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Trouble in the Gap: A Bioethical and Sociological Analysis of Informed Consent for High-Risk Medical Procedures

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Abstract

Concerns are frequently raised about the extent to which formal consent procedures actually lead to "informed" consent. As part of a study of consent to high-risk medical procedures, we analyzed in-depth interviews with 16 health care professionals working in bone-marrow transplantation in Sydney, Australia. We find that these professionals recognize and act on their responsibility to inform and educate patients and that they expect patients to reciprocate these efforts by demonstrably engaging in the education process. This expectation is largely implicit, however, and when it is not met, this can give rise to trouble that can have adverse consequences for patients, physicians, and relationships within the clinic. We revisit the concept of the sick role to formalize this new role expectation, and we argue that "informed" consent is a process that is usually incomplete, despite trappings and assumptions that help to create the illusion of completeness.

Keywords

Informed consent; Sick role; Bioethics; Sociology, Medical; Bone marrow transplantation; Qualitative research; Australia

Introduction

Health care professionals have long struggled with how best to incorporate appropriate and thorough consent processes into their interactions with patients prior to medical treatment. To this end, most health care organizations and professional groups have developed standardized routines and legalistic documents for patients to sign upon hospital admission and/or before treatment begins. Concerns are frequently expressed, however, by health care professionals and also by scholars in legal studies, bioethics, and the social sciences about the extent to which these formalized procedures actually lead to "informed" consent. Scholars in the sociological literature have recently sought to highlight problems in the practice of consent by focusing on the intersection between bioethics and social science. Bosk (2010), for example, argues that medical sociologists have exposed a rift between *principle* and *practice* in consent processes: Whilst the discourse of bioethics focuses on basic principles such as respect for autonomy (e.g., Beauchamp and Childress 2009), empirical sociological research in the 1970s showed how the reality of knowledge asymmetry between patients and physicians acts as a practical barrier to patients' decisional authority, and thereby "demonstrated how much a more muscular concept of informed consent was needed in clinical and experimental settings" (Bosk 2010, p. S142).

In this paper, we extend this line of inquiry by focusing on the nexus between consent and the sick role (Parsons 1951; Parsons 1975). Each of these concepts on its own has generated a substantial literature, but the two are seldom considered together. Our overarching argument is as follows: As the practice of obtaining consent has become embedded in formal organizational practices in the clinic (partly in response to legal developments [National Health and Medical Research Council 2004a, 1] and pressures for more formalized professional codes of conduct), a strengthened version of consent has in fact emerged in recent years—one that is frequently referred to as "*informed* consent"—and this has placed new expectations on patients. However, these expectations are neither

well recognized, nor articulated in a way that produces a satisfactory conclusion to the consent process, especially for high-risk medical procedures. We propose that revisiting the concept of the sick role offers a fruitful avenue for theorizing about, and formalizing, this new role expectation.

To flesh out this argument, we briefly offer an overview of the concept of consent as it is formulated in bioethics (Beauchamp and Childress 2009; Kerridge, Lowe, and Stewart 2009) and of the sick role (Parsons 1951; Parsons 1975). We then turn to a clinical setting where consent poses a significant challenge, in order to present empirical evidence of some of our claims. In the concluding section, we discuss theoretical extensions and offer observations about how insights from this approach can be incorporated into medical practice.

Theoretical Framework

Biomedical Ethics and Expectations on Professionals

The discourse of biomedical ethics is primarily concerned with prescribing how sick people and research participants should be treated. It aims to prevent harm to these parties, whom it frames as vulnerable and whose autonomy is held to be a primary concern and of paramount value. Importantly, the threat of harm is seen to emanate from within relationships between patients and medical professionals and researchers. The reason for this is historical. The development of biomedical ethics in the 20th century was spurred by moral outrage over the role of physicians in human experiments conducted under the Nazi regime. Thus, it is no coincidence that the section on informed consent in the standard biomedical ethics text (Beauchamp and Childress 2009) is nested in the chapter on autonomy, which takes the Nuremberg trials as its point of departure.

Seeking consent for medical treatment is one of the main ways in which the principle of respect of autonomy finds expression in medical practice. When applied to medical treatment, consent generally refers to an autonomous authorization given by a patient for a specific medical procedure. The concept is commonly explicated in terms of several elements—those that concern the *validity* of consent and those that concern *information* (e.g., Beauchamp and Childress 2009; Kerridge, Lowe, and Stewart 2009). The validity of consent is vouchsafed by ensuring (i) that it is given *voluntarily* and (ii) that the person giving it is mentally *competent*. The criterion of voluntariness is a bulwark against coercion (i.e., consent obtained by coercive means is invalid). The criterion of mental competence is a bulwark against exploitation (i.e., consent obtained from someone who is not mentally competent is also invalid).

In addition to these elements of validity, consent entails elements that concern information in the form of (iii) *disclosure* and (iv) *understanding*. Disclosure refers to a duty that clinicians have to inform patients about (in particular) the risks and benefits of the treatments or procedures being considered. Understanding refers to the subjective outcome of activities that clinicians undertake to fulfill their duty to inform patients.

In recent years, greater emphasis has come to be placed on the informational elements of consent. The most tangible sign of this trend is the expansion of consent forms themselves to include detailed information, especially about the possible risks of treatment. The significance of this trend becomes clearer if we consider how the elements of consent that concern validity differ conceptually from those that concern information. Voluntariness and competence are *protective* of autonomy—they defend against threats to it—whereas

disclosure and understanding are *productive* of autonomy—they augment it by redressing the knowledge asymmetry in the doctor–patient relationship. The difference is between a reactive process and an active one. The increasing emphasis on the active, informational elements of consent is in keeping with the tenets of patient-centered care, which aim to facilitate and encourage the involvement of patients in their own care and increase their decisional authority. Thus the intensification of efforts to inform and educate patients more broadly can be seen as a trend that serves to strengthen consent by increasing the degree to which it is "informed."

Of the four elements of consent, in practice the greatest uncertainty surrounds the element of understanding. How can physicians know whether and to what extent their patients understand the information that is given to them? There is a growing literature on how to improve patient understanding during the informed consent process (see, for example, Flory and Emanuel 2004; Schenker et al. 2011; Schenker and Meisel 2011), but it tends to focus on interventions and techniques that the health professionals can use to enhance communication (Schenker et al. 2011). This literature has yet to engage with the issue of changing norms and expectations about *patient* behavior in the consent process. We contend that the intensification of efforts to inform and educate patients has placed new expectations on patients, but that patients are often unaware of these expectations because they are largely implicit. Further, we will argue that trouble arises when these expectations are not met. To illustrate this part of the argument, we draw on the concept of the sick role.

The Sick Role and Expectations on Patients

If bioethics is primarily concerned with how patients and research subjects *should be* treated, medical sociology is primarily concerned with how they *are* treated, and the sick role (Parsons 1951) is a seminal concept in this field. According to the Functionalist school of sociology from which this concept derives, health is necessary for the smooth functioning of society; and because illness interferes with a person's capacity to perform his or her normal social roles, it is a form of social deviance that is contained and rectified by means of an "institutionalized role or niche" (Williams 2005, p. 124). This role—the sick role—can be characterized as a contract or exchange between an individual and wider society, in which a person gains certain special permissions or exemptions in return for taking on certain responsibilities. The terms of the contract are roughly as follows: If someone is deemed to be legitimately sick, that person is exempted from his or her normal social obligations and from a degree of personal responsibility for the condition. However, these exemptions are "given at a price" (Parsons 1951, 151). The person has a responsibility not to linger in the sick role in order to take advantage of these exemptions; the person also is expected to seek medical assistance, to assume the transitional role of patient, and to cooperate with the physician in order to get well. The sick role has a set of complementary expectations that apply to physicians, who are essentially expected to competently apply their technical skills to facilitate a swift recovery (Williams 2005).

Because Functionalist sociology frames sick people not as vulnerable but as a *deviant* element of a social system that needs to be contained, it sits somewhat uncomfortably within a bioethics context. The concept of the sick role nevertheless retains a degree of explanatory power (Williams 2005; Varul 2010), and it is particularly useful for our purposes because it has been the main means of theorizing—and thereby recognizing, describing, and accounting for—expectations that are placed on patients. This is important particularly because biomedical ethics is largely silent on such issues. In this article, we focus on the

expectations that are placed on sick persons, but we also discuss expectations surrounding the physician's role in the consent process.

Table 1 summarizes the foregoing discussion, showing the expectations placed on physicians and patients that derive from biomedical ethics and from the sick role, respectively.

Table 1. Role expectations placed on patients and on physicians

Actor	Theoretical Frame	Role Expectations	Explicit	Implicit
Patient	Sick Role	• Seek medical assistance when ill.	x	
		• Cooperate with physician to get better and do not linger in the sick role.	x	
Physician	Bioethics	• Obtain patient's consent before beginning treatment.	x	
		• Assure that patient's consent is valid (i.e., given voluntarily, by a mentally competent person) and informed (i.e., given with disclosure and understanding).	x	
Patient	Sick Role / Bioethics	• Participate in the consent process by demonstrating engagement in physician's efforts to secure patient's understanding.		x

In essence, the sick role can be defined as "the set of patterned expectations that define the norms and values appropriate to being sick, both for the individual and others who interact with the person" (Cockerham and Ritchey 1997, p. 117). When social norms or expectations are not fulfilled, furthermore, *trouble* in social relationships commonly results. As Parsons points out, an important emphasis in social science "is on the factors responsible for 'something's going wrong' in a person's relationships to others during the process of social interaction" (1951, 148). Importantly, this proposition applies to the sick role itself. Thus, we can expect that trouble in relationships will arise when people do not conform to the sick role.

Nonconformity with the sick role is an issue that has already received a lot of attention. For example, there is an extensive literature on problems surrounding noncompliance with (or nonadherence to) recommended medical regimens and treatment (e.g., DiMatteo et al. 2002; DiMatteo, Haskard, and Williams 2007). In addition, we contend that a different kind of trouble can and does arise in the lead up to and in the process of treatment, as a result of changing expectations that have emerged due to the practice of seeking informed consent for treatment. In what follows, we illustrate our argument

empirically with data from a set of interviews conducted in the bone-marrow transplantation setting, a context that is particularly fraught with concerns about informed consent because of the extreme nature of the treatment, the likelihood of serious side effects, and the high degree of uncertainty that attends decision-making.

Methods

Setting

Allogeneic bone-marrow transplantation (hereafter simply BMT) is a complex sequence of procedures that involve a patient, a donor, and a team of health care professionals with highly specialized skills in an aggressive effort to treat advanced cancer and several other life-threatening conditions. BMT is an extremely challenging treatment for patients and is usually recommended only after previous treatments have been unsuccessful. Patients who undergo BMT face prolonged hospitalization, often in isolation, recurrent invasive medical procedures, and a range of severe and toxic side effects, which can themselves be life-threatening. Professionals' decisions to offer (or recommend) BMT, and patients' decisions to consent to it, typically involve complex trade-offs between probable harms and benefits.

Before raising the prospect of BMT with a patient, the transplant team considers whether the patient's disease is treatable with BMT and then assesses whether the patient is an acceptable candidate for BMT from a medical point of view. Many of the procedures and entities involved in BMT will be entirely new to the vast majority of patients and are not commonly part of lay knowledge (e.g., human leucocyte antigen typing, stem cells, graft-versus-host disease, and chimeras). Specialized professionals working in the BMT setting, therefore, go to considerable lengths to educate and inform patients as part of the consent process. These efforts occur in a context where the law and policy guidelines have had much to say about standards of disclosure, but very little about the problem of understanding.

Participants, Data Collection, and Analysis

The data reported here constitute part of a larger study designed to examine the principles and practices of those involved in the consent process in high-risk medical procedures. In this paper, we draw largely on interviews conducted with 16 health care professionals who specialize in the BMT setting. The study also included interviews with 16 patients, which we refer to here only in passing. Methods and findings related to the interviews with patients have been reported elsewhere (Forsyth et al. 2011).

The health professionals in the study were sampled from the bone-marrow transplant units of three tertiary teaching hospitals in Sydney, Australia. A stratified, purposive sampling technique was used (Miles and Huberman 1994) in order to recruit individuals representing the various roles in the transplant team. These include the transplant hematologists (a subspecialty within hematology), who function as the transplant team leaders (n=7); and other members of the transplant team (n=9), who are involved in the consent process and patient care during and after the BMT procedure. These other team members included three nurses, two transplant coordinators, one care coordinator, one radiation oncologist, one patient representative, and one social worker.

Participants were identified through the three study sites. The transplant hematologists were approached directly with a request for an interview. Next, the other transplant team members were identified through the BMT units, with input from the transplant team leaders; these potential interviewees also were approached directly with a

request for an interview. Of the health professionals approached for interviews, one declined to participate.

Semi-structured interviews with the transplant hematologists focused on their interactions with patients during consultations. Topics included communication of the risks and benefits of the transplant, expectations of physicians and patients, patients' involvement in the information exchange and decision-making process, and the responsibility patients had for their own health. Semi-structured interviews with the other transplant team members focused on their role in providing patients with information about the transplant and its side effects, the patients' involvement in the process, and the role of family and support systems.

Each participant was interviewed privately at the study site by a member of the research team. Interviews averaged one hour each. Interviews were digitally recorded, with interviewees' permission, and professionally transcribed. To supplement the interviews, two of the authors attended patient education sessions at one of the hospitals as nonparticipant observers. Data were collected between 2007 and 2009. Ethics approval was obtained from the Human Research Ethics Committee (HREC) of the University of Sydney and the HRECs responsible for each of the participating hospitals, in accordance with ethical standards of Australia's National Health and Medical Research Council.

The authorship team systematically coded the interview data, using an interpretive approach that drew from the bioethics literature and the medical sociology literature, coupled with a keen awareness of emergent themes in the data related to the sick role within the context of consent. Thus, we tacked between the interviews and relevant theoretical literature to develop a set of codes and to hone our understanding of the observations reported next.

Results

Our study began after the patients had already sought medical assistance for their illness (the first expectation placed on patients, according to the sick role, as shown in Table 1). We are interested in the next set of expectations shown in Table 1 that pertain to the physician's role and, subsequently, the patient's role in the consent process. Thus, following Table 1, our observations from the interviews are organized according to the perceptions from the health care team about (a) expectations placed on physicians about their role in the consent process and (b) expectations placed on patients about their role in the consent process. In both cases, we provide evidence of reported behavior from interviewees that conforms to these expectations or fails to do so. We then present evidence of (c) intimations of trouble when expectations are not met. (In the quotes from our interviews, the letter H denotes quotes from the transplant hematologists, and the letters TM denote those from the other transplant team members.)

Expectations Placed on Physicians

Consistent with legal and bioethical requirements of informed consent, the transplant hematologists stated that they had a duty to inform patients about the complex procedures being considered and the serious, and potentially fatal, side effects:

> I feel it is my duty to convey to them the complexity and the potential complications (H3).

> I usually say, “I really, really need to talk to you about some potentially unpleasant things” (H1).

When asked to describe the consent process, the interviewees referred to a range of activities and materials, including face-to-face meetings that are designed to allow substantial discussion between the patients and the health care team, with opportunities for questions and feedback, so as to maximize patient understanding. These discussions were reportedly customized to suit individual patients:

> The patients are so different that one conversation does not fit all (TM8).

Consultations with transplant hematologists are routinely supplemented by interactions with other members of the transplant team, such as the transplant coordinator. Patients also are provided with electronic and printed materials (e.g., Bone Marrow Transplant Network NSW 2006) and are invited to attend information sessions at the hospital that combine formal presentations by members of the transplant team and transplant survivors, with informal opportunities to talk to the presenters. These information sessions are formally evaluated and are described elsewhere (Ferguson, Jordens, and Gilroy 2010).

> The transplant coordinator will probably be the main source of follow-up information and we have books, of course. There’s the transplant BMT network book. ... They’re encouraged to read [it] and then come back with question. … They’ll often meet with some of the ward nurses (H7).

> There’s an information leaflet. … In the BMT network book there is a list of recommended web sites (TM4).

> We also offer them an information session … and potential patients and their families are invited. … We have various speakers at that session. Nurses, social workers, former patients are there so they have the opportunity to speak to people who have gone through the process (H6).

Expectations Placed on Patients

Professionals’ expectations of the role of patients during the consent process were signaled by the use of strongly normative language (illustrated by our italics):

> The patient *has to* participate and cooperate. … So, you know, *effort* is their *responsibility* (H3).

> *It should be compulsory* that they come to the information day (TM3).

> We would expect that *they have a responsibility* to listen … to try to understand (H7).

The interviewees also described some of the behaviors that would indicate patients are fulfilling this role expectation for active engagement in the consent process. These behaviors included attending educational events, paying attention, listening, asking questions, and providing feedback. However, professionals commonly referred to these behaviors by noting their absence:

> Quite a few of us [transplant team members] spent a lot of time going through all of the things that I know his transplant specialist did go through with him [already], *but he obviously wasn't hearing it* (TM4).

> I've been to consultations where *they haven't asked anything*, even though we say, "Have you got any questions? Would you like something else explained? Do you understand?" (TM4).

> Some patients will say very specifically, "*Don't tell me* about it, *I don't wanna know*, I just wanna get through each day and then get out of here, I'll deal with that as it gets there" (TM8).

> There was one young girl who, kind of, *pulled the blankets up over her head almost when you try to talk to her* (TM9).

The interviewees also conceded, however, that patients faced serious obstacles due to their condition, the quantity and technicality of the information for them to assimilate, and the frightening and uncertain nature of the procedure.

The patients interviewed for the study (reported elsewhere, Forsyth et al. 2011) were clearly aware of the efforts by the transplant team to educate and inform them. All were involved in consultations, were encouraged to attend education days, and received printed information, and each chose to engage with or ignore these educational measures according to their individual preferences. In fact, according to one evaluation, only 57 percent of patients attended the information day sessions (Ferguson, Jordens, and Gilroy 2010). These patients said nothing in their interviews that would indicate they were aware that the health care professionals treating them had strong expectations that the patients had a responsibility to engage with these educational measures, however. These expectations emerged only "off-stage" in research interviews where the health professionals evidently felt safe enough to vent their feelings about patients' behavior, as we discuss next.

Intimations of Trouble

Even though some members of the transplant teams acknowledged the obstacles faced by patients, we observed several indications of potential trouble for patients, the transplant hematologists, and interpersonal relationships when patients did not appear to engage in the consent process. Although we found no direct evidence that trouble had actually occurred, we highlight observations that signal the potential for adverse consequences. For example, we observed critical and sometimes judgmental comments from the health care team reflecting their frustration with patients' behavior during the consent process:

> I mean, what can you do? All you can do, I mean, we feel that we're obliged to explain some things, if she stops you telling her, then that's her choice, or she can not listen (TM4).

> You can't just hear the good news and not hear the bad. No life is like that (H6).

> Often they won't ask me questions, so they let me rave on, which actually worries me a bit. … At the end, I say to them, "So let me just check something with you—you understand that you may die actually having this? This is pretty serious" (H3).

> If he says, "That's not going to happen to me," that would start alarm bells ringing, because then I would say this person does not have a realistic expectation about what will happen or what could happen (H1).

> There are clearly patients who don't want to know anything, but I think it's unreasonable, it's an unreasonable expectation of me to take into a transplant a patient who hasn't been told at least some very basic information (H1).

Given such perceptions from the transplant hematologists and other members of the health care team, it is reasonable to infer that relationships between patients and the health care team could become strained when patients are deemed to have neglected their perceived responsibility to engage in the consent process. This in turn could adversely affect the psychosocial aspects of care.

Another area of potential trouble flows from the frequently observed complaint from patients during the post-transplant recovery period that they were not adequately forewarned of what was to come (Little et al. 2008). Due to changes in the legal standards of disclosure, this kind of complaint touches on possible legal trouble for physicians (i.e., it could form grounds for a case of negligence against the physician on the basis of "failure to disclose material risks" [Kerridge, Lowe, and Stewart 2009, 149]). Thus, when this kind of complaint was discussed in the interviews, it triggered a defensive response by the health care professionals along the lines of "I warned you, but you didn't listen":

> [Recounting a conversation with a patient] Well, you know, you were given the option to come to the patient information day, you didn't want to come—this would have all been explained for you at the patient information day (TM3).

> A man we had in here recently refused to read any information, he declined to come to the information day. … He felt that God would cure him, and then he got here and the whole process started. That's when he started asking questions, and then he was giving the impression that he hadn't been informed (TM4).

> Sometimes afterwards patients will say, “If I’d known it was like this, I wouldn’t have done it.” I say, “Well, we talked about it, I showed you the pictures, I said you can die from this, you can’t get much sicker than that,” and they say, “Yeah, but I just didn’t realize it” (H7).

While such attitudes suggest potential interpersonal trouble between patients and the health care team, they also bode ill for interpersonal relationships within the team itself. For example, although other members of the transplant team were actively involved in educating patients and providing them with information, these individuals clearly saw the informing role as primarily the transplant hematologist’s responsibility:

> I have no legal requirement to explain anything if I don’t want to. It’s not part of my role to totally educate, but I do (TM8).

> The consent process is expressly clinician to patient (TM1).

Moreover, some of these team members dodged patients’ criticism by deflecting it to the transplant hematologists for being poor communicators and unapproachable to patients.

> [The transplant hematologists] have never learned. … They don’t have the skill [to communicate well]. … That’s the sadness: that people can be intellectually and academically so clever, but they can’t communicate with their patients. And that’s just so disheartening because you can do more harm than good (TM1).

> Depending on how approachable the doctors are and how clued in they are to the situation, you know sometimes they’re helpful and sometimes they’re not, quite honestly (TM2).

> They [the patients] may give the impression of understanding because they don’t want to look silly to the doctor. … They may not want the doctor to think I’m a bit stupid if I ask, “Well, what does that actually mean?” (TM8).

In summary, the foregoing analysis of the interviews, guided by the theoretical elements of bioethics and the sick role as shown in Table 1, leads us to the following conclusions: (1) Health care professionals in the BMT setting recognize and act on expectations that they have a responsibility to inform and educate patients prior to treatment. (2) They expect patients to reciprocate by demonstrably engaging in the education process. (3) Patients are apparently unaware of this expectation and do not consistently act in a way that fulfills the expectation. (4) Not fulfilling it can lead to adverse consequences for patients, physicians, and interpersonal relationships within the clinic.

Discussion

Historically, expectations placed on physicians have been codified in ethico-legal discourse, and expectations placed on patients have been codified separately in quasi-contractual terms in sociology through the notion of the sick role. Because both sets of expectations are brought to bear in the context of clinical relationships, however, shifts in one have implications for the other. Herein lies the rationale for considering consent and the sick role together.

We have attempted to show how, in a particular clinical context, a shift in the expectations placed on physicians has affected those placed on patients. We began by observing that the consent process has become embedded in formal organizational practices and routines, both to satisfy legal requirements and to satisfy the underlying ethical principle of autonomy. We argued further that, whilst consent evolved initially as a reactive process designed to protect the autonomy of "essentially vulnerable" patients and research participants, it has increasingly functioned to augment patient autonomy rather than simply protect it. As health care professionals are increasingly expected (i.e., obliged) to attend to the informational elements of consent through greater *disclosure* of information and by ensuring that patients *understand* the information that is given to them, a more robust notion of consent has emerged (i.e., "informed" consent). Furthermore, because "informed" consent redresses the knowledge asymmetry that underpins the inequality in the physician–patient relationship, it also marks a shift in the relative social status of patient and physician roles.

The impetus for this shift clearly relates to wide social, cultural, and juridical changes: Patients are increasingly educated, active in their own care, less deferential to medical authority, more protected by legal precedent, and so on. But however one seeks to explain the impetus, it is worth attending to its practical effects on the roles of physicians and patients.

The Impact of "Informed" Consent on Professional Roles

The shift to "informed" consent has meant that physicians (and health care professionals more generally) are increasingly expected to perform an educative role in the consent process. There is uncertainty about the scope of this role, however, especially with respect to gauging a patient's understanding of the information being provided. For example, the American Medical Association's policy on informed consent emphasizes the "physician's obligation to present the medical facts accurately to the patient" and "to sensitively and respectfully disclose all relevant medical information to patients" (American Medical Association 1981, ¶1 and ¶2), but the policy is silent with regard to assuring patient understanding. The Veterans Health Administration's Informed Consent Policy requires practitioners to "ensure that the patient indicates understanding of the information provided," but only suggests that the practitioner "ask the patient to describe the recommended treatment or procedure in the patient's own words" and "encourage the patient to ask questions" (Veterans Health Administration 2009, 9). Australia's National Health and Medical Research Council (2004a, 2004b) has issued guidelines that suggest a range of communication strategies that make it more likely patients will understand the information that is proffered to them, but these guidelines are similarly vague on the question of how clinicians can or should gauge a patient's actual level of understanding during the consent process. Despite the paucity of detail in these, and similar, policies on this point, the issue is one that concerns many in the practice of medicine, as evidenced by the growing body of research aimed at enhancing communication and measuring patient

understanding (e.g., Flory and Emanuel 2004; Schenker et al. 2011; Schenker and Meisel 2011).

The Impact of "Informed" Consent on the Sick Role Contract

Our analysis of consent in the BMT setting suggests that health care professionals in this clinical context expect patients to reciprocate the educational efforts that are increasingly a feature of the consent process by demonstrably engaging with them; and that if patients do not fulfill this expectation, trouble can result for both patients and the health care professionals involved in their care. The professionals' expectations appear to be largely implicit, however, because their patients are apparently unaware of them. We thus propose that the long-standing behavioral norms of patients' rights and responsibilities that constitute the sick role should be augmented by adding a new responsibility for patients: "that the patient should demonstrably engage with efforts of health care professionals to inform and educate them" during the consent phase of the doctor–patient relationship.

It could be argued that this expectation falls under the general expectation, already encapsulated in the sick role, that patients should "cooperate" with their physician in order to get well. Whether patients understand "cooperation" to include *trying to understand* the information that is given to them is an open question. We would argue that "information needs" are widely framed and understood as a matter of preference, that preferences vary widely, and we suggest that many patients might be surprised to find that they are judged harshly for not trying hard enough to understand the information that is given to them. Whatever the truth of the matter, however, it is important to point out where expectations are changing, because the potential for "trouble in relationships" arises where expectations are not met.

Trouble in the Gap

It is one thing to give information and quite another to ensure that it is understood. Understanding does not depend solely on the efforts of health care professionals as information-givers; it demands an effort on the part of the patient as information-receivers. The "gap" between giving information and ensuring understanding has been somewhat obscured by the tendency to focus on what professionals should do in the consent process and ignore how patients respond to their initiatives. It is unrealistic to expect that there be no gap at all: As our interviewees recognized, aspects of the patient's situation in BMT clearly work against understanding. But because a physician's duty extends beyond mere disclosure to understanding, to ignore the gap entirely is effectively to ignore an element of consent and is therefore ethically unacceptable. The gap between disclosure and understanding is an expression of the rift between principle and practice and is thus a phenomenon that sits on the border of biomedical ethics and medical sociology. The frustration expressed by the health care professionals in our interviews provides a way to understand it: Frustration is a typical indication of an incomplete social process. In other words, obtaining "informed" consent can be understood as a process that is usually incomplete.

Consent is commonly construed and widely understood as an "event" that is completed when a patient signs a document in the presence of a witness (usually a representative of the health care organization). We contend that the completeness is an illusion and that these documents only paper over a persistent, pedagogical problem. The notion of "implied" consent also provides a means of simulating closure of the process: If the patient turns up for the procedure, then consent is thereby assumed to have been given. Like a signature on a document, this enables the actors to all get on with the show.

But neither documents nor convenient assumptions assure that the patient's consent has been given on the basis of understanding. It is revealing that the main clinic involved in this study did not use a standardized consent form that covered the entire BMT procedure. This does not mean the health care professionals were ignoring the requirement to obtain consent. On the contrary, their efforts to inform and educate patients were readily observable—not only as reported in their interviews, but also as evidenced by the educational forums they ran and the detailed book they distributed (Bone Marrow Transplant Network NSW 2006)—and their frustration at the incompleteness of the consent process is evidence of how seriously they viewed it.

Implications for Education and Practice

It serves our understanding of both the ethical and sociological dimensions of care to know where and how "trouble" arises and to seek explanations. Our analysis has important implications for health care professionals engaged in patient care, for those involved in teaching ethics and communication skills to health care professionals, and also for the operation of health care organizations. In order to obtain informed consent for high-risk procedures, it is necessary but not sufficient to design and execute work routines that yield a patient's signature on a consent form. It is also important to recognize that health care professionals are faced with two distinct tasks in the consent process: One is to be explicit about their expectations concerning the patients' role in the process; and the other is to try to educate patients about the treatment being proposed. As noted above, much has been written about the second task. There are numerous guidelines and interventions that are designed to improve the communication skills of health care professionals. Yet, to date, the literature has been silent on the need to ensure that patients are aware that they are expected to play a role in the consent process that extends beyond merely signing a consent form. Our research suggests that overlooking the first task can lead to trouble.

In discussions with patients (and patients' families and lay caregivers), health care professionals should therefore strive to be clear when they expect patients to actively engage with the education process. Although this is a simple point, it was evident in this study that patients were unaware of this expectation, and some might not have acted on it for that reason. Furthermore, health care professionals themselves might benefit from learning that their frustration around the consent process might be due to a perception that the process is incomplete.

We recognize that this issue raises a paradox in high-risk settings such as BMT. Patients who need a bone marrow transplant are vulnerable because their life is at risk, and this can make it difficult for them to actively engage in the educational efforts of their professional carers. Yet, because of the considerable risks associated with treatment, it is crucial that they understand what they are consenting to. Our analysis thus raises a question for ongoing research: How can health care professionals effectively and sensitively facilitate the expanded role that is expected of patients in consent processes in high-risk settings?

While our empirical investigation was confined to the BMT setting, the expectations we observed and the potential for trouble resulting from their nonfulfillment are likely to arise in similar clinical settings—that is, settings where patients are "consented" for procedures that are complex, where the risks and benefits of treatment are finely balanced, and where the stakes are high.

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Statement of Competing Interests

No competing interests to declare.

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