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### Implementing Services for Pediatric Cystic Fibrosis Treatment in a Community Hospital

Paige M. Grube PharmD

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The speaker and mentors have no actual or potential conflict of interest in relation to this presentation

# Implementing Services for Pediatric Cystic Fibrosis Treatment in a Community Hospital

Speaker: Paige M. Grube, PharmD  
PGY1 Pharmacy Practice Resident  
Parkview Health

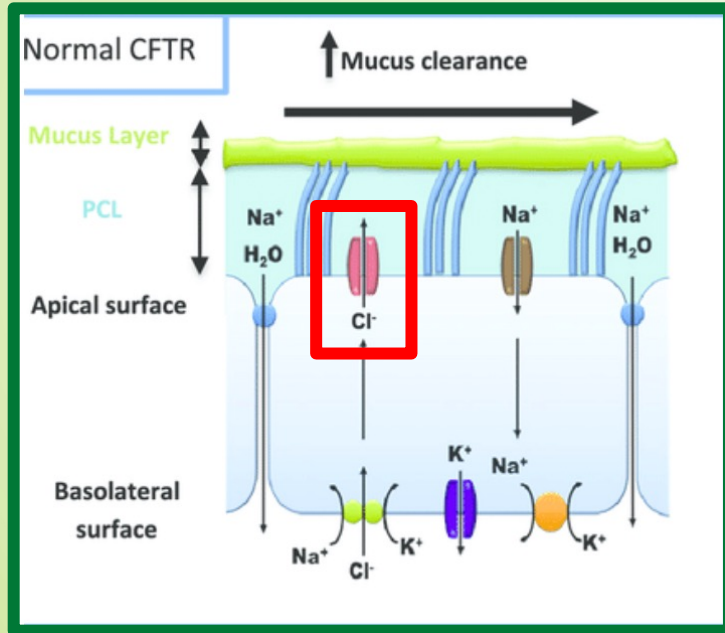
Mentors: Heather Rodman, PharmD, BCPPS, Sarah Ferrell, PharmD, BCPPS, Karen Dunkelberger, BSPHarm, MSHI, CPPS, and Abby Todt, PharmD, BCPS

# Cystic Fibrosis (CF)

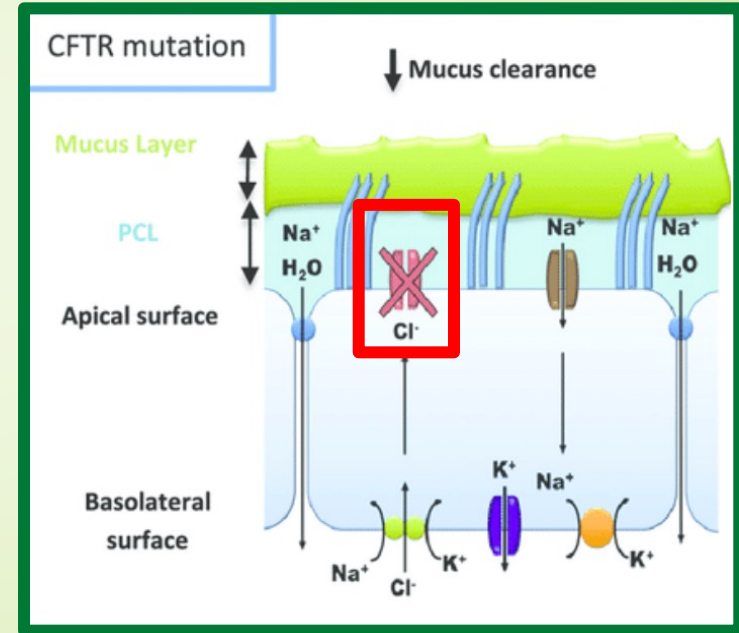
- Recessive genetic disorder
- Dysfunction of cystic fibrosis transmembrane conductance regulator (CFTR) protein
  - Regulates chloride
  - Reduces viscosity of fluids
- Effects many organ systems

# Pathophysiology

## Normal



## Mutation



# Implications

## Absorption

- Potentially reduced

## 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



# 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

# Assessment Question #1

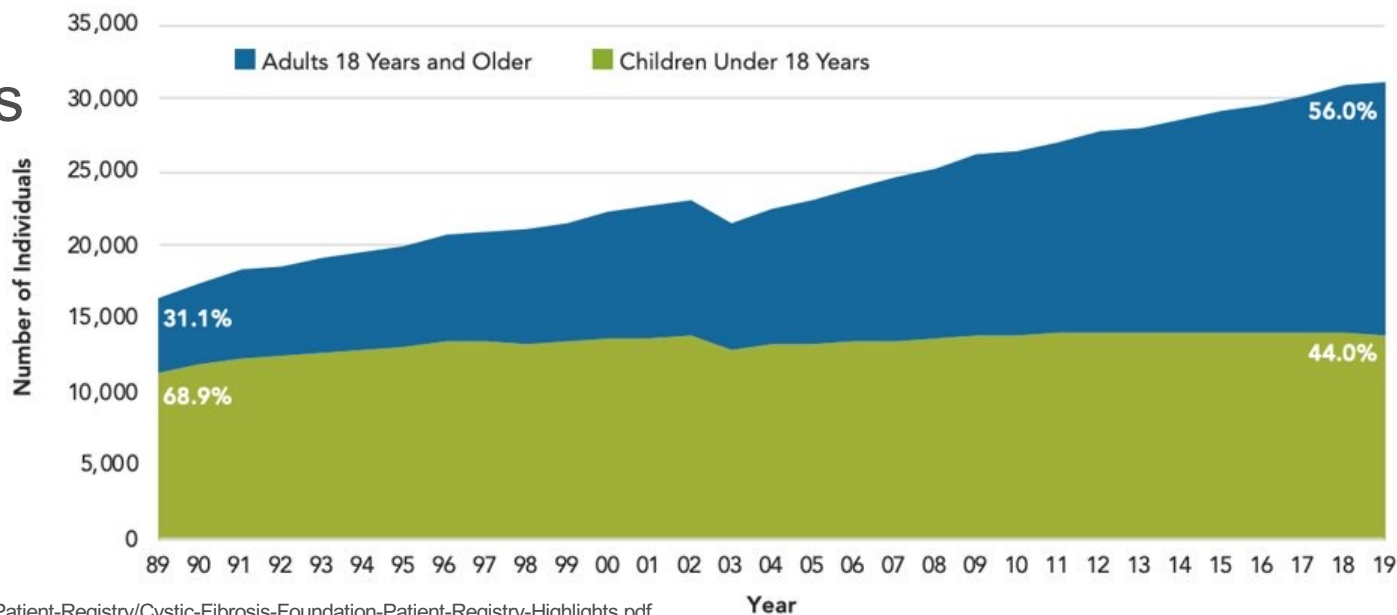
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# Incidence – America

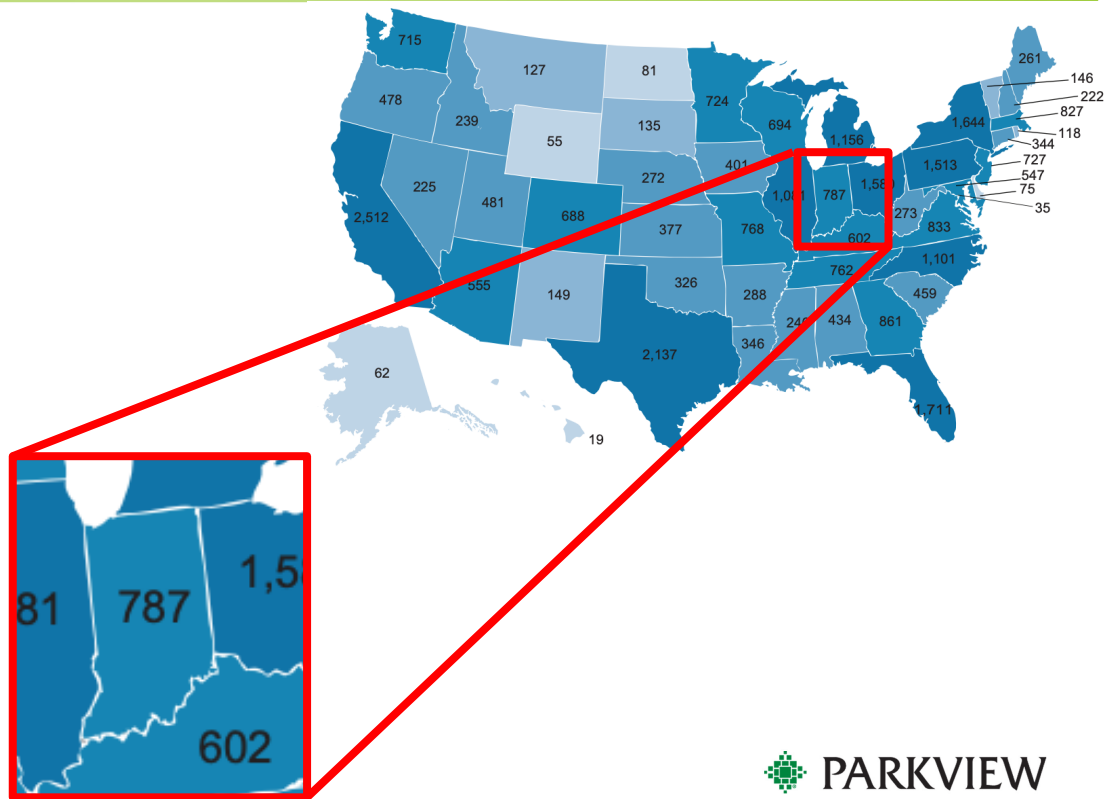
- Newborn screening estimates 1/4000 live births
- **Previously** most common life-threatening inherited disorder in Caucasians



# 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



# Literature Review - Oncology

## 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

# Literature Review - Infectious Disease (ID)

## Objective

- To describe implementation of antimicrobial management programs across a large health system of community hospitals

## Methods

- **Phase 1:** Establish multi-disciplinary team
- **Phase 2:** Formulary evaluation & training
- **Phase 3:** Care optimization phase & implementation
- **Phase 4:** Refining workflow efficiency

# Literature Review - Conclusions

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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# 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

## October 2021

Primary literature search to verify correct dosing, duration, and frequency of antibiotics for use in cystic fibrosis

Verify home medication policy

Begin literature search

## September 2021



# 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

## January 2022

Worked with order set team to create intravenous (IV) antibiotic order set

Began literature search regarding CF pharmacokinetics

Antibiotic dosing approved by important stakeholders

Antibiotic order set draft sent to order set team

## December 2021

# 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

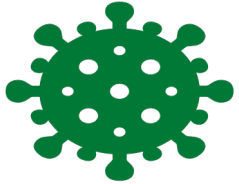


# Order Sets – Antibiotics (IV)

- 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



# Other Project Considerations



## ID Restrictions

- Ceftriaxone



## Therapeutic Interchange

- Ciprofloxacin



## IV Pumps

- Extended-infusion dosing



# 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

## April 2022

Implement protocol & educate pharmacy team  
Close other loose ends

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

## March 2022

# Cystic Fibrosis Protocol

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

## 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



# Aminoglycoside Kinetics

- 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



# Conclusions

Home  
medication  
procedure

Primary  
literature  
search

Antibiotic  
order set

Pharmacy  
protocols

Kinetic  
Calculator

Education

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