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Introduction and Summary

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This case study describes medical devices and other technologies used to manage urinary incontinence and reports on the firms that produce such devices. This subject was selected for detailed study as part of two larger OTA assessments of Federal policies and the medical devices industry and technology and aging in America. Urinary incontinence represents a medical problem that is prevalent among the elderly and has enormous consequences for medical care costs. It is also an area in which medical devices with widely varied characteristics are used to manage or cure the

underlying conditions. These devices complement other approaches to the management of urinary incontinence, and an analysis of the respective roles of alternative strategies is useful. Although the case study emphasizes mechanical devices over more conventional and widely used treatments for incontinence, such as drugs, surgery, and bladder-training procedures, these other treatments are also discussed. Evidence on the effectiveness and costs of alternative treatments is presented, and implications for public policy are discussed.

THE PROBLEM OF URINARY INCONTINENCE

Urinary incontinence is an embarrassing, potentially disabling, and costly health problem. Defined as an involuntary loss of urine sufficient in quantity and/or frequency to be a social or health problem, this condition disrupts the lives of 5 to 10 million Americans, their families, friends, and caregivers. The severity of incontinence ranges from occasional dribbling to total loss of control over excretory functions with incontinence of both urine and stool. It has adverse effects on physical health, psychological well-being, social functioning, and the cost of health care. When inadequately or inappropriately managed, it can lead to skin breakdown and recurrent urinary infections. Incontinent individuals often withdraw from their usual social activities and may subsequently become isolated and depressed. Because it is difficult for affected individuals and their families to manage at home, incontinence often plays a pivotal role in an individual's decision to enter a long-term care institution. The costs of labor, laundry, and supplies used to manage incontinence and its complications contribute to the growing costs of nursing-home care (111). Despite the availability of many effective forms of treatment, incontinent persons are rarely evaluated

thoroughly to determine the precise causes of the condition and are therefore often not treated optimally (112).

This deficiency in the care of incontinent persons results from a number of factors, including:

1. lack of knowledge on the part of health-care professionals about the underlying causes of incontinence, appropriate methods of diagnostic evaluation, and treatment options available (in some instances, health-care professionals even consider incontinence a normal condition in elderly patients and therefore do not evaluate or attempt to treat it);
2. reluctance on the part of affected individuals to discuss the problem with a health-care professional because of embarrassment and the misconception that it cannot be treated; and
3. the relatively small number of experts (urologists, gynecologists, neurologists, geriatricians, nurse clinicians, etc.) available to treat these patients, train other health-care professionals, and carry out well-designed research on the management of this important health problem.

Prevalence

Because little accurate data on the extent of urinary incontinence have been consistently maintained, estimates of its prevalence and change over time are difficult to make. Current data indicate that risk of urinary incontinence is strongly associated with age. From 10 to 20 percent of the community-dwelling elderly, whose median age is 72, are incontinent to some degree. But approximately 50 percent of all elderly persons in nursing homes, whose median age is 83, are incontinent. Not only is the prevalence much greater among the latter group, but the type of incontinence is also likely to be more severe. Although these population subgroups are not directly comparable, the differences in prevalence indicate the increased risk of urinary incontinence for persons 65 to 74 and 85 and over (85, 178). Risk of institutionalization is increased because of urinary incontinence. Thus, the very old (persons 85 and over) are most likely to suffer from incontinence and to be at risk of institutionalization.

The effects of these age-related differences will become more relevant as the aging of the U.S. population continues, especially within the older population itself. During the past decade, the elderly U.S. population has experienced a new era of increased longevity. In contrast to earlier periods when life expectancy advances were concentrated in infants and the very young, life expectancy at age 65 and 75 has markedly increased during the last 12 years (158). As a result, the very old are the fastest growing segment of the population. They currently comprise 9 percent (2.4 million persons) of the total older population, but are projected to increase to approximately 15 percent (5.1 million persons) by 2000. If present trends continue, this growth in the very old population will be accompanied by notable increases in the numbers and proportions of older persons

with some degree of urinary incontinence and a higher risk of institutionalization. Technologies that can prevent, treat, cure, manage, or reduce the severity of urinary incontinence will help to lessen its prevalence, minimize its impact, delay its onset, and reduce the likelihood of institutionalization among the elderly.

Types and Causes

Incontinence can be classified into several types, which have clinical and therapeutic differences. *Acute incontinence* refers to the sudden onset of episodes of involuntary loss of urine; it is usually associated with an acute illness or environmental factors that impair the mental or physical ability of the patient to reach a toilet or toilet substitute in time.

Established or persistent incontinence (i.e., repeated episodes of involuntary loss of urine not associated with an acute condition) can be divided into four types. *Stress incontinence* implies leakage of urine, either in small or large amounts, as intra-abdominal pressure increases. *Urge incontinence* involves leakage of varying amounts of urine because of the inability to delay voiding long enough to reach a toilet or toilet substitute; it can be caused by a variety of genitourinary and neurologic disorders. *Overflow incontinence* is caused by anatomic obstruction to bladder emptying and/or inability of the bladder to contract, with subsequent leakage of small amounts of urine. *Functional incontinence* occurs in those individuals who have chronic impairments of either mobility or mental function, are unable to toilet themselves independently and do not have sufficient help with this task, or who, because of psychological disturbances, are unwilling to maintain continence.

TREATMENTS FOR URINARY INCONTINENCE

The most appropriate treatment for an individual patient with urinary incontinence depends on a thorough evaluation of all relevant factors (genitourinary, neurological, psychological, and envi-

ronmental) that could cause or contribute to the condition. Most treatments discussed in this case study (e. g., sphincters, electrical stimulators, drugs, training procedures, and surgery) are appli-

cable for a specific type or types of incontinence and are attempts to cure the incontinence. Thus, a diagnostic evaluation to identify specific conditions is critical to the appropriate use of these treatments. Some of the treatments are nonspecific (e.g., bedpads, undergarments, and, in certain situations, catheters) and are palliative rather than curative; they should not be used exclusively until a diagnostic evaluation has excluded treatable conditions.

Devices for incontinence can be divided into those that attempt to prevent or delay urine flow and those that collect urine before or after it leaves the bladder. Devices such as the pessary, a donut-shaped piece of inert material inserted into the vagina to support the bladder outlet in women with stress incontinence, and the external penile *clamp* are used relatively infrequently at the present time. Newer techniques such as the artificial *sphincter*, which is an inflatable cuff surgically implanted around the urethra, and *electrical stimulators*, which contract muscles of the pelvic floor in stress incontinence and inhibit bladder contraction in urge incontinence, have been used increasingly over the last 10 to 15 years (124).

Catheters are commonly used to manage incontinence, despite the well-known risks (e.g., infection) associated with their use (166). Probably the most actively marketed products used to manage incontinence are *undergarments* and *bedpads*. In general, these products are designed with a layer of highly absorbent material sandwiched between layers designed to keep the patient and the bed or clothing dry. A wide variety of techniques, which we have labeled *training procedures*, have also been described in the management of incontinence. We have categorized these training procedures into five basic techniques: pelvic floor (Kegel) exercises, biofeedback, bladder retraining, habit training, and behavioral modification.

Effectiveness

Few studies have systematically examined the efficacy, safety, and long-term cost effectiveness of the various treatments for urinary incontinence. Most published studies are reports of case series. The relative efficacy of various treatments has rarely been examined.

costs

Similarly, few studies have systematically examined the costs of incontinence. A small number of reports have considered various components of the cost, such as the added costs of labor or supplies used to manage incontinence in long-term care institutions (111). It has been estimated that \$8 billion is spent on incontinence in this country, and urinary incontinence accounts for one-third of costs of geriatric wards, but the basis of these estimates has not been described (20). The costs of incontinence go far beyond economic considerations: withdrawal from social activities, psychological distress, burden on family and caregivers, and the subsequent predisposition to institutionalization are all important potential effects of incontinence that are difficult to quantify.

One report has examined the overall costs of incontinence in nursing homes in this country. If only “first-order” costs are considered (i. e., the costs of managing incontinence without the costs of any complicating conditions), incontinence adds between \$3 and \$11 to the daily costs of caring for a nursing home patient (111). The range of costs is accounted for by differing costs of various techniques of management. Of the three components of these costs (labor, laundry, and supplies), the labor involved in managing the incontinent patient was the major contributor.

If one assumes that there are approximately 600,000 nursing home patients with some degree of urinary incontinence and that in three-quarters of these patients the incontinence is sufficiently severe that catheters or other specific management techniques are used, the yearly costs of incontinence in U.S. nursing homes can be estimated at between \$0.5 and \$1.5 billion (first-order costs only). This cost range represents between 3 and 8 percent of the total expenditure on nursing home care in this country. The costs of incontinence in the community are much more difficult to estimate. No studies have addressed these costs in any detail.

Loss of productivity in those individuals afflicted with incontinence and in those caring for the incontinent patient could be substantial. Incontinence can place physical, psychological, and

economic burdens on patients and caregivers, costs that are difficult to estimate. And as mentioned before, incontinence is often cited as a major factor in the decision to institutionalize a dependent person.

The potential cost effectiveness of evaluation and specific treatment for incontinence has never been systematically addressed. Although the proportion of incontinent patients that can be com-

pletely cured is unknown, many can clearly benefit from an evaluation that identifies treatable conditions; in some instances, treatment would lead to substantial amelioration of the incontinence. Some experts estimate that one-third of incontinent patients can be completely cured and most others kept dry and comfortable with appropriate management (174).

THE MANUFACTURERS OF INCONTINENCE PRODUCTS

The manufacturers of urinary incontinence products are a heterogeneous assortment, ranging from very large, diversified firms to very small ones. The products, too, vary considerably. Some are designed for broad consumer use; others for very discrete types of incontinence. The latter may have a high unit cost and require surgical implantation. Any effort to describe “the incontinence products industry” must recognize this diversity. To facilitate systematic collection of data from manufacturers, a questionnaire was designed and sent to 38 companies who had agreed to respond; 21 companies replied. (See app. C.)

Industry Structure

At least 48 companies are involved in the manufacture of one or more incontinence products. These companies vary dramatically in their size, the number of products manufactured, and other corporate characteristics. In many cases, it is virtually impossible to isolate the incontinence products component of a much larger corporation.

Marketing

Companies have primarily marketed incontinence products as medical devices rather than as consumer products, even those products with the characteristics of consumer goods (e.g., incontinence pads).

Manufacturers distribute them through various distributors and dealers or directly to users; 85 percent of those companies responding to a survey conducted by the authors use distributors and/or dealers to reach the users. Most of the manufacturers’ promotional efforts have been directed toward physicians and others in the medical field, but the recent entry of two large paper-products firms into the disposable incontinence product market may herald a new marketing strategy directed toward the consumer.

An active advertising campaign designed to destigmatize incontinence can provide important information to consumers. But it can also potentially mislead the public. Because the emphasis is on encouraging the use of an undergarment, the consumer may be led to believe that this is the appropriate first line of treatment. The importance of careful evaluation to search for remediable conditions is not likely to be stressed, nor will other techniques for managing the problem be suggested.

The incontinence-products industry is extremely competitive, and price is one of the important mechanisms used by some companies to capture an increased share of the market. Except for services delivered as part of an acute hospitalization, Medicare coverage for incontinence products is quite limited. Coverage for urinary incontinence products under Medicaid varies from State to State.

POLICY IMPLICATIONS

As a great source of health and social cost, the problem of urinary incontinence raises important issues for public policy. With regard to the various urine-collection pads, pants, and sheets, a number of competitive products are available, all of which can greatly facilitate the management of the incontinent patient. The difficulty seems to lie in both patients' and providers' awareness of these and other alternative treatments.

Information

Both individuals with urinary incontinence and health professionals lack information on the variety of products and treatments available. To date, there has been very little education through either formal mechanisms or advertising to broaden awareness of possible options. The entry into the disposable pad market of a second major firm may make direct advertising to the public more extensive.

The Government could do a great deal to destigmatize this socially unacceptable problem. Private merchandising could also influence consumer attitudes. Once advertising taboos are broken, the pattern of active advertising across the media, observed earlier with such previously "undiscussed" products as sanitary pads, will likely be repeated for incontinence products.

Health professionals should know more about the management of incontinence than does the lay public. At present, there is no guarantee that this is the case. Beyond a few specialists in urology and geriatrics, few physicians have been formally instructed in the diagnosis, treatment, and management of incontinence. The need for better medical education about incontinence was recently noted in the report on geriatrics and medical education by the Association of American Medical Colleges (5). Professional education could be expanded to include more than management. Physicians could be taught to appreciate the potential for successful treatment and know-how to evaluate patients with incontinence. Government support for training, educational materials, and the like might improve the likelihood that physi-

cians would be educated about the range of incontinence products.

Research

The state of knowledge in the field is rudimentary for so prevalent a health problem. Well-designed randomized clinical trials to test the efficacy of alternative treatment approaches have not been conducted. Most studies to date have weak designs; many have no control groups, despite the frequent observation of placebo effects. Before such controlled trials are carried out, however, more precise classification of incontinent patients and rigorously defined outcome measures need to be developed. Practical research is similarly needed. Better techniques for inexpensive assessments are necessary if more patients are to be properly evaluated. Diagnostic tests that are simple to perform and could be carried out at a patient's bedside or in an office setting would greatly increase the chances for better clinical evaluations and subsequent management.

Within the Government, the appropriate focus of responsibility for the necessary research support is unclear. The National Institutes of Health, specifically the National Institute on Aging, has evidenced interest in incontinence research, but has not yet organized clinical trials of therapeutic modalities. The National Center for Health Services Research has sponsored limited work in this area and could potentially do more.

Specific attention needs to be directed to the question of what types of interventions are effective with different types of patients. For example, many incontinent nursing home patients are cognitively impaired and limited in mobility. Surgical approaches, drug treatment, and bladder retraining (as opposed to habit training) are less likely to be productive in this patient population. A clinical classification of incontinence corresponding to the likelihood of effective intervention could be used as a framework for assessing the utility of new approaches.

Reporting the consequences of incontinence has not been systematic. The Food and Drug Administration requires records of adverse reactions

from drug treatments for incontinence, but no agency organizes the collection of information on the complications of untreated or undertreated incontinence. This type of data might be collected through clinical studies sponsored by the National Institutes of Health, or it could fall under the purview of the Centers for Disease Control.

Payment

Medicare covers the costs of diagnosis and evaluation of incontinence and, for institutionalized persons, incontinence supplies. However, supplies for noninstitutionalized persons are not covered by Medicare, except for patients' home health services, and they are only erratically reimbursed by Medicaid. There is no clear mandate to pay for these products. Some argue that, because incontinence is often cited as a major cause of nursing home admission, paying for management products for ambulatory patients might be a good investment. The debate is essentially the same one heard for various interventions designed to reduce nursing home use. Because we cannot identify those at high risk of nursing home admission, there is some danger that subsidizing a large number of incontinent persons would prevent few admissions; the cost to third-party pay-

ers such as Medicare and Medicaid is likely to be additive rather than substitutive.

A new Medicaid reimbursement system for nursing home care currently under development reflects the variation in the costs of such care. Several States have developed case-mix reimbursement mechanisms that acknowledge the increased costs associated with incontinence. However, under such approaches, the emphasis is on the costs of caring for such patients rather than on encouraging treatment to improve their condition. As with all cost-reimbursement approaches, the worse a patient's condition, the greater is the reward to the caregiver. An experiment conducted by the National Center for Health Services Research is currently underway to test the effects of paying nursing homes an incentive to accept incontinent patients and a bonus if the institutions are able to improve the patients' functional condition (170).

The costs of incontinence are substantial. For many, the use of disposable incontinence products is essentially a convenience issue and the question of affordability is really one of willingness to spend. For others on a very limited budget, the convenience may be financially out of reach. These persons may be at greatest risk of nursing home placement because of limited resources.

ORGANIZATION OF THIS CASE STUDY

The remainder of this case study provides a background for the findings and conclusions summarized above, and is divided into three chapters. In chapter 2 the prevalence, types, and causes of incontinence and alternative treatment approaches are discussed. Chapter 3 contains a

review of the evidence available on the safety and effectiveness of alternative treatments. Finally, chapter 4 gives an overview of the costs involved in evaluating and managing incontinence and its complications.