

Evolution of the Role of the Transplant Pharmacist on the Multidisciplinary Transplant Team

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Transplant pharmacists have been recognized as an essential part of the transplant team by their colleagues along with several governing and professional organizations. The specific education, training and responsibilities of the transplant pharmacist have not been clearly delineated in the literature. Various pharmacists across the country have been called upon to serve on the transplant team necessitating standardization of their fundamental and desirable activities. Therefore, the purpose of this manuscript is to describe the training and role of a transplant pharmacist on the patient care team and provide a roadmap to implementation of novel transplant pharmacy services.

Key words: Multidisciplinary, pharmacist, pharmacy, role, transplant

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Overview

Pharmacists have been involved in the care of transplant recipients for several decades with, the first published report outlining specific activities of a dedicated transplant pharmacist published in 1976 (1). This first introduced the transplant pharmacist as an individual with specific expertise in transplant pharmacology who actively participated in the medical management of organ transplant recipients and provided direct patient medication counseling (1). Studies outlining direct medical and economic impact of pharmacists participating on patient care teams across multiple disciplines over the past two to three decades have advanced the role of the pharmacist on the organ transplant team (2–15).

The perception and role of the pharmacist on the multidisciplinary transplant team has been further justified and expanded by changes in the United Network of Organ Sharing (UNOS) bylaws and Centers for Medicare and Medicaid Services (CMS) accreditation standards for transplant centers (16–19). UNOS bylaws were amended in 2004 to identify pharmacists as a necessary component of the transplant team and included a description of the specific roles and responsibilities which are outlined later in this manuscript (16,18). CMS has outlined the specific expectations for transplant centers to demonstrate compliance with UNOS bylaws, including the utilization of a pharmacology expert, universally accepted as the transplant pharmacist.

Given these mandates for the specific composition of the multidisciplinary transplant team, the demand for transplant pharmacists has increased rapidly and dramatically. So much so that, in order to meet the needs of these new accreditation standards, some transplant centers may have hired and/or identified pharmacists without specific organ transplantation training due to lack of available fully trained personnel.

In an effort to describe the education and training needed to satisfy the role of the transplant pharmacist, the American Society of Transplantation (AST) Community of Practice of Transplant Pharmacists and the American College of Clinical Pharmacy (ACCP) Immunology/Transplantation Practice and Research Network (PRN) have constructed this manuscript. The aim is to provide an overview of the education and training of pharmacists, outline of the

current state of transplant pharmacy, and provide guidance to centers who wish to develop a designated transplant pharmacist position in the future.

Pharmacist Education and Transplant Training

In 2009, the ACCP Immunology/Transplantation PRN published their history report which detailed education and certification of their members; 87% held a doctor of pharmacy degree (PharmD) and 60% held certification by the Board of Pharmacy Specialties and/or other certifying bodies, including multiprofessional organizations, that offer certification examinations to pharmacists (20). Traditionally, pharmacists were eligible to sit for board examination after completing a 4-year Bachelor of Science (BS) degree. In the 1990s, these BS programs were converted to a PharmD. The PharmD degree requires a minimum 6 years to complete, following a similar design to several combined BS/MD degree programs available in the United States. Following completion of the formal didactic curriculum, pharmacists passing their board examinations were eligible to pursue employment in their practice setting of choice. Before 1990s the majority pursuing a career in organ transplantation gained an understanding of the complex pharmacology, pharmacokinetics and pharmacodynamics of immunosuppression through 'on-the-job training'. Fortunately, pharmacy practice today has evolved to provide pharmacists looking to specialize in the management of distinct patient populations, including organ transplantation, the opportunity to receive advanced training through residency and/or fellowship. The current postgraduate training standard for transplant pharmacists should include the completion of a 1-year general pharmacy practice residency, followed by a 1-year specialized transplant residency (Table 1) (21). Specialized fellowship training in basic and clinical research, specifically for transplant pharmacists, is also available and has assisted some transplant pharmacists to become independent researchers.

Table 1: Education and training recommendations for future transplant pharmacists

Completion of an ASHP accredited PGY1 pharmacy practice residency and PGY2 pharmacy specialty residency in solid organ transplant.
Completion of a research fellowship in solid organ transplantation can provide excellent preparation to conduct transplant-related research. However, to develop necessary clinical competence, fellowship training is not a substitute for PGY2 residency training in solid organ transplant.
Additional formal education opportunities are available to augment the transplant pharmacists practice potential; including areas in research, public policy and business administration.
Continuing education credits focused on organ transplant subject should be obtained annually.

Table 2: Transplant pharmacists activities

Time primarily dedicated for care of transplant recipients
Attend daily rounds with prospective evaluation of individual pharmacotherapy
Coordinate development and implementation of drug therapy protocols, assists in ensuring protocol adherence and measure outcomes with these protocols
Provide medication reconciliation, medication therapy management and discharge counseling
Provide education and training to members of the transplant team and practitioners in training
Facilitate cost containment strategies and pharmacotherapy optimization to maximize patient and center specific outcomes
Provide pre- and posttransplant medication education
Lead and assist with clinical and pharmacoeconomic research
Provide 24 h a day, 7 day a week pharmacotherapeutic support evidenced by daily documentation of activities in the patient's medical record

Roles and Responsibilities of the Transplant Pharmacist

The transplant pharmacist has traditionally taken on a role as a clinician in the day-to-day management of organ transplant recipients. However, given their education, training and advanced certifications, some pharmacists are also ideally suited to perform research. Basic activities of a transplant pharmacist based on current practice trends and surveys of currently practicing designated transplant pharmacists are highlighted in Table 2.

Clinical responsibilities

Clinical transplant pharmacists must combine the principles of several subspecialties to be effective team members. In essence, they need to know how to care for the whole transplant patient not just the new allograft. Oftentimes this involves optimizing pharmacotherapy from the intensive care unit to the ambulatory care clinic for adult and pediatric recipients. Knowledge of drug delivery, pharmacoeconomics, drug information, drug literature evaluation, statistics, immunology, pharmacokinetics, pharmacology, pharmacogenomics, pathophysiology, pharmacotherapy, pharmacovigilance, regulatory standards and safety are a necessity. Transplant pharmacists have substantial knowledge regarding novel and traditional immunosuppression, but must mesh this with other pharmacotherapy knowledge in areas such as infectious diseases, cardiology, hepatology, nephrology, pulmonology, endocrinology, hematology, pediatrics and critical care to optimize outcomes in patients with multiple comorbidities.

Although serving on the inpatient clinical team, the transplant pharmacist has a number of responsibilities during the pre-, peri- and posttransplant period. These include continual assessment of drug therapy prescribing, appropriateness, effectiveness and safety monitoring including drug concentrations and pharmacokinetics, pharmacodynamics, drug (drug, food, over-the-counter and dietary

supplement) interactions, drug administration, delivery and costs. Also they assume the role of admission and discharge medication reconciliation/facilitation/planning in conjunction with the nurse coordinator, midlevel practitioner, social worker and other members of the patient care team. Another major emphasis of practice is patient and caregiver education, not only in the posttransplant period but also during the pretransplant work-up to identify barriers related to access to medications posttransplant. In addition, the transplant pharmacist is frequently asked to evaluate and participate in discussions to determine which immunosuppression regimens and other drug therapies are best for the individual and most likely to result in positive outcomes. As a result, the transplant pharmacist, in conjunction with the rest of the patient care team, can play a vital role in coordinating drug therapy as they follow the patient throughout their continuum of care.

In the past decade, the transplant pharmacist's role has expanded significantly from the inpatient setting into the outpatient setting. In the ambulatory care or clinic setting, transplant pharmacists evaluate patients in a similar manner as described above on the inpatient team, but with particular focus on disease state management and minimizing long term complications utilizing the principles of medication therapy management. In this arena, usually more time can be dedicated to discuss side effects and changes in drug therapy with the patient in attempt to proactively manage and enhance medication adherence. Thus, a significant amount of time is focused on improving education and adherence which are factors associated with allograft loss (22–24). They may also assist in billing, prescription coverage assistance and cost reduction measures to aid the patient and health care facility. Transplant pharmacists in the ambulatory setting are also able to bill for their services at some centers, which may enable more centers to provide pharmaceutical care in the clinic. With the growing number of ambulatory practitioners there will be improved continuity of care between the inpatient and outpatient settings. Also, in this setting pharmacists have an opportunity to explore their impact through evaluating outcomes on routine basis after clinical initiatives are implemented.

Pediatric transplant programs are also an avenue where transplant pharmacists can play a significant role in optimizing pharmacotherapy in the inpatient and ambulatory care settings. The unique dosage forms, weight based dosing requirements and compliance issues associated with patient and caregiver education can be uniquely handled by a designated transplant pharmacist. Medication nonadherence was blamed on 14–31% of late acute rejections and 14% of grafts lost in a recent review of pediatric transplant trials evaluating adherence (25). Addition of a transplant pharmacist with a focus on medication adherence to the pediatric transplant setting may provide additional resources to cater to the unique pediatric challenges and impact short- and long-term patient outcomes.

Also the transplant pharmacist is a very accessible member of the patient care team. They often facilitate the development and implementation of immunosuppressive and nonimmunosuppressive drug and monitoring protocols. Following implementation, the transplant pharmacist is often called upon to measure the outcomes and effectiveness of these protocols and suggest modifications based on internal findings and the published literature.

Research responsibilities

A substantial number of the research questions explored in transplant surround immunosuppression and its sequelae. The transplant pharmacist's education, training and role uniquely position them to be an integral part of the research team. The design and execution of clinical research, specifically in transplant, necessitates a bridge between the different levels of care and a working knowledge of the logistics of medication use system. In addition, the transplant pharmacist is able to assist with obtaining pilot data, study design, data collection, and analysis. Many centers have adopted transplant PharmDs as their directors of clinical research or given them leading roles within their research teams associated with the development of research protocols, navigation/implementation of industry sponsored trials, regulatory and reporting efforts.

Literature support for transplant pharmacy

To date, the literature describing the role and impact of transplant pharmacists on daily patient care has been limited to sporadic reports. In comparison to pharmacy colleagues in critical care, whose research emphasizes the impact of pharmacists' recommendations on length of stay and intensive care unit costs, transplant pharmacists have focused on evaluating clinical and pharmacoeconomic outcomes associated with changes in drug therapy (26). Mitchell in 1976 first outlined the activities of a pharmacist on daily rounds with the transplant team (1). Since then there has been an evolution in the role and impact of transplant pharmacists, literally from the bench to the bedside and back again. Burckart recently recounted his experience with cyclosporine monitoring in the Pittsburgh heart transplant program in 1982 (27). Using limited resources and antiquated equipment, he and his team along with other pharmacists at the time were able to move therapeutic drug monitoring of calcineurin inhibitors into a mainstay of posttransplant care (27). It was not until recently that the transplant pharmacy community has begun outlining the true impact their practice has had on patient, allograft and economic outcomes.

In 2004, Martin and Zavala (28) described the expanding role of pharmacists on the transplant team. They conducted a survey of 118 transplant centers around the United States to determine how many transplant programs identified a pharmacist as part of their team. Forty-one (35%) of the centers responded and 28 centers reported pharmacists involvement on their team. Of the 28 centers,

25 of the identified pharmacists had PharmD degrees and were funded through the department of pharmacy. Fifty-seven percent of pharmacists spent >80% of their time taking care of patients, and the majority of pharmacists focused on kidney transplant recipients (28). This survey represents the paucity of data present in the literature describing the role of transplant pharmacists. However, this report also highlights that the primary role of the transplant pharmacist still remains clinical.

The majority of literature highlighting the impact of transplant pharmacists focuses on patient adherence and the impact of clinical pharmacy services in the ambulatory care setting. Chisholm and colleagues in 2001 evaluated the impact of clinical pharmacy services on immunosuppressive medication adherence in kidney transplant recipients (29). At 1 year posttransplant the adherence rate in patients who received clinical pharmacy services was $96.1 \pm 4.7\%$ versus $81.6 \pm 11.5\%$ in the group that did not see a pharmacist, $p < 0.001$. In addition, the authors observed that patients who received pharmacy services were more likely to reach target immunosuppressive blood levels when compared to the control group (29). In a subsequent study, Chisholm et al., demonstrated that clinical pharmacy services had a positive impact on blood pressure control in African American kidney transplant recipients (30). One group received clinical pharmacy services including medication review and recommendations for drug therapy management of blood pressure, while the control group did not. Mean blood pressure throughout the study period was significantly lower in the treatment versus the control group (30).

Wang et al. (31) recently described the impact of transplant pharmacists on prescribing habits and patient outcomes. Renal transplant recipients seen in the outpatient clinic between 2005 and 2006 were evaluated by pharmacists prior to being seen by their physician. Pharmacists evaluated laboratory values and medication regimens and provided recommendations to attenuate toxicity and improve efficacy. Recommendations were graded and stratified based on acceptance by the treating physician. Patients were then followed for 2 successive months or on a subsequent visit to determine if the patients' problem had resolved, improved or worsened based on the pharmacists' recommendation. Thirty-seven patients were included in the analysis, 81.8% of the time recommendations were considered 'significant' based on predefined criteria, and 96% of the time was accepted by the physician. Primary recommendations pertained to medication selection and improved the patient's underlying problem 94.2% of the time (31). Although there are several limitations to this study, it outlines the impact of pharmacists in the transplant ambulatory care setting.

There is limited data correlating the direct impact of pharmacy clinical services on patient outcomes. This is likely due to the complexity of measuring impact based on surro-

gate markers although the roles and responsibilities have been outlined in several publications (17, 32). The impact of transplant pharmacists however is demonstrated in their ongoing research efforts. An informal survey of the ACCP Immunology/Transplantation PRN 263 person membership conducted between August 2009 and December 2009, with a response rate of 51% (133 of 263), indicated that 46% (61 of 133) of respondents have presented as first author at a national meeting while practicing as a transplant pharmacist. Twenty-nine respondents also indicated that they have been the first author on abstracts that have been accepted for oral presentation at a national meeting. In addition, 51 respondents indicated that they have been first author on a peer-reviewed publication while practicing as transplant pharmacists. Transplant pharmacists have been asked to participate on several national consensus conferences and advisory groups including: the Drug Substitution in Transplantation National Consensus Conference sponsored by the National Kidney Foundation (NKF), Washington, DC, 1998, the Consensus Conference on Reproductive Issues in Transplant Recipients, sponsored by the AST, American Society of Transplant Surgeons (ASTS), and the NKF in Bethesda MD, 2003, AST Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants, St. Louis, MO, 2001, the Non-Adherence Consensus Conference (sponsored by AST, ASTS, HRSA, ASN, IPTA and UNOS), Tampa FL, 2008 and the High Risk Renal Group (sponsored by, International Transplant Nurses Society), Washington, DC, 2008. More recently, transplant pharmacists also contributed to the International Society of Heart and Lung Transplant guidelines for the care of cardiac transplant recipients, which included language describing the role of the transplant pharmacist on the multidisciplinary team (33).

Governing/Professional Body Support for Transplant Pharmacy

Over the past several years, an array of professional, regulatory, and other organizations have formalized the role of the pharmacist within transplantation. These far reaching organizations include AST, UNOS, ACCP, the American Society of Health-System Pharmacists (ASHP) and CMS.

In 2004, the UNOS bylaws were amended to include very specific information on the roles and responsibilities of a designated transplant pharmacist. The bylaws mandate that 'all transplant programs should identify one or more pharmacists who will be responsible for providing pharmaceutical care to solid organ transplant recipients'. The clinical transplant pharmacist should be a designated member of the transplant team and will be assigned primary responsibility for providing comprehensive pharmaceutical care to transplant recipients in a culturally competent manner. The transplant pharmacist will work with patients and their families, and members of the transplant team,

Table 3: Example questions asked by CMS surveyors for transplant pharmacists during the accreditation process

1. What are your responsibilities as a transplant pharmacist?
2. Please discuss any initial or ongoing training you received regarding the transplantation process, or working with transplant recipients and living donors.
3. Describe your role in evaluation and follow-up of organ transplant and organ donor patients.
4. Describe your responsibilities and participation in the multi-disciplinary team.
5. Are there pharmacological screening criteria used in the transplant program evaluation, are these selection criteria followed?
6. How are the medications updated on the patient profile, how is this communicated and verified by the transplant team. How are medication changes and updates communicated to the transplant or donor patient pre- and postprocedure?
7. What are your responsibilities for patient education, pre-op, post-op?
8. What are your discharge criteria for organ transplant patients?
9. What role do you play in staff education and how often?

including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel at the transplant program. The transplant pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy, who performs or

oversees evaluation of medications and aids the team of other healthcare personnel and support staff in regard to pharmacotherapeutic related issues (16).

The bylaws go on to state specific responsibilities that the transplant pharmacist should perform during the peri- and postoperative phases. These include patient and health care education and counseling on medication therapies, monitoring and recommending changes to medication therapy to optimize outcomes, and communicating medication related issues to patients, caregivers, and other health care providers. It is important to note that these changes to the bylaws were the result of an organized, dedicated, and coordinated effort of the leaders within the transplant pharmacy profession. This ensured that the pharmacist role within transplant patient care that was formalized within these bylaws was perfectly aligned with the profession's best practice standards (16).

CMS must designate a transplant program as an approved center in order to receive reimbursement for services rendered. Because the vast majority of transplant recipients have Medicare as a primary or secondary insurance, CMS payments are the lifeblood for nearly all transplant programs. Over the past several years, CMS has been surveying and accrediting transplant programs with formal, on

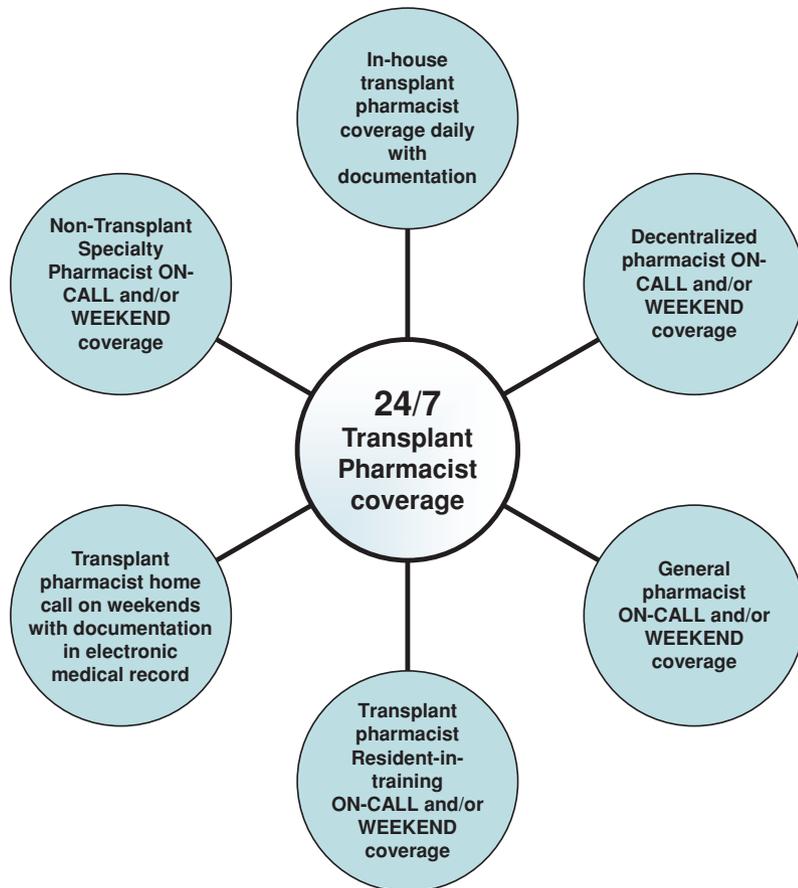


Figure 1: Transplant pharmacist coverage varies from center to center and is dependent on the funding source, resource allocation and goals and objectives of the transplant program. An ideal model to provide comprehensive transplant pharmacist coverage is lacking and provides a welcoming platform for future clinical research. This figure depicts various options for coverage commonly used today. Ideally transplant trained pharmacist should cover the services 24 h a day, 7 days a week (as depicted in the center); however this is often not possible. Additional options for coverage are represented by the additional circles surrounding the center. We define 'In-house' 5-day work week, normal business hours, 'On-call remote' is at home; and pharmacist does not come to facility but provides documentation in an electronic medical record, 'On-call as needed' is at home; comes into the facility if needed, while 'at home' daily review of medical records on weekends with documentation in the electronic medical record. For example, in smaller centers and centers with limited resources may rely on on-call services or supervised cross coverage by decentralized, general clinical, nontransplant specialty or resident in training pharmacists.

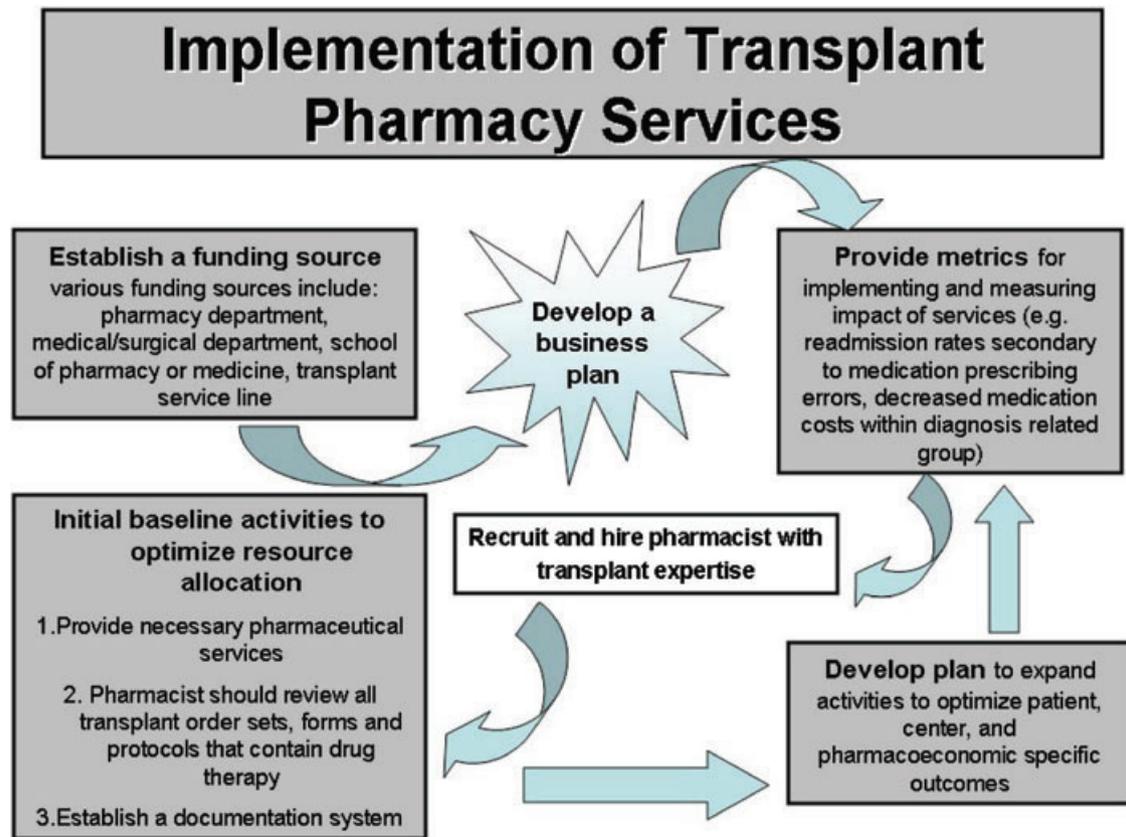


Figure 2: Simple representation of the approach to implementation of novel pharmacy services on the transplant team. Integration of the transplant pharmacist into the team will depend on their aptitude and skill level; however the basic activities of each transplant pharmacist should meet the minimum standards outlined in this manuscript.

site visits of the centers. These surveys are independent of the Joint Commission and UNOS visits, but are similar in the type and scope of review that occurs. On March 30, 2007, CMS published the Medicare Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants. This 86 pages document delineates the specific requirements that CMS mandates each transplant center to meet in order to achieve accreditation. The document also compares each of these requirements to the UNOS bylaw requirements (OPTN policies). Pharmacy services are briefly described in this document, but not to the degree or detail as within the UNOS bylaws. The CMS document states, 'The transplant center must identify a multidisciplinary transplant team (composed of individuals from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology) and describe the responsibilities of each member of the team'. The document does not specify that a pharmacist must be the expert with pharmacology knowledge; however, during a public comment and response period, CMS noted that OPTN policies (UNOS bylaws) delineate the specific role of the pharmacist within the transplant team and no further clarification was necessary within the CMS document (18).

After completion of these rules, CMS developed a document to assist transplant centers in planning for the survey visits. The document states that the pharmacy will be toured and that the transplant pharmacist(s) will be interviewed during the visit. Personnel files for the transplant pharmacist(s) will be reviewed, including documentation of transplant pharmacy expertise and continued education and transplant pharmacy competency. Additionally, all of the methods in which the transplant pharmacist documents patient care activities within the medical record, will be evaluated. CMS is looking for documentation that a transplant pharmacist reviews and reconciled home medications upon admission and discharge, and documents that a medication education discharge program is routinely occurring for each transplant recipient. During the interview, the CMS surveyors usually ask some, if not all, of the questions outlined in Table 3 to the transplant pharmacist(s) (18). A common question is how often must documentation be provided to detail the involvement of the transplant pharmacist? And should this include weekends? Centers have adopted several interpretations of the CMS requirements based on their resources which are highlighted in Figure 1.

How to Implement Transplant Pharmacy Services

Centers wishing to integrate a pharmacist into their transplant team can adapt the example provided in Figure 2. The optimal ratio of transplant pharmacists to number of transplants is truly undefined and is ultimately dependent on each center's practice model and the requirements for that pharmacist will evolve to meet each center needs. Other considerations include the type of organ transplant, local collaborative practice rules, funding source and the quality of the pharmacist placed in the designated role. Recently, the American Society of Health System Pharmacists awarded one center for its *pharmacist lead* efforts in reducing medication related adverse effects, delayed discharges, readmission, infection and acute rejection rates as well as improvement in patient medication assistance and outpatient capture of medication related revenue. Additional information about these efforts can be found at <http://www.ashpfoundation.org/MainMenuCategories/Awards/AwardforExcellenceinMedicationUseSafety/2010Recipient.aspx> [accessed 3/5/11]. Illustrating pharmacist lead efforts in reducing costs, including transplant pharmacists hours in the CMS reports, allocating research involvement with associated dollars, and optimizing outpatient pharmacy prescription revenue are some methods for implementing new transplant pharmacy services. Today investment in the transplant pharmacist can lead to improvement in inpatient and outpatient medication resource allocation and compliance through contracting, billing and education.

Future Direction of Transplant Pharmacy

Transplant pharmacists are uniquely positioned to aid the transplant team in patient education, patient transition between levels of care and medication therapy management. Broader expansion of transplant pharmacy services into the pediatric and ambulatory care settings has the potential to impact both patient and center specific outcomes. Results of ongoing economic evaluations of transplant clinical pharmacy services are needed to fully describe the impact of transplant pharmacists, suggest appropriate staffing levels, and provide fiscal support for the economic value associated with the increased expenditures. Implementation of a transplant pharmacist will optimize patient, allograft and pharmacoeconomic outcomes. Pharmacist lead protocol development, implementation and continual quality assessment through clinical research will enrich the potential for the improved long-term benefits of transplantation.

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