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Features

Patients' Interests in their Family Members' Well-Being: An Overlooked, Fundamental Consideration within Substituted Judgments

Jeffrey T. Berger

INTRODUCTION

Patients' expectations for decision making by their health surrogates are often discordant with commonly accepted standards for substituted judgments, and actual decisions by surrogates are similarly discordant. This descriptive-normative divide stems, in part, from a narrow view of the personhood of patients that is predominant in medicine and also in biomedical ethics. This limited view of patients leads to an incomplete mapping of their important concerns, particularly concerns based on patients' social sense of self. One particular concern that is typically overlooked within substituted judgments is patients' interests in how treatment choices affect the well-being of their family members. Academic discourse tends to portray the interests of patients and their intimates as distinct and competitive; for example: *Should patients choose without regard to the consequent burdens on their family? What family interests, if any, ought to limit a patient's decisions?*

In fact, these interests are often indistinct, mutual, and reciprocal. The effect of a patient's decision on the family is not only a concern of the family. Often, it is a serious, if not critically important, interest of the patient. An examination of patients' interests in family well-being may illuminate and perhaps narrow the rift between normative and descriptive aspects of substituted judgment. For this discussion, the term "surrogate" may include other intimates whose welfare the patient includes among his or her personal interests and who are substantively affected by treatment decisions.

BACKGROUND

Capacitated patients make choices about healthcare by integrating a host of values and interests, such as emotional and financial concerns, spiritual needs and religious obligations, and concern for family. Patients often involve family members in these delibera-

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tions, and when patients have lost decision-making capacity, family members must extrapolate or construct a decision for the patient while they wrestle with their own interests. Although surrogacy is imperfect, it serves a vital role in clinical care.

Dan Brock offers the following justification for surrogacy: (1) surrogacy has been endorsed by our democratic political process; (2) it promotes self-determination of the incapacitated person; (3) family members will perform best in this role; (4) family members will be most affected by decisions, the patient excepted; (5) justice requires consideration of the effects on family; and (6) the family is a moral unit with responsibility for its members.[1] Half of these involve family interests.

Of the widely accepted standards for decision making, namely, known wishes, substituted judgments, and best interests, the substituted-judgment standard is perhaps the most widely employed in decision making for incapacitated patients.[2] Standards for substituted judgments require that decisions reference patients' important values, beliefs, and specific preferences for care.[3] Under the standard, surrogates should strive to make decisions that patients would most likely have made.[4]

Despite the broad application of the substituted-judgment standard, a number of unresolved issues exist.[5] I will discuss two issues in particular that are closely related to one another. First, surrogates often fail to replicate and fail to strive to replicate the patient's decision. Second, results of studies examining attitudes and preferences of patients and surrogates seem to challenge the normative assumptions on which the standard is based.

First, the literature clearly documents that surrogates fail to accurately represent patients' wishes in one-third to nearly one-half of decisions.[6] Although surrogates tend to choose overtreatment, some studies also find undertreatment relative to patients' preferences.[7] Other studies find that some surrogate decisions more closely reflect surrogates' preferences for their own treatment, than they do the preferences of the patient.[8] Therefore, some surrogates use decision-making processes other than the identifying patients' choices. These surrogates engage in an ethically disconcerting abrogation of the substituted-judgment standard and patients' autonomy. Do surrogates simply ignore the substituted-judgment standard, or attempt, but fail to achieve, this perhaps too-rigorous a standard? Clinicians, by and large, appear to overlook these lapses.

It is interesting that patients also appear, for the most part, unalarmed by the flaws of their surrogates. This leads to the second concern regarding disparities between empiric studies, which are concerned with the sociological and cultural dimensions of substituted judgments, and the preconceptions underlying the standard. These studies suggest that patients may care less about decisional accuracy and may be more concerned with issues of trust in, and fidelity by, their surrogates.[9] For example, patients maintain their selection of health agent even when they are informed that their agent is not likely to replicate their treatment choices.[10] One interesting study suggests that many patients do not expect or even want their surrogates to follow their explicit wishes.[11] Another study reports that patients are likely to modify their preferences to accommodate family concerns.[12] Therefore, the core element of the standard, striving to replicate patients' decisions, may not be essential for many patients.

What the standard requires of patients (identifying and communicating health preferences) and what it requires of surrogates (extrapolating a patient's decision) differs from what many patients and their surrogates expect of each other. Patients may not require that surrogates follow expressed wishes, and surrogates may not require that patients leave preferences for treatment. Thus, the standard often fails patients, and surrogates often fail to meet the standard.

This apparent normative-descriptive uncoupling stems in part from a sociologically impoverished, but widely held, view of the prototypical patient.[13] This view is evidenced by many physicians who, while eliciting their

patients' treatment preferences, limit their conversations to concerns of direct medical benefits and burdens, overlooking patients' broader socially based interests. Typical templates for living wills concretize this medical approach by linking treatment preferences largely to condition and prognosis.[14] Patients' decisions are often thought of as more "authentic" if they narrowly focus on immediate self-interests, and are somehow thought to be "tainted" by considerations that are less atomistic. As Nancy Jecker notes, "our tendency is to discredit decisions to forgo treatment that are made on the basis of the . . . burden treatment places on family members."[15] Therefore, abbreviated views of the personhood of patients in academic discussions and in clinical practice[16] tend to limit the integration of patients' family-centered concerns in both the preferences identified and left by patients and the deliberations of surrogates.[17] This occurs despite ample evidence that patients are deeply concerned with the effects of their illness and treatment choices on their family members.[18] Parenthetically, the literature is peppered with discussions of broader notions of "self," but these have not been widely integrated.[19] These still-underacknowledged concerns of patients may well account for both the apparent inaccuracy in surrogates' decisions and patients' acceptance of this inaccuracy.

RELEVANCE OF PATIENTS' CONCERNS FOR THEIR FAMILY'S WELL-BEING

Paradigms of the personhood of patients in which the patients' interests and their families' interests are less discrete are certainly morally valid. Mappes and Zembaty contend, "if one wants to be the kind of person who performs actions that further the interests of other family members and perhaps even identified those interests as one's own, one acts autonomously. . . . When one identifies with the interests of others and acts accordingly, one is *also* acting in one's self-interest."[20]

For many patients, particularly those of some minority cultures, distinguishing a patient's self-interests from a patient's family's interests may be artificial and unnecessary. To illustrate, one writer notes of his Pakistani culture, "you *are* your family and your family is you."[21] Blackhall and colleagues found differences between Whites, African-Americans, Korean-Americans, and Mexican-Americans, with the Hispanic group most strongly considering the impact of illness on the family.[22] In Buddhist thought, patients who forego life-sustaining treatments so the family does not suffer, emotionally or financially, perform a valued act of compassion.[23] Family-centered interests should be better recognized among the more commonly addressed interests that underlie substituted judgments.

Patients' interests in the well-being of their family ought to be a routinely explored content area in substituted judgments for the following reasons. (1) It is an important concern of patients. (2) Family members commonly sacrifice for each other in various aspects of life, including financial, emotional, and health-related ones, and this mutual sacrifice is generally sociologically and anthropologically functional. For example, parents often hold their children's welfare over their own, siblings donate and accept organs amongst themselves, and adult sons and daughters assume caretaking and financial responsibilities for aging parents. (3) It can promote greater cross-cultural sensitivity among clinicians of patients who, for cultural reasons, fundamentally define themselves in terms of family. (4) Surrogates' self-interests already influence substituted decisions, but this influence is unopposed by an assessment of surrogates' interests from the patient's perspective.[24]

PATIENTS' INTERESTS IN FAMILY TO BOLSTER THE ETHICS OF THE SUBSTITUTED-JUDGMENT STANDARD

Studies of patient-surrogate pairs report nonconcordance by surrogates in a third or more of surrogate decisions.[25] Before concluding that the substituted-judgment standard is untenable, it is useful to examine research designs common to these studies. Typically,

these studies compare the preferences of patients with the choices of surrogates. Each of these are elicited using the limited models that focus narrowly on the triad of condition-treatment-medical outcome. Therefore, preferences that are generated and then analyzed are oversimplified, inexpansive, and perhaps not terribly robust in authenticity. Could this account for a portion of the apparent discordance between the choices of patients and surrogates?

Regardless, decisional concordance, although it nearly monopolizes this area of research, should not be the only valid outcomes measure. The literature suggests other ethically relevant measures of appropriate surrogate behavior. One alternative outcomes measure is surrogate decisions that are acceptable to patients, based on patients' trust in their surrogates, rather than on the accuracy of the decision. Another alternative outcomes measure is surrogate decisions that are acceptable to patients because their primary concern is that their surrogates are comfortable with the decisions they make. Here, an overriding interest of the patient is their surrogate's well-being. Current norms for good surrogate decisions are most appropriate for patients who live largely in social vacuums. A more expansive view of decisions by and for patients is warranted. If, according to the substituted-judgment standard, surrogates must strive to make the patient's decision, and many patients strongly consider the burden on family in their preferences, then the standard does support some surrogate decisions that attend to the well-being of surrogates. Perhaps good substituted judgments are better described as those that the patient would find highly acceptable for a range of reasons and concerns. Under this interpretation, I suspect the majority of "problematic" surrogate decisions are, in fact, appropriate.

A more robust interpretation of the substituted-judgment standard would require patients, as before, to communicate their health values and preferences. Patients would identify those whose well-being they consider to be a self-interest, and what approaches to surrogate decision making are acceptable and unacceptable. For example, a patient may want the surrogate to focus primarily or exclusively on achieving concordance with the patient's direct medical preferences. Alternatively, a patient's primary concern may be the surrogate's comfort with a decision. Some patients may prefer that the surrogate make decisions that best relieve the burden on the surrogate. Patients may include or exclude one or more of these considerations, and may choose to combine or to rank them.

A re-implemented standard would require surrogates to attend to these concerns and priorities of the patient. In doing so, surrogates may be more likely to confront their own nonpatient-centered agendas and biases and to discern the differences, if any, between their own interests and patients' concerns for their interests.

The major thrust here is to operationally expand the substituted-judgment standard to more explicitly allow for, if not embrace, a social dimension of patients that has been relatively neglected, despite its centrality in human life.

CONCERNS

An obvious related concern is the group of surrogates who exert their own interests while they are deciding for others. John Hardwig identifies several issues.[26] These include protecting patients from undue interests of surrogates, deciding whose interests among various family members should be considered, and that surrogates who act on their own interests unfairly treat incompetent patients who, if competent, would choose to ignore the interests of family members. These concerns are most troubling within a construct that views the interests of patients and surrogates as separate and competitive, but are less problematic within a patient-centered construct that can also account for surrogates' interests. In the latter model, the patient (contemporaneously or prospectively) determines

whose interests and what interests are germane. Therefore, it promotes fair treatment of the patient, in that the patient's concerns for family would similarly affect the decisions that are made, whether the patient has or has not lost decision-making capacity. Furthermore, to completely neglect such an important interest of patients because of concern about possible inappropriate behavior by family distorts the likelihood of harm and conflicts with a basic assumption underlying all of health-related surrogacy (clinical care, clinical research, organ harvesting), namely, the trustworthiness of the family.

Still, numerous concerns exist. For one, patients may wish to identify their family-related interests and may wish to address whether and how these should be accounted for in health decisions. However, there are neither well-developed mechanisms with which patients can communicate and record these concerns, nor clear methods by which surrogates and health professionals can integrate these concerns into substituted decisions. Furthermore, problems similar to those with conventional directives—their limited influence on decisions—would be likely.

A great challenge for surrogates is to integrate patients' concerns for the well-being of family into decisions when patients are not likely to have left serviceable preferences in this regard, and neither physicians nor advance directive documents are likely to have stimulated such discussions. Surrogates will likely need to determine whether and how deeply the patient held a particular family-related interest (for example, relief of a spouse's emotional distress), and how the patient would have wanted this concern to affect decisions. Of course, it is not known how surrogates might perform in the task of separating their own interests from the patient's concerns of the surrogates' interests.

Earlier, I noted that patients' identified preferences may be of limited authenticity when they have been elicited when broader interpersonal interests have been excluded. Concerns of authenticity must be raised when patients' preferences form a basis for apparent sacrifice by the patient for the benefit of the family. The authenticity of capacitated patients' stated interests in the well-being of the family may be obscured or diminished by controlling influences such as the patient's illness itself, dysfunctional family dynamics, or depression—which is highly prevalent and underdiagnosed in the setting of major disease. What protections should patients have?

The integration of patients' authentic family-related interests into decision making is made far more complex by the onset of decision-making incapacity. Family members become the best source of this information, but, in dysfunctional families, they are likely participants in the controlling relationship, or have wielded other undue influences over the patient. Reliance on family members to identify these interests may be further confounded by the considerable prevalence of psychiatric illness among caregivers of chronically and critically ill patients. These surrogates may unknowingly bias their decisions with concerns of their own well-being. Perhaps the added stress of serving as health surrogate could be attenuated through discussions in which the conflicting and harmonizing interests of surrogates are clarified.

Arguably, integrating patients' family-related concerns into substituted judgments introduces yet another order of ambiguity into these decisions, making many surrogate decisions more unsettling to clinicians. Can clinicians and surrogates construct useful information about incapacitated patients' family-related interests? Is this article pragmatically disconnected? The alternative of ignoring this interest of patients poorly serves them and their family members. Moreover, greater attention to patients' interests in family well-being can have valuable consequences. The first is the broadening of medicalized views of the personhood of patients. Second, since surrogates' interests inevitably affect surrogates' deliberations, to explicitly consider family well-being from the *patient's perspective,* however challenging, is likely to improve the

status quo. Third, additional considerations are added for surrogate decisions to enter incapacitated patients into clinical research. Fourth, a research agenda in this area of patient care is stimulated.

RESEARCH AGENDA

There is much to be studied. First, we need clearer empiric evidence that a core consideration of patients is their interests in family well-being, and that patients want this consideration integrated by their surrogate decision makers.

Second, greater study is needed of interfacing interests within families as they pertain to health. In particular, this work must account for various ethno-culturally based requirements for self-effacement and self-advocacy within families. We need to better understand the authenticity of health choices in and across these systems. How are competing health-related interests negotiated within families, and how they are weighted and acted upon?

Third, conceptual and policy work is needed regarding what limits, if any, should apply to the type of interests considered, the magnitude of the patient's sacrifice or trade-off, and the degree to which these should direct treatment. There are also implications for social policy. For example, what are societal responsibilities to uninsured or underinsured families whose ill members choose a shorter and less expensive trajectory of serious illness to spare the family?

Fourth, we need validated measures to identify these concerns of patients, and methods to document their preferences and to guide surrogates. Although I have significant ambivalence about advance directives, perhaps modified directives could at least help stimulate an assessment of these issues. Domains for assessment could include whether family burden is relevant, the valence of sacrifice (that is, refusal of an otherwise desired treatment or acceptance of an otherwise undesired treatment), the type of sacrifice (such as physical or emotional), and the magnitude of the sacrifice (minor or major).

Fifth, does a reinterpreted substituted-judgment standard result in greater or less patients' satisfaction, families' ability to cope, and clinical confidence?

Other issues to examine are the degree to which patients consider family burden and the manner in which they integrate these concerns into decisions. Which patients are more or less likely to do so and why? How do patients respond to surrogates who plan to exert their own interests? How do clinicians currently address and respond to patients' family-related concerns? These are just some of the many questions to be asked.

CONCLUSION

The substituted-judgment standard is problematic in that surrogates often fail to achieve it, and patients often dismiss it. A shift in emphasis from the narrow accuracy of substituted judgments to the quality of these judgments may bridge this normative-descriptive chasm. This latter approach focuses on decisions that patients are most likely to find acceptable, based on an array of essential patients' concerns, including the well-being of people for whom they care deeply. Standards for decision making should better account for the diversity of patients' personal needs and requirements, the varied processes they use for health deliberations, and the multidimensional content of their decisions.

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Autonomy and the Role of the Family in Making Decisions at the End of Life

Jonathan M. Breslin

INTRODUCTION

How should healthcare professionals (HCPs) handle situations in which patients apparently let family or other intimates influence their decision making at the end of life? For many, the answer to such a question would be to eliminate, as much as possible, their influence on patients' decisions and to encourage them to make a decision for themselves. This is likely to be the approach taken by many HCPs when they are faced with such a situation. The reason that HCPs would likely take this approach is because the dominant decision-making paradigm in Western medicine has been the two-party physician-patient dyad, based on what I refer to as the traditional individualistic concept of autonomy. Under this traditional concept of autonomy, patients are viewed as, to quote George Agich, "robust and independent,"[1] and are expected to make decisions that are free from any outside influence. Although this interpretation of autonomy has received criticism from numerous authors and is no longer dominant among bioethicists, it seems to remain a dominant concept among many HCPs in the clinical setting. I believe this is due largely to two factors: (1) older-generation healthcare professionals who were trained prior to the criticisms of patients' autonomy within the last 20 years may not have been exposed to such criticisms and the alternative views of autonomy that have been presented in the literature; and (2) the concept of autonomy that tends to get passed down to younger-generation healthcare professionals, through bioethics education in their disciplines, is the relatively simple and straightforward traditional individualistic concept.[2]

My goal in this article is to encourage the adoption of a more meaningful understanding of autonomy in the clinical setting by arguing that the traditional individualistic concept of autonomy should be replaced with a relational interpretation of the concept. I begin by offering a case example to demonstrate how the individualistic concept of autonomy can create problems in the clinical setting. I proceed to argue that there are two main problems with the individualistic concept of au-

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tonomy. First, and most importantly, many patients simply do not fit the individualistic model of decision making that underlies the traditional concept of autonomy, which means a significant proportion of the patient population is not accounted for within the dominant decision-making framework. Second, relying on the traditional concept of autonomy may result in the unfortunate consequence of patients being alienated from their families in times of illness, and may even promote conflict between patients and families. I then introduce a relational interpretation of autonomy as an alternative, since such an interpretation would maintain what is important about the concept of autonomy (that is, control over one's life) while it incorporates the insight that influence from others does not necessarily impede autonomy, and can actually enhance it. I maintain that shifting from the traditional individualistic interpretation of autonomy to a relational interpretation will provide a more rich and meaningful understanding of how autonomy works in the clinical setting, and will help HCPs better understand how to handle situations in which patients are not acting as robust, independent decision makers.

THE CASE

Consider the following case as an example of the type of situation reflected in the question above. The patient was a woman in her sixties, suffering from end-stage lung cancer. She had been admitted to the ICU, as she had many times recently, due to exacerbation of her symptoms. Since her respiratory status was steadily declining, the healthcare team felt it was necessary to discuss with her what her wishes would be regarding intubation in case her status continued to deteriorate. When the resident broached the topic with the patient on several occasions, she was very evasive, refusing to even discuss the issue—until she finally gave a very revealing response: "Don't you see?" she said to the resident, "You're going to tear my family apart by forcing me to make this decision." As it turned out, the reason she was reluctant to engage in a discussion and make a decision was because she was afraid her adult children would react negatively if she decided against intubation. She thought that they would want her to keep fighting her illness and decide in favor of intubation, while she seemed tired of fighting, but was afraid that she would cause significant disharmony within her family by deciding against the intervention. Since the resident's interpretation of the situation was that the patient's family was influencing her decision, his instinct was to try to eliminate the influence on her decision by encouraging her to make her own decision independent of her family's wishes. The strategy did not work, however, and the patient still refused to make a decision regarding intubation, leaving the resident at a loss on how to proceed.

THE INDIVIDUALISTIC CONCEPT OF AUTONOMY

The concept of autonomy has a long history, tracing back to ancient Greek political philosophy. Directly translated from the Greek, autonomy literally means "self-rule" (*autos-nomos*), and was used in reference to politically independent city-states. Since its political beginnings the concept of autonomy has been extended to the realm of moral philosophy, being used in reference to individuals who are able to control (rule) their own lives. Thus, as Beauchamp and Childress note, personal autonomy has traditionally been understood to mean, at a minimum, "self-rule that is free from both controlling interference by others and from limitations . . . that prevent meaningful choice."[3]

In recent decades, this notion of autonomy has come to play a significant role in Western healthcare, in part as a response to the traditional paternalistic nature of medicine. To ensure that patients' values and interests are protected in the healthcare setting, many argued that HCPs should respect the moral right of patients to make autonomous decisions,

that is, decisions that are essentially free from controlling influence by others.[4] This individualistic concept of autonomy is nicely characterized in the following passage by Joseph Kupfer: "The autonomous person is one who chooses for himself what to think and what to do. . . . Moreover, his beliefs are arrived at independently, by means of critical reasoning."[5]

Notice how the language in Kupfer's description of the autonomous person is clearly individualistic: the autonomous person chooses *for himself or herself* what to think and do; his or her beliefs are arrived at *independently.* As noted by Agich, this individualistic understanding of autonomy has prevailed in healthcare because it gains support from the Western liberal values of independence of thought and action;[6] influence by others on one's decision making is considered an impediment to and a violation of one's autonomy. Thus, in the context of healthcare, families and other intimates who exert influence on the patient's decision (directly or indirectly) are considered to be interfering with the patient's right to make an autonomous decision. This is exactly why the instinct of the resident in the case above was to isolate the patient from her family and to encourage her to make her own decision.

PROBLEMS WITH THE INDIVIDUALISTIC CONCEPT OF AUTONOMY

A significant problem with the traditional interpretation of autonomy is that many patients simply will not fit into the individualistic decision-making paradigm. In a 1999 study that examined the question of whether patients would want their advance directives or their surrogates' decisions followed if the patients became incapable, Terry and colleagues found that concern for others played a significant role in patients' decisions. Of the 135 patients interviewed who responded that they would want their advance directives followed, 18 percent stated that their main reason for their decision was to protect the surrogate from the burdensome process of having to make the decision.[7] Of the 158 patients who stated that they would prefer their surrogates' decisions be followed, 21 percent said their main reason was concern for their surrogates' best interests.[8] Both statistics represent situations in which patients make important medical decisions with the interests of others at the forefront of their thoughts. As the authors note, the findings suggest that concern for others plays a significant role in the decision making of many patients and, therefore, that we need "a socially embedded notion of autonomy—one that sees humans as social beings and situates the patient in his or her family."[9]

It is not surprising that studies like that by Terry and colleagues report that concern for others plays a significant role in the healthcare decisions of many patients. After all, we are social animals; as it is in life generally, most patients will have intimate others of some sort who will be affected by their end-of-life decisions, and many of those patients will be genuinely concerned with how their decisions affect their intimate others. But even if patients do not make end-of-life decisions *for the benefit* of their intimate others, their inherent social nature will mean that their relationships will still influence their decision making in other ways. For instance, patients who are married or in some other committed relationship will likely prefer to make end-of-life decisions in consultation with their partners, as they probably would with other significant life decisions. A person who would not accept a job or purchase a house without consulting his wife would likely also not make a decision to refuse resuscitation without consulting his wife. And to expect that he should make such a decision for himself, based on his own values, and not be influenced by the interests of his family, represents an impoverished view of human decision making. As Reust and Mattingly note in their study of family involvement in medical decision making, patient participants described the decision-making process as "richly populated, in con-

trast to the two people of the standard physician-patient dialogue."[10]

Moreover, intimate others can influence patients' decisions in less direct ways. In addition to speaking of the affect of decisions on their intimate others, patients in the Reust and Mattingly study spoke of how treatment might affect their roles in the family. For instance, the decision to undergo chemotherapy for a mother of young children is not just a medical issue of how the treatment will affect her capacity for physical activity, but is also an issue of how the treatment may affect her role as a mother, that is, her ability to be active with and for her children.[11] Thus, the fact that she is a mother means her decision will be influenced by others in ways that would not affect the decision of a childless woman faced with the same decision. As Reust and Mattingly conclude, "The defect of standard medical ethics is its failure to acknowledge patients as social beings, as individuals whose lives are intertwined with the lives of intimates. It construes patients as dependent on physicians for health-related expertise but otherwise wholly independent to decide."[12]

Not only are many patients in general not individualistic in their decision making, but there are also groups of patients in which particular patients may be less likely to fit into the standard model. One such group is patients who come from cultural or religious backgrounds that value a different concept of autonomy and decision making. For instance, numerous authors have written about the stark differences between medical ethics in East Asia and in the Western world.[13] In contrast to the individualistic view of autonomy and decision making that has dominated Western medical ethics, both Fetters and Fan note that the dominant model of decision making in Japan could be referred to as a "family autonomy"[14] or "family sovereignty"[15] model. Based on cultural values of harmony, consensus, and deference to authority, Japanese culture prioritizes the family unit, rather than the individual, as the most fundamental unit of society.[16] In the context of healthcare, this means it is the family unit that has ultimate decision-making authority, not the individual patient. A recent study comparing the views of Japanese living in Japan, Japanese-speaking Japanese-Americans, and English-speaking Japanese-Americans, reports that while the most acculturated group (the English-speaking Japanese-Americans) had a greater desire for personal autonomy in decision making, all three groups preferred a group decision-making model.[17]

Another example of this kind of cultural difference in views on autonomy and decision making is the Jewish community, which prioritizes family and community-oriented values. These values are particularly important among Jews partly because of the influence of Jewish religious beliefs and partly because of the history of anti-Semitism and forced communal isolation that has plagued the Jewish people.[18] In a 2001 study of the values that underlie end-of-life decisions by elderly Jewish Israelis and their family members, Leichtentritt and Rettig found that family considerations played a significant role in the thoughts of the participants. Participants referred to such interpersonal values as loyalty, interdependence, devotion, altruism, compassion, duty, and responsibility; loyalty was the value most commonly mentioned.[19] Of course this does not mean that all East Asians or all Jews subscribe to a family- or community-based notion of medical decision making—there can be at least as much variation between patients within the same cultural group as between patients in different cultural groups. But in multicultural societies such as Canada and the United States, it is important to recognize that patients who are admitted to the hospital in the Western world may not share values and views on decision making with the Western HCPs who treat them.

Another group of patients that may not fit the individualistic model of decision making is the elderly, a group that is becoming progressively more visible in hospitals and healthcare institutions as our population ages.

As the older patient becomes increasingly impaired, he or she also becomes increasingly dependent physically, psychologically, and emotionally. This increased general dependence can translate into increased dependence in the realm of medical decision making. According to Kapp, "Many individuals of advanced years possess less desire for information about, and control over, healthcare decision making than do their younger counterparts. Many older persons welcome the opportunity to share what they perceive as the burden, not just the right, of decision making. Contrary to the pure autonomy model, some persons may not want to be empowered exclusively."[20]

When elderly patients are uncomfortable with making important healthcare decisions without their adult children, isolating them from their families and encouraging them to make an independent decision can be both counterproductive and harmful. When patients are afraid or intimidated, or feel isolated from their loved ones, encouraging them to make their own decision independent of their loved ones may only serve to intensify those feelings.

One final point worth mentioning about the reliance on the traditional concept of autonomy in healthcare is that encouraging patients to make decisions for themselves, free from family influence, can actually promote conflict between patients and their families. Consider the case at the beginning of this article as an example: the patient was reluctant to make a decision about intubation because she thought her children would be upset with her if she refused the intervention. Urging her to focus on her own interests and to make a decision for herself may cause her children to feel angry and resentful that she did not listen to their concerns, which may in turn make them more inclined to try to override her wishes, which in turn would make her angry and resentful of her children. Kapp suggests that one reason that older patients may want to share decision-making authority with their family members is to alleviate the tension and guilt that may arise among family members who feel they might have to try to override the patient's wishes on a particular issue.[21] Family harmony is an important value for many patients, and for some it is important enough to override other important values (such as the importance of retaining decision-making authority). In appropriate situations, therefore, family harmony should be considered an important value in the healthcare setting. It is important to remember that the isolation, pain, discomfort, and disorientation that often accompanies illness can make patients particularly anxious and vulnerable. What many patients need when it comes time to make important end-of-life decisions is emotional support and comfort from their intimate others, not further isolation from them.

THE RELATIONAL ALTERNATIVE

The traditional individualistic concept of autonomy makes sense in a context of independent patients who make individualistic decisions. What has become clear from the discussion thus far, however, is that, contrary to the individualistic model, many patients make end-of-life decisions in consultation with, for the benefit of, and out of concern for intimate others. Thus, it seems inappropriate to have an individualistic concept of patients' autonomy serve as a central underlying concept in medical ethics. What is needed is a concept of autonomy that takes patients as they *actually are* (that is, social beings) as its starting point.

This view of people as social beings is exactly the starting point of a relational interpretation of autonomy—the view that humans are beings-in-relationships and not asocial individuals. In philosophical circles this starting point is also known as the relational ontology. As Nedelsky states, it is an important feminist precept "that any good theorizing will start with people in their social contexts. And the notion of social context must take seriously its constitutive quality; social context cannot simply mean that individuals will, of

course, encounter one another. It means, rather, that there are no human beings in the absence of relations with others."[22] The claim of a relational interpretation of autonomy is that humans are social beings, and they can still be autonomous even when they don't make independent and individualistic decisions. So the important question is: *Can persons still be autonomous when others influence their decisions?*

If we take a step back and look generally at what it is that we find valuable about autonomy, we will have to answer "yes" to this question. Autonomy has become an important value in Western society because we prefer having control over the courses of our lives, rather than having our lives controlled by others. This idea has become particularly important in the context of healthcare, because of the vulnerability that accompanies illness and the inherent power imbalance that exists between physicians and patients. Promoting a concept of patients' autonomy helps put some power into the hands of patients by helping to protect them from the controlling influence of physicians.

However, control over the course of one's life is not precluded by allowing others to influence one's decisions; not all influences are *controlling* influences. As Barclay states, "autonomous agency does not imply that one mysteriously escapes altogether from social influence but rather that one is able to fashion a certain response to it."[23] Because autonomy involves fashioning a certain response to social influence, it requires that we recognize the procedural component of autonomy—the capacity to reflect upon one's desires, values, relationships, and so on. Childress refers to this capacity as "second-order autonomy": being able to critically reflect upon the life plan that one has chosen for oneself.[24] Diana Meyers refers to the skills that enable people to reflect on their values and preferences as "autonomy competency."[25] However one describes this capacity, the crucial point is that one can be influenced by others without forgoing one's autonomy, as long as one is free to accept or reject those influences. Suppose, for instance, that the patient in the case example decided to accept intubation to maintain family harmony. The fact that she made her decision out of concern for her family does not *itself* render her decision nonautonomous. It would be considered nonautonomous if she were pressured or coerced by her family to accept intubation when she would otherwise have chosen to refuse the treatment. In that case, her family would be imposing their interests and values on her and acting as a controlling influence. But in the hypothetical scenario, the patient made the decision to accept the well-being of her family as a deciding factor because she identifies with their interests. Thus, although she was influenced by her family, this does not necessarily mean that such influence impeded her autonomy.

The case in favor of a relational interpretation of autonomy gains strength when we consider that influential relationships can actually enhance autonomy when they contribute to both the development of our reflective capacity and our decision-making aptitude. Being able to discuss important decisions with intimate others allows us to receive valuable input from others, which can help us to see new possibilities and can help us to learn to reflect more deeply and critically on our lives. In the study mentioned above, Reust and Mattingly noted that patients described being able to work through issues with their intimate others as an important way "to explore pros and cons, consider fresh insights and perspectives, express and come to terms with their fears, and arrive at their own way of balancing competing values."[26] Because our intimate others know us well and are likely to have at least a basic idea of what our values and priorities are, they are in a good position to actively help us reflect upon those values and priorities. Moreover, as Jecker notes, intimate others can help patients exercise their autonomous decisions by offering emotional support, bridging communication gaps between patients and healthcare teams, and en-

couraging patients to express themselves.[27] Reust and Mattingly report that families advocated for patients primarily to enhance their autonomy, as in the case, for example, of an adult child who steps in to stop procedures for an aged mother who wouldn't speak up herself.[28] So not only is it the case that intimate others do not necessarily impede autonomy, as the traditional concept of autonomy assumes, but there are many ways in which intimate relations can actually help enhance the autonomy of patients.

The significance of a relational concept of patients' autonomy goes beyond just recognizing that influence from intimate others does not necessarily impede, but can also enhance, patients' autonomy. Because the starting point for relational autonomy is the relational ontology, adopting a relational view of patients' autonomy will encourage HCPs to acknowledge the general significance of relationships on the lives of their patients. For most patients, the significance of their relationships will be positive; for others it may be negative. Whatever the impact on the lives of patients, relational autonomy reminds HCPs that patients are social beings and, thus, patients must be taken in their social contexts in order to be properly understood.[29]

CONCLUSION

Incorporating a relational view of autonomy into practice would not require doing anything above and beyond what HCPs already do when faced with difficult ethical situations. The difference, however, lies in the kinds of questions asked, the type of information gathered, and how that information is incorporated into the action plan. For example, as I have described in this article, culture can be an important element in end-of-life decision scenarios. Since it is unrealistic to expect that HCPs will be aware of the beliefs of the many cultural groups with which they will come into contact in the healthcare setting, it is important to explore whether a cultural element is at play in particular cases. This would also involve exploring, as Levine and Zuckerman suggest, what patients' expectations are, regarding the roles of their families in the decision-making process, and exploring the expectations of the families on the same subject.[30] Such exploration will help to ensure that no *assumptions* are made about the role of the family in decision making, so that both individualistic and relational decision makers will be accommodated. Other important questions that healthcare professionals should try to answer might include: Who are the patient's family members? Are there any other people, such as close friends or other relatives, whom the patient would consider among his or her intimate others? Are there any strange family dynamics at play? Have the patient's decisions in the past tended to be self- or other-motivated? Does the patient identify with his or her past other-motivated decisions, or have family members acted as controlling influences on those decisions? Does it seem as though anybody involved is exerting a controlling influence on the patient in this situation? How are decisions typically made in this patient's family?

Exploring these kinds of questions would have helped the resident in the above case to deal with his patient's reluctance to make a decision about intubation. Early in the patient's hospitalization, the resident should have explored the expectations of the patient and her family regarding the involvement of the family in making decisions. Since they seemed to be a relatively close family, the patient likely would have stated that she would want her family involved, and her family, if asked, likely would have said that they wanted to be involved as well. Rather than pushing the patient to make a decision based on an outmoded individualistic understanding of autonomy, the resident should have explored the patient's reluctance with him. Once the patient expressed concern about how the decision might impact the harmony of her family, the resident should have immediately ex-

plored that concern with the patient. Why is she concerned about family harmony? How confident is she that her children would react in the way she fears they might? Have they discussed decisions like this previously? Have the children reacted unfavorably in similar situations in the past? Perhaps the resident should then approach the patient's children with their mother's concerns—it may be the case that she is simply mistaken about how they would react; or, if she is correct, it may be advantageous to discuss the issue with them privately to give them time to reflect on the situation. Getting the feelings of those involved out in the open and dealing with them would likely be a better approach than pressuring the patient to make a decision, independent of her family, and risking upsetting her children. Initially discussing the issue with the children privately, before bringing them into the room with their mother for a discussion, would also help the resident gauge whether the children are likely to be a controlling influence 1on their mother. This would help avoid the unfortunate scenario of the children pressuring their mother into accepting intubation when she would rather reject the intervention.

The contribution of a relational view of autonomy to situations like the case discussed in this article is the recognition of three basic claims: (1) the traditional concept of autonomy applies only to patients who are individualistic decision makers, and many patients do not fit the individualistic paradigm; (2) intimate others can play a significant role in the development, exercise, and expression of autonomous decision making for many patients; and (3) as long as intimate others do not exert a controlling influence, patients can make decisions relationally and still be autonomous. I believe that adopting a relational interpretation of autonomy, and taking steps like the ones described in this article to incorporate relational autonomy into practice, will go a long way toward helping healthcare professionals understand the role of the family in decisions at the end of life.

NOTES

1. G.J. Agich, *Autonomy and Long-Term Care* (New York: Oxford University Press, 1993), 3.

2. Admittedly, my only evidence for this claim is anecdotal, based on my personal experience in clinical ethics. It would be interesting and informative to conduct a survey of healthcare professionals to see if this claim is supported by empirical evidence.

3. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics,* 5th ed. (New York: Oxford University Press, 2001), 58. It is the first part of this statement—freedom from controlling influence by others—that is significant for the purposes of this article.

4. It is important to point out that the concept of autonomy is commonly used in two different but interrelated general contexts: (1) to refer to a human capacity, i.e., the *ability* to govern one's life; (2) to refer to particular decisions or a person's decision-making process. It is generally argued that the autonomy in the first context is actually a prerequisite for the second, i.e., that in order for one to make an autonomous decision, one must have the capacity to do so. This capacity to be autonomous is referred to by some as the "procedural component" of autonomy.

5. J.H. Kupfer, *Autonomy and Social Interaction* (Albany, N.Y.: State University of New York Press, 1990), 9-10.

6. See note 1 above, p. 3.

7. P.B. Terry et al., "End-of-Life Decision Making: When Patients and Surrogates Disagree," *The Journal of Clinical Ethics* 10, no. 4 (Winter 1999): 288.

8. Ibid., 289.

9. Ibid., 291.

10. C.E. Reust and S. Mattingly, "Family Involvement in Medical Decision Making," *Family Medicine* 28, no. 1 (1996): 44.

11. Ibid., 41.

12. Ibid., 44.

13. M.D. Fetters, "The Family in Medical Decision Making: Japanese Perspectives," *The Journal of Clinical Ethics* 9, no. 2 (Summer 1998): 132-146; R. Fan, "Self-Determination vs. Family-Determination: Two Incommensurable

Principles of Autonomy," *Bioethics* 11, nos. 3-4 (1997): 309-22; K. Hoshino, "Bioethics in the Light of Japanese Sentiments," in *Japanese and Western Bioethics,* ed. K. Hoshino (Dordrecht, the Netherlands: Kluwer Academic Publishers, 1997); A. Akabayashi, M.D. Fetters, and T.S. Elwyn, "Family Consent, Communication, and Advance Directives for Cancer Disclosure: A Japanese Case and Discussion," *Journal of Medical Ethics* 25 (1999): 296-301.

14. Fetters, see note 13 above, p. 132.

15. Fan, see note 13 above, p. 319.

16. Fetters, see note 13 above, p. 135.

17. S. Matsamura et al., "Acculturation of Attitudes Toward End-of-Life Care: A Cross-cultural Survey of Japanese Americans and Japanese," *Journal of General Internal Medicine* 17 (2002): 537.

18. R.D. Leichtentritt and K.D. Rettig, "Values Underlying End-of-Life Decisions: A Qualitative Approach," *Health and Social Work* 26, no. 3 (2001): 151.

19. Ibid., 155.

20. M.B. Kapp, "Who's the Patient Here? The Family's Impact on the Autonomy of Older Persons," *Emory Law Journal* 41 (1992): 782-3.

21. Ibid., 783.

22. J. Nedelsky, "Reconceiving Autonomy: Sources, Thoughts and Possibilities," *Yale Journal of Law and Feminism* 1, no. 7 (1989): 9.

23. L. Barclay, "Autonomy and the Social Self," in *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self,* ed. C. Mackenzie and N. Stoljar (New York: Oxford University Press, 2000), 54.

24. J.F. Childress, *Who Should Decide? Paternalism in Health Care* (New York: Oxford University Press, 1982), 60.

25. D.T. Meyers, *Self, Society, and Personal Choice* (New York: Columbia University Press, 1989).

26. See note 10 above, p. 42.

27. N. Jecker, "The Role of Intimate Others in Medical Decision Making," *Gerontologist* 30, no. 1 (1990): 66.

28. See note 10 above, p. 42.

29. The reader might wonder at this point how the account of relational autonomy I offer here differs from the concept of "family autonomy" defended by John Hardwig, or the communitarian view defended by authors like Jeffrey Blustein or James Nelson. There is one major and important difference between these other views and the view of relational autonomy that I defend. What these views and relational autonomy have in common is the recognition of the importance and significance of relationships. The difference is that both Hardwig and communitarian authors are concerned with establishing the interests of intimate others as *limits* on the autonomy of individuals. In other words, on these views the autonomous decision making of individuals ought to be limited by concern for the interests of family and the larger community. The relational view I defend here, on the other hand, does not maintain that the autonomous decisions of individuals should be limited by concern for others, only that individuals can still be autonomous even when they exist within relationships and allow those relationships to influence their decisions.

30. C. Levine and C. Zuckerman, "The Trouble with Families: Toward an Ethic of Accommodation," *Annals of Internal Medicine,* 130 (1999): 151.

Application of Systems Principles to Resolving Ethical Dilemmas in Medicine

George F. Blackall, Michael J. Green, and Steve Simms

INTRODUCTION

Ms W, a 23-year-old woman, was hospitalized in the intensive care unit (ICU) of a large urban teaching hospital with a diagnosis of metastatic sarcoma that was considered terminal. Two years earlier, Ms W had had a sarcoma surgically removed from her left thigh. She was feeling well until four weeks before this hospitalization, when she developed night sweats and difficulty breathing. At the time her symptoms appeared, Ms W was engaged to be married and was preparing to graduate from college. She had no history of mental illness, and had a high-functioning and intact family.

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Ms W was a highly intelligent individual who was an accomplished collegiate athlete and leader on her college campus. Her family described her as open and approachable, and part of a tightly knit family who was always able to "talk things out." When the sarcoma recurred, a great change took place in Ms W. To her family's surprise, she became uncharacteristically withdrawn and sullen. She ceased open communication with family members, and soon withdrew into silence. While her family initially tried to engage Ms W in conversation about her disease, this failed to alter her mood, and the family soon joined her in silence.

When Ms W was admitted to the hospital, she was told that there was no cure for her disease, and she was offered palliative care to treat her symptoms and to help keep her comfortable. In the ICU, the staff quickly became invested in her care. Although death is a common occurrence in any ICU, there was something about Ms W that drew people to her in a way that surprised even the experienced ICU staff. She was a promising young woman who

was liked and admired by those who knew her (the dean of her college appeared in the ICU in full academic regalia to award Ms W her diploma), but her life would be prematurely ended.

During the initial stage of her hospitalization, Ms W remained withdrawn and uncommunicative, refusing to take the medications that her nurses and physicians believed to be important. With time however, she began to express herself, making statements that the ICU staff found disturbing, such as: "How many of these pills do I need to take to kill myself? Can you give me enough medicine to end this? What's the quickest way to die?" While the ICU staff was deeply moved by Ms W's plight, they felt it was wrong to participate in assisted suicide, and they struggled to find an appropriate way to respond. As the requests for assisted death continued, the ICU staff became increasingly frustrated; they felt powerless to change her condition and were frightened by her statements. Eventually, in an effort to "get her to stop saying those things," the ICU staff requested a consultation from a hospital-based psychologist who was also a member of the hospital's ethics committee.

When the consultant visited Ms W, she was sitting up in bed with her eyes closed. She was ashen-looking and had a nasal cannula delivering oxygen. She appeared to be air hungry and her speech was barely audible. Her mother and brother stood in a corner of the room with their arms folded. Ms W motioned for the consultant to come closer and whispered, "Will you please shoot me tonight?"

ANALYSIS

Ms W's case raises a number of important issues relevant to the care of terminally ill patients. Foremost is how to deal with requests for assisted death. Sometimes the primary issue is a moral one—for example, should physicians or other healthcare providers aid patients who request help with dying? In such cases, the methodologies of bioethics are well-suited for addressing the issue, with an emphasis on fact gathering, determination of competency, delineation of the ethical issues and competing ethical claims, and then moving toward resolution.[1] Other well-suited models that are useful for addressing ethical conflicts include mediation,[2] mediation combined with a medical advisory panel,[3] and facilitation.[4] But in some cases, the moral issues are secondary, such as when requests for assisted suicide are not really genuine expressions of a wish to die, but instead are about something altogether different, such as a conflict in relationships or a breakdown in effective communication. In these cases, the compelling nature of the life-and-death situations can so impair communication that people are distracted by the "ethics," to the exclusion of the relationships. Then, the traditional or well-suited approaches to resolving ethical dilemmas in medicine are less helpful, because their narrow focus on normative issues provides little guidance for addressing the impasse in relationships.[5] Since ethical conflicts in medicine are often laced with such interpersonal dimensions, clinical ethicists can benefit from broader approaches that explicitly address the role of the interpersonal aspects of ethical dilemmas.

So, when faced with a patient's request for assisted death, how can one know whether this is a genuine moral issue, or if the patient's plea is driven by other psychological forces?[6] These are not mutually exclusive.[7] The moral issues raised by assisted death have been dealt with extensively elsewhere.[8] To further the discussion of the influence of psychological issues on ethical dilemmas, this article proposes a systems-based model that focuses on building collaborative relationships as a means of resolving ethical dilemmas.

What was conspicuous in Ms W's case was her inability to express her needs effectively and maturely. Concurrently, the ICU staff was distracted by the intense emotions generated by Ms W's provocative statements. They heard only what she said, not what she needed. By

applying "systems principles" that help to identify a person's underlying needs in the context of intra- and interpersonal relationships, this article proposes a strategy for broadening the scope of ethics interventions.

A SYSTEMS FRAMEWORK

A systems framework can be helpful for understanding the complex relationships involved in many cases for which ethics consultations are sought. For the purposes of this article, systems principles posit that families are social units in which relationships are interlocking and interdependent, in which an ongoing tension exists between the individual's longing for communion and struggle for agency.[9] Individuals in families face an ongoing tension trying to balance feeling close and connected to family members (communion) and needing to establish an identity separate from one's family of origin (agency). Consequently, when one person changes, all family members are affected.

When serious illness strikes a family and life-and-death decisions need to be made, the family's ability to adapt to adversity is typically challenged. During times of crisis, instability in family systems may impair the ability to respond to and resolve conflict. In this case, Ms W's family was impaired in the sense that they went from being communicative and connected to being fragmented and disconnected. When people cannot resolve conflict, the anxiety created by the unstable relationship may drive one or both parties to seek support from a third party, a situation that family therapists call triangulation.[10] Although this triangle temporarily reduces tension, it obscures the conflict, and, as the conflict grows, people feel misunderstood and cut off from one another. The parties then become more entrenched in their positions and start believing that the solution lies in the other party (that is, "If she would just stop saying these things, it would be OK") rather than in the relationship itself ("How can we find a solution we both find acceptable?").

An impasse in a relationship (defined simply as a relationship being developmentally "stuck") can develop between clinical staff, patients, and families in the face of medical adversity.[11] During such an impasse, despite attempts to move the process forward, the outcome remains unchanged. In Ms W's case, the staff expended extraordinary efforts to get Ms W to stop requesting assisted death; they talked at length with the patient, they discussed the matter among themselves, and they expended a great deal of emotional energy in trying to figure out how to "fix" the problem. Yet, despite such efforts, the outcome was unchanged, and Ms W continued to ask for assisted death.

As this impasse became more entrenched, the physicians and nurses became increasingly frustrated with their attempts to help the patient and family. The medical staff framed the issue in terms of a request for physician-assisted suicide, a request that made them feel uncomfortable. What the staff failed to see, however, was the underlying distress that was driving the requests. Of course there are cases in which a request for death is simply that: a genuine expression of a desire to die. But in Ms W's case, it wasn't so clear, and framing the issue in terms of physician-assisted suicide, while helping to clarify ethical issues, did not break the impasse.

A broader approach is the model of the symptomatic cycle.[12] This model helps to clarify interpersonal conflicts by providing a map for understanding how instabilities in human systems can escalate out of control (see figure 1). This model shifts the emphasis from *symptoms* to *relationships.* Micucci argues, "Symptoms in families evolve in a context of interpersonal isolation, characterized by conditional acceptance and efforts to control one another."[13] The attempts to control others escalate the presenting symptom, which can narrow everyone's focus to the presenting problem, and important relationships deteriorate. Consequently, people feel an increasing sense of isolation, which in turn fuels further distress. The focus then moves onto *fragments*

of behavior ("Get her to stop saying those things!") rather than more meaningful *patterns* of behavior ("She is becoming alone and isolated").

Framing the case of Ms W in terms of the symptomatic cycle, the "symptoms" were her suicidal statements and requests for staff assistance in her death. The more that the ICU staff and Ms W's family tried to get her to stop making disturbing statements, the more the symptoms increased. This pattern was frustrating for the ICU staff because they believed they were doing all they could to be helpful to the patient and family. When their efforts were met with anger, hostility, or opposition, the staff wondered what was wrong with this patient and family. A common response to the frustration generated by these situations is to seek a psychiatric consult. While rendering a psychiatric diagnosis such as depression, psychosis, or even a personality disorder is potentially helpful to patients, doing so may lead staff to wrongly conclude that the problem and solution lie solely within the patient. In contrast, systems ideas frame a conflicted situation in relational terms, and provide an opportunity to bring people together in a way that facilitates a meaningful and productive outcome. In this case, viewing Ms W's requests for death as purely an ethical dilemma blinded the staff to a broader way of approaching the impasse. The net impact of separating the ethical dilemma from the interpersonal aspects of the case was to further entrench the impasse.

BASIC PRINCIPLES REGARDING FAMILIES WHO FACE MEDICAL ADVERSITY

In an effort to address the underlying causes of interpersonal conflicts in cases such as Ms W's, four basic principles apply.

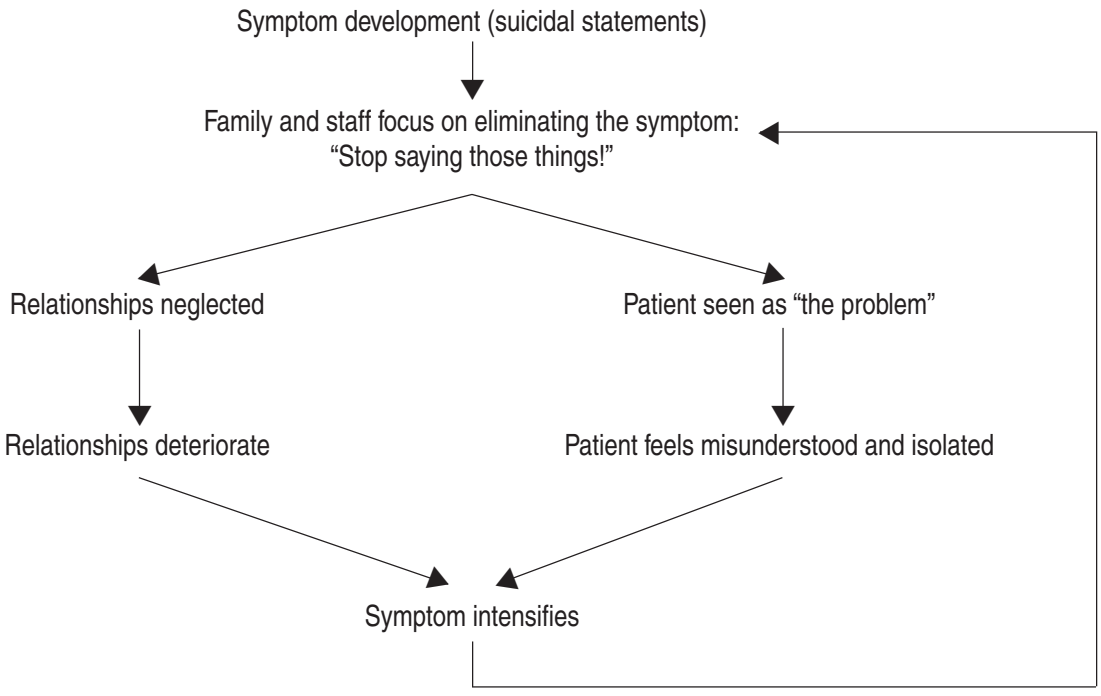

Figure 1. How the symptomatic cycle was used to assess difficulties in Ms W's case. Adapted from figure 2.1 in Joseph A. Micucci, *The Adolescent in Family Therapy: Breaking the Cycle of Conflict and Control* (New York: Guilford Publications, 1998), 19. Used with the kind permission of Guilford Publications.

ALL PARTIES BRING COMPETENCIES

All patients, families, and medical staff bring a pre-existing set of competencies—defined as one's sense of mastery over a given task—to the illness experience. This differs from the traditional notion of competence in ethics, which is a legal determination of a person's decision-making capacity. Competency for a patient and family can include many things, among them being a successful student, parent, or professional. When illness strikes, however, unfamiliarity with the role of patient may undermine existing competencies. In the case presented here, Ms W was a competent college student, daughter, sister, and fiancée. She was successfully navigating the developmental challenges of young adulthood. When her cancer recurred, her sense of competence was undermined and was expressed in an uncharacteristic wish for death.

ISOLATION + DISCONNECTION = PSYCHOLOGICAL DISTRESS

Isolation and disconnection from important relationships breed conflict and lead to psychological distress. As mentioned earlier, people strive toward communion, yet also need agency. In times of illness, individuals' different coping styles can create conflict. Ms W was coping in a manner that clearly lead to isolation from her family and the medical staff. Paradoxically, her provocative statements drew attention to her, but because the statements were so frightening, people began to withdraw, thereby increasing her isolation. As Ms W's important relationships deteriorated, her "symptomatic behavior" escalated in the form of making increasingly graphic and provocative statements about her death. As a result, the impasse was solidified. Feeling powerless, like the staff, the family was paralyzed in their attempts to help because of the horror of hearing Ms W's request for death.

BLIND SPOTS FUEL CONFLICT

The intense emotions generated by the life-and-death drama of serious illness can distract people from existing competencies. While Ms W was successful academically and socially, her current strategy for dealing with distress was ineffective, and resulted in isolation. There is nothing wrong with an ill person wanting to be alone. Indeed, being alone can provide an opportunity for healthy reflection. However, Ms W was *isolated*—that is, she lacked meaningful connection to others around a difficult issue.

INCLUDE STAFF IN PROBLEM SOLVING

These first three principles apply to patients, families, and medical staff. It is common for medical staff to put the onus of change on the patient and family. When medical staff feel incompetent, isolated, and disconnected, psychological distress can develop in them as well. In Ms W's case, the staff felt powerless because, despite their best efforts, Ms W continued to make clear, stark, and disturbing statements about her desire to die. Their feeling of powerlessness led to anger, and they began to feel incompetent, which furthered their isolation, not just in relation to the patient, but also with each other.

INTERPERSONAL DIMENSIONS OF ETHICAL DILEMMAS

How does one broaden her or his awareness of the interpersonal aspects of an ethical dilemma? Here are some of the signs that an interpersonal impasse is contributing to an ethical dilemma.

ANGER

Doctors and nurses feel anger toward the patient and family. The anger is driven by a sense of powerlessness in relation to the patient and family. This is not the same as a difference in moral beliefs. It is possible to work with patients who have different moral beliefs and find common ground in the relationship. People do not feel powerless when they have expressed their position on an issue: for example: "Ms W, I respect your wish to die. However, I'm unwilling to help you die. However, I believe that I can help to relieve your pain or other troubling symptoms."

URGENCY

There is a global sense of urgency around the case. This is different than a medical emergency; the urgency is around a need to "fix the problem," often identified as the disturbing symptom. The desire for the problem to "go away" is driven by the anxiety and sense of powerlessness produced by the symptom.

SENSE OF FAILURE

There is an impending sense of failure that fuels the urgency to fix the problem. This feeds the symptomatic cycle in that the harder people try to fix the problem, the worse it gets.

BLAME

Those involved with the case start to assign blame. Blame is often the final stop in clinical medicine before the patient receives a psychiatric diagnosis. Blame protects against feelings of failure and shifts the burden of responsibility for change to the patient. Blaming the patient also insulates the staff from examining how they contribute to the impasse. In Ms W's case, the ICU staff viewed her as a person who wanted them to kill her. As a result, they isolated themselves from her, and their interactions with her became defensive.

WHAT TO DO

When confronted with an impasse involving a patient and family, a clinician or consultant can take concrete steps using systems principles to help resolve the conflict.

FOCUS ON COMPETENCE

A good place to start is to highlight the competence of those present: "Ms W, I'm very sorry that your disease has come back and that you see death as your only option. I can see that your family cares deeply about you and you about them. One of the things that troubles me is that it appears that you are facing this challenge in your life alone." Starting the conversation by highlighting competencies enables the physician or consultant to: (1) convey a sense of respect and trust to the patient, (2) directly validate the expressed concerns of the patient, and (3) shift the viewpoint from blame and a sense of powerlessness to one of hope. This contrasts with a less effective approach, such as: "Ms W, physician-assisted death is against the law and we won't participate in it," which suggests that the physician is about to abandon the patient and does not provide the patient with choices. Emphasizing competencies initiates the process of reframing the dilemma from a conflict to a collaborative process in which all parties feel heard and understood.

In the present case, the intervention began by highlighting the competencies of all of the involved parties (patient, family, and staff). This took the form of first talking with the patient about why she was requesting help with her death. She replied, "I can't breathe!" This presented an opportunity to both advocate for the patient and appeal to the competencies of the staff. When this was explained to the staff, they were able to quickly relieve Ms W's respiratory distress. Treatment of respiratory distress is a relatively straightforward intervention in an ICU. Why then did the ICU staff miss something so simple? The answer may lie in the power of Ms W's requests for death. The emotional upheaval generated by her requests was so distressing that it distracted staff from their primary role of providing competent medical care.

CLARIFY ROLES

Clarifying roles is another step in helping patients, families, and staff resolve a dilemma. This is accomplished by asking the referring parties: "How can I be helpful?" While it may sound simplistic, the question gets people thinking about what they need. This is an important component in guiding staff in their efforts to help patients and families. If the patient and family request more than the medical staff can provide, the intervention can be broadened by including other professionals (that is, chaplains, social workers, or other consultants). This approach allows the staff to view a request for help as a successful intervention, not a personal failure. For Ms W's

case, the consultant also met with the ICU staff to discuss their feelings about the case. They expressed frustration and a global sense of powerlessness over "not knowing what to do." While well-intentioned, the staff was at a loss as to how they could effectively respond to Ms W's requests for death. They were adamant that they would not participate in assisted suicide, but felt shame over avoiding her. A part of the conversation was to help the ICU staff clarify their role in Ms W's care. They knew that what they did best was to take care of critically ill patients. They helped patients live, not die. Ms W, even though dying, was not technically critically ill. In short, she was in the wrong place. This realization lifted the staff's burden of guilt and feelings of having failed the patient. Ms W was transferred to an oncology floor of the hospital, where staff was better trained for the types of medical and psychological problems she was experiencing.

FOCUS ON RELATIONSHIPS

Focusing on relationships is more difficult than clarifying roles. The first task is to tolerate the intense emotions surrounding the conflict. When we feel powerless, we tend to act in ways that instill a sense of control. The net impact may be a well-intended but misguided attempt to control others. The resulting pressure may distract the individual from the critical work of concentrating on competencies, which shifts the frame of the relationships from control to collaboration. In the face of the intense emotions that can accompany conflicts, asking oneself these simple questions might prove helpful in defusing conflict: "If this were a collaborative relationship, how would I behave? What would I do?"

As the distance in Ms W's relationships increased, so did her desperation. By emphasizing the loving and supportive relationships in the family, the consultant began a conversation about death that was tolerable for the family and allowed Ms W to serve as a guide. Ms W's two biggest fears were suffocating to death and dying alone. Once her family understood how they could be helpful, they could access their pre-existing competencies (that is, organize around-the-clock schedules to be with Ms W). This was also the beginning of a painful family discussion about where Ms W would like to die (at home versus in the hospital).

KEEP THE CONVERSATION GOING

Pulling away from disagreements about medical adversities can lead to an impasse. Demonstrating to the patient and family that the medical staff will not abandon the relationship is critical for any progress to occur. This is particularly relevant when the patient rejects attempts to move forward and break an impasse. In these situations, the focus needs to remain on validating the patient's concerns, even when there is disagreement. It is also crucial that caregivers demonstrate an ongoing commitment to the relationship with the patient. Offering something like, "Ms W, I won't kill you. But I can still be of some help to you. I'm willing to keep talking about this until we find common ground," sends a clear message that the patient and family will not be abandoned or isolated. This can help to move forward. It is also critical to convey such a message to clinical staff. Inevitably, there will be divisions and differences of opinion among staff, and between them and families, regarding ethical conflicts. However, highlighting the competencies and roles of the staff can be helpful in moving people toward developing a broader view of the presenting dilemma. It creates the possibility of collaboration, rather than control; for example: "If she would just do this . . . then we wouldn't have this problem."

During Ms W's two-week hospitalization, her medical management was stabilized, and she became increasingly articulate about her wishes for the end of her life. Her family, while grief stricken, was able to reframe their contributions. Instead of viewing themselves as powerless to alleviate her suffering, they recognized that they had an important role to play in her death. Family members remained close to Ms W despite the intense feelings that death can generate. Ms W was discharged to her home and received hospice care, and she died

six weeks later, at home, surrounded by her family.

CONCLUSION

The case of Ms W illustrates how interpersonal aspects of an ethical dilemma can be an integral part of resolving the conflict. In Ms W's case, the ethical dilemma of physician-assisted suicide was a mask for the struggle of a patient to get adequate palliative care and find a different way to relate to those she loved as she was dying. By shifting toward building relationships and away from exhibiting controlling behavior, the medical staff was able to concentrate on delivering medical care and being supportive, while family members became actively involved in caring for Ms W at the end of her life. The process proposed here is not about trying to "get patients to change their minds." The systems approach is an attempt to frame the engagement of ethical dilemmas as a concurrent process of building collaborative relationships while exploring the salient moral issues. In this case, the request for assisted death was driven by the patient's fear and isolation. If Ms W actually wanted help in dying, the systems-based approach used here would have revealed that at some point. Although the initial response of the ICU staff was to frame the problem as an ethical dilemma, blind spots around the interpersonal aspects of the conflict led to an impasse. A systems framework that emphasizes the competence of the patient, family, and medical staff, combined with efforts to build collaborative relationships to decrease everyone's isolation, helped move the dilemma to a more satisfactory conclusion.

ACKNOWLEDGMENTS

Identifying information has been altered and portions of the case have been fictionalized to protect the identity of the patient. Special thanks to Philip Wilson, PhD, and Benjamin Levi, MD, PhD for their thoughtful comments on earlier drafts of this manuscript.

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Dawning of Awareness: The Experience of Surrogate Decision Making at the End of Life

Jane Chambers-Evans and Franco A. Carnevale

While out for an evening with friends, Sarah received a call; her mother had collapsed and had been rushed to the hospital. Her mother was in a coma when Sarah arrived at the hospital and remained so until the moment of her death a week later. Full life support was provided in the intensive care unit (ICU) over the next week, while physicians and nurses waited with Sarah to see if there would be any improvement, any sign of life. At the end of the week, the team sat down with her and suggested that all treatment be stopped. Many times in the past her mother had told her, "If there is no hope, let go," so Sarah agreed with the team. Sarah was 22 years old. She had never felt so alone.

The literature on surrogate decision making is expansive. The substituted-decision standard[1] and the best-interest standard[2] outline two specific methods to guide decisions on behalf of individuals who are no longer competent to make decisions for themselves. Lack of congruency in decision making between surrogates and patients and surrogates and healthcare professionals has been explored extensively.[3] There has been an ongoing examination of the role of the family members as surrogates,[4] and the courts have intervened to resolve conflicts that arise when professionals and surrogates cannot agree.[5]

Despite this, the clinical reality of a 22-year-old woman who finds herself alone, afraid, and in a position in which she must make end-of-life decisions for her 47-year-old mother in an ICU often seems quite removed

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from the world presented in academic journals. The current ethical and legal literature suggests that a shared decision-making approach is preferred;[6] however, physicians and nurses struggle to involve surrogates in end-of-life decision making while they attempt to prevent the invariably difficult role from becoming a burden. Surrogates, each from a unique background and experience, expect to have a role in making decisions, but are often overwhelmed by the environment, the information being shared, and the actual responsibilities for which they feel completely unprepared. The ever-present emotional and spiritual angst that accompanies the anticipation of death is often sandwiched between the technological push to save lives and the struggle of surrogates to try to understand what is happening, as well as how it should be interpreted.

There has been little examination of the actual experience of surrogates as they make decisions. Having an understanding of the cognitive and emotional processes of surrogates will assist physicians, nurses, ethicists, and other professionals to tailor professional interventions to assist surrogates in fulfilling their roles.

To this end, we interviewed surrogates who were involved in making end-of-life decisions for a family member in an ICU, to learn about the experience of making decisions to stop treatment. These surrogates also participated in analysis of the data collected in our study, so that the reflections on what had been discussed would be as rich as possible. These results were analyzed and expanded through comparison with the literature and have been oriented to the clinical setting, to provide clinicians with some foundations to use in enhancing shared decision making at the end of life.

REVIEW OF THE LITERATURE

DECISION-MAKING STANDARDS

It is clear in law and in practice that a competent adult has the right to both make and be involved in decisions to consent to or refuse care. Laws in most jurisdictions provide a method for an adult who becomes incompetent to be represented by a surrogate who can reflect the patient's values and beliefs and make decisions on the patient's behalf, or by a court if a surrogate does not exist.

Two ethical decision-making standards have evolved: the substituted-judgment standard and the best-interest standard. Substituted judgment requires that surrogates "reach that decision which the incompetent patient would have chosen had he or she been competent."[7] This presumes that the substitute decision maker is able to preserve the patient's self-determination by thinking and deciding as the patient would have. The literature suggests that evidence should be categorized in terms of its proximity to the actual decisions the competent patient would make (for example, the primary source would be an advance directive). If the surrogate has little or no relevant knowledge, then decisions will need to be guided by the best-interest standard.[8] There is controversy, however, on whether the preservation of patients' autonomy is possible through a third party, and it has been suggested that different principles apply when making decisions for oneself than when doing so for another.[9] The prevailing belief, however, continues to be that the use of a surrogate decision maker seeks to extend the autonomy of the capable patient into a time when the patient is no longer capable.

In the absence of knowledge about a patient's values and beliefs, the best-interest standard endeavors to ascertain the most important interests of the patient. The decision maker attempts to determine "the medical course of action most likely to maximally contribute to the patient's welfare."[10]

CONGRUENCY OF PATIENTS' PREFERENCES WITH THOSE OF SURROGATES AND PROFESSIONALS

Recent research in the field of patients' preferences reports that most patients want end-of-life decisions to be made by family members, and that, in making decisions on their behalf, families consider their quality of

life, cognition, competence, seriousness of illness, and subsequent hope of recovery.[11] While most studies report that patients trust that family members will make appropriate choices on their behalf, recent studies indicate that there is little congruence between patients and their family members on such decisions.[12] Despite these findings, a recent study has reported that if a conflict arises between what has been stated on a prior basis by the patient and what the surrogate believes to be the best decision, patients preferred that their surrogate's decisions take priority over their previously stated wishes.[13]

WHAT ROLE SHOULD THE SURROGATE HAVE IN DECISION MAKING?

Three authors have outlined the debate about how patients' families should be involved as surrogates. Hardwig, in a controversial approach, suggests that the interests of family members and patients should be respected equally in any decision-making process, and argues that individuals cannot be separated from their interconnected lives in the family.[14] Nelson tempers this discussion by suggesting that, while the patient's decisions could not be totally void of any reflection on their impact on families, a more equitable approach might be to work toward a consensus that would suit all family members.[15] Blustein suggests a re-orientation of the family role that would mimic a more communitarian concept of family, in which members are interrelated and interdependent, and in which family members act as mentors and facilitators while they provide support to the patient.[16] It is unclear that any of these approaches would be clinically viable; for example, family members may not want to accept that their needs are of equal importance to those of the patient. When one member of a family is ill, the other members usually cede their own interests, especially in end-of-life situations, and often refuse to pay attention to even the most significant of their own needs. While consensus-building is the ideal, it is not always possible, due to such factors as multiple perspectives, geographical distance, and family conflict. Finally, while family members typically strive to provide support, fulfilling the role of a surrogate decision maker may be impossible when a surrogate does not accept the role or does not feel capable of fulfilling it.

Further, in an increasingly secular world, it is often difficult for family members to have their religious convictions understood or respected. For family members who are trying to balance convictions that are integral both to their family and to their faith, a conflict with healthcare professionals that arises from a misunderstanding or a clash with current thinking in medicine will only increase the burden and frustration of the family's surrogate experience.[17]

Families can be frustrated by what they may see as a distressing lack of certainty in "prognostication" on the part of professionals.[18] Uncertainty about diagnosis and prognosis can create an environment in which families feel that discussions contain only an illusion of truth, and that pertinent information remains hidden. The aura of mistrust that can sometimes accompany these difficult discussions may play a major role in the ongoing struggle to find an appropriate patient-professional partnership for making decisions.[19]

SHARED DECISION MAKING

Patient-professional relationships have shifted along a spectrum in the last two decades, from "medical paternalism" toward "patient sovereignty."[20] At the far end of paternalism, physicians are dominant, authoritarian figures who have the right and responsibility to make decisions regarding the medical best interest of patients. At the far end of sovereignty, patients have full responsibility and control over all decisions concerning their own care, and while practitioners share information and knowledge, they do not exert influence on the decisions made by patients.[21]

Neither of these approaches reflects the interactions that are necessary to plan and execute reasonable, respectful care in the real world. Current practice and ethical analysis

lean toward what may be perceived as a shared approach, in which clinicians and family members work together to build consensus.[22] These approaches recommend (1) sharing information between professionals and surrogates, (2) developing a team approach,[23] (3) interpreting treatment options for family members, and (4) understanding the patient's context.[24]

The large and oft-quoted SUPPORT Study attempted to improve end-of-life decision making, but failed to gain many of its expected outcomes.[25] While the types of information shared increased and additional team members became involved to assist in the translation of information, the study measured little change in the actual approaches of the physicians in the study.[26] One qualitative study explored the experiences of family members who were asked to withdraw treatment, and found that surrogate decision makers need to understand not only the current medical situation of the patient, but need an opportunity to review the life of the patient and the role of the surrogate in relation to the patient and family members to be able to withdraw treatment.[27]

To further expand knowledge of surrogates who make decisions at the end of life, we undertook a phenomenological study. We sought to further explore the cognitive and emotional processes and the lived experiences of surrogates who must make very difficult decisions to withdraw treatment. An enhanced understanding of these cognitive and emotional processes will help us to tailor and sensitize clinicians' approaches to end-of-life discussions. We found that a shared decision-making process, while most desirable, requires careful attention to the presentation of information and the support and preservation of the roles and relationships of surrogates.

METHODS

Approval for the study was received from the McGill University Health Center research ethics board.

THEORETICAL FRAMEWORK

We chose an interpretive approach as the theoretical framework for the empirical component of this study. Also called *interpretive phenomenology* or *hermeneutics,* this qualitative methodology is based on a conception of human agency in which moral life is rooted in the context in which it is lived.[28] An interpretive approach seeks to understand human experience through thick contextual description.[29] It is based on a notion that understanding in human experience inescapably involves interpretation. An encounter or an experience is interpreted in terms of acquired understandings or a search for meaning. An experience of a particular encounter will reshape a person's "interpretive framework," the system of understandings that are brought to subsequent encounters, so that she or he will approach other encounters with a new or different interpretation.[30]

STUDY DESIGN

The phenomenon we explored was the primary surrogate decision maker who makes end-of-life decisions in an ICU. The principal investigator (or PI—the first author) conducted face-to-face interviews with the participants in the study: two broad-fact-finding participants (BFs) and six primary surrogate decision makers (PSs). The data were analyzed and interpreted throughout the data collection process and included the participants. The steps followed in the collection, analysis, and interpretation are integral to the design of the study, and are outlined in table 1.

In the interpretive approach, it is an asset for the PI to have an understanding of the experience or situation that is being explored. In this study, the PI had worked in the ICU setting for 15 years; 13 as a clinical nurse specialist with the specific role of patient and family counselor. Her knowledge of the ICU environment and of the experience of patients and families who face critical illness and death was useful in developing probing questions that would gain rich experiential data from the participants, in conducting sensitive

interviews with participants who were still mourning their loss, and in the interpretation of the transcripts of the interviews.

SETTING

An ICU of a tertiary level academic teaching hospital was the setting in which the PSs were identified and recruited. All interviews were conducted at the participants' homes or the in the PI's office, according to the preference of the participants.

PARTICIPANTS

The goal of interpretive phenomenology is to gain a richer understanding of the phenomenon being studied, so we chose participants specifically for their ability to share and articulate their experiences. The BFs were identified by the PI following consultation with colleagues; she made an effort to identify people with extensive, relevant experience. Both of the BFs were volunteers in different areas of the hospital, and had acted as surrogates in their own families; they were able to describe the reactions, emotions, and problems they faced, and their interactions with staff. They were also able to talk about their discussions with family members of other hospital patients about the world of the patient and family in terminal illness.

The BFs were approached individually by a colleague of the PI and asked if they were interested in meeting the PI to discuss the possibility of participating in the research. Both agreed, met with the PI, who explained the interview and analysis process and responded to their questions. The BFs gave their verbal and written consent to participate in the study. All of the PSs were identified and approached by the nurse manager of the ICU after a detailed discussion of the goals and design of the study with the PI. All of the PSs had acted as the primary surrogate decision maker on behalf of a patient who had died in the ICU approximately six months prior to the study; had an ability to speak in either English or French; and had indicated a willingness to discuss their experience. The PI chose the PSs to include different ages, genders, and relationships with patients. The PI met with potential PSs to discuss the research, explain the interview and analysis process, and respond to questions. PSs who participated in the study gave verbal and written consent.

Due to the time and financial constraints of a one-year research fellowship and the need for two interviews per participant (and potentially more, depending on the interpretive process), the study was limited to eight participants.

DATA COLLECTION AND ANALYSIS

Phenomenology seeks a deeper understanding of an experience or phenomenon. Other methodologies usually delineate between the collection and analysis of data, but phenomenology requires a blending of, or a cyclical or interactive approach to seeking and

Table 1
Design of the Study

1. The principal investigator (PI) consulted colleagues in the intensive care unit to identify the two broad-fact-finding participants (BFs).
2. The PI conducted initial interviews with the BFs, which were taped, transcribed, and interpreted.
3. The PI conducted second interviews with the BFs and shared the data with the BFs to confirm the PI's interpretation of the data.
3. The PI used the interviews with the BFs to create narratives about their experiences to develop a guide for the interviews with the primary surrogate decision makers (PSs).
4. The PI conducted initial interviews with the six PSs, which were taped, transcribed, and interpreted.
5. The PI's research advisor reviewed random samples of the PI's interpretations and discussed them with the PI.
7. The PI conducted second interviews with the PSs and shared the data with the PSs to confirm the PI's interpretation.
8. The PI created narratives about the experiences of the PSs.
9. The PI created the final study narrative, based on the interpretation of all of the BFs' and PSs' narratives.

interpreting data in the form of rich text and discussion, which helps to provide a confirmed narrative. To enrich the knowledge of the PI and to avoid a potential misinterpretation of the experience of patients and families, the PI interviewed both of the BFs; the interviews provided a foundational understanding of the experience of surrogates who make decisions at the end of life from the point of view of the patient and family. The PI taped the interviews, transcribed them verbatim, and made an initial interpretation in which she searched for meanings and descriptions of the BFs' experiences.

In a second interview with each BF, the PI and the BFs reviewed, discussed, and confirmed the PI's initial interpretations. These interviews were rich in reflection and questioning, and the new interpretations were included in the understanding of the experiences of the BFs. The interpretations of these interviews were used to create rich narratives about the experiences of the BFs and to prepare guides to use in the interviews of the PSs. The interviews provided points of reference and comparison and areas for further probing in the PS interviews.

The initial interviews with each of the six PSs were conducted as described in table 1. The second interviews provided an opportunity for reflection, questioning, and new interpretation. The new interpretations were shaped into a more comprehensive understanding of the PS's experiences. Benner suggests, "the researcher needs to make explicit as many assumptions as possible prior to the beginning [of] the study and establish boundaries to the lines of inquiry for the study, but these must be held tentatively and allowed to be challenged, altered, extended and transformed by what is learned in the field."[31] It is important to have a broad understanding of the global "world" that is being studied, and, through the process of interview and interpretative analysis, to gain a richer understanding of the experience or phenomenon.

A qualitative research advisor who was familiar with the ICU environment, the experiences of families at end of life, and with interpretive phenomenology reviewed a random sample of the transcripts to validate, confirm, or challenge the PI's interpretations of themes.

A final narrative was created from the interpretations of the interviews of the BFs and from the confirmed interpretations of the PSs. As Benner suggests, the reflection process included "continual interpretation of the similarities (pattern recognition) in each experience and the need to be attentive and responsive to the unique features of every individual case."[32]

RESULTS

CHARACTERISTICS

The participants in the study ranged in age from their early twenties to early eighties and were wives, husbands, daughters, sisters, and mothers. Their occupations were varied—some were students, some retired, and some continued to work inside and outside the home. The subjects struggled alongside their family members through both chronic illnesses that had lasted many years and acute episodes that were unexpected. In some cases, the two overlapped (see table 2).

THEMES

All of the participants felt that they had had a role in making decisions. There were differences in what they thought their role should have been and what type of decisions they should have been included in, but they felt that it was their responsibility to be involved. The role of the surrogate is not an easy one; several issues arose that are common to many of their stories. Prior to presenting the main body of results related to making decisions, we will present these common issues as reflections the subjects shared about the whole decision-making experience.

Four separate themes arose from questions or concerns of the participants, questions such as, "Did I do the right thing?" or concerns related to personal struggles to "set aside one's own beliefs," "to hold onto the 'whole' story

of the patient," and "to maintain the dignity and identity of the patient throughout the last days of life."

"Did I Do the Right Thing?"

The haunting question, "Did I do the right thing?" was mentioned first and most often by surrogates. One person stated, "You want at the end to not 'wish that maybe we should have,' there was none of that," (Interview BF1, l. 1457). Another participant reflected, "Because in this case, you don't want to be wrong. Otherwise, you know. The thing I love most in my life I don't want to kill it. So that's the part that really I agonized over a lot. Even after it had been done, it was, it was still agonizing. To figure out. Maybe you did. You know you question yourself. You say, did I do the right thing? Did I do the wrong thing?" (Interview 6, l. 798-826). The participants' phrases seem to reflect their internal moral struggle to balance their decision-making role with their emotional struggle as family members making decisions that have major implications, including potential losses, for both the patient and the family.

The Struggle to Set Aside One's Own Convictions

Several of the participants described the struggle of trying to set aside their own beliefs during the decision-making process. There seemed to be a sense that even if they didn't agree with the decisions of the patient or weren't able to accept the timing or the determination of the patient, the duty of the surrogate was to set these feelings aside and focus on the wishes of the patient.

Some felt torn between their desire to hold on and their need to let go. A participant who had cared for her husband at home through the ups and downs of a chronic, degenerative illness talked about how difficult it was to accept that her husband was ready to "give up." "I said, 'Don't talk like that, you're just weak. You don't eat.' And then he said, 'No, I'm not getting out of here.' So that's when I realized that mentally he was prepared too. But I still didn't want to admit it," (Interview 3, l. 348-352). They had already fought through so many difficulties, so it seemed that there was still time to continue to fight. The struggle occurred when the patient and the surrogate did not share the same perspective on the need or the willingness to continue.

The Struggle to Hold onto the "Whole Story of the Patient"

Family members often felt that they were the only ones who "had the whole story" of the patient. The environment in hospitals is chaotic, due to changing staff, shortage of

Table 2
Characteristics of Participants

Participant #	Gender	Age	Employment Status	Relation to Patient	Illness of Patient (Chronic vs. Acute)
BF1	F	40-49	Full time volunteer	1st experience, mother 2nd experience, sister	Acute Chronic
BF2	F	60-69	Retired	Sister	Chronic
PS1	M	70-79	Retired	Partner	Acute
PS2	F	30-39	Self-employed	Daughter	Acute and chronic
PS3	F	50-59	Employed	Wife	Chronic
PS4	F	30-39	Employed	Daughter	Chronic
PS5	F	20-29	Student	Daughter	Acute and chronic
PS6	M	50-59	Employed	Husband	Acute

beds, and frequent transfers. Surrogates reflected that these factors interfered with professionals' ability to provide the kind of care that families and professionals wish for. One of the concerns that many of the participants talked about was to keep both family members and professionals focused on the patient. Family members felt this was a crucial role for them. Problems were often related to the number of people who were involved, the volume and types of information that needed to be shared, and the potential for misinterpretation. Some talked about professionals who did not seem to take the time to find out what was most important to the family.

Vigilance on the part of the surrogate in carrying and sharing the information and the values of the patient were part of the focused approach described in this response: "She had over 100 x-rays and every time she went in they never had the total package. They didn't know whether it was her first or her one-hundredth x-ray," (Interview BF1, l. 155-158). Another subject described the role of the surrogate as "keeping everyone informed; reporting to everyone in the family and dealing with family members who 'second guessed' everything you said," (Interview BF1, confirmation interview). This type of vigilance requires emotional energy at a time when many were feeling overwhelmed and fatigued; the participants described themselves as shocked at this time and almost numb.

Maintain the Dignity and Identify of the Patient throughout the Last Days of Life

Some of the patients had been completely independent prior to the sudden onset of illness but regained neither consciousness nor the ability to make decisions once they entered the hospital. Their family members were clear that they needed to have an important role. Other family members watched their patient go through a gradual loss of function. These families struggled not against the role of being a surrogate, but rather against taking on the role either too soon or unnecessarily. There was a sense that individuals must be allowed to maintain their ability to be independent as long as possible. Part of the surrogate's role was to support this independent thinking and take over only when there were no other options.

One subject described the many ways that she and her husband had tried to hide his deteriorating condition from their children, to prevent them from seeing him in a diminished state. "They hadn't seen their father . . . since April. Their father, we could tell he wasn't well. But my husband for my children's sake was making believe," (Interview 3, l. 762-769). In their day-to-day life, the patient and his wife had also created different roles and reorganized their way of functioning as a couple, so that the patient could retain some of his independence. The patient's wife described the role: "He was doing all my transactions, my arrears, my bank transactions everything. My insurance . . . you know in other words he was all there. . . . It became the role that he had taken on even though he couldn't do the physical. It kept him going through all those years; otherwise I think he would have gone a long time ago," (Interview 3, l. 101-4; 967). Describing the situation after her husband died, the subject said that although this had been somewhat of an illusion, struggling to keep up a brave front allowed her husband to have a sense of dignity. She said that it was important to make sure that she didn't take over any roles that he could still manage if he was to maintain his feelings of self-worth.

These four themes represent the psychological environment of the participants during the process of decision making. The next section focuses on the process of making decisions on behalf of another at the end of life.

MAKING END-OF-LIFE DECISIONS

The process of making end-of-life decisions is complex. The interpretation of the interviews suggests that the process seemed to follow a series of steps. The steps can be described as "struggling to understand," "coming to terms," "transforming reality," and "needing to find peace with the decisions."

Struggling to Understand

Surrogates' struggles to understand involved more than just receiving information. Participants were often frustrated that both the amount and type of information provided to them made it difficult for them to understand: "and again I just, the terminology used for the layman is not, not that simple," (Interview 6, l. 1387). Several participants felt that there was too little information; this sometimes led them to feel that information was being withheld or was purposely made obtuse. "It was very hard to have faith. I like to, I'm a person who likes to be informed. Ignorance is not bliss. And I find that professional people tend to not to go into it deeply because they figure you're too ignorant maybe to understand and I think it's the wrong thing to do. They should be very candid about expressing in layman's terms the scenarios, that the person gets enough information to make an educated decision," (Interview 6, l. 553-64). This participant found it hard to understand because the information received did not satisfy the participant's need for a certain type of information.

Another participant described the responsibility to share information as difficult because the participant was afraid that he did not understand what was being said: "I said to the boys, 'I don't want to tell you anything. I want you to come though, come by, see her, and we'll talk to the doctors. The doctor's gonna give [the news]. There's many things maybe I lost or something.' So we went there and we went to see the doctor and after that they called their sisters," (Interview 1, 882-886). It was important for the family members to not only "get" the information, but also to try to understand what the information meant, both now and for the future.

Depending on the type and the quantity of the information they received, some participants searched for more information from other sources. Several used the internet, some sought second opinions from physicians known to the family, others relied on information from colleagues or friends who had been through similar situations. Most were disturbed at having to seek out further information in these ways, but felt that they could not make sense of what professionals were saying if they did not have what they considered to be appropriate background information. On the other hand, some participants felt that they had received information that was useful and understandable. "It helped—the way they approached me. They put the facts on the table. They really told you the pros and cons," (Interview 3, l. 1045).

Those who received information that they perceived as adequate moved more quickly toward digesting the information and getting ready to make decisions. Digesting the information included thinking about and trying to make sense of it. Those who did not receive enough information searched until they were satisfied with their understanding and then began to digesting the information.

Coming to Terms

Once participants had received and digested information, a second step had to be accomplished before they moved to making decisions. In every situation, there was a process of coming to terms with the diagnosis and prognosis, in other words, recognizing the reality of the information and its implications.

Participants found it difficult to accept a diagnosis or a prognosis of such profound meaning. They described needing to be present to "see what the professionals are seeing" then beginning to "match" the words that were being said by the physician with their own vision of the patient. "When [the doctor] told me she was paralysed he said, 'the brain is a funny thing.' Her brain doesn't tell her that she's paralysed. She doesn't know. It was true. She didn't mention that. It never comes that 'maybe I'm paralysed' or 'I can't move my arm'. . . . She never, never mentioned that. This was helpful—I knew she wasn't worrying about that," (Interview 1, l. 1124-30).

Because of the shock and the disbelief, the participants often had difficulty reconciling the professional's perceptions of the patients

with their own. "Well she's on life support systems, but all the reflexes are the wrong reflexes. She can't hear. She can't see. And she's totally nonresponsive . . . she's got a tube down her throat. She's hooked up. She's got a catheter. A tube coming out of her head. And she's staring into space. Otherwise she looks perfectly healthy, radiant, and relaxed. Four hours ago we were talking," (Interview 6, l. 157-74).

The perceptions of the surrogate had to be translated into new beliefs about what was happening to the patient and what that really meant. This was not always easy; because some participants felt that the messages they received were mixed, they were reluctant to believe what they heard. For example, one daughter was very skeptical when the physicians told her that her parent would die. There had been a previous experience in the family in which death had been predicted and yet the patient recovered. "The man recuperated incredibly. I mean look there's a photograph of him after his last illness. . . . He was ready to travel again. There was nothing, besides the fact that he walked with a walker, he was terrific. His brain was there. He knew us. He remembered stuff and he was fine. And you were wrong and we were right. So I mean you may know the medicine but we know the man," (Interview 2, l. 99-101, 109-115). The family was hopeful that a similar recuperation would be possible.

Another family struggled because the messages from both the patient and the staff did not seem clear. "He bled five times out of those arteries and still recovered. My sister went in . . . and found him in a pool of blood . . . but again he still recovered. I would always call and ask what his blood pressure was like? Stable, stable, stable!" (Interview BF1, l. 1081-83). The participant was unable to believe that the patient was really going to die because he had defied death so many times.

Most of the participants found that having the opportunity to talk to others, often those in waiting rooms who were going through similar experiences, and especially to their own family members, made the job of accepting the diagnosis and prognosis, if not easier, then somewhat more secure. When extended family members had not yet been involved, it was at this point they were called and asked to come to the hospital. When they were already involved, part of the process seemed to be ensuring that everyone had the same ideas about what they were seeing. "It's tough but when he stopped talking completely that's when I said there's something bad. So this is where we called my son in St. Louis and so forth. And from that point I realized he was going," (Interview 3, l. 356). Family talks often involved discussion about who the person had been in the past and who the person was expected to be now.

Several factors contributed to "coming to terms" with what was happening. If the family had already had a previous experience in which the patient recovered despite dire predictions, the "matching" process could be hampered by a real reluctance to believe that this time would be any different.

Pre-existing conflicts within the family left participants feeling isolated and alone. The "aloneness" heightened participants' sense of fragility and, in one situation, it caused a participant to recreate, through pictures, the family that no longer existed because of divorce and acrimony. "So I brought the flowers in and I felt like the others should have been there. Like I was really mad that they didn't come down. So at least I brought a picture and I put it by her bed . . . pictures of the family and the cat. . . . And I guess it made me feel better. I don't know if it helped her but it made me feel better," (Interview 5, l. 680-690). The "aloneness" created by conflicts left the participant with no one to talk to about the patient and no one to support the participant, who had to make the decisions.

One of the participants had past memories of conflicts with the patient that had not been resolved. The patient was unconscious from the moment of admission and the surrogate was aware that there would be no opportunity to discuss the resentments and linger-

ing anger. The participant reflected that there had always been the hope that there would be time to have the discussions. A friend had suggested that the participant attempt to talk to the patient even though the patient could not respond in any way. Even after trying this, an empty feeling remained because there was no way to solve the problem. This made the process of saying good-bye even more difficult.

Most of the participants discussed the role that the shock or the emotional impact of the incident played and how they felt paralyzed or numb. The raw emotions often prevented them from being able to hear or to think straight. "The whole time with my brother, I don't think any of us ever expected this end. We were totally unprepared. I never even talked about advance directives. We were going to get to it after the crisis," (Interview BF1, l. 1381-2). "We didn't, we didn't expect that because it happens so fast, we didn't see it come," (Interview 1, l. 22-24). In both of these situations, emotions had an impact on the participants' abilities to recognize and accept what was happening—the ongoing process for the participants of matching what they heard with what they know.

Many of the participants had had an opportunity to discuss end-of-life wishes with the patient at some point in the past. In every family in which this had taken place, the discussions were seen as very helpful to the surrogate as they struggled to "come to terms."

Transforming Reality

Once the process of "coming to terms" with the diagnosis and prognosis had been accomplished, a process of "transforming reality" began. Once the participants understood the diagnosis and the prognosis, they could understand a new reality—that there was no turning back. The patient was dying, or would no longer be able to recover.

In the earlier process of coming to terms, there was a need to match the words that were said by the physician about the new reality of the patient with the participant's own beliefs. Once participants understood the new reality, a second process of matching began. Family members had to match their understanding of the new reality (the patient cannot live as he or she is) with their perceptions about who the patient was and whether or not the patient would accept the new, predicted future.

Some of the participants described how their patient had been in excellent health, but then experienced a sudden, catastrophic illness that had ended the patient's life. Other patients died following many years of living with a chronic illness and its ramifications. Participants whose patients suffered from an acute, catastrophic illness experienced a shock of going from "absolute health to death," (Interview 6) that was so overwhelming that they had trouble transforming reality. Participants whose patients survived a chronic or long-term illness described a need to shift their thinking from "fighting to survive so that they could continue to live" to "finding a willingness to let go." One of the participants described her struggle to identify the difference between her past need to be aware of signs and symptoms of the chronic illness and a new need to see new signs and symptoms as indicative of the approaching end of life. Another facet of chronic, long-term illness was an inability or unwillingness to think about death. One woman reflected that, despite the multiple problems that existed, she and her family had never even thought that death would be the outcome. There had been no discussion with professionals about this possibility either, even though the patient had suffered from a progressively deteriorating condition.

In each of the study interviews, the participants felt able to say what the patient would have wanted and, in several cases, there had been opportunity for the patient and the surrogate to talk together prior to the illness or injury that finally caused death. "I knew from before, like my mother always told me 'Do not keep me alive by machine.' So like I knew, I agreed with the doctor right away that

that was the right thing to do," (Interview 5, l. 278-280). Knowing the patient's wishes made an emotional situation less difficult.

The difficult aspect of this part of the decision-making process was being sure that this was the right time to stop. Even when a surrogate accepted the reality of no return, it seemed important to be sure that every chance had been given and no question had been left unasked. A final step in transforming reality was the struggle to identify which limits or deficits the patient would have accepted, and then knowing that the time had come for treatment to stop. Participants described their discussions with physicians at this point as confirmatory or agreement-seeking: "If he had been absolutely fine and his surgery had worked really well . . . it would have been a totally different situation. But that wasn't the situation. The situation was—his quality of life stank. Four days and not a flicker of change. And the fact that his quality of life was so rotten and that he had metastatic disease. This looked like it was time for it to be the end," (Interview BF1, l. 890-899). Being able to identify that a "bottom line" had been reached made making the decision to stop treatment more palatable.

It seems as if making a decision was less emotionally significant than the complicated processes of coming to terms, transforming the reality, and identifying the end. When these steps had been accomplished, the decision, although still emotionally difficult, seemed clear. Making the decision seemed to be the end result of the transformative reflection. Participants did not speak about making a decision as separate from the reflection, but more as part of the process.

Needing to Find Peace with the Decision

Many participants said that after they made a decision to stop treatment, they needed to find peace with the decision; they did this in different ways. Some participants confirmed their decision with others: "So after his best friend listened to the doctor [and knew that] we gave our decision I said, 'What do you think? Did we do right?' He says, 'My dear, I'm not his brother but I think you did right. I know him. He'd never want to accept this'," (Interview 3, l. 1335-47). For one person it happened through being present during the withdrawal of treatment. This person was able to confirm the decision made by seeing that what was predicted actually happened. Through this process the participant came to feel that the decision made had been the right one. "If she dies then she's meant to die . . . so they stopped the machine. My wife didn't, she lay there immobile. And I watched the heart monitor and within about seven minutes the heart stopped," (Interview 6, l. 280-2; 305-7). Death was confirmation that life could not have continued without machines, a life that the patient would not have accepted.

Others talked about how they finally realized that the life that had been predicted would not have been acceptable to the patient; this was important in being able to find peace with the decision that had been made. "It's much better than if he'd had more metastatic disease and was in palliative care in pain for months, conscious—knowing he was dying. That would have been brutal. I can see him jumping out the window," (Interview BF1, l. 906-8).

For many participants, the loss of the patient was their first experience with death. Experiences with death, similar to experiences with making decisions, were often affected by the participants' preconceptions, their relationships with others, and their ability to understand what was happening. Several remarked that the death, as it happened, didn't match what they thought it would be like. "My expectations were that it would take much less time. I didn't think she'd hold on for a day. And when she did start to slow down, it shocked me that it was so sudden. So like I thought it would take maybe, it would be a steady decline, for maybe a couple of hours," (Interview 5, l. 611-13). Participants said that they found it difficult to interpret what was happening and their role in it because they didn't know what death would be like. For example, one surrogate talked about how the uncertainty surrounding the dying process,

which lasted several weeks, made the family's goal to be with the patient at the time of death very difficult to achieve. The difficulty of dealing with both the hospital environment and the vision of the patient, head shaved and covered in tubes, was mentioned by another participant as part of the struggle to find peace with the death.

Others talked as if they were trying to turn the situation over and over in their heads in some way, in an effort to begin to come to terms with the death. Their words were a reflection of the conversation that was going on inside their head: "There is no easy way for this process to run its course because the facts are so strong. And overwhelming. You know the diagnosis of the person, not being able to survive because medically they're dead. . . . It's just the evidence is so strong there . . . the process [of finding peace with the death] comes after the fact. I think because it's the process to find a place to put it that you can live with it," (Interview 6, 1. 140-1152). Many participants stated that they continued on a daily basis to try and make sense of what had happened and to find peace with the decision that they had made—and the interviews were approximately six to seven months after the death.

Some of the participants were not present at the time of death, yet the same processes of finding ways to come to terms both with their decision and with the death occurred. One participant whose experience had been particularly difficult was not present during the time of her father's death. In her reflections after the death, she felt that, given the circumstances, this had probably been a good thing. For her, witnessing the death of her parent would have made the situation even worse. In contrast, another participant who had been closely involved in every aspect of the last few months of treatment, surgery, and complications found that missing the actual moment of death made her feel as though the experience was incomplete. She remembered going over every detail with the family.

One of the participants' experiences was significantly different from the others. She described the situation as the worst experience of her life. She felt that the staff had completely misinterpreted the essence of her family and their values and beliefs. Much of the conflict sprung from a belief on the part of the participant that there was no relationship between the staff and the family. This lack of relationship with the staff and the staff's lack of understanding of the family's culture and beliefs was coupled with a very wooden approach from the staff, which the family found disgusting. The participant described one of the professionals by saying: "She obviously just knows how to deal with a certain type of person who's raised in a certain type of way. And no other. Just get her away from me," (Interview 2, l. 493-96). The family had a fundamental belief that they did not want to be involved in certain decisions about death; the very conception of such decision making, to them, seemed wrong: "I think that's where my bitterness lies. Because I didn't feel like I . . . wanted to be pushed that way. I don't think there were any decisions to be made," (Interview 2, 1. 332-343).

From the perspective of the staff, a family who felt this way might be labelled unrealistic. It is clear, however, that both the participant and her family understood that death was likely to come soon; they had even requested that there be "no resuscitation" in the event of a cardiac arrest—a very clear decision had been made and articulated by the family. They simply believed that it was wrong to be involved in decisions about allowing someone to die—the decisions they had made were the only ones that they could make—the others were "up to God not doctors," (Interview 2, l. 362). As a result of the very bad feelings between the staff and family, the perception of the participant was that the staff were deliberately cruel because the family didn't want to follow the usual process.

There was a profound clash of cultures—the family culture and the healthcare culture—and the result of the family's traumatic experience was that, at seven months after the death, the participant had not yet begun to come to terms with her parent's death. She

did not go through the same thinking processes that had helped others, even in their sorrow, to be prepared for death.

DISCUSSION

Participants talked about their role in end-of-life decisions as a process, not as something that happened at a single point in time or as a task. Participants talked about the thinking they had done, the reflections that had haunted them, their fears about not knowing what was "the right thing to do," and their incredible sense of loss. While grief might be described as learning to live with loss, the processes taking place in these interviews seemed to be "pre-grief": a recognition that loss was coming. The surrogates were struggling to come to terms with the fact that the patient would no longer be part of their lives.

Our aim in doing this research was to understand the cognitive and emotional processes, the lived experiences of surrogates during the process of making decisions at the end of life. We examined four specific points from this body of work: the significant shifts in understanding during the experience of being a surrogate, the surrogates' experience as a challenge to identity, a re-examination of meaning, and, finally, an examination of what professionals can learn through the experiences of surrogates.

In both the "coming to terms" and the "transforming reality" concepts, there were mentions of "matching processes." Drawing on his work on cross-cultural discourse, Taylor describes a "fusion of horizons" which, in the "coming to terms" process, might be translated as the recognition, on the part of surrogates, of the meaning of what is being said, and, on the side of the professionals, of a state of certainty that may lead to a place of no turning back.[33] This fusion requires, at a minimum, a recognition of the world in which the other exists. Akin to this fusion—perhaps a precursor to it—matching might more aptly be described as a "dawning of awareness." The dawning of awareness that takes place during the process of "coming to terms" seems to symbolize a cognitive, emotional, perhaps even spiritual awakening to further cues to come. At this stage, it is almost as though there is an awareness that the day has dawned, but there is no certainty yet what the day will bring.

Just as dawn gives way to the harshness of full daylight, each participant was presented with a new, grim reality. During a time of transformative reflection, participants began to understand that the patients would not be able to survive as the persons they were before. As the dawning of awareness becomes reality, the horizons of surrogates and professionals must become more intricately entwined, to enable the surrogates' transformative reflections to lead to a convergence of the "physician-predicted future," with the expectations or hopes that the family members brought with them. Ultimately, the "transforming of reality" and the process of transformative reflection continues throughout the dying and into the grieving.

A second point of interest taken from the data suggests that the intellectual and emotional struggle facing surrogates may be representative of a challenge, both to the identity of the surrogates and to their concepts of family. The transformative reflection process involves trying to understand a set of clinical data that will ultimately result in the complete transformation of one's world. Not only are the data, as discrete packets of information, often complex, but the ramifications they present embody a very fundamental challenge to the expression of one's self-concept in relation to one's world. Taylor suggests that people develop their identities based on the culture, ideals, history, and behavior that have been developed through their relations with their immediate world or family.[34] When one associates one's personal identity with a certain constellation of family members, it is understandable that a permanent loss through death can precipitate an identity crisis. Am I still a wife if I no longer have a husband? If my husband is dead, does he completely cease to exist in me? Will memories be enough to keep alive what he has meant to me?

Through the "coming to terms" and the "transforming reality" processes, participants were able to begin their explorations of their past world, compared with their present reality. In some cases, they moved toward a new future without the patient as a physical member of their world. In coming to terms, participants acknowledged that the relationship that existed was altered forever. In the phase of transforming reality, the very significant step of examining who the patient has been in the past in relation to who the patient will be in the hypothetical predicted future, while trying to determine whether the patient would or would not accept the assigned fate, can become an overwhelming burden.

Taylor would suggest that part of the burden comes from having to discover if one can exist with one's new vision of self that does not include the person who has died. In fact, he would suggest that despair or breakdown will be the result when one is not able to reconcile the loss and discover a new vision of self or a new personal identity.[35] One might consider that the struggle to understand information, the questioning, the confirmation through conversation about the decisions made, and the discussions about who the patient was prior to the illness and injury, all reflect the processes of deconstructing and reconstructing not only the identity of the patient, but of the surrogate. Being alone, having previous conflicts in the family, and previous illness experiences or conversations with the patient are factors that affected the process, acting either as facilitators or hindrances. The one participant's radically different story reflected a transformation process that was arrested by an inability to come to terms. The most significant factor communicated to the researcher by the family was the lack of a relationship with the healthcare team, and what the family perceived to be the staff's fundamental misunderstanding of the family's "identity" as a family. This misunderstanding on the part of the team led to a mistrust by the family so profound that the process of transformative reflection was inhibited—in fact, it was arrested.

> Without words, it comes. And suddenly, sharply, one is aware of being separated from every person on one's earth and every object, and from the beginning of things and from the future and even a little, from one's self. A moment before one was happily playing; the world was round and friendly. Now at one's feet there are chasms that had been invisible until this moment. And one knows, and never remembers how it was learned, that there will always be chasms, and across the chasms will always be those one loves.[36]

This brief and poignant excerpt from Lillian Smith's "The Journey" give voice to the painful transformations that take place through death and grieving. In our study, it is clear that the transformative reflections began with the dawning of awareness that one's world was about to change and led to some distant and undefined point in the future.

The concept of meaning is a third point of interest. Taylor says meaning is created through language, through which we seek words to express who we are, how the world—our world—is unfolding, and how we can make sense of it.[37] The need to have a language that can describe what is occurring is essential. Yet, when one is suffering, it is difficult to find the words to express the experience or to create a narrative. Younger goes so far as to suggest that suffering attacks one's world and one's self, actually destroying one's ability to communicate.[38] What has been described in this study as transforming reality would be described by both Taylor[39] and Younger[40] not only as reconstructing an identity, as described above, but also as reconstructing the narrative, to create some sense of meaning through words. Being able to make decisions seems to be linked to an ability to create this meaning and to begin the process of living with a reconstructed, although naïve, identity (which will continue to be reconstructed throughout the grieving process).

The final point for reflection examines the role of healthcare professionals. Much of the processes of "coming to terms" and the "trans-

formation of reality" appear to be internal struggles that surrogates must conquer alone. However, before transformative reflections could assist surrogates, participants in the study indicated that there was a need to understand and translate information from professionals into something they could understand and handle. Transformative reflections can be facilitated or hindered by the approach, the language, and the compassion of the team that assists surrogates. Most models in the literature include an interconnected approach, in which understanding the illness process and making decisions based on a patient's values and beliefs are emphasized.[41] The promotion of a "good" understanding of the trajectory of illness and of the expected outcome is well-defined, but understanding and facilitating the translation of a patient's values and beliefs to meaningful decisions is not as clear.

Our illumination of surrogates' experiential reflections can help clinicians to tailor their explanations and their discussions, which can assist surrogates in their process of transformative reflection. When clinicians remember that surrogates process information differently, clinicians are able to understand that they should assess each surrogates' preferred method of exchange. This involves understanding how surrogates use language and understand and interpret medical facts. When clinicians begin the communication process by probing exactly what surrogates understand, this action allows clinicians to identify the language that the surrogates use. Clinicians then can use similar language to address inaccuracies or misunderstandings and to begin the process of assessing the level of distress present. The use of a team approach ensures that information will remain consistent and that physicians and nurses remain connected, sharing reflections and assessments of the surrogate and the support that is needed and provided.

As clinicians work with surrogates, it is useful for clinicians to understand that the dawning of awareness signals or triggers a process of coming to terms and transformative reflections. When surrogates are in the process of coming to terms, clinicians can probe the surrogates' perceptions and discuss their beliefs about what is happening and why. Most importantly, clinicians can consider the particular context, or world, of the patient and his or her surrogate, as that world defines who the surrogate "is" and how the surrogate's identity is challenged by his or her present circumstances. This is key in the phase of transforming reality. Drawing on this information about a surrogate's context will allow clinicians to prompt discussions that reflect a convergence of the past, the present, and the expected future of the patient, with a clear and honest reflection of the prognosis.

These forms of interaction require an engaged and compassionate approach. Participants showed a strong need to feel that members of the patient's healthcare team cared about them, and that their relationship was honest and sincere. While this may be a challenge, given the chaotic and fractured systems within which most clinicians work, re-orienting how information is shared and the discussions that ensue facilitates an authentic partnership between professionals and surrogates. Finding even simple ways to demonstrate compassion by approaching the patient and the surrogate with dignity and respect, by the judicious and sensitive use of touch, and by attending to the emotional needs of the surrogate through a team approach will enhance the relationship and help to diffuse or diminish some of the anxiety that is bound to be present.

Understanding the complexity of the processes that surrogates must face accentuates the difficulties of fulfilling the role of substitute decision maker, as currently defined in the bioethics literature. Our findings provide some new ideas on how a professional's approach can facilitate or hinder a surrogate's ability to fulfil his or her role. Attending to how information is interpreted and the ways that surrogates use and process information assists clinicians in providing appropriate and supportive interventions, so that surrogates

can make decisions that are more congruent with those of the patient.

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Organ Donation

Evolution of a Living Donor Liver Transplantation Advocacy Program

Lisa Anderson-Shaw, Mary Lou Schmidt, Jeanine Elkin, William Chamberlin, Enrico Benedetti, and Giuliano Testa

INTRODUCTION

Living donor liver transplantation (LDLT), introduced as a standardized technique in Chicago in 1989, has proved successful in almost eliminating mortality on the pediatric waiting list for liver transplant. Rates of successful grafts and patients' survival in LDLT are equal and often superior to those of cadaveric liver transplantation. The same goal of reducing mortality on the waiting list that prompted worldwide acceptance of pediatric LDLT has been, in recent years, the main impetus promoting adult-to-adult LDLT.

It has been reported that 15 to 20 percent of patients waiting for a liver transplant will die without receiving one.[1] The newly introduced Model End-Stage Liver Disease score (MELD) system allows fast transplantation for very sick patients with a high MELD score, while forcing a longer wait for patients with a moderate score, despite encephalopathy, intractable ascites, and/or portal hypertension. In fact, MELD scores are calculated by a formula whose variables reflect only the laboratory values of patients, and do not take into account the clinical manifestations of their disease process. Consequently, patients who have great life limitations because of their liver disease, but who present with laboratory values that are not grossly abnormal, may face extremely long and painful waiting times. Moreover, in the MELD system, patients with

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hepatocellular carcinomas that are greater than five centimeters in diameter are, in essence, excluded from the cadaveric waiting list. LDLT offers the unique chance of readily available treatment to many patients who are affected by end-stage liver disease.

The donor operation requires removal of either the right or the left side of the liver. In technical terms, the operation is called a hepatectomy. The donor will undergo either a right or a left hepatectomy. The decision of which side of the liver will be donated depends on the size of the donated liver and the size of the patient who will receive it. The University of Illinois Medical Center at Chicago (UIMCC) has an active LDLT program, where it is proposed as a possible therapeutic option to all candidates for liver transplantation. Patients who are thought to particularly benefit from a LDLT are those with life-limiting symptoms of liver decompensation that is not reflected by laboratory parameters such as intractable ascites and/or encephalopathy, or patients affected by hepatocellular carcinoma.

The donor evaluation is performed following a strict protocol, and only those potential donors who are found to have no medical conditions that may jeopardize a prompt recovery are accepted. Since the inception of our program, it was felt that all potential donors should be fully evaluated by a trained professional who was independent of the transplant team, to determine the willingness to donate and the absence of coercion. With time it became clear that the potential donors were also in need of in-depth counseling concerning insurance, power of attorney, and work-related and financial issues. It became evident that these issues were often ignored or underestimated by the potential donors. To manage these issues, UIMCC became the first hospital to implement a donor advocacy program. Within this program, informed consent is obtained by the transplant team and is reassessed by a member of the hospital's medical ethics consult service to check for the absence of coercion and guarantee the potential donor's right to refuse surgery until the last moment. In addition, the UIMCC ethics committee works closely with the medical ethics consult service to develop a program that guides donors through the donor advocacy process, which takes place early in the donor work-up phase.

ETHICAL QUESTIONS

Living organ donation has always raised difficult ethical questions. Such questions include: *How should autonomy and paternalism be balanced? When is it justified to expose a healthy person to harm primarily for the benefit of another?* and *Can truly informed consent ever be possible in this situation?* In addition to these questions, other considerations should be taken into account, including: *How should living donors be chosen? By whom? Should volunteers have any input in determinations of their own suitability? How should potential donors be evaluated for physical, emotional, and social suitability? What is our responsibility to living donors in protecting them from the potential harms that may result from donation?*

In using a living organ donor, we put an otherwise healthy person at risk primarily for the benefit of another. Consequently, there is a strong ethical responsibility to ensure that the process of selecting donors takes into account not just the physical suitability of the donor, but also evaluates other contextual issues, so that appropriate safeguards are in place to protect the interests of the living donor.

The ethics of living organ donation has continuing salience, largely because the need for cadaveric organs continues to exceed the supply.

The main ethical question concerning living organ donation is very well stated by Spital: "Throughout the history of living organ donation, concern about harming the donor has appropriately taken center stage in debates about the acceptability of this procedure. The most troubling ethical question has always been how can one justify exposing a healthy person to the risk of major surgery to benefit someone else?"[2]

How is it, then, that "we" choose living organ donors? Who decides whether a potential living donor has "what it takes," physically, psychologically, and socially? Is the autonomous consent of the potential donor sufficient? Although this article primarily describes our advocate process for living *liver* donors, we believe that living donor advocate programs would also be appropriate in living kidney, lung, pancreas, and small bowel transplantation. Our approach could be used as general guidelines for all such living donor advocate programs.

A BRIEF HISTORY OF LDLT

First, we must look back, historically, to the living organ donor data. Although living kidney donation has been practiced for 50 years and has minimal morbidity/mortality issues, living liver donation is still very new, and the process of living liver donor assessment is not nearly as standardized. The timeline of LDLT is summarized in table 1.

The first adult-to-adult LDLT at UIMCC was performed in July 1999. Prior to the procedure, in October 1998, the transplant team came to the UIMCC Ethics Committee to review their new program and to seek assistance with the donor selection process. The transplant team reviewed the current donor and recipient criteria and discussed the overall ethics of the surgical procedure. The UIMCC medical director was supportive of the ethics committee's involvement with the LDLT program. The committee was very interested in participating in the donor selection process, and gave some general suggestions to the transplant team related to ethical issues such as coercion and informed consent. Three LDLT procedures took place between July 1999 and December 2000, before the formal donor advocacy process was initiated. Between January 2000 and January 2002, no LDLT procedures were performed at UIMCC.

BEGINNING OF THE FORMAL LDLT ADVOCATE PROCESS

In February 2002, a formal living liver donor interview process was established and a member of the UIMCC medical ethics consult service provided the first "donor advocate" interview. Since we began this service, 32 potential donors have been involved in our donor advocate interview process. Prior to January 2004, only adult-to-adult LDLTs were performed at UIMCC, but recently we have begun to perform adult-to-child LDLT procedures. The same advocacy approach is used for the living donor of a pediatric graft as is used for the living donor of an adult graft. Although the physical risks to living donors are different, based upon adult or pediatric recipients and various other health-related indicators, we strongly believe that the ethical issues related to either living donor are the same.

Why have a "donor advocate?" In the beginning, we wanted to make sure that potential donors were not feeling any coercion in their decision to make this type of donation. The interviews were informal—the first two

Table 1
Brief Timeline of LDLT

Date	Location	Type	Result
12/1988	Brazil	LDLT: parent to child	Recipient died
7/1989	Australia	LDLT: mother to son	Successful
11/1989	Univ. Chicago	Pediatric LDLT program started	--
1995	Europe & Asia	Adult-to-adult programs started	Currently practiced in approx. 30 centers
1997	U.S.	Adult-to-adult programs started	Currently routinely practiced in approx. 20 centers

took place in the cafeteria. The literature, although supportive of a donor advocate process, did not prove helpful in guiding this process or in offering any specific interview questions or tools to help us, so we simply started by discussing issues related to coercion and informed consent. As our process continues to evolve, we will surely clarify and define exactly what is meant by our use of the term "advocate." However, at the present, we would define our role of advocate as more of a donor "protector" and "educator," in that it is our job to assist in the process of informed consent as well as to highlight areas for the donor that might be potential problems in the donation process.

Through numerous discussions with the ethics committee's members and continuous reviews of the literature, our donor interview guidelines have taken shape (see appendix 1). One trained member of the Ethics Consult Service team, usually the director of the service acting as the donor advocate, interviews the potential living organ donor. It should be noted that, during this interview process, potential living donors are informed again, having been informed by the transplant team initially, that they are free to "back out" of this donation at any point in the work-up. All that is needed is a phone call or a discussion with the donor advocate, or any member of the transplant team. It has been the experience in our program that no potential living organ donor has made this call to back out of their donation. Potential living donors, have, however, been disqualified as a donor according to clinical or psychological criteria. Clinical decisions to withdraw a donor are made by the transplant team's physicians.

After each interview, the donor advocate prepares an interview summary using to the interview program outline, and sends a copy of this summary to the LDLT nurse coordinator. In addition, the advocate places a copy of this summary on the secured UIMCC intranet Ethics Consult Service web-board for review by the other members of the consult service/donor advocate team. This is very important, as it allows for almost instant peer feedback and eliminates the need for a team meeting, which can be very difficult to schedule. This real-time feedback is important to the interviewer, who can then follow up with the transplant team as appropriate.[3] We do not ask for a vote among team members on whether to accept or reject the potential donor, but rather ask that team members express any concerns that need to be followed up, either with the potential donor or the transplant team. On at least two occasions, an "emergency" meeting has been called between the ethics consult service and the transplant team to discuss some issues of concern related to the interview outcomes. This indicates that our process has been a thoughtful and important one in dealing with donor advocacy.

"IMPARTIAL OTHER" INTERVIEW EVOLUTION

The consensus statement from the Live Organ Donor Consensus Group (2000) regarding live organ donors suggests, "an independent advocate for the donor should be identified whose only focus is the best interests of the donor . . . and that donor advocates should be empowered with full veto authority if they believe donation to be ill advised."[4] This veto power by an independent team of advisors (or donor advocate) was originally included in the New York State Health Department's proposed new rules for live liver transplants, but was stricken from the final proposal.[5] The issue of veto power by a donor advocate is a controversial one, and one that we currently do not endorse. The donor advocate, although he or she keeps the best interest of the donor at heart, is only one step, albeit an important step, in the potential living donor work-up. Discourse among the various providers involved in the living donor work-up process is essential to this process. The opinion of the donor advocate team is given very high consideration by the transplant team, and this must be an essential component to any donor advocacy program.

Our team believes that the best independent advocate for the donor must not be related in any way to the transplant team, as it

is the only way to ensure the highest level of impartiality possible. Currently, our system calls for the ethics consultant/trained donor advocate to perform the confidential donor interview, to tell the donor that this information will be shared with a small donor advocate team (consisting of a registered nurse, a social worker, a medical doctor, and the pastoral care advisor), none of whom are employed by the transplant team. Ultimately, it is the surgical team who is responsible for the final decision on whether the donor goes ahead with surgery or not—but not without input from our donor advocate.

Our process typically begins with a monthly meeting between the LDLT nurse coordinator and the director of the ethics consult team. At this initial meeting, information on the potential living donor is reviewed so that we can discuss any major concerns prior to the interview process. After this meeting, the transplant nurse coordinator contacts the potential donor to set up an interview with the ethics consultant who acts as the donor advocate. We try very hard to conclude this interview process prior to the actual scheduling of the surgery, as we believe that having a date set for surgery may be somewhat coercive for the potential donor. The confidential donor advocate interview takes place in a private office between the potential donor and the advocate only. Should potential donors bring other family members with them, we ask the family to wait in the guest waiting area. The meeting lasts approximately 45 minutes. At the conclusion of the interview, potential donors are encouraged to write down any unresolved questions they have for the transplant team, and are given the ethics consultant's contact information in case they have any follow-up issues to discuss later. Typically, potential donors do not have contact with other members of the donor advocate team.

Although our surgeons have had experience, particularly in Germany, using paid donor advocates from the community rather than from the institution, we have not explored this option, nor have we been requested to do so by any of our potential living liver donors. This is an interesting concept, however, and one that needs further study. Although one could argue that simply being employed by the same institution as the transplant team is enough to create a conflict of interest within our donor advocate team, we strongly believe that this is not the case. Because the advocate team members are in no way dependent on the transplant department for monetary support, nor are we subject to any disciplinary sanctions related to the department, we truly do function independently. Our advocate team members are employed in various other departments within the institution and are not directly compensated for their advocate team role.

LIVING DONOR LIVER TRANSPLANT INTERVIEW GUIDE

We have written a donor interview guide, which is in constant revision, that helps direct the process at UIMCC (see appendix 1). We assess the following information.

General information. We collect information on the donor's age, relationship to intended recipient, family members, financial/emotional responsibilities, circumstances under which the potential donor was approached about the possibility of donation, the reason(s) the potential donor wishes to donate, reasons why this person has chosen to go through the donation work-up, the possibility of other family/friends' willingness to be a donor.

Issues of coercion. Does this potential donor feel that he or she can "back out" of the donation process? Does this potential donor feel any pressure to go through with donation by family, friends, recipient, transplant team? Does the potential donor feel personal pressure/obligation to go through with this procedure?

Personal responsibility issues. Is the potential donor employed, and, if so, what arrangements have been made for time off? Has the potential donor made financial arrangements for self or others while off work? What

would happen, financially, should the potential donor need to be off work for an extended time due to medical complications?

Advance directive issues. Does the potential donor have any form of advance directive and a will for his or her estate? If the potential donor has dependents, have legal arrangements been made for their care should the potential donor experience major health complications or death?

Two packets of advance directive forms and information are given to the potential donor—one for the donor and one for the intended recipient. Although these documents are not required, we encourage donors to fill out an advance directive, or, at the very least, to have a discussion related to advance directives with family members. We believe that by discussing advance directives, we can communicate the serious nature of this procedure, and this also allows the potential donor and recipient a way to bring up such serious but often uncomfortable issues with their family members prior to the surgery.

Informed consent issues. Can the potential donor describe the morbidity/mortality associated with the donation? Does the potential donor understand what will be done during surgery and the postoperative and recovery phase? Has the potential donor reviewed the consent form? Has the potential donor discussed mortality/morbidity with the transplant team? Does the potential donor have any questions for the transplant team?

During the interview, we ask that the potential donor write down any questions that he or she has for the transplant team on a piece of paper during our interview so the donor will not forget these questions.

Other issues. What if the transplant fails and the recipient's condition does not improve? How does the donor think he or she might react? What does the donor know about the chance of survival for the recipient with/without this surgery? In general, how does the donor feel about this procedure at this time?

Interview concerns. Are there any concerns that the interviewer wishes to highlight for the transplant team? Are there any items that the transplant team needs to follow up on? For example, we may ask the team to follow up on advance directives, or perhaps have a social worker follow up regarding financial concerns.

Interview summary. A typed summary of the donor advocate interview is sent to the transplant team.

OTHER AREAS TO BE ASSESSED BY THE DONOR ADVOCATE

In addition, we suggest that other issues be evaluated during the donor advocate assessment, including the donor's and his or her family's ability to cope with recovery and temporary change in the donor's role (that is, childcare and other duties typically assigned to the donor), donor's employer arrangements and financial hardships that may result if the donor is not able to return to work in a timely way, and potential future insurance difficulties (life, health) that are not known at this time. Our program and interview process expands on the clinical, social, and psychosocial evaluations done by the transplant team members, and includes ethical issues that transplant team/evaluators often do not emphasize.

THE IMPORTANCE OF THE DONOR ADVOCACY PROGRAM

A unique strength of our donor advocacy program is the attention we pay to contextual issues, such as family social dynamics, advance directives, and financial issues that the potential donor may not have thought through yet. We are currently working on a donor knowledge assessment tool that is related to general anatomy, mortality, and morbidity. Our consent process has been revised due to the experiences we have had with our donor advocate interviews. With the assistance of the UIMCC Ethics Committee, our living donor consent process has been revised to reflect the steps in the process, including separate consent forms for potential living donor evaluation and the living donor surgery consent form, each with educational information attached. Prior to our donor advocate program,

there was a single consent form that encompassed both the evaluation and surgical aspects of the living organ donation.

We would like to see some national donor/recipient criteria (especially the acceptable threshold of benefit to recipient versus risk to donor) and a national registry for donor morbidity/mortality information to help us in our donor advocacy role. To be able to truly advocate for potential donors, it would seem appropriate that information on all living donors be available for review. It is interesting that there is currently no national registry to which living liver donor information is reported. So it is somewhat difficult to gather accurate data on all such procedures done in the U.S. or elsewhere.

THE NEED FOR A NATIONAL LDLT REGISTRY

The American Society of Transplant Surgeons (ASTS), in May of 2000, announced the creation of a National Registry that would track the number of LDLTs. At that time, the ASTS announced that there was not enough information on the procedure to accurately assign risk to the donor. Cronin and colleagues also support an organized registry, but with some reservations: "Realistically, however, specialty societies may not have enough clout to regulate the actions of surgeons and transplantation programs. In the absence of professional self-regulation, private health insurers and government agencies, such as the Health Care Financing Administration (HCFA), should provide oversight."[6] Broelsch and colleagues further point out the dangers of inadequate data: "Report of donor complications to these registries is not mandatory but is, in our opinion, an act of honesty and intelligence. Unfounded rumors or false reporting may lead to external peer control that will discredit the medical profession, limit its actions, and jeopardize the existence of living donor liver transplantation."[7] A more recent article by Hanto further highlights the lack of concise LDLT morbidity and mortality data because mandatory reporting, as such, has not been fully instituted. He notes that although the literature has reported two deaths among 706 living liver donors, discussions at professional meetings have revealed that the number of living donor deaths may be as high as six among the first 600 procedures. A mandatory registry that would record data on complications and death among living liver donors, he suggests, "could be used in efforts to minimize the risk" of this procedure.[8]

ISSUES OF OBLIGATION, RISK, DECISION MAKING, AND CONSENT

Ethically speaking, perhaps intimates and close relatives have a greater degree of obligation to donate organs and should be allowed to accept greater risks for donation than would a donor who is a stranger, because of their shared interests and moral obligations.[9] However, as Spital notes, even if an intimate or close relative wishes to accept this risk,

> there is no absolute right to donate an organ, because . . . physicians are moral agents who are responsible for their actions and for the welfare of their patients. Therefore, while the values and goals of the potential donor should be given great weight during the decision-making process, physicians may justifiably refuse to participate in living organ donation when they believe that the risks for the donor outweigh the benefits.[10]

To this end, Spital describes an ethic of care that is "designed to guide and explain behavior in personal relationships" that may transcend being informed to the fullest when making a consent decision.[11]

Perhaps it is not possible to ever obtain fully informed consent, but we believe that there is a burden to obtain consent that is as informed as possible, providing each potential living organ donor with all of the available data we have. Although there is currently no database that provides accurate morbidity and mortality data to potential living liver donors, the transplant community has been proactive in developing some guidelines to assist potential donors with the decision to donate. On 25 April 2002, the ASTS published

a position statement on adult-to-adult living liver donation:

> The person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ.[12]

Other contextual donor criteria concerns that we review include potential donors who have multiple dependents, who may be unemployed, who are single parents, or who may be vulnerable in other social contexts. The principle of autonomy, when decisions about living organ donors are made, cannot be the only factor that is examined. Other relevant contextual information must also be taken into account.[13] Donors have to be chosen carefully to avoid not just medically, but also morally, questionable outcomes.[14]

These risks to donors must be reviewed in the context of the benefits to the recipient. This concept is one of equipoise. Broadly defined, the term *equipoise* describes the balance between the risks and the benefits attributed to the two arms of a research study group. To achieve equipoise, the risks and benefits to subjects in research study groups must be equal. Cronin, Mills, and Siegler note, with regard to LDLT, that there is a "double equipoise, . . . which reflects a balance between potential benefits and risks for both the recipients and the donors. In certain situations, the use of a graft from a living donor cannot be justified ethically."[15] The Live Organ Donor Consensus Group writes, "The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ."[16] According to the ASTS, "While it may not be possible to firmly state that adult-to-adult living donor liver transplantation should not be done in situations in which the recipient has a poor chance of overall survival, the added risk to the donor must be balanced with a realistic estimate of the chances of success."[17] UIMCC transplant surgeons do not have a specifically stated threshold whereby double equipoise would be met for living liver donors, but, rather, we evaluate the risk to each potential donor to the survival of the recipient on a case-by-case basis. However, a significant mortality rate, such as a rate of 20 percent for a recipient's survival at one year, would not be justified to accept the risks of mortality and morbidity for the living donor. For clinical indications that are accepted in a cadaveric liver transplant, the accepted success rate should be the same for a living donor transplant. The donor advocates do look at double equipoise issues and have maintained that the mortality risk to the potential donor must be less than the expected survival of the recipient.

It is extremely important that the donor advocate assess potential living donors' understanding of the morbidity and mortality that is associated with the procedure that they wish to undergo. A recent study that examined three years of data from 1,000 living liver donors reports that the mortality rate for LDLT was 0.5 percent and the complication (morbidity) rate was between 10 and 40 percent (most complications were mild, although some donors required further surgery for bile leak, bleeding, or hernia repair).[18] Broelsch and colleagues state, "There are no minor or major complications only complications that may alter the recovery of the donor."[19] In another recent study, Brown and colleagues report on 449 adult-to-adult LDLTs between 1997 and 2000 with a mortality rate of 0.2 percent and morbidity of 14 percent, stating that complications in donors are relatively common.[20] Again, we must emphasize that without proper reporting mechanisms, the figures related to morbidity and mortality are incomplete, as suggested elsewhere in this article.

Despite, perhaps, the overall lack of understanding related to the aspects of informed consent, morbidity, and mortality, it appears that living organ donors are generally satisfied after the donation. A recent study reports,

> . . . for most donors the decision to donate was easy or not very difficult and was made spontaneously. The amount of information about the risks of LRLT [living-related liver transplantation] was limited at the time of decision but increased remarkably immediately before the operation. In 28 percent, family conflicts occurred. Retrospectively, all but two donors (91 percent) would donate again. On average, donors started working after nine weeks and felt fully recovered after 13 weeks. Adverse financial affects were experienced by 41 percent of the donors because of the donation, and four of those received compensation. Importantly, quality of life did not differ between donors and nondonors.[21]

Goldman reports similar results in 1993; of the 20 donors surveyed, the donors were usually extremely committed to donation and "seemed almost unswayable in their convictions about the procedure. The decision to donate was made very quickly; further information had little impact."[22] These donors exhibited considerable denial or minimization about the potential risks to donors and were annoyed or surprised when reminded about them. Almost all of the donors described their willingness to proceed as "simply part of doing whatever you can for your child."[23] A major benefit gained by the donors was an increase in self-esteem.

The experiences of the donor advocates at UIMCC are very similar to these research findings related to the spontaneity of LDLT decisions; we also find that subsequent information related to morbidity and mortality does little to change donors' minds on going through with donation.

PSYCHOLOGICAL EVALUATION OF POTENTIAL LIVING DONORS

In addition to the independent donor advocate assessment, a trained psychologist should do a psychological evaluation. The Live Organ Donor Consensus Group writes,

> Factors that need to be taken into consideration in the psychosocial evaluation of the potential donor include, but are not limited to, ambivalence, guilt, depression, substance abuse, and vulnerability to coercion; the extent to which the decision to donate is consistent with the potential donor's values, including religious beliefs and sense of charity and community; the nature of the relationship between the donor and the recipient; the potential benefits to the donor; the potential medical risks and urgency of the donation; and the potential economic risks associated with donation.[24]

In addition, the group states, "Psychological evaluation offers an opportunity not merely to veto donation, but to intervene proactively to enhance both the donor's decision to donate and the actual donation experience of all involved parties."[25]

At UIMCC, a trained psychologist who is employed by the department of transplantation performs a psychological evaluation on all potential living organ donors. It might be the case that the psychological evaluation reveals just cause for withdrawal of the potential donor from the transplant work-up. For example, severe depression or suicidal ideation by the potential living organ donor would result in withdrawal until appropriate therapy was initiated, at which time the individual may be re-evaluated as a potential living organ donor.

The results of the psychological evaluations are often not available for review by the donor advocate prior to his or her interview, due to scheduling issues. The donor advocate team would, in any case, prefer not to review the psychological evaluation prior to their interview so as not to unduly bias the donor advocate interview process. Once all the clinical, social, psychological, and donor advocate assessments are complete, the transplant team meets to review and make final recommendations regarding the potential living donor. The donor advocate has not been involved in this

final process until recently, but now routinely provides input at this meeting.

CONCLUSION

There is no question that living organ donation decreases the wait time for those who need organ transplantation. The answers to the questions that are related to living organ donation are not as easily answered. Since we began to map out our living organ donor advocate program in 1998, with the first LDLT procedure in 1999, our process and our program have evolved greatly based upon our experiences. Our donor advocate team, along with the UIMCC Ethics Committee and transplant team, have worked closely to develop interview guidelines, consent forms, and educational materials for our potential living organ donors. We discuss our process and program each month at our ethics committee meeting, when we receive a postoperative report on our living organ donors from the transplant team. Our advocate process and program is reviewed and revised based on experience, the literature, and the expertise of our members. Currently, the donor advocate team does not conduct post-transplant follow-up interviews with our living organ donors, but we plan to institute a formal evaluation process for our donor advocacy program in the near future. More research and discussion in this area would be welcomed.

Rejection of a potential living organ donor for various contextual reasons, as opposed to various clinical reasons, may be viewed as exercising medical paternalism. Paternalism of most kinds, especially in medicine, is not popular, at least in the U.S., as it implies that someone other than the individual decides what is in the individual's best interest. Even in a best-case scenario, when the steps of informed consent have been adequately addressed, it may well be the responsibility of the independent donor advocate "system" to act to protect potential living donors from what it is they wish to do. This protection may possibly even extend beyond the personal autonomy of the potential donor.

ACKNOWLEDGMENT

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APPENDIX 1

University of Illinois Medical Center Ethics Consult Service
Living Donor Liver Transplant Donor Advocate Interview © UIMCC 2005

Date of interview: _____
Donor advocate: _____

GENERAL INFORMATION:

Potential donor name: _____
Potential donor age: _____

Who is the intended recipient and what is the relationship of the potential donor to this person? _____

List potential donor family members (spouse, children, and grandchildren): _____

Is this potential donor responsible for any other family members? (physically, financially, emotionally) _____

How was this potential donor approached about the possibility of them being a donor? (Did they contact the recipient? Did the recipient contact them . . .?) _____

What are the reason(s) this potential donor states for wanting to donate to this recipient? _____

Why was this person "chosen" to go through the work-up for donation? _____

Are there other family/friends willing to be a donor? _____

ISSUES OF COERCION:

Does this potential donor feel that he or she can "back out" of this process at any time he or she wants to? _____
Why or why not? _____

Does this potential donor feel any form of coercion to go through with this donation by the recipient, other family members, friends, transplant team members, others? _____

PERSONAL RESPONSIBILITY ISSUES:

Does this potential donor have a job? _____

If so, what arrangements has she or he made for time off? _____

Has he or she made financial arrangements for self and/or others while off work? _____

What would happen if the potential donor had complications that extended his or her time off from work? _____

ADVANCE DIRECTIVE ISSUES:

Has the potential donor made out any form of advanced healthcare directive, in case decisional capacity is lost after surgery? (Living will/durable power of attorney for healthcare?) _____

Continued next page.

Does this potential donor have a will for his or her estate? _____

If this potential donor has dependents (i.e., minor children/elder parents . . .), have arrangements been made for the care of these dependents should the donor not be able to do so after the donation, or in the event of death as a result of the donation? _____

(2 packets of advance directive forms and information given to potential donor—one for the donor and one for the donor to give to a recipient for discussion and use, if desired) _____

INFORMED CONSENT ISSUES:

Can the potential donor describe the morbidity/mortality associated with this procedure? _____

What does he or she believe is the risk of death with this surgery? _____

Has he or she reviewed the consent form and/or signed any papers? _____

How many times have the morbidity/mortality issues been discussed with the transplant team members? _____

Does the donor believe that she or he is well-informed about this procedure, as well as the post-op recovery phase?

Are there any questions for the team members? _____

OTHER ISSUES:

What if the recipient rejects the donation—how would the donor feel about this? _____

What is the donor's understanding of the survival rate to the recipient—in terms of years with and without this transplant?

How does the donor feel about this? _____

INTERVIEWER'S CONCERNS: _____

INTERVIEW SUMMARY: _____

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Wanted Dead or Alive? Kidney Transplantation in Inmates Awaiting Execution

Jacob M. Appel

The United States Supreme Court has held since 1976 that prison inmates are entitled to the same medical treatment as the free public.[1] In most states, this care includes major organ transplants—a matter that has produced widespread debate following California's decision in 2002 to subsidize a $1 million heart transplant for a 31-year-old convicted robber in his fourth year of a 14-year sentence,[2] and Minnesota's provision of a $900,000 lifesaving bone-marrow transplant to an incarcerated murderer with leukemia.[3] This controversy surrounding the cost of prisoners' health needs—both economic and social—took a macabre turn in 2003 when Horacio Alberto Reyes-Camarena, a 47-year-old dialysis patient on Oregon's death row, formally requested a kidney transplant. Such a procedure would have been likely to save the state money in the long run, as the transplant itself would have cost between $80,000 and $120,000 with an approximately $12,000 additional annual charge for immunosuppressant drugs. Dialysis, on the other hand, costs Oregon $121,025 per patient each year.[4] The surgery also appeared to be in Reyes-Camarena's best medical interests; studies report that a kidney transplant can decrease mortality in end-stage renal patients by up to 82 percent.[5] However, with more than 59,000 Americans waiting for kidneys, nearly 200 of them in Oregon, the prospect of such a transplant drew considerable criticism.[6] A review panel ultimately rejected Reyes-Camarena's request—for undisclosed reasons.[7] Yet with a graying and increasingly ill prison population, the question is bound to resurface: Should death row inmates be eligible for kidney transplantation? A combination of ethical and practical considerations suggests that they should be considered.

The American healthcare system still has an ambivalent attitude toward the premise that, to paraphrase George Orwell, some patients are more equal than others. In a society

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that is reluctant to expand overall medical expenditures, care continues to be allocated based upon a patient's ability to pay. However, the medical community has grown increasingly unwilling to allow non-economic social factors, such as the sick individual's perceived moral worth, to shape the quality of his or her care. Negative experiences with the "God committees" of the pre-Medicare era, in which lay people and physicians used criteria of "social worth" such as "level of education" and "future potential" to decide which renal patients were to receive scarce dialysis treatments and which would die, have turned many in both the medical profession and the public at-large against this sort of rationing.[8] While some commentators argue that patients' past disease-inducing behaviors should be used to determine their eligibility for scarce medical resources, such as barring liver transplants for recovered alcoholics, far fewer argue that the general social value or moral history of patients should determine the quality or nature of their care.[9] When it comes to healthcare, "bad people" are as equal as the rest of us.

The case of a death row inmate who requests a kidney transplant challenges these general principles in two ways. First, the criminal justice system—and not the medical community—has made a determination of social worth; according to the state, the inmate's social value is so low that he or she deserves execution. Second, although kidney transplants increase survival rates over dialysis, the decision not to transplant is not an automatic death sentence. Ignoring for a moment the ethics of capital punishment and the morality of a physician facilitating the practice—both somewhat dubious propositions—it does not follow that just because the state can take an individual's life, the medical community can lower the quality of that life in the interval prior to execution. Reducing the food rations of death row inmates, for example, would certainly be unacceptable. The state's determination of social worth only finds that the condemned prisoner no longer deserves life—a far higher bar than a determination that he or she is no longer worthy of healthcare prior to death. Moreover, the accuracy of the state's determination is often questionable. Conservative estimates suggest that 75 percent of death sentences are overturned on appeal, and one in 15 death row prisoners is eventually exonerated of all charges.[10] If physicians were to use the state's imprecise and fluctuating determination of social value to determine transplant eligibility, even innocent individuals of high social worth would suffer—and some would inevitably die. Alternatively, an effort by doctors to re-examine the criminal justice system's decision and to deny transplant only in cases of obvious guilt would place physicians in the awkward "social worth" evaluating role they are seeking to avoid.

A second set of objections to death row transplantation relies not upon considerations of social worth, but instead upon those of medical prognosis. Life expectancy, for instance, is considered to be a perfectly legitimate factor in allocating kidneys among free individuals. To place a kidney in an inmate who will soon die, the argument goes, is nothing more than squandering an organ. Several false premises underlie this reasoning. First, only a small fraction of death row inmates are ever actually executed. Of those who are eventually executed, the Bureau of Justice Statistics estimates that their life expectancy on death row now approaches 13 years;[11] 13 years is also the estimated half-life of a cadaver-donor kidney transplant—meaning that half of all transplanted death row inmates would die of natural causes before their execution dates.[12] When all of these factors are combined, the number of organs that would be "squandered" is relatively small. Second, the difference between the use of "natural" life expectancy as a factor in the allocation of kidneys and the use of the probability of execution as a factor is morally significant. The former has long been a staple of medical justice. In a system in which scarce resources must be distributed on some basis, this sys-

tem affords optimal organ use *without* making or affirming value judgments about the lives of individuals. In contrast, the use of a prediction of life expectancy that incorporates the probability of execution inevitably subrogates "medical justice" to "social justice,"[13] and affirms value judgments about the "social worth" of individuals. Such an approach rejects the egalitarian notion that non-economic social factors should play no role in the allocation of healthcare resources.

The general public, and many in the medical community, may have a visceral objection to death row transplants. When it comes to kidneys, however, the economics should give them some solace. Since transplantation costs less than dialysis, the state can reallocate the revenue saved toward other healthcare projects—presumably including many lifesaving endeavors. More lives might be saved by re-allocating these funds than would be saved by making the kidneys available to free people, especially when one remembers that kidney transplant is often a life-enhancing rather than a life-lengthening procedure. Many people do not want to hear this, of course. Much of the public would probably be willing to sacrifice healthcare resources if it meant that convicted murderers would *not* receive medical care. Courts have had the wisdom to think otherwise. They have not carved out exceptions for transplant cases and/or death row inmates, and no convincing reason exists for them to do so.

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Organizational Ethics

Recommendations for the Ethical Conduct of Quality Improvement

Ellen Fox and James A. Tulsky

INTRODUCTION

In the last few decades, quality improvement (QI) activities have assumed increasing importance and influence in healthcare. While no single definition of QI is widely agreed on, QI activities are generally understood to be cycles of action, linked to assessment, with a goal to improve the process, outcomes, and efficiency of healthcare services.[1] Healthcare quality is now routinely assessed through customer satisfaction surveys, clinical performance measures, and analyses of patient databases. But quality assessment does not always translate to quality improvement—for QI to occur, the information produced by quality assessment must be translated into systematic improvements in healthcare practices. A wide range of approaches has been used to promote improvement. These include educational interventions, performance incentives, regulatory and policy requirements, and information technologies, such as automated alerts to provide feedback to providers. When linked with the ongoing assessment of quality, such approaches have been lauded as highly effective in improving the quality of care.[2]

The basic principles of healthcare ethics are well established and include respect for autonomy, beneficence, nonmaleficence, and justice.[3] More specific ethical standards relating to medical treatment are described in a variety of sources, including codes of ethics, professional guidelines, consensus statements, published scholarly literature, and organizational policies. Ethical standards relating to research are also described in, for example, *The Belmont Report*, reports from the National Bioethics Advisory Commission (NBAC), and federal regulations.[4] In contrast, ethical standards for QI have not been clearly or thoroughly articulated.[5] For example, how do the ethical standards for treatment or re-

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The members of the Veterans Health Administration National Ethics Committee are listed in appendix 1.

search, such as those pertaining to confidentiality and informed consent, apply to QI activities? The answer is far from clear.

This article, which draws on a report by the Veterans Health Administration's (VHA) National Ethics Committee (NEC), is a preliminary attempt to fill this gap by providing practical recommendations for the responsible conduct of QI.

IS QI RESEARCH, TREATMENT—OR SOMETHING ELSE?

While the field of quality improvement is progressing rapidly, the concept of QI is constantly evolving and the dividing line between QI and other activities is not always clear. Although most activities can be easily categorized either as QI or not QI, some activities can be more difficult to categorize. At times, for example, it may be difficult to distinguish between QI and research.[6] In the "Common Rule," research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[7] Although elegant in its simplicity, this definition is problematic in several respects. First, the definition is tautological in that the word "research" is contained in the definition itself. Second, it is not clear when knowledge should be considered "generalizable." Although the U.S. Department of Health and Human Services (DHHS) recently attempted to address this question regarding the use of personal health information, the answer is still not clear-cut:

> We understand knowledge to be generalizable when it can be applied to either a population inside or outside of the population served by the covered entity. Therefore, knowledge may be "generalizable" even if a research study uses only the protected health information held within a covered entity, and the results are generalizable only to the population served by the covered entity.[8]

Another problem with the definition of research provided in the "Common Rule" is that it hinges on the purpose for which the activity was designed, that is, the investigator's intent. But intent may be difficult to define, even for the investigator.[9] Moreover, projects may be intended for more than one purpose. For example, a single project may be designed both to improve healthcare operations in a particular setting as well as to produce knowledge that can be applied in other settings.

A variety of other criteria to clarify the distinction between QI and research have also been proposed. These include whether the clinician-patient relationship is disrupted, whether an activity requires specific recruitment, whether the patients involved in an activity directly benefit from the knowledge to be gained, and whether additional risks are imposed to make the results generalizable.[10] In addition, NBAC has argued that a key distinction is whether the program in question is new or already established:

> If the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved. However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.[11]

While all of these criteria are plausible, no clear consensus has yet developed on how to distinguish QI from research. Further, some activities—such as demonstration projects or program evaluations—may not be "pure" examples of either QI or research, but rather a

"hybrid" of the two. This problem was aptly summarized in a recent report by the Institute of Medicine:

> As an applied field of study, Health Services Research (HSR) is closely related to non-research investigations that are directed toward assessing and improving the quality of operations in healthcare organizations. Indeed, HSR and healthcare operations form two ends of a continuous spectrum. Some HSR projects are clear examples of research; applying scientific methods to test hypotheses and produce new, generalizable knowledge. Other projects are certainly clear examples of internal exercises to assess the quality of the operations of the specific organization with no intention of producing generalizable knowledge. Many of these quality assessment or quality improvement (QA or QI) exercises are never intended to have any application beyond the specific unit within the organization that carries out the operation. In fact, many projects may start out as operations assessment and then become more like research, and many research projects involve doing very much what would be done in an internal operations assessment. As a result, for many projects, it is difficult to decide whether they are more like research, or more like QA or QI.[12]

As with the distinction between QI and research, the distinction between QI and treatment is not always clear. For example, it is a common practice in medicine for physicians to try therapies or administer drugs in a manner that differs from generally accepted practice standards.[13] Presumably, physicians also monitor the outcomes of these activities, at least informally, in an effort to improve care. When should such activities be considered QI rather than treatment? DHHS defines treatment as follows:

> Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to the other.[14]

In contrast, DHHS classifies QI under "health care operations," defined as:

> Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.[15]

DHHS further explains, "Treatment refers to activities undertaken on behalf of a single patient, not a population." Therefore, when a physician administers a therapy with the intent of improving care for that patient alone, the activity should be considered treatment; but if the physician administers the same therapy as part of a larger activity that is designed to improve care for a population of patients, the activity should be considered QI. But again, this distinction may not be particularly helpful, since many activities are intended to improve care both for individual patients and for a population.

Although some activities are clear-cut examples of either treatment, QI, or research, some activities cannot be so easily categorized. To the extent that QI differs from both research and treatment, however, the ethical frameworks that have been developed for these other areas may not be applicable. This report presents a new framework for thinking about the ethical conduct of QI.

WHY RECOMMENDATIONS FOR THE ETHICAL CONDUCT OF QI?

In the United States, as in other countries, a range of specific safeguards protects patients in the clinical setting. For example, physicians and other healthcare professionals have a widely recognized fiduciary duty to promote the interests of their patients. Professional ethics standards also require healthcare providers to protect patients' confidentiality and assure informed consent. Clinical behaviors are routinely scrutinized by peer review and other oversight mechanisms. Licensing standards, accreditation requirements, and statutory and case law further protect patients' interests. Healthcare providers who violate professional, regulatory, or legal standards are subject to a variety of sanctions and disciplinary actions.

Similarly, various government regulations, organizational policies, and professional guidelines have been developed to protect patients involved in research involving human subjects.[16] For example, federal law requires that, except for carefully defined exceptions, research at organizations that receive federal funding for research be reviewed by an institutional review board (IRB). This review must assure that informed consent is obtained from each subject, when appropriate; that research risks are reasonable in comparison to expected benefits; and that subjects are selected equitably.[17]

In contrast, there are no equivalent procedures to protect the rights and welfare of patients in QI activities. Yet there are at least six reasons why special protections for patients involved in QI activities may be warranted. First, the lack of a clear-cut distinction between QI and research, paired with the absence of clear ethical standards for the conduct of QI, provide a powerful incentive for investigators to "game" the existing system of protections by designating projects as QI rather than as research.[18] By doing so, they can avoid many of the time-consuming processes of research review, including stringent requirements for informed consent.[19] Until parallel standards are developed for QI, there will be a strong motivation to circumvent the system of research protections in favor of the more permissive environment of QI. For example, in one QI project, investigators initiated a program of pre-operative ultrasound screening in an attempt to prevent pre-operative blood clots, but later discontinued the program when it proved ineffective.[20] Some would argue that this project, approved as QI, was actually research, and should have been reviewed as such. Although the prevalence of this problem is not known, several other examples of research-like projects that have been labeled QI—and many more projects that are neither clearly QI nor clearly research—have come to the attention of the NEC; for example, through requests for guidance from the Ethics Consultation Service at VHA's National Center for Ethics in Health Care.

Second, some healthcare institutions are responding to the lack of a clear-cut distinction between research and QI by treating all QI projects as if they were research—that is, by requiring IRB review. This is problematic for several reasons. IRBs are already overburdened and are not equipped to handle a substantial increase in workload. The standards that apply to IRBs are in some ways ill-suited to QI. And, perhaps most importantly, IRB processes can be cumbersome and therefore discourage improvement efforts. Establishing specific protections for patients involved in QI might help to alleviate this problem.

Third, while QI is essential to good patient care and has brought tremendous benefits, QI activities are not entirely without potential burdens or risks to the patients involved. For example, psychosocial or financial harm can result from improper disclosure of personally identifiable information from databases. Embarrassment or resentment can result from being asked to address personal or sensitive topics in questionnaires. And patients may be inconvenienced or even potentially harmed by innovations intended to improve care. The actual frequency and severity of the potential burdens or risks associated with QI is completely unknown, however, because QI

projects are rarely tracked and reported in a systematic fashion.

Fourth, QI projects can create potential conflicts of obligation. Whereas treatment activities are primarily designed to enhance the well-being of an individual patient,[21] QI activities are primarily designed to improve the process, outcomes, and efficiency of healthcare services. When healthcare providers are involved in QI activities, they may face conflicts between their obligations to each individual patient and their obligations to all patients cared for by the system. For instance, a QI project might call for functional assessments to be performed on all patients in a new intensive case management program after one, three, and six months. Though such assessments may seem harmless, they are not entirely without risk. For patients who do not have paid medical leave from their jobs, the extra time required to complete these assessments might have a significant financial impact. For mental health patients with paranoia or obsessive thinking, repeated assessments could conceivably exacerbate these problems. Under such circumstances, physicians participating in the QI project would need to weigh their obligations to the individual patient against their obligations to improve care for all patients through QI.

Fifth, patients involved in QI may not always be able to protect their own interests. Patients may assume, incorrectly, that everything done to them in the clinical setting is intended to benefit them and them alone, or patients who are dependent on the healthcare system for their care may feel compelled to do whatever is asked of them for fear that they may jeopardize the care they receive. In this sense, patients involved in QI projects could be unwittingly used as means toward an end.

Finally, most healthcare professionals have easy access to patients and patients' records, but not all are trained in QI principles and methods. While ongoing QI efforts are encouraged, some QI activities may be poorly designed and unlikely to yield useful results, in which case not even minor burdens to patients can be justified. These concerns may be amplified as healthcare organizations offer financial rewards for involvement in QI activities.[22]

Thus, activities that are determined to be QI (as opposed to research or treatment) are not immune from ethical concerns about protecting patients. Instead of focusing on the distinction between QI and other activities, healthcare organizations should focus on assuring that the rights and interests of all patients are adequately protected, including those involved in QI. At the same time, however, healthcare organizations should take care that efforts to protect patients do not unnecessarily encumber the QI process. Healthcare professionals and organizations have an ethical obligation to monitor and improve the quality of care they provide.[23] By ensuring that healthcare providers adhere to standards of care, and by making efforts to minimize deviations from standards, an organization is taking important steps to safeguard the well-being of its patients. Thus, the ethical imperative to adequately protect patients must be balanced against the ethical imperative to continuously improve the care of patients. The principles and procedures suggested below aim to achieve this balance.

ETHICAL PRINCIPLES TO GUIDE QI

Principle 1: QI activities should produce benefits that outweigh their potential burdens or risks. In QI, as in treatment and research, it is unacceptable to impose even relatively minor burdens on patients unless a project can reasonably be expected to be valuable.[24] Therefore, QI projects should be well-designed, and the measures they use should be reliable and valid. To increase the likelihood of benefit, QI projects should be conducted by well-supervised personnel with adequate training in QI principles and methods or with access to consultative advice.

In addition, efforts should be made to anticipate and minimize even minor harms to patients that could result from QI activities. For any given QI project, potential inconveniences or other burdens to individual pa-

tients should be justifiable when weighed against the expected benefits to be gained, including benefits to participating patients, future patients, or the healthcare organization. Because the goal of QI is to improve the process, outcomes, and efficiency of healthcare services, the benefits of a QI project should be considered in relation to that goal.

Principle 2: QI activities should respect each patient's right to self-determination. A patient's right to self-determination is well-established in law[25] and in ethics.[26] Each patient's right to have his or her healthcare choices respected deserves the same respect in QI as it receives in treatment and in research. Although informed consent is the standard process by which respect for patients' choices is ensured,[27] an exhaustive informed consent process is not always practical. In practice, many minor treatments or procedures (such as splinting a broken finger or drawing blood for routine tests) are performed on the basis of "presumed consent" or after only a cursory informed-consent discussion.[28] Furthermore, the patient's signature on a consent form is required only for a minority of treatments or procedures.[29] In research, too, there are accepted circumstances under which the requirement of informed consent is waived entirely, or for which verbal consent, but not written consent, is required.[30]

In general, the thoroughness of the informed-consent process should be proportionate to the potential burdens or risks associated with the intervention. For instance, in clinical practice, physicians typically explain potential burdens in greater detail as the risks of a test or treatment increase.[31] Similarly, in research, standards are codified in federal regulations in which the need for written documentation of informed consent depends on the study's risks.[32]

In most cases, specific informed consent for a particular QI project is not required. Instead, "general" or "blanket" consent to QI activities (as might occur during a patient's admission to an in-patient facility) is generally sufficient for QI activities that pose no significant burdens or risks beyond those the patient would otherwise experience. On the other hand, when activities require the patient's cooperation (as in, for example, a customer satisfaction survey), patients should be informed that their participation in the activity is optional and that refusal to participate will not jeopardize their care. In addition, explicit informed consent is necessary whenever a QI activity involves significant burdens or risks. In some cases, consent may not be a reasonable option (for example, a QI project in which attempts at cardiopulmonary resuscitation are videotaped). For such cases, formal provisions should be made for proxy consent or waivers of consent, just as they are in clinical care and research.[33]

Principle 3: QI activities should preserve patients' privacy and confidentiality. In both research and treatment, demonstrating respect for patients' privacy and confidentiality is essential. In research, investigators often use codes to identify individuals, and may "delink" these identifiers to protect the privacy of individual patients. These strategies offer important protections. Indeed, federal regulations that determine the need for research review are tied to the extent to which data can be recorded anonymously.[34] Similarly strict requirements exist in the treatment setting. An example is the requirement for certification established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that facilities must demonstrate respect for "the needs of patients for confidentiality, privacy, and security."[35] In addition, the final privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) underscore the importance of protecting personal health information in the contexts of medical treatment, healthcare operations, and research.[36]

To assure that privacy is protected and confidentiality maintained, all QI activities should be conducted within the context of a healthcare setting in which accepted clinical standards for privacy and confidentiality are upheld. QI activities are an integral part of the healthcare organization's activities, and, as a result, the systems and protection that sup-

port privacy and confidentiality standards for clinical practice must be present. For example, access to confidential patient information should occur on a "need to know" basis, and information should generally be stripped of patient identifiers before it is exported.

Staff members with access to QI data should receive formal training regarding their organization's privacy and confidentiality policies and should agree as a matter of record to respect these policies. The organization might also maintain systems—such as an audit trail of access to information—to monitor and trace breaches of confidentiality. Finally, data analysis should make use of anonymous, or "de-identified," data whenever possible. Where this is not possible, QI activities should identify patients by codes to limit potential breaches of confidentiality. In both linked and de-identified databases, data privacy officers may be very helpful; for example, they can ensure that the codes for linked data are maintained securely and that "de-linked" data are rendered anonymous before they are released.[37]

Principle 4: QI activities should be fairly distributed across patient groups. Fairness is a central principle of the ethical conduct of research, and of the ethical practice of clinical medicine.[38] In research, fairness includes equal access to the potential benefits of research, and equal exposure to its burdens.[39] In clinical care, fairness requires that patients have equitable access to medical services and are not treated in a discriminatory fashion.

In QI activities, justice suggests two requirements. First, the potential burdens or risks of any QI activity should be distributed fairly across the population under study. For instance, risks of a loss of confidentiality, or burdens of surveys or questionnaires, should not be borne disproportionately by a single group, unless that group would also be expected to benefit disproportionately from the QI activity. Second, the potential benefits of a QI activity should be distributed fairly. For instance, an intervention designed to improve cardiac care should be implemented across a broad cross section of cardiac patients for whom the results would be relevant.

ASSURING THE ETHICAL CONDUCT OF QI

The effectiveness of protections for patients depends on the identification of a person or group who is responsible for the ethical conduct of the particular activity in question. For research activities, this person is the principal investigator; in medical practice it is most often the attending physician. For QI projects, however, the responsible person is not always clear. Indeed, QI activities may be conducted across organizations or units of service, and may be the product of collaboration between clinical and administrative personnel. Nevertheless, it is important to identify the individual who is ultimately accountable for the appropriate conduct of a given QI project, and who has the authority to assure that applicable ethical standards are followed.

In addition to the need to define a locus of responsibility for individual QI projects, there is also a need to define an administrative locus of responsibility for all QI activities that take place within a healthcare organization or an organizational subunit. QI is not an activity that is performed by an individual acting in isolation, but by a group of individuals acting on behalf of an organization. Furthermore, to be effective, QI must have organizational support: specifically, it must involve individuals with the authority to impose corrective action in response to assessment results.[40] Organizations should have one or more designated QI program office, standing committee, or other administrative entity that has specific responsibility for QI oversight.

As a matter of good management, organizations should not wait for problems to arise, but rather should promote the ethical conduct of QI proactively using a systematic approach. This approach should include educating individuals about relevant policy, tracking QI projects, handling questions and complaints,

assessing adherence to requirements, and instituting corrective action when necessary.

For all QI activities, consideration should be given to potential ethical concerns before an activity is performed. The level of scrutiny should correspond to the potential burdens and risks of the QI activity: activities that involve greater burdens or risks require more thorough scrutiny. For those that involve minimal burdens or risks beyond those inherent to the clinical encounter itself (for example, projects involving only retrospective or concurrent review of existing clinical data, routine patient satisfaction surveys, or educational interventions designed to promote evidence-based practices), self-regulation and retrospective review by the QI activity leader and the office that oversees QI may be sufficient to assure that ethical issues have been adequately addressed. But for other types of QI activities (for example, those involving evaluation of an innovative clinical program or service, collection of new data from patients other than by routine satisfaction surveys, or systematic assignment of interventions), a formal, prospective, external review process may be appropriate. Whenever burdens or risks are substantial enough to warrant formal review, and whenever there is an expectation of results worthy of publication, it is prudent to consider whether the QI activity contains one or more components that meet the definition of research found in the "Common Rule," and therefore require IRB review.

Who should conduct a formal review, when one is necessary? Possibilities include an interdisciplinary group that is convened specifically for this purpose; a pre-existing group outside the QI office but within the organizational unit, such as an ethics committee; or a group outside the organizational unit, such as a multisite review committee. In any case, the group should include individuals who are familiar with QI methods and individuals who are familiar with ethical standards, but should not include individuals who are involved in the QI project under review.

CONCLUSION

Beyond the general recommendations above, we will not suggest any specific policies or procedures for assuring the ethical conduct of QI. Before a particular approach can

Table 1

Recommendations for the Ethical Conduct of Quality Improvement

1. Healthcare organizations should recognize that QI cannot always be meaningfully differentiated from other activities that occur in the clinical arena, notably treatment and research.
2. Healthcare organizations should ensure that the rights and interests of patients involved in all healthcare activities—including QI—are adequately protected.
3. Healthcare organizations should take care that efforts that are designed to protect patients do not unnecessarily encumber the QI process.
4. QI activities should produce benefits that outweigh their potential burdens or risks.
5. QI activities should respect each patient's right to self-determination.
6. QI activities should preserve patients' privacy and confidentiality.
7. QI activities should be fairly distributed across patient groups.
8. Healthcare organizations should clearly define the locus of responsibility for the ethical conduct of QI.
9. Healthcare organizations should proactively and systematically promote the ethical conduct of QI.
10. Healthcare organizations should develop specific policies and procedures that fit their unique circumstances and needs.

be recommended, a variety of approaches should be tried and their results compared. Moreover, we are not convinced that there is one best solution for all healthcare organizations. A policy developed for a large tertiary-care medical center might be wholly inappropriate for a community clinic or nursing home. Similarly, a policy developed for a setting in which QI includes large-scale, methodologically rigorous data collection efforts might not make sense for another setting in which QI includes only small-scale cycles of designing, implementing, and assessing modest interventions intended to improve performance in specific, limited settings. For these reasons, we recommend that healthcare organizations use the general guidance provided in this report to develop their own unique policies and procedures that are appropriate to the types of QI activities they perform.

Our recommendations offer a starting point for thinking about how best to protect patients who are involved in QI activities (see table 1). Additional discussion is needed at several levels: within healthcare organizations to translate the general guidance offered here into specific policy, between and among healthcare organizations to ensure that protections are fair and consistently implemented, and that they function well, and at the societal level to assure that all patients receive the ethical treatment they deserve.

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DISCLAIMER

The views expressed in this article do not necessarily represent the views of the Department of Veterans Affairs or the official policy of the Veterans Health Administration.

APPENDIX 1

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NOTES

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Personal Perspectives

Ethical Evaluation of "Retainer Fee" Medical Practice

Mervin H. Needell and John S. Kenyon

THE PROBLEM

Modern changes in the economics of healthcare are pressuring doctors to increase their patient loads while decreasing their fees for services performed.[1] As a result, many practitioners see once highly regarded medical care threatened by a variety or combination of the following consequences:

- Tight office schedules, long delays for appointments, and little flexibility to accommodate patients whose problems consume more than the 15 minutes that third-party payers allot to primary physicians per patient visit.[2]
- Authorization by insurance companies, health-maintenance organizations (HMOs), and Medicare to pay only for services based on cost-control. This often means providing a minimum quantity and quality of acceptable care, even if other choices are preferable. Reports indicate that to cover expenses, doctors must now increase their patient loads, sometimes to levels that deny patients needed individual attention.[3]
- Insufficient time to return telephone calls promptly, if at all.
- Congested emergency rooms, with long delays for patients who have minor illnesses that their harried primary physician cannot find time to manage.
- Patients referred to specialists for problems that do not necessarily require a specialist's care.
- Frequent changes in patients' primary physicians, abetted by:
  - Patients who require hospitalization treated by a dedicated "hospitalist."
  - Employers who seek cheaper plans, which may provide a narrower range of coverage.
  - Insurance company rosters that list and "de-list" doctors based on economic criteria.
  - Dissatisfied patients who float from doctor to doctor seeking more attention.
  - "Physician extenders," such as nurse

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practitioners and physician assistants, who are now being increasingly used to reduce the amount of time that (higher paid) physicians spend with patients.
- Less time for patient-care advocacy.
- Less time and economic incentive for primary physicians to maintain and update their credentials.[4]

These changes reduce the public's confidence in doctors and distance patients from their doctors, resulting in a form of rationing through fear and inconvenience.

Although some patients may expect or need minimal service and remain satisfied under the current paradigm, other patients

- Have many concurrent medical problems and wish to use a "one-stop shop" physician, rather than shuttle among different subspecialists for each separate malady;
- Want to see their own doctor in the emergency room or at home (rather than wait for hours for an unfamiliar doctor);
- Choose not to wait for a doctor whose schedule consistently runs late;
- Want their doctor to intercede for them (with payers, employers, attorneys, medical consultants, nurses, and pharmacists);
- Value their relationship with their particular physician and his/her credentials, and do not wish to change doctors.

ATTEMPTS AT SOLUTION

Comprehensive insurance and managed-care programs have arisen in response to progressively increasing medical costs. These programs typically save money by setting limits to patient care. But cost-cutting has not solved waiting room delays and diminished professional time per patient visit. For example, in the interest of cost-containment, the *Miami Herald* reports that employers "herded workers into plans where they got doctors they didn't know and care they regarded as second rate, which was ladled out begrudgingly to boot."[5]

In response, some primary physicians in the United States and Canada have reduced the number of patients in their practices to accommodate the needs and wishes of those patients who are willing and able to pay extra for prompt access to and more personal attention from their physicians.[6] They do not claim thereby to solve all problems of current medical practice. Retainer fee medical practice (RFMP) offers patients round-the-clock cell phone access to its doctors, appointments on the same day they call, home visits when necessary, nutrition guidance, exercise physiology exams at patients' homes or health clubs, doctors to accompany them to specialists, and online access to their medical records.[7] In return for these benefits, and to compensate for the physicians' loss of income as a result of reducing patient load, each patient registered in such a practice pays a surcharge. This modification in medical practice has taken various names, such as Premier Care, Luxury Primary Care, Valet Care, Gold Card Care, VIP Care, Boutique Care, Deluxe Care, and Platinum Care. In this article, we refer to it as retainer fee medical practice, or RFMP. Variations exist among physicians' practices in the details of the arrangements, the amenities offered, and the amount of surcharge levied.[8]

To the extent that the circumstances described above fairly summarize current conditions in modern medical practice in the United States, a change of medical practice from the present fee-for-service or managed-care designs to RFMP would seem at first sight to be both socially and ethically desirable for those patients who are able and willing to pay for it. By reducing the size of practice rosters, RFMP makes adequate time available for physicians to attend to every patient in their practice. It does not claim to remedy the ills and shortcomings of contemporary medical care. Supporters of RFMP make the lesser claim that it serves an unfulfilled need and is available to those who can afford it. This principle accords with a capitalistic system such as ours. Whether or not medical care itself is ethically

consistent with a capitalistic system is beyond the scope of this analysis. Private practice has always been taken as an axiomatic paradigm in the U.S., but RFMP has generated a set of ethical concerns for the public and within the medical community. In this article, we explore the question: "Is it morally permissible for a physician to practice RFMP?" We do not want to give weight here to arguments that judge RFMP as merely socially desirable or undesirable. Social desirability is not incompatible with ethical impermissibility, or vice versa. Arguments that count in our analysis must have an ethical component. We do consider, however, a conditional argument that RFMP may be ethically permissible if only a few (but not too many) doctors practice in that style. By "argument," we mean a reason overridable by a stronger, competing reason.

We shall review and analyze relevant ethical concerns and arguments (both supportive of and opposed to RFMP) that have come to our attention. The chief ethical issues relate to access to care, quality of care, professional ethics and patients' rights, justice as fairness (including the cost of care), and physicians' reimbursement. Although we group these issues or arguments for the sake of convenient analysis, they are inextricably interrelated and are not neatly separate topics. For example, we would expect, with all things being equal, that decreasing the cost of care would increase access to care, and thereby improve the overall quality of care to the community while also fulfilling the ethical obligations of justice.

ACCESS

As the patient load of primary physicians in private practice increases, the time available for care per patient decreases. Patients then tend to wait longer to obtain appointments, endure waiting room delays, and spend less time in consultation with their doctors. As noted in the *Miami Herald*, "millions of Americans during the past decade have been enlisted in managed-care plans that tried to clamp down on medical spending by impeding access to care."[9] Although some patients may accept this inconvenience, others may bolt to another healthcare resource or deny themselves the care they seek. Either way delays or bars access to medical care. Since every physician's time and energy has realistic limitations, so must the number of patients and the time allotted to their patients be limited. It is reasonable to expect physicians to determine those limits for their own practices, according to their physical and emotional capacities. RFMP allows doctors to regulate their professional time per patient visit by limiting the number of patients on their individual rosters.

Various types of medical arrangements other than private practice care appeal to particular patients. For example, managed care has enrolled large numbers of workers and retirees. Others rely on comprehensive health insurance plans. These methods project attractive economic and utilitarian advantages and provide the public with alternatives to traditional private medicine.

On the other hand, third-party payers often limit benefits and present financial and practical barriers (such as copayments, restrictions in coverage, and rationing via frustrating or obfuscating administrative procedures), thereby impeding the care.[10] Such strategies represent cost-saving rationing, resulting in a market that puts goods out of reach of citizens, even when the citizens can afford to pay for these goods. Moreover, for patients who encounter delays and overcrowding in emergency departments, HMOs, and physicians' offices, access problems threaten quality of care through delayed or hurried treatment.

If only a few doctors limited their practices to RFMP, we would not expect an overall physician shortage. However, by excluding patients who are unable to pay a surcharge, conversion to RFMP by *all* primary doctors would surely constrain public access to medical care. We might need to determine how many RFMP physicians a community could accommodate without precipitating a shortage of medical care. At the present time, since only a few doctors have done so, that concern

is moot, except that RFMP doctors might be guilty of "free riding" (engaging in a practice that would be impermissible if all doctors did it), a philosophically suspect action, even if not illegal or immoral.

If a shortage were to occur as a result of RFMP, we would also have to address the ethical responsibilities of individual physicians to public safety, as opposed to the welfare of their individual patients. We could all probably agree that doctors are accountable to some degree for both their individual patients and for the health of and equitable distribution of health to the public at large. However, where lies the caregiver's greater responsibility? In traditional ethics, the patient-physician relationship has held priority over individual physicians' responsibility for political and public health issues.[11]

Moreover, where there is no shortage of doctors, patients with insurance/Medicare should always be able to find a licensed physician to attend them. According to Frank A. Riddick, Jr., "Physicians have an obligation to meet the needs of a community. You could do that with 10 percent of physicians in the area practicing boutique medicine." However, Riddick qualifies his contention, "if it gets much more than that then I think you really have to question the process."[12]

RFMP improves patients' access to medical care by ensuring prompt appointments, reducing or avoiding waiting room delays at physicians' offices, allowing adequate time spent with the doctor, and providing 24-hour on-call physician availability.[13] Moreover, critics of the market system acknowledge that even managed care and insurance plans have not fulfilled our needs. They look to a better and more "ethical" healthcare system, perhaps a single-payer universal program, which would facilitate simultaneous cost-control and universal access. As for RFMP, critics protest that it would exclude the neediest patients, cause "extravagant overhead costs and constraints on good medical practice and . . . endorse a system that stratifies patients even further according to their ability to pay."[14]

Large-scale social change may well be needed. However, only our policy makers can make major improvements on the public system. As a small-scale measure, implemented on an individual basis, RFMP does not purport to solve the access problems of all members of the society. The neediest patients are probably not those who cannot pay an extra fee; they are those who lack the resources to pay any fee or who earn too much to qualify for welfare assistance and too little to afford insurance. Given an imbalance of supply and demand for medical care, a level that society can afford for those unable to pay would probably not be acceptable to everyone. According to K. Sikora and others, "Widespread access may have to compromise quality."[15] In a society with scarce resources, tiers of need and demand necessarily call for different levels of response. RFMP is but one of those levels.

A capitalistic system such as ours offers alternatives. Those who prefer private practice care have the option to continue with the traditional system or, for a retainer fee, upgrade to RFMP. Just as not everybody flies first class or buys loge seats at the theatre, not everybody would choose RFMP for their medical care plan. All passengers on a plane touch down at the same moment and all spectators at a theater see the same play. RFMP patients receive the same care as others, but, in addition, pay for their privileges. This view neither ethically justifies RFMP nor condemns it as an unethical system.

QUALITY OF CARE

Quality healthcare may be defined differently by those who receive it, those who provide it, those who pay for it, and those who are personally uninvolved in the care. Patients would probably judge according to health outcomes (that is, the best health realizable). Physicians' perceptions of high-quality care also relate to adequate time with patients, clinical autonomy (freedom to make clinical decisions that meet the patient's needs), and continuity of patient-physician relationships.[16] According to G.D. Schiff and col-

leagues, high-quality care requires knowledgeable, caring, skillful, and humane caregivers achieved at the lowest reasonable cost, which should result in improved health for individuals and the community.[17] Although managed care has attempted to assess and improve quality of medical care, third-party payers tend to give emphasis to economic criteria. While the National Committee for Quality Assurance states, "the nation's healthcare system is riddled with 'quality gaps' that prevent millions of Americans from receiving 'best practice' care'," it admits, "among health plans that publicly reported their performance data, clinical care improved in most areas, such as coronary heart disease."[18] Disinterested parties, such as politicians and social planners, may use a combination of these criteria. The definition of quality care that is utilized in the following analysis will reflect the views of patients and physicians.

Provision of quality care is the primary ethical imperative for physicians. Judged intuitively, hasty examinations and hurried judgments and treatments are not likely to yield results as beneficial as careful and deliberate clinical care. Arguably, then, medical practitioners do better quality work when they have sufficient time to give their patients personal attention, exercise considered judgment, and are familiar with their patients' problems. Recent studies on overworked interns and residents have prompted mandatory rules guaranteeing relief from excessive hours on the job, for the benefit of both the interns and their patients.[19] Even truck drivers are not allowed to drive more than a limited number of consecutive hours.[20] To our knowledge, however, no such regulation governs the work of physicians in private practice.

The elaborate guidelines and protocols that are available to managed-care facilities include criteria and methodology for evaluating the quality of medical care. Nevertheless, Kongstvedt warns that predicting the future of outcomes, particularly in managed care, involves complex and daunting data analysis.[21] If this analysis is successful and fully implemented by managed-care organizations (MCOs), this strategy might well result in improved health outcomes and satisfy the unmet needs of patients and physicians. However, one can argue that, at present, both insurance companies and MCOs demand cheaper care and delay paying beneficiaries' bills, but have rarely advocated for better-quality care for patients.[22] On the contrary, RFMP offers patients more attention at a time when managed care pressures physicians to crowd ever more patients into ever shorter appointments.[23] Under the price and time constraints of managed care, physicians protest that they cannot ethically deliver the quality of medical care they and their patients desire.[24] In RFMP, however, physicians claim improved quality of care, achieved by eliminating important causes of impersonal or hurried care, diagnostic errors and iatrogenesis (inadvertent adverse events), and greater attention to quality-of-life and psychosocial issues.[25] Thus patients who choose RFMP use their own financial resources in the service of their own interests. The RFMP physician fulfills the ethical duty to provide excellence in medical care, and to respect patients' needs, comfort, and right to self-protection.

PROFESSIONAL ETHICS

Primary care physicians complain that managed-care and health insurance plans promote disincentives to professional excellence. The *Bulletin of the American College of Surgeons* reports that some of these disincentives include disallowals of payment for lengthy office visits (even when medically necessary), limitations on quantity and selection of treatments by "gatekeepers," (often an insurance employee empowered to allow or disallow payment for a treatment proposed by a physician), rewards to physicians for undertreatment, and contracts that make medical providers assume "financial risk" for their patients (for example, capitation, a strategy to tie physicians' incomes to cost-saving treatments).[26] Third-party payers have also rewarded doctors directly or indirectly for with-

holding hospitalization, referrals, or specialty consultations. These measures create an unacceptable conflict between a patient's welfare and a physician's financial interest. Fixation on cutting costs rather than on improving quality of care invites both lower quality and higher costs.[27] To economize at the risk of compromised quality of care sabotages treatment, undermines professional excellence, and violates the avowed ethical duty of physicians to safeguard their patients' health above other considerations.

RFMP's proponents claim that ensuring adequate compensation removes economic pressure on doctors to overload patient appointments.[28] This practice would avoid an ethically suspect source of conflict of interest. RFMP physicians disagree with the judgment of managed-care institutions that improved medical decision making can result from tinkering with physicians' rewards.[29] Again, to deny expensive treatment on economic grounds to patients who can afford to pay for it violates their right of self-protection. A further possible benefit of RFMP, because it is not burdened by a congested schedule, is to provide such basic services as immunizations or perhaps prenatal care, that overcrowded medical delivery systems are more likely to overlook.[30] On the other hand, managed-care supporters would reply that rather than rewarding physicians for undertreatment, the rewards are to avoid overtreatment. Similar arguments can support financial incentives to physicians for overutilization of hospital facilities and specialists.

Primary doctors are trained to manage many conditions that specialists also treat. When overburdened, physicians are tempted to refer patients to specialists for relatively minor problems that primary doctors are qualified to manage. When primary care physicians no longer have the time to manage these conditions, they may refer these patients, which results in "dumbing down" of their practice style, the overutilization of specialists, inconvenience for patients, and more delay in resolving problems.

Switching physicians and health plans discourages ongoing patient-doctor relationships.[31] Moreover, patients in managed-care clinics may not even see the same physician on successive visits.[32] Continuity of primary care, then, is a further strength of RFMP. Thus, RFMP tends to strengthen the patient-physician relationship while it assures choice of physician. These factors should lead to increased patients' satisfaction with their care. The patient-physician relationship supports ethical goals of physician professionalism and promise keeping, and patients' right to choose their own physician (autonomy).

In addition to medical obligations, physicians, like everyone else, are morally obligated to obey the law. According to the Florida Board of Medicine, "there are no statutes pertaining to Retainer Fee Medical Practice per se."[33] Although physicians may not legally charge more for medical services than the Medicare promulgated fee schedule, Medicare does allow doctors to charge for noncovered medical services, such as voluntary cosmetic surgery.[34] Most private health insurance plans do not pay all fees and services, the difference often being covered by an additional copayment or "balanced" billing (supplemental billing for fees not paid by insurance).[35] However, at least one state, Massachusetts, banned this practice.[36] The RFMP fee also covers an annual comprehensive physical exam, a service that Medicare excludes.[37] RFMP physicians argue that they adhere to the law by ensuring that their fees pay only for noncovered extras, that is, services not paid for by insurance or Medicare.[38] They therefore fulfill their civic obligation to obey the law while allowing patients autonomy in selecting their physicians and type of practice. Furthermore, a review by the Massachusetts Board of Registration in Medicine reports it had found nothing illegal in RFMP.[39] The American Medical Association has not taken a position on concierge practices.[40]

The practice of medicine is a profession, distinct from a commercial enterprise. Yet, in judging RFMP, partisans invoke ethical dis-

tinctions intrinsic to each. Libertarian and egalitarian values conflict when patients are not allowed to supplement their Medicare or health insurance by buying extra amenities. A libertarian view, taken by O.F. Norheim, asserts that to forbid people to purchase healthcare in addition to that available in a publicly funded scheme cannot be ethically justifiable.[41] By this argument, RFMP protects patients' right to use their money as they see fit.

However, an egalitarian position sees that RFMP undermines cross-subsidized care, a technique that helps to pay for poor and uninsured patients with funds from those able to pay.[42] Limits based on ability to pay amount to discrimination against the poor. As Relman argued in the *Boston Globe,* "The implication that well-heeled patients have the right to something more is abhorrent."[43] Robin Fiore argues that, by Plato's (that is, Socrates's) definition of the goal of medicine, the physician's self-interest must be subordinate to the interests of the patient. Fiore says that anyone who practices medicine with a different primary goal is not a doctor but a "schmocter" (a term she borrows from Robert Nozick), that is, is unworthy of the mantle of medical professionalism. In this appeal to social justice, she concurs with Bernard Williams that "the proper ground for the distribution of health care should be ill health or need, not ability to pay," and that physicians are elites with power to subvert the general health system. She concludes that injustice results from unequal access to healthcare, and therefore that RFMP does not qualify as "a moral practice."[44]

Edmund Pellegrino has argued that a medical license is not entirely a proprietary asset. Public funds largely subsidize medical education; also, because physicians learn their skills by practice on the public, they owe something back to the public in return, namely, making medical care accessible and not restricting access.[45]

Other critics of RFMP believe that physicians should not favor the wealthy over the poor. According to one indignant correspondent to the *Miami Herald*, RFMP is a greed-ridden concept;[46] it eliminates patients' choice of individual physicians except at substantially higher costs—payable by the patient.

These three egalitarian arguments against RFMP appeal to professional integrity (Nozick, Williams, and Fiore), to the obligation of all those who have received a publicly subsidized medical education to repay their debt to society (Pellegrino), and to renounce any self-interest that exploits innocent others by abandoning those unable to pay or charging extortionate fees.

In response to Fiore and colleagues, proponents of RFMP can argue that Socrates distinguishes health, the primary goal of medicine, from wage earning, a necessary accompaniment to the craftsman's art, without which the craftsman would not be expected to work and for which he provides benefit to the patient.[47] Each society determines the level of compensation. Although our own capitalistic system traditionally has rewarded physicians generously, RFMP physicians hardly expect to earn as much as professional athletes, entertainers, or CEOs, although on the basis of merit (as opposed to market), a case might be made for physicians doing so. In forming an opinion about the moral qualities of RFMP, Fiore cites the injustice of unequal access to healthcare, without acknowledging the inequities of our prevailing system, which, as a matter of policy, favors some groups (for example, elderly citizens, via Medicare) and excludes others (for example, uninsured poor people). Fiore also does not address quality of care as an ethical imperative, which RFMP strives to improve, while she ignores indictments of managed care for sacrificing quality for the sake of economy. However, are physicians "schmocters" because they limit the volume of their practice to give adequate professional attention to those patients for whom they have assumed medical responsibility, and in return expect to be paid fairly for their time and services rendered?

Granting that physicians owe a debt to society, perhaps for several reasons, as Pelle-

grino argues, physicians continually repay their obligations to society in many ways. They spend time and money to maintain competence through continuing medical education, arrange for round-the-clock availability, and serve without pay on hospital committees and medical societies to monitor and improve medical care. Thus, RFMP can contend that, in return for supporting doctors' initial training, the public receives the ongoing services of competent, caring, and diligent physicians. The public on whom doctors learned their skills may not have freely chosen to be used as teaching material, but did so to receive medical care, which was otherwise unavailable to them. The complimentary care that they received compensated them for their contribution to education. Further, private practice physicians have traditionally lowered or waived fees for indigent patients.

Nevertheless, society does not hold physicians hostage to their education. It does not take recourse against a physician who chooses not to practice medicine (for example, who obtains a Master of Business Administration degree and goes to work for an insurer) to recover the original public investment. We may wish to consider imposing a period of mandatory public service on medical school graduates as part of a program to address the needs of the uninsured, as is done in many countries with state-subsidized medical education. However, it is not in the power of practicing physicians to make medical care universally or uniformly accessible. Access to care is ultimately a political and social decision.

The emergence of RFMP reflects the inability of the current model of healthcare delivery to meet the needs of a particular segment of the population. It is also a challenge to our political policy makers and the profit-motivated insurance industry to improve the system. Paying for medical care has a long and well-established precedent. Historically, those who are able to pay more have borne a portion of the burden for those unable to pay (cost-shifting). The current trend discourages this traditional practice, thus depriving patients and physicians of the option of private charitable care. RFMP allows physicians extra time to treat indigents by the voluntary reintroduction of private charitable medical consultative care, through a return to cost-shifting.

In response to the above third objection, RFMP physicians maintain that they are motivated by professional values rather than greed. They offer personal and direct care to their patients, as physicians have done traditionally. For RFMP, economics should never trump patients' interests. And if the meaning of "professional" entails placing clients' interests above one's own, RFMP physicians find the practice of large volume clinics ethically dubious, especially those with rotating primary physicians who give impersonal, discontinuous service. RFMP represents ethical improvement even over the crowded offices of overworked private practitioners.

Physicians have a time-honored reputation as sincere, hard working, intelligent, educated, and capable individuals. Many have dedicated themselves to the practice of medicine for noneconomic reasons such as altruism, intellectual curiosity, and social prestige. Still, they have alternative options available with which to earn a living. When physicians no longer believe that they are earning incomes commensurate with their level of knowledge and skill, many will opt out of medicine, risking a shortage and mediocrity of physicians. By compensating physicians well, RFMP promotes high-quality care, and actually facilitates, rather than obstructs, eventual access as well.

JUSTICE AS FAIRNESS

We have argued that RFMP encourages and facilitates both therapeutic and preventive visits to the doctor, and provides prompt medical attention. RFMP physicians are not tempted to refer patients with minor health problems, which they themselves could suitably manage, to expensive specialists, to reduce their overloaded schedules. In these

ways, it opposes institutionally centered, misguided, economically driven goals. Thus, RFMP can serve patients' interests by reducing cost and by increasing service. High-quality care for individuals results in improved health for the entire community and an ethically desirable outcome. At the same time, those willing and able to choose RFMP get to enjoy the use of their financial property.

Contrarians object that RFMP addresses the wrong problem; that is, our system needs affordable universal coverage, not expensive, elitist, and exclusionary schemes. An ethical medical practice must work for justice as fairness for all. Critics further contend that it defeats the spirit of equality of care for all. They also claim that RFMP is social discrimination, as it stratifies patients according to their ability to pay. Further, RFMP allows an inferior product to some (non-enrollees) while offering superior medical care to others (enrollees). An individual who can afford to buy into RFMP has access to a service that is not available to others who are treated under the public system. Detractors of RFMP theorize that the only morally legitimate way to rank individual claims on medical services is by clinical need.[48] Further, they state that RFMP promotes the notion that different people are entitled to different qualities of care. As noted in the *Miami Herald*, "maybe it works for selling soap, but it is inappropriate for healthcare."[49] A spokesman for Senator Bill Nelson of Florida noted: "We are not against a doctor providing quality care and being adequately compensated in the private market. But you cannot impose a tiered system on seniors getting Medicare."[50] At stake in these arguments are ethical concerns of justice as fairness, and the special humane ethic of medical care, rather than crass commercial insensitivity in providing medical care.

RFMP physicians may plausibly respond that they do not presume to remedy the existing social stratification that characterizes every aspect of a capitalist society, from healthcare to pastoral care, legal services, access to food and nutrition, education, housing, auto safety, et cetera, many of which can be characterized as special, humane values. The economic stratification of healthcare, while subject to ethical challenge on egalitarian grounds and defended as a capitalist norm, has always existed in the U.S. Broader services and wider treatment networks are open to people who are willing to pay more for their medical care or to select comprehensive insurance. For several years, large corporations have been sponsoring executive annual medical check-ups at posh resorts.[51] While the very rich have always been able to strike their own deals with individual physicians, RFMP doctors across the country now have begun to put such amenities within the grasp of the upper-middleclass. Paul Ginsburg notes, "if private patients want to join a membership-only practice, they should."[52]

Our society has already recognized that different people are entitled to different qualities of care (for example, disabled, those over 65 years old, private insurance, corporate medical retreats, Medicaid, HMOs, the uninsured). RFMP is merely another category of care within an already stratified system.

The objection from Florida Senator Nelson's office to tiers within the Medicare system fails to consider the various options that exist under present regulation, which may readily be categorized as tiers. His argument suggests that Medicare should function as a rigid monolith without regard to differing preferences and requirements on the part of its beneficiaries, who have funded the program.

In further disagreement with RFMP, critics claim that, by imposing a surcharge on fixed fees, RFMP frustrates the intent of Medicare and insurance and managed-care contracts designed to limit escalation of the cost of medical care. Aaron and Schwartz argue that cost-containment measures must apply to everyone, regardless of personal means, to keep healthcare within everyone's reach.[53] In pursuit of this goal, Medicare, the federal health program for people 65 and older, limits its payment to doctors for covered services. Demanding more in the form of a retainer fee, Ginsburg says, "is a way of evading that requirement."[54] Even if RFMP is technically le-

gal, ethics forbids circumvention or disregard for the spirit of the law.

The RFMP defense avers that, as currently practiced, neither Medicare nor managed care fulfills the "spirit" for which they were implemented. If these programs do not promote the best interests of all beneficiaries, they should be opposed when they fail. No system devised so far has reconciled economic with ethical medical care goals. Medicare fee schedules do not pay for the level of service that many beneficiaries desire and can afford. The public cannot reasonably expect physicians to underwrite unrestricted service in return for restricted reimbursement. Further, Medicare is inadequate to meet every patient's medical needs; for example, it does not cover hearing aid prostheses. Moreover, mixed private and managed-care treatment is commonly allowed, both legally and ethically (for example, privately purchased appliances such as infusion pumps, the purchase of expensive drugs, and expensive infertility treatments). According to Norheim, to forbid people to voluntarily purchase healthcare in addition to that available in the publicly funded scheme is not ethically justifiable.[55]

Opponents of RFMP worry that when physicians "opt out" of publicly defined benefit packages, it will erode the quality-enhancing covenant of the overall medical system. Uniform sharing of costs encourages overall improvement. However, under a multitiered system, one that allows RFMP patients and providers to internalize an "everyone for himself or herself" ethos erodes incentives for improving the system overall. Justice as fairness demands placement of everyone's interests ahead of special interests. They reason that cost-containment measures must apply to everyone, including those able and willing to pay, if cost inflation is not to place healthcare beyond everyone's reach. Even a right to life has to be qualified, as there cannot be an indefinite duty for taxpayers to fund every treatment that might possibly be beneficial. Equality of care may be the price we must pay to avoid the vexatious consequences of a multitiered system.[56]

RFMP proponents reply that although cost-containment is prudent, managed economic systems do not have a secure record of fiscal success. In the *Miami Herald,* Wasserman argues that HMOs have suffered a "rash of . . . bankruptcies. . . . Creating a costly corporate bureaucracy whose sole purpose was to hold down costs never made much sense . . . it's fair to say that managed care has failed."[57] Many HMOs barely survive. Socialist systems have attractive aspirations and may work for small groups and communes, but, when applied to large-scale communities, demonstrably yield inefficiency and dissatisfied patients. Rather than brave the long queues and the uncertainty of being treated by their assigned medical professional at home, many patients flee the British and Canadian systems to the U.S. for private medical care in expectation of the prompt delivery of the competent care of their choice.[58] They apparently believe that market competition will more likely give them a higher quality of healthcare than will state-managed care. Not everyone agrees that this flight is widespread or is indicative of the superior quality of healthcare in the U.S.[59]

Finally, according to the *New York Times*, critics of RFMP maintain that physicians who are already in practice who deny their patients access to their services on the basis of ability to pay, in effect unjustly abandon their lower-income patients to cater to the wealthy.[60] In that view, the elitist consequences of RFMP amount to breach of contract and violation of the professional ethical duty of non-abandonment of patients.

RFMP proponents argue in reply that both medical ethics and the common law allow physicians to terminate their relationships with patients. Rather than retire or relocate for economic or professional reasons, physicians now have a way to treat their patients well while earning an acceptable living. At the same time, their patients retain access to care that would otherwise be lost. RFMPs' perspective sees the abandonment that is actually taking place as the one precipitated by reimbursement mechanism schemes that are

unacceptable to physicians. These schemes break faith with physicians by denying fair wages for work done. By not rescinding this injustice, society itself is guilty of abandoning the medical profession.

PHYSICIAN REIMBURSEMENT

During the past century, physicians have resisted political efforts to centralize and socialize medical practice, not only because they foresee a weakening of the quality of care, but also because control of medical practice would pass into the hands of nonprofessionals and because others would control doctors' financial destiny. Physicians contend that price controls by Medicare, Medicaid, and HMOs invariably lower physicians' fees and the quality of care, while they ultimately raise costs.[61] However, according to David U. Himmelstein, a national health plan, that is, a single-payer system managed by the government, would cover all our citizens, simplify reimbursement for providers, allow free choice of physicians and hospitals, and provide public accountability for quality and cost.[62]

On the other hand, RFMP helps to reverse this undesirable trend by paying the physician for rendering medical care more realistically than inadequate third-party pay schedules propose. It restores to physicians some control over their fees that they had lost with the advent of managed care. It reduces government control over professional choices in medical decision making. Ethical justification for this argument is grounded in promoting autonomy (both patients' and physicians') and fulfilling professional obligations (by restoring professional prerogatives and responsibilities) and justice (achieving fair compensation).

SUMMARY

This article examines the reasons that some physicians have recently opted to reduce the size of their practice rosters to allow more time for each patient in exchange for a retainer fee from patients. These physicians also offer supplementary, nonmedical amenities to patients as part of their service. Because physicians have reduced the size of their practice rosters and have increased the price tag for their services, some patients have lost access to their care. We have tried to assess the ethical propriety of such a change in the design of medical practices by weighing plausible, ethically relevant arguments favoring and opposing RFMP.

Physicians are ethically obligated first and foremost to promote and protect the health of their patients. RFMP fulfills this duty directly by ensuring prompt and ample professional time for the care of patients. It does so indirectly by allowing time for physicians' continuing education, which in turn should upgrade the quality of care. It also advances the ethical goals of autonomy as it allows patients to choose their own physicians and to spend their money as they please. On the other hand, these ethical positives are offset by the cost of retainer fees that may exclude access of patients to their physicians' care. Even if ethical tradition obligates physicians primarily to patients under their specific care, as professionals and as private citizens, they also have a responsibility to support the health of the entire community. RFMP does little to advance this cause, except that by optimizing the conditions under which their own private patients receive healthcare, they call attention to shortcomings in prevailing public healthcare policies, which by comparison fall short of that standard. An assumption that health is not properly a market commodity, and that all people should receive healthcare on equal terms, would expose RFMP to moral reproof.

From an ethical perspective, we find sufficient cause for concern and caution in this innovative style of practice. Nevertheless, the weight of arguments presented here does not seem to justify unequivocal moral condemnation of RFMP. As neither pro nor con views seem to have settled the ethical question, definitive moral judgment on RFMP will probably depend on the outcome of future experience and ongoing evaluation. The implications of RFMP for any future healthcare system are not clear, at least to us.

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Urine Trouble: Practical, Legal, and Ethical Issues Surrounding Mandated Drug Testing of Physicians

Martin Donohoe

INTRODUCTION

Healthcare organizations and medical schools have increasingly adopted mandatory pre-employment and random, not-for-cause drug-testing programs for physicians.[1] This article discusses the history of drug testing in the United States, the recommendations of policy-making bodies, the prevalence of substance use and abuse among physicians, and the data on the costs and benefits of such drug-testing programs.

When used appropriately, random and for-cause drug testing of physicians who have been rehabilitated of a substance-abuse disorder have been successful in maintaining abstinence and preserving doctors' careers. However, mandatory pre-employment and random, not-for-cause testing programs are based on poor science, are financially wasteful, and are unlikely to meet the programs' implicit goals of creating a safer clinical environment and diminishing errors while improving the quality of patient care. These programs usually ignore alcohol and tobacco (the major deleterious substances affecting performance and health), are often not designed to help those few doctors who abuse other substances get appropriate treatment, can create dissent among staff, and may inhibit an organization's ability to hire individuals who are unwilling to compromise their personal ethics by capitulating to what they consider to be an unjust policy.

The invasion of privacy posed by pre-employment and random, not-for-cause drug testing programs could potentially lead to other types of unwarranted testing and the dissemination of physicians' personal health data beyond the confines of their institutions. Indeed, increased drug testing is just one example of the increasing erosion of privacy in the U.S. I will describe the broader problem of erosion of individual privacy and will draw parallels with recent measures designed to protect patients' privacy.

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While the public has been increasingly concerned about the erosion of patients' rights to privacy, it also has expressed a desire for greater accountability by physicians, increased disclosure regarding the overall competency of healthcare providers, enhanced standards to protect the safety of patients, and higher standards for the quality of medical care. This article will describe effective interventions that not only protect the privacy of patients and healthcare providers, but also protect patients from incompetent and impaired physicians and enhance patients' safety and the quality of care.

DRUG TESTING: HISTORY, PREVALENCE, POLICIES, AND RECOMMENDATIONS

Substance use involves the taking of legal or illegal substances that does not lead to impairment of performance. Substance abuse involves a pattern of repeated, pathological use with adverse health consequences, habituation, tolerance, withdrawal symptoms, and impaired performance. "Impairment" refers to one's inability to perform competently one's duties as a result of substance use or abuse.

Drug testing in the U.S. began in the Armed Forces in the early 1970s, when reproducible assays were first developed.[2] By the late 1970s, prisoners were being screened, and, in the early 1980s, workers with defense contractors were screened.[3] Since 1986, when President Reagan instituted an executive order requiring federal agencies to institute drug-testing programs,[4] testing has spread throughout the public and private sectors.[5] The federal Drug-Free Workplace Act (DFWA) of 1988 mandates that all recipients of federal government contracts of $25,000 or more per year, and all recipients of federal government grants, must have written drug policies on employee substance use and abuse, establish a drug-free awareness program, and make a good-faith effort to maintain a drug-free workplace.[6] However, the DFWA does not provide instructions on how to implement its provisions.[7] Under the Omnibus Transportation Employee Testing Act of 1991, employers are only required to test workers who apply for, or currently hold, safety-sensitive positions in the transportation industry. There are no other federal laws that require private businesses to have drug-testing programs.[8]

Increasing use of drug testing has been noted in industry, despite opposition from the American Civil Liberties Union (ACLU) and other organizations.[9] In 1987, 21 percent of corporate members of the American Management Association, the nation's largest management development and training organization, had instituted drug-testing programs;[10] by 1996, 81 percent of major firms in the United States tested for drugs.[11] Among Fortune 1,000 companies, there has been a 1,200 percent increase in periodic and random employee drug testing since 1987.[12]

In 1988, the American Hospital Association recommended that healthcare institutions adopt comprehensive policies to address substance abuse, including pre-employment testing, for-cause testing, and post-accident testing, regardless of job description.[13] The American College of Occupational and Environmental Medicine finds it ethically acceptable, with appropriate constraints, to screen current and prospective employees for the presence of drugs, including alcohol, that might affect their ability to perform work in a safe manner.[14] The American Medical Association (AMA) also supports pre-employment drug screening.[15]

The purported goals of physician drug testing are to create a safer climate for patient care; to protect the university or institution from malpractice and wrongful hiring lawsuits; and to promote a positive view of the institution from patients and other "health care consumers."[16] In our competitive healthcare marketplace, when one hospital in a community institutes an employee drug-testing policy, others follow suit to avoid a negative image, which the public, which is generally uninformed about the nature of substance-abuse testing and treatment,[17] may attach to those without such a policy. To date, no court has held an employer legally liable for not having a drug-testing program. On the other hand, em-

ployers have incurred substantial legal costs defending their drug-testing programs against workers' claims of wrongful dismissal.[18]

While only 9 to 15 percent of hospitals surveyed in the late 1980s and early 1990s required testing,[19] the percentage is increasing.[20] That this trend parallels the impressive growth of drug testing in industry is not surprising, given the increasing corporatization of American medicine. In 1999, Montoya and colleagues found that two-thirds of 44 randomly selected large teaching hospitals had formal physician drug-testing policies.[21] For-cause testing and pre-employment testing were most common; 13 percent of policies mandated random, not-for-cause testing. In general, policies were vague on procedural details and unclear regarding responsibility for implementation of policy guidelines. Only half mentioned employee confidentiality, and less than half of these were explicit on access to and storage of records. All five major academic and community teaching hospitals in Portland, Oregon, where this author practices, now require pre-employment drug testing.[22]

SUBSTANCE USE AND ABUSE BY PHYSICIANS

Prevalence data on substance use and abuse by physicians and physician-trainees are marred by overreliance on convenience sampling, self-report, and variable definitions of substance-use and impairment.[23] Nevertheless, taken together, medical students do not differ significantly from age-matched peers in substance use patterns, except that they are less likely to smoke tobacco. In a survey of 23 medical schools, the AMA found that the substances most commonly used by medical students over a 30-day period were alcohol (87.5 percent), cigarettes (10 percent), marijuana (10 percent), cocaine (2.8 percent), tranquilizers (2.3 percent), and opiates (1.1 percent).[24] Less than 1 percent of respondents felt they were dependent on any substance other than tobacco. In a national survey, Hughes and colleagues found that alcohol was used by 87 percent and marijuana by 7 percent of third-year residents over the preceding 30 days, with 5 percent reporting daily alcohol use and 1.3 percent reporting daily marijuana use;[25] 1.5 percent reported using cocaine over the last month; 3.7 percent benzodiazepines (tranquilizers); none used these substances on a daily basis. The findings of a national survey conducted by Robert and colleagues (with a 52 percent response rate) are as follows: about one-fourth of students at nine medical schools suffered symptoms of mental illness, including 7 to 18 percent with substance-use disorders.[26] Among house staff, emergency medicine and psychiatry residents report higher levels of substance use.[27] House staff self-medication with benzodiazepines was not uncommon in the early 1990s;[28] today, house staff who self-medicate are more likely to use antihistamines for sleep, or selective serotonin re-uptake inhibitors for depression.[29]

Practicing physicians are no more likely to abuse substances than other professionals.[30] Physicians have lower rates of use and abuse of tobacco, marijuana, cocaine, and heroin than the general population, and do not appear to be at increased risk for alcoholism.[31] However, unsupervised use of benzodiazepines and minor opiates within the past year was reported by 11.4 percent and 17.6 percent, respectively, with higher rates of opioid use among anesthesiologists.[32] Whether such use impairs performance, through oversedation, or improves performance, through control of anxiety and pain, depends on the user, but such self-treatment is unwise at best and unethical at worst.[33] Prevalence rates for lifetime impairment of practicing physicians by drugs or alcohol range from 2 to 14 percent.[34]

THE "SCIENCE" AND COSTS BEHIND DRUG TESTING

Random testing is an imperfect way to identify drug abusers and is subject to both false-positive and false-negative results. Test characteristics relating to the metabolism of different substances can lead to situations in which a physician who snorts cocaine every Saturday night is likely to test negative on a

Monday, whereas an individual who attends a party and is subjected to large amounts of secondhand marijuana smoke, or who unsuspectingly ingests a brownie made with cannabis, will test positive two to three days later.[35] Moderate poppy seed biscuit ingestion can cause a false-positive test for opioids;[36] ibuprofen a false-positive for cannabinoids; and selegiline, an anti-Parkinson's drug, a false-positive for amphetamines.[37] Tonic water can show up as cocaine and Nyquil as an opiate or amphetamine.[38] Seriously impaired alcoholics, who far outnumber marijuana and opioid abusers, can easily be missed even though their mental and physical impairments (including withdrawal tremors, confusion/delirium, memory loss, and subtle nerve damage) are likely to cause greater morbidity. Until a Drug Enforcement Agency (DEA) ban on the use of hemp seed oil in 2003, many food products made with this ingredient contained trace amounts of tetrahydrocannabinol (THC), the active agent in marijuana. These products, which included pasta, candy bars, and salad dressings, could have caused false-positive results for marijuana.[39]

Multiple means of sabotaging drug tests and escaping detection, including adulteration, dilution, and the purchase of "drug-free urine," are described on a growing array of websites.[40] Ingesting large quantities of liquids, taking diuretics, or adding water or household bleach to a urine specimen can sometimes mask illicit drug use.[41] While many labs test for common adulterants, and some use temperature-sensitive cups to detect nonfresh urine and check specific gravity to detect possible dilution, it is not known how well the labs recognize "fixed" samples.[42]

Employee drug testing is expensive. The federal government's drug-testing program spends from $35,000 to $77,000 to find one user.[43] Most of the workers identified are occasional moderate users rather than drug abusers, and more than half test positive only for marijuana. If one out of 10 test positives is a drug abuser—what many consider a high estimate—then the average cost of finding one drug abuser would range from $350,000 to $770,000. If half of the detected drug abusers would have been detected anyway, through other means, the cost of using testing to find one otherwise hidden drug abuser is as high as $700,000 to $1.5 million.[44] Costs are likely to be higher when physicians are tested, due to lower rates of substance use and abuse.

There is no solid evidence that drug testing deters drug use;[45] only 8 percent of companies that test have performed any cost-benefit analysis.[46] Frequently cited estimates of lost productivity are based on data that the National Academy of Sciences concluded are flawed: "the data . . . do not provide clear evidence of the deleterious effects of drugs other than alcohol on safety and other job performance indicators."[47] Further, drug testing can have a negative impact on workplace morale, and the urine collection process itself is degrading and demeaning, particularly when it involves direct observation.[48] An analysis of 63 high technology firms in the computer equipment and data processing industry reports that drug testing actually reduced, rather than enhanced, productivity by creating an environment of distrust and paranoia, rather than one in which employees were treated with dignity and respect.[49] Some employers have dropped pre-employment screening because it unduly hindered their ability to recruit workers with the proper skills.[50]

PHYSICIANS' ATTITUDES TOWARD DRUG TESTING

Physicians' opinions regarding mandatory drug testing is mixed.[51] In one study of practicing physicians in the Midwest, 60 percent said that requiring drug testing to obtain hospital privileges infringed on their rights to privacy; 38 percent lacked confidence in the testing procedure.[52] While 56 percent of the surveyed doctors said that they would submit to mandatory testing without protest, 8 percent would refuse testing, 7 percent would hospitalize their patients in another institution, and 7 percent stated that they would file a lawsuit.[53] In a 1994 survey of family practice residency directors' attitudes toward man-

datory pre-employment drug testing, almost half disagreed with mandatory substance-abuse testing and said it should not be a condition of acceptance for a house officer position.[54] Program directors and medical students do not see testing as a positive aspect of a program.[55] In one study, 22 percent of senior medical students said that they would not rank, or would rank lower, a program with mandatory pre-employment drug testing.[56]

THE PHYSICIANS' DILEMMA: TO BE OR NOT TO BE TESTED

Since no laboratory test is 100 percent specific, false-positive results are inevitable. For nondrug users, the only type of positive test that would result from their urine being examined is a false-positive test. Rational, nondrug-using physicians might not willingly choose to risk their futures in medicine from potential false-positive tests. By participating in a drug-testing program, they put their public reputation and future employability in jeopardy (and in turn may disrupt long-standing relationships with their patients), threaten the large public financial investment in their training, and risk wreaking emotional and financial havoc on their families. Even so, given financial exigencies and the ubiquity of pre-employment drug testing, there is often no real choice for such persons. Furthermore, even if their initial test is later shown to be a false positive, even temporary removal from the workplace can cause undue suspicion and embarrassment, decrease income (especially for those paid per diem), and disrupt the continuity of patient care.

TESTING, TREATING, AND DISCIPLINING IMPAIRED PHYSICIANS

All rational physicians are in favor of improving the health of their professional colleagues, providing treatment in the most expeditious and confidential manner for those who have exhibited strong evidence of job impairment, and insuring the safe delivery of error-free care to their patients. Voluntary treatment programs for substance-abusing resident physicians have been supported by the Association of Program Directors in Internal Medicine,[57] and programs for substance-abusing doctors are available in every state and have been very successful.[58] This is likely due to physicians' high levels of education, motivation, and functioning, as well as possession of a professional career that provides financial and personal resources that can support and sustain treatment and recovery.[59] Nearly all (90 percent) of state licensure applications ask about substance abuse and inquire about functional impairment from substance use, not simply substance use *per se*.[60] If a physician self-reports and/or cooperates with treatment, state medical boards may not pursue disciplinary action.[61] Physician wellness and remediation programs have been fairly effective in ensuring the confidentiality, or at least the limited dissemination, of clients' information.[62]

In contrast, the medical profession has been slow to discipline adequately impaired or poorly performing doctors, which erodes the public's trust. Of 1,715 doctors who were disciplined for substance abuse by state medical boards between 1990 and 1999, only 32 (4 percent) had to stop practicing, even temporarily; others faced increased monitoring.[63] Stories of "bad doctors" who continue to harm patients are frequently reported in the lay press.[64] Some of these practitioners have not been adequately disciplined nor have they been stripped of their licenses or practice privileges due to impaired performance secondary to substance abuse. Increased restrictions on, and suspensions of, the licenses of these physicians is clearly warranted. Additionally, medical schools and training programs should improve and mandate curricula on physicians' impairment and substance abuse[65] and on reducing errors.[66]

THE GROWTH OF DRUG AND OTHER PRE-EMPLOYMENT TESTING

Trends in drug testing in the healthcare sector parallel those in public education.[67]

Over the past few years, in response to affirmative Supreme Court decisions, the number of schools that require expensive, mandatory drug testing has grown substantially.[68] School-based drug-testing programs promulgate misconceptions regarding drug use/abuse, increase the acceptability of drug testing in areas outside of medicine, and may enhance the public's willingness to accept the misguided notion that pre-employment and random, not-for-cause drug testing of physicians is an accurate and appropriate way to enhance patients' safety and the quality of care.

The explosive growth of drug testing in many spheres of employment has been fueled by popular misconceptions surrounding substance use and abuse, "junk science," business interests like the Institute for a Drug-Free Workplace (comprised of representatives from the United States Chamber of Commerce and corporations, including pharmaceutical and drug-testing companies),[69] and the public relations campaigns of a multi-billion dollar industry whose entrepreneurial interest lies in magnifying the severity of drug-related problems in the workplace and extolling the benefits of drug testing as a solution.[70]

In conjunction with the ascendancy of drug testing to meet the real and perceived needs of corporate employers, the following unscientific, poorly validated, and invasive (yet highly profitable) testing industries have blossomed: personality and "integrity" assessment,[71] polygraph testing,[72] background checking,[73] "snitch" programs,[74] and examination of prospective employees by substance-sniffing canines.[75]

DRUG TESTING AND THE EROSION OF PRIVACY

Employee drug and other pre-employment testing programs erode individuals' privacy. Many drug-testing programs require one to divulge prescription and nonprescription medications that one is using, since some of these can cause false-positive or false-negative test results.[76] More than one-third of the American Management Association's members reported that they tape phone conversations, videotape employees, review voice mail, and check computer files and e-mail.[77] Companies frequently conduct database searches of applicants' credit reports, driving and court records, and workers' compensation claims.[78] Some prohibit coworkers from dating, or ban off-the-clock smoking and drinking.[79] Nearly half of the Fortune 500 companies report that they collect data on their workers without informing them; a majority share employee data with prospective creditors, landlords, and charities;[80] 35 percent check medical records before they hire or promote; and some check urine pregnancy tests, using the same sample obtained for pre-employment drug screening.[81] It is not surprising, then, that the Federal Trade Commission found that 80 percent of Americans polled said that they are worried about what happens to information that is collected about them.[82]

The slippery slope of workplace drug testing for physicians and others could lead to the analysis of employees' hair for drug use, as hair is subject to external contamination from passive exposure and different sensitivities based on hair color;[83] testing urine for metabolites of medications used to treat conditions that may impair performance, such as antidepressants, anti-Parkinsonian agents, antihistamines and cold remedies, anti-seizure medications, and drugs for coronary and cerebral vascular disease; and genetic testing for diseases that may affect the length of one's potential career, such as tests for Huntington's disease or other early-onset dementias.

Today, as many as 10 percent of companies use genetic testing for employment purposes.[84] While 37 states have enacted legislation that prohibits discrimination in employment or insurance on the basis of genetic information, these laws provide little practical protection, as the burden of proof is on the applicant and discrimination is difficult to prove.[85] Some individuals who are at risk for genetic conditions have experienced discrimination based on their risk status.[86] Currently, only 15 states have enacted laws that help protect employees from genetic discrimina-

tion in the workplace; a few other states and the federal government have legislation pending.[87] In the last year of his presidency, Bill Clinton signed an executive order prohibiting federal agencies from using genetic information in any hiring or promotion decisions.[88] Of note, the American Medical Association opposes pre-employment genetic testing.[89]

There is no way to completely safeguard that information obtained through testing programs will not be shared with life, home, or health insurance companies (and, by extension, with pharmaceutical companies) or with future employers.[90] Indeed, one state's medical board's actions may be disseminated among other states' boards through the Federation of State Medical Boards,[91] and, in almost all states, may be made available to the public.[92] The National Practitioner Databank, which one day might be accessible to the general public, may contain information on actions resulting from physician impairment.[93]

It is unclear to what extent Fourth Amendment protections against unreasonable search and seizure and the Americans with Disabilities Act may protect physicians regarding disclosure of information or testing of bodily fluids.[94] Court challenges to drug testing based on the First, Fifth, and Fourteenth Amendments that alleged violations of due process and equal protection are generally unsuccessful.[95] It is interesting that the Canadian Human Rights Commission disallowed random and pre-employment drug testing of public employees, calling it a human rights violation under the Canadian Human Rights Act.[96]

Ethical questions abound regarding privacy, bodily integrity, and confidentiality. These unanswered questions include: Which physicians should be tested (clinicians, researchers, administrators)? How often? Who should have access to physicians' test results (and, by extension, potentially to other personal health data)? Also, if staff physicians' test results are going to be known to their division chief, department chair, and potentially to the dean and president of the university (as required by the local policies I reviewed),[97] then one might argue that staff physicians should be privy to their results (which is not the case in these policies). Physicians may reason that the decisions that the division chief, department chair, dean, and president make on a daily basis affect far more people (patients, employees, and members of the community) than those that physicians make, and that, indeed, their superiors are the individuals responsible for the educational, clinical, and social missions and the economic well-being of the hospital and university.

PATIENTS' PRIVACY

Ironically, the trend toward increasing drug testing of healthcare and other professionals and the multiple erosions of privacy discussed above come at a time when patients are expressing increasing concerns over privacy and access to their confidential medical records.[98] A study by the Institute for Health Care Research and Policy at Georgetown University reports that between one-fifth and one-fourth of Americans polled believe that their personal medical information has been improperly disclosed by a healthcare provider, insurance plan, government agency, or employer.[99] According to the same study, one in seven Americans polled, to safeguard privacy and avoid embarrassment, stigma, or discrimination, has withheld information from healthcare providers, provided inaccurate information, doctor-hopped to avoid a consolidated medical record, paid out-of-pocket for care that is covered by insurance, or avoided care altogether.[100] A Princeton study reports that a large majority of Americans polled oppose giving doctors free access to their medical records and are concerned about government agencies and researchers violating their privacy.[101] The Health Insurance Portability and Accountability Act (HIPAA) of 1996, implemented nationwide by the U.S. Department of Health and Human Services, attempts to address the public's concerns.[102] Unfortunately, HIPAA offers limited and burdensome protections to prevent the exchange of health information for marketing purposes.[103] Furthermore, implementation has been marred by confu-

sion, which has complicated cooperative care among different providers who provide care simultaneously for the same patient.[104]

CONCLUSIONS

Pre-employment and random drug testing of physicians is ill-justified. Tests are expensive, are based on poor science, represent an unwarranted invasion of privacy, and are unlikely to meet the purported goals of diagnosing functional impairment, improving patient safety, and enhancing quality of care.

Patients' and doctors' desires for privacy safeguards may clash with patients' demands for increased accountability by healthcare providers. To achieve both greater privacy and enhanced accountability, the medical profession will need to be more proactive in disciplining impaired and incompetent providers, improving substance-abuse education and training, and reducing errors through continuous quality improvement and other means.

SUGGESTED ALTERNATIVES/MORE EFFECTIVE WAYS TO IMPROVE QUALITY OF CARE

In our efforts to protect patients while safeguarding physicians' privacy, we should not rely on public relations gimmicks or costly, unscientific, and ineffective measures like pre-employment and random, not-for-cause drug screening. Instead, we should promote reference checking of new staff members to appraise previous job performance; train supervisors to identify, confront, and refer impaired physicians to drug-treatment programs; pay increased attention to physicians' job and life-satisfaction (including the early identification and treatment of depressive disorders, especially common in female physicians,[105] and marital discord); and support knowledge testing (through mandatory recertification), periodic hospital recredentialing, skills appraisal by colleagues and supervisors, and intermittent impairment testing (for example, periodic evaluation of vision, reflexes, and coordination) to determine doctors' fitness to perform their jobs safely.[106] Such testing can uncover not only impairment from substance abuse, but also that resulting from important physical disabilities (including dementia),[107] mental illness, and sleep deprivation,[108] which should prompt treatment or work-modification for the impaired physician (or the impaired worker in any major industry, for that matter). If impairment testing suggests drug abuse, then screening, treatment, license restriction and/or suspension, and follow-up drug testing are not only reasonable, but likely to benefit the physicians and their patients.

Institutions that are committed to improving job safety and quality of care should instead focus their attention and resources on system factors that cause or contribute to the majority of medical errors.[109] They can invest in computerized medication-ordering systems to avoid prescribing errors[110] and more ancillary staff to assist residents in non-educational tasks, which contribute to sleep deprivation, and in turn can lead to errors.[111] They should also enhance procedural training and oversight; encourage reporting, frank discussion, and analysis of errors; improve sign-out protocols; and reverse the trend toward downsizing registered nurses in favor of less-well-trained (and less expensive) licensed practical nurses and clinical nursing assistants.[112]

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DISCLAIMER

The author has never smoked cigarettes or marijuana. He drinks alcohol on a fairly regular basis, but has never drunk "on the job," nor has he been tested for driving under the influence, nor does it affect his job performance. His only experience with narcotics was medperidine after inpatient surgery, which provided a euphoric, pain-relieving ex-

perience. He left the hospital off pain medication, and gained an appreciation for how those whose lives are plagued by mental illness or the effects of poverty or who lack his personal resources may be derailed by the use of powerful, mind-altering substances.

NOTES

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