Patient adherence or patient self-management in transplantation: an ethical analysis

Adherence of patients to transplantation regimens has been problematic. Patient self-management of the chronic diseases that frequently lead to transplantation is now the standard of practice, although that practice has been incompletely implemented. Through its focus on developing patients' skills and confidence in their ability to perform medical management, maintain important life roles, and manage the negative emotions that often accompany chronic conditions, patient self-management has the potential to support effective adherence of patients in an ethically satisfactory way. A professional decision to transplant should carry with it a commitment to help patients self-manage, including patients with low levels of literacy. Viewing adherence as patients' work to be accomplished within a framework of patient self-management offers an option for improving transplant outcomes. Testing this option is an important next step. (*Progress in Transplantation.* 2009;19:90-94)

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In the course of some chronic diseases, transplantation becomes an option. Although transplants offer various levels of normality, the transplant must subsequently be cared for in addition to the chronic disease. Because of the need for complex immunosuppressive medication regimens, the approach to management of these patients has been highly focused on ensuring adherence, defined as following the provider's recommendations.

The philosophy of care for most chronic diseases has migrated to patient self-management (PSM),[1] defined as ability to detect and manage signs and symptoms, treatment, and physical and psychosocial consequences inherent in living with a chronic condition.[2] This movement was historically led by diabetes, in recognition of the fact that PSM was essential to survival. In the United Kingdom, the Expert Patient Program is based on a convincing set of recommendations to the National Health Service that patients' ability to manage their long-term chronic illness be developed further.[3] A randomized trial of short-term effects of the Expert Patient Program supported this recommendation[4] and builds on a significant body of research on Lorig's model, reviewed in the section on PSM later in this article.

How does the current almost exclusive focus in the literature on management of patients' adherence with regimen before and after transplantation fit with the now dominant focus on PSM of the underlying disease? Are these 2 philosophies of care competitive? Or does PSM provide an opportunity to delay need for transplantation, sustain the organ longer, and reduce disparities in transplantation outcomes[5] as well as improving patient-defined well-being and dignity? Beyond the potential for improvement in these important outcomes, the standard of care for chronic disease is changing to PSM because it is ethically more appropriate.

In this article I explore how a PSM framework is ethically and substantively important for management of patients before and after transplant. I first examine what is known about how to deal with issues of adherence in these patients, then review the philosophy and practice of PSM and ways in which it might be applied to transplant patients, and finally propose a set of ethical precepts that accommodates both.

Urgency of Adherence

It is easy to see why adherence of patients has seemed important. Medical recommendations after transplantation are designed to prevent or attenuate acute and chronic graft rejection, opportunistic infections, malignant neoplasms, secondary complications, and toxic effects associated with immunosuppressive medications. So transplant recipients must take medications daily; follow a schedule of blood work and biopsies; engage in home monitoring of vital signs; follow dietary and exercise guidelines; avoid prolonged sun exposure; abstain from alcohol, nicotine, and illicit substances; attend clinic appointments; and communicate regularly with the transplant coordinator.[6]

A meta-analysis of 147 studies of kidney, heart, liver, pancreas/kidney-pancreas or lung/heart-lung recipients published between 1981 and 2005 describes the current state of knowledge. This summary cites 18 studies in which nonadherence was predictive of morbidity and mortality in transplant recipients. It also notes that in major reviews, evidence regarding psychosocial factors that increase risk for nonadherence is inconsistent, and the magnitude of the actual impact of such factors on transplant recipients' behavior is unclear.

Nonadherence to immunosuppressant regimens has been frequently studied; on average, a health care provider can expect to see 23 nonadherent patients for every 100 patients during a given year of follow-up. Nonadherence is most common in kidney patients, with a rate of 36 cases per 100 per patient year, a rate twice that for heart transplant and 5 times greater than that for liver transplant. This relatively high rate is surprising because many transplant programs already screen candidates to ensure they are likely to adhere to posttransplant medical care,[7] although later follow-up offers an opportunity for more in-depth assessment of adherence issues. Mekechuk[7] notes a prominent gap in the transplant adherence literature: understanding the condition from the point of view of the patient, particularly the adolescent.

Adherence with regimen is, of course, a problem in many areas of medicine. It has been widely studied, and these studies offer some suggestions for transplant practice. A meta-analysis of 116 articles indicated that patients' adherence in many medical conditions showed a significant positive correlation with the objective severity of patients' disease conditions and their awareness of this severity. Such a finding suggests that patients' personal models of their illness and in particular their understanding of illness severity should be monitored.[8]

In a review[9] of 37 trials of interventions to enhance medical adherence in chronic medical conditions (again, not transplant-specific), investigators found that adherence increased most consistently with behavioral interventions that reduced dosing demands. Interventions that involve information, monitoring, and feedback delivered over multiple sessions are probably also effective. Yet, neither of these approaches yielded an impact on clinical outcomes.[9]

Thus, the empirical literature on nonadherence in both transplant and other fields of medicine suggests it is common, hard to screen for, improves with lessened demands of the regimen, and may be most responsive to a thorough understanding of a patient's beliefs about the illness and the regimen, and in general of patients' perspectives.

For the transplant field, at least 2 very important questions remain unanswered. (1) Although the optimal level of adherence is most likely considered by transplant professionals to be 100%, the clinical threshold for nonadherence has yet to be determined for specified posttransplant behaviors. How nonadherent with medication use or lifestyle modifications can a patient be before experiencing medical consequences?[10] (2) Although inability to understand the complexities of therapy or skill and judgment in carrying it out and a documented history of nonadherence with medical care have been relative contraindications to transplantation,[10] it is important to "push the envelope" and understand how modifiable these factors are. A first step is development of psychosocial and behavioral factors (including patients' beliefs) that are predictive of poor transplant outcomes. Such standardized assessment does not exist, even though assessment for medical selection criteria is well established.[11] Should documented efforts to improve modifiable barriers be required before a decision about whether a patient is eligible for transplantation? Clearly, yes, for reasons of good patient care and of justice for historically disadvantaged populations.

So far, this discussion has focused largely on the commonly used metric of organ viability and on the importance of patients' adherence with medical regimen to sustain the organ. But from an ethical perspective, adherence is a command; it does not offer direction in dealing with the adverse effects and changes in all life spheres (including identity) that accompany a transplant. It is based on an assumption that, with sufficient will, patients will adhere to the medical regimen. It ignores limitations in the quality of medical care, availability of social and economic means to sustain the transplant, and ways in which the health care delivery system places obstacles in the way of adhering. As a framework, it does not recognize patients' autonomy or invest in development of patients' capabilities to self-regulate their life commitments, despite the effects of a life-threatening disease.

So, although patients' adherence is on its face compelling, it is not currently clear how to accurately predict it, and interventions to achieve adherence are significantly underdeveloped. We are left with requirements for patients to be fully adherent yet no standard of care on the part of health care providers to assist patients in meeting this goal: a perfect setup for blaming the victim. Such is the case even if the pretransplant informed consent is explicit about what the posttransplant regimen will require. As central as the regimen is to achieving a functioning organ, adherence can also be seen as an ideology, a pervasive system of beliefs undergirding the social imperatives for patients to place highest priority on doing what the provider recommends. Yet adherence ignores important human outcomes. PSM offers a different way of thinking about the problem.

How Is PSM Relevant?

Although PSM is a generic concept, the most widely disseminated program authored by Kate Lorig (The Chronic Disease Self-Management Program) provides an example for examination of the concept. This program conceptualizes the day-to-day tasks of PSM as follows: medical management of the condition, maintaining important life roles, and managing negative emotions such as depression that often accompany chronic conditions. PSM requires knowledge, clinical judgment, problem solving skills, and self-efficacy (confidence in one's ability to manage the disease). Lorig's community-based, peer-led program is built on patient-perceived needs, was developed and evaluated for 28 years, and has now been designed to be Internet based. At 1 year, online participants with several chronic diseases showed improvement in health distress, fatigue, pain, and shortness of breath in comparison to control subjects who received usual care.[12]

The Chronic Disease Self-Management Program has been criticized because studies of it involved self-selected volunteers rather than representative samples of beneficiaries, thus inevitably lacking external validity. Critics also note that evidence to date is indicative of short-term benefits, with underprivileged groups least likely to benefit. Individuals who are unable to reach independence must still be supported.[13,14]

Although cautions raised about Lorig's program must be addressed, given today's disease treatments and places of care, patients must be able to manage significant amounts of their day-to-day care, and so multiple models to assist patients to become competent and confident with managing chronic disease must be developed and tested. Effectiveness of PSM has been well established with diabetes and asthma (improving health care utilization, days lost from work, and quality of life) but not yet well established for others such as chronic obstructive pulmonary disease.[15] No comparable literature for transplant patients could be located. PSM is built on the notion that early intervention to increase patients' sense of ability to manage their perceived illness symptoms is essential. Illness representation (patients' beliefs about what is causing their disease and what can be done about it) and self-efficacy theory are prominent in this effort.[16]

Experience with adoption of PSM in the United Kingdom started with the assumption that it is a key element in managing resource demand in chronic disease and that PSM is an empowering right (and responsibility) for patients. Although National Health Services providers acknowledged and supported the subjective experience of living with a long-term condition, experience with the program has also documented evidence of a continuing professional agenda focused on adherence. Provider transition from directing patients to helping them make their own decisions is apparently difficult.[2]

In contrast to adherence, PSM offers the opportunity to reclaim or develop confidence and moral agency. It reframes transplantation as one element in the continuum of management of a chronic disease. It acknowledges that patients must be able to reason independently enough to live with and manage a chronic disease. Indeed, it is difficult for the health professional to provide in advance rules to fit every situation the patient may encounter. In addition, a fundamental dimension of human well-being is the exercise of cultivated effective agency (ability to take control).[17] Because such profound events occur under its jurisdiction, the health care sector has responsibility (although not unlimited) to build patient agency.

PSM is now the standard of care in a number of the diseases that may lead to transplantation. Based on data from the late 1990s, Healthy People 2010[18] notes that 40% of persons with diabetes have received formal diabetes education, as have 6.4% of persons with asthma. These examples show how underdeveloped PSM services are, leaving large portions of the populations with these conditions without the education necessary for effective self-management and control of symptoms. Thus, many patients arriving at transplantation are unlikely to be practicing PSM for their original chronic disease(s) competently and confidently. Additionally, other chronic diseases such as new-onset diabetes mellitus occur after transplantation in approximately 15% to 20% of kidney transplant patients, appear to have a negative influence on graft function and survival rates, and in addition to the posttransplant regimen, must be managed by patients.[19]

Besides development of self-efficacy (well-described in the preceding examples from Lorig), understanding a patient's belief system is essential. Individuals construct their own common-sense model of disease and treatment (which frequently is discrepant from that of health care providers), and on which they act. For example, for patients with heart failure, education improved adherence. The Beliefs in Heart Failure Tool was developed to measure these beliefs; strong belief in the necessity of one's medications and a lower level of concern about them were associated with higher medical adherence. Patients' beliefs about chronicity, consequences, and ways to control a disease were also related to self-efficacy in maintaining a change in diet or exercise regimen.[20] Similar findings from kidney transplant patients indicated that those with lower belief in the need for medication did not adhere as well.[21] Thus, incorrect beliefs of patients are a modifiable factor that would support adherence, as is the patient's experience of symptom control.

Use of technologies such as mobile phones for transmitting symptoms and measurements, with immediate feedback to patients on how to proceed with illness management, supports PSM. This phase of guided self-management helps to bring a condition under control with professional support before the patient assumes responsibility for self-management as a stable maintenance phase is established. Such systems have been used to improve adherence in diabetes, hypertension, heart failure, and asthma. They facilitate accurate titration of treatment to reduce symptoms and are an active form of PSM education that helps patients make the transition from feeling controlled to taking control.[22] Of course, support from health care providers is essential.

And most recently, necessity not only for self-management education for initial acquisition of knowledge and skills, but also continuing enhancement of those skills and ongoing support for PSM over the course of the illness has been acknowledged. National standards for diabetes self-management education now require educators to establish a plan with their patients, to ensure they receive this continuing support,[23] usually for the rest of a life.

An Ethical Framework

A set of ethical precepts to define responsibilities of the provider and the patient and conceptual work yet to be accomplished in PSM in general and transplant in particular is offered here.

The first and most basic ethical precept is that a professional decision to transplant carries with it a commitment to help patients manage the underlying chronic disease plus the transplanted organ or tissue for as long as is necessary. This commitment involves transparency about the limitations of medical knowledge as applied to individual patients and admittance of patients' expertise in self-management as well as in setting life goals. A definition of health in the context of transplantation, and strategies to maximize it, will set a goal; strategies by which to reach it will follow. PSM is one such strategy. To create a reasonable chance for it to be implemented, payment for services that prepare and support patients to self-manage and development of a specialized work force, such as certified diabetes educators, are important.

Second, some evidence indicates that in addition to being ethically superior to the framework of adherence, PSM can yield better clinical outcomes. Limited empirical data suggest that when kidney transplant patients with independent and active coping styles suffer a loss of autonomy in the management of medication regimens and become more dependent on family and health care staff, they tend to react with a poor adjustment to treatment. Such individuals may respond better to interventions that emphasize self-control and autonomy (read PSM).[24] Such an approach affirms the patient's responsibility to collaborate with treatment, and if this responsibility is not met, it affirms providers' responsibility to investigate why.[25]

A third ethical commitment is to strongly push current limits of preparation for PSM of patients with low educational levels and health literacy as well as ensuring they have the resources necessary for PSM. Such individuals not only have lower levels of disease-specific knowledge but also know less of the practical and instrumental knowledge critical to self-management. Patients need to interpret their symptoms and make decisions about how to take medications and deal with adverse effects. Technologies that allow remote assistance, as noted earlier, have rarely been tested with patients with low literacy.[26] Summaries of controlled trials form the basis for practice guidelines; yet it is unusual for the reviews or the primary studies to include applicability of the evidence to disadvantaged populations.[27]

In established PSM fields (most especially diabetes), ethically important quality-oriented innovations abound, as does important work yet to be accomplished. For example, a summary of guidelines for management of type 2 diabetes suggests that treatment goals should be based on a discussion of the benefits and harms of specific levels of glycemic control with the patient. It is recommended that the goal for hemoglobin A1c level should be based on individualized assessment of risk for complications from diabetes, comorbid diseases, life expectancy, and the patient's preferences.[28] On the other hand, direct measurement of outcomes that are important to the patient remains uncommon (only 14% of randomized trials assess such outcomes as primary end points),[29] and standardization of outcome measures has not yet been accomplished. Parallel work in the transplant field is obvious.

Perhaps most basic of all, in merging need for adherence with the PSM approach, is the conception of the former. The trajectory theory of chronic illness defines daily living including adherence as patients' work. It focuses on skills, energy, and resources needed to get the work done, rather than the simplistic approach of identifying physiological or behavioral characteristics as precursors to adherence (as does most of the transplant literature). Each prescriptive regimen has a burden, which changes over time because of the severity of the symptoms and how an individual experiences them.[30]

Such a theory requires measuring not only objective medical indicators but also subjective conditions about the body, conception of self, and resources such as knowledge and coping. Collaborative goals for patients depend on addressing uncertainty, trust, and confidence in the provider, shared understanding of prognosis, and the patient's belief in therapies. Arguably, these adherence-oriented goals are best met by a PSM approach.

Summary and Recommendations

Considerable attention has been given to ethical guidelines in the procurement and distribution of transplantable organs and tissues. Indeed, the major ethical analysis in transplantation is entirely devoted to these questions.[31] The urgency of this issue has overshadowed another important ethical issue: the management approach that best sustains the transplant as well as the patient's well-being and dignity, making transplantation a patient growth experience and perhaps easing the demand for organs.

Transplantation often occurs within the context of a chronic illness for which the standard of care includes preparation and adequate support for PSM. Although patients' adherence with the medical regimen is important to sustaining the transplanted organ, this goal and many others may best be achieved by investment in development of patients' knowledge, beliefs, skills, clinical judgment, and confidence inherent in the PSM approach.

Obviously, which approach works best is an empirical question that has not yet been tested but should be tested not only with traditional outcome measures but also with patient-oriented outcomes. The first step in transition to a PSM approach is to understand the balance that is possible between patient-oriented goals and a safe level of adherence and then to work out the inevitable conflicts. The second step is to develop PSM training programs both for patients and for providers. Then consider redeployment of professional time to support patients in their self-management endeavors.

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