

Butler University Digital Commons @ Butler University

Scholarship and Professional Work – COPHS

College of Pharmacy & Health Sciences

2016

Development and Implementation of a Pharmacist-managed Outpatient Parenteral Antimicrobial Therapy Program

Eun Kyoung Chung

Cole B. Beeler

Eva W. Muloma

Danielle Osterholzer

Kendra M. Damer Butler University, kmdamer@butler.edu

See next page for additional authors

Follow this and additional works at: http://digitalcommons.butler.edu/cophs papers



🏕 Part of the Pharmacy and Pharmaceutical Sciences Commons, and the Therapeutics Commons

Recommended Citation

Chung, Eun Kyoung; Beeler, Cole B.; Muloma, Eva W.; Osterholzer, Danielle; Damer, Kendra M.; and Erdman, Sharon M., "Development and Implementation of a Pharmacist-managed Outpatient Parenteral Antimicrobial Therapy Program" (2016). Scholarship and Professional Work - COPHS. Paper 229. http://digitalcommons.butler.edu/cophs_papers/229

This Article is brought to you for free and open access by the College of Pharmacy & Health Sciences at Digital Commons @ Butler University. It has been accepted for inclusion in Scholarship and Professional Work - COPHS by an authorized administrator of Digital Commons @ Butler University. For more information, please contact fgaede@butler.edu.



Development and implementation of a pharmacist-managed outpatient parenteral antimicrobial therapy program

Eun Kyoung Chung, Cole B. Beeler, Eva W. Muloma, Danielle Osterholzer, Kendra M. Damer and Sharon M. Erdman

Abstract:

Purpose: The development and implementation of a pharmacist-managed outpatient parenteral antimicrobial therapy (OPAT) program in a county teaching hospital are described.

Summary: A pharmacist-managed OPAT program was developed and implemented at a county teaching hospital to provide consistent evaluation, approval, and monitoring of patients requiring OPAT for the treatment of infection. The developmental and implementation stages of the OPAT program included (1) a needs assessment, (2) the identification of resources necessary for program operation, (3) delineation of general OPAT program operations and activities of individual OPAT clinicians, (4) the development of patient selection criteria, including a plan of care algorithm, and (5) acquisition of administrative support to approve the program. In this program, the OPAT pharmacist plays an integral role in the management and oversight of OPAT patients, working under a collaborative agreement with infectious diseases physicians. The OPAT pharmacist assists with appropriate patient and regimen selection, confirmation of orders on discharge, assuring that laboratory tests for safety surveillance are performed and evaluated, performing routine monitoring for adverse events and line complications, and assuring the removal of the vascular access device upon the completion of OPAT.

Conclusion: The OPAT program provides structured monitoring, patient follow-up, and led to improvements in patient outcome with minimization of treatment and line-related adverse events.

Outpatient parenteral antimicrobial therapy (OPAT) is the practice of administering parenteral antimicrobial therapy in settings outside of a hospital, such as the home or other outpatient facility (e.g., infusion center, physician office, skilled nursing facility). The use of OPAT has grown

substantially since the practice was first described in 1974. This increased use has been attributed to the development of antibiotics that can be administered once or twice daily, technological advances in vascular access and infusion devices, high OPAT acceptance by patients and healthcare professionals, the availability of reliable OPAT services in the community, and efforts to reduce overall healthcare costs.¹ Additionally, as healthcare providers and institutions are increasingly evaluated on metrics such as quality of care and hospital length of stay, OPAT will likely be utilized at a higher rate. In addition, OPAT has been shown to be safe and effective for a wide range of infectious diseases (ID), including skin and soft tissue infections (cellulitis, osteomyelitis, and septic arthritis), bacteremia, endocarditis, pyelonephritis, meningitis, brain abscess, and intraabdominal infections.^{1–11}

In 2004, the Infectious Diseases Society of America (IDSA) published guidelines outlining the safe and effective practice of OPAT, with specific recommendations addressing (1) appropriate patient evaluation and selection, (2) essential elements of an OPAT program, (3) roles and responsibilities of individual OPAT team members, (4) appropriate selection and administration of antibiotics for OPAT, and (5) laboratory monitoring parameters and recommended frequencies according to the antimicrobial agent used. The IDSA guideline recommendations on appropriate patient and antibiotic selection for OPAT support current antimicrobial stewardship efforts directed at ensuring judicious and cost-effective use of antimicrobial agents. 1,5

Common models for the delivery of OPAT include the infusion center model, the self-administration model, and the long-term care facility model. 1,4,6,9,11,12

In the infusion center model, OPAT is administered in a variety of settings (e.g., hospital clinic, emergency department, urgent care center, physician's office, freestanding infusion facility). The primary limitation of this model is the need for frequent patient transportation to receive OPAT.

The self-administration model involves the administration of parenteral antimicrobials by patients or their caregivers in the home after they have received appropriate training by a healthcare professional (usually a home care nurse) in infusion technique and line care. Once the patient displays competency with self-administration, periodic nursing visits are performed for surveillance laboratory monitoring, line dressing changes, and (if applicable) infection-site assessments. The self-administration model is typically less costly than the infusion center model or long-term care facility model and is associated with higher patient satisfaction because it allows the patient to return to the home environment and daily life activities. With this model, the patient must still travel for periodic clinic visits or radiographic tests; however, the frequency of travel is substantially less than with the infusion center model.

The long-term care facility model involves the administration of OPAT in skilled nursing facilities, which may be more appropriate for patients with physical, psychological, behavioral, financial, or social limitations for whom home administration of OPAT is not safe or feasible. This form of care is more costly than the infusion center or the self-administration model, and the patient may still need to travel for follow-up clinic visits and radiographic tests during the course of OPAT. Regardless of the model of delivery of OPAT, there is the potential for the pharmacist to play an

integral role in optimizing drug therapy and minimizing adverse effects and line complications associated with parenteral antimicrobial therapy.

Pharmacist-managed ambulatory care clinics have been implemented for patients with a variety of disease states, including asthma, hyperlipidemia, hypertension, diabetes mellitus, human immunodeficiency virus infection, and hepatitis C, as well as patients requiring anticoagulation therapy or pharmacogenetic testing. There is evidence that clinical outcomes in patients receiving care within pharmacist-managed programs are either comparable 14,20 or superior 18,19 to those achieved in physician-managed programs. The increasing use of OPAT as a cost-saving measure provides a prime opportunity for pharmacists to become involved in this form of care. To date, there are a limited number of pharmacist-managed OPAT programs in the United States, and published data outlining their development and implementation are lacking. This report describes the development and implementation of a pharmacist-managed OPAT program at a county teaching hospital with limited resources.

Background and OPAT program justification

Eskenazi Health (EH, formerly Wishard Health Services) is a 316-bed safety-net hospital in Indianapolis, Indiana, with approximately 15,000 adult hospital admissions annually. The EH system also comprises a large outpatient clinic network that provides nearly 1 million clinic visits annually. Prior to July 2008, EH lacked a systematic or coordinated approach to the management of patients receiving OPAT, with many practices deviating from the recommendations set forth in the IDSA guidelines on OPAT. Any clinician with prescribing authority, including a resident physician, could order OPAT without involvement or consultation by an inpatient ID physician regardless of infection type, antibiotic prescribed, or duration of therapy. In many cases, this led to the use of OPAT without (1) a clear, established plan of care specifying the antibiotic therapy (including duration of therapy) and laboratory orders for monitoring, (2) designation of a physician to supervise the OPAT course, including therapeutic drug monitoring, adverse-effect monitoring, and evaluation of response to therapy, (3) a scheduled follow-up clinic appointment with a primary care physician or other healthcare provider to monitor response to therapy, and (4) specific arrangements for removal of the vascular access device on completion of OPAT. In addition, OPAT was occasionally used in patients with infections that could have been managed with oral antibiotic therapy (e.g., community-acquired pneumonia, complicated urinary tract infections), in patients who were not clinically stable, and in patients with suboptimal home settings or without responsible caregivers to assist with the administration of parenteral antibiotics.

At EH, there is a subset of uninsured or underinsured patients who receive OPAT funded by Health Advantage, a charity program that provides medical care to low-income patients who are not eligible for other assistance programs. Prior to the development of the formal OPAT program in 2008, this subset of patients obtained their antibiotics and supplies for administration from the EH inpatient pharmacy at the time of hospital discharge and then returned to the hospital periodically during the course of therapy to obtain medication and supplies, with the frequency of visits depending on the duration of therapy and the physical stability of the parenteral antibiotic used. Patients received instruction in the proper administration of antibiotics from inpatient pharmacists before discharge. Prior to 2008, i.v. antibiotics were administered without infusion pumps (often

using the "drip-count" method), and routine weekly nurse home visits for blood collection for surveillance safety laboratory tests and line dressing changes were not performed. Since infusion pumps and state-of-the-art infusion devices were not used, suboptimal antibiotic therapy was occasionally selected in order to provide dosing convenience or address drug stability issues (for example, vancomycin might be selected instead of nafcillin for methicillin-susceptible *Staphylococcus aureus* infections, or carbapenems might be avoided due to stability issues).

The lack of healthcare provider supervision and coordinated care of patients receiving OPAT led to suboptimal patient care and serious adverse consequences on several occasions. The heightened need for coordinated care and quality assurance for patients receiving OPAT became evident as adverse outcomes caused by inadequate management of OPAT mounted. Institutional observations revealed multiple hospital readmissions and emergency department visits by patients receiving OPAT due to adverse events (e.g., nephrotoxicity, neutropenia), inadequate response to antibiotic therapy, or complications associated with vascular access devices that were not removed after the completion of therapy (e.g., endocarditis, pulmonary septic emboli). Among patients who developed endocarditis and septic pulmonary emboli due to retained vascular access devices, readmission and subsequent courses of therapy led to additional expenditures (in excess of \$10,000 per patient on average), which was especially noteworthy for patients enrolled in Health Advantage, who receive all of their care within the EH system, which is funded by county tax dollars. Many of the adverse events and readmissions may have been prevented with appropriate monitoring and management of OPAT. Therefore, the need for improvement in all of the aforementioned performance areas served as the basis for justification of the development of a formal OPAT program at EH.

Program planning and development

In 2005, a pharmacist-managed OPAT program, including a physician-staffed clinic, was proposed as a means to provide consistent and comprehensive care to patients requiring OPAT. The initial proposal highlighted the differences between OPAT practices at EH and the recommended practices outlined in the IDSA guidelines on OPAT. This information was presented at a meeting of the hospital's anti-infective subcommittee for initial comment and approval and then presented to managers and directors within multiple departments (e.g., medical management, ID).

During the process of planning for the OPAT program, it was recognized that it would be best to outsource the home infusion services to a home care agency. But the outsourcing of home infusion services for Health Advantage—eligible patients would lead to increased direct costs associated with nurse visits, laboratory monitoring, and care coordination. However, based on a comprehensive analysis of the costs of managing avoidable OPAT complications, it was determined that the improved care provided by a formal OPAT program would ultimately decrease overall OPAT-associated costs by preventing complications stemming from inadequate monitoring (e.g., line-related complications due to retained vascular access devices). The planning group decided that outsourcing the home infusion services to a home care agency would (1) expand the selection of antimicrobial agents available for OPAT to include those delivered via state-of-the-art infusion devices and drug delivery systems, (2) allow for nurse home visits for the purposes of blood sampling for laboratory monitoring, i.v. line site evaluation and dressing changes,

infection assessment, and compliance assessment, and (3) enable continuous monitoring throughout the course of therapy.

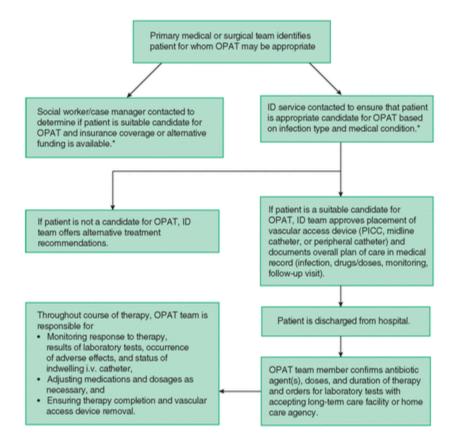
Pursuant to a review of feedback from stakeholders regarding the initial proposal, a final OPAT program proposal was developed by the hospital's ID clinical pharmacist and ID physicians in September 2007. The proposal included (1) descriptions of deviations in existing OPAT services from the IDSA guideline on OPAT recommendations, (2) an OPAT program policy and procedure outlining the process for OPAT patient assessment, evaluation, and monitoring, (3) a report describing recently observed complications in OPAT patients with retained vascular access devices and the associated costs, (4) annual estimates of the number of Health Advantage—eligible patients who would require OPAT and cost projections for providing coordinated OPAT services, and (5) a cost analysis by local home infusion service providers of commonly used antibiotic regimens and services (this was important because the OPAT program would require that outside vendors provide medications, supplies, and nurse visits for patients eligible for Health Advantage). The OPAT proposal was formally presented to the anti-infective subcommittee, the pharmacy and therapeutics committee, and the hospital administration; it was approved and implemented on July 1, 2008.

OPAT program process

An algorithm (Figure 1) describing the process for OPAT patient evaluation, selection, and monitoring at EH was developed jointly by the ID department and the departments of pharmacy and transition support (medical management) using the IDSA guidelines on OPAT. According to a quality mandate set forth by the hospital administration to assure appropriate patient selection for OPAT, the primary medical or surgical team must contact the inpatient ID consultation service for review and approval of OPAT before discharge. In addition, a vascular access device for the purpose of administering OPAT cannot be placed unless recommended by the ID service. The predischarge review of the patient (typically conducted by an ID physician and an ID pharmacist) can be in the form of either a brief review of the medical record or a formal consultation by the inpatient ID consult team with the latter typically employed in difficult cases that require extensive medical record review and physical examination. Simultaneously, the social worker or case manager evaluates the patient's insurance coverage, home or living situation, social history (including use of illicit substances), willingness and ability to administer OPAT, and caregiver support in order to determine the feasibility of OPAT. Appropriate patient selection is integral to the successful and safe use of OPAT, which is best utilized in patients who have infections requiring parenteral antimicrobial therapy, who are medically stable and in whom the risk of sudden life-threatening changes in health is minimal, who have a clean and safe home or outpatient environment for the administration of parenteral antimicrobial agents, and who are willing to participate and comply with all aspects of care (Figure 2). Lastly, in the EH program it is recommended that patients with a recent history of intravenous illicit drug use receive OPAT in a supervised setting (e.g., skilled nursing facility, infusion clinic) due to the risk of noncompliance and possible abuse of the vascular access device.

Figure 1

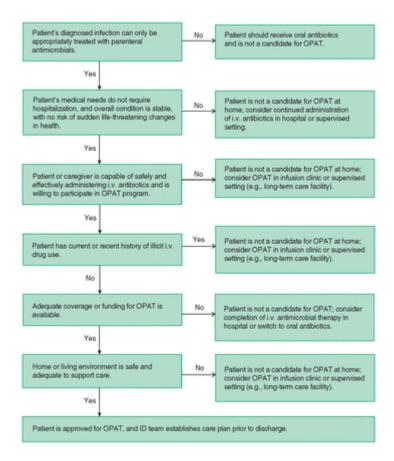
Flow chart of outpatient parenteral antimicrobial therapy (OPAT) process at Eskenazi Health. ID = infectious diseases, PICC = peripherally inserted central catheter. Asterisks denote simultaneous activities. If the patient has a current or recent history of i.v. drug abuse, administration of i.v. antibiotics in a supervised setting (skilled nursing facility), daily intramuscular injections, or daily infusions (with daily removal of the catheter) is advised.



If OPAT is deemed appropriate for a patient, an inpatient ID physician or pharmacist approves the placement of the vascular access device (a peripherally inserted central catheter [PICC], a midline catheter, or a peripheral catheter, depending on the expected duration of OPAT) and documents an overall OPAT plan of care using a template (Figure 3) in the hospital's electronic medication order-entry system. The OPAT template outlines (1) the indication(s) for parenteral antibiotic therapy, (2) the recommended antibiotic(s), dose(s), and frequency of administration, (3) the tentative therapy completion date, (4) specific laboratory values to be monitored and the monitoring frequency, (5) the fax number for transmittal of laboratory test results, (6) contact information for OPAT program personnel, and (7) details of OPAT clinic follow-up appointments, if applicable. After the patient's discharge from the hospital, an OPAT team member (usually the OPAT pharmacist, the social worker, or the case manager) confirms the antibiotic, laboratory, and OPAT clinic orders with the accepting facility or home care agency. If OPAT is not approved by the inpatient ID team, alternative recommendations (e.g., conversion to oral therapy, discontinuation of antibiotic therapy) are provided.

Figure 2

Outpatient parenteral antimicrobial therapy (OPAT) patient selection algorithm used by Eskenazi Health. ID = infectious diseases.



Once the patient is discharged, members of the OPAT team provide oversight of all aspects of outpatient antiinfective use for the entire course of therapy, including therapeutic drug monitoring and dosage adjustment, monitoring of laboratory results and the occurrence of adverse effects, evaluation and resolution of line-related complications, monitoring of response to therapy, and ensuring that therapy is completed within the specified timeframe, with subsequent removal of the vascular access device. The majority of these daily functions are performed by the OPAT clinical pharmacist according to an OPAT scope of practice document that delineates the services provided by the pharmacist on behalf of the OPAT physician (appendix). In addition, most patients discharged with orders for OPAT (regardless of setting) are scheduled to see the OPAT physician on an outpatient basis for evaluation of response to therapy and assessment of treatment-related adverse events and line-related complications. In order to provide this follow-up care, the OPAT clinic was established as a half-day, once-weekly clinic staffed by an ID physician and the OPAT pharmacist, with the intent of adding clinic time and space, if needed, based on patient volume. Because the OPAT clinic was established within the EH medicine clinic, each examination room or work area was already equipped with needed supplies, with existing clerical, nursing, and ancillary staff available to assist with OPAT clinic activities. The nurse who was assigned to the OPAT clinic received hospital-based training on the care and removal of PICC and midline catheters. Lastly, to enhance patient monitoring and acquisition of quality-assurance data, a

consultant was hired to create an electronic OPAT database (Microsoft Access, Microsoft Corporation, Redmond, WA) accessible from the hospital intranet.

Figure 3

Sample template for predischarge note in medical record outlining established plan of care for patient receiving outpatient parenteral antimicrobial therapy.

Infectious Diseases Department OPAT Note

This patient is a suitable candidate for outpatient parenteral antimicrobial therapy (OPAT) based on the infection type and antimicrobial agents required to treat the infection. The recommended plan of care for the treatment of this patient's [insert infection type and causative organism(s), if known] is as follows:

- Drug(s), Dose(s), Anticipated Duration of Therapy: [list i.v. and oral agents, with doses and anticipated stop date]
- Laboratory Monitoring:
- · Basic metabolic panel [specify frequency]
- Complete blood count with differential [specify frequency] [The following are added to the note only if applicable:]
- Vancomycin trough concentration [specify frequency and target serum trough concentration]
- Gentamicin peak and trough concentrations [specify frequency and target serum concentrations]—standard dosing
- Tobramycin peak and trough concentrations [specify frequency and target serum concentrations]—standard dosing
- Gentamicin or tobramycin random concentrations, or 2- and 10-hour concentrations for patients on extended-interval dosing
- [Insert name] will follow the patient's labs as an outpatient. Please fax all test results to [insert fax number] and page [insert OPAT program pager number] with all critical lab results.
- A follow-up appointment has been scheduled with Dr. [insert name] in the OPAT clinic in the [insert building name, address, and room number for clinic] on [insert date] at [insert time]. Please give the details of this clinic appointment to the patient (or accepting facility) at discharge.

Pharmacist duties and responsibilities

The responsibilities of individual team members within an OPAT program have been described elsewhere. Unlike other OPAT programs described to date, the OPAT program at EH is a pharmacist-managed program, with expanded responsibilities for the OPAT pharmacist. This pharmacist serves as the codirector of the program and also as the inpatient ID clinical pharmacist responsible for daily patient rounds with the inpatient ID consult team. Therefore, the pharmacist assists with all aspects of OPAT before and after discharge, including appropriate patient selection; the selection of antimicrobial agents and doses; coordination and development of monitoring plans; predischarge patient education on the anticipated plan of care, potential adverse effects, and monitoring requirements; continuous patient monitoring; provision of clinical pharmacy services throughout the course of OPAT (under the protocol and scope of practice described in the appendix); ensuring the appropriate duration of OPAT and removal of the vascular access device; documentation of patient visits and changes to the plan in the OPAT database and medical record; and continuous communication with physicians regarding individual patient care issues and overall program quality-assurance issues. When the patient arrives for each OPAT clinic visit, the pharmacist conducts an interview using a standardized questionnaire (Figure 4) to obtain a comprehensive medication history, evaluate compliance with the OPAT regimen, determine the presence of treatment-related adverse effects or complications associated with the vascular access device, and assess the current status of the infection. Once the patient has been evaluated by the physician, the physician and the pharmacist discuss the patient's progress and the potential need for changes to the OPAT plan of care. This information is then documented in the OPAT database and the electronic medical record. If changes are made to the established OPAT plan of care, the pharmacist communicates the changes to the home infusion company or skilled nursing facility.

Figure 4

Medication reconciliation and patient interview form used by pharmacists at Eskenazi Health's outpatient parenteral antimicrobial therapy (OPAT) clinic. PICC = peripherally inserted central catheter.

				Date			
	OPAT	Eskenaz	n Reconciliation ti Health lis, Indiana	Form			
atient Name (Last, First, M	Dr.						
Aedical Record Number (M	RNI:						
llergies (Reaction):							
regnant □ Yes □ No Bro	east Feeding D Yes 0	3 No					
Medication (include dose, route and frequency)	Time of Admin	Adherent?	Side Effect? Y/N	Refils Needed?	Comments		
ICC Line:	Any Problems?						
PICC Line:	Erythema or imitation?						
	Are the nurses having difficulty drawing blood from the PICC?						
Side Effects:							
	Diarrhea? (Number of episodes/day, duration)						
	Skin Rash? (Location/guality/duration)						
Symptoms:	Fever or Chills?						
	Night Sweats?						
	Is site of infection stable, getting better, or worse?						
	Pain? (Stable/worse/better)						
	Redness/Swelling? (Stable/worse/better)						
	Drainage from infection site?						
completed by:				Date:			

Discussion

The primary goals of establishing the pharmacy-managed OPAT program at EH were to assure appropriate patient selection and provide enhanced oversight and quality of care for patients discharged with orders for OPAT. The success of this type of OPAT program and the subsequent improvement in patient care are highly dependent on a good working relationship between ID physicians and pharmacists, who must collaborate to make complex decisions integrating laboratory results, physical examination findings, radiographic findings, and home care assessments to improve the care of each patient. Pharmacist responsibilities are performed under a collaborative agreement with the ID physician, who is ultimately responsible for the overall care of the patient.

As part of a performance-improvement initiative, the clinical outcomes, adverse effects, and line complications experienced by patients in the EH OPAT program are continuously evaluated. During the period July 1, 2008–January 14, 2010, 203 patients received OPAT for a mean duration of 34 days (range, 4–94 days). The main clinical indications for OPAT included osteomyelitis (n = 77, 38% of cases), skin and soft tissue infections (n = 47, 23%), bacteremia (n = 26, 13%), and septic arthritis (n = 16, 8%). Clinical cure (assessed at the end of the prescribed OPAT course) was

achieved in 93% of patients. Adverse drug events necessitated a change in therapy in 6% of patients and hospitalization in 2% of patients. Line complications necessitated a change in therapy in 2% of patients and hospitalization in 5% of patients. The vascular access line was removed in 97% of evaluable treatment courses at the completion of OPAT, with 3 patients requiring retention of the i.v. access device at the request of the primary physician. In addition, the formal OPAT program at EH has decreased costs and unnecessary usage of both oral and intravenous antimicrobials through the use of mandatory ID service review and approval of all OPAT courses.²² Overall, the OPAT program appears to be safe and effective for the management of patients with a variety of infections.

Through organized planning and a collaborative interprofessional effort, a pharmacist-managed OPAT program was developed and implemented at a large county teaching hospital; the program can serve as a model for other healthcare systems.

Conclusion

The OPAT program provides structured monitoring, patient followup, and led to improvements in patient outcome with minimization of treatment and line-related adverse events.

Appendix Sample protocol and scope of practice for pharmacist-managed outpatient parenteral antimicrobial therapy

Drug Therapy Management Protocol for Patients Receiving Outpatient Parenteral Antimicrobial Therapy (OPAT)

This drug therapy management protocol was developed to establish drug therapy management (DTM) by a pharmacist under a physician-initiated written protocol for patients being followed by the Outpatient Parenteral Antimicrobial Therapy (OPAT) Program who are receiving outpatient parenteral antimicrobial therapy at home, in a skilled nursing facility, in prison, or at an infusion center. The procedures, protocols, practices, and other items contained within these documents are intended to be guidelines for the pharmacists and physicians of this institution. In no instance should the contents of these documents be considered as standards of professional practice or as rules of conduct or for the benefit of any third party. The documents herein are guidelines only, and allow for professional discretion and deviation where the individual healthcare provider deems variation to be appropriate.

- A. At the time of approval of this protocol, the individual physicians authorized to prescribe drugs and responsible for the delegation of DTM for OPAT are [insert names]. This protocol shall not be affected by changes to the preceding list of physicians. However, physicians joining the OPAT team shall be provided a copy of this protocol.
- B. The clinical pharmacists who will implement the DTM for OPAT patients as delegated under this DTM protocol include [insert names].
- C. In accordance with the incorporated OPAT treatment guidelines, attached as [reference Exhibit A], the clinical pharmacist may provide care for patients in the OPAT program under this DTM protocol, to include:
 - 1. Assessment of the therapeutic needs of each patient receiving outpatient parenteral antimicrobial therapy for the treatment of an infection on behalf of [insert physician name(s)]. Disease states/infections include but are not limited to cellulitis, osteomyelitis, diabetic foot infections, urinary tract infections, pyelonephritis, endocarditis, meningitis, brain abscess, liver abscess, peritonitis, lung abscess, pneumonia, bacteremia, line infections, and vascular graft infections.

- 2. Evaluation of pharmacologic and non-pharmacologic treatment regimens.
- 3. Ordering and interpretation of pertinent laboratory studies.
- 4. In accordance with pharmacologic privileges, attached as [reference Exhibit B], performance of drug evaluation, drug utilization review, and drug regimen review; and participation in the selection of antimicrobial agents (including initiation, renewal, and dosage adjustment pursuant to pharmacist's level of privileges and treatment guidelines).
- 5. Provision of patient education regarding disease state(s)/infection, pharmacologic, and non-pharmacologic therapy, including the schedule for lab monitoring and potential adverse effects.
- Documentation of patient visits, patient care, and treatment decisions in the OPAT database and medical record, when necessary. The referring physician will have access to the OPAT database and all medical records.
- 7. Consultation with referring physician and other members of the health care team, as appropriate, to include ancillary services (podiatry, dietary, social work, etc.), general medicine, orthopedics, and general surgery. Other subspecialty medicine consults will be in consultation with the referring physician.
- 8. Obtain authorization from the physician for deviations from the treatment guidelines.
- 9. The schedule for physician review of DTM and status reports of the patient to the physician will be based on the clinical condition and tolerance of recommended outpatient therapy of each individual patient. The services provided to the patient by the pharmacist will be conveyed verbally on a weekly basis, during each clinic visit, and on an as needed basis. A supervising physician will also meet on a periodic basis with the clinical pharmacist to review the DTM protocol and patient care.
- 10. This protocol does not delegate diagnosis or prescription to the clinical pharmacist.

This DTM protocol was formulated and approved by:

Name .	, 96.35	Date	
(marriproprose title)	Outpution Antinionhial Though Pro	gram	
lower same of body	ted health quere)		
Noncon Plantacy	harvison for other side), finant same of b	replacificable prove)	
Chief Dancaster Office	ar for other title). Steam name of Registed	Assist quare).	
Asspending Practition	NATE OF THE PARTY.		
Name	, Plants Jt.	Date	

References

- 1. Tice AD, Rehm SJ, Dalovisio JR, et al. Practice guidelines for outpatient parenteral antimicrobial therapy. IDSA guidelines. *Clin Infect Dis.* 2004; 38:1651–72.
- 2. Tice AD, Strait K, Ramey R, et al. Outpatient parenteral antimicrobial therapy for central nervous system infections. *Clin Infect Dis.* 1999; 29:1394–9.
- 3. Mackintosh CL, White HA, Seaton RA. Outpatient parenteral antibiotic therapy (OPAT) for bone and joint infections: experience from a UK teaching hospital-based service. *J Antimicrob Chemother*. 2011; 66:408–15.
- 4. Theocharis G, Rafailidis PI, Rodis D, et al. Outpatient parenteral antibiotic therapy (OPAT) at home in Attica, Greece. *Eur J Clin Microbiol Infect Dis.* 2012; 31:2957–61.
- 5. Chapman AL, Seaton RA, Cooper MA, et al. Good practice recommendations for outpatient parenteral antimicrobial therapy (OPAT) in adults in the UK: a consensus statement. *J Antimicrob Chemother*. 2012; 67:1053–62.

- 6. Kieran J, O'Reilly A, Parker J, et al. Self-administered outpatient parenteral antimicrobial therapy: a report of three years experience in the Irish healthcare setting. Eur J Clin Microbiol Infect Dis. 2009; 28:1369–74.
- 7. Bernard L, El-Hajj, Pron B, et al. Outpatient parenteral antimicrobial therapy (OPAT) for the treatment of osteomyelitis: evaluation of efficacy, tolerance and cost. *J Clin Pharm Ther*. 2001; 26:445–51.
- 8. Tice A. Documenting the value of OPAT: outcome studies and patient registries. *Can J Infect Dis.* 2000; 11:45A–48A.
- 9. Matthews PC, Conlon CP, Berendt AR, et al. Outpatient parenteral antimicrobial therapy (OPAT): is it safe for selected patients to self-administer at home? A retrospective analysis of a large cohort over 13 years. *J Antimicrob Chemother*, 2007; 60:356–62.
- 10. Amodeo MR, Clulow T, Lainchbury J, et al. Outpatient intravenous treatment for infective endocarditis: safety, effectiveness and one-year outcomes. *J Infect*. 2009; 59:387–93.
- 11. Barr DA, Semple L, Seaton RA. Self-administration of outpatient parenteral antibiotic therapy and risk of catheter-related adverse events: a retrospective cohort study. *Eur J Clin Microbiol Infect Dis.* 2012; 31:2611–9.
- 12. Paladino JA, Poretz D. Outpatient parenteral antimicrobial therapy today. *Clin Infect Dis.* 2010; 51(suppl 2):S198–208.
- 13. Bungard TJ, Gardner L, Archer SL, et al. Evaluation of a pharmacist-managed anticoagulation clinic: improving patient care. *Open Med.* 2009; 3:e16–21.
- 14. Cording MA, Engelbrecht-Zadvorny EB, Pettit BJ, et al. Development of a pharmacist-managed lipid clinic. *Ann Pharmacother*. 2002; 36:892–904.
- 15. Crews KR, Cross SJ, McCormick JN, et al. Development and implementation of a pharmacist-managed clinical pharmacogenetics service. *Am J Health-Syst Pharm.* 2011; 68:143–50.
- 16. Johnson KA, Chen S, Cheng IN, et al. The impact of clinical pharmacy services integrated into medical homes on diabetes-related clinical outcomes. *Ann Pharmacother*. 2010; 44:1877–86.
- 17. Morgado M, Rolo S, Castelo-Branco M. Pharmacist intervention program to enhance hypertension control: a randomised controlled trial. *Int J Clin Pharm.* 2011; 33:132–40.
- 18. Munzenberger PJ, Vinuya RZ. Impact of an asthma program on the quality of life of children in an urban setting. *Pharmacotherapy*. 2002; 22:1055–62.
- 19. Rathbun RC, Farmer KC, Stephens JR. Impact of an adherence clinic on behavorial and virologic response in treatment of HIV infection: a prospective, randomized, controlled pilot study. *Clin Ther*. 2005; 27:199–209.
- 20. Smith JP, Dong MH, Kaunitz JD. Evaluation of a pharmacist-managed hepatitis C care clinic. *Am J Health-Syst Pharm*. 2007; 64:630–6.
- 21. Beeler C, Chung EK, Osterholzer D, et al. Incidence of adverse events and line complications during outpatient parenteral antimicrobial therapy in patients at an inner-city, county teaching hospital. *Abstract presented at ID Week 2012*, San Diego, CA; 2012 Oct.
- 22. Conant MM, Erdman SM, Osterholzer D. Mandatory infectious diseases approval of outpatient parenteral antimicrobial therapy (OPAT): clinical and economic outcomes of averted cases. *J Antimicrob Chemother*. 2014; 69:1695–700.