

Serving underserved transplant recipients: experience of the Medication Access Program

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Objective: Programs have been established to help underserved, solid-organ transplant recipients and other patient populations address the burden of medication regimen costs. The purpose of this study was to describe one such program, the Medication Access Program (MAP), and the population of solid-organ transplant recipients it serves. An additional objective was to compare characteristics of recipients whose MAP enrollment was continued versus those who were discontinued during the annual re-enrollment period.

Methods: Enrollment into MAP is based on referral from a pharmacist or another health care professional/transplant team member. To enroll, a recipient must complete an application which includes information about demographics, health care coverage, income, and medication regimen. To maintain enrollment, patients must complete a renewal application on an annual basis. Data were collected from renewal applications for 2012 and 2011 (for those who did not return the 2012 renewal applications). Chi-square analyses and Student's *t*-test for independent samples were conducted to compare the characteristics of those who renewed their MAP enrollment in 2012 and those who were discontinued because they did not return the renewal application. Multivariate stepwise logistic regression was conducted to determine variables predictive of MAP continuation status.

Results: In total, 246 recipients were included. The majority qualified for Medicare (67.9%), did not qualify for Medicaid (69.9%), and did not have private health care coverage (63.8%). Significantly more continued recipients qualified for Medicare compared to discontinued recipients ($P=0.002$). Discontinued recipients had a greater number of past discontinuations than continued recipients ($P=0.01$). In the logistic regression analysis, qualifying for Medicare was significantly associated with continuation status ($P=0.001$).

Conclusion: MAP is designed to increase medication access for low-income solid-organ transplant recipients through enrollment into medication assistance programs, education regarding medication therapy, and availability of medication assistance programs. Health care providers should use historical monitoring to identify high risk patients and implement programs that will facilitate continuity of care.

Keywords: health care access, solid-organ transplant, medication

Introduction

Immunosuppressant therapy (IST) adherence plays a critical role in maintaining graft function following solid-organ transplantation. However, according to a meta-analysis by Dew et al¹ IST nonadherence occurs in 22.6% of solid-organ transplant recipients on an annual basis, and underserved transplant recipient groups such as low income patients and minorities are particularly vulnerable to increased risk of IST nonadherence.²⁻⁵ Consequences of nonadherence to IST may be severe, including graft rejection and failure. For example, in the renal transplant population, a meta-analysis by Denhaerynck et al found that IST nonadherence contributed to 20% of late acute rejection episodes and 16% of graft losses.⁶ Barriers to adherence among

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solid-organ transplant recipients are numerous and include the complexity of medication regimens, the need to adhere to regimens for as long as they maintain the transplanted organ, and the high cost of IST and other medications needed to treat comorbid conditions.⁷

In 2011, estimated costs of outpatient medication regimens for solid-organ transplant recipients ranged from \$18,200–\$34,600, depending on the transplanted organ.⁸ Thus, medication regimen costs represent a significant burden to solid-organ transplant recipients. Although Medicare pays for 80% of the cost of outpatient IST for the first 36 months following transplantation (note, those over 65 years of age and those who are disabled are eligible for lifetime Medicare coverage), many recipients may be unable to afford the 20% co-payment required to obtain IST.^{9,10} They must also identify other means of covering medication expenses when their 36-month Medicare eligibility expires. A survey of renal transplant recipients conducted by Gordon et al noted that 31% reported IST cost had a somewhat to great negative impact on their lives and 29% experienced general financial strain post-transplant.¹¹ Likewise, a survey of liver and renal transplant recipients found that 40.6% experienced financial difficulties secondary to transplantation, and approximately 47% of the sample reported having less monthly income than in the year preceding the transplant surgery.¹² These studies suggest that financial hardship is commonplace among solid-organ transplant recipients and may have an adverse effect on their ability to acquire needed medication.

Increasingly, programs have been established to help underserved, solid-organ transplant recipients and other patient populations address the burden of medication regimen costs.^{13–18} Such programs improve patient access through enrollment in pharmaceutical manufacturers' medication assistance programs (PMAPs) and other programs/services such as Medicare Part D. Prior studies indicate medication assistance programs may decrease patients' out-of-pocket expenses and increase medication adherence, which in turn may improve health outcomes.^{14–18} For example, a formalized program located at an outpatient pharmacy and designed to help liver transplant recipients acquire post-transplant medications decreased nonadherence from 25% to 10%.¹⁶ However, apart from a very few studies, there is a dearth of information available in the literature regarding medication assistance programs serving solid-organ transplant recipients. The purpose of the current study was to describe the Medication Access Program (MAP) and the population of solid-organ transplant recipients it serves. An additional objective was to compare the characteristics of recipients whose MAP enrollment

was continued versus those who were discontinued during the annual re-enrollment period. This assessment was to determine if there are clear risk factors for failing to renew this important health care service. Identification of such risk factors would enable health care professionals to intervene to facilitate uninterrupted program services.

Methods

Program description

MAP has its main office located on the campus of Georgia Regents University (GA, USA). Its mission is to provide medication access to solid-organ transplant recipients who reside in the state of Georgia in the US. Transplant recipients are enrolled in MAP based on a referral from a MAP pharmacist or another health care professional/transplant team member, and this referral for MAP enrollment may occur at any time post-transplant. To enroll in MAP, a solid-organ transplant recipient completes an application which includes information about demographics, health care coverage, income, and medication regimen. The applicant is also asked to provide financial records such as tax forms to substantiate income level, and to sign consent and health information disclosure forms.

A MAP medication financial specialist located in MAP's main office reviews the application to verify an applicant's eligibility for program enrollment; consultations between medication financial specialists and individuals referred to MAP typically take place via telephone. Since enrollment into PMAPs and other medication assistance programs/services is generally based on income/financial status, this is also the primary eligibility criteria for MAP enrollment. Once verified, the applicant is officially enrolled in MAP. Approximately 45% of individuals referred to MAP complete the enrollment process. Following enrollment, MAP provides education on the availability of medication assistance programs and assists transplant recipients in enrolling into these programs (eg, PMAPs, Medicare Part B, Medicare Part D, various foundation programs), including completing the necessary application paperwork. This study was approved by the Human Assurance Committee at Georgia Regents University.

Data collection

To maintain enrollment in MAP, patients must complete a renewal application on an annual basis. The renewal application is similar to the initial enrollment application, requiring data on demographics (eg, age, marital status, donor type, type of transplant, disability), income, monthly

medical expenses, private health care coverage, Medicare eligibility, Medicare Part D enrollment, Medicaid eligibility, and benefits (Veterans' Administration, social security, disability) eligibility. In the current study, we collected this data from the renewal applications for 2012 and 2011 (for those who did not return the 2012 renewal applications). We then compared the characteristics of those who renewed their MAP enrollment in 2012 (referred to as "continued recipients") and those who were discontinued because they did not return the 2012 renewal application (referred to as "discontinued recipients"). We also examined recipient records for 2008–2011 to determine the number of times recipients had been previously discontinued as a result of not returning the annual renewal application (note, recipients are eligible to re-enroll in MAP after they are discontinued, provided all required documentation is completed).

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics 20.0 (IBM Corporation, Armonk, NY, USA). Participant characteristics were summarized by frequencies for categorical variables, and by means and standard deviations for continuous variables. Chi-square analyses were conducted to examine independency between categorical characteristics and group (continued recipients versus discontinued recipients). Student's *t*-test for independent samples were used to assess differences between group and continuous variables (age, annual gross income, monthly medical expenses). Multivariate stepwise logistic regression analysis was conducted to determine the value of demographics, income variables, and health care coverage variables as predictors of MAP continuation status (continued recipients versus discontinued recipients). The a priori significance level was 0.05.

Results

There were 246 recipients eligible for MAP re-enrollment and included in the study. The majority of recipients had deceased donor transplants (57.3%), renal transplants (55.7%), qualified for Medicare (67.9%), did not qualify for Medicaid (69.9%), and did not have private health care coverage (63.8%). Mean age of recipients was 51.74 years \pm 12.31 years, and mean annual gross income was US\$13,821.98 \pm US\$10,213.32 (Table 1). More than 83% of the total sample reporting income data (139 of 166) had annual gross incomes below the 2012 federal poverty guideline¹⁹ for a family of four, \$23,050. The majority of recipients (79.7%) also returned their 2012 renewal applications and were classified as "continued recipients", while a

minority of 20.3% did not return their 2012 renewal applications and were classified as "discontinued recipients".

As displayed in Table 1, there were no significant differences between continued recipients and discontinued recipients on any factor under consideration, with two exceptions. Significantly more continued recipients qualified for Medicare compared to discontinued recipients ($\chi^2=9.236$, $P=0.002$). Discontinued recipients had a significantly greater number of past discontinuations compared to continued recipients ($\chi^2=9.18$, $P=0.01$). In the logistic regression analysis, Medicare eligibility was the only variable significantly associated with continuation status (ie, continued recipients were more likely to qualify for Medicare), accounting for 18.3% of the variance in the model (adjusted $R^2=0.183$, $P=0.001$). The regression model was as follows:

Continuation status = 0.462 + Medicare eligibility (−0.388).

Continuation status was coded as 0 = continued recipient and 1 = discontinued recipient; Medicare eligibility was coded as 0 = no and 1 = yes.

Discussion

MAP is funded by the not-for-profit Carlos and Marguerite Mason Trust, and its target population includes underserved (ie, low income), solid-organ transplant recipients. Since its 1999 inception, MAP has helped over 765 recipients receive more than \$48 million in immunosuppressive and other medications, at no cost to recipients. MAP's program objectives are to:²⁰

- Increase statewide accessibility of prescription medication to individuals who have received a kidney, liver, heart, lung, or pancreas transplant;
- Promote awareness of medication assistance programs to Georgia's transplant recipients and health care professionals;
- Increase medication adherence.

To accomplish these objectives, MAP: 1) provides education to solid-organ transplant recipients and health care professionals regarding medications and the availability of medication assistance programs; and 2) assists recipients and their health care providers in the process of enrolling into medication assistance programs. Beyond enrollment into appropriate medication assistance programs, the MAP staff also includes two clinical pharmacists, and medication therapy management services are provided on a monthly basis for each MAP patient (usually in outpatient clinic settings). The MAP pharmacists: review drug therapy, including IST and medications to treat comorbid conditions;

Table 1 Medication Access Program solid-organ transplant recipient characteristics

Characteristics	All recipients n (%)	Continued patients n (%)	Discontinued patients n (%)	P-value ^a
Sex				0.240
Female	91 (37.0%)	76 (38.8%)	15 (30%)	
Male	117 (47.6%)	90 (45.9%)	27 (54%)	
Missing	38 (15.4%)	30 (15.3%)	8 (16%)	
Race/ethnicity				0.865
African American	103 (41.9%)	83 (42.3%)	20 (40%)	
American Indian/ Alaska Native	2 (0.8%)	1 (0.5%)	1 (2%)	
Asian	8 (3.3%)	7 (3.6%)	1 (2%)	
Hispanic	13 (5.3%)	11 (5.6%)	2 (4%)	
White	82 (33.3%)	65 (33.2%)	17 (34%)	
Other	1 (0.4%)	1 (0.5%)	0	
Missing	37 (15.0%)	28 (14.3%)	9 (18%)	
Marital status				0.852
Divorced	61 (24.8%)	48 (24.4%)	13 (26%)	
Married	89 (36.2%)	73 (37.2%)	16 (32%)	
Single	77 (31.3%)	59 (30.1%)	18 (36%)	
Widowed	16 (6.5%)	13 (6.6%)	3 (6%)	
Missing	3 (1.2%)	3 (1.5%)	0	
Donor type				0.486
Deceased	141 (57.3%)	114 (58.2%)	27 (54%)	
Living	46 (18.7%)	35 (17.9%)	11 (22%)	
Missing	59 (24.0%)	47 (24.0%)	12 (24%)	
Type of transplant				0.869
Heart	22 (8.9%)	16 (8.2%)	6 (12%)	
Kidney	137 (55.7%)	112 (57.1%)	25 (50%)	
Liver	32 (13.0%)	25 (12.8%)	7 (14%)	
Lung	6 (2.4%)	4 (2.0%)	2 (4%)	
Pancreas	1 (0.4%)	1 (0.5%)	0	
Kidney/liver	2 (0.8%)	2 (1.0%)	0	
Kidney/pancreas	9 (3.7%)	7 (3.6%)	2 (4%)	
Missing	37 (15.0%)	29 (14.8%)	8 (16%)	
Medicare eligible?				0.002
Yes	167 (67.9%)	142 (72.4%)	25 (50%)	
No	64 (26.0%)	43 (21.9%)	21 (42%)	
Missing	15 (6.1%)	11 (5.6%)	4 (8%)	
Enrolled in Medicare Part D?				0.099
Yes	104 (42.3%)	91 (46.4%)	13 (26%)	
No	89 (36.2%)	70 (35.7%)	19 (38%)	
Missing	53 (21.5%)	35 (17.9%)	18 (36%)	
Medicaid eligible?				0.243
Yes	27 (11.0%)	19 (9.7%)	8 (16%)	
No	172 (69.9%)	138 (70.4%)	34 (68%)	
Missing	47 (19.1%)	39 (19.9%)	8 (16%)	
Private health care coverage?				0.360
Yes	41 (16.7%)	35 (17.8%)	6 (12%)	
No	157 (63.8%)	124 (63.3%)	33 (66%)	
Missing	48 (19.5%)	37 (18.9%)	11 (22%)	
Disabled?				0.147
Yes	144 (58.5%)	119 (60.7%)	25 (50%)	
No	61 (24.8%)	45 (23.0%)	16 (32%)	
Missing	41 (16.7%)	32 (16.3%)	9 (18%)	
Disability benefits?				0.071
Yes	114 (46.3%)	96 (49.0%)	18 (36%)	
No	101 (41.1%)	75 (38.3%)	26 (52%)	
Missing	31 (12.6%)	25 (12.8%)	6 (12%)	

(Continued)

Table I (Continued)

Characteristics	All recipients n (%)	Continued patients n (%)	Discontinued patients n (%)	P-value ^a
Social security benefits?				0.296
Yes	96 (39.0%)	80 (40.8%)	16 (32%)	
No	116 (47.2%)	90 (45.9%)	26 (52%)	
Missing	34 (13.8%)	26 (12.3%)	8 (16%)	
Veterans' Administration benefits?				0.567
Yes	3 (1.2%)	2 (1.0%)	1 (2%)	
No	230 (93.5%)	184 (93.9%)	46 (92%)	
Missing	13 (5.3%)	10 (5.1%)	3 (6%)	
Number of previous discontinuations				0.010
0	209 (85.0%)	173 (88.3%)	36 (72%)	
1	29 (11.8%)	19 (9.7%)	10 (20%)	
2	8 (3.3%)	4 (2.0%)	4 (8%)	
Mean age ± SD	51.74±12.31	52.32±12.0	49.48±13.38	0.182
Mean annual gross income ± SD	\$13,821.98±\$10,213.32 ^b	\$13,556.72±\$9,545.15 ^c	\$15,129.32±\$13,154.11 ^d	0.552
Mean monthly medical expenses ± SD	\$797.23±\$2,277.02	\$674.70±\$2,040.38	\$1,363.41±\$3,133.58	0.140

Notes: ^aThe P-values represent the comparison between the continued recipients and the discontinued recipients; ^bmore than 83% of the total sample reporting income data (139 of 166) had annual gross incomes below the 2012 federal poverty guideline¹⁹ for a family of four, \$23,050; ^cmore than 86% of continued recipients reporting income data (119 of 138) had annual gross incomes below the 2012 federal poverty guideline¹⁹ for a family of four, \$23,050; ^dmore than 71% of discontinued recipients (20 of 28) had annual gross incomes below the 2012 federal poverty guideline¹⁹ for a family of four, \$23,050.

Abbreviation: SD, standard deviation.

identify, prevent, and respond to problems related to medications; address medication information questions; and make therapeutic recommendations by contacting the prescribing physician and other health care professionals involved in care.¹⁸ Additionally, a MAP clinical pharmacist who works in the Georgia Regents University Renal Transplant Clinic performs similar clinical services with MAP patients on a day-to-day basis.¹⁸ The goal of MAP's medication therapy management and clinical pharmacy services is to improve medication adherence and health outcomes.

Excluding missing data, MAP's patient population is predominately composed of males and African Americans who received renal transplants, are Medicare eligible, and are generally below the 2012 federal poverty guidelines for a family of four (\$23,050).¹⁹ Indeed, more than 83% of the sample who reported income data (139 of 166) had annual gross incomes below the federal poverty guideline. Additionally, the average medical expenses of recipients generally approximate or exceed their average annual gross income. This is consistent with prior studies concerning transplant recipients' socioeconomic status and ability to pay for medications.^{11,12} For example, a survey of US renal transplant centers conducted by Evans et al found that 70% of centers reported transplant recipients had very- or extremely serious problems paying for medications, with 47% of centers noting that more than 40% of their patients had difficulty purchasing IST.²¹ Moreover, 68% of centers reported graft failures and patient mortality as a result of nonadherence due

to IST costs. As demonstrated by this and previous studies, solid-organ transplant recipients, particularly those of low socioeconomic status, are at risk of increased financial burden and decreased medication access. MAP and similar programs are designed to combat the financial challenges faced by transplant recipients and other patient populations to facilitate increased access to needed medication.¹³⁻¹⁸ Such access may, in turn, foster positive outcomes, including decreased graft rejection and improved health-related quality of life.¹⁸

An additional study objective was to compare the characteristics of recipients whose MAP enrollment was continued versus those who were discontinued during the 2012 annual re-enrollment period. The purpose of this analysis was to identify possible risk factors for failing to renew enrollment, as increased knowledge and understanding of such risk factors may enable MAP staff to intervene during the re-enrollment period to facilitate uninterrupted access to MAP services. Examination of independent variables gleaned from the enrollment application and recipient records found two significant factors in the bivariate analysis. The first was Medicare eligibility, wherein continued recipients were more likely to qualify for Medicare than discontinued recipients (of note, Medicare eligibility was the only significant independent variable in the logistic regression analysis regarding continuation status). We speculate that individuals who qualify for Medicare may be more familiar with the demands of completing applications to continue/renew program eligibility and/or access program benefits. As a result, these transplant

recipients may be more likely to return their annual MAP renewal applications. The second significant factor in the bivariate analyses was past discontinuations. Discontinued recipients were more likely to have a greater number of past discontinuations compared to continued recipients (28% of discontinued patients compared to 12% of continued patients had at least one past discontinuation). As past behavior is often predictive of future behavior, this finding was unsurprising and suggests health care providers should use historical monitoring to identify high risk patients and implement programs that will facilitate continuity of care.²²

There are limitations to this study. This was a retrospective analysis of data, and comparison groups were determined by circumstance rather than randomization. As a result, confounding factors cannot be eliminated and causal inference cannot be made. Likewise, missing data on certain factors may impact interpretation of results. Due to feasibility issues regarding data access, outcomes of MAP enrollment such as medication adherence were not examined (although such results have been reported elsewhere for a sub-group of MAP recipients for whom outcomes data were available through the Georgia Regents University Renal Transplant Clinic).¹⁸ However, as the purpose of the study was descriptive in nature, akin to a case report, a more rigorous design and inclusion of outcomes was beyond the scope and intention of the investigators.

Conclusion

The goal of MAP is to increase medication access for underserved, low-income solid-organ transplant recipients through education and enrollment into medication assistance programs. MAP recipients who are not Medicare eligible and have a greater number of past discontinuations are more likely not to enroll in continuous care without significant prompting. Improved understanding of recipient behavior regarding re-enrollment into MAP and similar programs may help health care providers develop strategies to intervene with recipients and ultimately facilitate continued access to services.

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Disclosure

The authors report no conflicts of interest in this work.

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