

ASHP Guidelines on Pharmacy Services in Solid Organ Transplantation

Evidence of pharmacists' contributions to the care of organ transplant recipients has existed since the 1970s. Since then, literature describing pharmacist's impact on clinical and pharmaco-economic outcomes has grown exponentially,¹⁻¹⁴ with pharmacists establishing themselves as integral members of the transplantation community and expanding their presence in multiple areas, including pharmaceutical industry, research, academia, quality improvement, and clinical settings.¹⁵⁻²⁰ Transplant pharmacists (sometimes referred to as *clinical transplant pharmacists* or *solid organ transplantation pharmacists*) have a strong presence in the areas of pharmacogenomics, innovative collaborative drug therapy management (CDTM), and prospective practice management.

The United Network for Organ Sharing (UNOS) and the Centers for Medicare & Medicaid Services (CMS), respectively, require transplantation centers document the participation of a clinical transplant pharmacist or pharmacology expert on multidisciplinary transplantation teams in order to meet accreditation standards. These regulations make transplant pharmacy the only pharmacist specialty practice in the United States to have such a requirement.²¹⁻²⁴ These mandates outline the responsibilities of the transplant pharmacist in preoperative and postoperative pharmaceutical management and education of transplant recipients. In response to the demand for pharmacists to meet these accreditation standards, some transplantation programs may meet the need by utilizing pharmacists without specific transplantation training or experience due to lack of fully trained personnel or funding resources.

As of 2016, there were over 30,000 solid organ transplantations performed annually in the United States, and over 500,000 have been performed since the year 2000.²⁵ Despite the volume of transplantations per year, there was a median of 1.4 transplant pharmacist full-time equivalents (FTE) per 100 transplantations performed, according to a national workforce survey conducted by the American Society of Transplantation across accredited U.S. transplantation programs.²⁶ The median number of FTE did not increase beyond 1.4 FTE even in programs with >400 transplantations per year. These data indicate that transplant pharmacy services are provided by nonspecialists in many of these programs. Currently, there is no standard of practice for the provision of transplant pharmacy services, as the CMS Conditions of Participation allow for a broad interpretation for how to best meet the needs for each patient.²⁷ This broad interpretation allows for a wide spectrum of transplant pharmacy services, with some centers providing a more inclusive model than others. This variability has led to recent CMS citations during program-specific surveys when the pharmacists involved in the care of transplant patients and donors were unable to provide sufficient evidence of qualifications, training, and expertise in transplantation.

Purpose

In 2011, the American Society of Transplantation, Transplant Pharmacy Community of Practice, in collaboration with

the American College of Clinical Pharmacy Immunology/Transplantation Practice and Research Network, developed a white paper that provided a blueprint for the training and qualifications of pharmacists working in transplant patient care and detailed the contributions of pharmacists serving the transplantation population.²¹ These guidelines augment the previously published work by promoting understanding of the evolving role of pharmacists' contribution to the care of transplant recipients and living donors, helping define the role of the transplant pharmacist, suggesting goals for providing services to meet institution-specific needs, and describing best practices for transplant pharmacy services. These guidelines were developed based on primary literature, expert consensus on best practices, and CMS and Organ Procurement and Transplant Network (OPTN) bylaws, and are meant to aid transplant pharmacists, administrators, physicians, surgeons, allied health professionals (e.g., nurses, dietitians, financial coordinators, business managers), accreditors, surveyors, and others with a need to understand transplant pharmacy services.

Although the nature of these services are unique to each solid organ and with each institution's protocols and resources, these guidelines describe both transplant pharmacist services that meet the minimum required by regulations (as of publication) as well as optimal services. In conjunction with pharmacy, transplant surgery, and medicine administrators, each transplant pharmacist should use his or her professional judgment to individually weigh the factors that determine which services should be provided. These factors include the patient populations served, the number of pharmacists and time dedicated to services provided to the care of transplant patients, whether corresponding duties are required of transplant pharmacists in other areas of the hospital, and the extent of time dedicated to administrative, research, and quality endeavors. Finally, it should be noted that the many responsibilities described in these guidelines could not be provided by a single pharmacist. When used in these guidelines, the term *transplant pharmacist* should not be interpreted to imply that a single pharmacist could or should be expected to provide every service described.

Pharmacy Services in the Pretransplantation Phase

The pretransplantation phase includes all activities related to the assessment and evaluation of a donor or candidate's readiness for transplantation and the execution of any plans to increase a donor or candidate's success. This includes the initial assessment and any re-evaluation that may occur during the waiting list period, as described in Appendix A.

Pharmacologic Evaluation. At a minimum, a transplant pharmacist should be present during the multidisciplinary patient selection committee meeting. Transplant pharmacists are expected to present an objective assessment of the candidate's pharmacologic and nonpharmacologic risks pertaining to transplantation.^{28,29} Although each assessment

should be tailored to the individual patient, an assessment of anticoagulation, drug interactions, medications related to mental health, medications for chronic pain, medication allergies, hormonal contraception and replacement therapy, current use of immunosuppressants or immunomodulators, issues with drug absorption, illicit substance use or abuse, and use of herbal supplements or nutraceuticals should be completed. Although not universal, an assessment of immunologic risk as it pertains to induction therapy selection and need for desensitizing therapies during the selection meeting provides an opportunity to discuss protocol versus off-protocol decisions and may expedite the perioperative immunosuppressant selection process. The impact of current pharmacologic therapies on pretransplantation testing (i.e., false-positive drug screens, timing of vaccinations in relation to antibody titers) and peri- and post-transplantation risks should be discussed at this time.

Nonpharmacologic Evaluation. In addition, an assessment of nonpharmacologic risks and socially related risks should be presented, in conjunction with members of the multidisciplinary team, including transplant social workers and financial coordinators.^{28,29} Transplant pharmacists are well-suited to identify gaps in health literacy, markers of medication nonadherence, and preexisting intolerances and adverse effects to pharmacotherapy that may affect post-transplantation immunosuppressant adherence. Along with financial coordinators, pharmacy technicians and community/specialty pharmacy partners, transplant pharmacists should be involved in conversations regarding pharmacy benefit and out-of-pocket medication costs and proactively understand the specific distribution requirements of each patient's pharmacy benefit manager.

Mitigation Plan. Along with the initial assessment, a thorough mitigation plan, when warranted, should be presented, along with any risks identified. Risks may be identified in one of two ways. The first is a basic chart review, which includes assessing the demographics of the patient (age, race, height, weight, body surface area, body mass index, distance from transplantation program, type of insurance), basic vitals, a complete medication list (including nonprescription medications, dietary supplements, and herbal remedies) and immunologic history (cause of end-stage organ disease, calculated panel reactive antibody, unacceptable antigens, deceased versus live-donor transplant). This type of review is limited in the breadth of information available and in its dependence on the accuracy of information provided. A more comprehensive face-to-face assessment includes the elements of the basic chart review and may include a health literacy assessment, an interview to elucidate barriers to adherence, accuracy of the medication history, and provision of initial medication education. Documentation of transplant pharmacy services in the pretransplantation setting must meet the regulatory requirements for individual centers based on policies developed in accordance with CMS Conditions of Participation and UNOS policy.

Pharmacy Services in the Perioperative Patient

Pharmacist involvement in the care of a patient receiving a transplant is intended to facilitate transition from the

pretransplantation phase through inpatient discharge from the transplantation encounter. Transplant pharmacists work with healthcare professionals in all settings of care to ensure a seamless medication-use process, provision of transplantation medication education, and discharge planning through each transition of care.^{21,22}

Direct Patient Care of the Transplant Recipient. Transplant pharmacists are charged with providing comprehensive pharmacy services to transplant recipients during the pretransplantation hospitalization.^{1,2,27,29} Activities routinely performed as part of this suite of services are outlined in Appendix A. In 2015, the transplant pharmacist workforce was surveyed to enumerate several data points, including perioperative pharmacy services performed.²⁶ Notably, the vast majority of the surveyed pharmacists routinely performed medication and laboratory review, recommended changes to both transplantation-related and unrelated medications, performed bedside rounding as part of the multidisciplinary team, and provided medication education to the transplant recipient. As part of comprehensive pharmacy services, the transplant pharmacist serves as the medication expert, provides drug information to all members of the team (including information regarding drug-drug interactions), and participates in collaborative decision-making, especially at the bedside, for the transplant recipient.

Certain medications used for induction and maintenance therapy as well as in the treatment for rejection warrant restrictions on use per center-specific policy. The role of the transplant pharmacist may focus on the recommendation and approval of high-risk medications, such as mono- and polyclonal antibodies, intravenous immune globulin, and certain formulations of immunomodulators (e.g., intravenous calcineurin inhibitors) to ensure appropriate use, patient safety, and cost containment. Having a bedside presence facilitates the determination of optimal therapy, selection, and dosing recommendations in a timely manner. To facilitate the bedside presence, it is recommended that designated transplant pharmacists be provided handheld technology or portable computers. Other factors to consider include the integration of the transplant pharmacist's clinical duties into hospital information systems (e.g., computerized provider order entry systems) as well as the workflow and communication with decentralized, floor-, or unit-based pharmacists.

Direct Patient Care of the Living Donor. The proportion of living related and unrelated directed donation of kidney and liver allografts is increasing.^{3,4} Many factors contribute to this trend, most notably, kidney paired and chain donation and the increasing success of living-donor liver transplantation. The transplant pharmacist is responsible for providing comprehensive pharmacy services to the living donor as well as the transplant recipient.^{1,2,30} These services include pain management, bowel care, fluid and electrolyte management, and education on aftercare regimens. Moreover, the expertise of the transplant pharmacist is needed to modify existing medication regimens to minimize the risk to the retained kidney or liver lobe to ensure its long-term health and viability.^{5,6}

Multidisciplinary Team Participation. Transplant pharmacists are required members of the multidisciplinary transplant team.^{1,2,21-24,26,27,29,30} Transplant pharmacists provide

valuable services to the team, as described in Appendix A. Fruitful collaboration with all members of the team should be undertaken by the transplant pharmacist. In addition to active participation in preoperative evaluation and as a member of the patient selection committee, the transplant pharmacist works closely with their primary surgical and medical colleagues as well as with consultants in the perioperative period to contribute to medical decision-making as described previously. Further collaboration with the transplantation coordinator, social worker, financial coordinator, and others should be undertaken to enhance medication access to confirm and expand on work done during the pre-transplantation phase. When appropriate, additional collaboration on scientific research with members of the team can help provide high-risk patients with novel approaches to pharmacotherapy.

Medication Access and Planning. As described by Spivey and colleagues, access to pharmacotherapy is strongly correlated with adherence behaviors, which is closely tied to allograft survival.³¹ Moreover, decisions regarding medication coverage by CMS in the United States rely nearly exclusively on the Food and Drug Administration (FDA) labeled indications. Labeled indications are most common for immunomodulating agents in kidney transplantation and are absent in lung transplantation. Thus, access to critical medications for allograft and patient survival vary by organ.³² The transplant pharmacist engages with transplant coordinators, social workers, finance coordinators, and physicians to advocate for and garner access to such critical medications through multiple avenues. Strategies to ensure access include federal and private insurance coverage, pharmaceutical manufacturer access programs, foundation grants, local government support, and others and should be undertaken by members of the transplant team in consultation with a transplant pharmacist. Importantly, transplant pharmacists can provide critical information to enhance the success of appeals both in drug information and navigating the industry. A critical practice recognized in transplantation is the bedside delivery of transplantation-related medications. Alongside retail and specialty pharmacy colleagues, transplant pharmacists are integral in the logistics of coordinating the initial supply of medications upon discharge. Bedside delivery of medications is critical for hands-on discharge education (including the use of patient-directed filling of medication pill boxes) and verification of the accuracy of dosing, dosage forms, and formulation (i.e., innovator versus generic). This crucial step in discharge planning enables identification of insurance barriers to access medications, such as the need for prior authorization, formulary management, or need for patient assistance programs.

Patient and Caregiver Education. As the medication expert, the transplant pharmacist is the most qualified person on the multidisciplinary team to provide or oversee medication-related education to the recipient and caregiver. As described previously, adherence to the post-transplantation regimen is directly related to long-term organ survival.^{8,9} Appropriate education enhances medication adherence, extending allograft life. Using education level-appropriate language, the transplant pharmacist provides medication education to the recipient and caregiver and assesses the adequacy of understanding using validated scales, tests, or

recall approaches such as teach-back. Strategies include multimodal interventions, which may include traditional verbal education, web- or video-based technologies, visual aids for low-literacy or illiterate patients, hands-on medication training, and applications on smart phones.

Documentation. CMS program accreditors directly examine the medical record for evidence of comprehensive pharmacy services provided to individual transplant recipients and transplant pharmacist involvement in multidisciplinary rounds.^{1,2,21,22} In the perioperative period, the transplant pharmacist is required to follow their hospital's multidisciplinary care policy. Each hospital policy at minimum must detail how the transplant pharmacist is involved in the transplant phase and discharge phase of care for each transplant patient. Transplant pharmacists should be able to provide evidence of collaboration on medication-related decision-making; sufficient completion and understanding of patient and caregiver education prior to discharge; and the discharge medication regimen, goals, frequency of testing, and expected adherence ability. It is critical that there is evidence of the transplant pharmacist's involvement in the transplant and discharge phase of transplant.

Pharmacy Services in the Post-Transplantation Phase and Ambulatory Setting

Because transplantation immunosuppression is the cornerstone of allograft success, transplant pharmacists are essential in the long-term management of transplant recipients. Ideally, transplant recipients should have access to a transplant pharmacist for the duration of their allograft, and the transplant pharmacist must be part of the multidisciplinary team providing care to transplant patients, as described in Appendix A.

Direct Patient Care. Monitoring immunosuppression and allograft function, making appropriate adjustments after transplantation, and managing co-morbid disease states are integral roles of the transplant pharmacist. As transplant pharmacists transition from a retrospective, chart-review model to a role that involves prospective and real-time decision-making, participation on inpatient rounds and in the ambulatory setting is critical. Provision of direct patient care through participation in selection and adjustment of critical medication regimens, discussion and mitigation of medication-related adverse events, and facilitation of education regarding and consideration of evidence-based practices by the medical and surgical teams at the time of decision-making is an expected element of pharmacotherapy provided by a transplant pharmacist. The ideal is to be physically present during rounds and clinic visits and represent a visible, well-integrated member of the multidisciplinary team. Depending on the number of patients and their acuity, these activities may be tailored to focus on the most critically ill patients or on medications that bear a heightened risk of causing significant patient harm when they are used in error, associated with high rates of adverse effects, or the activities may be based on a triage system developed with or without clinical decision support software. Documentation of the transplant pharmacist's activities during the encounter and resultant

discussion with the multidisciplinary team will be utilized to facilitate transitions of care from the inpatient to outpatient encounter as well as from each clinic visit to the next.

In addition to the management of transplantation immunosuppression, the selection and adjustment of post-operative antimicrobial prophylaxis regimens and involvement in antimicrobial stewardship is a standard role for transplant pharmacists.³³ Through transplantation- and organ-specific guidelines, centers each have their own specific antimicrobial prophylactic protocols.^{2,3,33,34} After discharge, the metabolic function of patients' organs are often evolving. Patients with impaired renal function or impaired hepatic function often require close monitoring and medication dose adjustment in the ambulatory setting.

Drug-drug interactions are also a concern when starting or stopping prophylactic medications, primarily in aspergillosis prophylaxis, for which azole antifungals are the drugs of choice.³⁴ These medications have substantial interactions with calcineurin inhibitors and mammalian target of rapamycin (mTOR) inhibitors, and dosage adjustments must be taken into account both when azoles are started, stopped, or have dose adjustments.³⁴

Medication and Adherence Education. Two critical services provided by the transplant pharmacist that help ensure the long-term success of transplantation are communicating drug therapy regimen changes to other healthcare providers and providing patients with the tools they need to understand their complicated medication regimens.¹¹ Access to transplantation-specific medication expertise is an integral part of patient adherence, welfare, and satisfaction, and such education enhances the transplant center's ability to provide high-quality, individualized care to each patient.^{11,35,36}

Drug therapy regimen changes can be relayed in a number of ways and these methods will vary according to the established practice at a local center. A common means of communication is verbally during multidisciplinary patient care rounds and patient care discussions. Written documentation in the medical chart, computerized order entry, and use of collaborative practice protocols can also serve as communication between members of the transplantation team. Conveying medication changes to patients and their support may include use of web- and app-based medication lists, handwritten medication sheets, in-person changes made during clinic visits and phone calls.

The provision of medication education is an essential requirement in transplantation. Often, this education is provided by transplantation coordinators, nursing staff, dedicated educators, or pharmacy technicians, in addition to transplant pharmacists. If the primary education is provided by someone other than a transplant pharmacist, the transplant pharmacist should serve as the final assessor of the comprehension of the salient points of medication adherence. Although this process most often is initiated peri-operatively, provision of adherence education in the post-transplantation phase is critical for maintaining the patient's adherence skills as well as real-time assessment of the patient's changing adherence needs over time. Ongoing pharmaceutical education throughout the continuum of care is a necessary service each center should provide. The transplant pharmacist has the insight and knowledge to tailor each regimen while staying in compliance with department-specific protocols. At a minimum, the transplant pharmacist should

provide structured education either during the pre-evaluation or waiting-list period through discharge from the transplantation hospitalization. Essential components include provision of education focused on names, indications, adverse effects, monitoring, and goals of therapy of transplantation immunosuppression and associated antimicrobial therapy. A self-assessment checklist or competency should be demonstrated prior to discharge from hospitalization, and targeted education should be provided on an ongoing basis in the post-transplantation setting focused on areas of deficiency. Education should be provided beyond the immediate post-transplantation time period, at annual transplantation visits at a minimum, but ideally more frequently, to ensure lifelong adherence. Essential activities that transplant pharmacists should be involved with either directly or in a supervisory role include bedside delivery of transplantation medications, education on use of aids such as medication pill boxes, supervised filling of medication pill boxes, visual use of medication lists, installation of adherence mobile health technology applications, and continued aid from the transplantation team for medication refills, medication access, or delivery, as well as help navigating the health insurance marketplace.

Execution of Protocols. Transplant pharmacists play an integral role in the development and maintenance of organ-specific post-transplantation immunosuppression protocols.²¹ These protocols should address not only the direct postoperative hospital stay but also include care throughout the life of the allograft. Through collaborative practice agreements and CDTM, the transplant pharmacist is involved in routine follow-up of post-transplantation care to assist in compliance with each center's protocols.

The need to deviate from protocols due to various factors is a common occurrence. The transplant pharmacist is uniquely positioned to identify adverse drug effects identified through both laboratory monitoring and direct patient interaction. Detailed monitoring of protocol deviations, either from a research standpoint or from a quality- or process-improvement initiative, helps programs identify areas of need for protocol and policy revisions. When adverse drug effects are identified, the transplant pharmacist is involved in decision-making and face-to-face patient interaction regarding planned follow-up and further monitoring of immunomodulatory medications.^{20,36} Evidence of therapy management and patient education in all settings should be easily accessible within the medical record.

Transitions of Care. The transition of care from the inpatient transplantation event to the post-transplantation clinic is a critical threshold for the transplant patient to cross. The transplant pharmacist serves a critical role in discharge planning, patient education, and meeting center length-of-stay goals.^{13,17,34}

The optimal model is for transplant pharmacists to have direct involvement in medication reconciliation from the inpatient encounter to the outpatient transplantation team to convey critical information and ensure patient safety. Most important are medication changes made during the discharge process, which may encompass formulation changes, dose adjustments, therapeutic substitutions made due to insurance formularies, and follow-up processes related to prior authorizations and patient assistance applications. Transplant pharmacists often serve as a resource for medication optimization, medication access, and patient advocacy.^{7,8,18,19,21,26}

Management of Allograft Injury and Loss. Even with optimal adherence and medication management, patients are still at risk for acute and chronic immune-mediated allograft injury. Development of protocols for the management of cell-mediated, antibody-mediated, and chronic allograft rejection or dysfunction is an integral role of the transplant pharmacist.²¹ Because rejection or dysfunction in each organ presents differently, the transplant pharmacist must be familiar with the immune-mediated complications specific to each organ type. Treatment of these immune-mediated disease states often requires administration of biological medications. These treatment modalities are high-cost, high-toxicity regimens, and should only be used when necessary. Through development and implementation of evidence-based protocols, the transplant pharmacist should lead the biological medication stewardship program within the transplant patient population.¹⁵

Many renal allografts are lost secondary to patient death from cardiac disease, highlighting the importance of managing comorbid conditions following transplantation. Disease states such as infections, diabetes, hypertension, hyperlipidemia, heart failure, hyperparathyroidism, and osteoporosis are common after transplantation.^{6,16,18,37,38} To compound the challenge of managing these conditions, many of the medications necessary for transplantation exacerbate these disease states.

As transplantation centers grow and transplant patients live longer, the need for transplantation center providers to become medical hubs increases.³⁹ Through CDTM and collaborative practice agreements, many of these comorbid conditions can be managed by a transplant pharmacist along with immunosuppression. The transplant pharmacist has the ability to combine transplantation-specific medications and disease-specific best practices to optimally manage patients' pharmacotherapy.

Pharmacist Involvement in Treatment of Key Patient Populations

Transplant pharmacists participate in the care of high-risk patient populations following transplantation, as described in Appendix A. In particular, a transplant pharmacist may have great impact on the care provided to pediatric patients, given the inherent risks and unique issues associated with this population. Pediatric transplant recipients present distinctive pharmacology challenges, such as an evolving immune system, variances in pharmacokinetics, pediatric-specific disease states, growth and cosmetic considerations, coming of child-bearing age, and many more. Because of these factors, transplant pharmacists caring for pediatric patients need to be knowledgeable in pediatric dose calculations, routes of administration, and dosage forms. Pediatric patients may require dosage forms not commercially available, and transplant pharmacists serve as a resource for compounding and acquisition for outpatient use. Along with pharmacology challenges, pediatric transplant recipients also have added communication and socioeconomic barriers often unique to this population.

Transplant pharmacists also have a key role in the long-term and ambulatory care of pediatric transplant recipients. A pediatric transplant pharmacist's responsibilities include immunosuppression and opportunistic infection prophylaxis management, assessment of adherence and participation in

treatment of nonadherence, reinforcement of education with parents and patients (if appropriate), growth-related medication dose adjustment, recommendations to ensure proper vaccinations, and participation in transitioning adolescents to teenage or adult care. Furthermore, this population may be exposed to immunosuppression for decades. Transplant pharmacists collaborate with providers to optimize regimens, including adjunct therapies, that consider chronic effects of immunosuppressants.

Pregnancy following transplantation is not uncommon, and it is recommended that transplant pharmacists have a key role in contraception, pre-conception, and perinatal care. These high-risk mothers should be managed by both transplantation practitioners and specialists in high-risk pregnancies.^{40,41} Clinicians are challenged to find medications regimens that are safe, due to limited data regarding safety during pregnancy or breast feeding. To optimize care of patients who desire pregnancy or who are pregnant following transplantation, transplant pharmacists should work with transplant physicians to create a plan for transitioning to a safe immunosuppression regimen for pregnancy, including a monitoring plan that accounts for the changes in pharmacokinetics of immunosuppression that occur as a pregnancy progresses, and provide education to patients regarding their new regimens, including post-partum implications, such as medication safety while breast-feeding.

An important regulatory requirement transplant pharmacists fill in the care of women of childbearing age is the provision of risk evaluation and mitigation strategies and elements to assure safe use education for mycophenolic acid products.⁴⁰ As part of transplantation medication education, transplant pharmacists provide important education regarding timing of pregnancy and conversion to alternative immunosuppressive agents. Furthermore, transplant pharmacists work closely with transplant and OB/GYN teams for immunosuppressive management during preconception, conception, and post-delivery care.

The breadth and scope of healthcare conditions within the transplant population is constantly expanding, and as the population changes and medication management evolves, so too must the transplant pharmacist. Specialty populations, such as human immunodeficiency virus-positive, geriatric, bariatric, cystic fibrosis, and pediatric patients, as well as patients with multiple comorbid disease states, require knowledge of transplant immunomodulation and the ability to tailor the application of treatment best practices to the transplant-specific framework where appropriate. The experienced transplant pharmacist clinician is uniquely equipped to provide patients with the optimal care plan in these situations.

Transplant Pharmacist Administrative Responsibilities

Due to the regulatory requirements unique to transplantation programs, transplant pharmacists perform many administrative duties, as described in Appendix A. As integral members of the multidisciplinary transplantation team, transplant pharmacists have the essential skill set that allows them to develop, maintain, and govern transplantation policies and protocols, contribute to quality measures, and ensure a high level of care for all transplant recipients and donors.

Transplantation is perhaps the most highly regulated of all pharmacy specialties. It is imperative that transplant

pharmacists become familiar with the requirements in all phases of transplantation based on their center's internal policies, which must be written in accordance with regulatory agencies. As a member of the multidisciplinary team to have roles in all three phases of transplantation (pretransplantation, perioperative, and post-transplantation), transplant pharmacists are suited to have a designated role in formulary management, development of collaborative practice agreements, and medication-use evaluation. Transplant pharmacists have been instrumental in analysis of center-specific protocols to ensure efficacy and safety and minimize cost to help maintain transplantation as a fiscally solvent option for centers.

It is an expectation that transplant pharmacists will facilitate quality improvement efforts related to pharmaceutical care, including but not limited to the evaluation of adverse drug events, outcomes, cost and optimization in accordance with UNOS- and CMS-prescribed Focused Quality Assessment and Performance Improvement (FQAPI) activities. Several transplant pharmacists from around the country have assumed roles within transplantation quality and facilitate the FQAPI process.^{23,24} They are able to fill this unique position through their experience conducting clinical research, performing analysis of medication-related adverse events, and facilitating care during the pre-transplantation, perioperative, and post-transplantation periods. Center- and organ-specific transplantation protocol development and continuing review is paramount to ensuring quality of care. To facilitate ongoing review of center- and organ-specific protocols, transplant pharmacists use internal and external data to evaluate and optimize safety and efficacy. Several transplant pharmacist-led evaluations of induction, maintenance, and de novo immunosuppressant studies have been published.⁴²⁻⁴⁵ In addition, transplant pharmacists are in a unique position to aid in development of guidelines and protocols to monitor and treat infectious diseases and the various metabolic and endocrine issues that arise following transplantation as a result of post-transplantation immunosuppression.

Transplantation-specific competencies are required as part of annual performance evaluations for transplant pharmacists caring for transplant recipients. The transplantation pharmacy community is eager to standardize pharmacist competency and knowledge in this specialty area to ensure the level of clinical expertise is similar among transplant pharmacists from center to center.

Professional Development of Pharmacists in Transplantation

Transplant pharmacists are expected to participate, lead, and manage quality improvement initiatives related to clinical practice, as described in Appendix A. Areas of involvement include transplant pharmacist professional groups on a local, state, and national level, as well as scholarly activity including research, publication, presentation of symposia, and didactic and hands-on preceptorship of pharmacy trainees. Several societies exist for the growth and professional development of transplant pharmacists. Resources include the ASHP Section of Clinical Specialists and Scientists Networking Session on Immunology/Transplantation, the American College of Clinical Pharmacy (ACCP) Immunology/Transplantation Practice and Research Network, the American Society of

Transplantation (AST) Transplant Pharmacy Community of Practice, and the International Society for Heart and Lung Transplantation Scientific Council on Pharmacy and Pharmacology. These are pharmacist-based transplantation societies that host live educational opportunities during annual meetings, offer online webinars, publish newsletters on relevant and timely topics, and provide essential networking opportunities. In addition to the educational aspect of these societies, transplant pharmacists have opportunities for leadership positions not only within the pharmacist-based organizations but within the larger societies, including regulatory organizations such as UNOS. Transplant pharmacists have been elected to influential positions on the board of directors as well as member-at-large and committee chair positions, where they are able to share the work of the profession and provide pharmacist-specific knowledge in areas of public policy and strategic development.

The Board of Pharmacy Specialties recognized solid organ transplantation pharmacy as a specialty in 2018.⁴⁶ It is ASHP policy that “pharmacists who practice where a pharmacy specialty has been formally recognized by the profession should become board certified in the appropriate specialty area,” while recognizing an obligation “to be sensitive to the needs of current practitioners as prerequisites evolve.”⁴⁷

Advancing the Education and Training of Pharmacists in SOT

ASHP supports an increase in the number of education and training opportunities in transplantation for pharmacists as well as pharmacy students, fellows, and residents. Transplant pharmacists have important roles in the education of other practitioners that aids in advancing the transplant pharmacy profession. Current college of pharmacy curricula have minimal focus on transplantation, with many pharmacy students' first exposure to the topic delayed until introductory or advance pharmacy practice experiences rotations.⁴⁸ Teaching through lectures or precepting on rotation is an important venue to introduce transplant as a specialty for young practitioners. Postgraduate training of pharmacists provides a pipeline of clinicians, educators, leaders, and scientists who are experts in this specialty and committed to quality care of the transplant patient. There are currently 42 ASHP-accredited postgraduate year 2 training programs as well as two fellowships in transplantation. A recent workforce survey indicated that of the 278 transplant centers listed in UNOS, 33 centers could not participate in the survey due to not having a dedicated transplant pharmacist.²⁶ A primary goal of these guidelines is to promote the expansion of training of pharmacists in transplantation to allow for all transplant patients to have access to a transplant pharmacist to ensure consistency in the care provided to all transplantation recipients across all centers. Appendix B contains a list of recommended readings, references, and resources that complement the references and resources provided in these guidelines.

Conclusion

Every transplantation program in the United States is required to identify transplant pharmacology experts as part of

multidisciplinary teams to provide safe and effective care to transplant recipients and living donors and support to maintain organ function. These services span inpatient and ambulatory direct patient care of transplant recipients and donors and are tailored to meet regulatory and compliance standards. ASHP supports the expansion of pharmacy education and postgraduate and fellowship training to include transplantation and patient- and program-specific outcomes, to develop a workforce with the necessary specialized training to deliver these required and essential pharmacy services.

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Appendix A—Summary of Recommendations

Pretransplantation Phase

The pretransplantation phase includes the initial assessment and any reevaluation that may occur during the waiting-list period. The transplant pharmacist assesses

- Pharmacologic risks (e.g., anticoagulation, drug interactions, medications related to mental health, medications for chronic pain, medication allergies, hormonal contraception and replacement therapy, current use of immunomodulators, issues with drug absorption, illicit substance use, use of herbal supplements).
- Immunologic risk as it pertains to induction selection and need for desensitizing therapies.
- The impact of current pharmacologic therapies on pretransplant testing and perioperative and post-transplantation risks.
- The potential for medication non-adherence.

The transplant pharmacist also assesses nonpharmacologic risks and socially related risks in conjunction with members of the multidisciplinary team, including transplant social workers and financial coordinators. The transplant pharmacist presents risks and mitigation plans as part of the multidisciplinary selection committee. The transplant pharmacist must document transplant pharmacy services provided in accordance with regulatory requirements for individual centers based on policies developed in accordance with CMS Conditions of Participation and UNOS policy.

Perioperative Phase

Transplant pharmacists work with healthcare professionals involved in all settings of the transplantation encounter to ensure a seamless medication-use process, provision of transplant medication education, and discharge planning through each transition of care. The transplant pharmacist provides

- Consultation services for medications related to induction, maintenance, and discharge immunosuppression and their potential impact on other treatments or disease-state management.

- Guidance on patient-specific medication selection, dosing, dosage adjustments during the critical period of improvement in allograft function.
- Drug information to transplantation surgeons, organ specific physicians, nurses, and other clinicians.
- Care to living donors, including pain management, bowel care, fluid and electrolyte management and education of after care.
- Provides medication education to the recipient and caregiver prior to discharge.

The transplant pharmacist must also document transplant pharmacy services provided in accordance with regulatory requirements for individual centers based on policies developed in accordance with CMS Conditions of Participation and UNOS policy.

Post-Transplantation Phase and Ambulatory Setting

Because transplantation immunosuppression is the cornerstone of allograft success, transplant pharmacists are essential in the long-term management of transplant recipients. Ideally, a transplantation recipient will have access to a transplant pharmacist for the duration of their allograft, and the transplant pharmacist will be part of the multidisciplinary team providing care to these patients. The transplant pharmacist modifies existing immunosuppression regimens according to patient-specific needs, adverse effects, and laboratory parameters, and provides ongoing medication and adherence education. The transplant pharmacist detects, monitors, and creates treatment plans for acute cellular rejection, antibody-mediated rejection, and chronic allograft vasculopathy; modifies opportunistic infection prophylaxis and treatment regimens based on renal function and tolerability; and provides guidance in detection and management of opportunistic infections.

Treatment of Key Patient Populations

The transplant pharmacist maintains specific knowledge and experience in the treatment of pediatric and pregnant patients. The transplant pharmacist also provides pharmacotherapy management for comorbid disease state management.

Administrative Responsibilities

Due to the regulatory requirements unique to transplantation programs, transplant pharmacists perform many administrative duties. Transplant pharmacists develop, maintain, and govern transplantation policies and protocols; contribute to quality measures; and ensure a high level of care for all transplant recipients and donors. The transplant pharmacist provides formulary management, engages in and maintains collaborative practice agreements, and undertakes medication-use evaluations. The transplant pharmacist facilitates quality efforts related to pharmaceutical care, including but not limited to the evaluation of adverse drug events, outcomes, cost, and optimization of safety and efficacy in accordance with UNOS- and CMS-prescribed FQAPI activities. The transplant pharmacist develops and maintains center- and organ-specific transplantation protocols and transplant-specific competencies as part of annual performance evaluations.

Professional Development

Transplant pharmacists participate, lead, and manage quality improvement initiatives related to clinical practice. The transplant pharmacist should engage in professional organizations on a local, state, and national level. The transplant pharmacist should participate and lead scholarly activities, including research, publication, presentation of symposia, and didactic and hands-on preceptorship.

Appendix B—Recommended Readings, References, and Resources

The following list represents suggested readings that should be considered in addition to the references and resources provided in the guidelines. The suggested readings are grouped into applicable categories and are then listed in alphabetical order by the primary author.

Laws, Policies, and Guidelines

1. Department of Health and Human Services, Centers for Medicare and Medicaid Services. Organ transplant interpretive guidelines update. Effective June 13, 2008.
2. Organ procurement and transplantation network (OPTN) policies. Effective date: January 17, 2019. Available at: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (accessed 2019 Feb 26).
3. United network for organ sharing (UNOS) bylaws. Effective date: February 1, 2015. Available at: https://www.unos.org/wp-content/uploads/unos/UNOS_Bylaws.pdf (accessed 2019 Feb 26).

Internet Resources

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Primary Literature

Surveys

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Practice

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