

Rady Children's Inflammatory **Bowel Disease** Center

IBD FAMILY DAY

MARCH 16, 2024



Main Agenda

Staff introduction

Time	Event	
08:30-09:00	Sign In/Registration	
09:00-09:05	Welcome to IBD Family Day; Staff Introduction	
09:05-09:15	What are the Goals of IBD Care at the Rady IBD Center?	
	• What can I expect from the care at the Rady IBD Center?	
_	• What is the Rady IBD Center's general IBD care approach?	
09:15-09:25	What Research Opportunities are there at the Rady IBD Center?	
	Why should I participate in Research?	
	• What study opportunities are there at the Rady IBD Center?	
09:25-09:35	Psychology and IBD	
	Why do we screen patients for depression/anxiety?	
	What interventions are offered?	
09:35-09:50	Diet and IBD	
	What is the role of diet in IBD Care	
	Review of IBD Diets	
09:50-10:05	Surgery and IBD	
	• What is the role of surgery in IBD care	
	Review of IBD surgeries	
10:05-10:30	Q&A, Panel	
10:30-11:00	Break and Booth visits	
11:00-12:00	Concurrent Sessions	
	Parents/Caregivers	
	Patients	



Goals of Care at Rady's Inflammatory Bowel Disease (IBD) Center

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MARCH 2024

Overview

- •Brief overview of IBD
 - Natural Course
- Therapeutic Options
- Measures of Health
- •Overriding goals of therapy

Rady Children's Hospital-San Diego

What is IBD?

Inflammatory bowel disease (IBD)

 Group of disorders characterized by chronic inflammation of the intestines/digestive tract

 Associated with extraintestinal issues – joints/liver/skin/eye/bone





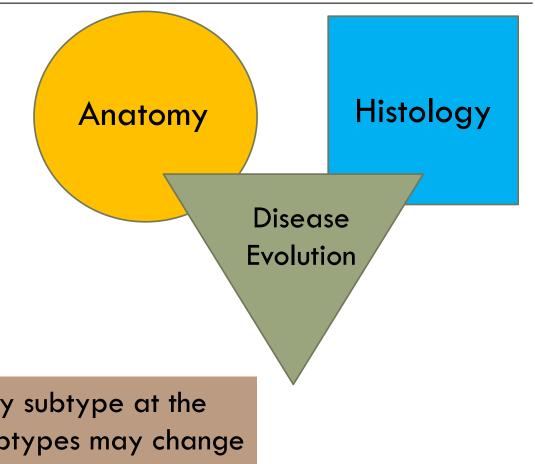
Types of IBD

3 main subtypes

Crohn's

Ulcerative Colitis

Indeterminate Colitis

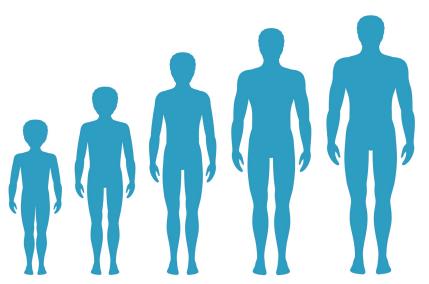


<u>BOTTOM LINE</u>: We provide a preliminary subtype at the time of diagnosis but as things evolve subtypes may change

Age of Disease Onset matters

PEDIATRIC IBD is NOT ADULT-ONSET IBD

- Additional considerations in children
- ° Growth
- Development



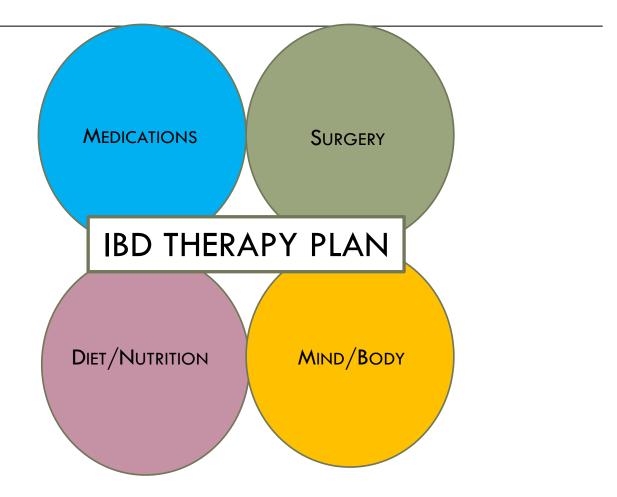
Natural history of IBD

Crohn's	Ulcerative Colitis
Extension of Disease to other parts of GI Tract (1 in 3)	Extension of Disease from Limited Colon to Entire Colon (3 out of 4) (Majority present with Entire Colon involvement)
Changing from inflammation only to development of strictures/fistulizing disease	
Poor growth, inability to obtain normal adult height or true height potential	Extraintestinal manifestations common – 1 in 5 (majority involving joints or liver)
Increasing need for surgical management – ONE in THREE at 5 years from diagnosis	Risk of surgery – 5% at 1 year; 15-20% at 10 years
Cancer	Cancer

Treatments

Multidisciplinary

- Medications
- Surgery
- Diet/Nutrition
- Mind/Body





How do we come up with a treatment plan?

We decide treatment as a team **TOGETHER** – • YOU & IBD CARE TEAM

Patient Concerns/Health Goals

- Risk and **Benefits**
- Disease treatment chosen based on your CHILD's specific needs/concerns

Feasibility

- Schedule
- Affordability/Insurance Coverage



Medications

Many Options

Mechanism of Action –

- $^{\circ}$ All act on the immune system, many immunosuppressive
- ° Class of medications how a medication works
 - Anti-TNF, Anti-Interleukins, Anti-Integrins, JAK Inhibitors
- Important thing to remember is what class of medications your medication is in and
- What works for you?

WHAT IS A BIOSIMILAR?

A biosimilar is a biological product

FDA-approved biosimilars have been compared to an FDA-approved biologic, known as the reference product. Reference and biosimilar products are:







Large and generally complex molecules

Produced from Living organisms

Carefully monitored to ensure consistent quality

A biosimilar is highly similar to a reference product

For approval, the structure and function of an approved biosimilar were compared to a reference product, looking at key characteristics such as:







Molecular structure

Bioactivity

The data from these comparisons must show that the biosimilar is highly similar to the reference product.

A biosimilar has no clinically meaningful differences from a reference product

Studies were performed to show that biosimilars have no clinically meaningful differences in safety, purity, or potency (safety and effectiveness) compared to the reference product:











Additional clinical studies as needed

Studies may be done independently or combined.

INTERCHANGEABILITY⁴

Switching between the reference product and biosimilar product → No increase in safety risks or decrease in clinical efficacy. Clinical data must demonstrate that the biosimilar product will produce the same clinical response in <u>any given</u> <u>patient.</u>

Because Biosimilars are NOT COMPLETELY IDENTICAL with the reference product, consultation with the provider is still needed at this time.



Biosimilars

Many insurance companies are asking patients to switch to a biosimilar from a brand name

Feel free to ask your provider about this

Know that many patients have undergone this switch without problems

ALSO Know that we will continue to ensure that you/your child are responding the same to the biosimilar as you/your child had to the brand name agent

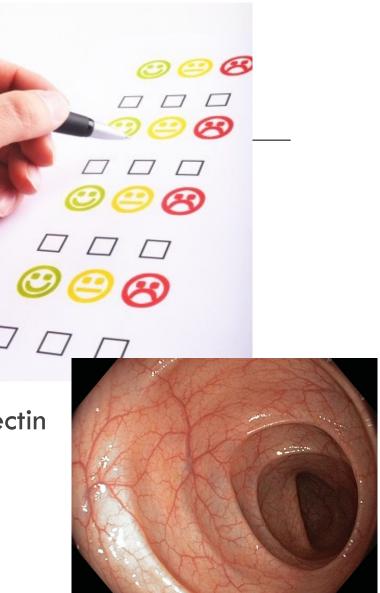
Measures of Health

Self-report

- ° Symptoms (PUCAI (not just for UC))
- Quality of Life/Depression/Anxiety (12y and older)

Objective

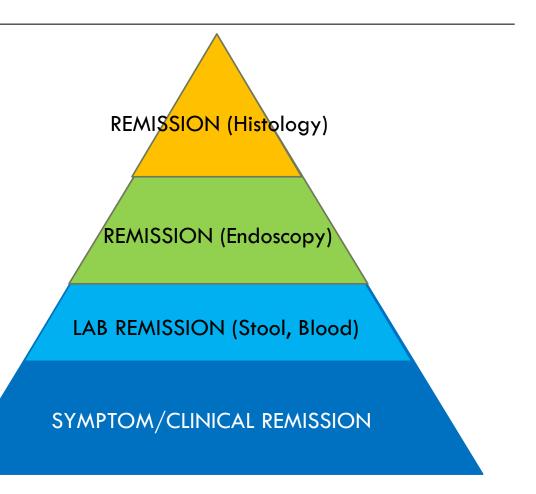
- Inflammatory markers C reactive protein/ESR/Calprotectin
- General labs (Blood counts, chemistries)
- Endoscopy & Histology
- ° Imaging



Goals of Therapy

Remission

- Symptoms (Clinical)
- Laboratory/Endoscopy/Histology
- Symptoms are just part of the picture
- Different levels of remission



GOALS FOR INFLAMMATORY BOWEL DISEASE THERAPY



Ideal remission changes the natural course of IBD

True for ALL IBD

Reduced rates of disease relapse

Reduced rates of hospitalization and surgeries



How to achieve goals of therapy

We are a team

Open honest and frequent communications with your provider

- Frequent follow up - at least 3-4x per year (usually every 3-4 months)

Important to adhere to treatment plan

Adhere to monitoring plan

- Inclusive of symptoms, labs, endoscopic evaluations



Withdrawal of Medications

IBD is not "temporary" or curable. It is a chronic disease.

Once we withdraw medications, one is likely to flare

- The better the remission, the lower the likelihood of flaring, but often remission is not forever
- 50% of patients who have achieved deep remission within 1-2 yrs

HOWEVER, in children, goals include

- ° Obtaining final adult height
- ° Obtaining ideal bone health





In Summary

IBD is a chronic disease requiring chronic therapy to maintain remission

➢Therapies are multifaceted

>We aim to work WITH YOU to achieve the best health outcomes (ideal remission) for YOUR CHILD

Achieving deep remission can change the natural history of the disease

Follow-up and regular check-ins are essential to achieving goals of therapy

