Outpatient Parenteral Antimicrobial Therapy (OPAT): A Pharmacist's Perspective

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Goals and Objectives

- Define OPAT and discuss advantages/disadvantages of OPAT
- Review practice models and special considerations for OPAT
- Review indications and contraindications for OPAT
- Discuss the specific role of pharmacists & ID pharmacist
- Discuss common issues with parenteral antibiotics (e.g. stability)
- Describe methods to simplify therapy and ensure safety
- Design an antimicrobial regimen & monitoring plan for OPAT
- Review special patient populations and final planning

Advantages & Disadvantages of OPAT*

- Advantages
  - Decreased length of stay
  - Reduced risk for complications
  - Improved bed management
  - Reduced healthcare expenses
    - Inpatient: $1200-1500/d
    - Outpatient: $400-500/d
  - Cure-effective
  - Increased patient satisfaction
  - Maintain normal activities

- Disadvantages
  - Requires excellent communication between MD, pharmacist, home health nursing
  - Not all patient care data contained in one chart – separate agencies keep records
  - Potential for adverse outcomes
    - Less oversight of care
    - Slower response time

Conflicts of Interest

- I have no funding sources or conflicts of interest to disclose

OPAT Case

- JR is 68yo male with a diagnosis of mitral valve endocarditis. Treatment was initiated with vancomycin and ceftriaxone. Blood cultures were finalized as Enterococcus faecalis and therapy was changed to ampicillin 2g IV q4h & gentamicin 90mg (1mg/kg) IV q8h. Baseline Clcr = 50 ml/min (Scr 1.2mg/dL). First gentamicin trough = 1.3mg/L. Team “curbsided” an ID fellow/physician who recommended to discharge the patient on hospital day 10 with the antimicrobial therapy above based on excellent response.
- You review the discharge orders which reflect current dosing (ampicillin 2g IV q4h & gent 90mg q8h) x 6 weeks; no labs/levels
- Adjust the OPAT plan to optimize efficacy, safety, & practicality…

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OPAT Indicated vs. Contra-indicated

- Indications
  - Stable
    - Hemodynamically stable, afebrile
    - Responding, ready for discharge
  - Safe home environment
  - Verify understanding and injection/admin. technique
  - Empiric Therapy/Diagnosis
  - Practical regimen
  - Safe regimen for outpatient
  - Reimbursement

- Contraindications
  - Clinically unstable
  - Hemodynamically unstable, febrile
  - Inadequate response
  - Unsafe home environment
  - Poor understanding/technique
  - Definitive Therapy/Diagnosis
  - Empiric therapy/no diagnosis
  - Impractical regimen
  - Unsafe regimen for outpatient
  - No reimbursement

* OPAT = outpatient parenteral antimicrobial therapy or “home IV antibiotics.”


4/2/2013
Key Considerations for OPAT

- Is antimicrobial therapy needed?
- Is parenteral antimicrobial therapy needed?
- Benefits, risks, and economic considerations reviewed?
  - Do the patient’s medical care needs exceed resources?
- Is the home environment safe and adequate?
- Are the patient and/or caregiver competent, reliable?
- Is the proposed OPAT regimen safe, effective & practical?
- Is there appropriate follow-up?


Practice Models for OPAT Delivery

- **Home Administration – nurse visits and/or self admin**
  - Team approach: MD, home infusion pharmacy, home health nursing
  - MD delegates all monitoring & schedules visits when necessary
  - Nurse communicates important information by phone/fax
  - A minimum level of patient / family competency required

- **Stand-alone infusion center or hospital clinic**
  - Allows for quality control of process; enhances communication
  - Good for patients unable / refuse to self-administer at home
  - Safer environment for high risk agents (e.g. amphotericin B)
  - Requires significant investment of space, equipment, personnel


- **Long-term care facility, nursing home**
  - Ideal for patients who require greater oversight of care and/or do not demonstrate minimum level of competency

- **Physicians office**
  - Ideal for patients who require greater oversight of care and can have antimicrobial therapy administered intramuscularly

- **Other facilities**
  - Dialysis centers for patients receiving scheduled dialysis
  - Board and care facilities for homeless patients


Most Common Indications for OPAT*

- Bone-Joint Infections
- Skin-soft tissue Infections
- Vascular Infections (bloodstream, endocarditis)
- Respiratory tract infections/Cystic fibrosis
- Urinary tract infections
- Central nervous system infections
- Intra-abdominal infections
- Other

* Heintz et al. Annals of Pharmacy Therapy 2011. 1) Bone-joint 2) BSI 3) SSTI 4) UTI 5) RTI 6) CNS 7) IAI

Key Elements for OPAT Program

- **Health Care Team**
  - Physician: ID, primary team
  - Pharmacist: clinical/ID, home infusion
  - Nurse: inpt, home-health, community care
  - Case manager (discharge planner)

- **Communication is essential**
  - Written policies & procedures
  - Personnel requirements of OPAT team
  - Patient assessment, training, education
  - Patient monitoring, outcome assessment

Role of a pharmacist in the care of OPAT (Home Infusion & Clinical Pharmacy)

- Knowledge of dosage forms, stability of medications in solution, administration techniques, & catheter care
- Assist with simplification of antibiotic regimen
- Review antibiotic regimen for efficacy & safety
  - Appropriate/safe dosage, labs, drug levels ordered
- Communicate compliance issues (e.g. home infusion Rph)
- Assess feasibility of OPAT: psychosocial, cost/insurance
- Assess potential for antibiotic complications
- Patient, family and/or care-giver education

Initial Assessment of OPAT and IV administration options at home

- First, assess if OPAT is necessary
  - If so, check if peripherally inserted central catheter (PICC) placed
    - Central line access ideal (compared to peripheral lines)
      - Safer & fewer complications, can concentrated solutions, less irritating
    - If not, assure PICC is not ordered and not placed (cost-savings)
- Administration options
  - IV slow push
    - Administer over 1-2 minutes
  - Intermittent infusion
    - via syringe pump, gravity flow, elastomeric infuser
  - Continuous infusion
    - via portable infusion pump (CADD, computerized ambulatory drug delivery)

Benefit of an ID-trained pharmacist

- Assist in decision making, especially if no ID consult
  - Recommend ID physician consultation when appropriate
  - Suggest clinically appropriate alternative antibiotic recommendations to improve safety/practicability/efficacy
- Develop monitoring plan with primary team
  - What labs to order and how frequent to check
  - Determine goal drug blood levels
  - Resource for home health nursing & home infusion pharmacy
  - End of treatment goals & expected duration of treatment (stop-date)

IV push and/or IM administration

- Drug is supplied in ready-to-use syringe
  - Lowest supplies cost
  - Easiest method for small children
  - Only for antibiotics that can be given rapidly safely
  - Generally, IV push administered over 1-2 minutes
  - Assess available supportive data
    - Cephalosporins and Penicillins
    - Meropenem & ertapenem* (not imipenem)
    - Daptomycin*

* No difference in PK or toxicity with 2 minute bolus vs. 30 min infusion. 
Wiskirchen DE, et al. Pharmacotherapy 2013; 33(3); Chakraborty J. Antimicrob Chemother 2009; 64(1)

Intermittent infusion

- For antibiotics that require longer infusion (≥ 30 min)
  - Vancomycin, aminoglycosides, carbapenems, fluoroquinolones…
- Supplied to patient pre-mixed in syringe, IV bag, elastomeric infuser or vial for reconstitution
  - patients can be trained to mix solutions
- Requires tubing for connection to IV catheter
  - IV bags will also need a rate control device
- Greater time requirement
  - More than two doses/day can hinder compliance

Stability of antibiotics in IV solution

- Good stability
  - penicillin G, nafcillin, piperacillin/tazobactam, cephalosporins, vancomycin, aminoglycosides, acyclovir
- Limited stability
  - daptomycin, Ambisome, echinocandins
- Unstable for prolonged/continuous infusions
  - ampicillin, am/sulbactam, carbapenems, TMP/SMX
Unstable antibiotics

- Administration options for unstable antibiotics
  - Intermittent infusion by gravity flow
    - If possible, use products available for simplified drug reconstitution immediately prior to administration
      - Add-Vantage® system
      - Mini-loop phleb® adapters
      - Vial man® adapters
  - Elastomeric pump / infuser device
    - Disposable infusion device & closed system
    - If possible, optimize dosing to limit # of infusions
    - If possible, use products available for simplified drug
  - Light sleepers & young children may have difficulty

Properties of Common Antimicrobials

<table>
<thead>
<tr>
<th>Drug</th>
<th>Half-Life (h)</th>
<th>pH (6.8)</th>
<th>Max Dilution (mg/mL)</th>
<th>Duration of stability by storage Temp°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>≥ 18MU</td>
<td>6.5</td>
<td>ND</td>
<td>21 d</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>≥ 18MU</td>
<td>6.2</td>
<td>ND</td>
<td>21 d</td>
</tr>
<tr>
<td>Ertapenem</td>
<td>≥ 18MU</td>
<td>7.5</td>
<td>ND</td>
<td>21 d</td>
</tr>
<tr>
<td>Meropenem</td>
<td>≥ 18MU</td>
<td>5.5</td>
<td>ND</td>
<td>21 d</td>
</tr>
<tr>
<td>Pip/Tazo</td>
<td>≥ 18MU</td>
<td>7.0</td>
<td>ND</td>
<td>21 d</td>
</tr>
<tr>
<td>Piperacillin</td>
<td>≥ 18MU</td>
<td>7.0</td>
<td>ND</td>
<td>21 d</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>≥ 18MU</td>
<td>6.5</td>
<td>ND</td>
<td>21 d</td>
</tr>
</tbody>
</table>

Simplification of home regimen

- Limit number of antibiotics used (consolidation)
  - Cefepime/metronidazole → pip/tazo CI OR ertapenem 1g/d
- If possible, choose antibiotics given once daily
  - Ceftriaxone, Daptomycin, Ertapenem, Triazoles/Echinocandins
- If possible, optimize dosing to limit # of infusions
  - q8h → q12h: Cefepime 1g IV q8h → cefepime 2g IV q12h
  - q4-6h → continuous infusion: Nafcillin 2g IV q4h → 12g IV CI
- If possible, switch to aggressive oral therapy
  - Use antimicrobials with excellent bioavailability (more later)

Continuous infusion

- Ideal for antibiotics dosed q4h or q6h – practicality
  - nafcillin, penicillin G, piperacillin/tazobactam
- Use with antibiotics with time-dependent activity
  - Maximize time > MIC, efficacy, esp. if high MIC
- Small electronic pump can be stored in fanny-pack and allows for easy ambulation
  - Limited manipulation of catheter – enhanced safety
  - Light sleepers & young children may have difficulty

Recommended Dosing/Preparation for CI

- Recommend loading dose prior to starting cont. infusion
  - Pen G: 12 MU IV as cont. infusion (CI) over 24 H in 100 mL D5W
  - Severe/large: ≥ 18MU in 150-250 mL (max concentration = 0.2MU/mL)
  - Nafcillin: 6-9 grams IV as CI over 24 H in 100 mL of D5W
  - Severe/large: ≥ 12 grams in 150-250 mL (max concentration = 100mg/mL)
  - Cefazolin 3 grams IV as CI over 24 H in 100 mL of D5W
  - Severe/large: ≥ 6 grams in 150-250 mL (max concentration = 100mg/mL)
  - Cefazolin/Cefepime 2-3gms IV CI over 24h in 100 mL of D5W
  - Severe/large: ≥ 6 grams in 150-250 mL (max concentration = 40mg/mL)
  - Pip/Tazo 10.125 grams in 100mL NaCl or D5W
  - Severe/large: ≥ 13.5 grams in 150-250 mL (max concentration = 100mg/mL)

- If possible, choose antibiotics given once daily
- Limit number of antibiotics used (consolidation)
- If possible, use the same administration method if > 1 antibiotic to be given same time
  - Check compatibility (Y-site, admixture, in syringes)
- If not compatible consider double lumen line
- Assess treatment complexity with other healthcare activities
  - Parenteral nutrition (TPN)
  - Tube feedings
  - Wound vacs, dressing changes
  - Other medications
    - Check compatibility

- Maximize time > MIC, efficacy, esp. if high MIC
- Add-Vantage® system
- Mini-loop phleb® adapters
- Vial man® adapters
- Disposable infusion device & closed system
- If possible, optimize dosing to limit # of infusions
- If possible, use products available for simplified drug
- Light sleepers & young children may have difficulty
Transition to Oral Antimicrobial Therapy

- Treatment with oral therapy depends on many factors
  - Severity and site of infection
  - Bioavailability of drug (pharmacodynamics/kinetics)
  - GI tract function
  - Supportive data for oral therapy
  - Patient compliance and reliability
  - Drug-drug interactions (e.g., cipro with divalent cations)
- Many benefits of oral therapy
  - Less expensive
  - Less utilization of medical resources
  - Patient preference

Simplification: Consolidation or IV-PO

Mini Case:
- 56yo male with cholangitis & abscess. Blood/obsscess cx growing ESBL producing E. coli. ID consult recommends meropenem 500mg IV q6h x 2-3 weeks then signed off. Primary MD feels the patient can finish therapy at home on day 6 and orders the meropenem for home therapy.
  - Can this regimen be simplified?
    - Meropenem 1g IV q8h
    - Ciprofloxacin 500-750mg PO BID (if stable, susceptible)
    - PLUS PO metronidazole given site of infection for anaerobic coverage

Simplification: Cessation of Therapy

- In responding patients, many infections can be treated w/ short courses (5-7 days): “10-14 days” often unnecessary
  - CAP: 5-7 days in most patients (3-5 days after afebrile)
  - HAP/HCAP/VAP (most pathogens): 7-8 days
  - Complicated intra-abdominal infections: 4-7 days
  - Cellulitis (uncomplicated, including MRSA infections): 5-7 days
  - Diabetic foot ulcer, non-limb threatening (cellulitis): 7-14 days
  - Osteomyelitis: 2 weeks IV Aggressive PO if (ID input needed)
  - Coag neg staph catheter-related bloodstream infxn: 5-7 days

Safety issues

- Limit number of times catheter is accessed per day
- Catheter-related complications: infection, thrombophlebitis, clots
- Avoid antibiotics with more challenging administration
- Patient (or family) demonstrating poor understanding
- Use antibiotics with low risk for adverse effects
  - Beta-lactams, vancomycin, fluconazole, acyclovir, caspofungin
- Extra care to avoid adverse effects
  - Infuse large vancomycin doses over longer time (500mg/30min)
  - First doses in hospital or clinic & assess tolerance
- Review other medications for potential DDIs or additive toxicity

Simplification: Antimicrobial Therapy

- Requires understanding of antimicrobial PK / PD
  - Criteria for switch to oral
    - Resolution of Fever
    - Improved Clinical Function
    - Decrease in WBC count
    - Normal GI tract absorption
    - Tolerating orals
    - If not certain, confirm with infectious disease physician

Transition to Oral Antimicrobial Therapy

- Normal GI tract absorption
  - If not certain, confirm with infectious disease physician

Simplification: IV to PO switch

<table>
<thead>
<tr>
<th>Antimicrobial agent</th>
<th>Oral F</th>
<th>% Concentration = (Dose PO / Dose IV) x F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin/cephalexin</td>
<td>75-95%</td>
<td></td>
</tr>
<tr>
<td>Doxycycline</td>
<td>90-100%</td>
<td></td>
</tr>
<tr>
<td>Metronidazole</td>
<td>95%</td>
<td></td>
</tr>
<tr>
<td>Azithromycin</td>
<td>35-50%</td>
<td></td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>50-60%</td>
<td></td>
</tr>
<tr>
<td>Clindamycin</td>
<td>70-85%</td>
<td></td>
</tr>
<tr>
<td>Fluoroquinolones</td>
<td>85-100%</td>
<td></td>
</tr>
<tr>
<td>Flucon/Voriconazole</td>
<td>≥ 90%</td>
<td></td>
</tr>
<tr>
<td>Trimethoprim/sulf {l}</td>
<td>90-100%</td>
<td></td>
</tr>
<tr>
<td>Rifampin</td>
<td>90-95%</td>
<td></td>
</tr>
<tr>
<td>Linezolid</td>
<td>&gt; 95%</td>
<td></td>
</tr>
</tbody>
</table>

Frequency of Adverse Effects in OPAT

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cr</th>
<th>Crh</th>
<th>Cn</th>
<th>Gm</th>
<th>Staph</th>
<th>Serrat</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Courses administered</td>
<td>791</td>
<td>489</td>
<td>4703</td>
<td>942</td>
<td>3275</td>
<td>727</td>
<td>479</td>
</tr>
<tr>
<td>Courses stopped (n)</td>
<td>32</td>
<td>18</td>
<td>159</td>
<td>34</td>
<td>26</td>
<td>40</td>
<td>42</td>
</tr>
<tr>
<td>% adverse effect, % of course</td>
<td>4.1</td>
<td>3.8</td>
<td>2.9</td>
<td>1.7</td>
<td>8.0</td>
<td>6.4</td>
<td>6.0</td>
</tr>
</tbody>
</table>

Antibiotic Monitoring (IDSA 2004)

- Minimum weekly labs for most antibiotics
  - Complete blood count
  - Chemistry panel
- Liver function tests
  - Consider for antifungals, nafcillin, clindamycin
- Other tests
  - Daptomycin – CPK
  - Amphotericin B – magnesium, in addition to chem 7
  - Vancomycin & Aminoglycosides – drug levels (e.g. trough)
  - More frequent testing with higher risk meds/patients

Antibiotic Monitoring (IDSA 2004)

<table>
<thead>
<tr>
<th>Antibiotic Agent / Class</th>
<th>Frequency of Testing (per week)</th>
<th>Comments / Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>1 or 2</td>
<td>Monitor weekly troughs, ototoxicity</td>
</tr>
<tr>
<td>Beta-lactams</td>
<td>1</td>
<td>Watch electrolytes (will formulate)</td>
</tr>
<tr>
<td>Quinolones</td>
<td>1</td>
<td>Consider change to PO, watch DD</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>1</td>
<td>Consider change to PO</td>
</tr>
<tr>
<td>Linezolid</td>
<td>1</td>
<td>Consider change</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>1</td>
<td>Baseline and weekly creatine kinase</td>
</tr>
<tr>
<td>Linezolid</td>
<td>1</td>
<td>Consider change to PO, watch DD</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>1</td>
<td>Weekly vancomycin trough levels</td>
</tr>
<tr>
<td>Rifampin</td>
<td>1</td>
<td>Consider change to PO, watch DD</td>
</tr>
<tr>
<td>Amphotericin</td>
<td>2</td>
<td>Avoid if possible, linezolid preferred</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>1</td>
<td>Consider change to PO</td>
</tr>
<tr>
<td>Acyclovir</td>
<td>1</td>
<td>PO valacyclovir may be an option</td>
</tr>
<tr>
<td>Ganciclovir</td>
<td>2</td>
<td>PO valganclovir may be an option</td>
</tr>
<tr>
<td>Famotide, Celestine</td>
<td>1</td>
<td>Avoid if possible, valganclovir preferred</td>
</tr>
</tbody>
</table>

Therapeutic Drug Monitoring (levels)

- Indicated for aminoglycosides & vanco to assess toxicity
  - Trough levels (< 0.5mg/L for AG, 10-20mg/L for vancomycin)
- Get baseline value, confirm adequate dose – efficacy
  - Trough for vancomycin
  - Peak or random level per algorithm for aminoglycoside
- Follow subsequent values to assess for accumulation and possible impending renal toxicity
  - Vancomycin troughs weekly with long term treatment
  - Aminoglycoside troughs 1-2 x weekly with long term treatment

OPAT Case

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- You review the discharge orders which reflect current dosing (ampicillin 2g IV q4h & gent 90mg q8h) x 6 weeks; no labs/levels
- Adjust the OPAT plan to optimize efficacy, safety, & practicality...

OPAT Case

- The primary team arranges for PICC placement
- On rounds the clinical pharmacist is made aware of the OPAT plan and reviews the case for appropriateness
- Please evaluate
  - 1) Efficacy of the proposed regimen
  - 2) Safety: compatibility, dosing, monitoring
  - 3) Practicality: frequency of dosing, novel dosing strategies
- What if JR needed to receive therapy in an infusion center that requires once daily dosing (e.g. Medicare)
### OPAT Case (Cont)

- You change therapy to penicillin G 18MU IV CI over 24h based on PK/PD, stability (amp not stable), practicality.
- You adjust the gent from 90mg IV q8h to 80mg IV q12h.
- On day 18 the following labs are noted:
  - gent tr = 1.2mg/L, Scr = 1.5mg/dL, K+ = 5.4 mEq/dL
- Do you adjust the gentamicin dose? If so to what?
- Do you adjust the Penicillin dose (note K+)?
  - Why did the potassium increase?

### Decision-Making Algorithm for OPAT: Review

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient have an infection warranting antimicrobial therapy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does patient require intravenous antimicrobial therapy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient meet OPAT criteria?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there more than one acceptable drug and/or dosage regimen that can be employed safely &amp; effectively?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a big cost difference between these acceptable treatment regimens?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consider using the least expensive regimen, but assess practicality</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Special Populations

- **Pediatric patients**
  - Increased complications, CI often problematic (pulling on line)
- **Homeless**
  - Some board & care facilities accept OPAT
- **Medicare patients**
  - Limited drug benefit for OPAT – work with case manager
- **End-stage renal disease patients on hemodialysis**
  - Administer via dialysis access – coordinate with nephrologist
  - Post dialysis (PD) dosing at dialysis center is more practical
  - Cefazolin: Cefepime/Ceftazidime 1g IV daily → 2g IV PO MWF
  - Meropenem: Imipenem 500mg/d → 1g IV PO MWF
  - Vancomycin 500mg IV PO MWF and adjust per weekly predialysis level

### Final planning

- Order central catheter once decision for OPAT made
- Arrange to have PICC removed after completion of therapy
- Plan ahead, make arrangements before discharge day
- Change to OPAT regimen day of or before discharge
- Check for tolerability
- Order drug levels, adjust doses before discharge
- Teach patient/family and assess competency
- Identify who will be responsible for care post discharge
- Outline plan of care for labs, nursing visits, appointments

### Conclusion

- Outpatient administration of parenteral antimicrobial therapy many advantages vs. inpatient administration
  - Cost, safety, patient satisfaction
  - Various practice models are available for OPAT
    - Home, LTCF, infusion center, doctors office, etc.
  - OPAT requires careful patient selection & communication
    - Clinical stability, socio-economic status, patient follow-up
  - A team approach to OPAT is preferred
    - Pharmacists can play a key role in designing a treatment plan
    - Optimize efficacy, safety and practicality of the regimen

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