

# Impact of a nurse practitioner-led dedicated outpatient parenteral antibiotic therapy clinic on patient outcomes and administrative workload: a retrospective cohort study

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## Abstract

**Background:** Outpatient parenteral antibiotic therapy (OPAT) enhances patient safety, improves outcomes, and reduces healthcare costs by decreasing 30-day readmissions and adverse events. However, the optimal structure and follow-up protocols for OPAT programs remain undefined. Identifying high-risk patients for readmission and managing adverse drug events (ADEs) are critical components of OPAT care.

**Objectives:** This study aimed to evaluate the impact of a dedicated OPAT clinic on hospital readmissions, and quantified the administrative workload required to manage patients on OPAT post-discharge.

**Design:** A retrospective, pre-post cohort study compared patient outcomes before and after the implementation of a dedicated OPAT clinic across a single clinic and multiple hospitals.

**Methods:** Patients discharged on OPAT from October 2018 to March 2019 (control group) and from September 2021 to February 2022 (intervention group) were included. The primary outcome was 30-day hospital readmission. Secondary outcomes included administrative workload measured by telephone calls and nursing tasks. Data were analyzed using univariate and multivariate logistic regression models to identify independent risk factors for readmission.

**Results:** A total of 361 patients were included (median age 63 years, 62.1% men). Of these, 239 patients (66.2%) received OPAT post-clinic implementation. Common diagnoses included bacteremia (17.7%) and osteomyelitis (17.5%), with MRSA (17.2%) and Streptococci (14.4%) as predominant pathogens. The median OPAT duration was 14 days, and the median hospital stay was 7 days. Readmissions within 30 days occurred in 24.9% of patients, while 27.7% visited the emergency department. ADEs were reported in 18.9% of patients. Readmission rates decreased from 30.5% in the pre-clinic cohort to 20.1% in the post-clinic cohort ( $p \leq 0.05$ ). The OPAT clinic managed 690 calls, illustrating the substantial administrative burden associated with coordinating care. Most calls addressed lab results (22.6%) and peripherally inserted central catheter-related issues (11.3%).

**Conclusion:** The implementation of a dedicated OPAT clinic was associated with reduced readmissions and improved patient management, suggesting that structured follow-up care may improve outcomes. This study highlights the administrative challenges of OPAT, emphasizing the need for dedicated personnel and efficient coordination. Future research should focus on optimizing OPAT care models and establishing sustainable funding strategies.

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## Plain language summary

### Impact of a dedicated outpatient clinic on reducing hospital readmissions for patients on intravenous antibiotics

Outpatient parenteral antibiotic therapy (OPAT) allows patients to receive intravenous antibiotics at home instead of in the hospital. While OPAT can be beneficial, it carries risks, such as adverse drug reactions and hospital readmissions. This study examines the effectiveness of a dedicated OPAT clinic in reducing these risks. Our research involved comparing patient outcomes before and after the OPAT clinic was established at the University of Toledo. Patients discharged from the hospital on intravenous antibiotics were included if they were 18 years or older and were seen by our Infectious Diseases team during their hospital stay. We excluded patients who received follow-up care from other groups or expired within 14 days post-hospitalization. The OPAT clinic, started in September 2021, aimed to ensure patients' medications and lab tests were managed correctly, educate patients on potential side effects, and monitor any complications. The clinic's staff included a nurse practitioner and registered nurses who coordinated care, managed lab results, and handled patient inquiries. Our study found that the OPAT clinic significantly reduced hospital readmissions. Of the 361 patients studied, those treated through the OPAT clinic had fewer readmissions compared to those treated before the clinic's establishment. The clinic also managed numerous administrative tasks, highlighting the need for sufficient staffing and support for such programs. The findings suggest that a well-structured OPAT clinic can improve patient outcomes by reducing readmissions and managing adverse drug reactions. Future studies should explore optimal staffing, reimbursement models, and coordination strategies to enhance the effectiveness and sustainability of OPAT programs. The study underscores the critical role of Infectious Diseases specialists in ensuring safe and effective OPAT care.

**Keywords:** administrative burden, hospital readmission, outpatient parenteral antibiotic therapy

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## Introduction

The impact of outpatient-parenteral antibiotic therapy (OPAT) on patient outcomes has been well established. Previous studies have demonstrated that OPAT programs improve patient safety, efficacy outcomes, provide cost savings, reduce 30-day readmissions, and minimize adverse events.<sup>1</sup> The Infectious Diseases Society of America (IDSA) guidelines emphasize the need for laboratory monitoring, including serum levels for vancomycin, and expert review before initiating OPAT. However, these guidelines do not specify the optimal frequency for outpatient follow-up visits for patients on OPAT.<sup>2</sup>

Identifying patients at high risk for readmission remains inconsistent, with potential risk factors including patient age, central venous access devices,

infected prosthetic material, discharge to skilled-nursing facilities, extended OPAT duration, recent hospital discharges without IV antibiotics, multidrug-resistant organisms, and certain antibiotics like aminoglycosides or vancomycin.<sup>1,3-7</sup> Furthermore, the treatment of specific infections, such as endovascular, urogenital, or bone and joint infections, also increases readmission risks.<sup>4</sup>

Adverse drug events (ADEs) are common in patients on OPAT, with catheter-related issues being the most frequent. ADEs can result in premature discontinuation of therapy, hospital readmissions, and emergency department visits. Therefore, consistent therapeutic drug monitoring under the supervision of an infectious diseases (ID) physician is crucial.<sup>6,8</sup> The early post-hospital care phase presents significant

risks, underscoring the potential benefits of a dedicated OPAT clinic in reducing readmissions and effectively managing ADEs.<sup>9,10</sup>

The potential to reduce readmissions and address ADEs suggests that a well-designed OPAT program can improve patient outcomes. A dedicated OPAT clinic could specifically reduce readmissions among high-risk patients.<sup>1</sup> The optimal structure for an OPAT program, however, remains undefined. Effective coordination among healthcare providers, timely responses to ADEs and catheter-related events, consistent laboratory monitoring, and efficient handling of patient inquiries require trained personnel. The administrative burden associated with OPAT programs, while described in some centers,<sup>11</sup> has been inadequately documented in terms of comprehensive workload measures such as telephone encounters and coordination efforts.

We describe the structure and report the outcomes of a dedicated outpatient ID clinic designed for patients on OPAT. We emphasize the nature of the administrative effort necessary to coordinate care for patients on OPAT after hospital discharge.

## Methods

### *Study design*

This study was a single-clinic, multi-hospital, retrospective, pre-post cohort study comparing patient outcomes discharged on OPAT before and after the implementation of a dedicated OPAT clinic on September 1, 2021. The control group included patients discharged between October 2018 and March 2019, while the intervention group included patients discharged between September 2021 and February 2022. The Institutional Review Board at the University of Toledo approved this study.

This study was conducted and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.<sup>12</sup>

### *Inclusion criteria*

Patients were included if they (1) were discharged from the hospital on intravenous antibiotics

during the study periods, (2) were aged 18 years or older, and (3) were evaluated at least once by the University of Toledo Division of Infectious Diseases group in the inpatient setting.

### *Exclusion criteria*

Patients were excluded from the study for the following reasons: (1) follow-up care by an ID group other than the University of Toledo Division of Infectious Diseases, (2) outpatient antibiotics received at an infusion center, (3) follow-up care for complications at a clinic and/or hospital other than the study settings, or (4) expiration within 14 days post-hospitalization.

### *Study setting*

On September 1, 2021, the University of Toledo Division of Infectious Diseases implemented a dedicated OPAT clinic with the intent to establish care for patients on OPAT within 1 week of discharge. All patients discharged on OPAT were contacted by the OPAT clinic nurses upon hospital discharge to establish a follow-up clinic appointment. The purpose of the OPAT clinic was to ensure the following: (1) medications and labs were being administered as ordered, (2) patients were tolerating the medications as administered, (3) other outpatient visits with other physicians had been scheduled, (4) patients received education regarding potential medication side effects, and (5) patients were aware of and instructed to recognize the potential complications of OPAT care.

The OPAT clinic also designated an OPAT registered nurse to manage all OPAT-related issues and to monitor lab results. All telephone calls to our OPAT clinic are documented in the electronic medical record (EMR) by the registered nurse who accepts the call. Telephone calls to or from the OPAT clinic were categorized into several groups including calls associated with lab testing and results, scheduling issues, and PICC-related concerns.

Patients receiving OPAT were followed in various settings, including their homes, skilled nursing facilities, and dialysis centers. The study included all patients discharged on OPAT, regardless of whether they received their care at home or in an institutional setting such as a nursing home.

Patients were contacted by the OPAT clinic staff upon discharge, and the goal was to schedule the initial OPAT clinic appointment within 7 days of discharge to ensure early monitoring of their therapy and overall health status. Most patients attended one to two OPAT clinic appointments per course of therapy, with additional visits scheduled as necessary based on the patient's clinical needs or complications related to their OPAT regimen.

#### Data collection

Documented notes in the institutions' EMR were utilized to gather information on patient demographics, diagnoses, microbiology, antimicrobial regimen, comorbidities, hospital course, hospital readmission, emergency department visit within 30 days after discharge, adverse drug reactions, complication of catheter-related thrombosis, history of intravenous drug use, site of OPAT, and nature of the call to the OPAT clinic. Two reviewers examined the patients' notes on the EMR and inconsistencies were addressed before moving on to data analysis.

OPAT duration was defined as the number of days from the date of discharge to the end date of the antimicrobial regimen stated on the patient notes. Readmission was defined as an unplanned hospitalization for any cause within 30 days from the initial hospitalization discharge date. This excluded patients who were only seen in the emergency department and were not admitted to the hospital. Readmission to facilities within the northwestern Ohio and southeastern Michigan region was also obtained to the extent that it was possible to identify these readmissions through the EMR. Calls to the OPAT clinic were categorized into calls associated with issues with the PICC, laboratory results, appointment scheduling, patient education, and antimicrobial orders.

#### Primary and secondary outcome measures

The primary outcome of this study was hospital readmission to the University of Toledo/ProMedica hospital system within 30 days of initial hospital discharge. The secondary outcomes included tracking emergency department visits and ADEs, as well as quantifying the daily tasks and workload on the OPAT designated nurse. This workload encompassed monitoring the total

number of telephone calls to the OPAT clinic, examining the reasons for the telephone calls, addressing in-basket messages to the EMR, coordinating dose adjustments to medications, addressing questions and concerns related to PICCs, triaging clinical concerns, and addressing adverse drug reactions.

#### Statistical analysis

All analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA). Medians and interquartile ranges (IQRs) were reported for non-parametric continuous variables, and frequency was reported for nominal and categorical variables.

Univariate and multivariate analyses for risk factors associated with readmission were examined. Factors associated with readmission that were significant or borderline significant ( $p < 0.1$ ) in univariate analysis were eligible for the multivariate logistic regression model. In particular, sex, use of OPAT clinic, chronic kidney disease, end-stage renal disease, MRSA, *Candida* spp., IV therapy at the hospital, and planned duration of therapy were considered. A backward elimination selection method was utilized to develop the final logistic regression model.

#### Results

A total of 361 patients were included, the median age was 63 (IQR: 52–72), with 62.1% being men. A total of 239 patients (66.2%) received OPAT after the OPAT clinic's establishment. Common diagnoses included bacteremia (17.7%) and osteomyelitis (17.5%). Methicillin-resistant *Staphylococcus aureus* (MRSA) (17.2%), *Streptococci* (14.4%), and *Pseudomonas* spp. (11.6%) were the most frequently identified pathogens. The median OPAT duration was 14 days (IQR: 8–33), and the median hospital stay was 7 days (IQR: 4–12). Cephalosporins (44.0%) and vancomycin (35.2%) were the most frequently prescribed antibiotics (Table 1).

Before the intervention, 31.2% of patients were readmitted within 30 days, compared to 21.8% after the intervention, with a risk difference of 0.09 (95% CI: -0.01, 0.19). Emergency department visits occurred in 30.3% of patients prior to the intervention and 26.4% afterward, resulting

**Table 1.** Clinical characteristics of patients discharged with OPAT, stratified by pre- and post-implementation of the OPAT clinic.

Patient characteristics	All patients (N=361)	Pre-OPAT (n=122)	Post-OPAT (n=239)
Age, years, median (Q1, 3)	63 (52, 72)	63 (50, 72)	63 (53, 73)
Male sex	224 (62.1)	71 (58.2)	153 (64.0)
Readmission	90 (24.9)	38 (31.2)	52 (21.8)
Antimicrobial indications			
Osteomyelitis	63 (17.5)	18 (14.8)	45 (18.8)
Bacteremia	64 (17.7)	28 (23.0)	36 (15.1)
Cellulitis	36 (10.0)	13 (10.7)	23 (9.6)
Abscess	37 (10.3)	8 (6.6)	29 (12.1)
Endocarditis	7 (1.9)	1 (0.8)	6 (2.5)
Prosthetic joint infection	21 (5.8)	4 (3.3)	17 (7.1)
Pneumonia	16 (4.4)	5 (4.1)	11 (4.6)
Urinary tract infection	10 (2.8)	2 (1.6)	8 (3.4)
Microbiology			
MRSA	62 (17.2)	36 (29.5)	26 (10.9)
MSSA	39 (10.8)	17 (13.9)	22 (9.2)
Staphylococcus coagulase negative	31 (8.6)	9 (7.4)	22 (9.2)
<i>Streptococci</i>	52 (14.4)	17 (13.9)	35 (14.6)
<i>Enterococci</i>	38 (10.5)	8 (6.6)	30 (12.6)
<i>Klebsiella</i> spp.	27 (7.5)	7 (5.7)	20 (8.4)
<i>Escherichia coli</i>	24 (6.7)	6 (4.9)	18 (7.5)
<i>Pseudomonas</i> spp.	42 (11.6)	10 (8.2)	32 (13.4)
<i>Candida</i>	15 (4.2)	1 (0.8)	14 (5.9)
Culture negative	71 (19.7)	25 (20.5)	46 (19.3)
OPAT antimicrobial class			
Penicillin	18 (5.0)	3 (2.5)	15 (6.3)
Cephalosporins	159 (44.0)	41 (33.6)	118 (49.4)
Carbapenems	27 (7.5)	2 (1.6)	25 (10.5)
Vancomycin	127 (35.2)	65 (53.3)	62 (25.9)
Other	25 (7.0)	9 (7.4)	16 (6.7)
Comorbidities			
Chronic kidney disease	50 (13.9)	25 (20.5)	25 (10.5)

(Continued)

**Table 1.** (Continued)

Patient characteristics	All patients (N=361)	Pre-OPAT (n=122)	Post-OPAT (n=239)
End stage renal disease	30 (8.3)	15 (12.3)	15 (6.3)
Type 2 diabetes mellitus	136 (37.7)	49 (40.2)	87 (36.4)
Obesity	74 (20.5)	25 (20.5)	49 (20.5)
Coronary artery disease	31 (8.6)	16 (13.1)	15 (6.3)
Atrial fibrillation	42 (11.6)	23 (18.9)	19 (8.0)
Site of OPAT administration			
Home	183 (50.7)	46 (37.7)	137 (57.3)
Dialysis center	31 (8.6)	19 (15.6)	12 (5.0)
Hospice care	7 (1.9)	5 (4.1)	2 (0.8)
Hospital	8 (2.2)	2 (1.6)	6 (2.5)
Long-term care facility	22 (6.1)	9 (7.4)	13 (5.4)
Rehabilitation center	12 (3.3)	2 (1.6)	10 (4.2)
Skilled nursing facility	98 (27.2)	39 (32.0)	59 (24.7)
Planned OPAT duration, days, median (Q1, Q3)	14 (8, 33)	21 (10, 34)	14 (7, 30)
Hospitalization length, days, median (Q1, Q3)	7 (4, 12)	7 (4, 12)	7 (4, 12)

MRSA, Methicillin-resistant *Staphylococcus aureus*; MSSA, Methicillin-susceptible *Staphylococcus aureus*; OPAT, outpatient parenteral antibiotic therapy.

in a risk difference of 0.04 (95% CI: -0.06, 0.14). The proportion of patients that experienced an adverse event was 18.0% before the intervention and 19.3% post-intervention, with a risk difference of -0.01 (95% CI: -0.10, 0.07) (Table 1). Adverse drug reactions were identified through chart documentation, and the determination was made primarily by the attending ID physician during follow-up visits. In some cases, adverse drug reactions were noted by other providers and reviewed by the study team. We did not rely solely on laboratory results to define adverse drug reactions, though abnormal lab values (such as a serum creatinine increase of 50% above baseline) were used to help identify nephrotoxicity when applicable.

Univariate analyses identified numerous characteristics within the patient population that were associated with readmission (Table 2). The multivariate regression model, which was derived

from the results of the univariate analyses, confirmed reduced odds of readmission for patients treated through the OPAT clinic. Comorbidities including chronic kidney disease, end-stage renal disease, *Candida* infection, and OPAT treatment at a hospital setting were significant predictors of rehospitalization. In our analysis, we considered end-stage renal disease as a distinct and more severe stage of renal impairment, and its inclusion alongside chronic kidney disease helps capture the broader spectrum of kidney disease severity in our patient population.

Between September 2021 and February 2022, the OPAT clinic received and made telephone calls 690 times. Of the calls, 156 (22.6%) were calls associated with lab testing and results, 78 (11.3%) were calls about PICC-related problems, and 57 (8.3%) were order confirmation with physicians and other healthcare staff. Before the establishment of the OPAT clinic between

**Table 2.** Predictors examined for hospital readmission.

Predictors	Univariate odds ratio (95% CI)	<i>p</i> value	Multivariate odds ratio (95% CI)	<i>p</i> value
Age, years	1.00 (0.99–1.02)	0.74		
Male sex (ref = M)	1.83 (1.13–2.97)	0.01	1.72 (1.03–2.89)	0.04
OPAT clinic	0.62 (0.38–1.00)	0.05	0.58 (0.34–1.00)	0.05
<b>Antimicrobial indications</b>				
Osteomyelitis	0.94 (0.42–2.15)	0.90		
Bacteremia	1.06 (0.47–2.38)	0.89		
Cellulitis	1.92 (0.79–4.66)	0.15		
Abscess	1.20 (0.48–3.01)	0.69		
Endocarditis	1.30 (0.23–7.35)	0.77		
Prosthetic joint infection	0.65 (0.17–2.53)	0.53		
Pneumonia	0.75 (0.19–2.97)	0.68		
Urinary tract infection	1.39 (0.32–6.02)	0.66		
<b>Microbiology</b>				
MRSA	0.37 (0.15–0.93)	0.04		
MSSA	0.62 (0.24–1.59)	0.32		
Staphylococcus coagulase negative	2.55 (0.76–8.51)	0.13		
Streptococci	1.26 (0.61–2.62)	0.54		
Enterococci	0.70 (0.34–1.46)	0.34		
<i>Klebsiella</i> spp.	1.42 (0.56–3.62)	0.47		
<i>Escherichia coli</i>	1.49 (0.58–3.84)	0.41		
<i>Pseudomonas</i> spp.	0.72 (0.30–1.73)	0.47		
<i>Candida</i>	3.15 (1.02–9.68)	0.05	3.65 (1.20–11.11)	0.02
Culture negative	1.42 (0.66–3.05)	0.37		
<b>OPAT antimicrobial class</b>				
Penicillin	1.54 (0.56–4.24)	0.40		
Cephalosporins	0.80 (0.49–1.30)	0.37		
Carbapenems	1.06 (0.43–2.59)	0.90		
Vancomycin	1.16 (0.71–1.91)	0.55		
Other	0.95 (0.37–2.45)	0.91		
<b>Comorbidities</b>				
Chronic kidney disease	2.50 (1.29–4.83)	0.01	2.27 (1.16–4.46)	0.02

*(Continued)*

**Table 2.** (Continued)

Predictors	Univariate odds ratio (95% CI)	p value	Multivariate odds ratio (95% CI)	p value
End stage renal disease	3.15 (1.42–7.01)	0.01	2.52 (1.11–5.71)	0.03
Type 2 diabetes mellitus	0.78 (0.46–1.32)	0.36		
Obesity	0.96 (0.52–1.78)	0.89		
Coronary artery disease	0.48 (0.18–1.29)	0.15		
Atrial fibrillation	1.10 (0.52–2.34)	0.80		
Site of OPAT administration (ref=Home)				
Dialysis center	1.79 (0.80–4.03)	0.45		
Hospice care	0.54 (0.06–4.63)	0.34		
Hospital	5.43 (1.25–23.64)	0.03	6.23 (1.39–27.99)	0.02
Long-term care facility	1.52 (0.58–3.97)	0.76		
Rehabilitation center	1.09 (0.28–4.19)	0.74		
Skilled nursing facility	0.83 (0.46–1.52)	0.14		
Planned OPAT duration, days	0.98 (0.96–0.99)	0.01	0.97 (0.95–0.99)	0.01
Hospitalization length, days	0.98 (0.96–1.01)	0.17		

MRSA, Methicillin-resistant *Staphylococcus aureus*; MSSA, Methicillin-susceptible *Staphylococcus aureus*; OPAT, outpatient parenteral antibiotic therapy.

September 2021 and February 2022, the hospital received and made 60 calls. A total of 19 calls (31.7%) were associated with PICC-related issues and 12 (20.0%) were calls about scheduling issues.

### Discussion

Our study demonstrates that a dedicated ID OPAT clinic significantly reduces hospital readmissions, highlighting the critical role of ID physicians in care transitions. The OPAT clinic’s structured follow-up and monitoring likely contributed to these improved outcomes. The study also underscores the substantial administrative burden associated with OPAT, suggesting that additional support from case management and ID pharmacists could optimize clinic efficiency.

Laboratory monitoring, though time-consuming, is crucial for patient safety. However, the necessity and frequency of such monitoring should be

evaluated to balance safety and resource utilization. Future studies should explore optimal staffing, reimbursement models, and effective coordination strategies to enhance OPAT program efficacy and sustainability.

Our OPAT clinic was staffed by one nurse practitioner and two registered nurses. These results highlight the important role of a post-discharge OPAT service led by a registered nurse and nurse practitioners in reducing readmissions and improving care coordination for patients on OPAT. While ID physicians provided oversight and expertise in clinical decision-making, the day-to-day management and coordination of patient care by the dedicated nursing staff were central to the success of the program.

The optimal staffing of personnel of an OPAT clinic has not been established, although clinic or nurse-led OPAT has been associated with OPAT success.<sup>10</sup> Previous studies have also indicated that a visit to an OPAT clinic correlates with a



lower likelihood of readmission and that patients evaluated specifically by an ID physician are less likely to be readmitted to the hospital.<sup>13</sup> OPAT clinics that are managed by registered nurses can reduce readmissions, establish lines of communication with high-risk patients including persons who use opioids, and generate cost savings for hospitals.<sup>14</sup> Our registered nurses routinely completed tasks that included fielding telephone calls from patients, home healthcare agencies, outpatient pharmacies, and nursing homes; facilitating setting up outpatient appointments; communicating with insurance companies and completing prior authorizations; and transferring critical information to the ID physician charged with oversight of the patient. In our experience, our OPAT nurse practitioner and registered nurses routinely completed tasks in the outpatient clinic that are typically completed by case managers and pharmacists in the inpatient setting. We propose that the optimal structure of an OPAT clinic includes support from case management services and ID pharmacists.

Additionally, our study offers a quantitative measure of the post-hospital discharge administrative burden associated with OPAT. OPAT administration requires a substantial degree of coordination, with numerous telephone calls necessary to properly facilitate OPAT.

From this, our study offers insight into several potential efficiencies that can be gained through a carefully designed OPAT program. The transition-of-care process on the final day of the hospital admission should be carefully designed to include components of patient education on the OPAT process since poor post-discharge communication has been associated with higher rates of readmission.<sup>15</sup> Improvement in the coordination of care upon discharge could improve OPAT care. Identification of the location of patient discharge; establishment of lines of communication between the patient, inpatient ID team, outpatient ID team, outpatient pharmacy, and outpatient laboratories; and identification of insurance obstacles and other barriers to care must be established prior to discharge. Improvements in clinical documentation of OPAT care plans may improve post-hospital OPAT care,<sup>16</sup> and a dedicated OPAT discharge order set may also help to reduce unnecessary post-discharge telephone calls. The nature of the involvement of ID

providers and teams in the transition-of-care process merits further study.

Obtaining labs is a particularly time-consuming aspect of post-discharge planning; this consumed most of our telephone calls, with 22.6% of the total telephone calls by our registered nurses committed to managing and following up on laboratory results. Current OPAT guidelines from the Infectious Diseases Society of America (IDSA) recommend extensive OPAT laboratory monitoring.<sup>2</sup> Most of these recommendations for laboratory monitoring are supported by low-quality evidence, and many of these recommendations have not been evaluated through clinical study. Previous research on the necessity of laboratory testing has produced contradictory results. In one clinic's experience, if the required laboratory testing was unavailable to the treating physicians, patients were more likely to be readmitted. In their experience, the risk of hospital readmission was 2.53 times as high in patients who did not have the availability of the recommended monitoring laboratory test results.<sup>2</sup> In the absence of a dedicated multidisciplinary program to coordinate care between patients, inpatient clinicians, outpatient clinics, home health agencies, and infusion companies, as few as 30% of laboratory tests may be received by the provider.<sup>9</sup> The necessity of laboratory monitoring can also be supported by literature showing that certain antibiotics may require more intensive follow-up laboratory monitoring and outpatient visits. For instance, oxacillin and nafcillin potentially require intensive outpatient monitoring; earlier data have suggested that patients treated with oxacillin often require antibiotic switches due to adverse drug effects.<sup>17</sup>

In contrast, another clinic's experience suggests that abnormal OPAT labs lead to therapy modification in only a small number of patients and that patients may be ordered more labs than necessary upon discharge. Many patients with abnormal labs do not require a therapy change, and patients who undergo therapy modification often do not do so in response to laboratory data.<sup>18</sup> In our clinic, vancomycin is the most common antibiotic to require dosing changes in response to abnormal labs, though our study did not include enough patients to evaluate many antibiotics. These contrasting results suggest that the IDSA OPAT Guidelines merit reconsideration of their

recommended labs. Laboratory monitoring is time-consuming and difficult to achieve successfully due to numerous administrative factors. Further study is warranted to assess which recommended OPAT laboratory monitoring is justified and cost-effective for safe OPAT administration, based on the specific antimicrobial being prescribed.

OPAT is an unfunded mandate for ID physician practices. No compensation model has been developed to support outpatient practices as they coordinate care between physicians, patients, home health agencies, outpatient pharmacies, etc. The only revenue source to support clinic staff at an OPAT clinic currently would be generated through outpatient appointments over the course of antibiotics. Hospital systems should support physician practices for the costs of their OPAT programs, and payment models should be developed by the Center for Medicare and Medicaid Services and private insurance providers to support ID physician practices for the costs incurred in the monitoring of OPAT patients. While our study underscores the significant administrative burden involved in managing an OPAT clinic, it is important to compare these findings with the structures of other OPAT programs. Various programs, including nurse-led and multidisciplinary models, have documented varying degrees of administrative challenges, particularly related to tasks such as managing laboratory results, coordinating care, and responding to patient inquiries.<sup>10,11</sup> Some programs have implemented centralized case management or expanded staffing, such as pharmacists or administrative support, to alleviate the workload on clinical teams. Our results align with programs that emphasize the importance of dedicated personnel to manage the complexities of OPAT care, although the structure and support mechanisms in our OPAT clinic may vary from other models.

Our study has several limitations. As a single-center study, our results may not be generalizable to other practice settings. There is also a potential for misclassification bias for those who may have sought post-hospital care outside of our hospital systems, as we could only capture the readmission and follow-up visits within our EMR system. Patients who expired within 14 days of discharge were excluded to focus on those whose outcomes were more likely to be influenced by the OPAT program. However, it is possible that some of

these deaths could have been related to OPAT complications, and this exclusion may have led to an underestimation of OPAT-related adverse outcomes. Finally, our medical records review could only determine the intended duration of outpatient treatment; if some patients had small deviations from the duration of outpatient treatment, which may not have been captured within the medical records review.

An additional limitation of this study is the relatively short time periods assessed for each cohort, which may limit the generalizability of the findings. Additionally, the retrospective design inherently introduces the potential for confounding factors that were not accounted for in our analysis. Future prospective studies with longer follow-up periods are needed to further validate these findings.

Before the establishment of the OPAT clinic, administrative tasks such as phone calls and follow-up actions were inconsistently documented in the EMR, as there was no formalized process for capturing these activities. This could have led to an underestimation of the administrative burden during the pre-intervention period. Electronic messages, such as patient portal communications and faxes, were not systematically captured during the pre-intervention period and may not have been consistently documented in the EMR. This limitation could result in an underestimation of the true administrative burden associated with OPAT care.

In addition, the gap between the control period (2019) and the intervention period (2021) was due to several factors, including the COVID-19 pandemic, which significantly impacted healthcare systems worldwide, disrupted hospital operations, and delayed the establishment of the OPAT clinic. Institutional resource constraints and logistical challenges also contributed to the delay. During this period, routine care was interrupted, and there was an increased focus on infection control, which may have influenced hospital readmission rates and the ability to follow OPAT protocols. Given the observational nature of this pre-post study and the time gap between the two periods, it is difficult to establish causality. Changes in healthcare practices, patient management protocols, and external factors such as the pandemic likely contributed to the observed differences, and as such, our findings should be

interpreted as associations rather than direct causal relationships.

## Conclusion

The development of models for optimal care of patients receiving OPAT will require continued refinement. Future research should focus on multicenter assessments of OPAT care models, the cost-effectiveness of laboratory monitoring, and the development of compensation models for outpatient ID practices. Additionally, studying the impact of improved EMR systems on OPAT care coordination could provide further insights into enhancing patient outcomes and reducing administrative burdens.

We would also advocate for a multicenter assessment of current approaches to OPAT care to evaluate the extent of financial support to physician practices to ID physician practices by hospital systems relative to outpatient staffing needs. Models of care that establish improved efficiencies in OPAT care and establish the importance of the ID physician in the transition of care process should be described. Perhaps most importantly, ID professional societies must engage in advocacy for change in the payment models that support OPAT so that the costs of OPAT do not entirely fall to outpatient ID physician practices.

## Declarations

### *Ethics approval and consent to participate*

The Institutional Review Board at the University of Toledo College of Medicine approved this study. The study approval number is 301362-UT. A waiver of consent to participate was granted by the Institutional Review Board of the University of Toledo College of Medicine, as the study involved the retrospective analysis of de-identified data.

### *Consent for publication*

Not applicable, as no identifiable patient data were included in the study.

### *Author contributions*

**Makoto Ibaraki:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Writing – original draft; Writing – review & editing.

**Zachary Gruss:** Formal analysis; Methodology; Writing – original draft; Writing – review & editing.

**Emily Wings:** Formal analysis; Methodology; Writing – original draft; Writing – review & editing.

**Jaclyn E. Geronimo:** Investigation; Project administration; Writing – review & editing.

**Janine M. Varnes:** Investigation; Project administration; Writing – review & editing.

**Joel A. Kammeyer:** Conceptualization; Data curation; Formal analysis; Methodology; Project administration; Writing – original draft; Writing – review & editing.

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### *Competing interests*

The authors declare that there is no conflict of interest.

### *Availability of data and materials*

Data cited in the research above is available to be shared.

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## Supplemental material

Supplemental material for this article is available online.

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