Impact of a Clinical Pharmacist on IBD Care

Brendan Boyle, MD, MPH
Jennifer Dotson, MD, MPH
Megan McNicol, PharmD

Nationwide Children’s Hospital
Plan of care

“We’ve reviewed your results and repeat procedures. Your disease is active, let’s plan to change therapy.”
Plan of care

“We’ve reviewed your results and repeat procedures. Your disease is active, let’s plan to change therapy.”

Sounds like a simple change... what could possibly go wrong?
Plan of care

“We’ve reviewed your results and repeat procedures. Your disease is active, let’s plan to change therapy.”
What is the need?

- Delays in therapy
- Phone hold time
- Pharmacy confusion/clarification
  - Who, what, where?!
- Family finances – going broke
- Family frustration

Can’t a pharmacist help with all this?
OBJECTIVES

- Describe increased use of specialty medications for IBD treatment
- Evaluate challenges associated with the use of specialty medications
- Define the role of a clinical pharmacist within an IBD center
- Describe active QI projects
The Rise of Biologics

IBD TREATMENT
IBD Treatment: Nationally

- Pediatric IBD biologic use increased from 19.1% in 2007 to 45.9% in 2015
  - Use per-year was significantly higher in pediatric vs. adult IBD patients

Yu; Aliment Pharmacol Ther. 2018
IBD Treatment: NCH

- Increased use of biologic therapies
  - Approximately 700 patients in our IBD center
  - 63% of population is on a biologic medication

- Medication distribution

<table>
<thead>
<tr>
<th>Medication</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab (Remicade/Inflectra)</td>
<td>59%</td>
</tr>
<tr>
<td>Adalimumab (Humira)</td>
<td>33%</td>
</tr>
<tr>
<td>Vedolizumab (Entyvio)</td>
<td>5%</td>
</tr>
<tr>
<td>Ustekinumab (Stelara)</td>
<td>3%</td>
</tr>
<tr>
<td>Certolizumab (Cimzia)</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>
IBD TREATMENT:
WHAT IS A SPECIALTY MEDICATION?
Specialty Medications

Limited Access
Require special claims processing that delays patient’s therapy

High Maintenance
Involve significant patient education and monitoring

High Cost: 67x more
Average specialty Rx
$3,500

Treats Complex Diseases

High Complexity
Requires complex process of delivery to patient, manufacturing, and handling

Average traditional Rx
$52

There is no industry/regulatory standard definition of a specialty drug.
Specialty Medication Costs

SPECIALTY DRUG SPENDING IN US BILLIONS ($)

From 2012 to 2020, spending on specialty drugs is expected to increase by **361%**
Why would we need a Specialty Pharmacy?

- Need for prior authorization
- Directing prescriptions to specialty pharmacy
- High copayments
- Coordinating delivery of medication to patient

Gaps in care often amount to **20-40 days**
Specialty Pharmacy Map

External SP

External Specialty Pharmacy

NCH Clinic

Insurance company

Manufacturer HUBS

Contracted Specialty Pharmacy

Patients

Prior authorization
Prescription
Revenue
Education
Medication Dispensed
NCH Specialty Pharmacy

Timeline

- Business Plan Created
  - Jan 2015

- Increased Staffing +4 FTE (manager)
  - July 2015

- URAC Kick-Off
  - Sept 2016

- CF Clinic Go-Live 2 FTE
  - Jan 2017

- Rheum Clinic Go-Live +3 FTE
  - Feb 2018

- URAC Accreditation Obtained
  - Feb 2018
NCH Specialty Pharmacy
Timeline

- **Endo Clinic Go-Live** +3 FTE
  - June 2018

- **Neuro Clinic Go-Live** +2 FTE
  - Aug 2018

- **GI Clinic Go-Live** +2 FTE
  - Nov 2018

- **Derm Clinic Go-Live** +1 FTE
  - July 2019

**Current Services:**
- 6+ Clinics
- 18 FTE

Nationwide Children's
When your child needs a hospital, everything matters.
NCH Specialty Pharmacy

Current Services

Cystic Fibrosis
- 1 Clinical RPh
- 0.5 Staff RPh
- 2 CPhT

Gastroenterology
- 1 Clinical RPh
- 0.5 Staff RPh
- 1 CPhT

Rheumatology
- 1 Clinical RPh
- 0.5 Staff RPh
- 2 CPhT

Endocrinology
- 1 Clinical RPh
- 0.5 Staff RPh
- 1 CPhT

Dermatology
- 0.5 Clinical RPh
- 0.5 Staff RPh
- 1 CPhT

Neurology
- 1 Clinical RPh
- 0.5 Staff RPh
- 1 CPhT

Unique Scenarios
- Adolescent Gynecology
- Employee Health Plan
NCH Specialty Pharmacy

Current Services

- **Cystic Fibrosis**
  - 1 Clinical RPh
  - 0.5 Staff RPh
  - 1 CPhT

- **Gastroenterology**
  - 1 Clinical RPh
  - 0.5 Staff RPh
  - 1 CPhT

- **Dermatology**
  - 0.5 Staff RPh
  - 1 CPhT

- **Rheumatology**
  - 0.5 Clinical RPh
  - 0.5 Staff RPh
  - 1 CPhT

- **Endocrinology**
  - 1 Clinical RPh
  - 0.5 Staff RPh
  - 1 CPhT

- **Neurology**
  - 1 Clinical RPh
  - 0.5 Staff RPh
  - 1 CPhT

- **Unique Scenarios**
  - Adolescent Gynecology
  - Employee Health Plan

- **Gastroenterology**
  - 1 Clinical Pharmacist
  - 0.5 Staff Pharmacists
  - 1 Pharmacy technician
The Role of a Pharmacist

INSTITUTION LEVEL INTEGRATION
Creating Value:
Integrated Specialty Pharmacist

- Improved patient access
- Pediatric-trained clinic pharmacist
- Simplified process for clinic staff & patients
- Integrated care
- Copay assistance
The Role of a Pharmacist: What do I do everyday?

DIVISIONAL LEVEL
INTEGRATION
My Role: GI Clinic

- Monday: Specialty Pharmacy Staffing
- Tuesday: AM: IBD Clinic; PM: Specialty Pharmacy Staffing
- Wednesday: Specialty Pharmacy Staffing
- Thursday: IBD Clinic
- Friday: AM: IBD Clinic; PM: Clinic prep/QI

- Additional clinic time as needed for injection training and patient consults
- Pharmacy staffing includes: patient refill calls, insurance navigation, pharmacy projects, prior authorization work
My Role: GI Clinic

- Medication and Injection Teaching
- Medication Consults
- Adherence Counseling
- Vaccine Recommendations
- Prior Authorizations and Insurance Concerns
- Medication Access Issues
- Follow up with Specialty Pharmacy Patients
- Research and Quality Improvement
- Therapeutic Drug Monitoring
My Role: GI Clinic

Medication/Injection Teaching

- Pharmacy information
- Copay information
- Warnings
- Side effects
- Storage/Handling
- Injection Technique
- First dose given together
My Role: GI Clinic

Medication Consults

- Drug information questions
- Drug interaction checks
- Providing patient education
My Role: GI Clinic

Adherence Counseling

- Medication adherence
- Refill history
- Adherence tips/tricks
- Monthly patient calls
My Role: GI Clinic

**PA/Insurance Concerns**

- Recommending preferred products
- PA submission
- Appeals process
- Copay/patient assistance programs
Appeals and LOMN

Standard Appeal Templates:

- Dose escalation
- Biologic use first-line
- Denied lab work
- Site-of-care
- Off-label use
Letter of Medical Necessity for Dose Escalation or Alteration of Anti-TNF Therapy:

To whom it may concern:

*** is under our care for inflammatory bowel disease (IBD). *** is currently receiving Humira therapy for treatment, and requires drug dosing adjustment to ensure maximal therapeutic success of drug ***.

There is strong evidence that patient specific factors including body mass, degree of inflammation, albumin level, presence of anti-drug antibodies, and concomitant medications can alter anti-tumor necrosis factor (anti-TNF) drug levels (1). Prevailing evidence supports the correlation of higher infliximab concentrations with longer duration of response in Crohn’s disease patients (2). Specifically, in pediatric patients, higher infliximab concentrations have been associated with sustained, durable remission (3). Similarly, higher adalimumab concentrations have been associated with improved outcomes including decreased C-reactive protein levels, an established marker of disease activity (4). Conversely, the presence of anti-drug antibodies has a negative effect on treatment resulting in lower drug concentrations, shorter duration of response, and increased risk of infusion reactions (2, 5-11).
Impact on NCH IBD Team

Nursing:
- Reduced phone time with insurance company and pharmacy
- No longer responsible for injection trainings
- Additional time for IBD teachings and nurse triage line

Insurance Specialist
- Contact for clinical questions and complex situations

Providers:
- Streamlined insurance denial process
- Resource for drug information questions
Pharmacy Integration

ACTIVE NCH PROJECTS

SHOW ME THE DATA!!!
IMPACT OF A CLINICAL PHARMACIST

Improving Access:
Time to Biologic Therapy
Project Title: Improvement in Time to Therapy for IBD Patients on Subcutaneous Biologic Therapies

**Aim**

- Increase % of biologic initiations within 15 business days of a treatment decision, for patients newly started on subcutaneous biologic therapy, from 33% to 60%, by July 31st 2019 and sustain for 6 months.

- Improve time to therapy for patients with uncontrolled IBD conditions

**Key Drivers**

- Required laboratory testing and clinic notes
- Standardized PA workflow
- Standardized appeal process
- Streamlined process for pharmacy filling and injection training

**Interventions**

- Initiate TB testing at diagnosis
- Develop process map
- Presentation to providers
- Frequent PA follow-up
- PharmD navigating appeal process
- PharmD pending appeal letters
- Streamlined communication with patients following approval
- Pend script to appropriate pharmacy
- PharmD completes injection training in clinic

PA=prior authorization
GI New-Start **Injectable** Biologic Prescriptions

**GI Provider**
- Send new biologic prescription to NCH Specialty Pharmacy

**NCH SP**
- Investigate patient benefits, determine necessary pharmacy, confirm TB tests
- Obtain prior authorization
- PA approved? (YES or NO)
- Can NCH fill? (YES or NO)

**Letter of medical necessity/peer-to-peer**

**Review and Sign Pended Rx**

**Educate Family**:
1. Medication Approval
2. Patient Assistance Info
3. Pharmacy Info
4. Arrange delivery of medication
5. Coordinate Teaching

**Pend Rx to physician for appropriate SP**
PharmD integration

Time to Therapy for Subcutaneous Biologic Therapies

Chart Type: p-Chart

<table>
<thead>
<tr>
<th>Therapy by day 15</th>
<th>3</th>
<th>5</th>
<th>1</th>
<th>13</th>
<th>10</th>
<th>10</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total new starts</td>
<td>15</td>
<td>14</td>
<td>5</td>
<td>17</td>
<td>13</td>
<td>14</td>
<td>8</td>
</tr>
</tbody>
</table>
Time to Therapy - Adalimumab

PA approval: Anti-TNF agents used as first-line

- 66% of requests denied on initial PA submission
- Prior to PharmD integration: Average = 13 business days
- After PharmD integration: Average = 6 business days to approval
Time to Therapy - Adalimumab

PA approval: Tried and failed conventional therapy

- 8% of requests denied on initial PA submission
- Prior to PharmD integration: Average = 6 business days
- After PharmD integration: Average = 3 business days to approval
Time to Therapy - Adalimumab

Average time from PA initiation to first dose

• Prior to PharmD integration:
  • 21 days using an external specialty pharmacy
• After PharmD integration:
  • 7 days when using NCH specialty pharmacy
  • 15 days when using external specialty pharmacy
Optimized and personalized therapy: Therapeutic Drug Monitoring
Impact of a Clinical Pharmacist

**Aim**

Increase percentage of post-induction anti-TNF levels obtained in pediatric patients with Inflammatory Bowel Disease (IBD) on anti-TNF therapy from 40% to 90% by December 31, 2017 and sustain for 12 months.

Increase use of therapeutic drug monitoring “Treat-To-Target”

**Key Drivers**

- Reliable tracking method/Anti-TNF TDM database
- Timely and Appropriate Ordering
- Timely and Appropriate lab collection

**Interventions**

- IBD RN communicates new anti-TNF starts with data analyst and project leader
- Update Infliximab EPIC Order Set to include order for anti-TNF level
- Create adalimumab order set to include anti-TNF level
- Provider education and guideline updates
- Establish a reminder system for providers
- Establish protocol in infusion clinic for recognition of need for lab collection
- Establish reminder system for patients
- Ensure timely outpatient follow up visits for patients
IMPACT OF A CLINICAL PHARMACIST

Cost of Care:
Biosimilar Utilization
Why Choose a Biosimilar?

- Infliximab biosimilar is as safe and effective as the originator product in pediatric IBD
  - Measured by disease activity scores, blood tests, and stool biomarkers
  - No difference in immunogenicity
  - No difference in adverse effects/infusion reactions

Richmond; Arch Dis Child. 2018
Yoo; Ann Rheum Dis. 2013
Jorgensen; Lancet. 2017
Why Choose a Biosimilar?

- Biologics are the fastest-growing segment of US prescription drug spending
  - Accounted for **43%** of total drug spending in 2016
- Previous studies in pediatric IBD demonstrate biosimilar to be 38% cheaper than the originator

![Expenditures on biologics (billion dollars)](image)

Winegarden; FDA. 2017
Richmond; Arch Dis Child. 2018
Impact of a Clinical Pharmacist

Aim

Among eligible IBD patients* initiating IV anti-TNF therapy, we aim to increase the % initiating biosimilar therapy rather than the originator from a baseline of 1% to 50% by June 1, 2020

Key Drivers

- Education
- Cost
- Insurance

Interventions

- Providers: division presentation, information sheets, and process map for all new start patients
- Patients: education sheets and biosimilar education during new diagnosis IBD teaching
- Infusion pharmacy and nursing staff: information sheets and nursing in-service
- Enroll all patients in copay assistance programs when applicable
- Identify cost-savings with biosimilar use using wholesale acquisition cost (WAC)
- Outpatient process map: Insurance specialist will attempt PA for biosimilar before the originator product
- Inpatient process map: specialty pharmacist determines preferred product for insurance prior to starting IV anti-TNFα therapy

*Eligible = IV Anti-TNFα naïve patient diagnosed with: CD or ≥18 years with a diagnosis of UC or IC
Why Choose a Biosimilar?

1. Diagnosis of Crohn’s Disease
2. Diagnosis of Ulcerative Colitis or Indeterminate Colitis
3. Starting infliximab inpatient?

- **Is the patient ≥ 18 years?**
  - Yes: Begin PA process for Inflectra
  - No: Obtain PA for Remicade

- **Inflectra PA approved?**
  - Yes: Use Inflectra
  - No: Obtain PA for Remicade

- Contact PharmD to decipher preferred product
Impact of a Clinical Pharmacist

**Aim**

Among eligible IBD patients* initiating IV anti-TNF therapy, we aim to increase the percentage of new starts initiating biosimilar therapy rather than the originator by June 2022, leading to a decrease in health care costs.

**Key Drivers**

- Education
- Insurance

**Interventions**

- **Providers**: division presentation, information sheet, and process map for all new start patients
- **Patients**: education sheet and biosimilar education during new patient teaching
- **Pharmacy and nursing staff**: education meetings and nursing in-services
- **Insurance**
  - Outpatient process map: Insurance specialist will attempt PA for biosimilar before originator product
  - Inpatient process map: specialty pharmacist determines preferred product for insurance prior to starting IV anti-TNF therapy

---

*Eligible = IV Anti-TNFα naïve patient diagnosed with: CD or ≥18 years with a diagnosis of UC or IC

---

**67% of infliximab new starts received a biosimilar in the first 2 months of QI initiative!**
IMPACT OF A CLINICAL PHARMACIST

Population Health and Management: Hepatitis B Vaccinations
Impact of a Clinical Pharmacist

**Specific Aim**

Increase rates of hepatitis B (HBV) vaccination in new IBD patients who are HBV non-immune (HBsAb < 10 IU/mL), from 7 to >90% for receiving the first dose of HBV vaccine, by 3/1/19 and sustain through 9/1/19.

Improve vaccination rates in immunocompromised children

---

**Key Drivers**

- **Patient identification**
- **Vaccine delivery**
- **Team engagement and education**
- **Optimizing EMR for vaccine delivery**

---

**Interventions**

- Pre-visit patient identification
- Confirmation of no immunity
- Provider alert
- Establish vaccine algorithm
- Stock vaccine(s) in GI clinic
- PharmD pre-orders vaccine
- Review flow with clinic & infusion RNs
- GI practitioners
- GI RNs, infusion clinic RNs
- Pharmacy
- Patients, PCPs
- Follow up doses 2 & 3 with vaccine road map for GI clinic, infusion clinic
- Incorporate HBV in pre-visit assessment and infusion therapy plan
Update immunizations based on impactSIIS and assess need for repeat Hepatitis B series. Pend HBV order within upcoming visit.

3 dose series complete?

YES

Pend order for Hep B surface antibody 8 weeks after HBV dose #3

NO

Update excel tracker to reflect immunization given and assess future immunizations needed

Is patient now immune?

YES

Reassess annually

NO

Begin repeat 3-dose HBV series

Clinic Staff

Administer Hepatitis B vaccine

GI Provider

Review pended HBV order and sign

Sign pended order for surface antibody testing

Reassess annually

GI Pharmacist

NO

Clinic Staff

Administer Hepatitis B vaccine
Impact of a Clinical Pharmacist

Pts with new IBD dx and Hep B non-immune receiving HBV

% patients receiving vaccine

Eligible pts receiving Hep B vaccine  Process Stage Mean  Process Stages  Control Limits (N/A)  Goal(s)
Future Directions

- Immunizations:
  - Pneumococcal vaccines

- Specialty Pharmacy Expansion:
  - Infusions / PA process?
    - Medical vs pharmacy - billing

- Transition of Care:
  - Patient and family education
Impact of a Clinical Pharmacist on IBD Care

Brendan Boyle, MD, MPH
Jennifer Dotson, MD, MPH
Megan McNicol, PharmD

Nationwide Children’s Hospital