Implementing Services for Pediatric Cystic Fibrosis Treatment in a Community Hospital

Paige M. Grube PharmD

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Implementing Services for Pediatric Cystic Fibrosis Treatment in a Community Hospital

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The speaker and mentors have no actual or potential conflict of interest in relation to this presentation.
Cystic Fibrosis (CF)

- Recessive genetic disorder
- Dysfunction of cystic fibrosis transmembrane conductance regulator (CFTR) protein
  - Regulates chloride
  - Reduces viscosity of fluids
- Effects many organ systems

Pathophysiology

Normal CFTR

Mutation

### Implications

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Absorption</strong></td>
<td>• Potentially reduced</td>
</tr>
</tbody>
</table>
| **Distribution** | • Potentially less protein  
• Protein-bound drugs are cleared faster → volume of distribution (Vd) and clearance (CL) increased |
| **Metabolism** | • Unknown  
• Potentially increased due to increased hepatobiliary blood flow          |
| **Excretion**  | • Variable depending on severity of illness, mutation type, etc.             |

Cystic Fibrosis Center

- CF Foundation recommends pharmacists participate in patient care
  - Complex disease state
  - Interdisciplinary team required for proper patient care
Cystic fibrosis patients require specific medications and drug dosing due to:

a) Additional genetic material at chromosome 21
b) Genetic mutation in the CFTR protein
c) Genetic mutation in the hemoglobin-Beta gene on chromosome 11
d) Genetic mutation in the FBN1 gene
Assessment Question #1

Cystic fibrosis patients require specific medications and drug dosing due to:

a) Additional genetic material at chromosome 21
b) Genetic mutation in the CFTR protein
c) Genetic mutation in the hemoglobin-Beta gene on chromosome 11
d) Genetic mutation in the FBN1 gene
Incidence – America

- Newborn screening estimates 1/4000 live births
- Previously most common life-threatening inherited disorder in Caucasians

Incidence – Indiana

CF centers in IN:
1. St. Joseph Regional Medical Center
2. Riley Hospital for Children
3. Indiana University Medical Center
4. Lutheran Hospital
5. Parkview Regional Medical Center

Impact on Healthcare

Fort Wayne
- Lutheran reported caring for 75-100 patients
- 7-9 CF patients per day seen in clinic 3 Mondays per month

CF Registry
- 31,199 patients in the registry in 2019 aged 12 and up
  - 21,391 hospitalizations
  - 34% of patients 12-17 years old hospitalized at least once in 2019
Relevance

- 74 pediatric beds in an adult hospital
- Starting a pediatric CF center – currently given partial accreditation
- Focus on inpatient care as pediatric clinical specialist is not 24/7
**Objective**

- To develop and implement an interdisciplinary oncology program in a community hospital

**Methods**

- **Phase 1:** Development of guidelines and references
- **Phase 2:** Development of a patient-centered model
- **Phase 3:** Continuous communication process

<table>
<thead>
<tr>
<th>Objective</th>
<th>Methods</th>
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</table>
| • To describe implementation of antimicrobial management programs across a large health system of community hospitals | • **Phase 1**: Establish multi-disciplinary team  
• **Phase 2**: Formulary evaluation & training  
• **Phase 3**: Care optimization phase & implementation  
• **Phase 4**: Refining workflow efficiency |

Phased approach was central to success
Both received funding for a new pharmacist position
Saw cost savings and a reduction in errors
Lacked objective metrics

Assessment Question #2

A key area of implementing new pharmacy services is:

a) Improve marketing strategies
b) Evaluate insurance coverage
c) Provide education to staff
d) Increase ordering of medications
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A key area of implementing new pharmacy services is:

a) Improve marketing strategies
b) Evaluate insurance coverage
c) Provide education to staff
d) Increase ordering of medications
Purpose & Methods

• Prepare pharmacy for inpatient treatment of CF patients

1. Create appropriate protocols and order sets to care for CF patients

2. Provide staff pharmacists with appropriate training & resources

3. Create & manage the electronic support needed within our institution
Implementation Timeline

August 2021
Meet with important stakeholders
• Nurse Practitioner
• Pediatric pulmonologist
Finish admission order set

September 2021
Verify home medication policy
Begin literature search

October 2021
Primary literature search to verify correct dosing, duration, and frequency of antibiotics for use in cystic fibrosis
Order Sets - Admission

- Cultures – sputum, acid-fast bacilli (AFB)
- Inhaled medications
  - Albuterol
  - Dornase alfa
  - Hypertonic saline
  - Antibiotics
- Vitamins
- Salt supplementation
Home Medications

Automatically use home supply

- Pancreatic enzymes
- Fat-soluble vitamins (ADEK)
- Cystic fibrosis transmembrane conductance regulator (CFTR) modulators

Policy – Patients’ Own Supply

Policy – Formulary
Implementation Timeline

November 2021
Took antibiotic dosing recommendations to important stakeholders to get feedback
- Changes made
- Conversations about extended-infusion beta-lactams

December 2021
Antibiotic dosing approved by important stakeholders
Antibiotic order set draft sent to order set team

January 2022
Worked with order set team to create intravenous (IV) antibiotic order set
Began literature search regarding CF pharmacokinetics
Order Set Creation

- Owned by one of the service lines
- Service line designates a medical content expert
  - Develop and approve clinical content
  - Obtain feedback and consensus from other service lines
  - Responsible for ensuring evidence-based practice
- Approved by all stakeholders
- Order set sent to electronic health record (EHR) team for build
Order Sets – Antibiotics (IV)

- **Includes:**
  - Beta-lactams, aminoglycosides, fluoroquinolones, tetracyclines
  - Others → clindamycin, linezolid, sulfamethoxazole-trimethoprim, vancomycin

- **Considerations:**
  - Extended-infusion dosing
    - Cefepime, ceftazidime, meropenem, nafcillin
    - Piperacillin-tazobactam
  - Safety for other pediatric patients
<table>
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<tr>
<th>Other Project Considerations</th>
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<tbody>
<tr>
<td><strong>ID Restrictions</strong></td>
</tr>
<tr>
<td>• Ceftaroline</td>
</tr>
<tr>
<td><strong>Therapeutic Interchange</strong></td>
</tr>
<tr>
<td>• Ciprofloxacin</td>
</tr>
<tr>
<td><strong>IV Pumps</strong></td>
</tr>
<tr>
<td>• Extended-infusion dosing</td>
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</table>
Order Sets – Antibiotics (oral)

• Includes:
  • Beta-lactams, fluoroquinolones, tetracyclines
  • Others → azithromycin, clindamycin, ethambutol, linezolid, rifampin, rifabutin, sulfamethoxazole-trimethoprim

• Considerations:
  • Oral tablets, capsules, and suspensions
  • Set doses based on weight/age
Implementation Timeline

February 2022
- Draft aminoglycoside, vancomycin, and antibiotic (IV and oral) protocol for pharmacy to dose consults

March 2022
- Finalize protocol and take to formulary subcommittee
- Create pharmacist education to roll out before protocol goes live

April 2022
- Implement protocol & educate pharmacy team
- Close other loose ends
Cystic Fibrosis Protocol

- Consult placed by provider for pharmacy to dose
  - Antibiotic chosen by provider
  - 3-in-1 pharmacy protocol

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<th>Aminoglycosides</th>
<th>Vancomycin</th>
<th>Antibiotics</th>
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<td>- Same dosing as available in the order set</td>
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<td>- Goal peak and goal time undetected</td>
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<tr>
<td>- Recommended lab monitoring</td>
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<td></td>
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Aminoglycosides: Recommended initial dosing, Goal peak and goal time undetected, Recommended lab monitoring
Vancomycin: Recommended initial dosing, Goal trough, Recommended lab monitoring
Antibiotics: Same dosing as available in the order set, Includes both IV and oral
• Pharmacokinetic equations
  • Parkview pharmacists familiar with utilizing nomogram for extended-infusion dosing in adults
  • How to calculate peak and time level is undetectable based on 2- and 6-hour random levels
    • Guidance with examples in protocols

• Pharmacokinetic spreadsheet
  • Aminoglycoside kinetics calculations
  • Input patient specific data → new dose/frequency guidance
Education for Pharmacists

- Online slide presentation
  - Basics of cystic fibrosis
  - Disease progression
  - Medications → what, why, how
- Competency quiz
  - Content questions
  - Pharmacokinetic scenarios
- Announcements once project components are active
Challenges

- Previous protocols/policies
- Coordination between:
  - Pharmacy and providers
  - Pharmacy and EHR team
- **Timeline implementation**
Future Directions

Implement oral antibiotic order set

Integrate pharmacy into outpatient clinic

Publish process and findings
References