Advancing Home Infusion Clinical Practice Through Research – Abstracts Presentation
Pharmacist-Focused Vancomycin Dosing Competency Program
Concentrating on Dosing Strategies to Reduce Adverse Events

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¹Option Care Health
Background

• 2009 Consensus Guidelines:

  Support an AUC of at least 400mg*hr/L for optimal bacterial killing for the treatment against *Staphylococcus Aureus*

  Serum trough goals of 15-20mg/L served as a surrogate marker for a probable AUC:MIC of 400mg*hr/L

• 2020 Consensus Guidelines:

  Support an AUC of at least 400mg*hr/L for optimal bacterial killing for the treatment against *Staphylococcus Aureus*

  Support the measurement of AUC:MIC between 400-600mg*hr/L to reduce overall drug exposure and limit toxicities

American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), and the Society of Infectious Diseases Pharmacists (SIDP)
Purpose

• Pharmacists have not routinely received extensive training on AUC-based dosing strategies since the previous guidelines supported trough-based dosing strategies.

• A competency program is essential to prepare pharmacists for the implementation of AUC:MIC dosing into their clinical practice setting.

It is hypothesized that completing the educational program will set the standard for vancomycin knowledge between all pharmacists by providing a thorough review of traditional and AUC-based dosing strategies along with increasing confidence in using the AUC:MIC ratio dosing strategy.
Methods

- Pre-competency survey
- Competency Program
- Post-competency survey
Pre-competency survey
Methods

Pre-competency survey → Competency Program → Post-competency survey
Competency Program
Methods

Pre-competency survey → Competency Program → Post-competency survey
Post-competency survey
Seven Competency Objectives

1. Assessing appropriateness
2. Ability to use valid tools
3. Recommending dose adjustments
4. Create an appropriate monitoring strategy
5. Patient specific pharmacokinetic calculations
6. Understanding basic drug properties
7. Self-declared confidence
Results

- Majority (59.3%) of pharmacists surveyed have been practicing pharmacy for >10 years.
- 57.6% of pharmacists have been practicing in home infusion for 0-5 years.
Results

• Scores increased for each competency objective

• Highest increase: Assessing appropriateness (↑ 56.2%)

• Lowest increase: Ability to use valid tools (↑ 8.1%)

<table>
<thead>
<tr>
<th>Competencies</th>
<th>Pre Learning Test</th>
<th>Post Learning Test</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessing appropriateness</td>
<td>32.2%</td>
<td>88.4%</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Ability to use valid tools</td>
<td>68.6%</td>
<td>76.7%</td>
<td>0.12</td>
</tr>
<tr>
<td>Recommending dose adjustments</td>
<td>37.3%</td>
<td>74.4%</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Create appropriate monitoring strategy</td>
<td>33.9%</td>
<td>67.9%</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Patient specific pharmacokinetic calculations</td>
<td>37.3%</td>
<td>73.6%</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Understanding basic drug properties</td>
<td>53.4%</td>
<td>74.4%</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Self-declared confidence</td>
<td>6.0 (4.0-9.0)</td>
<td>8.0 (6.0-9.0)</td>
<td>&lt;0.01‡</td>
</tr>
<tr>
<td>Trough based dosing</td>
<td>8.0 (7.0-10.0)</td>
<td>8.5 (7.3-10.0)</td>
<td>0.46</td>
</tr>
<tr>
<td>AUC:MIC dosing</td>
<td>4.0 (2.0-5.5)</td>
<td>7.0 (5.0-8.0)</td>
<td>&lt;0.01‡</td>
</tr>
</tbody>
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* Statistical significance p<0.05 using Chi-Squared test for categorical variable
‡ Statistical significance p<0.05 using Welch's t-test for continuous variables
Results of multiple-choice questions have been expressed as % (correct/total), and results of 1-10 scale questions have been expressed as median score (inter-quartile range)
Results

- Statistically significant increase for each competency category except:
  - Ability to use valid tools
  - Self-declared confidence: Trough based dosing

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Results of multiple-choice questions have been expressed as % (correct/total), and results of 1-10 scale questions have been expressed as median score (inter-quartile range)
Conclusion

• This project has led to the creation of a formal training program to standardize vancomycin dosing competency for pharmacists, ultimately creating a clinical competency strategy to provide optimal patient care.

• Although it may be difficult to generalize knowledge assessment data from a small cohort, it was shown that reinforcing strategies for dosing vancomycin increased pharmacists’ knowledge and confidence.

• In the long-term, by implementing this competency program to all pharmacists at this organization, the goal is to reduce adverse events rates related to dosing and monitoring vancomycin. Future expansion of this study will be necessary to analyze this.
Development and Implementation of an Ethanol Lock Therapy Protocol to Reduce CLABSI in Adult HPN Patients

Susan Chhen, PharmD
PGY-1 Pharmacy Resident
Fairview Pharmacy Services
Catheter-line Associated Bloodstream Infections (CLABSI)s

• One of the most common complications in parenteral nutrition (PN) patients

• PN patients at high risk for recurrence

• Treatment: antibiotics and possible line removal

• Antibiotic locks to salvage line – do not infiltrate biofilms

• Ethanol is bactericidal, fungicidal and eradicate biofilms
Research Project

Objectives

• Develop an ethanol lock therapy protocol
• Characterize patients with documented CLABSI who would benefit from ELT

Methods

• Literature search, guideline review, ELT team
• Retrospective chart review of adult TPN patients with CLABSI at our institution between 1/1/16 – 7/13/19
ELT Protocol – Eligibility

• CVAD compatible with ethanol
• History
  • Recurrent line infection
  • Risk of limited/losing venous access or poor vascular access
• TPN formula allows for 2 hour dwell time
• Able to perform ELT procedures in home
• Ineligible
  • Do not meet above criteria
  • Allergy to ethyl alcohol or concurrent therapy with metronidazole, disulfiram or citrate
ELT Protocol

Lock procedure
- Confirm ethanol compatible CVAD
- Frequency and dwell time: min = 2 hrs.; max = 24 hrs.
- Dose = 2 mL

Compounding
- 98% dehydrated alcohol, dilute with SW to 70% ethanol
- Draw up desired volume in syringes
- BUD = 9 days refrigerated

Administration
- Flush with normal saline (NS) before
- Instill 2 mL of 70% ethanol solution into IV catheter lumen
- After dwell time, flush ethanol through lumen with NS
Patient Characteristics

• Of 154 documented CLABSIs, 52 patients met inclusion criteria

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Total CLABSI cases</td>
<td>79</td>
</tr>
<tr>
<td>CVAD types</td>
<td></td>
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<tr>
<td>PICC</td>
<td>54%</td>
</tr>
<tr>
<td>CVC tunneled catheter</td>
<td>20%</td>
</tr>
<tr>
<td>Implanted port</td>
<td>26%</td>
</tr>
<tr>
<td>Short bowel syndrome</td>
<td>48%</td>
</tr>
<tr>
<td>FHI nursing agency</td>
<td>50%</td>
</tr>
</tbody>
</table>
Results

- Polymicrobial CLABSIs = 31%
- Mixed bacteria + fungi = 7%
- Catheter removed = 85%
- Catheter salvaged = 8%
- 14 patients had recurrent episodes of CLABSI
- CLABSI rate = 5.1

<table>
<thead>
<tr>
<th>Bacteria Species</th>
<th>% Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Streptococci</td>
<td>4%</td>
</tr>
<tr>
<td>Enterococci</td>
<td>6%</td>
</tr>
<tr>
<td>Staphylococci</td>
<td>47%</td>
</tr>
<tr>
<td>Klebsiella species</td>
<td>11%</td>
</tr>
<tr>
<td>Enterobacter</td>
<td>6%</td>
</tr>
<tr>
<td>Pseudomonas</td>
<td>6%</td>
</tr>
<tr>
<td>Acinetobacter</td>
<td>3%</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>4%</td>
</tr>
<tr>
<td>Candida species</td>
<td>14%</td>
</tr>
</tbody>
</table>
Limitations

• Single center
• Small sample size
• Retrospective nature
• Lack of comparator group
Clinical Implications

• Standardize ethanol lock therapy (ELT)
• Implement ELT in at risk HPN patients
• Create quality improvement projects
• CLABSI reduction and prevention in health systems
Future Research Directions

• Continue to collect CLABSI data at our organization
• Evaluate outcomes of HPN who receive ELT compared to patients who do not receive ELT in a home infusion setting
• Collaborate with other home infusion institutions
Development of Home Infusion Pharmacist Outpatient Parenteral Antimicrobial Therapy Collaborative Practice Agreement Within a Health System Setting

Diane Marks, RPh, BCPS; Erick Siegenthaler PharmD, MHA
Froedtert Home Infusion
Froedtert and the Medical College of Wisconsin
Milwaukee, WI
background

• Froedtert Home Infusion (FHI) services developed July 2017
  • Embedded within the Froedtert and the Medical College of Wisconsin (FMCW) health system
  • Shared electronic health record (EHR)
  • 98% referrals from five hospital system
  • 70% referrals for antimicrobials

• FHI Pharmacists work closely with Infectious Disease (ID) clinic staff to manage patients
  • Duplication of work, inefficiencies in operations and non-standardized processes

• FHI Pharmacists were asked to develop an ID Outpatient Parenteral Antimicrobial Therapy (OPAT) Collaborative Practice Agreement (CPA) in June 2019
Wisconsin Ch 450.033
Services delegated by physician

A pharmacist may perform any patient care service delegated to the pharmacist by a physician.

A collaborative practice agreement (CPA) is a legal document in the United States that establishes a legal relationship between clinical pharmacists and collaborating physicians that allows for pharmacists to participate in collaborative drug therapy management (CDTM).
Methods

CPA Development
- Revise existing ID OPAT CPA to include FHI Pharmacist role
- Develop workflows for ID clinics staffed/not staffed by ID Pharmacist

CPA Guidelines
- Amphotericin B Liposomal
- Daptomycin Treatment Guideline
- Extended-Infusion Beta-Lactams Treatment Guideline
- Vancomycin/Aminoglycoside Dosing and Monitoring Guidelines
- Guideline for Monitoring Outpatient Parenteral Antimicrobial Therapy

CPA Approval Process
- Review by Clinic Medical Directors
- Ambulatory Pharmacy, Nutrition and Therapeutics (PNT) Committee
- Froedtert Health PNT Committee
Collaborative Practice Agreement

Collaborative Practice Agreement (CPA) for Outpatient Parenteral Antimicrobial Therapy (OPAT) and Oral Antimicrobial Therapy

Operation:

Under The Wisconsin Medical Practice Act sections §448.03(2)(e) and 450.033 and Wisconsin Administrative Code §Med17.06 pharmacists are permitted to practice under a Collaborative Practice Agreement (CPA) with individual physicians. It is the intent of this document to authorize pharmacists to work in a collaborative fashion with and under the direct supervision of the physician(s) affiliated with Froedtert and the Medical College of Wisconsin. This document summarizes guidelines for collaboration between the pharmacists in the Froedtert Hospital Infectious Diseases (ID) Clinic, Froedtert Hospital Pulmonary Clinic, and Froedtert Home Infusion and physicians affiliated with Froedtert and the Medical College of Wisconsin for monitoring of outpatient parenteral antimicrobial therapy (OPAT) or oral antimicrobial therapy. This agreement is voluntary and may be terminated at any time by any of the parties. This document will be reviewed by all parties at least biennially.

Escalation Pathway:

In situations where the pharmacist utilizes their clinical judgment and feels that escalation is necessary to provide effective patient care, the pharmacist should follow the following pathway:

Pharmacist > Responsible Physician > Clinic Medical Director

If an APP is involved in the patient’s care:

Pharmacist > APP > Responsible Physician (Supervising Physician) > Clinic Medical Director
Collaborative Practice Agreement

Objective:
To allow Froedtert ID, Pulmonary, or Froedtert Home Infusion clinical pharmacists, in collaboration with and under the supervision of physicians affiliated with Froedtert and the Medical College of Wisconsin, to write orders for the administration and monitoring of medications as outlined in the antimicrobial treatment and monitoring guidelines (listed below).

Goals:
1. Standardize the monitoring and dosing of antimicrobials.
2. Increase the safe and efficacious use of antimicrobials.
3. Assess and manage adverse side effects associated with antimicrobials.
4. Reduce provider workload as related to monitoring and adjustment of antimicrobials.

Workflow:
1. Patient requirements:
   a. All patients are required to have established care with a provider affiliated with Froedtert & the Medical College of Wisconsin
   b. If patient is enrolled in Froedtert Home Infusion services, the patient will be managed by the Home Infusion Pharmacist with collaboration from the clinic pharmacist.

2. See Appendix 1-3 for specific workflows
Collaborative Practice Agreement

Guidelines for Therapy:
1. Amphotericin B Liposomal (Ambisome) Guideline
2. Antifungal Therapeutic Drug Monitoring Guideline
3. Daptomycin Treatment Guideline
4. Extended-Infusion Beta-Lactams Treatment Guideline
5. Intravenous Polymyxins for the Treatment of MDR Gram-Negative Infections Guideline
6. Vancomycin AUC Dosing Guideline
7. Aminoglycoside Dosing Guideline
8. Guideline for Monitoring Outpatient Parenteral Antimicrobial Therapy
Collaborative Practice Agreement

Appendix 2 – Froedtert Home Infusion Workflow

1. Patients will have a Home Infusion pharmacy referral placed by an inpatient or outpatient physician, and the need for OPAT will be determined.

2. The Home Infusion pharmacist will review the OPAT discharge summary.

3. Shared EPIC patient lists
   a) Froedtert Hospital ID provider will place the patient on the Shared EPIC list named: *ID_OPAT for Froedtert Infectious Disease Clinic patients.
   b) The Home Infusion pharmacist will place the patient on the Shared EPIC list named: *ID_OPAT_CHD for the Community Division patients
Collaborative Practice Agreement

4. The clinical pharmacist will review the patient’s plan of care for appropriate drug, route, frequency, indication, and lab monitoring, and adjust according to the Guidelines for Therapy listed below.
   a) All laboratory and referral orders must be sent to the provider for co-signature
   b) Medication orders may be signed by the pharmacist on behalf of the provider, as allowed per this CPA. If deemed appropriate by the pharmacist or at the providers discretion, medication orders will be sent to the provider for co-signature

5. The clinical pharmacist will maintain the AMS Intervention Date and Comments section of the patient list for monitoring and communication.

6. When a patient has reached their end of therapy date, the patient will be removed from the patient list by the pharmacist, unless therapy has been modified.
Methods

Information Technology
- Development of electronic referral order
- Complete EHR referral module training

Implementation
- Meeting between FHI pharmacist and each clinic's staffing (RN, RPh, MA) to review and discuss change in workflows
- Meeting internally with FHI pharmacists to review guidelines, CPA, and new workflow

Follow-up Survey
Survey sent to ID Clinic staff members (MD, RPh, RN) to assess:
- Confidence in FHI's ability to function within the CPA
- Overall satisfaction with new CPA
- Reduction in workload and efficiency related to the CPA
- Patient care and safety

Wisconsin Ch 450.033
A pharmacist may perform any patient care service delegated to the pharmacist by a physician.
Electronic Referral Order
Implementation

• Topics addressed with ID Clinic Staff prior to implementation:
  - Overview of ID OPAT CPA
  - Role of Froedtert Home Infusion Pharmacists
  - Home Infusion Pharmacist Referral which activates ID OPAT CPA
  - Access for Home Infusion Pharmacists to Patient List (tracking/communication)
  - Abstracting & monitoring of laboratory data
  - Standardized documentation in EHR
  - Communication with ID providers, pharmacists, clinic nurses & homecare nurses
  - Management of line occlusions
  - Coordination of end of therapy with follow up appointment/imaging/line maintenance
  - Clinical questions
  - Communication with other providers in group about these process changes
  - Go-live date
Implementation

• Froedtert Home Infusion Pharmacist Education

- Overview of CPA workflows
- Discussion of meeting minutes with ID providers
- Review of standardized documentation, escalation pathways, etc.
- Review of medication guidelines
- Pharmacokinetic dosing and monitoring competency
Results

• Volume
  - 282 referrals received between October 1, 2019 through March 31, 2020

• Subjective Outcomes
  - Anecdotal feedback has been very positive from ID clinics, inpatient providers involved with the discharge process, home care nurses and FHI pharmacists

• Objective Measurement
  - Survey distributed to ID providers, pharmacists and nurses to measure outcomes
  - Survey collected from ID Clinic staff (n=10; MD = 7, RPh = 2, RN = 1)
  - Decreased participation due to COVID pandemic
Results

• ID Clinic staff rated FHI abilities very highly:
  - Medication Dosing (9.3)
  - Lab Monitoring (8.9)
  - Coordination of Therapy (8.3)
  - Overall Management of Patients (8.9)

• Peer group felt HI pharmacist’s ability to dose and monitor labs was excellent
Results

- Clinic staff generally agreed that FHI involvement through CPA improved care:
  - Coordination of Care Improved (4.4)
  - Workflow Efficiency Improved (4.2)
  - Patient Safety Improved (4.2)
  - Quality of Care Improved (4.2)
Results

Since Home Infusion implementation, how satisfied/dissatisfied are you regarding:
(5 = Very Satisfied, 1 = Very Dissatisfied)

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>MD/APNP/PA</th>
<th>Pharmacist</th>
<th>RN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>4.4</td>
<td>4.3</td>
<td>4.5</td>
<td>5</td>
</tr>
<tr>
<td>Amount of Time Saved</td>
<td>4.4</td>
<td>4.3</td>
<td>4.5</td>
<td>5</td>
</tr>
<tr>
<td>Involvement of Home Infusion</td>
<td>4.6</td>
<td>4.6</td>
<td>4.5</td>
<td>5</td>
</tr>
</tbody>
</table>

Estimated amount of time saved (hours) per week managing outpatient parenteral antimicrobial therapy

- Total: 3.7
- MD/APNP/PA: 2.4
- Pharmacist: 7.5
- RN: 5
Discussion

• CPA implementation process took approximately 4 months
  • Time may vary depending on organization’s structure, workflows, and collaborative practice infrastructure
  • Processes may differ for HI pharmacies not part of a health system structure, or state regulations

• Overall, a successful development and implementation of a HI pharmacist outpatient parenteral antimicrobial collaborative practice agreement
  • Follow-up will include meetings with ID clinic staff and/or redistribution of survey to assess process

• Utilization of the home infusion pharmacist may lead to positive outcomes including improved patient care, efficiency of workflow and staff satisfaction/time savings
  • Survey has low validity due to small number of responders (COVID-19 change of focus)
Discussion

• Results suggest opportunity for HI Pharmacists to expand role through collaborative practice agreements
  • Identify areas that pharmacists are already managing care, or opportunities to improve workflow/efficiency for staff and for referral sources
  • FHI is currently working to develop and implement a CPA for managing parenteral nutrition therapy through the GI clinic
• Additional research is needed to validate outcomes and expand CPA opportunities across different provider types and locations
Health-related quality of life in patients with Primary Immunodeficiency (PIDD) and concomitant mental health issues

Haydan Smith, MS
Allyson Checkley, PhD
Loretta Kristofek, RN, BSN
William Bolgar, PharmD
PIDD and mental health disorders commonly overlap

1 in 1200

- Primary immunodeficiency (PIDD) affects approximately one in 1200 people in the United States\(^1\)
- Treatments include intravenous and subcutaneous immunoglobulin therapy\(^2\)
  - 42% of intravenous immunoglobulin therapy and 93% of subcutaneous immunoglobulin therapy is given inside the home\(^3\)

1 in 5

- Mental health disorders, including anxiety and depression, affect approximately one in five people in the United States\(^4\)
- Treatments include psychotherapy, medication and psychosocial treatments\(^5\)
- Patients prone to high-risk behavior, which can lead to other illnesses\(^5\)
- Other issues include loss of cognitive abilities during psychotic episodes\(^5\)

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3. 2008 Patient Treatment and Outcomes Survey Results. Immune Deficiency Foundation.
Effects on medication adherence and quality of life

Patients with mental health disorders have lower medication adherence to their psychotropic medications

- Rates reported between 50-75%¹

Quality of Life (QOL) surveys examine mental and physical health — but they don’t single out PIDD’s effects

- Surveys include all comorbidities², making it difficult to understand how PIDD alone is affecting QOL, mental, and physical health.

Patients with both mental health disorders and PIDD can suffer from:

- Lower quality of life
- Possible increased rate of infection due to poor medication adherence
- Possible lack of symptom control due to poor medication adherence

The purpose of this study was to examine the differences in QOL and medication adherence for PIDD patients with and without concomitant mental health disorders.
Study methods

Included all PIDD patients from the Immunoglobulin Diagnosis, Evaluation and Key Learnings (IDEaL) Registry

• Prospective, IRB-approved study of patients receiving Ig replacement therapy through one national home infusion company
• Data collected following patient consent

Data were collected from:

• SF-36v2 - QOL
• History and Physical (H&P) – Mental Health Diagnoses
• Medication Profile – Mental Health Medications
• Shipping Records – Medication Adherence
Study distribution of mental health disorders in registry patients

- **58.2%** No mental health disorder
- **30.1%** Mental health medication no diagnosis
- **11.7%** Documented mental health disorder
Patients with a mental health disorder had significantly lower mental component and mental health score on the SF-36v2.

**p < 0.01**
Patients with a mental health disorder had slightly lower medication adherence.

- **Patients with a mental health disorder**: 87.6%
- **Mental health medication no diagnosis**: 89.0%
- **No mental health disorders**: 92.6%
Conclusions and what can be done

**Quality of life (QOL) and mental health disorders**
- PIDD patients with concomitant mental health disorders had decreased mental health QOL compared to patients without
- Prevalence of mental health disorders was higher than the national average in our PIDD patients

**What can be done**
- PIDD patients with mental health disorders may need increased monitoring to ensure medication adherence and proper symptom management
Prescriber Acceptance Rates of Pharmacist Recommendations in a Home Infusion Setting

Rachel Dellevar, PharmD¹, Vien-Son Pham, PharmD¹, Tiffany Fancher, PharmD¹

¹Coram/CVS Specialty Infusion Services
Background

- Pharmacists receive specialized, medication-focused training, allowing them to offer valuable insight for optimizing plans of care.

- In home care, teams of healthcare professionals involved in patient’s overall care:
  - Greater levels of interprofessional communication and collaboration required for positive patient outcomes.

- Acceptance rates previously studied in other pharmacy settings, including hospital, managed care, and retail, but studies are lacking in the area of home infusion.

Objectives

• Primary purpose:
  • Determine how often various types of pharmacist recommendations made within a home infusion pharmacy setting are either accepted without modification, accepted with modification, or rejected

• Other objectives:
  • Evaluate reasons for the rejection of recommendations
  • Analyze the time to provider response
Methods

• Study conducted in Wisconsin from October 22, 2019 – January 31, 2020

• Recommendations included if they were made by a pharmacist in regards to a therapy being received by a patient on service with the pharmacy where the study was conducted
  • Did not include dose changes if orders were ‘Pharmacy to Dose’

• Fisher’s Exact Test used to evaluate the relationship between recommendation type and acceptance rates
Methods

• Pharmacists asked to document details of each recommendation made:

**Date of recommendation:** _______  **Patient:** ______________________  **Age:** ____

**Drug(s):** ________________________________________________________________

**Type of change recommended:** ☐ drug  ☐ dose  ☐ administration  ☐ drug monitoring  ☐ other

**Brief Description:** __________________________________________________________

**Date of provider response:** _______  (<1 hr from request? ☐ yes  ☐ no)

**Outcome:** ☐ accepted  ☐ rejected  ☐ conditionally accepted

**Reason for rejection or compromise (if applicable):** ________________________________________________________________
Results

- 51 total recommendations - average 3.4 per week
- No association found between type of recommendation and outcome of prescriber response (p=0.2165)

<table>
<thead>
<tr>
<th>Recommendation Type</th>
<th>No. Accepted Without Modification (%)</th>
<th>No. Accepted With Modification (%)</th>
<th>No. Rejected (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Dose (n=22)</td>
<td>17 (77.3%)</td>
<td>3 (13.6%)</td>
<td>2 (9.1%)</td>
</tr>
<tr>
<td>Change in Monitoring (n=10)</td>
<td>7 (70%)</td>
<td>2 (20%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Start, Stop, or Change in Drug (n=9)</td>
<td>8 (88.9%)</td>
<td>0 (0%)</td>
<td>1 (11.1%)</td>
</tr>
<tr>
<td>Change in Administration (n=6)</td>
<td>3 (50%)</td>
<td>2 (33.3%)</td>
<td>1 (16.7%)</td>
</tr>
<tr>
<td>Other (n=4)</td>
<td>1 (25%)</td>
<td>1 (25%)</td>
<td>2 (50%)</td>
</tr>
<tr>
<td>Total (n=51)</td>
<td>36 (70.6%)</td>
<td>8 (15.7%)</td>
<td>7 (13.7%)</td>
</tr>
</tbody>
</table>
Results

• In total, 58.8% (n=30) of recommendations were made in regards to antibiotic therapies

• Greatest number of recommendations made for vancomycin (n=16)
Results

- Majority of responses received <1 hour from the time of request

<table>
<thead>
<tr>
<th>Reason for Rejection</th>
<th>No. (%)</th>
<th>n=7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber had access to additional information not available to the pharmacist</td>
<td>4 (57.1%)</td>
<td></td>
</tr>
<tr>
<td>Prescriber exhibiting extra caution</td>
<td>2 (28.6%)</td>
<td></td>
</tr>
<tr>
<td>Unable to accommodate request</td>
<td>1 (14.3%)</td>
<td></td>
</tr>
</tbody>
</table>

- Bar chart showing responses received within:
  - <1 hour: 38 responses (74.5%)
  - >1 hour same day: 5 responses (9.8%)
  - Not same day: 8 responses (15.7%)
Discussion

• Study included all recommendations made by pharmacists, regardless of level of significance of the change recommended
• No association found between type of recommendation made and outcome of prescriber response
• Limitations of study:
  • Short duration
  • Small sample size
  • Limited geographical area encompassed
Conclusions

• Study shows that pharmacist recommendations are most often accepted, and provides initial insight into the impact that pharmacists have on patient care.

• The type of recommendation made may not have significant impact on prescriber response.

• More studies needed:
  • Larger sample sizes and greater geographical areas.
  • Comparing recommendations made across home infusion pharmacies.
  • Analyzing recommendations/outcomes by different software programs (e.g., Epic Access).
  • Sub-categorizing different types of recommendations by level of significance.
Adverse Drug Reaction Reporting and Application Practices in Home-Based Infusion Services

Ashley W. McCracken, PharmD, MBA
PGY2 Community Pharmacy Administration and Leadership Resident
Johns Hopkins Home Care Group
Adverse Drug Reactions (ADRs)

- Potentially preventable healthcare burden
- Costs the U.S. upwards of $30 billion annually
- Increased focus on ADRs by accrediting bodies such as:
  - The Joint Commission (TJC)
  - Centers for Medicare and Medicaid Services (CMS)
  - URAC
- Infusion related ADRs generally complex
Background

NHIF Data Initiative

• Standardize collection, analysis, and summary of patient outcomes data

• One of six core data elements included ADR reporting specifically:
  • Severity
  • Intervention
  • Outcome

http://www.nhia.org/data/
Background

NHIA Benchmarking Group

• Started in 2014
• Industry collaborative of health-system affiliated home infusion providers
• Aim is to share best practices and foster transparency
Purpose

Phase I
• Assess current ADR reporting, collection, and review practices at peer institutions

Phase II
• Develop workflow to help standardize the collection and reported metrics of ADRs within ambulatory infusion services
Phase I

**Multi-site Industry Survey**

**Methods**

- Eleven question survey focused on ADR reporting to internal and external list serves utilizing the NHIA benchmarking Group
- Three follow-up focus groups

1. Program demographics
2. What staff have access to ADR report?
3. Is your ADR reporting platform standard across your site(s)?
4. What reporting system does your site(s) use?
5. Is your reporting system within your EHR?
6. What data is collected on ADR report?
7. How often is ADR information reviewed?
8. Who reviews collected information?
9. Has collected data impacted workflow?
   a) If yes, how?
10. What are top barriers to ADR reporting?
11. Interest in focus group participation?
Survey Demographics

- = 2 internal (Hopkins affiliates)
- = 10 external (6 health-system, 2 chain, 2 independent)
## Results

### Standardization

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is your ADR reporting platform standard across institutional sites?</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Is your ADR reporting system within your EHR?</td>
<td>33%</td>
<td>67%</td>
</tr>
</tbody>
</table>
Results

Access, Barriers, and Frequency

What staff have access to ADR report?

- All Staff: 43% (n = 12)
- Pharmacists, Technicians, and Nurses: 36%
- Pharmacists and Nurses: 14%

What are top barriers to ADR reporting?

- 36%
- 14%

How often is ADR information reviewed?

- Quarterly: 77%
- Monthly: 31%
- Daily: 23%
Results

**ADR Information Collected**

What data is collected on ADR report? (n=12)

- Patient Demographics, Dose, Route, Description, Intervention (100%)
- Outcome (79%)
- Follow-up Needed (64%)
- Clinician(s) Involved (57%)
- Preventable vs Non-Preventable (43%)
- Severity (7%)

★ = NHIF Documentation Recommendation
Conclusion
• High variation and lack of standardized collection methods between sites regarding ADR reporting
• Future need to define workflow including metrics and application

Limitations
• Small sample size
• General biases
  • Manager reporting
  • NHIA development and distribution
• Difficulty obtaining site/center specific data examples
Phase II

Purpose
Develop workflow to help standardize the collection and reported metrics of ADRs within ambulatory infusion services
Phase II: Implement Workflow

Methods

- Designed ADR reporting SmartForm within Epic
- Pilot SmartForm within three ambulatory infusion suites
  - Required documentation
  - Discrete data elements with cascading logic

http://www.nhia.org/data/
# Preliminary Results

## January 14, 2020 – April 30, 2020

### n = 546 encounters

<table>
<thead>
<tr>
<th>Did an ADR occur during encounter?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25 (4.6%)</td>
<td>521 (95.4%)</td>
</tr>
</tbody>
</table>

### n = 25 patients with ‘Yes’

<table>
<thead>
<tr>
<th>Did an ADR occur during encounter?</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Serious</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17 (68%)</td>
<td>8 (32%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>
Next Steps

1. Survey pilot sites
2. Finalize standard operating procedure
3. Integrate workflow into non-oncology infusion suites
4. Develop toolkit to streamline data sharing with NHIF initiatives
Future Directions

Delphi Consensus

- Develop list of ADR and risk
  Preparation

Feedback
- 1st round
- Analysis of results

Feedback
- 2nd round
- Analysis of results

Feedback
- 3rd round
- Analysis of results

Expert panel ranks risk factors in terms of potential impact and requiring intervention
70% agreement required
Acknowledgements

• Michael Grimes, PharmD, MBA
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• Ashley Pham, PharmD
Flow rate accuracy of ambulatory elastomeric and electronic pumps used to deliver continuous infusions at home

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Declaration of interests

• This project was funded by the South Australian Premier’s Research Industry Fund Collaboration Pathways Program.

• CPIE Pharmacy Services provided in-kind support for this study.

• J Hobbs and M Ryan (Flinders University) performed the experiments and compiled the data.

• JK and AJ Sluggett are shareholders in Infusion Innovations Pty Ltd (infusion device patent application PCT/AU2017/050019).
Background

- In Australia, IV antibiotics often given over 24-h continuous infusions at home
  - Conditions at home may differ to lab testing conditions

- In practice, patients could be exposed to changes in pressure or height difference during the day, which could impact on pump performance
  - Differences in PICC lines or connectors can exert a back pressure
  - Devices are usually tested at the same height as the infusion site

- **Aim:** To determine the impact of variation in infusion pump height and back pressure on infusion flow rate and volume delivered.
Methods

• Series of simulated infusions with 4 elastomeric and 1 electronic infusion device

L to R: Baxter Infusor LV10, Leventon Dosi-Fuser®, Nipro Surefuser™, B. Braun Easypump® (27 h), ambIT® Continuous
Methods

- The infusions were conducted in the laboratory under the standard testing conditions for ambulatory infusion devices
- Outcomes were determined using gravimetric analysis
- Key outcomes presented today:
  - Infusion flow profile for each device
  - % of total volume delivered over 24 hours (27 h for Easypymp)
- Each device type was tested at 10 different height (0, ±20, ±40cm) and/or back pressure (10-30mmHg) combinations, with each experiment repeated 5 times.
Results: Infusion flow profiles
Results: % of total volume delivered at 24 h

Volume delivered at 24 h
(height 0cm, pressure 0mmHg)

- Baxter LV10: 99%
- Dosi-Fuser: 89%
- Easypump (27 h): 96%
- Surefuser: 94%
- AmbIT: 94%
Discussion

• Flow rates and volume delivered varied considerably with elastomeric pumps when height/back pressure differences were applied.
  - Minor variations may not have a clinically significant impact
  - Consistent flow rates may be preferred for 24-h infusions of drugs with a narrow therapeutic index and/or a short half-life
  - Further studies of volume delivered in real-world settings are warranted
Conclusions

• Study limitations:
  • Simulated infusion with distilled water
  • Single electronic device tested
  • Consistent ambient temperature

• Overall, findings suggest it is important to understand device advantages and limitations when selecting a pump to deliver a 24-hour infusion in the home and advise patients to minimize vertical displacement.
Acknowledgements

• Co-authors: J Hobbs, M Ryan, A Mohtar, A Sluggett, B Ritchie, K Reynolds