Introduction

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I

Genetic technology has enabled us to test fetuses for an increasing number of diseases and impairments. On the basis of this genetic information, prospective parents can predict – and prevent – the birth of children likely to have those conditions. In developed countries, prenatal genetic testing has now become a routine part of medical care during pregnancy. Underlying and driving the spread of this testing are controversial assumptions about health, impairment, and quality of life. While the early development of prenatal testing and selective abortion may have been informed by the questionable view that they were just another form of disease and disability prevention, these practices are now justified largely in other terms: prospective parents should be permitted to make reproductive decisions based on concern for the expected quality of their children's lives. These practices, and their prevailing rationale, reinforce a trend in biomedical ethics that began in the 1970s, one giving a central role to quality of life in health care decision making.

In this Introduction, we will briefly review how quality of life came to assume such importance in health care and reproductive practice and policy. We will then discuss some of the conceptual and ethical issues raised by attempts to measure health-related quality of life and to use such measures in the evaluation of health care interventions. Next, we will examine the bearing of these issues on the current rethinking of disability, a category that has been widely associated with poor quality of life. We will describe the tension that has arisen between the emerging understanding of disability as an interaction between health and nonhealth conditions and environmental factors, and the effort to systematically measure health-related quality of life. Finally,

we will preview the discussions of these issues by the contributors to this volume.

Concerns about quality of life first surfaced in the public debate as a basis for limiting medical interventions. As physicians became capable of indefinitely sustaining the mere biological functioning of individuals who had lost (or appeared to have lost) all capacity for consciousness, a sharp controversy emerged in the 1970s over whether continued health intervention was an appropriate use of health care resources, especially when it went against the previously expressed wishes of the patient or the current wishes of the family. An emerging consensus that the patient herself should make that decision whenever possible was reflected in the development of standardized living wills, medical powers of attorney, and do-not-resuscitate orders. This consensus has not reached two controversial areas: physician assistance in bringing about death sought by competent individuals hoping to avoid a continued existence with chronic impairment or pain, and the withdrawal of life support sought "on behalf" of cognitively incapacitated patients who have left no written instructions (for a summary of, and comprehensive references on, these debates, sce Battin, 2003).

The controversy over end-of-life treatment thus continues, now focused on the morality and legality of physician-assisted suicide and of decision making for those who appear unable to decide for themselves. In the former case, the salient issue is typically the right of competent individuals to enlist physicians' assistance in committing suicide; in the latter, the difficulties of ascertaining the prior or hypothetical wishes of the patient and their relevance to the present decision. In both areas, the notion of quality of life is firmly entrenched as an important, if often suspect, consideration. On the one hand, interventions that are technically feasible, but produce no discernible improvement in quality of life, are often opposed as pointless and undignified. On the other hand, the opposition to withdrawing life support from individuals who retain some cognitive functioning, or the possibility of recovering it, often emphasizes the quality of life still possible for those individuals.

Patients are not the only group to have become more concerned about the quality of life that results from medical interventions. The interest of health researchers, policy makers, and administrators predates the public's by at least a decade. Beginning in the 1960s, a variety of medications were developed to increase patients' functioning or to lessen their pain, discomfort, depression, or anxiety without curing their diseases or increasing their prospects for survival. In order to assess the benefits of

these new medications, the pharmaceutical industry financed the design and use of some of the earliest quantitative measures of quality of life. That industry continues to play a major role in developing and utilizing increasingly sophisticated quality-of-life measures (Walker, 1993; Spilker, 1996). In the past thirty years, quality-of-life measurement has been eagerly taken up by researchers, epidemiologists, public and private health administrators, health economists, and health policy makers.[1] Together with estimates of survival and tests of physiological function, these measures have now become a standard part of the calculus employed to compare the "cost-effectiveness" of treatments for the same and different health conditions, a calculus that is used to justify trade-offs among limited medical resources.

The roughly concurrent emergence of drugs that improve the quality of living without extending life, and of medical interventions that extend life without improving or restoring its quality, raised issues about the very meaning of quality of life, and about its importance as a goal of health care practice and policy. While the growing use of treatments that appear to improve life quality without increasing longevity suggests a greater concern for patient welfare, the increasing scrutiny of life-preserving and other expensive medical technologies suggests a greater concern for resource allocation. The expense of many of these technologies has been a major stimulus for cost containment, as well as for a precise, objective assessment of the actual improvements that these technologies produce. The result has been the imposition of cost-effectiveness analysis in professions where rationing had rarely been explicit. Interventions sought by desperate patients and families, as well as interventions opposed by patients or their families as undignified or pointless, are routinely challenged by health economists, administrators, and policy makers because they are not "cost-effective."

A concern about quality of life also came to play a central role in reproductive decision making during the same period. In 1973, the U.S. Supreme Court recognized early and midterm abortion as a constitutional right. After *Roe v. Wade*, a woman could have a legal abortion through the second trimester anywhere in the United States, for any reason. Genetic and other reproductive technologies were soon providing a stock of reasons for aborting that women had never previously had, through the use of tests that could reveal a variety of diseases, susceptibilities, and impairments. Because public acceptance of such tests depended on their being seen as noncoercive, they could not be presented as public health measures intended to eliminate or

reduce genetic diseases and defects. Rather, prenatal tests were justified as tools for expanding individual reproductive choice. Whether this represented eugenics "though the back door," as some critics claimed (e.g., Duster, 1990), or the distinct, if still unwelcome, intrusion of a consumer mentality into reproductive decision making (Lippman, 1991), the use of prenatal tests soon became a standard part of medical care for pregnant women deemed to be "at risk" of bearing diseased or disabled children.

The notion of quality of life, given currency by other developments in health care, offered a convenient "child-centered" rationale for prenatal testing and selective abortion: couples should be concerned not only about whether to have children, or indeed about whether it is moral to do so (e.g., Brock, 1995; Purdy, 1996), but also about the quality of life that a particular child could be expected to have. If the chromosomal or genetic constitution of a fetus appeared to preclude a life of reasonable quality, it was appropriate to abort. Until recently, selective abortion escaped the controversy that has accompanied efforts to limit the medical care given to severely impaired neonates (e.g., Kuhse and Singer, 1985) – a limitation also justified by low expected quality of life – in part because newborns are generally accorded higher legal and moral status than fetuses. Despite the continuing controversy over abortion in general, abortion for disease and impairment was seen, even by many who were troubled or ambivalent about abortion in general, as a responsible exercise of reproductive choice (see Asch, 1999).

Although prenatal testing has rarely been publicly justified in terms of its cost-effectiveness, public health administrators and policy makers concerned about the costs of "heroic" lifesaving interventions for neonates could hardly be oblivious to the actual and potential savings implicit in selective abortion. Many of the most expensive health conditions are not, and never will be, detectable by prenatal genetic testing, because they arise from accidents of various sorts or have complex etiologies in which genetic variations play only a slight or probabilistic role. Nevertheless, there is evidence that the incidence of several diseases and impairments thought, correctly or not, to impose significant health care costs has fallen – or has failed to increase as expected because of other factors, such as increased maternal age – as the vast majority of women who employ prenatal testing chose to abort fetuses found to have the conditions tested for (Huether, 1983; Huether, 1990; Kuppermann, Gates, and Washington, 1996; NDAD, 1996). Meanwhile, the costs and risks of prenatal testing have continued to decrease (Roan, 2004), creating a situation in which health care administrators and policy

makers have strong incentives to encourage prospective parents to make quality of life a critical factor in their reproductive decisions.

From Quality of Life to Health-Related Quality of Life

Despite its obvious appeal and growing currency in discussions of health policy and health care, the notion of quality of life raises a difficult conceptual issue for health professionals and policy makers: what outcomes (or types of outcomes) are connected closely enough with health to be taken account of in assessing the impact of health interventions on quality of life? Health care cannot be concerned with all aspects of life or well-being without giving it an impossibly broad mandate. That is just what the World Health Organization (WHO) appeared to have done in 1947, adopting a definition of "health" that made it virtually coextensive with quality of life: health was "not merely the absence of disease, but a state of complete physical, mental, and social well-being."[2] That definition, which set no limits on the scope of health policy or health care, was widely criticized and, though it remains a piece of interagency political rhetoric, plays no scientific role today even at the WHO.

But its rejection leaves a difficult question: if health is something less that complete physical, mental, and social well-being, how is its scope to be limited? Health professionals, researchers, and policy makers have acknowledged the need for such limits, and have introduced the notion of health-related quality of life (HRQL) as a way to set them. HRQL assessment tools evolved from older mortality and morbidity indicators, augmented by measures of functional status, subjective health experience, and perceived components of "social health." These instruments were designed to assess the patient's performance in, or satisfaction with, areas of activity affected by her physical and mental functioning. Since virtually all areas of activity are affected by health, however, these measures had to limit themselves to the areas most directly or substantially affected by health. Yet without an understanding of what counts as "health-related" in this sense, that term does more to label than to resolve the issue. The proliferation of HRQL instruments has not been informed by a careful analysis of, or an explicit agreement on, that issue.[3]

The lack of agreement about what falls within the bounds of health poses a serious practical problem, because narrower measures of health cannot serve as adequate proxies for broader ones. The notion of HRQL depends, both historically and conceptually, on the common observation that there is an uncertain relationship between diagnostic

categories – the signs and symptoms that doctors use to identify disease, injury, and other conditions of ill health – and the full range of outcomes that, arguably, should be taken into account in assessing the success of a health intervention. Most health professionals recognize that diagnostic measures, such as ejection fractions and viral loads, correlate poorly with how well the patients functions at a "macro" level, from walking and stretching to getting and holding a job, let alone with how satisfied the patient is with his health or his life.[4]

Uncertainty about what aspects of quality of life count as health-related arises in part because a wide variety of economic, social, and psychological factors mediate the impact of health conditions on the activities and states of mind that people value, and because those activities and states of mind vary in how closely they appear to be related to health. Thus, for example, an instrument assessing the quality of life associated with pulmonary diseases or interventions would surely take too narrow a view of what counted as health-related if it took no account of patients' chronic pain, pervasive anxiety about breathing, or perceived incapacity to engage in routine activities because of shortness of breath. But what about the difficulties the patients had in getting jobs that required strong lung capacity? What about their difficulty in getting jobs because of a true or false belief that their conditions were contagious? What about the high blood pressure, anxiety, or marital conflict associated with their unemployment? Should any or all of these employment difficulties be considered health-related and thereby be included in what the pulmonary specialist should be assessing as HRQL?

If the health professions lack an account of what aspects of living or features of the environment are health-related (i.e., directly or substantially related to health conditions), they also, and perhaps more basically, lack a theory of quality of life itself. What qualities should a life have; what does it mean to live well? Has a person's quality of life improved or declined if his expectations increase faster than his lung capacity, leaving him more frustrated than he was before treatment? What if his decline in lung capacity is offset by his embrace of a more leisurely and personally rewarding lifestyle? Is his quality of life enhanced by a breathing apparatus that dramatically improves his respiration if he is ashamed to appear with it in public?

Health researchers and methodologists implicitly answer such questions when they select items and assign weights for their HRQL assessment instruments. Yet the answers they give are rarely the product of sustained reflection. Rather than responding to philosophical questions

about what it means to live well, their instruments tend to be modified and refined in response to psychometric and statistical considerations. Nevertheless, this lack of reflection on the meaning of fundamental concepts has not precluded a rough consensus. Surveying some 300 instruments currently in use, Ann Bowling notes that despite the differences in the specific components of quality of life included in those instruments, there is broad agreement about the general categories of items that need to be represented and measured (Bowling, 1997; see also McDowell and Newell, 1991).[5] But this agreement appears to reflect conformity to precedent, or a methodological preference for comparability, rather than any clear, widely accepted conception of HRQL. Bowling and other HRQL scholars readily admit that despite substantial progress in developing quantitative tools to operationalize and measure specific components of HRQL, attempts to bring these tools together into a single, integrated assessment instrument have been utter failures, because of the lack of consensus on the definition of the terms "health," "health-relatedness," and "quality of life."

Objective and Subjective Components of HRQL

One of the most basic, and recalcitrant, issues in assessing quality of life is whether it should be regarded as subjective, based on the patient's own judgments and feelings, on objective measures of functioning and participation, or on some combination of the two. Is it enough to look at subjective measures, the individual's satisfaction with his health status or condition, or should we also include measures of physiological functioning, bodily performance, role fulfillment, and social participation in our assessment? Most HRQL instruments in fact include both types of measure, to varying extents, but this inclusiveness itself needs justification. Otherwise, it obscures sharp disagreements about the extent to which quality of life or HRQL is an objective matter; it risks treating conflicting accounts of quality of life as if they were just different aspects of a complex phenomenon.

The objective measures incorporated in HQRL instruments typically concern "functional status," which refers to the full range of human functions: (1) physiological functions, such as blood pressure, digestion, and respiration rate; (2) the capacity to perform basic physical and cognitive activities, such as walking, reaching, focusing attention, and communicating, or the various combinations of these needed to perform routine activities of daily living, such as eating, bathing, dressing,

transferring, and toileting; and (3) socially shaped tasks or life roles, such as those needed by children for school and play and those needed by adults for work, household maintenance, and participation in social activities. Given its breadth, functional status is a composite measure more often used by rehabilitation therapists than by physicians. Rehabilitation professionals have developed clinical tools to assess many of these functional capacities, at least those at the more basic levels. For this reason, there is a vast rehabilitation research literature describing clinical questionnaires and other tools to assess physiological functioning and capacities for the "activities of daily living." Assessment tools for the more complex social tasks and life roles are arguably needed, but they are less frequently attempted. It should be clear that functional status categories go beyond standard medical diagnostic categories, in that people with the same diagnosis can nevertheless have different levels of functioning.

The subjective measures incorporated in HQRL instruments typically concern the patient's satisfaction with his health state and functional status. Clinical questionnaires assessing these matters have a long history, going back to the late 1940s if not earlier (Bowling, 1997), and their availability and familiarity may have influenced the early stages of the development of HRQL instruments. Even more than ratings of functional status, judgments of satisfaction vary widely for the same or similar health conditions.

The discussion of subjective quality of life in the health literature has been confused by the failure to make two basic distinctions, clear in theory even if vague or uncertain in application. The first is that between satisfaction as a mental state – a feeling, mood, or affect – and as a judgment or belief. (This distinction is especially important, and elusive, in mental health, where one main concern is how a patient feels. It may be hard to distinguish how the patient feels from what he believes about how he feels.) Feeling satisfied, in the sense of feeling pleasure or euphoria, is very different from believing that one's needs, desires, or preferences are being satisfied. The former is a psychological state, which can be inapt but not mistaken, while the latter is a judgment, which can be mistaken.

The second distinction sometimes overlooked in the quality of life literature is that between the patient's preferences and his choices. A generation of health professionals who have, at least officially, rejected paternalism have good reason to be concerned about the latter – the patient should be free to decline treatment that the physician finds medically

valuable or necessary, even for reasons that the physician thinks are bad. But if it is imperative to honor the patients' choices about health intervention – to do as he decides – it hardly follows that it is necessary to adopt the patient's preferences in assessing the outcome of an intervention that he consents to. Why should the physician or researcher be obliged to evaluate its success by the same criteria as the patient?

Over the past few decades, hundreds of HRQL instruments have been developed, some designed for specific diseases, others more generic (see the standard texts, McDowell and Newell, 1991; Bowling, 1997). Almost all of them attempt to mix objective components (functional status) and subjective ones (self-reported health perceptions or levels of satisfaction). Given the obvious conceptual difficulties involved in combining these distinct and possibly incommensurable measures of well-being, a surprisingly large number of survey articles on HRQL blithely assert that the only viable candidates for HRQL instruments are "holistic" ones that merge subjective and objective measures (Day and Jankey, 1996). Some leaders in the field have argued forcefully, as does one of our contributors, that "quality of life" is inherently a measure of subjective reaction to one's health and functional status (Patrick and Erickson, 1993; Gill and Feinstein, 1994; Nord et al., 2001). They acknowledge that there are potential regularities between health or functional status and (subjective) quality of life, but insist that these must be empirically established, not conflated into a single notion. Reducing quality of life to functional status, or conflating the two in a single HRQL score, ignores or obscures the individual's own perceptions of how well life is going for her or replaces them with professional judgments in the guise of functional assessment. Yet hybrid measures continue to predominate, without clear justification.

This dispute among methodologists reflects broader disagreement, of far older vintage, about what it means to live well. The idea of well-being has played an important role in Western philosophical and moral inquiry for millennia, in perennial debates about what makes human lives go better or worse, what makes a life worth living at all, what we should promote in our own and others' lives, and whether the standards for living well are culturally variant or universal (see., e.g., Griffin, 1986; Nussbaum, 1990; Nussbaum, 1992; Brock, 1993; Griffin, 1993; Sen, 1993; Sumner, 1996; Nussbaum, 1998). These debates raise questions that are clearly relevant to those seeking to measure HRQL. Is quality of life or well-being to be understood mainly or exclusively in terms of pleasure and pain; in terms of happiness in some

broader but still subjective sense; in terms of the satisfaction of actual desires, or of adequately informed desires; in terms of inherently valuable activities and achievements; or in terms of all, or some combination of, these diverse elements? If the last, then how, if at all, should those elements be combined in an overall assessment?

We can hardly expect health methodologists to resolve issues that have vexed generations of philosophers, but it is not unreasonable to expect them to acknowledge the conflict, and to recognize that it cannot be resolved by methodological refinement alone. The uncertainty about what counts as health-related, and what constitutes quality of life, suggests the need for a broader inquiry into what health professionals and policy makers should be measuring, and for what purposes. While the health context is often thought to present special considerations and constraints, it is important to bring the philosophical analysis of well-being to bear on the problematic notion of HRQL.

Health-Related Quality of Life and People with Disabilities

It might appear that people with disabilities would welcome the growing interest of health professionals and policy makers in quality of life. Many of the challenges facing individuals with impairments arise not only from their biomedical conditions, but also from a physical and social environment that renders those conditions disabling. Having an instrument that took account, not only of their physical or mental condition, but also of the effects of features of the world in which they live, would give a better picture of the quality of their lives. And yet the increased attention of health professionals to a broader range of causal factors and outcomes may also have some troubling implications for people with disabilities.

This is so for several reasons. First, as health professionals and policy makers have broadened the range of outcomes they regard as health-related, they have taken a correspondingly broader view of what counts as a health problem. In the case of mobility impairments, for example, difficulties in caring for oneself, in performing the activities of daily living, and in getting from place to place are typically seen, no less than difficulties in moving one's arms or legs, as the "consequences of a health condition" and thus, in an important sense, as health problems. This expansive view of health problems appears to contradict, and to undermine, the effort of two generations of disability activists to present such difficulties as problems of environmental fit and social justice. Their