

# Practicality of the Usage of Medical Foods to Assure Compliance and Meet Nutritional Requirements: Patient Perspective

MEDICAL FOODS WORKSHOP:  
Science, Regulation  
and Practical Aspects

AUGUST 13-14, 2019 WASHINGTON, DC

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Disclosures: UC Narrative Advisory Board, IBDGAPPS Advisory Board,

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# Objectives

## The IBD Patient Point of View

- IBD– Patient Experience
- Modification of Diet Alone (MODA)
- Distinctive Nutritional Requirements
- Medical Foods: Patient Information from the Crohn's & Colitis Foundation
- Medical Foods: Patient Challenges
- Summary

# IBD – Patient Experience



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# Medical Foods – Patient Perspective

IBD is a complex disease

- No one size fits all approach to treatment
- Treatment may change over time
- Disease may range from mild, moderate, to severe

Given the complexity, treatment decisions are difficult

- Drug therapy may come with serious and life threatening side effects
  - Fear biologics
- Patients are looking for treatment options that lead to positive health outcomes
  - without risks of serious/life threatening side effects
- Enteral therapy, especially in pediatric Crohn's disease has been shown to induce and retain remission
  - Side effects are consider less serious than other therapies

# Modification of Diet Alone (MODA)

Patients are open to diet modifications

- Evidence by popularity of SCD diet, Low-FODMAP, etc.
- These diets are often difficult for patient to manage and sustain
- Precision Nutrition in IBD
  - Foundation recently launched an RFP
  - Answer the question – “what should I eat”
  - Focus of the RFP
    - Understand the mechanisms of response to food in IBD patients and their correlation to disease outcome
    - Pre-clinical model-based studies to identify signatures and/or mechanisms of response to food and their correlation to IBD

## References:

Crohn's & Colitis Foundation – Precision Nutrition in IBD: <https://www.crohnscolitisfoundation.org/research/grants-fellowships/precision-nutrition-IBD>

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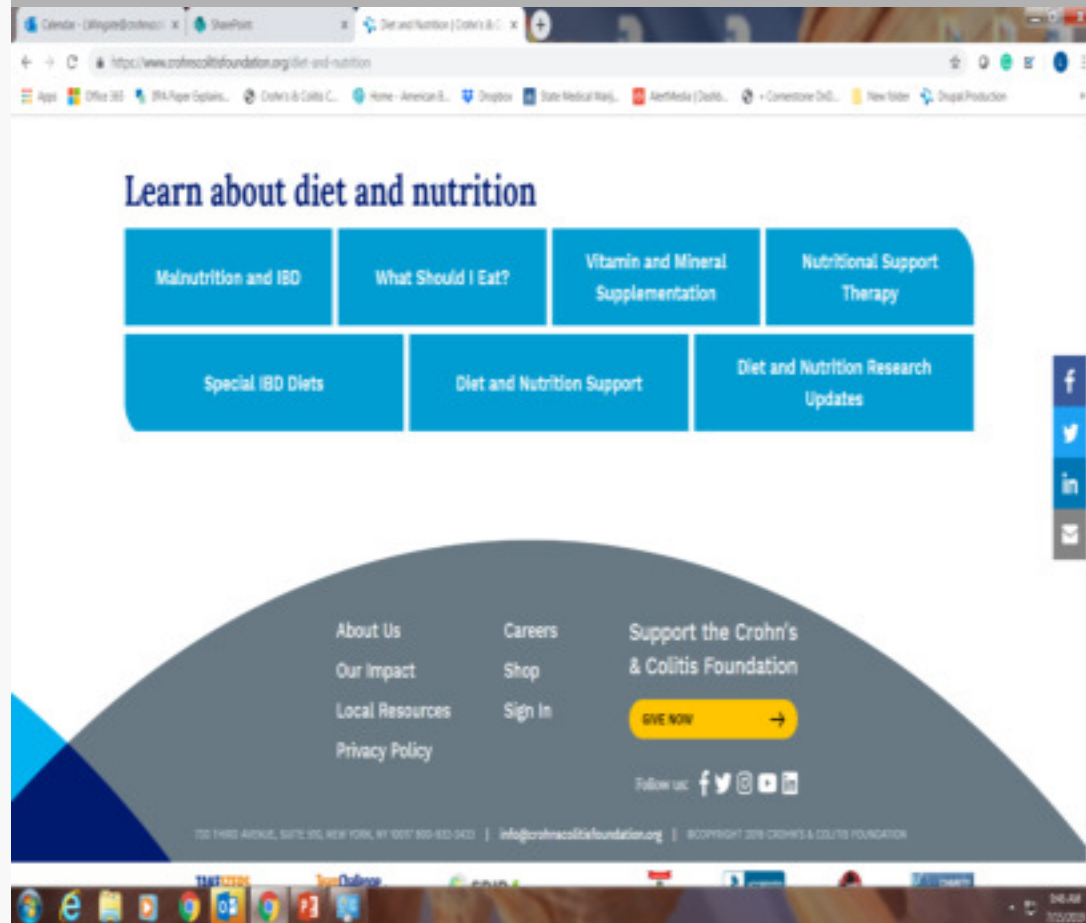
# Distinctive Nutritional Requirements

- IBD Patients often experience
  - Vitamin deficiencies – B12, calcium, D
  - Malnutrition – 1/3 patients from IBD Qorus study identified as malnourished
  - Iron deficiency Anemia
- Medical foods are generally not used to manage malnutrition, anemia, and vitamin deficiencies
- Distinctive Nutritional Requirements has little meaning to a patient or caregiver
- Evidence supports using medical foods
  - Induce remission in children with mild to moderate CD
    - Pediatric patients can even delay the need for biologic or other therapies
  - Evidence is growing to support use in Adult IBD – CD-Treat
- Enteral nutrition supports positive health outcomes for IBD

## References:

- IBD in Clinical Practice: Malnutrition Update for Healthcare Providers 2018
- Levine A, et al, *Crohn's Disease Exclusion Diet Plus Partial Enteral Nutrition Induces Sustained Remission in a Randomized Controlled Trial*, *Gastroenterology*, 2019, June 4, accessed July 15, 2019

# Medical Foods – Patient Information Provided by Crohn's & Colitis Foundation



- Dedicated section of website for diet and nutrition
- Total visits 39,000 annually

Education focused on:

- Nutrition and malnutrition
- Medical foods – as treatment

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# Medical Foods – Patient Information Provided by Crohn’s & Colitis Foundation

## Parenteral and Enteral Nutrition

### PARENTERAL NUTRITION

Feeding intravenously, bypassing the usual process of eating and digestion.

**A** Feeding through the central vein

**B** Feeding through peripheral veins

### ENTERAL NUTRITION

Liquid supplemental nutrition is either taken by mouth or is given via a feeding tube.

Nasal or oral feeding tube terminates at, either:

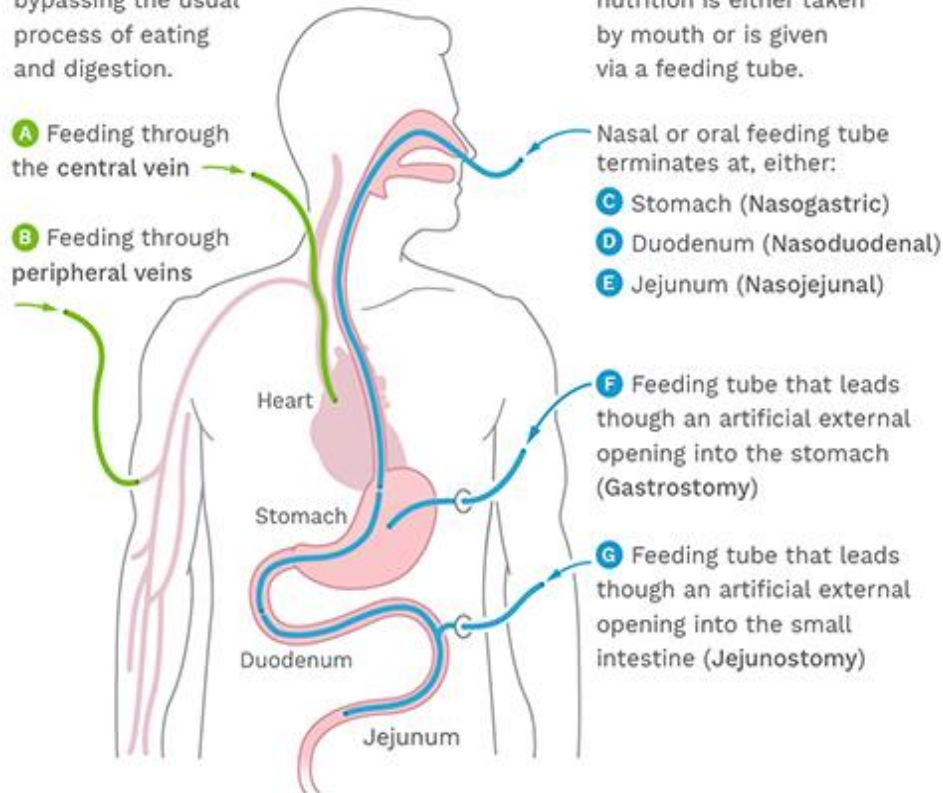
**C** Stomach (Nasogastric)

**D** Duodenum (Nasoduodenal)

**E** Jejunum (Nasojejunal)

**F** Feeding tube that leads through an artificial external opening into the stomach (Gastrostomy)

**G** Feeding tube that leads through an artificial external opening into the small intestine (Jejunostomy)



- Dedicated resources explaining:
  - Enteral nutrition
    - Nasogastric tube
    - Nasoduodenal tube
    - Gastrostomy/Jejunostomy tube
    - Partial Enteral Nutrition
    - Exclusive Enteral nutrition
  - Parenteral Nutrition
  - Over 1,100 visitors nutritional support page annually

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# Medical Foods – Patient Challenges

- Coverage of enteral therapies varies
  - Most insurers will cover administration by NG tubes
  - Patient-reported preference for - oral formulations, but pay out-of-pocket
- Limitations of enteral therapies
  - Insurance coverage can be challenging– especially for pediatric population
  - Adherence – challenging to stay on therapy – limited or no regular food
- Foundation Member survey\*
  - 1,052 respondents, Fall 2018
  - 9.4% of respondents report lack of coverage for liquid or oral nutrition
    - Reported out of pocket costs ranged \$25 - \$5,400 annually

\* **Reference:** Crohn's & Colitis Foundation Advocacy and Access to Care Survey, December 2018

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# Summary – Patient Perspective

## Research and policy need to advance

- Understand the role of diet modification alone as a therapeutic strategy in IBD
- FDA definition of medical foods should consider
  - Disease severity, heterogeneity, and positive health outcomes for patient
  - Incorporating variation of delivery (oral, NG tube, etc.) of enteral nutrition
  - Expanding the definition to have broader applicability and applying it more flexibly
  - Evidence-based approach that can accommodate new and emerging research

### References:

Toa Zuo and Siew C. Ng, *The Gut Microbiota in the Pathogenesis and Therapeutics of Inflammatory Bowel Disease*, NCBI, **Frontiers in Microbiology**, 2018 Sep 25, Accessed July 15, 2019

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