GI Health Foundation

Impact of IBD on Healthcare Systems

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IMPACT OF IBD ON HEALTHCARE SYSTEMS

IBD Quality Indicators for the Practicing Healthcare Provider

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Variability in Care

- Surrogate for inferior care
- May represent misuse of healthcare resources:
  - Overuse: ED utilization
  - Underuse: steroid sparing therapy
  - Misuse: colonoscopy

Melmed GY, Siegel CA. *Gastro and Hep*. 2013; 9(5);286; Egberg M, et al. *Inflamm Bowel Dis*. 2018; 24(9): 1660.

Why Do We Need Quality Improvement?

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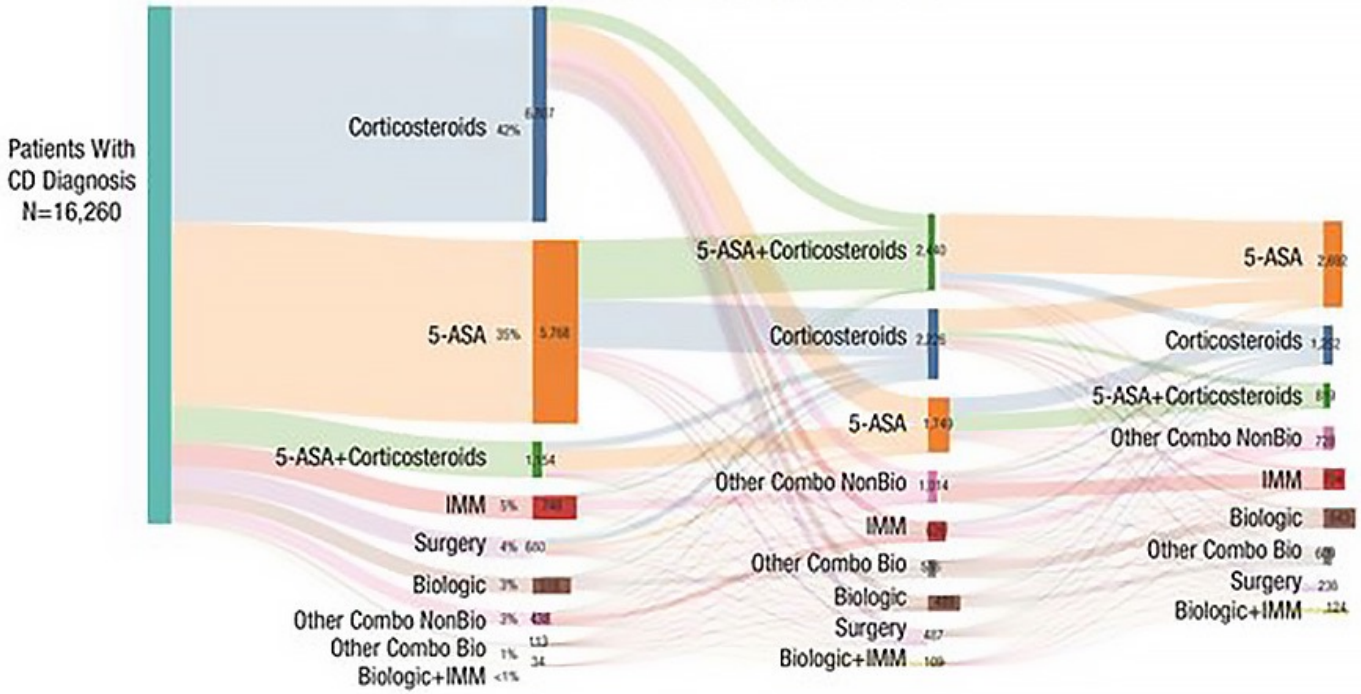
Are Patients with Inflammatory Bowel Disease Receiving Optimal Care?

Table 4. Suboptimal Care in Inflammatory Bowel Disease

Clinical Parameter	Proportion (%)
Suboptimal dosing of 5-ASA agents	21/33 (64)
Failure to use topical 5-ASA therapy	9/12 (75)
Treatment with corticosteroids >3 months	27/35 (77)
Failure to utilize steroid sparing medications*	16/27 (59)
Suboptimal dosing of immunomodulatory agents	9/11 (82)
Inadequate preventative measures for metabolic bone disease*	21/27 (78)
Inadequate surveillance for colorectal cancer	3/9 (33)

Reddy SI et al. *Am J Gastroenterol*. 2005; 100: 1357.

Variability in treatment for Crohn's disease



Corey Siegel. World Congress of Gastroenterology. 2017.

Table 2: Donabedian Model with Domain Descriptions from AHRQ[93, 94] and Examples for the IBD Population

Domain	Description	IBD Examples
Structural	Structural measures are characteristics of the larger care setting including measures of the human and material resources available to the health care system and organizational factors	Electronic medical records, accreditation status, and nurse or medical assistant availability. Examination room number and turnover. Hospital volume, teaching status, staff deployment, and qualifications
Process	Process measures describe activities *performed for, on behalf of, or by a patient*. Process measures are often the first to benefit from evidence- based guidelines, however, are also often the first to suffer from provider practice variation. Process measures provide a better estimate and are more sensitive and responsive to change. These measures are easier to quantify and associate with outcomes.	Scheduling of surveillance colonoscopies, yearly influenza vaccination rates, and additional health maintenance items Controller medication (such as immune-modulators) refill rates.
Outcomes	Outcome measures describe what happens to patients as a result of the care received. Outcome measures are the best reflection of the impact care has on the patient; therefore, patients have a particularly vested interest in outcome measures as they closely reflect the individual's health status.	Disease activity/remission, surgical interventions, steroid exposure rates, hospitalization rates, or admission lengths of stay. Patient Reported Outcomes (PROMs)

Egberg M et al. *Inflamm Bowel Dis*. 2018; 24(9): 1660.

Quality Indicators: Infrastructure

- IBD Unit/Clinic
- Access to healthcare professionals: pharmacist, ophthalmologist, rheumatologist, obstetrician, dermatologist
- Access to all of the following health care professionals: dieticians, mental health worker/psychologist, stoma therapist
- Dedicated IBD nurse
- At least one gastroenterologist with specialized IBD training
- Timely access to an Endoscopy Unit
- Access to CT and MRI with at least one modality with enterography
- Access to a GI radiologist and a GI pathologist
- Access to a surgical program that performs at least 10 ileoanal pouch operations a year
- Access to a fellowship trained colorectal surgeon
- Integrated in a hospital with an emergency department

Strohl M et al. *World J Gastroenterol*. 2018;24(22):2363.

Clinical Performance Measures

- IBD: Type, anatomical location and activity all assessed
- IBD preventive care: corticosteroid sparing therapy
- IBD preventive care: corticosteroid related iatrogenic injury – bone loss assessment
- IBD preventive care: influenza immunization
- IBD preventive care: pneumococcal immunization
- Testing for latent TB before initiating anti-TNF therapy
- Assessment of hepatitis B virus before initaiating anti-TNF therapy
- Testing for Clostridioides difficile –inpatient measure
- Prophylaxis for venous thromboembolism –inpatient measure
- IBD preventive care: tobacco user: screening and cessation intervention

Treatment

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IF a patient with IBD is initiating anti-TNF therapy, THEN tuberculosis risk assessment should be documented and tuberculin skin testing or interferon gamma release assay should be performed
IF a patient with IBD is initiating therapy with anti-TNF therapy, THEN risk assessment for hepatitis B virus should be documented
IF a patient with IBD requires at least 10mg of prednisone (or equivalent) for 16 weeks or longer, THEN an appropriately dosed corticosteroid-sparing agent or operation should be recommended
IF a hospitalized patient with severe colitis does not improve within 3 days of treatment with intravenous corticosteroids, THEN sigmoidoscopy with biopsy should be performed to exclude CMV AND surgical consultation should be obtained
IF a patient in whom a flare of IBD is suspected with new or worsening diarrhea, THEN the patient should undergo testing for *C difficile* infection at least once
IF a patient with IBD is initiating azathioprine/6-MP, THEN TPMT testing should be performed before starting therapy

Surveillance

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IF a patient with ulcerative colitis is found to have confirmed low-grade dysplasia in flat mucosa, THEN proctocolectomy or repeat surveillance within 6 months should be offered
IF a patient with extensive ulcerative colitis or Crohn's disease involving the colon has had disease for 8 to 10 years, THEN surveillance colonoscopy should be performed every 1 to 3 years

Healthcare Maintenance

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IF a patient with IBD is on immunosuppressive therapy, THEN patients should be educated about appropriate vaccinations, including

- Annual activated influenza
- Pneumococcal vaccination with a 5-year booster
- General avoidance of live virus vaccines

IF a patient with Crohn's disease is an active tobacco smoker, THEN smoking cessation should be recommended and treatment should be offered or suitable referral provided at least annually

Steroids: Adverse Effects

- Increased risk of mortality, OR = 2.1
- Up to 90% of patients exposed to corticosteroids experience an adverse effect, including:

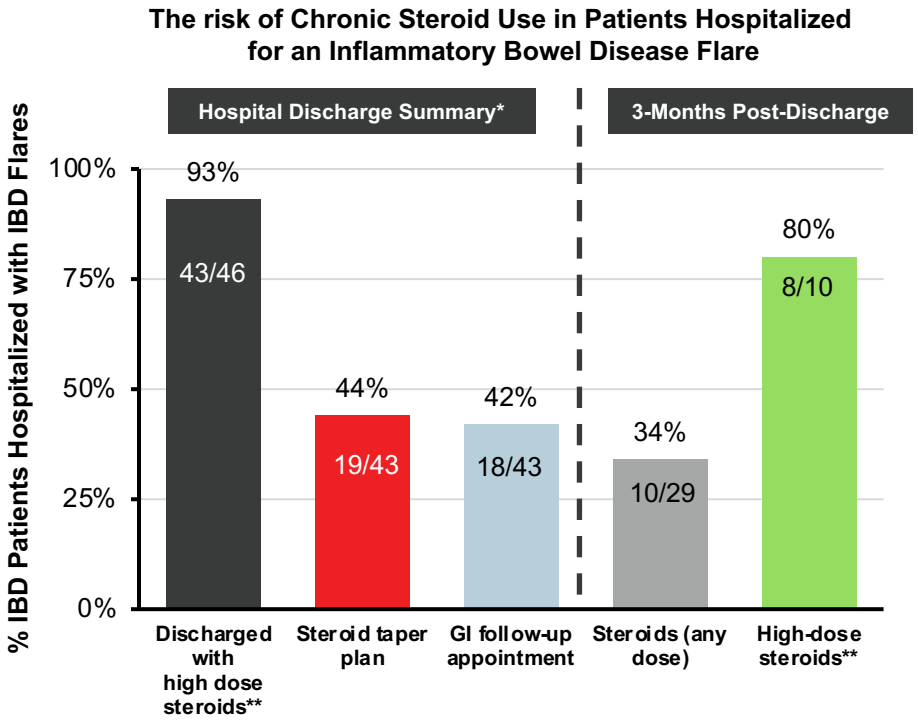
Skin	Skin thinning, purpura, acne, hirsutism, striae
Endocrine	Weight gain, increased blood sugar, adrenal suppression, Cushing syndrome
Eyes	Cataracts and glaucoma
Heart	Edema, hypertension, premature atherosclerosis
GI	Peptic ulcer disease, NAFLD
MSK	Metabolic bone disease, osteonecrosis, myopathy
Psych	Depression, psychosis, sleep disturbance
Immune	Infection

- Number needed to harm = 4

George L, Cross R. *Gastro Clinics of North America*. 2020;49(4):705; Lichtenstein G, et al. *Clin Gastro Hep*. 2006;4(5):621.

Steroid Sparing Therapy

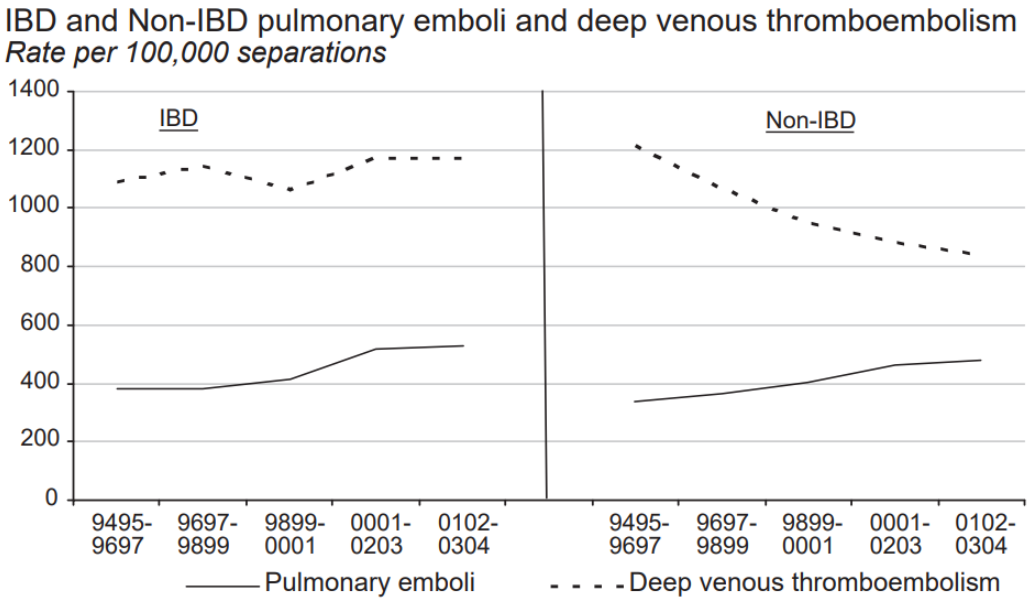
- Reddy et al. *Gastroenterology*. 2005.
- 77% of patients had received a prolonged steroid course, median dose 20mg/day
- In 60%, no attempt was made to transition to steroid sparing therapy
- Steroids are not effective for maintenance of remission!



Paperwork provided to the patient to take-home at the time of hospital discharge.
* High dose steroids is defined as dose-equivalent of of prednisone ≥20 mg per oral (PO).
[1]Hanauer S. *NEJM*. 1995;346:8966; Tse C et al. *Gastroenterology*. 2020;159(2):e39

VTE Prophylaxis

2 to 3 fold increase in VTE risk compared with general population
Specifically increased in flares
VTE prophylaxis is recommended for patients hospitalized with IBD flares without severe bleeding
29.1% of Gastroenterologists were unaware of recommendations for VTE prophylaxis
35% reported they would give VTE prophylaxis to hospitalized patients with severe UC



J Clin Gastroenterol. 2013 Jan;47(1):e1-6; Bernstein C et al. *C J Gastroenterol.* 2007; 21(8):507; Andrade A et al. *Clin and Translational Gastro.* 2018; 9(4):142Ti.

C difficile Testing

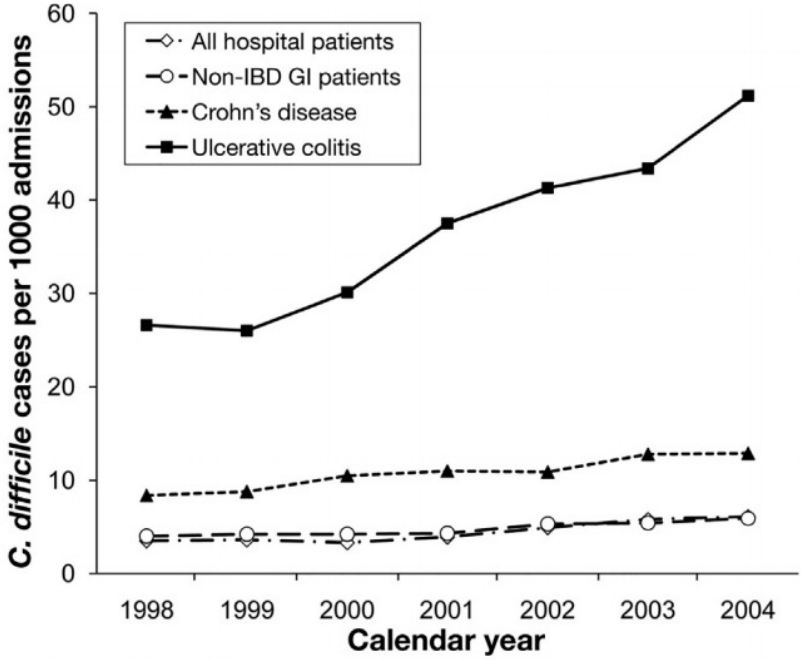


Table 2. Adverse Outcomes of C difficile Infection Complicating Inflammatory Bowel Disease
Subsequent IBD flare
More likely to fail medical therapy
More frequent need to escalate IBD therapy
Higher surgery rates
Higher mortality rate than for IBD alone
More frequent CDI recurrences
Increase emergency room visits
Longer hospital stay
Increase health care costs

Data from Rodemann et al[13]; Issa et al15; Ananthakrishnan et al16; Dubberke et al[19]; Jodorkovsky et al[30]; Khanna and Pardi[31]; and Jen et al[53]; Khanna S et al. *Clin Gastro and Hep*. 2017;15:166.

Tools

IBD Checklist for Monitoring & Prevention™

CORNERSTONES HEALTH

Name: _____

MR#: _____ D.O.B.: _____

Vaccine Preventable Illnesses	Dates Completed
Varicella (Chicken Pox – Live Vaccine) Check Varicella Zoster Virus IgG. If negative consider vaccination. Can be considered in patients on "low dose" immunosuppression (prednisone ≤20mg/day, MTX, 6-MP, azathioprine), but not on biologics. Can administer > 4 weeks prior to starting biologics.	
Herpes Zoster (Shingles – Non-Live Recombinant Vaccine (RZV)) Recommended for patients taking low-dose immunosuppressive therapy and persons anticipating immunosuppression. Recommendations regarding the use of RZV in patients already on higher does immunosuppression have not yet been made by the CDC.	
MMR (Live Vaccine) Contraindicated in immunosuppressed patients and those planning to start immunosuppressants within 4 weeks.	
Diphtheria and Pertussis (Non-Live Vaccine) Vaccinate with Tdap if not given within last ten years, or if Td ≥ 2 years.	
Influenza (Non-Live Vaccine) One dose annually to all patients during flu season. Avoid intranasal live vaccine in immunosuppressed patients.	
HPV (Non-Live Vaccine) Related to cervical and anal cancer. Three doses approved for females and	

Therapy Related Testing	Dates Completed
Mesalamines Annual renal function monitoring.	
Corticosteroids – See Bone Health Document plan and use of corticosteroid-sparing therapy. Consider ophthalmology exam.	
Thiopurines TPMT, CBC, and liver function prior to initiating therapy. Routine CBC and liver function monitoring while on therapy.	
Methotrexate CBC, liver, and renal function prior to initiating therapy. Routine CBC, liver, and renal function monitoring while on therapy.	
Anti-TNFα/Anti-IL-12/23 Tuberculosis (TB) screening prior to initiating therapy with PPD skin testing and/or QuantiFeron-TB Gold assay. Chest X-Ray if high-risk and/or indeterminate PPD or QuantiFeron-TB Gold. Perform annual TB risk assessment and consider re-testing if high risk (including travel to endemic region). See Hepatitis B vaccine. CBC, liver, and renal function prior to initiating therapy and periodic monitoring while on therapy.	
Natalizumab Enrollment in TOUCH program. Check JCV antibody and treat if negative. Retest JCV antibody q 4-6 months prior to initiating therapy. Routine CBC and liver function monitoring while on therapy.	

https://www.cornerstoneshealth.org/ibd-checklists/.

Health Maintenance Checklist for Adult IBD Patients

Vaccine-Preventable Illnesses	Which Patients	How Often
Influenza (inactive)	All	Annually
Pneumococcal PCV13	If on/planning immunosuppression	Once[1]
Pneumococcal PPSV23	If on/planning immunosuppression	At baseline, repeat in 5 years and again after age 65
Tdap	All	Every 10 years
HPV	All aged 11–26 years	Once[1]
Meningococcal meningitis	All adult patients at risk of meningitis	Once[1]
Hepatitis A	If non-immune	Once[1]
Hepatitis B	If non-immune	Once[1]
MMR (live vaccine)	If non-immune[2]	Once[1]
Varicella (live vaccine)	If non-immune[2]	Once[1]
Herpes Zoster	All aged ≥ 50 years[3]	Once[1]

Cancer Prevention	Which Patients	How Often
Cervical PAP smear	All on systemic immunosuppression[4]	Annual
Skin screen	All on systemic immunosuppression[4]	Annual
Colonoscopy	All with colonic disease for >8 years	Every 1–3 years

Other Screenings	Which Patients	How Often
DEXA Scan	High risk; women with low BMI, post-menopausal, chronic steroid exposure	At least 2 years apart
PPD or IGRA	Prior to anti-TNF or anti-IL-12/23	Once (repeat if TB exposure)
Smoking status	All	Annual
Depression check	All	Annual

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1. Recommended timing and spacing of vaccines available in ACIP recommendation
2. Patients treated with systemic immunosuppressive therapy (steroids, thiopurines, anti-TNFs) should not receive live (attenuated) vaccines e.g. measles, mumps, rubella, nasal influenza, varicella, and yellow fever
3. The CDC's ACIP recommends the subunit vaccine (Shingrix) over the live vaccine (Zostavax), and that Shingrix can be administered to patients who have already received Zostavax. Patients receiving anti-TNFs, anti IL-12/23 or >20 mg prednisone should NOT be given the live zoster vaccine.
4. "Systemic immunopsuppression" currently includes azathioprine, mercaptopurine, methotrexate, anti-TNFs, anti-IL-12/23

ADDITIONAL INFORMATION

- ACG
- ACIP
- ACOG
- AGA
- NCI Skin Screen
- National Osteoporosis Foundation

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Indicators

Corticosteroid use: proportion of patients in steroid free remission, proportion of patients currently taking prednisone
Number of days per month and year lost from school or work because of IBD
Number of days hospitalized per year because of IBD
Number of ER visits per year for IBD
Proportion of patients with malnutrition
Proportion of patients with anemia
Proportion of patients with normal disease-targeted health-related quality of life
Proportion of patients currently taking narcotic analgesics
Proportion of patients with nighttime bowel movements or leakage
Proportion of patients with incontinence in the past month

Summary

- There is a gap between what we know and what we do in the treatment of IBD
- Significant variation in care reflects lower quality of care
- Quality Improvement guidance exists
- Process metrics focus on preventative health measures, using safer medications, and excluding competing diagnoses

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