

## **Understanding Decision Making for Choosing Dietary Therapy in Children with IBD**

### **A. Study Purpose and Rationale:**

Inflammatory Bowel Disease (IBD) represents a chronic relapsing disease process with a wide range of clinical presentations and manifestations and an unclear etiology [1]. This diagnosis is life-changing for families and generally means that the patient will require medical therapy indefinitely [1]. Though medication is the mainstay of treatment, dietary therapies do exist, with varying degrees of data to promote their efficacy [2]. They range in restrictiveness from the most restrictive Exclusive Enteral Nutrition (EEN) diet, consisting of 4-12 weeks of exclusive formula consumption, to the CD-TREAT diet, which eliminates only gluten, lactose, and alcohol [2].

Data also suggest that diet may play a role in the pathogenesis of IBD, as studies of immigrants to Western countries demonstrate a higher incidence of IBD among immigrants than their native compatriots [3-6]. Many patients with IBD will often notice that certain foods lead to worsening of symptoms, and will avoid these foods [7-8]. However, dietary modification is not without risk, as these patients may develop deficiencies in micro and macronutrients [9].

Though dietary therapy is less commonly physicians' treatment of choice in the US than it is in Europe (where it is first-line treatment for induction of remission) [10], many patients may choose to partake in some form of dietary therapy from the onset of diagnosis [7]. Fear of causing relapses or flares often lead those with IBD to avoid certain of their favorite foods [11]. However, they do not discuss when in the disease course this study's survey was administered. The decision-making process for dietary changes early in the disease course is not well understood. Understanding the motivations for making dietary changes will be helpful for physicians to properly counsel patients with IBD about the most efficacious and appropriate dietary therapies. Our study attempts to elucidate these decision-making factors so that physicians can better use dietary therapies when appropriate to achieve improved clinical outcomes in pediatric patients with IBD.

### **B. Study Design:**

The study will be a prospective questionnaire based study involving questionnaires administered to the parents or legal guardians of patients recently diagnosed with IBD, as defined as diagnosis within the past 6 months, at otherwise scheduled visits for regular IBD care. The questionnaires will be formulated with Likert scale questions to assess the attitudes regarding the perceived difficulty of making dietary changes, desires for autonomy, concern about affordability as well as other questions deemed relevant to the decision-making process in concert with the CHONY IBD dietician.

**C. Subject Selection:**

The subjects will be the caregivers of patients with newly diagnosed IBD who present to the CHONY gastroenterology clinic for general care.

**D. Statistical Procedures:**

The initial variable of concern will be whether the family intends to make dietary changes. Data from each question on the Likert scale will be compared between the two groups of dietary planners and non-planners.

**E. Study Procedures:**

No Procedures will be performed.

**F. Study Drugs:**

No study drugs, approved, or investigational drugs will be given in this study.

**G. Medical Device:**

No medical devices will be used in this study.

**H. Study Questionnaires:**

A questionnaire will be designed to be given for caregivers of patients to complete at regularly scheduled visits for evaluation for and maintenance of IBD.

**I. Recruitment of Subjects:**

Subjects will be provided consent forms while at otherwise scheduled appointments for evaluation for or maintenance of IBD prior to completion of the study questionnaire.

**J. Confidentiality:**

Data will be de-identified, with each subject given a unique study ID.

**K. Potential Conflicts of Interest:**

None

**L. Location of Study:**

The study will take place in the Morgan Stanley Children's Hospital Gastroenterology Clinic.

**M. Potential Risks:**

The study has minimal risk to the subjects involved. There is a risk of subliminally encouraging the use of alternative therapies.

**N. Potential Benefits:**

There may not be direct benefits to the patients during the time of the study. However, the understanding of the decision-making process regarding dietary therapy may allow

physicians and dieticians to better advise patients on the most evidenced-based dietary therapies for those who are most interested.

**O. Alternative Therapies:**

N/A

**P. Compensation to Subjects:**

No monetary compensation will be provided for participants.

**Q. Costs to Subjects:**

This study will not incur additional cost to the subjects.

**R. Minors as Research Subjects:**

The questionnaire will be administered to parents of patients. Methods to maintain confidentiality are detailed above.

**S. Radiation or Radioactive Subjects:**

No radiation is involved.

**References:**

1. Fakhoury M, Negrulj R, Mooranian A, Al-Salami H. Inflammatory bowel disease: clinical aspects and treatments. *J Inflamm Res*. 2014;7:113-120. Published 2014 Jun 23. doi:10.2147/JIR.S65979
2. Nazarenkov N, Seeger K, Beeken L, et al. Implementing Dietary Modifications and Assessing Nutritional Adequacy of Diets for Inflammatory Bowel Disease. *Gastroenterol Hepatol (N Y)*. 2019;15(3):133-144.
3. Barreiro-de Acosta, M.; Alvarez Castro, A.; Souto, R.; Iglesias, M.; Lorenzo, A.; Dominguez-Muñoz, J.E. Emigration to western industrialized countries: A risk factor for developing inflammatory bowel disease. *J. Crohn's Colitis* 2011, 5, 566–569.
4. Li, X.; Sundquist, J.; Hemminki, K.; Sundquist, K. Risk of inflammatory bowel disease in first- and second-generation immigrants in SwedenA nationwide follow-up study. *Inflamm. Bowel Dis*. 2011, 17, 1784–1791.
5. Damas, O.M.; Avalos, D.J.; Palacio, A.M.; Gomez, L.; Quintero, M.A.; Deshpande, A.R.; Sussman, D.A.; McCauley, J.L.; Lopez, J.; Schwartz, S.J.; et al. Inflammatory bowel disease is presenting sooner after immigration in more recent US immigrants from Cuba. *Aliment. Pharmacol. Ther*. 2017, 46, 303–309
6. Benchimol, E.I.; Mack, D.R.; Guttman, A.; Nguyen, G.C.; To, T.; Mojaverian, N.; Quach, P.; Manuel, G.D. Inflammatory bowel disease in immigrants to Canada and their children: A population-based cohort study. *Am. J. Gastroenterol*. 2015, 110, 553–563.
7. Zallot, C., Quilliot, D., Chevaux, J.-B., Peyrin-Biroulet, C., Guéant-Rodriguez, R.M., Freling, E., Collet-Fenetrier, B., Williet, N., Ziegler, O., Bigard, M.-A., Guéant, J.-L. and Peyrin-Biroulet, L. (2012), Dietary beliefs and behavior among inflammatory bowel disease patients. *Inflamm Bowel Dis*.

8. Cohen AB, Lee D, Long MD et al. Dietary patterns and self-reported associations of diet with symptoms of inflammatory bowel disease. *Dig Dis Sci*. 2013;58(05):1322–1328.
9. Sousa Guerreiro C, Cravo M, Costa AR et al. A comprehensive approach to evaluate nutritional status in Crohn's patients in the era of biologic therapy: a case-control study. *Am J Gastroenterol*. 2007;102(11):2551–2556
10. F.M. Ruemmele, G. Veres, K.L. Kolho, A. Griffiths, A. Levine, J.C. Escher, J. Amil Dias, A. Barabino, C.P. Braegger, J. Bronsky, S. Buderus, J. Martín-de-Carpi, L. De Ridder, U.L. Fagerberg, J.P. Hugot, J. Kierkus, S. Kolacek, S. Koletzko, P. Lionetti, E. Miele, V.M. Navas López, A. Paerregaard, R.K. Russell, D.E. Serban, R. Shaoul, P. Van Rheenen, G. Veereman, B. Weiss, D. Wilson, A. Dignass, A. Eliakim, H. Winter, D. Turner, Consensus guidelines of ECCO/ESPGHAN on the medical management of pediatric Crohn's disease, *Journal of Crohn's and Colitis*, Volume 8, Issue 10, October 2014, Pages 1179-1207
11. Jimmy K. Limdi, MBBS, Divya Aggarwal, MBBS, John T. McLaughlin, MBChB, PhD, Dietary Practices and Beliefs in Patients with Inflammatory Bowel Disease, *Inflammatory Bowel Diseases*, Volume 22, Issue 1,