GI Health Foundation

Impact of IBD on Healthcare Systems

Supported by an educational grant from Janssen Biotech, Inc.

IMPACT OF IBD ON HEALTHCARE SYSTEMS

Challenges in IBD for the Community Gastroenterologist

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Challenges in IBD for Community GI

- Most Community GI challenges mirror those of Academic GI
- Delay in diagnosis
- Patient challenges are similar
- Diagnostic testing and treatment options are similar
- Patients more complicated in Academic Center
- Staffing more extensive in Academic
- Academic pharmacy vs Specialty Pharmacy vs standard pharmacy
- Medication Approval process more challenging in Community

Diagnostic Delay Is Common in the United States and Is Associated With Worse Outcomes

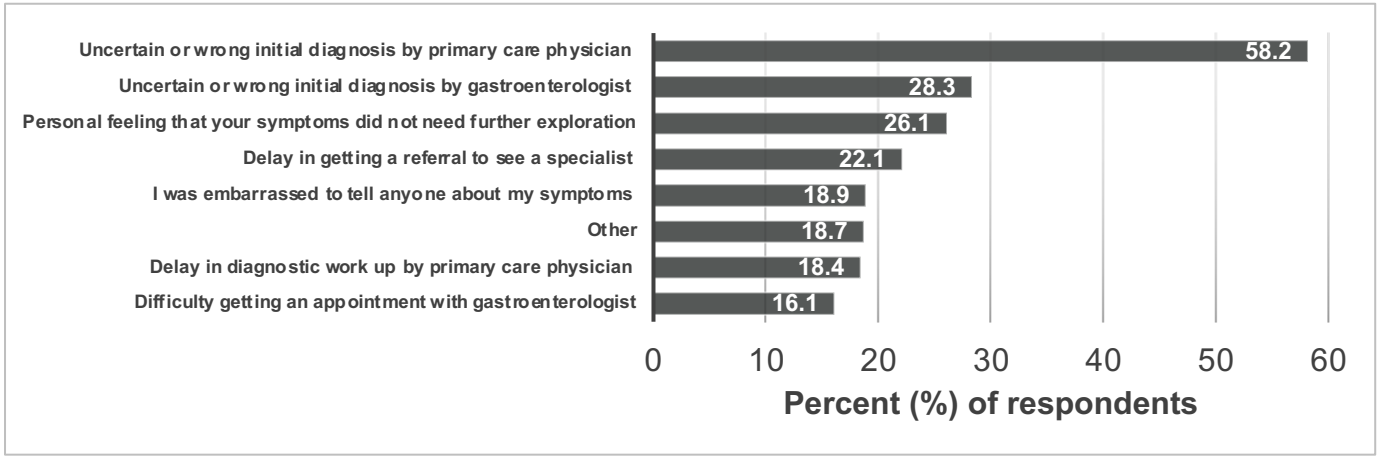
U.S. patients reporting significant delay in diagnosis

	CD*	UC
Delay > 1 year	390 (70%)	92 (48%)
Delay > 2 year	293 (52.2%)	71(37%)

* p<0.001

- Online patient cohort of IBD patients – IBD Partners
- Self-reported diagnostic delay and perceived reasons for delay
- Clinical data on disease complications also collected
- 757 (68%) patients reported a delay in diagnosis

Perceived reasons for delay



Adjusting for age at diagnosis, ileal disease location and biologic use, diagnostic delay of greater than 2 years was significantly associated with disease complications (aOR 1.71, 95% CI 1.01 – 2.91, p = 0.047).

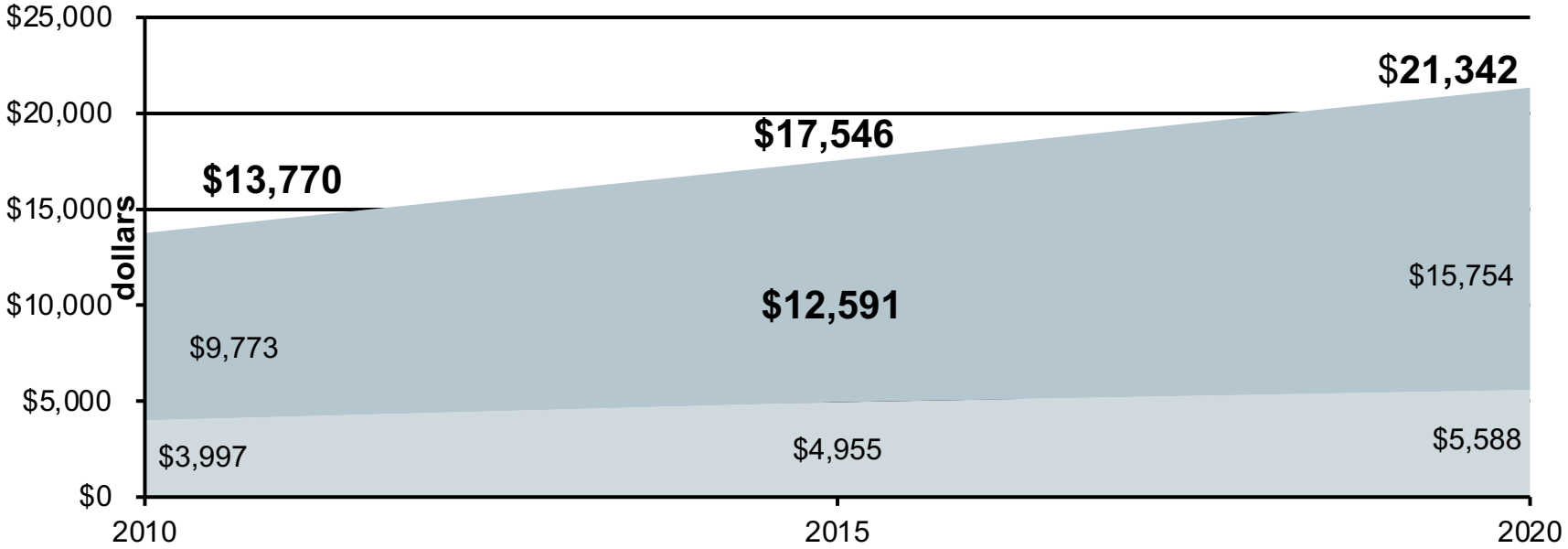
Gallinger Ungaro et al. DDW 2019.

Sequelae of Diagnostic Delay Swiss IBD Cohort

- Short vs Long Delay in Diagnosis: Crohn's disease
- Intestinal stenosis p=0.008
- Perianal fistula p=0.020
- Internal fistula p=0.012
- Any fistula p=0.001
- Resection surgery p=0.070
- Fistula surgery p<0.001
- Any complication p=0.001

Schoepfer et al. *JCC* 2019; 13: 1334-42.

Employer vs Employee Insurance Contribution



Health Insurance Coverage of the Total Population. KFF (Kaiser); 2019.

Challenges of Diagnostic Testing

- Many tests needed to make an accurate diagnosis, treatment plan, and prognosis
  - CBC,CMP,ESR,CRP, FE, TIBC, B12, Folate, Vit D, C diff pcr and eia, lacto, calprotectin, stool for pathogens
  - Supplemental lab tests: Urinalysis, amylase, lipase, TPMT, IBD serology, TPMT
- Colonoscopy and upper endoscopy, capsule endoscopy, CTE or MRE. Ultrasound of intestine: Europe!!!
- Double balloon enteroscopy (specific indications). Available at select IBD centers
- If fistula, MRI of pelvis +/- , EUS, EUA.

Biologic Treatment Issues

The FDA approved dosing regimen of a biologic is critical to its effectiveness, Dose escalation is needed in more refractory patients. Too often these are delayed or denied due to:

- Insurance approval issues, delays, denial of a biologic, dose, or interval
- Delay in completion of pre-biologic required testing (TB test and others)
- Poorly communicated “change of insurance” or lapse of insurance
- Financial issues
- Scheduling challenges (for infusions)
- Insurance delays in sending biologics to home or infusion unit
- Lack of understanding by payors and some patients, as to the critical need for proper dosing interval with no lapses

Dual Biologic Case

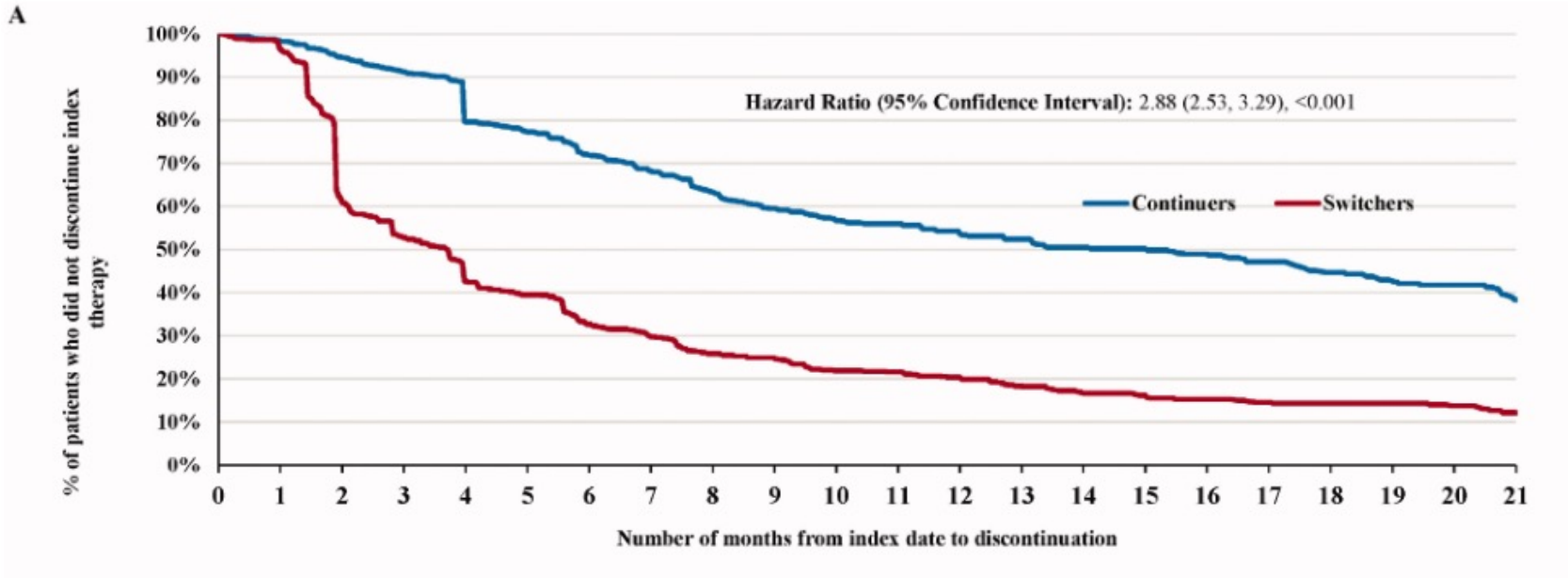
- 23 yo female recent college grad with severe colonic CD referred for follow up care.
- Dx with CD at age 12, no resections, and recent care at major Southeast IBD Center.
- Due to advanced syx, prior biologic failure (secondary LOR Remi, non-response to ADA & recent clinical trial, **started Jan 2021 on vedo, golimumab,(both covered)**
- With move to Georgia, **vedo coverage maintained, golimumab denied, Appeal in progress.**
- **Symptoms have increased**
  - Increased daily abdominal pain
  - 6-8 diarrhea stools a day
  - Rectal bleeding 2-4 times a day
  - XS fatigue
  - Polyarthralgia
- Labs: CRP increase from 10 to 60, vedo-10, gol-2.5, so vedo incr to q 4, gol to q 2 from pharma-still contesting denial of gol (no coverage issue prior site)
- **Colonoscopy- showed increased ulceration sigmoid, desc colon stenosis**

Challenges With Biologic Therapy

1. While dosing for CD=UC, there are often dosing differences between IBD and other immunologic disorders (RA, Psoriasis, psoriatic arthritis, ankylosing spondylitis, uveitis) where IBD dosing may be 2-fold or greater
2. Payors/pbms historically have made some incorrect dosing approvals. Delays, denials, even approval wrong drug/wrong dose
3. If biologic is delayed, blood level drops, antibodies may form.
4. This leads to loss of efficacy and IBD flare

Biosimilar Issues 2021-2022

- Insurers have switched originator infliximab (Remicade) forced switch to Inflectra, Remsima, Renflexis, Avsola
- Required explanation to patients, LOMN, P2P, Appeals, and other challenges
- Required office visits, new orders for labs and Rx with biosimilar infliximab
- Some have flared and switched back
- One payor: Covered Remicade - biosimilar - Remicade



Lin et al. *Current Medical Research and Opinion*, 2022

Delay of Treatment – Ustekinumab

77yo female with UC dx 2000, J-pouch, dx rev. to CD, Humira 2010 to 2018, uste since 2018, recently q 4w, doing extremely well, and due to the SAD list change, **did not receive uste July 5 to Nov.11**, due to:

1. (9/3/21) Missing claim history, no record of injection for 120 days
2. (9/12/21) Not medically necessary
3. (9/12/21) No TB test within 12 months
4. (9/28/21) Dosing frequency for drug more frequent than the Food and Drug Administration's (FDA's recommended dosing frequency for the patient's diagnosis)
5. Finally, AFTER many calls, approval at 90 mg q8 weeks, not q 4w

Advocacy – Step Therapy

- **S. 464/H.R. 2163 Safe Step Act of 2021**
- **Purpose: Improve Step Therapy protocols and ensure that patients are able to safely and efficiently access the best treatment for them**
- **While step therapy can be an important tool to contain costs, the insurance selected medication/biologic may not be the best one for the individual patient** and it can have negative consequences of delaying access to the most effective treatments
- **Safe Step Act has passed in 32 states**
- **The protocol for federal insurance &18 states is "step therapy" or "fail first"**
- The Safe Step Act of 2021 outlines 5 exceptions to "fail first" protocols
  - Patient already tried and failed the insurance preferred or required drug
  - Use of the insurance directed biologic is expected to be ineffective and will cause irreversible consequences
  - The required drug is likely to cause an adverse reaction
  - The required drug will prevent a patient from working or fulfilling Activities of Daily Living
  - Patient is stable on the drug selected by their provider and current or recent insurance
  - A Group Health plan must respond to an exemption request withing 72 hr/24 hr(hi risk)

Other Challenges

- Getting general care for IBD patients when coverage is marginal
- Emotional/psychiatric support
- School issues and accommodations
- Work place issues and accommodations
- Disability issues
- Financial challenges for patients

BlueCross BlueShield
of Alabama

May 31, 2022

[redacted]

[redacted]

Dear [redacted]

Thank you for being a valued Blue Cross and Blue Shield of Alabama customer. We have reviewed your request for a prior authorization for the drug, Humira(CF) Pen 40 mg/0.4 mL subcutaneous kit, on May 31, 2022 and have determined this is a duplicate request for a previously denied medication. Benefits will be provided based on the prescription drug coverage for this contract.

The quantity of the drug requested is more than the policy allows. Drug dispensing limits help encourage drug use as intended by the FDA. The submitted documentation (i.e. chart notes or medical literature) does not support the treatment of your condition with a dose that is higher than the FDA approved labeling. Our records indicate that you have been stable on a dose that is higher than the FDA approved labeling of Humira for at least 12 months, and your doctor has not attempted to gradually reduce your dose to be within FDA dosing guidelines. Therefore, we have approved Humira 40mg/0.4mL every 2 weeks. Approval of a higher dosing frequency (i.e. weekly) will require documentation that you have tried and failed a recent reduction to every 2 week dosing. [Reference: Blue Cross and Blue Shield Dispensing Limits Program]

See the following pages for additional information. If you need help understanding this notice or our decision, you may call our Customer Service Department at the number on the back of your Blue Cross ID card.

Thank you again for being a valued Blue Cross and Blue Shield of Alabama customer.

Sincerely,
Pharmacy Review

CC: Dr. Douglas Wolf

Blue Cross Blue Shield of Alabama Response

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- Sincerely,
- Pharmacy Review
- CC: Dr. Douglas Wolf

Conclusion

- Many IBD patients have multiple chronic and complicated issues and deserve the best quality of care to achieve remission.
- Need to reduce diagnostic and management delays
- Biologic therapy has been the cornerstone of IBD therapy for moderate-severe CD/UC
- Insurers need to improve processes to reduce treatment delays
- Optimal communication with the payor/pbm is needed to provide our patients with the best care.
- Teamwork & Advocacy will help achieve these desired outcomes.

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