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Is 'informed consent' an 'understood consent' in hematopoietic cell transplantation?

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Abstract

Hematopoietic cell transplantation (HCT) is a complex and highly specialized medical treatment that is associated with significant risks, including death. Furthermore, transplantation is offered to patients who often have no other curative treatment alternatives. The routine-consent process for HCT typically occurs before HCT and is influenced by many factors related to patients, physicians and the transplant per se. These factors can impede the consent process and subsequently result in a failure of proper engagement in and an understanding of the procedure with resultant adverse consequences influencing patients and even the patient–physician relationship. We contend that informed consent is a dynamic and ongoing process and that better patient education can assist in the decision making, fulfill the ethical principle of respect for autonomy and engage the patient to maximize compliance and adherence to therapy. This manuscript reviews the key literature pertaining to the decision-making and consent process in HCT and proposes guidelines for improving the consent process. Strategies for improving patient comprehension, engagement and enhancing consent forms are discussed.

INTRODUCTION

Over one million hematopoietic cell transplants have been performed worldwide since the first report of successful hematopoietic cell transplant in 1957. In current medical practice, hematopoietic cell transplantation (HCT) has become a standard treatment modality for a wide variety of indications ranging from malignant to non-malignant hematologic diseases, as well as for some non-hematologic disorders. In the past six decades, numerous advances have occurred in our field ranging from newer medications to improved techniques in supportive care, in addition to growing clinical experience in performing HCT, and thus transforming HCT from an investigational procedure to a routine and acceptable therapy for

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CONFLICT OF INTEREST
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several indications. However, it remains a 'high-stakes' medical treatment with the potential for cure counterbalanced by the possible development of significant morbidity and mortality. One example is the elimination of leukemia and development of moderate-to-severe chronic GVHD with a tremendous negative impact on the quality of life as well as on the reduction in life expectancy. This makes the decision-making process and consequently the informed consent for HCT a complex undertaking; the fact that the patient is in a vulnerable state and facing a life-threatening illness adds to this complexity.

Informed consent is a fundamental component of modern clinical practice. The legal basis for informed consent can be traced back to *Schloendorff v. Society* of *New York Hospital*,[1] in which Justice Cardozo famously wrote that 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body' (It is interesting to note, however, that Ms Schloendorff did not ultimately prevail in her lawsuit.); Ms Schloendorff sued the Society of New York Hospital. While the legal discussion of informed consent largely begins with Schloendorff, the current model, that informed consent must be obtained before an intervention and that risks and benefits must be disclosed, arose in Salgo v. Leland Stanford Jr. University Board of Trustees.[2] Martin Salgo sued Stanford University when he lost the use of his legs after he underwent aortography, because he was not informed by his surgeon that paralysis was a risk. The court held in *Salgo* that physicians have a duty to disclose any facts that are necessary for a patient to make an informed decision regarding treatment. This is important as, legally, it sets the standard for informed consent as the 'reasonable patient standard'. The reasonable patient standard holds that informed consent requires the physician to disclose to the patient that information which a 'reasonable person' would want in order to make a decision. This is contrasted with the 'reasonable physician' standard, which holds that informed consent requires the physician to disclose that information that a 'reasonable physician' would consider important and necessary to make a decision. This distinction is important as physicians and patients can disagree regarding what information is needed to make a decision.

Ethically, informed consent fulfills the ethical principal of respect for persons. As Jay Katz[3] notes, informed consent is a relatively new concept, as paternalism was the dominant approach through most of medical history. Katz[3] describes at length the ethical development of informed consent as a tension between beneficence, or seeking to benefit the patient, and autonomy, in his classic book *The Silent World of Doctor and Patient*. Beneficence commits a physician to help the patient and not place undue burdens of decision making, and questions whether the patient can even make a good decision because of the lack of knowledge and the burden of disease. Autonomy, on the other hand, is committed to ensuring that a competent patient has the information needed to make an informed decision and ultimately respecting that decision.

For the present purposes, informed consent is the communication between the physician and patient that leads to the patient agreeing to undergo a medical intervention.[4] A valid informed consent involves a patient with sound decision-making capacity, an intentional decision by the patient with understanding free from undue influence by the medical staff and an ability to communicate the acceptance of treatment to the treating physician.[5] The ideal informed consent thus requires that the patient appreciates his clinical situation,

understands the consequences of the proposed treatment and alternative therapy options, appreciates the specific implications of this information into his future and integrates this information into his decision.[6] The physician and the health-care team are responsible for providing the relevant information regarding the details of the transplant procedure, risks/benefits of undergoing HCT and alternatives to transplant to facilitate decision making. In reality, it is a challenge to relay accurately every detail of the transplant procedure, without bias and in the available time before the transplant.[6] A patient suffering from a terminal illness who has just undergone intensive chemotherapy, as is the case with most malignant hematologic diseases requiring HCT, may still be assimilating the information of a recent diagnosis of cancer and find the option of undergoing transplantation foreign and complicated. Further, a patient may perceive the transplant procedure as the only remaining option.[7] Given these factors, the informed consent process becomes truncated into a list of potential risks recited to a patient who has already committed to the procedure followed by the requisite signatures on a consent form.[8]

Consent forms are designed to document that physicians have provided patients with information relevant to help in the decision-making process and that patients have understood the proposed treatment. They tend to be several pages in length often written in a legal prose;[9] it is assumed that patients have read the consent forms and understood them. In reality, however, it is known that often patients do not read informed consent forms.[10] Within the research informed consent literature, 69% patients self-reported that the consent form had no role in their decision to participate in a cancer therapeutic clinical trial.[11] Consent forms are commonly too complex, and poorly comprehensible for most patients.[12] Furthermore, there are often a number of different consent documents that need to be read, understood and signed (e.g. biobank repository, qualitative data consents) and can add to the complexity and information overload to the patient.

In this commentary, we have reviewed the current medical literature on (a) the decision-making process behind an informed consent in HCT and (b) the actual informed-consent process. We will summarize these processes, describe barriers that prevent a good informed consent from occurring and the resultant impact of a ‘poor’ informed consent on the patient. Informed consent in this article is in reference to both autologous and allogeneic HCT, and includes informed consent in the clinical/service setting as well as the research setting. Finally, we discuss avenues for improving the informed consent process in HCT based on the general literature on informed consent.

Factors influencing the decision-making process in HCT

The transplant setting is 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.[13] TRM can vary from 3% in autologous HCT to upwards of 30% depending on the type of allogeneic HCT. This ongoing risk, because of GVHD, infection, organ failure and so on, can persist even upwards of 1 or 2 years after undergoing transplant can be a difficult concept to grasp. Then, there is the additional risk of the primary disease recurring. All these risks are often competing, and can be difficult to predict in a linear decision-making approach.

A complex range of factors have been shown to influence patients toward transplantation. Many of these factors overlap and more than one factor can occur concurrently. These factors are summarized in Table 1.

Patient factors—Studies show that patients tend not to recall information on risks and complications.[5] Multiple studies have shown that patients have high knowledge needs regarding their disease at the time of their outpatient informed consent visit.[5,14,15] Yet, almost half of the patients have already decided to undergo HCT before their first visit to the transplant clinic.[5,6] At the time of the outpatient informed consent visit, patients also have a moderate to high degree of anxiety.[5,14] The outpatient informed consent visit can help lowering this anxiety and make patients feel better.[14] However, consequent to the anxiety and heightened emotional state, patients tend not to recollect risks and complications but rather focus on details such as the name of the high-dose chemotherapy, or the process of extracting and storage of the hematopoietic cells.[5] In terms of the factors deemed most important in deciding to undergo transplant, a belief that HCT was their best chance for a good outcome followed by trust in their physician and treatment team were rated the highest.[5] Extremes of age and less than high school education may hinder patients' ability to provide a substantial informed consent.[7] Patients who wish to have an active role in decision making tend to be younger and more highly educated.[16] In phase I and II cancer clinical trials, nearly 80% patients preferred a paternalistic approach, wanting their physicians to advise them what to do regarding trial participation; indeed, when patients acknowledged that they had the choice to decide, making such a decision was anxiety provoking.[17] Ultimately, perhaps, the most important patient factor that can overcome all of the above factors is patient participation and engagement in the treatment team's efforts to obtain patient understanding. Life-threatening situations, as in the case for an indication for HCT, may make patients more passive and less willing to participate actively in the decision-making process.[17] In an analysis of consent in the HCT setting, Jordens *et al*.[13] show that health-care professionals expect patients to reciprocate the educational efforts of the consent process by demonstrably engaging with them.[13] Further, because these expectations are largely implicit at the current time, the authors propose that health-care professionals should be clear about their expectation from patients regarding an active engagement in the consent education process.

Physician factors—If patients' consideration is for not making the decision for HCT themselves, this places the burden of decision making on the physician. Physicians are often influenced by their own experiences and biases, and these influences may be transmitted to patients by their tone or selective emphasis on certain words and descriptions.[18] Patenaude *et al*.,[18] in an eloquent argument, makes the case that in HCT, given the vast amount of technical information, uncertainties and high patient anxiety, the patient is best served when the transplant physician makes the recommendation for treatments, as opposed to taking a neutral approach, that is, use of therapeutic privilege. Therapeutic privilege refers to circumstances when information may be withheld from patients to prevent serious harm to the patient, and information that may cause severe distress, anxiety and harm.[19] Thus, depending on the degree of control the patient wishes to exert, the informed consent process can serve as a mutual trust-building exercise between the patient and physician, and partly a

ritual to satisfy a legal and ethical requirement.[18] This is in concordance with studies described above showing that patients rate trust in their physician one of the top reasons for deciding to undergo transplant.[5] The informed consent process thus also acts as a conduit for managing the vulnerability of the patient through physician interaction, education and trust building.[5]

While some might argue that such an approach is unjustifiably paternalistic, this need not be the case. Autonomy does not require that the patient always possess full information and make the decision herself in isolation from other people.[20] Rather, people routinely exercise their autonomy in ways that take into account the guidance of others. Instead of being unjustifiably paternalistic, making tailored recommendations based on the preferences and values of a patient can actually foster autonomy, by surmounting the vast amount of information and patient anxiety noted above and engaging in shared decision making.

Social factors—Decision making is not a process that solely occurs between the patient and physician. Forsyth *et al*.[21] conducted a qualitative study to investigate decision making in allogeneic HCT through in-depth interviews with patients, their significant others and transplant physicians, and in addition to the factors described above highlighted a number of social factors that will direct their decision to undergo transplant. These included particular family milestone events, the family's reliance on them, family support for/against HCT and the existence of a support network outside of immediate family as factors implicated in patient's decision making.[21]

Consequences of a failure to achieve understanding despite informed consent

Discordance between patient and physician expectations from transplant—An insufficient understanding of the risks of treatment can result in a difference in patient expectation from the transplant. Studies have shown that treating physicians are often able to give a concise prognostic estimate for HCT that is reflected in the real outcome.[22,23] However patients tend to perceive the transplant with more optimism than is due, resulting in an overestimation of the HCT success rate, particularly in high-risk disease associated with poor prognosis, despite realistic estimates by their treating physicians.[23,24] Such discrepancies may be harmful to the patient as a more realistic understanding and expectation may lead to a change in treatment decision against an aggressive treatment and a choice for best supportive care. A realistic understanding of prognosis may also help the patient and family prepare themselves.[23] Further, discordance between pre-HCT expectations and post-HCT functional status has been shown to be associated with psychologic distress.[25]

Impact on the patient–physician relationship and satisfaction

The actual personal experience of the transplant ordeal can increase the awareness of the limitations of the current medical information disclosure informed-consent process pretransplant. In a qualitative study, patients became dissatisfied with their treatment team (despite receiving appropriate and good care) because they felt inadequately prepared.[26] Additionally, fully informed patients are more likely to adhere to the treatment regimen[6] and may thus improve long-term compliance.

Avenues for improvement

Improve patient comprehension—In a systematic review of literature, it was shown that techniques aimed at improving patient comprehension including written and multimedia interventions, extended discussions and test/feedback techniques helped informed consent in clinical care as measured by recall.[4] As efforts in improving comprehension appear to result in better understanding compared with the current standard practice, this indicates that our current clinical consenting process may be inadequate for patient comprehension. However, it is worthwhile noting that improving patient comprehension by the mere provision of additional information does not ensure that this information is read and understood. Rather, it is the provision of useful information that is meaningful to the patient, for example, understanding the side effects of growth factor administration during hematopoietic cell mobilization is ultimately of greater value to patients rather than the technical aspects of how many cells are needed and the manner in which they will be preserved; even though patients invariably tend to recollect the latter. In a meta-analysis, extended discussions and enhanced consent forms appeared to be of benefit in improving participant understanding of research study.[27]

Enhancing consent forms—Health illiteracy is a common problem and affects nearly half of the adult population in the United States.[28] Research and interventions to improve the informed consent process for patients with low health literacy are needed.[28,29] Non-English-speaking patients can be additionally challenging to obtain consent. While verbal consent with an interpreter for clinical/service informed consent may be helpful in obtaining consent from non-English-proficient patients, a written record may be more difficult to obtain in the setting of research study consent. Translating informed consents in another language is often impractical given the costs of translation of consent forms in addition to creating a validated and culturally appropriate consent.[30] Denzen *et al*.[31] provide recommendations for readability in consent forms for BMT clinical research trials. Examples of these include the use of a two-column format, balancing text with white space, use of specific and larger font sizes and use of plain language with consistency throughout the document.[31] To this end, the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) is conducting the BMT CTN 1205, a randomized, multicenter, prospective study of easy-to-read informed consent for HCT clinical trials. This study uses a novel consent form based on the above recommendations[31] and will assess patient comprehension of the clinical trial in addition to satisfaction and anxiety related to the consent process.

Interactive technology—Interactive technology is widely used and popular in the current environment. It is being actively explored to improve patient education, overcome psychosocial barriers and aid in clinical decision making.[32] This strategy does not involve active physician presence but can potentially improve communication between patients and treating physicians. The availability of an interactive computer- or tablet-based program under the guidance of an educated health-care professional may provide a practical vehicle to improve patient understanding.[8] A prospective randomized clinical trial demonstrated that computer-based communication before the initial medical oncology consultation for patients with advanced cancer resulted in higher satisfaction with communication and improved treatment decision making.[33] Additionally, electronic interactive software can be used in

HCT to improve patient comprehension, aid patient engagement and target decisions about transplant. Rather than seeking answers in the general media and the World Wide Web, having access to accurate and updated information about the hematologic disease, prognosis, transplant complications and so on could be an invaluable tool for patients (and physicians). Several such 'mobile health' applications are already available for use to help track and manage chronic diseases such as diabetes.[34] The PRE-ACT (Preparative Education About Clinical Trials) e-health intervention is one such health communication and decision support tool that is in development for cancer patients to improve preparation for considering clinical trials as a treatment option.[35]

Timing of the consent—Often the informed consent is obtained immediately after the decision to undergo BMT is made. Providing consent forms in advance of the actual consent conference can provide patients with time to understand and contemplate the decision, and may result in improved understanding of the informed consent.[8] A pilot study designed to improve enrollment of cancer patients in a comprehensive cancer registry implemented a two-step consent process of mailing of a booklet about the registry along with a simplified one-page consent form to new patients before the first appointment to the Cancer Center.[36] The second step involved a research nurse meeting with the patient during the first or second visit to review the booklet, answer questions and obtain consent.[36] The consent rate was 78%, and even though 57% of patients did not read the booklet before the visit, patients felt prepared during the nurse visit. The nurse visit for the consent process required on an average 10 min, which included answering questions, reviewing the booklet and reading of the consent form.[36] A similar strategy of mailing informed consent forms before a potential study that a transplant patient may be suited for has been tried with success by some centers, and could be easily implemented widely. Additional separate visits with a research or study coordinator may also serve in aiding decision making with a minimal logistic and time commitment for patients.

Figure 1 gives an example of the consent process, breaking it down in different steps through the course of an allogeneic HCT consultation.

CONCLUSIONS

This article summarizes the literature on the decision-making process involved in patients choosing to undergo HCT. Given the overwhelming amounts of information regarding risks, benefits, prognosis and the like involved in HCT, transplant physicians should seek new avenues to facilitate informed decisions with their patients. Because HCT is a complex long-term treatment, patients also need a higher level of competence, capacity and health literacy to make a decision for undergoing HCT. Additionally, there are numerous factors, including patient, physician and social discussed above, that influence the decision making of patients, and physicians must be aware of these and take steps to improve the consent process. It is essential to note that if a patient desires a recommendation for a physician, providing a recommendation is not unjustifiably paternalistic. Rather, it may be in keeping with the values of the patient and may help foster trust and improved decision making.

Numerous approaches have been proposed to improve informed consent in HCT, including written and multimedia interventions, extended discussions and test/feedback techniques, novel consent forms, interactive technology and the timing of consent. These approaches show promise, but more research is needed.

There can be a wide difference and disconnect between the explanation of and the actual experience of undergoing HCT. A good informed consent should be viewed as an ongoing process before, during and even after the transplant, rather than just a pretransplant requirement.

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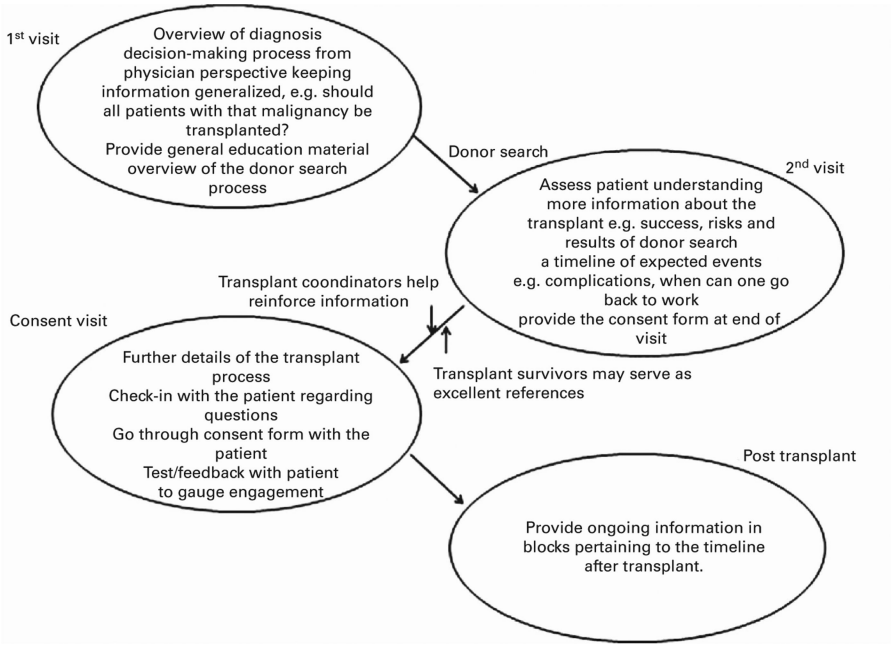

Figure 1.

Steps in informed consent process for a patient undergoing allogeneic HCT.

Table 1

Factors influencing decision making in HCT

Patient related	Physician related	Process related
• Age	• Physician–patient	• Enrollment in research
• Education	• Relationship	• Timing of discussion
• Health literacy	• Patient trust in the treatment team	• Time available for decision making
• Anxiety		
• Belief of success of transplant	• Expert opinion/bias	• Consent forms
• Understanding of the treatment plan		
• Societal roles and obligations		

Abbreviation: HCT = hematopoietic cell transplantation.