



Research Priorities for Fecal Incontinence: The Patient's Perspective

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IFFGD Meeting on Advancing the Treatment of Incontinence

Incontinence is a disorder that affects men and women of all ages, often with devastating personal and societal consequences. It can lead to social isolation, loss of employment, and institutionalization. The economic impact has been estimated at \$16 to \$26 billion annually in the U.S. Fecal incontinence is estimated to affect 2%–7% of adults while urinary incontinence occurs in a third of adults and is severe enough to interfere with the quality of life and work in 6%. In the IFFGD survey, *IBS in the Real World*, 25% of respondents with IBS reported loss of bowel control.

To address issues surrounding incontinence, IFFGD and the Office of Continuing Medical Education at the University of Wisconsin Medical School sponsored a meeting, **Advancing the Treatment of Fecal & Urinary Incontinence Through Research: Trial Design, Outcome Measures, and Research Priorities**, held November 3–5, 2002, in Milwaukee, Wisconsin.

This was an interdisciplinary conference with international participation from over 180 gastroenterologists, urologists, colon and rectal surgeons, gynecologists, neurologists, geriatricians, pediatricians, nurses, psychologists, patient advocates, and representatives of the National Institutes of Health (NIH). The purpose of the conference was to:

- Summarize the state-of-the-science regarding epidemiology, pathophysiology, and available treatments for fecal and urinary incontinence;
- Summarize available literature on outcome measures, predictors of successful treatment, and research design;
- Identify the priorities for research from the perspective of each professional subspecialty concerned with the management of incontinence.

Opening remarks at the meeting were presented by Nancy Norton, President of IFFGD and the driving force behind this symposium, and by William Whitehead, PhD, Chairman of the planning committee, which brought together a distinguished and diverse group of thought leaders and investigators for the conference.

This conference is an outgrowth of the first IFFGD sponsored meeting held in Milwaukee in 1999, the

Consensus Conference on Treatment Options for Fecal Incontinence.

The aim of the first meeting was to draft a statement to summarize available treatment options that could be used by primary care physicians in the treatment of patients. The Consensus Report was published in the *Diseases of the Colon & Rectum* (Volume 44, Number 1, January, 2001). While the report has had an impact on clinical practice, issues raised in the first conference led to the current meeting.

The research base of current health care delivery for incontinence is relatively limited. While there are many treatments available – medical, behavioral, and surgical – few randomized trials in support of these treatments have been published. The reasons for this include the wide range of causes and contributing factors to incontinence, multiplicity and differences in patient populations by age and by gender, and technical issues in validating as well as measuring outcomes, all of which have complicated consistent study designs. However, recent advances in methodology make new research opportunities possible. Additionally, the implementation by the U.S. National Institutes of Health (NIH) of two research networks focusing on urinary incontinence and on pelvic floor disorders has contributed to expanding the knowledge of how to conduct valid studies.

The ultimate goal of this meeting is to develop requests for research applications (RFAs) on the part of the NIH to fund research on the treatment of incontinence. The high quality of presentations and the interest demonstrated by the presenters and participants will surely play a positive role in making that happen – to the benefit of patients and everyone affected by this disorder.

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[This is a portion of the presentation entitled “Research Priorities for Fecal Incontinence: The Patient’s Perspective” by Nancy J. Norton at the IFFGD Symposium, *Advancing Treatment of Fecal and Urinary Incontinence Through Research*. The complete text can be viewed online at: www.aboutincontinence.org/Priorities2002.html]

Introduction

The topic that I will be discussing today is that of research priorities for fecal incontinence from the patient’s perspective. Much of the research for fecal incontinence has been focused on improving function. Although improving function is extremely important it is not the only aspect of treatment that needs to be considered in the healing process for people who are incontinent. I will present issues that I feel should be taken into consideration as we move forward with strategies for the future.

There is no question that one’s quality of life is severely compromised by fecal incontinence. Unfortunately, improvement in quality of life, the goal of every patient with fecal incontinence, does not necessarily accompany the beneficial changes that may result from targeted, medical intervention or surgical interventions.

In a recent prospective study of the long-term outcomes of pelvic-floor exercise and biofeedback for 89 patients, Pager and colleagues¹ found that although these interventions brought about long-term improvements in incontinence severity scores, as measured by the St. Mark’s² and Pescatori³ scales, there was poor correlation between severity scores and scores on the quality-of-life scale used in the study, the Direct Questioning About Objectives scale.⁴ The researchers write that, “Further research into the factors supporting clinical and quality-of-life improvements, and the relationship of these outcomes, is important,” and they conclude by suggesting that there are “aspects of treatment programs *independent of the primary intervention* [italics added] that are not being appropriately recognized.”¹

For patients, these remarks by Pager and colleagues are crucially important. We want to be continent, but treating incontinence is about more than containment of urine or feces. The patients in this study reported “talking about things” was the most helpful component. They were learning to cope with it and talking about it helped. Learning to cope is paramount. We need to work with patients to foster the ability for self care rather than dependency.

Research priority No. 1: Study and clarify the quality of life determinants in fecal incontinence.

A primary research priority must be studies concerning what genuinely brings about and constitutes quality-of-life improvements for patients with fecal incontinence. In addition, there must be studies to elucidate the relationship between fecal incontinence severity scores and quality-of-life scores. At the same time, quality of life scales must be routinely included in all studies of clinical interventions aimed at improving aspects of fecal incontinence, and the length of intervention studies should be sufficiently long to adequately assess changes in quality of life associated with the intervention. In fact, intervention studies should be sufficiently long simply to evaluate the quality of the intervention. For example, several recent studies have suggested that results for overlapping sphincteroplasty do not persist over the long term (5 years or more).^{5,6}

Clarifying quality-of-life determinants for patients with fecal incontinence would also support an essential moral fact about this condition: A full and humane consideration of quality-of-life issues—like that outlined by Soffer and Hull,⁷ for example—must be the starting point of any approach to the evaluation and treatment of fecal incontinence. Because patients with this condition can be desperate, they and their clinicians are vulnerable to trying risky, novel, or unproved interventions. There are lines that need not, and should not, be crossed.

Research priority No. 2: Validate and standardize both a single fecal incontinence severity scale and a single quality of life scale.

There are numerous scoring systems for the severity of fecal incontinence—Wexner,⁸ St. Mark’s,² Pescatori,³ Rockwood,⁹ among others—and there are numerous scoring systems for quality of life for these patients—the 36-item short Medical Outcomes Questionnaire,¹⁰ the Gastrointestinal Quality of Life Index,¹¹ and Rockwood’s specific Fecal Incontinence Quality of Life Scale,¹² also among others. If research cannot determine which among these different sets of scales best serve patients and clinicians alike, then professional organizations like the American Society of Colon and Rectal Surgeons should insist on a standard adoption across institutions of a single severity scale and a single quality-of-life scale.

Research priority No. 3: Link diagnostic tests with predictive outcomes and strategies for patient management.

The summary article of the April 1999 *Consensus Conference on Treatment Options in Fecal Incontinence*¹³ listed eight research priorities for fecal incontinence, three of which in particular merit renewed emphasis from the patient perspective. One 1999 priority was research evaluation of the utility of specific diagnostic tests in predicting treatment outcomes and in setting or altering treatment strategies. There is a multitude of objective tests of rectoanal function¹⁴—from anal manometry to rectal balloon manometry, from anorectal electromyography (EMG) to imaging studies—but the relationship between the objective “results” and patient-management strategies remains unclear.

Meanwhile, some of the current tests, like anorectal EMG, which involves placing standard concentric needles into four quadrants of the sphincter, are not only extremely painful but appear to be user dependent in terms of the desired result: insight into the integrity of the sensory and motor innervation of the rectoanal region. If such a diagnostic test does not offer additional information that factors positively into a patient's plan of care and outcome the test should not be performed.

Research priority No. 4: Develop new drug treatments for fecal incontinence.

Another 1999 priority was development of new drug compounds for fecal incontinence. The importance of this priority for patients has been underscored by the recent successful patient advocacy for the renewed availability of alosetron (Lotronex) in the US marketplace. Marketing approval for alosetron, indicated for the treatment of diarrhea-predominant irritable bowel syndrome (IBS), was withdrawn by the U.S. Food and Drug Administration in November 2000 because of concerns about safety.¹⁵ On June 7, 2002 the FDA announced the approval of a supplemental New Drug Application (sNDA) that permits the marketing of alosetron with restrictions. Up to 20% of IBS patients experience fecal incontinence,¹⁶ and for many, alosetron was a life-altering intervention. The patient advocacy for alosetron also served to make incontinence part of the IBS dialogue.

Research priority No. 5: Provide explanations for fecal incontinence and study how prevention is possible.

A third 1999 research priority was better understanding of the etiology of fecal incontinence. Patient acceptance of the condition is supported by clear explanations and furthered by the understanding

that clinical knowledge is leading to preventive measures of benefit to others. For example, it is known that the risk of fecal incontinence is increased by use of forceps or vacuum extraction, by high infant birth weight, and possibly by episiotomy.¹⁷ What is the risk of the development of fecal incontinence associated with these procedures compared with risks arising from an elective Cesarean delivery?

Mellgren and colleagues studied the long-term cost of fecal incontinence secondary to obstetric injuries. Their result demonstrated that there is a substantial economic cost, as well as a tremendous psychological burden on incontinent patients and their families because of the disability and treatment that is not always successful. Editorial commentary to the article suggested that, “the best solution would seem to be prevention of disease rather than subsequent evaluation and treatment. Prevention of sphincter injury during childbirth should be an achievable goal.” Prevention is always more cost effective than is subsequent attempted cure. There needs to be a greater dialogue between the colorectal community and the obstetric community.

Research priority No. 6: Understand—and analyze how education can counter—the societal metaphor of “incontinence.”

Finally, we must explore how our culture understands continence and incontinence—metaphorically as well as literally. A social stigma attaches to incontinence, suggestive of an impaired identity; in one way or another, patients with the condition are liable to being considered blameworthy. Such current attitudes are devastating, and they foster a state of secrecy about the condition. With secrecy comes misunderstanding—and the dialogue that is perpetuated correlates incontinence with infancy, dependence, and ultimately loss. The words we choose have significance. For example, Random House describes a diaper as a piece of absorbent material worn as underpants by a baby not yet toilet trained. Sufferers of incontinence are not infants, but rather are contributing members of society who seek a positive and supportive environment. Changing our dialogue to offer adult patients “protective undergarments,” not “diapers,” can have a profound affect on an individual's well-being.

With understanding and openness, societal attitudes can change. Indeed, witness how the stigmatization that was once associated with “cancer” has yielded to knowledge and candor over the last 20 years. We can accomplish a similar transformation of consciousness with respect to incontinence.

I have a personal interest in the future of incontinent patients and what is or isn't happening with research. I have lived with fecal incontinence for seventeen years.

When I say, “lived with” I mean just that. As an incontinent person I must find a way to live with it and not let it consume my life. It will certainly do that if one does not have the strength and support to take control of it. One does not escape incontinence; it is even in our dreams.

Incontinence is a symptom of something that has gone wrong—disease, injury or neglect. Whatever the cause, the ramifications of incontinence in and of itself are life altering. We are in a unique position to change the future for incontinent people.

I would like to thank all of you for your interest in incontinence and your participation in this meeting. We have the opportunity to continue our work together and build on the knowledge and technology that have brought us this far. Your individual contribution is greatly appreciated by all of us who live with incontinence. Thank you.

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