

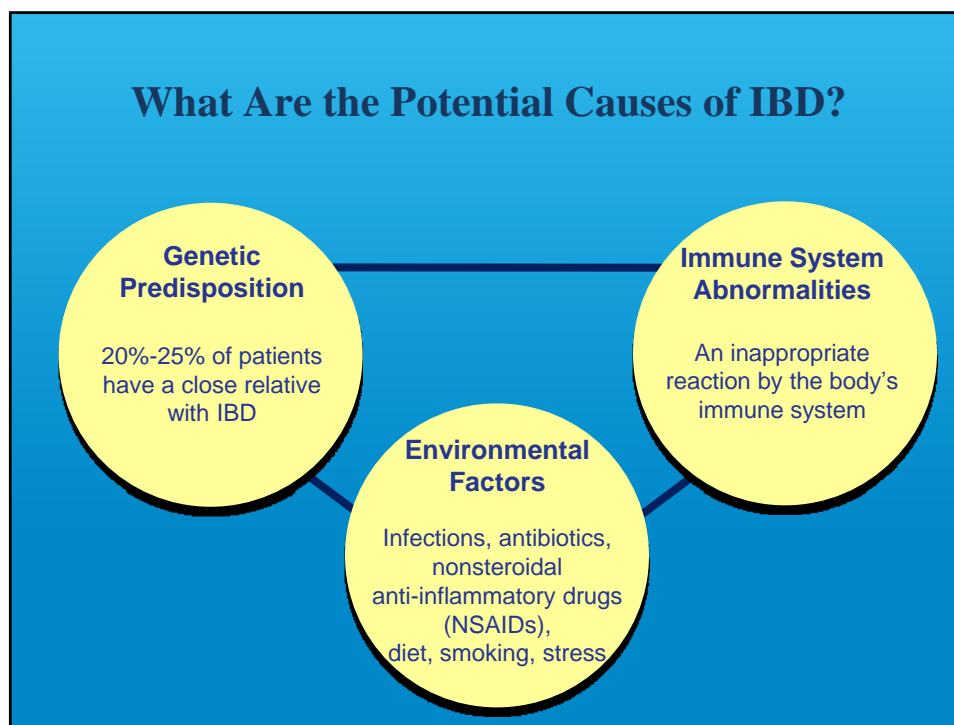
Objectives

- **Today's discussion will address the following topics:**
 - Traditional treatment options for patients with IBD
 - Complementary and alternative medicine options
 - Risks and benefits of different treatment options
 - Self-advocacy for optimizing care
 - Building a relationship with healthcare team

Overview of IBD

- More than 1.4 million Americans are currently living with IBD
- Equal incidences of ulcerative colitis and Crohn's disease
- Peak onset: 15 to 25 years of age
 - Second peak incidence: 50 to 65 years of age
- Symptoms, course of disease, and prognosis differ from one person to the next

What Are the Potential Causes of IBD?



Crohn's Disease vs. Ulcerative Colitis: The Differences

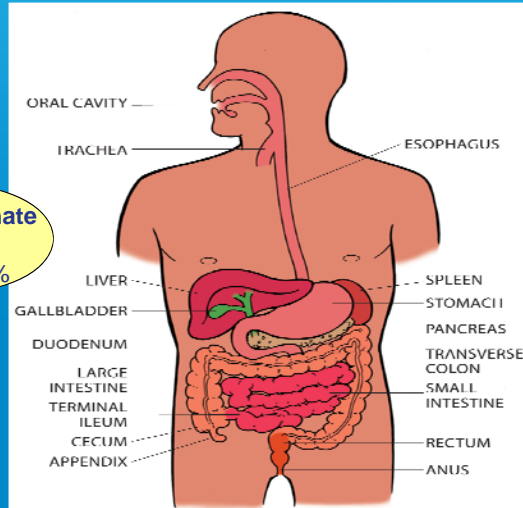
CROHN'S DISEASE

- Patchy, full-thickness inflammation
- Mouth to anus involvement (most commonly ileum and colon)
- Fistulas, abscesses, strictures

Indeterminate Colitis
10%-15%

ULCERATIVE COLITIS

- Continuous, superficial inflammation
- Inflammation in large intestine



Comprehensive IBD Management



The Traditional IBD “Medicine Cabinet”



Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Over-The-Counter (OTC) Medications

- **Address only specific symptoms**
 - Anti-diarrheal agents
 - Laxatives
 - Pain Relievers
- **NSAIDs may cause or worsen GI irritation**
- **Important: talk with your physician *before* taking any OTC medications**

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Antibiotics

Benefits

- Effective in pouchitis, perianal fistulas, abscesses, and in some patients with inflammatory CD

Risks

- Bacterial resistance
- Associated with flares
- Side effects include abdominal cramping and diarrhea
- *C. diff* infection

Antibiotics Typically Used:

- Ciprofloxacin (Cipro®)
- Metronidazole (Flagyl®)
- Rifaximin (Xifaxan®)

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Aminosalicylates (ASAs)

Benefits

- Most useful in inducing and maintaining remission in UC
- Generally well-tolerated
- Formulated to release medication to specific areas of the bowel

Risks

- Few serious side effects

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Aminosalicylates (ASAs) (cont)

5-ASAs Available in United States:

- Balsalazide (Colazal®)
- Mesalamine formulations
 - Delayed release tablets (Lialda®, Asacol®)
 - Controlled release tablets (Pentasa®)
 - Extended release capsules (Apriso™)
 - Rectal suspension (Rowasa®)
 - Rectal suppository (Canasa®)
- Olsalazine (Dipentum®)
- Sulfasalazine (Azulfidine®)

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Corticosteroids

Benefits

- Effective in inducing remission

Risks

- Numerous, including
 - Infection
 - Psychosocial impact: sleep disturbance, mood swings
 - Hypertension, diabetes
 - Physical appearance: weight gain, skin fragility
 - Growth delays and bone loss
- Concerns about dependency
- May stop working

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Examples: Prednisone, Budesonide

Immunomodulators

Benefits

- Used to maintain remission
- Usually taken along with another medication, such as prednisone, to induce remission as they may take 3-4 months to start working
- Once achieved, about 42% of adult patients stay in remission for at least one year

Risks

- Early reactions: fever, pancreatitis
- Adverse events: low white blood cells, elevated liver tests, infection (viral), lymphoma

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Immunomodulators (cont)

Examples:

- Azathioprine (Imuran®, Azasan®)
- 6-Mercaptopurine (Purinethol®)
- Methotrexate

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Biologics

Overview

- “Designer drugs” made to specifically block inflammation or stimulate anti-inflammatory processes
- Given via infusion (IV) or injection

Benefits

- Often administered to patients who do not or no longer respond to standard therapies; also given to patients with markers for severe disease
- 60% of patients respond within first few doses

Risks

- Risk of infections, injection site problems/infusion reactions, lymphoma

Over-the-Counter

Antibiotics

Aminosalicylates

Corticosteroids

Immunomodulators

Biologics

Biologics (cont)

FDA-approved biologics for IBD

Anti-TNF antibodies

- Adalimumab (Humira®)
- Certolizumab pegol (Cimzia®)
- Infliximab (Remicade®)

Selective adhesion molecule

- Natalizumab (Tysabri®)

Over-the-Counter

Antibiotics

Aminosalicylates

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Biologics

Risks of Anti-TNFs and Immunomodulators

If 10,000 patients were treated for 1 year

Event	Estimated Frequency
NHL (baseline)	2/10,000
NHL (on IMs)	4-9/10,000
NHL (on anti-TNF with prior IMs)	4-9/10,000
Hepatosplenic T-cell lymphoma	Unknown
Serious infections (lower for younger patients)	4/1,000
Tuberculosis	5/10,000

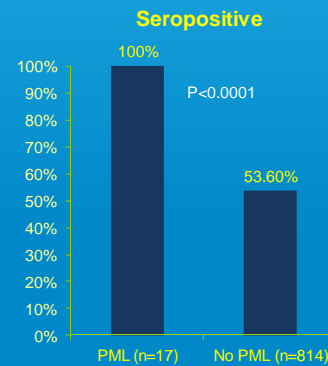
Anti-TNF, anti-tumor necrosis factor; IMs, immunomodulators; NHL, non-Hodgkin lymphoma.
Table adapted from Siegel CA. In *Inflammatory Bowel Disease: Translating Basic Science Into Clinical Practice*. Wiley, 2010.

Natalizumab and Progressive Multifocal Leukoencephalopathy

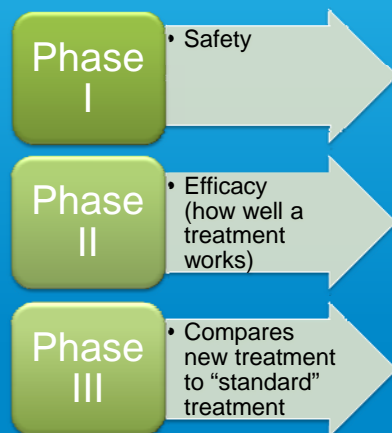
- PML is an infection of the brain by JC virus
- Fatal or debilitating outcomes are common
- Primarily affects immunocompromised individuals
 - Hematologic malignancies
 - HIV
 - Organ transplantation
- Observed in patients treated with natalizumab

Distinguishing Between High Risk and Low Risk Patients

- All natalizumab treated patients who developed PML had antibodies against JC virus prior to developing symptoms
- If antibody positive, risk higher if prior treatment with immunosuppression and with longer duration of treatment (1 in 90 risk with >2 years therapy)



Clinical Trials: The Basics



- Trials are appropriate for many different types of people
- Specific requirements vary by trial
- Fewer trials for children and older adults
- The more people who take part in clinical trials, the faster we will find better ways to treat and potentially cure IBD
- First step: Join CCFA Partners!
www.ccfapartners.org

Visit www.ccfapartners.org or www.clinicaltrials.gov for more information on clinical trials in your area

Surgical Philosophy

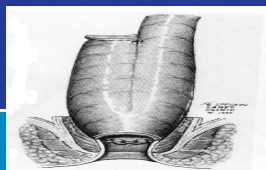
- | | |
|---|--|
| <ul style="list-style-type: none"> ▪ Ulcerative Colitis <ul style="list-style-type: none"> ▪ Operate for medically-refractory disease and for cancer or precancerous lesions ▪ Remove colon & rectum | <ul style="list-style-type: none"> ▪ Crohn's Disease <ul style="list-style-type: none"> ▪ Cure not available ▪ Operate for medically non-reversible manifestations of disease |
|---|--|

Cure

~~**Cure**~~

Types of Surgery in IBD

Ulcerative Colitis	Crohn's Disease
<ul style="list-style-type: none"> ▪ Proctocolectomy (removal of the colon and rectum) <ul style="list-style-type: none"> ▪ With ileostomy ▪ Restorative (ileoanal or J pouch) ▪ Disease is "cured" once the colon is removed 	<ul style="list-style-type: none"> ▪ Strictureplasty ▪ Resection of small intestinal segment ▪ Partial colectomy or proctocolectomy ▪ Perianal surgery ▪ Unlike UC, CD cannot be cured with surgery



Risks of Surgery		
General risks	Crohn's disease-specific risks	UC-specific risks
<ul style="list-style-type: none"> ▪ Complications, as with any surgery ▪ Small bowel obstruction ▪ Psychological implications of ileostomy 	<ul style="list-style-type: none"> ▪ Recurrent disease 	<ul style="list-style-type: none"> ▪ Pouch failure (8% 10% of patients) ▪ Difficulty getting pregnant

Complementary and Alternative Medicine (CAM)

▪ What is CAM?

- A group of diverse medical and health care systems, practices and products not presently part of conventional medicine¹

▪ National Center for Complementary and Alternative Medicine breaks CAM practices into 4 broad groups

- Natural products
 - Supplements, vitamins, probiotics
- Mind and body medicine
 - Meditation, acupuncture, yoga
- Manipulative and body-based practices
 - Massage, spinal manipulation
- Other CAM practices
 - Movement therapies, energy medicine, Chinese medicine

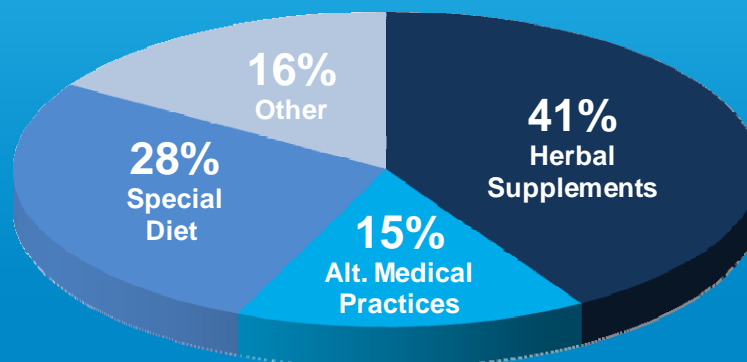
1- NCCAM publication # D347

CAM

- Up to 60% of patients with IBD use CAM¹
- 2 most common reasons IBD patients use CAM²
 - Wanted greater sense of control of self and their IBD
 - Lack of efficacy or side effects from conventional therapy

1- Hilsden et al, *IBD*. 2011;17(2):655-662.
2- Li et al., *Can J Gastro*. 2005;19:567-573.

What Forms of CAM Do IBD Patients Use? (N=1332)



Hilsden, et al. *Am J Gastroenterol*. 2003;98(7):1563-1568.

Probiotics and IBD

- **“Good” bacteria that restore balance to the enteric microbiota-bacteria in the intestines**
- **May be helpful in aiding recovery of the intestine and maintaining remission**
- **Various strains**
 - VSL#3[®], *Escherichia coli* Nissle 1917 (Mutaflor[®]), *Lactobacillus acidophilus* (Flora-Q[®])
- **Important to discuss with physician before initiating treatment**

Other Frequently Used Alternatives

- **Helminthic therapy (worms)**
 - Pig whipworm used to treat both UC and CD
 - Shows promise for symptom control and healing inflamed tissue
 - Clinical trials being conducted with FDA oversight
- **Curcumin, extract from turmeric**
 - Pilot study with UC and CD patients: ASA dosage reduction in UC patients and symptomatic improvement in CD patients¹
 - Large trial in quiescent UC: 2 relapses in treated group versus 8 in ASA-only group within 6-month treatment period²
 - Larger scale prospective studies needed
- **Fish oil supplements containing omega-3 fatty acids³**
 - May reduce pain and inflammation when added to standard therapy
 - Clinical trial results are inconsistent, no clear recommendation

1. Holt, et al. *Dig Dis Sci.* 2005; 2. Hanai, et al. *Clin Gastroenterol Hepatol.* 2006; 3. Feagan, et al. *JAMA.* 2008.

Weigh the Risks and Benefits of CAM

- **Pros:** Can provide benefit when used as adjuvant therapy, restores some sense of control
- **Cons:** Side effects, may undermine doctor patient relationship, expense (most not covered by insurance), optimal dosing may not be known, not FDA-regulated
- **Takeaways**
 - **Important to seek out good data to minimize potential risk**
 - Choose well-researched options
 - Consider the qualifications of the information resource
 - **Alternative therapies should complement, not replace, traditional therapies**
 - **Tell your doctor everything you are taking**

Self-Advocacy for Optimizing Care

Self-Advocacy for Optimizing Care: Key Points

- **Why is this important?**
 - Patients who are more involved in their healthcare are more adherent with treatment and have better outcomes
- **What are the keys to becoming an “empowered patient”?**
 - Choose the right healthcare team for you
 - Be prepared for your doctor’s visit
 - Keep track of your healthcare information
 - Get educated about your disease and treatment options
 - Build a support network

Self-Advocacy for Optimizing Care: Choosing a Healthcare Team

- **Choose a healthcare team/facility that you are comfortable with and trust**
 - **Use resources to research doctor’s experience and competence**
 - www.abms.org
 - www.docinfo.org
 - www.acg.gi.org
 - www.gastro.org
 - www.ccfa.org
 - **Interview the doctor**
 - How many patients do you treat with IBD?
 - Do you do research?
 - Who is on your treatment team?
 - How do I reach you if I am sick?

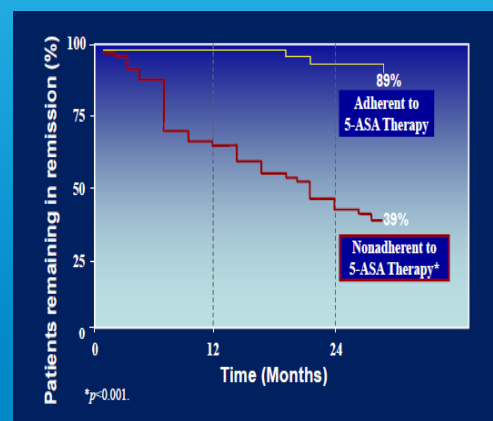
Self-Advocacy for Optimizing Care: Being Your Own Advocate

- **The most satisfied patients take part in talks and decisions about their healthcare.** Talk with your doctor in an open and honest way. This can lead to better and safer healthcare decisions.
- **Tell your doctor all of the treatments you are taking**
 - Helps foster trust
 - Reduces chance of interactions/side effects
 - Improves adherence

“Drugs don’t work in patients who don’t take them” – C. Everett Koop, MD

Adherence generally associated with improved outcomes

- Decreased risk of disease progression
- Reduced inflammation and increased healing of GI lining
- Possible decreased risk of colorectal cancer
- Evidence demonstrates patients who continue their maintenance medications are less likely to experience flares



Kane et al, *Am J Med.* 2003;114(1):39-43

Self-Advocacy for Optimizing Care: Prepare for your Doctor's Appointment—Make Lists

- Be prepared for your doctor's visit
 - Make a prioritized list!!!
 - Bring someone you trust with you
- Write down symptoms, side effects, questions, etc. you want to discuss
 - www.IBDetermined.org
 - www.cdfa.org

CROHN'S & COLITIS FOUNDATION OF AMERICA **IIBDetermined**

IBD Doctor Discussion Guide

This guide can help you and your doctor see how inflammatory bowel disease (IBD) is affecting you, and if you could be doing more to manage your IBD. Print this guide, complete the first part, and bring the guide with you to your next appointment.

Share the following information with your doctor:

- During the past month, I had the following average number of soft to loose bowel movements per day. (Note: It may be helpful to keep a daily diary of these symptoms for a week prior to your visit.)
- Over the past month, I would rate the severity of my abdominal pain as: None Mild Moderate Severe
- I've experienced the following average number of flare-ups over the past year. (Note: A flare-up is a period of symptom activity and can include abdominal pain, stool changes, urgency, loss of appetite, among other symptoms.)
- Since my last visit, I've experienced the following IBD challenges: _____
- I've done the following things to avoid or reduce these challenges (e.g., skipped meals, declined social engagements, avoided activities I enjoy): _____
- Emotionally, IBD has affected me in the following ways: _____
- I've experienced the following changes in appetite, diet or body weight over the past 6 months: _____
- I've experienced the following complications over the past month (e.g., joint pain, skin issues, eye issues, liver or kidney issues): _____
- Since starting my current treatment, my disease symptoms have improved in the following ways: _____ (Note: If you have not noticed symptom improvement with your current treatment, please indicate this here.)

Sample questions to ask your doctor:

- Which treatment options may be right for me?
 1. What are the benefits and risks/side effects of these options?
 2. How long might it take before I see an improvement in my symptoms?
 3. What can I do to ensure I'm getting the most from my medication?
 4. What else can I do, in addition to taking my medication, to effectively manage my IBD?

www.cdfa.org | www.IBDetermined.org

Self-Advocacy for Optimizing Care: Being Your Own Advocate

- Keep track of your medical history
- Know what health maintenance items you need
- Ask questions (and listen)!

Health Care Maintenance Chart

	YEAR	
PPD (Tuberculosis skin test)		
Vaccinations		
• Hepatitis A		
• Hepatitis B		
• HPV		
• Influenza		
• H1N1		
• Pneumococcal		
• Td/Tdap		
• MMR		
• Varicella/Zoster*		
Cancer screening		
• Cervical (Pap smear)		
• Breast cancer		
• Prostate cancer		
• Colon cancer / dysplasia screening (colonoscopy)		
• Skin cancer screening		
Screening other		
• Blood pressure		
• Ophthalmologic		
• Osteoporosis (DEXA scan)		
Laboratory exam		
• Complete blood cell count		
• Liver function tests		
• Creatinine		
• B12/Transferrin		
• 25-OH vitamin D		
• Lipids		
• Glucose		
• Other		

*See your doctor for contraindications in patients on biologic therapy. Therefore, they should be given prior to initiating biologics.

Revised 12/11/09

CROHN'S & COLITIS FOUNDATION OF AMERICA www.cdfa.org Information Resource Center: 888.694.8872

Self-advocacy for Optimizing Care: Get Educated

- **Knowledge is powerful. Learn more about IBD and your medical options.**
 - **Ask your doctor (and ask them to explain if you do not understand answer) and take notes**
 - What are my active health issues?
 - What are my treatment options?
 - What are the risks and benefits?
 - **Bring family member or trusted friend to appointments**
 - **Attend local education conferences**

Self-Advocacy for Optimizing Care: Finding Reliable Information Online

- **Consider the source, and use several**
- **Questions to ask**
 - Is this opinion or fact?
 - Who is the author?
 - When was the information last updated?
 - Look for posting/revision dates
 - Are there references/citations for the information?
 - Is there any bias/commercial interest with the information?
 - Find out if the site is associated with a specific product or service
 - Read the privacy policy
- **Visit www.ccfa.org or contact the Information Resource Center at info@ccfa.org**

Source: <http://ibdcolhns.about.com>

Self-Advocacy for Optimizing Care: Build Support Network

- **Hard to do it alone. So ask for help from friends, family, fellow patients**
- **Attend local support group meetings**
- **CCFA Community site (www.ccfacommunity.org)**
 - Forum/message board
 - Online support groups
- **Get involved**

Question and Answer Session

We Want Your Feedback!
www.surveymonkey.com/s/IBDdecisions

To Participate in CCFA Partners
www.ccfapartners.org

Please Consider Making a Donation
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