall definition of ‘safeguarding’ is: ‘Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights’ (CQC 2010b: 215). Outcome 9 concerns the ‘management of medicines’. Users should – among other things – ‘have information about the medicine being prescribed made available to them or others acting on their behalf’ (CQC 2010b: 104). Providers are prompted to ensure that ‘information is available for people about medicines advisable for them to take for their health and wellbeing’ (CQC 2010b: 107). The central component of outcome 10, ‘safety and suitability of premises’, is that users and ‘people who work in or visit the premises’ are ‘in safe, accessible surroundings that promote their wellbeing’ (CQC 2010b: 110). Outcome area V, ‘quality and management’, contains outcome 21, ‘records’. This outcome will not be met unless users ‘can be confident that ... records required to be kept to protect their safety and wellbeing are maintained’ (CQC 2010b: 171).

In compliance assessment, by contrast, the CQC uses the category of wellbeing repeatedly. CQC inspectors and assessors continuously investigate whether care providers meet essential standards. The Commission’s Judgement Framework guides inspectors’ assessment of compliance with 16 ‘key’ outcomes. Out of the 28 essential standards, these 16 are ‘most directly relate[d] to the quality and safety of care’. Among them are those that explicitly address wellbeing (CQC 2010g: 4-5). Inspectors consider a range of data to determine a provider’s compliance with the outcome statements. A provider is either judged to be compliant with the respective outcome or to raise minor, moderate, or major concerns about compliance. The judgements are validated against the Judgement Framework’s ‘descriptors’ and ‘case studies’. The latter state, for all 16 key outcomes in turn: what care looks like if it complies; and what care looks like if it raises major, moderate, and minor concerns about compliance (CQC 2010g: 33). Two characteristics of these descriptors and case studies are worth noting. Firstly, for *each* of the 16 key outcomes, the descriptions of care which complies and raises concerns contain the concept of wellbeing (CQC 2010g). For instance, the case study of care which fulfils outcome 10, ‘safety and suitability of premises’, portrays a ‘care home for people with dementia ... designed with safety, independence, wellbeing and dignity in mind, with a

clear layout suited to people's needs and appropriate adaptations for people with physical and sensory disabilities' (CQC 2010g: 91). Secondly, for outcome 1, 'respecting and involving people who use services', the specifications of services which raise minor, moderate, and major concerns about compliance additionally use the term 'quality of life'. Concern about compliance is greater the less service providers 'involve people' and 'carers in ... planning ... treatment ... which ... may affect their lifestyle and quality of life' (CQC 2010g: 35, 38, see also 40). Thus although only few essential care standards are expressly defined with reference to wellbeing, this concept informs CQC inspectors' assessments of providers' compliance with *each* of the 16 key outcomes. On closer scrutiny, the categories of wellbeing and QOL thus play a major role in CQC health and social care regulation.

The Commission also uses these categories in conjunction with the category of risk. Given the CQC's current move towards risk-based regulation (Lloyd-Bostock 2010a: 585), this might be expected. The CQC assesses care provision in view of the 'risks' it poses 'to the quality and safety of care'. Since high quality care involves the promotion of users' independence, wellbeing and QOL, 'risks to quality care' include risks to users' ability to gain independence, wellbeing and QOL. This is in addition to analysing 'risks to people's wellbeing because they cannot access services' (CQC 2010f: 20).

The CQC's central concern is care providers' compliance with essential quality and safety standards. Its regulatory tools include Quality and Risk Profiles (QRPs). These do 'not produce a judgement about' a provider's 'compliance with the essential standards', but 'an estimate of the *risk of potential non-compliance*' with the care codified in the essential standards' outcome areas and outcomes (CQC 2010h: 5-6, emphasis added). The 'focus' rests on the aforementioned 16 key outcomes (CQC 2010h: 11). For instance, a provider's QRP offers a summary estimate of the risk that care will not meet – and users will not experience – the outcomes in area II, 'personalised care, treatment and support' (outcomes 4-6). Plus, the QRP contains specific estimates of the risk that the provider will not meet outcome 4, 'care and welfare of people who use services', outcome 5, 'meeting nutritional needs' etc. Estimates are presented as coloured dials indicating a series of risk levels between 'low green' on the left and 'high red' on the right (CQC 2010h: 14). QRP estimates relating to the aforementioned outcome areas and outcomes specified with reference to wellbeing thus interlink the categories of wellbeing and risk. Following the definition above, the estimate of a provider's risk of non-compliance with outcome 10 includes an estimate of the provider's risk of not providing 'safe, accessible surroundings that promote ... wellbeing'.

The CQC's Judgement Framework is consistent with these considerations and confirms the links between risk and wellbeing. Partly drawing on providers' QRPs, CQC inspectors judge whether care providers comply – or raise minor, moderate, or major concern about compliance – with 16 outcomes central to the essential care standards (CQC 2010h: 6, 11). Their verdicts are validated against the Judgement Framework's

descriptors of care which complies, and of care which raises different levels of concern about compliance, with each of the 16 outcomes. Crucially, for all 16 outcomes, care which raises moderate concerns about compliance is partly identifiable by the fact that ‘people who use the service are generally safe, but there are risks to their outcome, health and wellbeing’ (CQC 2010g). Thus although QRPs establish explicit links between the categories of risk and wellbeing only in relation to a few outcomes – because only a few key standards explicitly address wellbeing – such links inform CQC inspectors’ assessments of compliance with *each* of the 16 key outcomes. Connecting the categories of risk, QOL and wellbeing is more important to CQC health and social care regulation than it might appear initially.

General Medical Council (GMC)

Founded in 1858, the General Medical Council is the UK’s independent regulator of the medical profession. It aims to ‘protect’ and ‘promote’ the public’s health and safety by ensuring that medicine is practised according to ‘proper standards’ and to ‘foste[r] good medical practice’ (Lloyd-Bostock and Hutter 2008: 71). Its regulatory tools include guidance based on overriding principles which doctors registered with the GMC must follow. The latest guidance addresses doctors treating patients at the end of their life. It thematises ‘challenging’ end-of-life decisions (ELDs) ‘about withdrawing or not starting a treatment when it has the potential to prolong the patient’s life’ (GMC 2010a: 9).

According to the GMC’s (2010a: 79-80) ‘understanding’ of case law in the guidance’s legal annex, ‘the courts do not consider that protecting life always takes precedence over other considerations’. If patients ‘lack capacity to decide’ for themselves, it is legitimate to ask whether life-prolonging treatment ‘would be more burdensome than beneficial’; ‘assessments of the likely quality of life for the patient with or without that treatment may be one of the appropriate considerations’. ‘There is no obligation to give treatment that is futile or burdensome’.

The GMC’s end-of-life care guidance echoes these passages. Doctors contributing to decisions about ‘potentially life-prolonging treatment ... must start from a presumption in favour of prolonging life’, but ‘there is no absolute obligation to prolong life’ (GMC 2010a: 12). Yet the guidance text and the legal annex do not address QOL considerations in the same way. The guidance describes situations in which doctors who treat patients reaching the end of life and lacking capacity are involved in, or responsible for, determining whether or not to provide life-prolonging treatment.

Together with carers, people close to the patient (especially parents of infant patients), legal proxies, and other members of the healthcare team, doctors should consider the likely overall benefit – benefits, burdens, and risks – of life prolonging treatment. This includes ‘clinical considerations’ as well as

considerations ‘of other factors relevant to the circumstances of each patient’ (GMC 2010a: 28, see also 45-6, 60-2). If a treatment is not considered to be of overall benefit, doctors have no obligation to provide it (GMC 2010a: 19, see also 49-50, 65).

Crucially, though, doctors treating adults ‘must be careful not to rely on your personal views about a patient’s quality of life and to avoid making judgements based on poorly informed or unfounded assumptions about the healthcare needs of particular groups, such as older people and those with disabilities’ (GMC 2010a: 29).

Doctors treating children ‘must be careful not to make judgements based on poorly informed or unfounded assumptions about the impact of a disability on a child or young person’s quality of life’ (GMC 2010a: 47).

The Council’s interpretation of case law and its guidance for doctors do not use the QOL concept identically. The legal annex expressly states that considerations of a life-prolonging treatment’s implications for the patient’s QOL are appropriate sources for ELDs. The guidance text does not make this point explicit. The guidance asserts that considerations of a treatment’s overall benefit – benefits, burdens, risks, and non-clinical factors relevant to each patient’s circumstances – are appropriate sources. But the QOL concept is used specifically in warnings that ELDs must not be based on doctors’ personal, poorly informed, or unfounded QOL considerations. Here the GMC also uses the QOL concept differently from NICE and the CQC. While NICE and the CQC do not apply it identically either, they both emphasise that considerations of the QOL implications of treatments, drugs or care enhance the potential of healthcare decisions to result in improved outcomes for patients and users. The GMC’s end-of-life care guidance does not make this point explicit. It employs the QOL concept for conveying that doctors’ personal, poorly informed, or unfounded QOL considerations undermine the potential of ELDs to yield desired outcomes.

Simultaneously, the guidance adds complexity to this issue. Following the Council’s decision making model, doctors conducting end-of-life care should use ‘clinical judgement ... to identify ... treatments’ which ‘are clinically appropriate’ (GMC 2010a: 16). If a treatment is not considered clinically appropriate, doctors have no obligation to provide it (GMC 2010a: 19). Crucially, clinical judgement includes ‘identify[ing] treatment options based on ... relevant clinical guidelines ... such as those issued by ... NICE’ (GMC 2010a: 23). And NICE (2009b) guidelines contain considerations of the HRQOL implications of treatments. This *implies* that although ELDs must not be based on doctors’ personal, poorly informed, or unfounded views about QOL, ELDs may ultimately be informed by NICE’s considerations of the QOL implications of life-prolonging treatments. This is wholly consistent with the GMC’s interpretation of case law and resonates with NICE’s employment of the QOL concept.

The ‘risk-based approaches that have spread across regulatory fields in the UK’ are also becoming important to GMC regulation (Lloyd-Bostock 2010a: 584-5). The Council’s end-of-life care document suggests at least three discrete links between the categories of risk and QOL. Firstly, the two terms are used to distinguish between acceptable and unacceptable ELDs. Acceptable ELDs draw on assessments of a life-prolonging treatment’s likely overall benefit, including its risks (GMC 2010a: 28-9, 45-7, 87). Yet if doctors’ personal, poorly informed, or unfounded QOL considerations enter into those assessments, the ELDs they inform lose their legitimacy. The distinction drawn by the concepts of risk and QOL appears particularly thorough in light of what the guidance text does not state. Albeit implied with reference to NICE, no paragraph explicitly asserts that an ELD, acceptable when based on considerations of a life-prolonging treatment’s likely overall benefit and risks, remains legitimate when influenced by doctors’ (say) scientific/objective, well-informed, or well-founded QOL assessments. Unlike the legal annex, the guidance does not expressly mention any considerations of the QOL implications of treatments that could render ELDs acceptable. Assessments of their risks have this potential. Secondly, the GMC seems to treat some QOL considerations as risk factors. Evaluating a life-prolonging treatment’s overall benefit enhances the potential of ELDs to produce desirable medical outcomes for patients. Simultaneously, the GMC warns of doctors’ personal, poorly informed, and unfounded QOL considerations, which appear to constitute threats to an ELD’s potential to produce desirable outcomes. Thirdly, QOL considerations constitute risks to doctors. ‘[P]ersistent failure to follow this guidance’, warns the Council, ‘will put your registration at risk’ (GMC 2010a: 7). A series of ELDs influenced by doctors’ personal, poorly informed, or unfounded QOL considerations would amount to such failure. From this angle, doctors’ QOL considerations increase the risk of being de-registered.

Diverse applications

QOL conceptions and their connections with the category of risk play important parts in UK health regulation. The centrality of QOL ideas to NICE’s work is well established, but their roles in CQC and GMC regulation have not been examined in-depth. Preliminary observations suggest that various healthcare regulators use QOL conceptions differently and create different links between them and the category of risk. NICE, for instance, uses the QOL concept in clinical and cost effectiveness assessments of health technologies. The concept is employed frequently and systematically, designating an outcome of health stimuli. NICE specifies five key dimensions of QOL. The CQC uses QOL and wellbeing conceptions in several areas of its health and adult social care regulation, but selectively in some of these areas. The categories designate care outcomes, but the CQC does not expressly specify what QOL or wellbeing means.¹¹

¹¹ One exception was a glossary relating to a previous approach to assessing commissioners, which defined wellbeing as ‘being healthy, happy and prospering’ (CQC 2010i: 14).

The GMC, finally, uses the QOL concept in regulatory guidance for doctors, but chiefly to designate the intentional content of doctors' assumptions, rather than healthcare outcomes or aspects of patients' lives. The term is used infrequently, yet in important warnings to doctors. It is not explicitly specified. The literature on QOL ideas in healthcare contains few sustained discussions of the diversity of their applications in health regulation. Closer investigations of these various applications can yield new perspectives on the healthcare operations of QOL ideas.

To this end, regulatory applications of QOL conceptions and their links to risk must be cast into sharper relief. It is important to specify in which areas and to which ends health regulators use QOL ideas and relate them to risk issues. It needs to be ascertained what regulators seek to capture, represent, and make intelligible through QOL and associated risk categories. Health regulators' approaches to assessments of QOL and related risks call for thorough investigations, and their proposals for managing QOL and risk problems need to be explored. One may expect that detailed accounts of these aspects will underscore the variations in regulatory uses of QOL and associated risk categories. The final section provides signposts for critical examinations which might help clarify these issues.

Context

The QOL concept's diversity of applications, including its notorious 'definitional heterogeneity' (Rapley 2003: 30), may be unsurprising. For 'quality of life' is not an 'object' (Rapley 2003: 65, see also 141; cf. Finn and Sarangi 2008: 1568). No observable entity in the world of things naturally demarcates the QOL category's boundaries. QOL conceptions are usually employed to isolate or capture aspects of human life and to make them intelligible – and measurable and manageable – *as* its 'quality'. Similar points have been made about the concept of risk (Hutter and Power 2005: 8-9; Power 2007: 4, 25). The absence of a referable QOL object and lack of consensus on what the concept should designate render applications and definitions of QOL categories particularly susceptible to a variety of influences. This also concerns the links between the concepts of QOL and risk in different settings. The QOL concept, Rapley (2003: 121) specifies, is a 'social phenomenon': its operationalisations are contingent on the 'cultural production' of life quality 'as a legitimate object of ... study'. Risk regulation scholars highlight the social factors impacting on the ways in which agents, including regulators, approach risk issues:¹² 'the social and economic institutions which shape ... our knowledge of, and management strategies for, risk, including the definition of ... "risk objects"' (Power 2007: 3-4). Referring to the works of the three organisations above, this section sketches

¹² Beck (1999: 149-50; 2008: 64-73); Douglas (1992); Douglas and Wildavsky (1983); Lupton (1999: 13, 29); Petersen and Lupton (1996: 18); Rayner (1992); Tansey and O'Riordan (1999); van Zwanenberg and Millstone (2005: 29).

lines of inquiry into three broader sets of factors which shape, and might therefore elucidate, the different uses of QOL conceptions and various links between QOL and risk categories in UK healthcare regulation.

Knowledges

Risk policy is shaped by selections of knowledges which are said to be contingent on 'non-scientific factors' (van Zwanenberg and Millstone 2005: 2; see also Lupton 1999: 29-30). Accordingly, analysts of regulation do not take its knowledge dimension for granted, but treat it as an area of social research. Schlander's (2007) study of NICE shows that NICE's objectives for health-technology assessments, notably its aim to produce QALY-based guidance, contributed to its neglecting relevant clinical evidence in its 2006 evaluation of attention deficit hyperactivity disorder treatments. Lloyd-Bostock (2010a; 2010b) questions the suitability of GMC registration and fitness-to-practise data as sources for regulating risks arising from medical practice. Data is filtered, limited, and shaped by the set-up of the GMC database, which is designed in accord with its legal functions and institutional purposes. Waring (2009) dissects potentially conflicting safety knowledges which inform the treatment of risks to patients in healthcare. The content of these knowledges hinges on whether they are constructed in clinical professionals' everyday interaction, filtered through standardised incident report forms, or reconstructed in risk management: 'knowledge ... often considered ... objective and scientific emerges within ... highly relative social, cultural, technological and political activities ... reflects wider cultural and professional concerns' (Waring 2009: 1723).

The CQC's work illustrates the importance of examining the exclusion, inclusion, and prioritisation of 'knowledges' (Lupton 1999: 29-32) for understanding regulators' uses of QOL and risk conceptions. QRPs contain estimates of the risk that care providers will not deliver essential care outcomes, e.g. 'surroundings that promote wellbeing'. These categories do not merely represent information on the potential that providers will violate fixed standards of 'surroundings that promote wellbeing'. Instead, the CQC taps several sources of qualitative information and quantitative items which represent how providers fare in light of a host of different standards. Not all of those items provide risk estimates and few of these standards are explicitly articulated in 'wellbeing' terms. For instance, the CQC collects data about a provider's scores on decor, lighting, bathrooms or toilets by Patient Environment Action Team standards; assessed outcomes for the NHS Litigation Authority's Risk Management Standards Criteria; or responses to particular questions in the CQC's adult inpatient survey. Each item is weighted according to conditions such as relevance to 'patient experience' or to the respective outcome (CQC 2010h: 7; 2010j). It is the weighted substance of this array of items which the concepts of risk and wellbeing help to capture and make understood as the 'risk' that the provider will not deliver 'surroundings that promote wellbeing'. This suggests that investigating the selection of data sources, items, their content and scoring standards, and the CQC's

weighting criteria is indispensable for elucidating its operationalisation of QOL, wellbeing, and associated risk categories.

Value judgements and ethics

Among the key factors shaping applications of QOL conceptions are value judgements and ethical considerations. In fact, quality of life *is* a value judgement of existence (Rapley 2003: 141) in many respects. Measuring health according to QOL criteria means measuring not how well health meets criteria objectively important to life's quality, but how well it fulfils criteria which subjects have judged as significant to QOL. Definitions of QOL are not driven by knowledge of components objectively pertaining to it, but by subjective evaluations of elements of human existence as decisive to QOL (Finn and Sarangi 2008: 1569). Furthermore, healthcare uses of QOL conceptions are guided by considerations of ethically acceptable healthcare arrangements and practices. Hence 'recognition of the ... moral dimension of the [QOL] concept is of considerable importance' (Finn and Sarangi 2008: 1569).

Operationalisations of risk conceptions have also been linked to moral judgements (Lloyd-Bostock and Hutter 2008: 73, 77; Petersen and Lupton 1996: 96). Firstly, the social value judgement of an event as undesirable (Renn 1992: 56-8, 72) may enhance attention to risks of such an event occurring. Links between QOL and risk categories are unusually explicit manifestations of the power of risk debates to raise 'the old question: *how do we wish to live? What is the human quality of humankind ... to be preserved?*' (Beck 1992: 28; see also Reuter 2007: 248). Yet secondly, critics argue, some forms of human behaviour are identified as risks ('bads') to be avoided simply because they deviate from a state of social reality valued as desirable, regardless of whether they pose any real threat (Douglas and Wildavsky 1983; Rayner 1992: 91).

The work of NICE illustrates the value dimensions of health regulatory uses of QOL conceptions. As mentioned, NICE's preferred device for establishing patients' descriptions of their HRQOL is the EQ-5D: health is described according to mobility, ability to self-care, ability to undertake usual activities, pain/discomfort, and anxiety/depression. The inclusion of these categories as QOL criteria constitutes the value judgement that being mobile or able to self-care contributes to a good quality life. Crucially, while determining QOL involves '*value judgements* about what is to *count* as QOL' (Rapley 2003: 66), no universal consensus on its components has been reached (Finn and Sarangi 2008: 1568). For example, in some areas 'functional capacity' (Arnesen and Nord 1999: 1425) is deemed decisive. Yet even within these domains, debates on whether social function constitutes a dimension or whether performance should be conceived in abstraction from social context continue (Murray 1994: 437-8; Murray and Lopez 1996: 24, 33-4, 92-3; Murray and Acharya 1997: 723-4). This

illustrates the significance of paying attention to the value judgements shaping health regulatory uses of QOL conceptions.

The ethical considerations informing operationalisations of such conceptions have been central to debates in the UK's health regulatory environment. In 2005, NICE recommended withholding Alzheimer's drugs from NHS patients because of their low QALY gain per unit of health expenditure.¹³ John Harris (2005a), editor of the *Journal of Medical Ethics*, alleged that using QALYs – as in this case – for deciding whether to treat a specific patient group was unethical because it entailed discrimination against those who could only expect few QALYs/£ from treatment. Two NICE representatives defended their institute in the *JME* (Rawlins and Dillon 2005: 683-4), emphasising that NICE operated in the 'real world' that Harris had left for a 'cost free ... universe'. NICE's QALY approach, they averred, was based on awareness of the tension between 'finite resources' and the NHS's 'egalitarian aspirations'. The retort's polemical tone cannot distract from its consistency with NICE's statement of the social value principles for the development of its guidance. NICE seeks to tackle the 'problem of distributive justice, or how to allocate limited ... resources fairly'. Vis-à-vis this problem, NICE has subscribed to 'procedural justice'. It also endorses 'respect for autonomy', 'non-maleficence' and 'beneficence'¹⁴ (NICE 2008b: 8-10; Schlander 2008). The debate between the moral philosopher and the regulator cannot be recapitulated here, but it illustrates the apparent gravitas of regulators' ethical considerations for their applications of QOL conceptions.

The GMC's application of the QOL concept is also instructive here. Unlike NICE and the CQC, which use it to describe consequences of health or care for patients or users, the GMC's end-of-life care guidance employs the QOL concept chiefly to designate the intentional content of doctors' considerations: 'you must be careful not to rely on your personal views about a patient's quality of life' (GMC 2010a: 29) or 'on poorly informed or unfounded assumptions about the impact of a disability on a child or young person's quality of life' (2010a: 47). The GMC does not specify which aspects of the patient's existence this concerns because it does not usually employ the QOL concept to represent properties of patients' lives. The term primarily designates the substance of certain considerations of doctors whenever they conceive of any component of patients' existence in QOL terms. At issue is the doctor's mind, not the patient's life. More specifically, the concept helps to represent medical practices, namely the content of those of the medical subject's ideas that are unacceptable influences on end-of-life decisions. This suggests that the GMC's uses of the QOL category are shaped by its wider ethical principles of medical practice. The QOL concept helps to inscribe the 'good doctor'

¹³ The decision was recently reversed.

¹⁴ 'Non-maleficence' embodies 'the maxim "first, do no harm"'. NICE's subscription to this principle, together with its conviction that 'any treatment or intervention can potentially have adverse consequences', seems consistent with its endeavours to assess treatments with a view to their QALY gain and the risks they pose (2008b: 8).

(GMC 2006) – and the morally acceptable ‘doctor-patient partnership’, which allows doctors and patients to make treatment decisions together (GMC 2008) – into the end-of-life care setting. In this setting, the good doctor must ‘give patients ... approaching the end of ... life the same quality of care as all other patients’ (GMC 2010a: 11). This, it seems, is deemed irreconcilable with ELDs based on a doctor’s personal or poorly informed views of patients’ differing QOL (regardless of which aspects of patients’ lives the doctor thereby isolates as decisive for their quality). In turn, the GMC’s notion that personal or unfounded views of QOL in ELDs increase the risk to a doctor’s registration is consistent with the value judgement that medical conduct, as codified by GMC principles, is ethical and that ELDs based on such views could violate these principles. Examining the ethical codes which guide the GMC’s work is vital for understanding its uses of the QOL concept and the links to risk.

Decisions on participation

Inquiries into the role of knowledges and value judgements in applications of QOL and risk conceptions raise questions about whose voices are heard and ignored. The question whose evaluations of health states in QOL terms should inform health policy has attracted controversy. The ‘experiential’ procedure (Phillips 2006: 41), which prioritises valuations by those living with the health states under scrutiny, is not universally accepted (Brazier et al. 2007: 112-7; Gold et al. 2002: 121-2). The ‘consensus’ approach (Phillips 2006: 45) involves eliciting quality weights for health outcomes from samples of entire populations (Gold et al. 2002: 121-2). Some sociologists of health argue that measuring, monitoring, and improving public health generally remain the prerogative of experts (Petersen and Lupton 1996: 8). Parts of the WHO’s work on QOL rely on expert ascriptions of disability weights to different health conditions (Murray and Acharya 1997: 713-6; Murray and Lopez 1996: 36-7, 90-6; Williams 1999: 4). Prioritising any group’s evaluation is considered particularly tricky because different groups are said to pass different verdicts on the QOL implications of the *same* conditions (Brazier et al. 2007: 112-4; Murray and Lopez 1996: 29-32; Phillips 2006: 44-6, 60; Rapley 2003: 145, 155; Schlander 2008: 534; Ubel et al. 2003). This is also said to apply to basic judgements of what should count as the defining elements of QOL. Rapley (2003: 73) mentions ‘differences between “lay” and “technical” views of ... what HRQOL “is”’. Moreover, existing QOL constructs have been criticised for reflecting ‘predominately white, western-centric notions of health, selfhood and function’ (Finn and Sarangi 2008: 1569).

Similar debates are known in the risk field. Beck (1999: 149) emphasises the significance of prevalent ‘relations of definition’: ‘the specific rules, institutions and capacities that structure the identification and assessment of risk in a specific cultural context’. Contemporary risk society allegedly grants scientific experts the monopoly of power to conceptualise the risk world (Beck 2008: 68-76). Petersen and Lupton (1996: 98) agree that the ‘identification’ of ‘health risks ... is increasingly regarded as the reserve of those

who have access to ... expert knowledges'. In his case study of risk management strategies pertaining to Australian drug policies, Duff (2003) found that scientists held the monopoly on the classification of illicit substance consumption as a 'high risk practice'. Drug users' own 'inexpert' knowledges and judgements about drug consumption were excluded from debates. Scholars such as Duff have criticised the prioritisation of expert views on risk and demanded greater involvement of lay publics (see also Funtowicz and Ravetz 1992; Giddens 1998: 59; van Zwanenberg and Millstone 2005: 1-36). Some analysts have identified democratising trends in risk regulation generally (Hutter 2010: 18), and healthcare regulation specifically (Macrae 2008: 55).

Healthcare regulators are increasingly faced with the question whether to consider public opinion and how to weight it (Lloyd-Bostock and Hutter 2008: 77). Two observations suggest that different regulatory applications of QOL conceptions are shaped by decisions on whose knowledges and value judgements should be considered. NICE's QALY-based assessments of health technologies incorporate three vital elements of information. Scientists measure a technology's impact on lifetime. Patients describe health effects with reference to standardised QOL criteria. Representative samples of the UK population value health effects – described in QOL terms by patients – and assign quality weights to them (Claxton and Culyer 2006: 375; Dolan et al. 2009; NICE 2008a: 28, 38). A QALY value is the product of lifetime and quality weight.

One of the functions of the QOL concept in GMC guidance is to warn that doctors discussing whether or not to attempt cardiopulmonary resuscitation (CPR) must 'bear in mind that some patients, or those close to them, may have concerns that decisions not to attempt CPR might be influenced by poorly informed or unfounded assumptions about the impact of disability or advanced age on the patient's quality of life' (GMC 2010a: 62). Here, the QOL concept is used to designate, neither aspects of the patient's life nor simply the intentional content of doctors' assumptions as seen by the GMC, but the content of doctors' (or other people's) assumptions *as envisaged by some patients or those close to them*. It is not immediately clear which source of information about these concerns the GMC is drawing on here. It does not appear to have conducted any surveys of patients or those close to them. Instead, these worries seem to have been reported by other organisations (possibly as they were consulted for guidance development). Further potential sources are complaints from patients, relatives or the public through GMC's fitness-to-practise channels (see Lloyd-Bostock 2010a; 2010b) or inquiries to the GMC's standards and guidance section. Finally, the GMC mentions that its end-of-life care guidance incorporated doctors' 'feedback' regarding this issue (GMC 2010b: 5). What these observations underline is that the three health regulators' different uses of the QOL concept and their various endeavours to connect it to the category of risk may be elucidated by investigations of their respective approaches to the question whose knowledges and judgements are relevant for regulatory work.

Summary

The aim of this paper was to outline a way of acquiring new perspectives on the operations of one of the health sector's most prominent and controversial concepts. Section 2 highlighted different ways in which UK health regulators use the quality of life concept and link it to the category of risk. While NICE's applications of the QALY framework are well known, the CQC's and GMC's operationalisations of QOL ideas have received little attention from social researchers. Yet it is precisely through case studies of *different* regulatory uses of QOL conceptions and *different* efforts to link such conceptions to risk problems – topics which have yet to receive sustained attention from social researchers working on QOL in healthcare – that fresh insights into the current healthcare uses of the QOL concept can be established. Correspondingly, the paper sought to provide signposts for critical examinations of three broader sets of factors – knowledge selection, value dimensions, and decisions on participation – which appear to shape health regulatory applications of QOL conceptions. Inquiries into these factors promise to elucidate those applications and thereby to contribute to a more multifaceted understanding of QOL ideas in contemporary health systems. Simultaneously, such inquiries have the potential to problematise these ideas: they might suggest that uses and definitions of the QOL concept are not simply contingent on what QOL is, but on what cultural activities in contemporary social conditions make the concept do and say.

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