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PRN OPINION PAPER

Observations from a systematic review of pharmacist-led research in solid organ transplantation: An opinion paper of the American College of Clinical Pharmacy Immunology/Transplantation Practice and Research Network

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Abstract

Introduction: The contributions of transplant pharmacists to clinical and translational research in the United States are ill-defined and have not been systematically reviewed.

Objectives: The American College of Clinical Pharmacy Immunology/Transplantation Practice and Research Network conducted a systematic review of available pharmacist-led research publications involving solid organ transplantation with the intent to quantify and describe pharmacist-led research endeavors and their changes over time.

Methods: An electronic search of Scopus was conducted to identify publications in the field of solid organ transplantation by pharmacist authors between January 1, 1975 and May 25, 2017. Articles were excluded if they were written in non-English languages or originated from non-US countries. Review articles, case reports, surveys, basic science research, pre-clinical studies, and non-transplant research were further excluded. Studies were categorized as one of four phases on the clinical and translational research spectrum, adapted from the Harvard Clinical and Translational Science Center description of a T1 to T4 classification system.

Results: A total of 10 354 publications were identified by the systematic search with 547 full-text English-language publications included in the analysis. Pharmacists served as the first author in 87% of the articles and as the senior author in 67% of the articles. A total of 71% of the articles included more than one pharmacist author. Transplant pharmacists published more studies that employed a retrospective or observational study design (55% and 78%, respectively). A total of 37% of studies were funded. On the spectrum of clinical and translation research, pharmacists were most involved in T3 (translation to practice) research (72%), followed by T2 (translation to patients) research (23%).

This paper represents the opinion of the Immunology/Transplantation Practice and Research Network of the American College of Clinical Pharmacy. It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

Conclusions: Transplant pharmacists are increasingly represented in the US literature and frequently published across domains. Further demonstrating the relevance of pharmacist-delivered interventions and outcomes is a critical area of practice focus.

KEYWORDS
pharmacist, research, systematic review, transplant

INTRODUCTION

The role of pharmacists on the multidisciplinary transplant team has been well recognized; however, their role and involvement in clinical and translational research is less well defined.[1-3] The transplant environment changed drastically in the United States in 2007 with the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation outlining requirements for quality assurance performance improvement (QAPI) programs to be established at each transplant center.[4] While an increasing number of transplant pharmacists

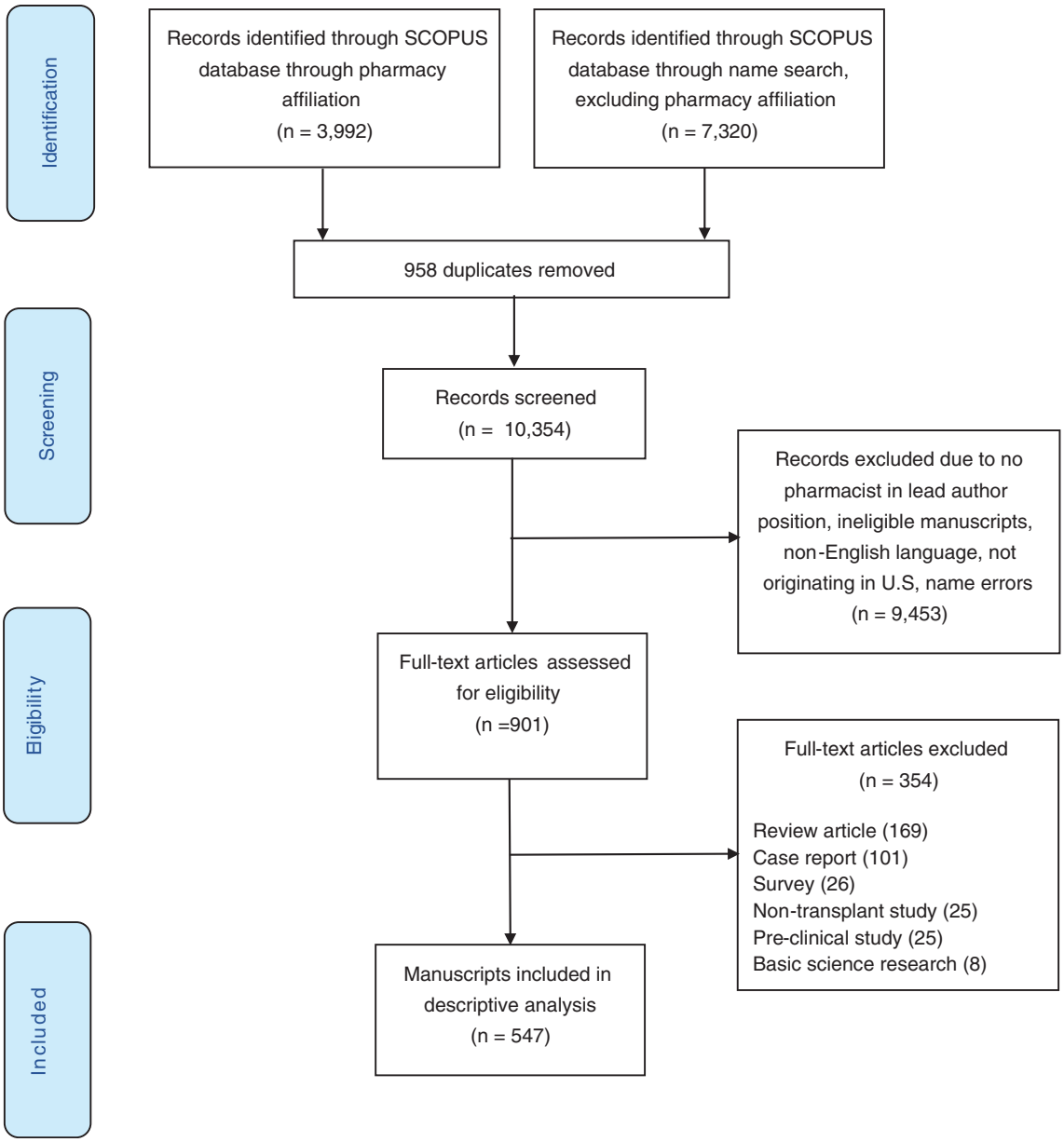

FIGURE 1 PRISMA flow diagram. Manuscripts identified through the initial search and the reasons why manuscripts that were excluded

TABLE 1 Content assessment tool

Study contents	Categories
Study design	Prospective
	Retrospective
	Cross-sectional
Study type	Observational
	Interventional
Study population	By transplant organ
	By age group
Data source	Single center
	Multi-center
	National database
Country involvement	United States only
	International
Funding source	Federal
	Other non-profit
	Industry
Type of research	T1, T2, T3, or T4
Subject domain	Pharmacology
	Clinical outcomes
	Patient-reported and behavioral outcomes
	Public health
Pharmacist-delivered intervention	Yes/No

Notes: T1, translation to humans; T2, translation to patients; T3, translation to practice; T4, translation to population health.

TABLE 2 Pharmacist authorship by position and publication era

Variables (N = 547)	N (%)
Authorship position, n (%)	
Pharmacist first author	475 (86.8)
Pharmacist senior author	365 (66.7)
Multiple pharmacists on publication	398 (70.6)
Years of publications, n (%)	
1975-1980	1 (0.2)
1981-1985	14 (2.6)
1986-1990	40 (7.3)
1991-1995	45 (8.2)
1996-2000	45 (7.9)
2001-2005	121 (22.1)
2006-2010	97 (17.7)
2011-2015	165 (30.2)
2016-May 25, 2017	19 (34.7)

serve as directors of clinical research or quality for transplant centers, many transplant pharmacists with primary clinical responsibilities are actively engaged in the development of clinical and research protocols, evaluation of clinical outcomes, navigation/implementation of industry-sponsored or supported trials, and regulatory and reporting efforts.[1,3] As transplant pharmacists report being tasked with higher-level clinical and translational research and/or QAPI responsibilities, the inability to assign a monetary value to the positive impact of transplant pharmacists as team members and obtain reimbursement has been suggested as a barrier to building the business case for the value of pharmacist-provided services.[2] While it is evident that transplant pharmacists are playing substantial roles within transplant research and QAPI, these contributions have not been systematically reviewed.

The American College of Clinical Pharmacy (ACCP) Immunology/Transplantation Practice Research Network (PRN) conducted a systematic review of available pharmacist-led research publications involving solid organ transplantation with the intent to quantify pharmacist-led research endeavors and describe changes over time. This review not only summarizes the types of research studies that transplant pharmacists have led, including study design, population, type of research, and funding, but also discusses the gaps in the current literature to aid in targeting future research and scholarly efforts.

METHODS

A protocol for the literature search, screening, and review strategy was developed with input from content experts and experts trained in performing systematic reviews. The protocol was designed with our primary purpose in mind: conducting a systematic review of available pharmacist-led research publications involving solid organ transplantation with the intent to quantify and describe pharmacist-led research endeavors and their changes over time.

Data sources and searches

On May 25, 2017, an electronic search of Scopus was conducted to identify publications in the field of solid organ transplantation by pharmacist authors. In the Scopus database, the following combinations of search terms were used: (TITLE-ABS-KEY [“liver transplant*” OR “liver-kidney transplant*” OR “lung transplant*” OR “pancreas transplant*” OR “organ transplant*” OR “heart transplant*” OR “heart-lung transplant*” OR “kidney transplant*” OR “kidney-pancreas transplant*” OR “intestin* transplant*” OR “multivisceral transplant*”] AND AFFIL[pharmacy]). In addition, historical membership lists from the ACCP Immunology/Transplantation PRN, the American Society of Transplantation Community of Practice (AST CoP) of Transplant Pharmacists, and the International Society of Heart and Lung Transplant (ISHLT) Pharmacy Council were obtained and each pharmacist was searched individually by last name and first initial, excluding manuscripts with AFFIL (pharmacy), so as to include pharmacists without an

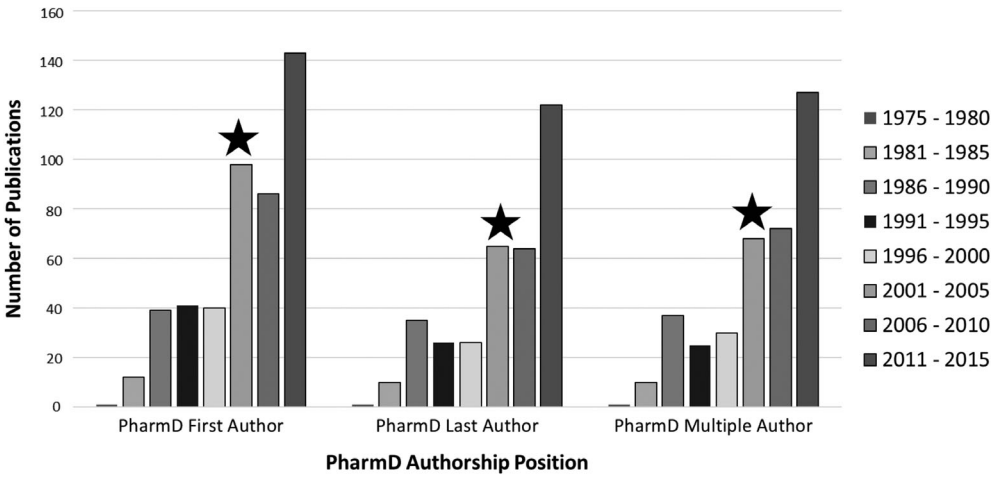

FIGURE 2 Pharmacist-led publications over time (1975-2015). This figure depicts the number of publications for each 5-year era where a pharmacist is the first author (far left bar chart), the last (senior) author (middle bar chart), or where pharmacists were in both the first and last author position (far right bar chart). The star in the 2001 to 2005 era indicates that it is the era in which the United Network for Organ Sharing bylaws changed to identify pharmacists as an integral member of the multidisciplinary team

affiliation to a department or college of pharmacy. The same search was performed using PubMed, which did not extract any further results.

Eligibility criteria and screening

We included biomedical or health science research articles with one or more pharmacist lead authors (defined as first author, last author, or both) from the publication year 1975 onwards. Articles were excluded if they were written in non-English languages or originated from non-US countries. Review articles, case reports, surveys, basic science research, pre-clinical studies, and non-transplant research were further excluded (Figure 1). Screening was conducted by one pair of researchers against the inclusion and exclusion criteria. Disagreements regarding inclusion were resolved via discussion within the pair. Referencing software was used to manage included and excluded publications and remove duplicate search results.

Publication content assessment

Based on the review aims, a content assessment tool was developed, reviewed, and approved by the research team (Table 1). Our main interest was describing transplant pharmacist-led clinical and translational research according to the following categories: study design, study type, study population, center/country involvement, funding source, T-phases of research spectrum, subject domain, and pharmacist-delivered intervention. Author's affiliations to center/country and funding source were identified from the publication.

Studies were categorized as one of four phases on the clinical and translational research spectrum, adapted from the Harvard Clinical and Translational Science Center description of T1 to T4 classification system (Appendix, Table A1).[5] This system classifies studies based on how the study results translate (eg, T1—Translation to humans; T2—Translation to patients; T3—Translation to practice; T4—Translation to population health). While it incorporates the drug development classifiers (Phases I-IV), it is not limited to drug-development and encompasses all types of research. Based on the primary objective, studies were categorized into one of the following four subject domains: pharmacology (eg, drug formulation, pharmacokinetics, pharmacodynamics, pharmacogenomics, dosing), clinical outcomes (eg, rejection, infection, metabolic complications, surgical complications, medication-related problems/adverse drug events), patient-reported and behavioral outcomes (eg, education, adherence, quality of life, satisfaction, patient-reported health care burden), and public health (eg, epidemiology, pharmacoeconomics).

The full-text documents of eligible publications were retrieved. Content assessment was delegated to pairs of researchers for independent review. Each article was reviewed by a first reviewer and then independently verified by a second reviewer. Disagreements regarding content category were resolved via discussion and, in the event that there was not resolution to this disagreement, it was escalated to an independent party for final determination.

RESULTS

A total of 10 354 publications were identified through the systematic search between January 1, 1975 and May 25, 2017. After applying the inclusion and exclusion criteria, 547 full-text English-language publications with pharmacist lead or senior authors were identified and included in the content review (Figure 1). Pharmacists served as the first author in 86.8% of the articles and as the senior author in 66.7% of the articles. Approximately 70% of the articles included more than one pharmacist author (Table 2). The number of

TABLE 3 Publication details

Variable (N = 547)	N (%)
Study design	
Prospective	245 (44.7)
Retrospective	298 (54.5)
Cross-sectional	4 (0.7)
Study type	
Observational	426 (77.8)
Interventional	121 (22.1)
Study population by organ	
Kidney	298 (54.4)
Liver	68 (12.4)
Pancreas	5 (0.9)
Simultaneous pancreas/kidney	14 (2.6)
Combined liver/kidney	0 (0)
Heart	37 (6.7)
Lung	46 (8.4)
Small bowel	1 (0.2)
Combined (multiple transplant populations included)	68 (12.4)
Healthy volunteers	10 (1.8)
Study population by age	
Adult	475 (86.8)
Pediatric	31 (5.7)
Non-age specific	41 (7.5)
Center involvement	
Single center	478 (87.4)
Multi-center	50 (9.1)
National database	19 (3.4)
Country involvement	
United States only	531 (97.1)
International	16 (2.9)
Type of funding	
None	344 (62.8)
Federal	110 (20.1)
Other non-profit	20 (3.6)
Industry	73 (13.3)
T-phase of research spectrum	
T1: Translation to humans	10 (1.8)
T2: Translation to patients	125 (22.8)
T3: Translation to practice	395 (72.2)
T4: Translation to population health	17 (3.1)

pharmacist-led clinical and translational research publications in the field of solid organ transplantation has increased drastically since 2004, reaching over 200 publications per decade in the recent era (Table 2). The increase of pharmacist authorship was observed in both first and senior authorship (Figure 2). It was common (90% of the time) for pharmacists from a single institution to work together, however, pharmacists also collaborated with researchers from other institutions within the United States or at the international level. The study design most frequently utilized was retrospective or observational, (54.5% and 77.8%, respectively). The study population predominantly included adults that received abdominal organ transplantation. Nearly, 40% of the published studies were funded by industry or local/national public entities (Table 3).

On the spectrum of clinical and translation research, pharmacists were most involved in T3 research (72.2%), followed by T2 research (22.8%). Only about 5% of the pharmacist-led publications were in T1 and T4 research categories (Table 3). Pharmacists published mostly in the research domains of clinical outcomes and pharmacology, followed by public health domain. Pharmacist involvement in patient-reported and behavioral outcomes research was less frequent in comparison to other subject areas (Figure 3). Of the 547 publications reviewed, only 10 papers (1.8%) focused on pharmacist-delivered interventions and their outcomes (Table 4).[6-15]

DISCUSSION

To the best of our knowledge, this is the first paper to systematically evaluate pharmacist-led research in a specialty practice. Transplant pharmacists have clearly demonstrated significant contributions to the literature as well as a transition from bench research to clinical research. The transplant pharmacists' research repository spans patient safety and allograft outcomes, impact on medication cost savings, and defining value in solid organ transplantation through improved health care utilization. In 2004, the United Network for

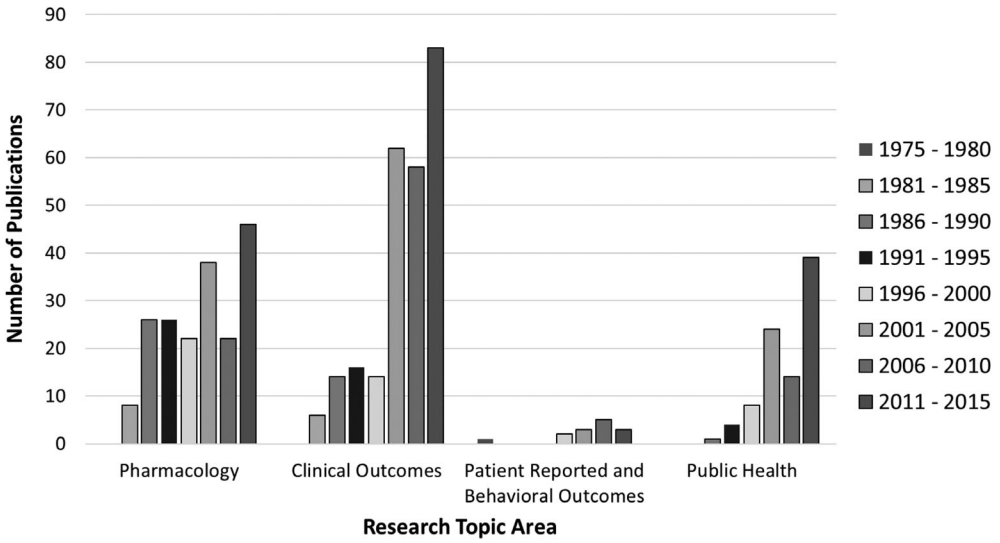

FIGURE 3 Pharmacist-led publications by subject domain (1975-2015). This figure depicts the number of publications by pharmacists during each 5-year era divided into research subject domain

TABLE 4 Research Publications on Pharmacist-Delivered Interventions

Reference	Study design	Setting	Study population	Pharmacist interventions	Outcomes
Byrns et al[6]	Retrospective cohort (n = 97)	Single center	Kidney and kidney/pancreas	Enrollment in a patient-assistance program (PAP) for CMV prophylaxis vs Pre-emptive monitoring for patients who cannot afford CMV prophylaxis	CMV viremia was lower in the PAP group (12.8% vs 36.2%, $P = .021$) at 1 year
Chisholm et al [7]	Prospective, randomized trial (n = 24)	Single center	Kidney transplant recipients	The intervention group received clinical pharmacy services in addition to routine clinic services, while the control group received no pharmacist interaction	The compliance rate for patients seen by clinical pharmacists was higher than those receiving standard care (96.1 ± 4.7% vs 81.6 ± 11.5%, $P < .001$); at 12 months, 75% of intervention patients remined compliant vs 33.3% of control ($P < .05$); levels in the intervention group achieved 64% of the time vs 48% in control group ($P < .05$)
Chisholm et al[8]	Prospective, randomized trial (n = 23)	Single center	African American kidney transplant patients	The intervention group received clinical pharmacy services in addition to routine clinic services, while the control group received no pharmacist interaction	Mean SBP was significantly lower in the intervention group at the second (137.8 ± 15.0 vs 168.9 ± 15.3), third (135.9 ± 11.7 vs 164.6 ± 20.1), and fourth (145.3 ± 16.8 vs 175.8 ± 33.9) quarters of the study ($P < .05$). Mean DBP was significantly lower in the intervention group at the second (76.0 ± 11.8 vs 84.9 ± 6.1) and fourth (77.0 ± 10.2 vs 91.8 ± 12.0) quarters ($P < .05$)
Chisholm et al[9]	Retrospective analysis (n = 36)	Single center	Kidney transplant recipients	Renal transplant recipients who were enrolled in the Medication Access Program (MAP) for at least 1 year and had diagnoses of hypertension, diabetes, and dyslipidemia. Control of chronic conditions were compared from pre- to post-enrollment	Patients enrolled in the MAP has more medication prescribed for control of diabetes, hypertension, and dyslipidemia. The patients saw a significant improvement in fasting blood glucose, HbA1c, LDL, total cholesterol, triglycerides, blood pressure, serum calcineurin inhibitor levels, and rejection rates, as well as health-related quality of life scores
Migliozzi et al[10]	Retrospective analysis (n = 50)	Single center	Kidney transplant recipients	Patients were enrolled in a combined home blood pressure monitoring and comprehensive pharmacist-run medication therapy management program. Their BP from 1 year prior to enrollment were compared with BP in the year after enrollment	Patients' mean SBP and DBP values were significantly lower at 30, 90, 180, and 360 days after program enrollment ($P < .05$)
Pinelli et al[11]	Retrospective analysis (n = 22)	Single center	Kidney transplant recipients enrolled in a Pharmacist Managed Diabetes and Cardiovascular Risk Reduction Clinic (PMDC)	Patients who were enrolled in the PMDC had their clinical outcomes compared between baseline and 3 and 6 months after entry into the clinic	Patients with a baseline HbA1c > 7.5% had a significant reduction by the end of follow-up (8.1 ± 1.0% vs 7.3 ± 1.2% at 3 months and 7.5 ± 0.8% at 6 months); 30- and 90-day readmission rates significantly decreased (18.1% vs 29.5% and 31.8% vs 38.9%, respectively), yet were similar at 180 days

(Continues)

TABLE 4 (Continued)

Reference	Study design	Setting	Study population	Pharmacist interventions	Outcomes
Staino et al[12]	Retrospective cross-sectional analysis (n = 219)	Single center	Kidney transplant recipients	During a 3-month period, pharmacist in-person clinic visits (n = 175) were compared with pharmacist chart review and recommendation documentation (n = 170)	Providers accepted a greater percentage of recommendations that were delivered directly compared with recommendations presented via a note in the patient folder following chart review (92% vs 28%, respectively; $P < .0001$)
Taber et al[13]	Retrospective analysis	Single center	Kidney transplant recipients	Follow-up analysis of a pharmacist-led team that developed key initiatives including improved medication reconciliation, development of a diabetes management service, and improved discharge medication dispensing, delivery, education, and scrutiny	Medication discrepancies reduced by >2 per patient; pharmacist-reviewed discharge medications reduced medication safety issues by 40%; delayed discharges reduced by 14%; 7-day readmission rates reduced by 50%
Taber et al[14]	Retrospective analysis of outcomes of single center (n = 583) compared with national database (n = 37 712)	Single center	Kidney transplant recipients	Follow-up analysis of a pharmacist-led team that developed key initiatives including improved medication reconciliation, development of a diabetes management service, and improved discharge medication dispensing, delivery, education, and scrutiny	Quality initiatives reduced length of stay in patients with delayed-graft function from 8 days to 4 days; overall LOS was reduced from 3.6 ± 1.5 to 3.3 ± 0.8 days, $P = .021$, as compared with a national LOS of 10 days; hospital costs reduced by 42%, while national costs increased by 12%; institutional 30-day readmission rates better than national in all patients and DGF patients (9% vs 15% and 12% vs 18%, respectively)
Chisholm-Burns et al[15]	Prospective, randomized controlled trial (n = 150)	Single center	Kidney transplant recipients at least 21 years old, at least 1 year post-transplant, on a calcineurin inhibitor, and obtain their medications from Avella Specialty Pharmacy for at least 1 year prior to study enrollment	Subjects randomized into the intervention group received a negotiated immunosuppression adherence contract and meetings at 3-, 6-, and 9-months to review the contract and discuss progress	The intervention group (n = 76) had higher adherence than the control group (n = 74) ($P < .01$). There were more patients that avoided hospitalization in the intervention vs the control (76.1 vs 42.7%, RR = 1.785, 95% CI 1314,2.425)

Abbreviations: BP, blood pressure; CMV, cytomegalovirus; DBP, diastolic blood pressure; DGF, delayed graft function; HbA1c, glycosylated hemoglobin; LDL, low-density lipoprotein; LOS, length of stay; SBP, systolic blood pressure.

Organ Sharing (UNOS) and the CMS formally recognized transplant pharmacists as an integral member of the multidisciplinary care team.[4] Our data revealed that with the advent of these additional regulations within solid organ transplantation practice in the United States, there was a resultant impact on the number of publications led by transplant pharmacists (Figures 2 and 3). As additional QAPI activities were required in solid organ transplantation in 2007, it was natural for the transplant pharmacist to become more involved in QAPI activities and related research.[4] It appears that there was an additional increase in transplant pharmacist-led publications by 2011 to 2015.[1]

The health care payment model in the United States is shifting from fee-for-service to value-based care with a focus on quality, outcomes, and cost. As one of the most accessible health care team members, this transformation has provided increasing opportunities to integrate pharmacists into a team-based approach to further optimize patient care. As a function of their basic daily activities, transplant

pharmacists provide critical medication therapy expertise and important medication adjustments, either independently or with mutual agreement from the prescriber, but without insurer reimbursement for effort. Some early state adopters, such as the state of Washington, have allowed pharmacists to practice under collaborative drug therapy agreements. It was not until 2015, however, that additional recognition enabled billing from major insurance carriers.[16]

Transplant pharmacists have had a substantial impact on advancing knowledge through publication, as demonstrated in this systematic review. For this reason, we urge transplant pharmacists to continue to publish their work, specifically as it relates to patient outcomes (phases T2-T4). It is difficult in today's health care environment to substantiate and incur additional salary costs, so it is imperative to continue to demonstrate through objective measures the impact of the transplant pharmacist. These publications will lay the groundwork for justification of additional transplant pharmacist positions within both clinical and academic entities. Considering the profession of pharmacy at large, we need to continue to strive to demonstrate positive impact in our quest to establish provider status.[16-18] It would be hard to imagine a better catalyst for this goal than for various specialties to increase their contribution to the literature and demonstrate their impact on patient outcomes and health care value.

Our manuscript does have some limitations. Because of the amount of time required to review and process the manuscripts, there was a delay in our analysis that inherently fails to describe manuscripts published after the initial Scopus search. Our analysis also did not include research publications co-authored by transplant pharmacists if they were not one of the lead authors. We hope that this can lay a foundation for future updates and refinements. It also would have been ideal to compare manuscripts led by transplant pharmacists with the total number of publications related to transplant published during the same time frame. In order to accurately define this total, considering the criteria applied to the target publications would have been a huge undertaking and led to a significant delay in publication. We feel, however, that this paper can serve as a framework for similar assessment by other pharmacy specialties. In addition, we provide references and descriptions of the clinical outcome manuscripts that describe and analyze pharmacist actions as the intervention to lay a groundwork for demonstrating the impact of the transplant pharmacist. This, in conjunction with other publications illustrating the transplant pharmacist role, should provide the beginning of a blue-print for identifying published data that supports an increase in transplant pharmacist positions, as well as the role of the pharmacist as an independent provider.[1-3,18-21] Because of the limited number of these studies, it is imperative that transplant pharmacists identify and publish pharmacist-based intervention research within solid organ transplantation to better justify transplant pharmacist roles in the clinical, research, and quality arenas.

CONCLUSION

A change in transplant regulation as well as a clearer definition of the role of the transplant pharmacist has led to significant growth in publications with a pharmacist as a primary or senior author. Our systematic review demonstrated that transplant pharmacists have increased their representation in the literature and frequently publish across domains. This paper, which has outlined the breadth and impact of transplant pharmacy publications, may serve as an example to other pharmacy specialties interested in creating a repository of their own. As roles and services have expanded, we have identified pharmacist-delivered interventions and outcomes as an area of critical need for future growth in publications. Professional organizations may aid in this endeavor by developing or maintaining support for investigators in clinical research, with a specific focus on research designed to highlight the impact of the transplant pharmacist in patient care.

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CONFLICT OF INTEREST

J.N.F. is also an employee of CareDx, Inc., a diagnostic company with no competing interests with the content of this manuscript. L.B. is on the Speakers' Bureau for Veloxis Pharmaceuticals.

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APPENDIX

TABLE A1 T-phases of clinical and translational research spectrum

Research type	Definition	Examples
T0—basic research goal: understand the human condition and environment as it exists	• Fundamental mechanisms of biology, disease or behavior • No immediately practical application	• Benchwork including: ○ Chemicals, molecules, devices, structures ○ Biomarkers, cells, proteins, DNA, tissues, chemistries ○ Radiology, biopsy ○ Natural histories, observations, patterns, classifications, correlations ○ Gene mapping, banking, sequencing
T0—Pre-clinical research Goal: understand the human condition and environment as it exists	• Connection between the basic science of disease with human medicine • Interventions developed to further understand the basis of a disease or disorder • **KEY—Testing carried out using ○ Cell or animal models of disease ○ Samples of human or animal tissues ○ Computer-assisted simulations of drug, device, or diagnostic interactions with living systems	• Preclinical studies including: ○ Chemicals, molecules, devices, structures ○ Biomarkers, cells, proteins, DNA, tissues, chemistries ○ Radiology, biopsy ○ Natural histories, observations, patterns, classifications, correlations ○ Gene mapping, banking, sequencing
Clinical/translational research		
T1-Translation to humans Discovery to candidate health application Goal: identify and analyze the effects of an intervention or relationship on the human condition or environment	• Application of preclinical studies to humans • First in humans (typically in healthy volunteers) • Proof of concept • T1 research expedites the movement from basic research to patient-oriented research (findings from basic research are tested for clinical effect and/or applicability) that leads to new or improved scientific understanding or standards of care	• Phase I clinical trials ○ Proof of concept ○ Health subjects or select population of patients ○ Small sample size ○ Tests for safety • Observational studies, for example, association of *BRCA* mutations and breast cancer; association between CYP3A5 genotype and tacrolimus PK in healthy volunteers
T2-Translation to Patients Health application to evidence-based practice guidelines Goal: identify and analyze the optimal effects of an intervention or relationship on the human condition or environment	• Investigators test new interventions under controlled environments to form the basis for clinical application and evidence-based guidelines • T2 research yields knowledge about the efficacy of the interventions *in optimal settings*	• Phases II and III clinical trials ○ Select population of patients ○ Larger sample size • Evidence synthesis and guideline development (eg, a randomized controlled trial of CYP3A5 genotype-guided tacrolimus dosing in transplant patients; CPIC guideline for tacrolimus and CYP3A5) • Observational studies (eg, predictive value of *BRCA* mutations in at-risk women; association between CYP3A5 genotype and tacrolimus dosing or patient outcomes in transplant patients) • Cost effectiveness/comparative effectiveness (eg, economic analysis of a clinical trial)

(Continues)

TABLE A1 (Continued)

Research type	Definition	Examples

T3-Translation to Practice
Practice guidelines to health practice
Goal: incorporate into practice the optimal intervention or relationship
	• Investigators explore ways of applying recommendations or guidelines in general practice
	• T3 research yields knowledge about how interventions work in *real-world settings*
	• Studies which examine use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services to increase knowledge and understanding of the structure, processes, and effects of health services
		• Phase IV clinical trials (eg, impact of CYP3A5 genotype-guided tacrolimus dosing per the CPIC guideline on patient outcomes and costs in a single-center kidney transplant program)
		• Health services research
		  ○ Dissemination
		  ○ Communication
		  ○ Implementation
		• Clinical outcomes research
		• Observational studies (eg, comparing clinical and cost outcomes of a new practice/process [e.g., immunosuppression protocol, infectious prophylaxis] to a historical control)
		• Cost effectiveness/comparative effectiveness

T4-Translation to Population Health Practice to population health impact Goal: provide communities with the optimal intervention or relationship	• Investigators study factors and interventions that influence the health of populations. T4 research ultimately results in improved global health	• *Population-level* outcome studies • Population monitoring of morbidity, mortality, benefits and risks • Social determinants of health • Population-based prevention and outcome studies • Investigating outcomes of mass screening • Comparative study of various health policies and their impact on health and health care utilization • Social determinants of health • Cost effectiveness/comparative effectiveness

Abbreviations: CPIC, Clinical Pharmacogenetics Implementation Consortium; CYP, Cytochrome P450; PK, pharmacokinetics.