INTRODUCTION

The topic of this paper 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. There are 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 chances 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 colleagues (1) found that although these interventions brought about long-term improvements in incontinence severity scores, as measured by the St. Mark’s (2) and Pescatori (3) 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 that are not being appropriately recognized.”

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 quality-of-life scores. At the same time, quality of life scales must be routinely included in all studies of clinical inter-

(continued on page 14)
ventions 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 Hill (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 rectoanl function (14)—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 rectoanl 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 (18) studied the long-term cost of fecal incontinence secondary to obstetric injuries. Their study 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 blaming worthy. 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 “dia-

References

(continued on page 79)