

## Committee 14

# Economics of Incontinence

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## I. INTRODUCTION

### 1. WHAT ARE THE “ECONOMICS OF INCONTINENCE”?

Understanding the economic impact of urinary incontinence on society is important for evaluating competing demands for the use of scarce health care resources. Knowing the magnitude of the economic impact of incontinence is also essential for the medical community and for government entities to determine funding priorities. The cost of incontinence includes both the direct use of resources for the care or treatment of incontinence and indirect economic effects that result from incontinence, such as the loss of productivity, resulting from morbidity or disability.

The economic issues surrounding incontinence revolve around two main issues: efficiency and equity. Efficiency is the concept of delivering services in the least costly manner, and equity is the concept of distributing the burden of cost fairly. With regard to either of these topics, one must first know the costs associated with incontinence.

In the context of health or health care, cost is conceptually equivalent to the value of resources consumed or lost as a result of illness. Thus, the economic costs of incontinence are equivalent to the sum of the values of resources consumed or lost by patients, treatment providers, government entities, or other segments of society as a direct or indirect result of incontinence. Since resources that are used to care for patients vary from medical personnel to equipment, supplies, spaces, etc, it is much easier to estimate direct costs by defining types of treatment services, measuring units of these treatment services used and multiplying these by the cost per unit of services.

### 2. WHY EVALUATE COSTS OF INCONTINENCE?

Costs can be evaluated from four different perspectives: society, payer, provider and patient, all of which have different interests. Since the economic impact on society is significant, regardless of where the burden falls, it would be helpful for government policymakers to know the overall burden of incontinence on society. It is also useful to have a number for cost comparison of various types of illness within a country, as well as a comparison between countries for a given illness.

Public or private insurance (third party) payers often incur major financial expenses in caring for patients. Therefore, these payers are interested in costs and the financial impact of a disease so that future health care financial budgets or insurance premiums can be planned. In addition, many European countries would like to determine the transfer payment, such as sick leaves or disability times, which is to be paid by the purchaser.

Providers, such as hospitals, managed care plans, health maintenance organizations and nursing homes are interested in the costs associated with a particular illness, such as incontinence or dementia, so that they can be taken into account for their capitation rates, global budgeting and/or service fees.

Finally, depending on different insurance coverage, patients would also like to learn what their shares of co-payment and out-of-pocket expenditures are. The coverage of surgery for incontinence and lack of coverage for incontinence supplies would have different cost implications for patients. Furthermore, there are loss of productivity and loss of wages costs that directly affect a patient's well being.

While the costs of incontinence vary depending on the perspective, it has been recommended that researchers first use a societal perspective [1–2]. Maintaining the societal perspective facilitates comparisons of costs of

various illnesses within a country, as well as comparisons of costs between countries for a given illness. Tallying societal costs and then exploring the costs of incontinence from different perspectives provides a lens through which one can better understand incontinence and the competing incentives.

One useful example is the international comparison (Canada, France, Sweden, UK, US) of the proportion of client incontinence costs paid by third party payers and by patients. The analysis followed patients for three months; all had urge or mixed incontinence. Costs included an initial visit, drug treatment, pad costs, extra costs for laundry, and treatment for urinary tract infections. It can be seen from Figure 1 that the costs from the patients' perspective varied depending on the country's insurance coverage and treatment/care practices.

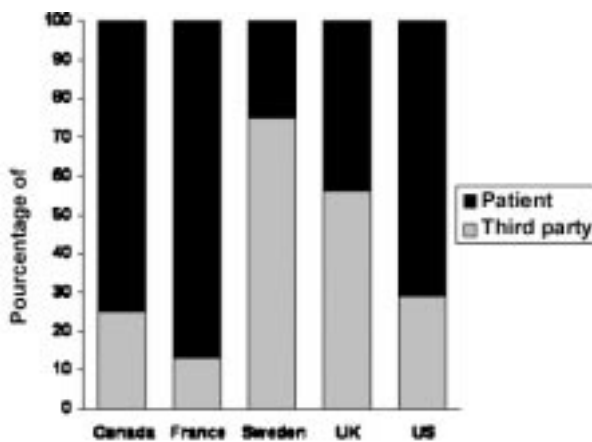


Figure 1 : Proportion of costs paid by health insurance and patients, 1997 [7].

### 3. COST-EFFECTIVENESS, COST-UTILITY, AND COST-BENEFIT ANALYSES

Estimating costs provides valuable information on the magnitude of the economic burden of an illness, which guides health policy decision-making. These data are also critical for comparing the costs and outcomes of medical interventions. In today's society, it is important to provide services that offer the most "value" for the least amount of money. To aid decision making, we often turn to cost and outcome analysis, which is a systematic method for comparing alternative medical interventions.

A medical intervention that yields better outcomes for less cost than an alternative intervention is considered dominant. Dominance is rare, since most new interven-

tions yield better outcomes at an additional expense. In these situations, it is important to ask whether the value is worth the investment. The three most commonly used cost and outcome methods are:

1. Cost-Effectiveness Analysis (CEA),
2. Cost-Utility Analysis (CUA), and
3. Cost-Benefit Analysis (CBA).

In cost-effectiveness analysis, interventions are compared to alternatives by estimating a cost-effectiveness ratio (CER). The CER is the ratio of the marginal cost of the intervention to the marginal health effect of the intervention, compared to the next less costly alternative. In traditional CEA, the health effect is measured in units that are relevant to the illness (e.g. incontinence episodes). Although this may facilitate interpretation of the results among incontinence experts, these CERs cannot be compared with CERs from a heart failure medication, because the outcome measures are not the same. To permit this type of comparison, many researchers have turned to using a single outcome measure, such as life expectancy that is adjusted to account for quality of life.

Cost-utility analyses are useful for comparing the cost of treating different diseases. This type of analysis is particularly important for diseases that have a major impact on quality of life, such as incontinence. The primary difference between a CEA and a CUA is the choice of outcome measures. A CUA uses a global outcome measure (utilities) that allows the comparison of dissimilar interventions. For example, with a CUA, a researcher could compare a new incontinence treatment to a new heart disease treatment.

The quality adjusted life year (QALY) model is the preferred measure for estimating utilities [1]. QALYs are estimated by multiplying each life year gained with an intervention by a quality-weighting factor that reflects the individual's utility or preference in the health state for that year. This type of analysis, while often still referred to as a CEA, is also known as a CUA because the QALYs represent utilities. Utilities are measured on a scale from zero (death or the worst health imaginable) to one (perfect health), and can be used as quality-weighting factors. Utilities are typically gathered through direct assessment, such as standard gamble or time tradeoffs methods, or through indirect assessment, such as the Health Utilities Index (HUI) [3] or the Euro-Qol (EQ-5D) [4].

Cost-Benefit Analysis represents a deviation from CEA and CUA models in that it attempts to measure benefits in dollars. Theoretically, this holds some advantages over CEA and CUA in that it permits efficiency analysis [3]. An increasingly common way to measure benefit is to use a survey that considers patients' willingness

to pay. This type of analysis accounts for the treatment outcome and the utility/preference, but is expressed by the patient's willingness to pay a given amount of money in return for a healthy status. Debate continues on the value of willingness to pay [4–5]. While researchers continue to explore better ways of developing the willingness to pay scenario [6], a CUA with QALYs still represents the most widely accepted cost and outcome method.

## II. METHODS OF ECONOMIC ANALYSIS

Detailed discussions on methods of measurement and estimation of costs of illness and outcomes have already been presented in the previous consultation volume [7]. Therefore, this section will provide a very brief summary.

### 1. DEFINITION AND MEASUREMENT OF COSTS OF ILLNESS

Costs of incontinence include direct costs and the value of lost productivity due to illness. Direct costs include diagnosis, treatment, routine care and consequence costs. Table 1 details the items associated with direct costs of incontinence. The value of productivity lost includes time lost due to incontinence. Since incontinence is not often associated with premature death, time loss in incontinence refers to work-related productivity loss. These values of productivity loss can be obtained from the amount of lost wages in different age/gender categories. Often, older adults are productive inside and outside the home in ways that are not reimbursed through wages (e.g. household work). These efforts can be valued by imputing estimates from national age-sex adjusted averages or by using minimum wage. It could be argued that productivity loss is a subset of indirect costs on the assumption that all patients are productive members of the workforce.

In estimating the cost of illness, it is important to first obtain the prevalence of incontinence. Differences in gender, community and institutions all impact the cost of illness associated with incontinence. Therefore, it is important to obtain accurate prevalence estimates for those sub-populations. There is a difference between disease prevalence and utilization rates for health services. In order to estimate direct costs for incontinence, it is necessary to evaluate the number and type of resources used in treatment (e.g. visits, tests, supplies, hospital days, medications, etc). At the same time, per unit costs of each service should be obtained from national surveys or statistics. Multiplying the quantity of the services by the unit cost of each service will yield the total costs of treatment.

*Table 1 : Direct costs associated with urinary incontinence*

<b>Diagnostic costs</b>	Laboratory tests Physician consultations Physical examinations Urodynamic evaluations
<b>Treatment costs</b>	Medication Surgery Behavioral Therapy Devices
<b>Routine care costs</b>	Incontinence pads and briefs Laundry, dry cleaning Hygiene and odor control products New clothing to replace those worn from frequent laundering Cleaning/replacing carpet and/or furniture Nursing time Disposable bed pads Indwelling urinary catheters
<b>Consequence costs</b>	Treatment for falls Treatment for skin infections due to incontinence Treatment of urinary tract infections Lengthened hospital stay Nursing home admission

### 2. DEFINITION AND MEASUREMENT OF OUTCOME

Combining measures of effectiveness and costs provides a powerful tool to evaluate the cost per unit of effectiveness of a specific intervention. As urinary incontinence is a multidimensional syndrome and treatments often do not provide a cure but rather an alleviation of symptoms, it is not easy to define a single disease-specific effectiveness measure that is acceptable and meaningful to patients, physicians and purchasers.

A composite construct incorporating all the dimensions of the disease (physical, psychosocial, etc) is preferred in economic evaluations over objective clinical measures, which cannot be transformed easily into such a construct. Subjective outcome measures, however, can be incorporated into this construct and at present, they are considered more relevant for economic analysis. The most commonly used objective clinical outcomes in incontinence treatment are measures of improvement in symptom severity: for example, reduction in number of incontinent episodes, or clinical tests such as pad tests or urodynamic measurements. These are often obtained from voiding diaries, self-report or interview. Recently, a new method for measuring response to surgical treatment of incontinence was described [8]. Results obtained from patient questionnaires, 24 hour voiding diaries, and 24 hour pad tests were scored into

five categories based on new criteria (cure, good response, fair response, poor response, failure), and scores were pooled to create a new response scoring system. The authors observed that this new tool was more accurate than previous methods (which evaluated each outcome separately using previously published criteria that assessed only cure, improvement, and failure).

Subjective quality of life measures should be responsive to treatment. Since the goal of treatment for incontinence is to improve the patient's quality of life, specific instruments more relevant and sensitive to measure incontinence outcomes have been developed. These include the Incontinence Impact Questionnaire [9], Urinary Distress Inventory, Incontinence Quality of Life [10] and Kings Health Questionnaire [11]. Since these disease-specific quality of life measures do not measure quality of life on a continuum anchored by perfect health and death, they cannot be used to quality adjust life expectancy. QALYs, which are the preferred measure for economic analysis in clinical trials, require patient preferences called utilities which are determined using a scale anchored by life and death. Utilities may be estimated through direct assessment, such as standard gamble or time tradeoffs methods, or through indirect assessment, such as the Health Utilities Index (HUI) or the EuroQol (EQ-5D). One of the primary limitations of utilities and QALYs, however, is that they are typically not responsive to treatment.

Other subjective measures that do not directly assess incontinence severity are rapidly emerging as important secondary outcomes [12]. Data regarding secondary outcome measures such as global assessment of patient satisfaction, symptom bothersomeness assessments, and anatomical and functional assessments can and should be collected using quantifiable criteria.

### III. DATA SOURCES AND DATA INTERPRETATION

With increasing frequency, studies are assessing the costs associated with urinary incontinence. Recent examples include descriptive studies that identified the cost of urinary incontinence in the US [13], Italy [14] and Sweden [15]. There have also been a few comparative studies with cost analyses [16–19]. Nevertheless, the use of economic analysis in urinary incontinence studies remains rare.

#### 1. DATA SOURCES

One obstacle to economic studies is the lack of available data. Most industrialized countries track the health of their citizens with complex surveys, such as the National Medical Care Expenditure survey in the USA,

the National Health Survey in Australia, National Population Health Survey in Canada, and the National Health and Lifestyle Survey in Ireland [20]. However, the vast majority of national health surveys do not query respondents about bladder control problems or urinary incontinence.

Several countries are collecting data on urinary incontinence (Table 2). The majority of studies are national health surveys that have been amended to include questions on urinary incontinence. For example, questions on bladder problems were added to the Scottish Health Survey in 1998 and to the Nurses Health Study (USA) in 2001.

Most national surveys that include data on incontinence have been cross-sectional studies. Although this study design provides data on incontinence prevalence, the data may be confounded by unobserved factors. Additional limitations of cross-sectional data include the sensitivity and specificity of the questions to identify incontinence, misclassification of incontinence type or severity, and inability to establish a causal relationship (for example, incontinence causes nursing home admission).

Several longitudinal data sets, which hold some advantages over cross-sectional data, include questions on bladder control (Table 2). These data sets may be used to assess the consequences of urinary incontinence on outcomes including health care utilization, falls, urinary tract infections and institutionalization. While these studies may provide critical data to determine the probability that people will use specific health care resources, none of these data sets include information on costs. Therefore, if researchers are conducting a cost analysis, costs need to be estimated from different sources.

#### 2. DATA INTERPRETATION

Estimating costs can be difficult. Most items that we purchase daily have a readily observable cost. In markets with perfect competition, the cost is determined by market conditions. In these situations, the market self-regulates, requiring little or no outside regulation. However, health care markets involve uncertain heterogeneous goods where there are large information asymmetries. All of these factors contribute to market failure, resulting in some need for external regulation [21–23]. Although all countries regulate health care to some degree, they do so in very different ways. This has implications for estimating costs, and places an even greater burden on researchers to describe explicitly where, when and how the costs were calculated.

Regulations can have a large effect on costs. Health care providers, as a nation, province, or health plan, can set and regulate prices for health services. Alternatively, the health provider can limit the treatments for



**Table 2 : Health surveys with information on urinary incontinence**

<b>Health Surveys</b>	<b>Year</b>	<b>Notes</b>
<b>AUSTRALIA</b>		
Women's Health project	1998	Longitudinal study of 3 age cohorts
National Continence Management Strategy (NCMS)		
Survey of Disability, Ageing & Careers 1998 (ABS 1999a)	1998	Cross-sectional
National Women's Longitudinal Health Survey	1996	Cross-sectional
<b>CANADA</b>		
National Population Health Surveys	1994/95	
	1996/97	Cross-sectional
<a href="http://www.statcan.ca/english/survey/household/health/health.htm">http://www.statcan.ca/english/survey/household/health/health.htm</a>		
<b>DENMARK</b>		
Denmark Survey of Health and Illness	1994	Cross-sectional
<a href="http://www.dda.dk/gbcat/s2323gb.html">http://www.dda.dk/gbcat/s2323gb.html</a>		
<b>UK</b>		
Scottish Health Survey	1998	Cross-sectional
<a href="http://www.show.scot.nhs.uk/">http://www.show.scot.nhs.uk/</a>		
Household Survey of England	1995	Cross-sectional
<a href="http://qb.soc.surrey.ac.uk/surveys/hse/hsecontent95.htm">http://qb.soc.surrey.ac.uk/surveys/hse/hsecontent95.htm</a>		
<b>US</b>		
Hospital Discharge Data		Cross-sectional
National Nursing Home Survey		Cross-sectional
National Medical Care Expenditure		Cross-sectional
National Health Interview Survey		Cross-sectional
National Overactive BLadder Evaluation (NOBLE)	2000	Cross-sectional
Health and Retirement Survey	1993–present	Longitudinal

which it will pay. Pharmaceuticals are often regulated in this fashion, where many providers limit access to expensive patent drugs by using formularies.

Various forms of regulation result in the same service having very different “costs” across health care providers. Accounting systems are used to identify “costs.” These estimates are usually in the form of charges that are highly (but not perfectly) correlated with economic costs, in the true economic sense. Therefore, different accounting systems can yield highly divergent cost estimates.

Most of the hospital accounting systems in the US focus on billing and payments. The charges listed on the bill usually overstate costs and are rarely paid in full by the purchaser. In the US, researchers have developed imperfect methods for adjusting the charges with a hospital specific ratio of costs to charges so that they have a better estimate of costs [24]. However, countries with nationalized health care systems often do not routinely generate bills. In these situations, researchers have developed methods for generating pseudo-bills and more detailed gross cost estimates [25–28]. In some instances, researchers rely on an average cost per encounter that is calculated by dividing the total annual cost by the number of inpatient days or the number of

outpatient visits. Pseudo-bill methods tend to be more precise than average encounter costs. This is particularly true for inpatient care, where average daily rates make the untenable assumption that costs are solely a function of length of stay.

Another common problem with accounting systems is the distinction between professional services and facility costs. Systems in many countries have evolved to pay the physician separately from the facility. Therefore, it is important to identify both the facility costs and the professional fees. These costs are sometimes kept in different databases. For instance, the Medicare program keeps inpatient facility information in the Part A database, while the outpatient and provider fees are kept in the Part B database.

Another caveat with accounting systems is that they always report the health care payer's costs or charges. Society's costs are usually of interest [1–2], therefore it is important to distinguish between provider-incurred costs and patient-incurred costs. This distinction is important for urinary incontinence, since most providers do not pay for routine care (e.g. pads and protection). These costs are usually borne by individuals, and in 1995 the routine care costs represented approximately 45% of the total cost of urinary incontinence [13].

The word “cost” is often casually used, yet researchers should be careful and explicit when cost data are presented. It becomes difficult to compare costs if they are not put in context. As mentioned above, it is important to provide information on what the costs represent and how they were obtained in order to judge how much they can be generalized.

It is also important to consider when and where the costs were gathered. Costs are time-dependent and it is important for studies to identify the year for which the costs were calculated. Economic studies can collect costs over many years and make projections about the future. When this is done, the costs should be adjusted so that they reflect a single year. Future costs should be discounted to represent the present value. There is controversy over the appropriate discount rate and therefore there is no international standard [29–31]. Despite the lack of consensus, it is important to discount future costs to reflect time preferences [1–2]. Given the uncertainty surrounding the discount rates, a sensitivity analysis should be done with alternative discount rates.

Costs borne in past years should be expressed in the current year’s dollars. In the US, past and future costs can be adjusted by the Consumer Price Index or other appropriate indices for all urban consumers ([www.stats.bls.gov](http://www.stats.bls.gov)). In the UK, the Health Service Cost Index or the Retail Price Index, published by the NHS Executive, Leeds, UK, can be used to adjust the costs of health care services; other indices would be used to adjust other items, such as wages ([www.statistics.uk.gov](http://www.statistics.uk.gov)). Most counties track inflation, thereby providing a method for inflating past costs. The best method for inflating costs is not free from controversy, and again this should be varied in a sensitivity analysis. See the articles by Berndt [32] and Cleeton [33] for detailed discussions on price indices.

While the use of economic analysis in health services research is increasing, a sufficiently large number of published studies provide insufficient background information. This problem was evident in the early 1990s [34], and unfortunately continues to persist [35–36]. While we hope that the future will see more economic analyses for urinary incontinence, studies that follow generally accepted standards [1–2] will minimize confusion and may encourage others to follow suit [37].

## IV. ECONOMIC ANALYSIS OF URINARY INCONTINENCE

### 1. GLOBAL COST OF ILLNESS

Cost of illness analyses describe the economic impact of a disease. These studies are used to determine health policy or to make decisions about broad treatment gui-

delines, and are descriptive in nature. Cost of illness studies quantify costs incurred by a population over a defined time, ignoring outcome. Prevalence-based studies estimate the total cost to society due to a given disease by aggregating data on the average amount of health care resources used and the average cost of treatments, forming population estimates [38]. Total cost can either be calculated from national statistics when available (top-down approach), or by collecting detailed costs for a cohort of patients during a given time and combining them with prevalence estimates (bottom-up approach). Alternatively, in incidence-based analyses, lifetime costs are estimated for a cohort of patients (from the time they contract the disease to death), adjusting for incidence estimates.

Cost of illness for urinary incontinence has been addressed by several studies, most of which focus on a particular sub-population (gender, age, institutionalization status), type of incontinence (stress, urge, mixed, neurogenic), or cost type (direct, indirect) [13,39–46]. The most recent estimates of the annual direct costs of incontinence in all ages are approximately \$16 billion: \$11 billion in the community and \$5 billion in nursing homes (1994 dollars) [47]. This cost estimate increased by 250% over 10 years, with previous estimates of \$6.6 billion (1984 dollars) [38] and \$10.3 billion (1987 dollars) [41]. This increase is greater than can be accounted for by medical inflation. Direct and indirect costs of care for the elderly alone were recently estimated to be \$26 billion (1995 dollars) [13].

One recently recognized condition related to incontinence is overactive bladder (OAB), which includes urinary urgency, frequency and nocturia, with or without urge incontinence. The National Overactive BLadder Evaluation (NOBLE) program in the US surveyed approximately 5,000 adults. The prevalence of OAB was estimated to be 16.9% in females and 16.0% in males [48]. A follow-up survey collected detailed information on treatment costs of OAB (with and without urinary incontinence). The cost data include routine personal care, treatment, and health related consequences due to OAB. The estimated costs of OAB for community residents in the US in 2000 were around \$9.14 billion. The estimated nursing home care costs (largely routine care costs such as pads, laundry, nursing aids, etc) were about \$4.4 billion. The total costs of OAB in 2000 were \$13.6 billion [49].

The US National Institutes of Health recently published disease-specific estimates of costs of illness comparing different diseases. The annual direct cost of urinary incontinence (\$17.5 billion in 1995 dollars) was comparable to the direct costs of other common acute and chronic diseases in women: gynecological and breast cancers (\$11.1 billion), osteoporosis (\$13.8 billion), pneumonia and influenza (\$15.8 billion) and arthritis



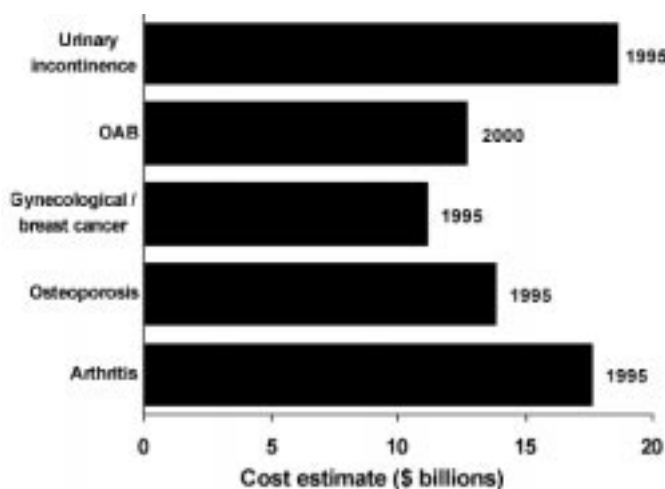


Figure 2 : Comparison of urinary incontinence direct costs with other illnesses in the US. Numbers beside each bar denote the year of the estimate [49–50].

(\$17.6 billion) [50]. While these illnesses vary in their effects on quality of life, daily functioning, indirect costs, and prevalence, this is a striking example of the large cost of illness of urinary incontinence. Figure 2 compares different cost estimates for selected illnesses in the US.

Several non-USA studies on the overall costs of urinary incontinence have recently been published. The total cost of illness can be calculated from national statistics (top-down approach) or by collecting detailed costs for a cohort of patients and combining them with prevalence estimates (bottom-up approach). By using the top-down approach, an Australian study [51] (based on [52] and extrapolated to longitudinal data from Women’s Health Australia, as described in [53]) estimated the economic cost of urinary incontinence in community-dwelling Australian women in 1998. An estimated 1.83 million community-dwelling women over the age of 18 years in Australia had urinary incontinence. The total annual cost of this urinary incontinence is estimated at AU\$710 million (US\$378 million at the 2001 conversion rate), or AU\$387 (US\$208) per incontinent

woman, comprising AU\$339 million (US\$182 million) in treatment costs or AU\$372 million (US\$200 million) in personal costs. An estimated 60% of women with incontinence in 1998 were aged 40 years and over. Assuming the prevalence of incontinence remains constant and allowing for inflation, the total annual cost in 20 years time will be AU\$1268 million (US\$682 million), 93% of which will constitute costs associated with women aged over 40 years. Urinary incontinence imposes a considerable burden on Australian health care resources.

An Italian study [14] shows that the annual treatment costs in 1997 were L351.85 billion (US\$166 million at the 2001 conversion rate), considering only the costs of diapers and drugs. A 1995 French study [54] estimated that the annual direct costs associated with incontinence treatment in women, excluding diapers and sanitary towels, were about 3 billion French Francs (US\$417 million). Table 3 provides a summary of the direct cost estimates in US dollar values for the four countries discussed above.

Cost-of-illness analyses of urinary incontinence have several limitations. There are limited data on incontinence prevalence, institutionalization due to incontinence, routine care costs, and the impact of incontinence on hospitalizations and outpatient medical management. In addition, estimating productivity loss and intangible costs for urinary incontinence is difficult and imprecise.

## 2. DIRECT COSTS

### a) Routine care or “self-help”

Routine care costs include pads or other protective products such as disposable and reusable underpants, laundry, and miscellaneous items such as skin care, odor control products and extra dry cleaning. Incontinence-related laundry costs include cleaning linens, bed pads and clothing.

One of the features of incontinence is that patients need to take care of themselves on an ongoing basis by changing incontinence pads, bed pads, underwear and clothing, laundry and occasionally skin care. Among community residents, these activities are usually done by

Table 3. International comparison of urinary incontinence community treatment cost estimates

Country	Cost estimate		Year
	Local currency	US\$ (millions)	
Australia [51]	AU\$710 million	378	1998
France [54]	FF3 billion	417	1995
Italy [14]	L352 billion	166	1997
US [50]	US\$17.5 billion	17,500	1995

the individual. If an individual is in a nursing home or has a disability, then they may have to be taken care of by aides. This type of care is no longer called self-help, although it is still considered a routine care cost. Because of the two different settings, community versus nursing home, the costs of routine care are different. Furthermore, the accuracy of data collection varies. It is much easier and more accurate to collect routine care costs in nursing homes than in the community. Costs in the community are largely self-reported and types of products used vary.

Since the last consultation on incontinence (1998), a number of refinements have been suggested for cost estimation. New studies have been carried out at the community level in the US and other countries. There has been a gap in understanding routine care costs at the community level and attempts have been made to address this. The cost of pad consumption is a major element in routine care costs. There have been four studies [14,52–53,55] in Australia and Italy, three studies in the US [56–58], and one on the international comparison of pad use in 12 countries [59].

A detailed residential survey [53] (based on the bottom-up cost approach) indicated that incontinent women in Australia spent a median AU\$12.89 per week on direct incontinence costs (US\$6.94 at the 2001 conversion rate), which comprised the personal costs of AU\$5.61 or 43.5% of total costs. Within personal cost, 70% of personal costs are incontinence pad costs. It has been found, as expected, that the more severe the status of incontinence, the higher the personal costs. Laundry costs were 16% of personal costs, while protection costs (e.g. bath towels, tissues, toilet paper, bed pad, old sheets, etc) and miscellaneous costs accounted for 13%. In Australia, quite a few patients used non-commercial products because they could not afford commercial products or they preferred the home remedies. This was the first detailed non-US study on direct personal costs of routine care at community level. In Australia, a detailed laundry cost formula was also developed by taking into account electricity, water and washing powder.

An Italian study [14] on costs of incontinence collected data on the number of pads used for stress incontinence and other incontinence conditions (urge or mixed), as well as data on the frequency of incontinence. Stress incontinent patients used a mean of 34 pads a month, while patients with urge and other incontinence conditions used 59 pads a month. Those with one or more incontinent episode per day used 56 pads a month, while those who had less than one incontinence episode per day use 25 pads. Overall, the cost per patient for diapers was L240,000 (US\$114 at the 2001 conversion rate). The annual costs of adult diapers and drugs for urinary incontinence was L352 billion (US\$167 million). These costs

represent out-of-pocket expenses for patients, with diapers comprising the bulk of the costs (94%).

A recent US study also compared types of pads used in community incontinent residents [58]. They divided the products into three groups:

1. mini pads, panty liners, toilet paper, tissue paper;
2. maxi-pads; and
3. incontinence products. They classified condition of incontinence as stress incontinence, detrusor instability, or both.

In this US study, it was found that 92% of patients used only commercial incontinence products and 8% used non-commercial. The daily usage was 1.7 pieces (mean) or 1.4 (at median). The median annual costs were \$46 for all subjects or \$76 for pad users (assuming the average costs per pad is around 10 cents). This study also confirms that costs and pad usage are significantly associated with number of incontinent episodes and quality of life.

Kornides & Moore [59] conducted an international comparison of incontinence pad use based on global commercial marketing data from Molnycke Corporation in Sweden in 1998. The per capita female use of heavy incontinence pads is highly associated with either per capita gross domestic product (high users such as the US and Canada, and low users such as Australia, Spain and Taiwan) or heavy government subsidies (Scandinavian countries), as shown in Figure 3.

These recent studies have provided additional refinement of costs of routine care in the community in all age groups, and have increased awareness of the economic importance of routine care around the world.

### ***b) Treatment***

Little is known about the costs and practice patterns for individuals with urinary incontinence patients in the managed care setting. Data from Day et al. [60] showed that within a health management organization, new prescriptions for urinary incontinence were filled at a continuous rate over the 3-year period. Although it would seem logical that the refill rate would also increase by the same proportion, the new prescription fill rate far exceeded that for refills, indicating that compliance with therapy was less than desirable. A similar study [61] indicated poor compliance in a study of 246 women with overactive bladder (OAB) from the UK, most of whom (83.5%) had been prescribed oxybutynin therapy for their symptoms. At 6 months, only 18.2% remained on therapy. Therefore, patient compliance with drug treatment is a key element for successful outcomes.

Both pharmacologic and non-pharmacologic treatments

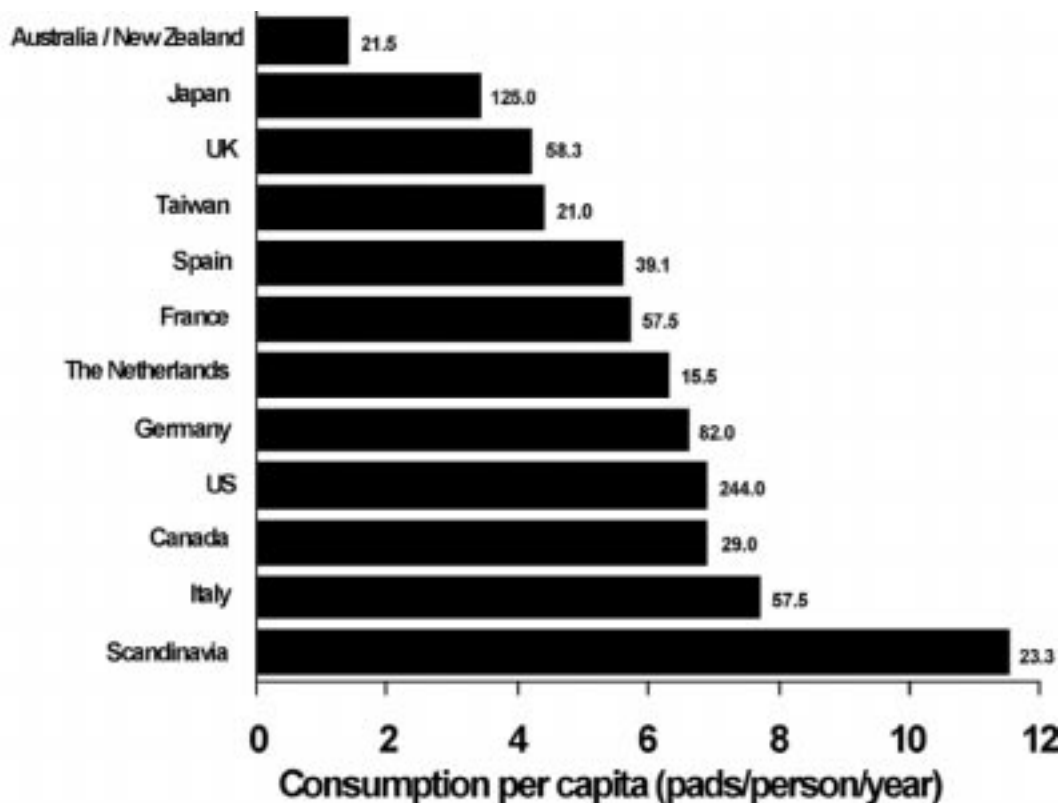


Figure 3 : Heavy incontinence pads used per capita, 1998. Numbers beside each bar denote population (millions) [59].

are available to patients who suffer from incontinence. Non-pharmacologic treatment (e.g. bladder retraining) can be successful, but has demonstrated only limited long-term efficacy because patients are often non-compliant with therapy. It has been suggested that treatment plans should combine drug therapy and behavioral modification, but such combinations have not been evaluated for their cost-effectiveness.

Patient compliance is critical to cost-effective treatment. Anticholinergic drugs, such as oxybutynin, are the drugs of choice for the treatment of incontinence. Although oxybutynin treatment is effective [62], it is frequently limited by poor acceptability, often due to adverse side effects, which in turn can lead to the discontinuation of treatment. To overcome the problems of intolerable side effects with immediate-release oxybutynin, extended-release formulations have been developed. However, not all studies have shown an improved rate of dry mouth rate [63–64].

New antimuscarinic compounds have been introduced for urge incontinence, because they have a greater selectivity for the bladder. Tolterodine was developed specifically for the treatment of OAB, of which a major component is urge incontinence. It has a greater selectivity for the bladder than other anticholinergic drugs, which may explain the lower incidence of dry mouth

[62]. Only half as many patients taking immediate-release (IR) tolterodine report dry mouth compared to oxybutynin [65]. A new, long-acting formulation of tolterodine (extended-release; ER) was recently shown to be 18% better in controlling urge incontinence episodes than the IR formulation, producing a 71% overall decrease in incontinence [65]. Tolterodine ER also has a better side effect profile than immediate release tolterodine and oxybutynin. There was a 23% lower occurrence of dry mouth for patients taking tolterodine ER compared to patients taking tolterodine IR, and the overall occurrence of severe dry mouth was only 1.8% for tolterodine ER patients [66]. Tolterodine ER's improved efficacy and acceptability combined with convenient, once-daily dosing may result in improved compliance with therapy. This appears to translate into greater cost-effectiveness in that tolterodine ER has a lower cost per successfully treated patient than tolterodine IR or oxybutynin [67].

A large USA managed care organization (more than 3 million members) collected data on women seeking care for urinary incontinence and pelvic floor disorder (PFD) [68]. There was an age-related increase in the incidence of women seeking care for all PFD symptoms from June 1997 to May 1999, from 2 to 19 consults per 1000 woman-years in the 30-to-39 year old and 70-to-79 year old age groups, respectively. Applying data

from the US Census Bureau, the authors estimated that there would be more than 620,000 consultations for PFD in the US in 2000, and that by 2030 there would be more than 1 million. According to these projections, there will be an 11% increase in women 30 to 59 years of age seeking care for PFD, which is consistent with the anticipated growth in the population. The greatest percentage increase in demand for services will occur among older women (60 to 89 years of age), where there is expected to be an 81% increase in demand for consultations. These are conservative estimates because they do account for changes in the characteristics of women or increased public awareness of PFD, two factors that are expected to increase the number of people seeking help for PFD.

A recent study [69] estimated the annual costs to society of pelvic organ prolapse (POP) operations in the US. The study estimated the number of POP surgeries identified in the 1997 National Hospital Discharge Survey, by direct medical costs to society estimated by national average Medicare reimbursement for physician services and hospitalizations. In 1997, the direct costs of POP surgery were \$1 billion (95% confidence interval \$775-1,251 million), including \$499 million (49%) for vaginal hysterectomy, \$279 million (28%) for cystocele/rectocele repair, and \$2 million (2%) for abdominal hysterectomy. Physician services accounted for 29% (\$298 million) of total costs and hospitalization accounted for 71% (\$715 million). Twenty-one percent of POP surgeries included urinary incontinence surgery (\$218 million). If all surgeries were reimbursed by non-Medicare sources, the annual estimated cost would increase by 52% to \$1.5 billion. It was concluded that the annual direct costs of operations for POP are substantial and similar to other surgical interventions for women (breast cancer, gynecological cancer, urinary incontinence).

These recent studies have provided additional refinement of costs of routine care in the community in all age groups, and have increased awareness of the economic importance of routine care around the world.

### ***c) Acute complication***

Acute complication due to urinary incontinence usually refers to urinary tract infection (UTI), skin irritation, falls and fractures, and extended length of stay in hospitals. Recent studies have provided further firm evidence that urinary incontinent older women were significantly more likely to have hip fractures than the general population [70–71]. In multivariate analysis, incontinence was independently associated with falls and fractures; women with weekly urge incontinence had a 26% greater risk of sustaining a fall (Odds Ratio = 1.26, 95% Confidence Interval [CI] 1.14-1.40) and a 34% increase risk of fracture (Relative Hazard = 1.34; 95% CI 1.06-1.69), after adjusting for all other causes (e.g.

age, frailty, poor overall health, and previous fall or fracture) [71]. More frequent incontinence was associated with increased risk, and women with daily urge incontinence had increased risks of 35% and 45% of sustaining falls and fractures, respectively. Previous studies have demonstrated that urge incontinence is associated with frequency/urgency and nocturia, suggesting that any OAB symptom, not just urge incontinence, has the potential to increase the risk of falls and fractures among elderly women. The NOBLE program [72] used multivariate analysis to estimate that individuals with OAB have more than twice the risk of being injured in a fall than those without OAB.

UTI and skin infection have also been associated with urinary incontinence. A 5% random sampling of the 1996-1997 California Medicaid Program (Medi-Cal) claims data showed that 22% and 8% of the OAB population received treatment for UTIs and skin infections, respectively. After OAB was diagnosed, the number of services received for UTIs and skin infection decreased by 40% and 60%, respectively, and was associated with potential cost savings [73]. Also, the NOBLE program used the multivariate analysis to estimate the association of OAB and UTI. It was estimated that an individual with OAB had more UTIs than individuals without OAB, after controlling for sociodemographic and other illness conditions [72].

Several recent studies [74–76] have suggested that there is a strong association between depressive symptoms and urge incontinence. Urge incontinence was classified as being idiopathic or neuropathic, depending on whether neurologic findings were absent or present. The results [74] were compared with those of continent controls. Depressive symptoms were highly prevalent among those with idiopathic urge incontinence, occurring in 60% of patients. In contrast, depressive symptoms were observed in only 14% of those with stress incontinence and 42% of those with mixed incontinence. Of all patients with incontinence, only those with idiopathic urge incontinence were significantly more likely than controls to have an elevated Beck Depression Inventory score or a history of depression.

### ***d) Chronic complication – long-term care***

Urinary incontinence has been considered one of the common factors contributing to decisions on admission to nursing homes [39,42,77]. Thom [77] found that in the US, the risk of nursing home admission was 2.0 times greater for incontinent women (95% CI 1.7-2.4) and 3.7 times greater for incontinent men (95% CI 2.7-3.8), after adjustment for age and co-morbid conditions. In addition, the risk of hospitalization was 30% higher in women following the diagnosis of incontinence (relative risk [RR] = 1.3, 95% CI 1.2-1.5) and 50% higher in men (RR = 1.5, 95% CI 1.3-1.6).



Once patients are admitted to an institution, nursing home staff consider urinary incontinence to be one of the most difficult conditions to manage, in terms of time, resources and stress. In Australia, 77% of Australian nursing home residents are affected by urinary incontinence and up to 25% of nursing staff time is spent on incontinence care. It was estimated that approximately AU\$450 million a year in 1991 dollars [52].

Two US studies [78–79] have evaluated the time and motion studies of added costs of caring for incontinent nursing home residents. Shih et al. [79] estimated incremental labor, supply and laundry costs associated with incontinence care at more than \$15 per resident per day, or more than \$5,000 per resident annually. Costs varied according to frequency of incontinence, and ranged from \$8.70 to \$17.28 per resident per day in 1997. Frenchman [57] provided a detailed breakdown by supplies, labor and laundry with total costs of \$17.21 per resident per day in 1999. Although these studies were carried out at different locations, cost results are quite comparable.

Finally, urinary incontinence has been associated with extended length of hospital stay or multiple admissions, independent of other co-morbid conditions [77]. Treating incontinence may prevent extended stays in hospitals or admission into nursing homes.

### 3. INDIRECT COSTS – PRODUCTIVITY LOSS

Loss of productivity is usually due either to the individual's premature death or due to illness. Urinary incontinence rarely causes premature death [80], but it may often affect individual's lost work time or interfere with job performance.

Although limited in number and scope, reports of studies to investigate the impact of urinary incontinence on workers' productivity are beginning to appear [81–86]. While incontinence is more prevalent in the elderly, it can also affect younger people who are more likely to be employed in the workplace [87–89]. Most studies of productivity and incontinence focus on women, since incontinence among men of working age is less common.

Recent surveys of white-collar women [81–82], female and army service members [83–86], public school teachers [84] and athletes [90] demonstrate that a relatively high proportion – 21%-33% – suffer from incontinence, with the potential to significantly impact their work productivity. This impact includes loss of sleep leading to fatigue at work, loss of concentration, and interference with job performance. Women reported taking time from work for frequent urination to reduce incontinence episodes. Women also reduced fluid intake to minimize incontinent events, which may cause dehydration and a greater risk of UTI. Many women

reported embarrassment, altered social interactions, loss of self-esteem, depression, and other factors that could impede work performance and reduce productivity. Incontinence is also associated with absence from work secondary to health care visits, shame, and the need to change clothing.

While it is probable that these factors contribute to lost productivity, to date no objective data have quantified the loss. Given the larger number of younger women in the work force and the relatively high prevalence of incontinence among this group [81,84–86], future efforts to objectively quantify the fiscal impact of their lost productivity is needed.

## V. ECONOMIC ANALYSIS OF URINARY INCONTINENCE TREATMENT STRATEGIES

More studies on CEA and CUA have been published since the last consultation. Rather than evaluating just the cost of the disease, these studies focus on particular treatments or procedures and their effectiveness in treating particular incontinence conditions.

### 1. COST-EFFECTIVENESS ANALYSIS

There have been a number of international cost-effectiveness studies. A US study [91] examined the cost-effectiveness of preoperative urodynamic testing in women with prolapse and stress incontinence, using a theoretical decision-analytical model. This study evaluated the cost-effectiveness of basic office evaluation before surgery in women with prolapse and stress incontinence symptoms, and compared it with that of urodynamic testing. Costs were obtained from US government data; effectiveness of treatment for urinary incontinence was based on published literature. The strategies of basic office evaluation and urodynamic testing had the same cure rate of urinary incontinence (96%) after initial and secondary treatment. Under baseline assumptions, the incremental cost-effectiveness of urodynamic testing was \$328,601 per case of urinary incontinence. According to sensitivity analyses, basic office evaluation was more cost-effective than urodynamic testing when the prevalence of pure detrusor instability was <8% or when the cost of urodynamic testing was >\$103. It was concluded that urodynamic testing is not cost-effective before surgery for prolapse and stress urinary incontinence symptoms. However, it should be noted that the assumption about the prevalence of detrusor instability and the routine use of sling procedures for all genuine stress incontinence may limit the broad applicability of the study.

In Australia, the Dowell Bryant Incontinence Cost

Index (DBICI) was used as an outcome measure following non-surgical therapy, to determine whether the magnitude of leakage would correlate with the magnitude of reduced personal cost [55]. The commercial price for a simple urethral occlusive device was compared to reductions in the cost of incontinence. The severity of leakage was significantly reduced on all parameters and the median personal costs of incontinence fell from AU\$6.52 per week (US\$3.49 at the 2001 conversion rate; inter-quartile range [IQR] 1.50-10.59) to a median of AU\$1.57 per week (US\$0.84; IQR 0-4.89). A significant correlation was observed between reduction in personal costs and reduction in visual analog scale, pad test loss, and quality of life scores. The pad test showed a median reduction of 83%, but the personal costs fell by a median of 71%, because some women do not stop using pads as soon as they are cured. Thus it was concluded that measurement of the personal costs of incontinence as an outcome measure actually provides a different dimension of the patient's burden, in keeping with the recommendations of the ICS standardization committee that cost impact is an important, but separate, measurement of the burden of the disease.

The manufacturer's recommended price of AU\$12.50 (US\$6.70) for the urethral occlusive device, to be changed each week, was not supported by the median reduction of personal cost of AU\$4.22 (US\$2.26; 95% CI 3.00-5.63). However, pad testing of the patient sample revealed that most patients had only moderate leakage (median baseline loss of 22 ml/hr, IQR 6-83.5 ml). Therefore, that sensitivity analysis for a cohort of patients with severe leakage and high costs might have reached different conclusions.

The Dutch Study [92] on sacral anterior root stimulation evaluated the costs of this procedure versus "routine care" for 51 incontinent patients with spinal cord lesions. Costs were measured at baseline (mean duration 7.5 months), to form the comparison "routine care" data set. Patients then underwent sacral posterior rhizotomy and implantation of a Brindley sacral anterior root stimulator, requiring an average hospital stay of 15.6 days. Post-implantation costs were measured again for an average 14 months' follow up.

For the sacral anterior root stimulation group, incidence rates and survival rates for the total Dutch population were calculated (controlled for mean age and average duration of conventional care of the patient population). The baseline pre-implantation costs were NLG4,710 (US\$1965 at the 2001 conversion rate) per patient per year. The implantation costs were high at NLG33,402 (US\$13,933) over 2 years (50% due to hospital stay and implantation surgery). After implantation, direct routine care costs dropped to NLG1,421 (US\$593) per patient per year. However, no significant overall

changes in Nottingham Health Profile nor Karinovsky index were observed, although other scores related to impact of incontinence upon household work etc showed significant beneficial effects. Long-term effects of bladder cancer and renal failure over 30 years were NLG20,999 (US\$8,760) for those with implanted stimulators and NLG33,723 (US\$14,066) for those without stimulation, but the methods of calculation were not elaborated. The long-term cost model showed the stimulation implantation care program to be cheaper than routine care after 8 years.

An economic model was developed in the UK to estimate the comparative cost-effectiveness of treating unstable bladder with tolterodine IR, tolterodine ER and oxybutynin. The model employs the purchaser, patient and societal perspectives over a one-year timeframe. The treatment population was based on the percentage of patients seeking treatment in the UK, and the treatment population was divided into successfully treated patients (STPs) and patients failing treatment. The percentage of STPs was calculated from clinical efficacy and adjusted by annual persistency; the percentage of STPs and the number of patients seeking treatment were multiplied to calculate the number of STPs. The prevalence of sufferers in the UK was estimated to be 19% of people 40 years and over (approximately 5.15 million sufferers), with only 5.9% of those patients seeking treatment [93]. Efficacy was considered approximately equal for tolterodine IR and oxybutynin; however, tolterodine ER has an 18% greater efficacy than tolterodine IR [66]. Persistence on therapy (measured as the percentage of patients remaining on therapy at 12 weeks) was higher for tolterodine than for oxybutynin [65]. Therefore, effectiveness, defined as the percentage of STPs, was higher for tolterodine than for oxybutynin (42.00% for tolterodine IR, 54.67% for tolterodine ER and 9.50% for oxybutynin [67]. Cost per successfully treated patient was lower for tolterodine than oxybutynin, with the lowest cost per successfully treated patient being for tolterodine ER (US\$1,473 for tolterodine ER, US\$1,992 for tolterodine IR, US\$5,729 for oxybutynin) [67].

## 2. COST-UTILITY ANALYSIS

Foote & Moore [94] measured changes in quality of life and calculated the cost per QALY gain for each of five treatments for incontinence shown in Figure 4. The York questionnaire was used because it provides a common yardstick to measure improvement in quality of life, and can also be employed to compare these treatments with any other medical treatment and to rank treatments overall in a league table.

The percentage improvement in quality of life on the York Questionnaire was similar for all five treatment groups varying from 1.21% (urogynecologist conserva-



tive treatment) to 2.09% (laparoscopic colposuspension). In contrast, there was a large difference between the costs, varying from \$901/year (urogynecologist conservative treatment) to \$6,124/year (open colposuspension). The most cost-effective treatment was the conservative treatment of urinary incontinence by the nurse continence advisor. However, confidence intervals were wide, as shown in Figure 4. These wide confidence intervals were due to loss of the York data when the quality of life gain was zero (making an infinite number with quality of life in the denominator for the cost/QALY), hence resulting in smaller numbers available for QALY calculation.

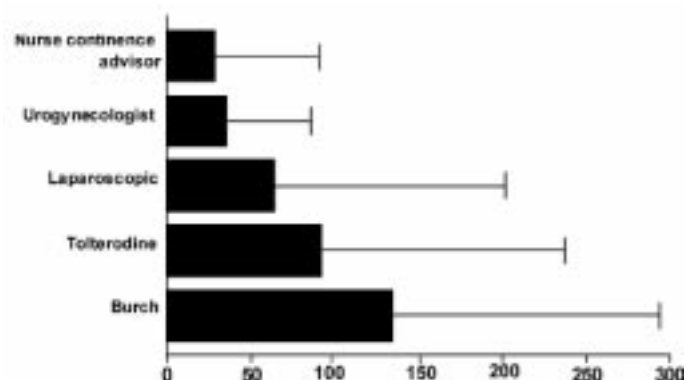
A review study on cost-effectiveness and cost-utility analysis of urinary incontinence surgical procedures was carried out [37]. The review identified 10 basic principles that should be incorporated in cost-effectiveness analyses (Table 4). These principles were derived by reviewing recommendations in publications describing standard methods for cost-effectiveness analysis of health care practices and comprise an appropriate minimum standard for performing and reporting cost-effectiveness analyses. This review of gynecologic surgical procedures suggests that much of the existing cost analysis literature does not adhere to basic recommended analytic guidelines. However, those authors who specifically planned to perform a CEA analysis met all or nearly all of the methodologic principles. Investigators who use CEA are strongly encouraged to use the many outstanding methodologic reviews of CEA. For example, Kung et al. [16] compared the cost per cure of stress urinary incontinence of laparoscopic Burch strategy and open Burch procedures. The probability of cure after each procedure was estimated from a retrospective cohort of 62 women with a mean follow up of 1.2 years for the laparoscopic Burch strategy and 2.7 years for the open Burch strategy. The authors found that the laparoscopic Burch dominated, with lower costs and a higher cure rate. However, the analysis would be more informative with a much longer follow-up, because most women who undergo an incontinence procedure have a life expectancy greater than 1–2 years.

### 3. COST-BENEFIT ANALYSIS

A willingness-to-pay survey [56], in which 411 Americans with urge incontinence were solicited via their membership of the National Association for Incontinence, found a mean willingness to pay US\$87.74 per month for a 25% reduction in micturition and incontinence episodes. For a 50% reduction in symptoms, respondents were willing to pay a mean \$244.54 per month (1997 dollars). Corresponding median reductions were \$27.24 and \$75.92, respectively. Using both mean and median results, willingness to pay increased

**Table 4 : Principles for performing and reporting cost-effectiveness analysis [37]**

<b>1. RESEARCH QUESTION</b>	<ul style="list-style-type: none"> <li>• Explicitly stated</li> <li>• Interesting, feasible</li> <li>• Appropriate for CEA</li> </ul>
<b>2. TIME FRAME</b>	<ul style="list-style-type: none"> <li>• Explicitly stated</li> <li>• Appropriate</li> </ul>
<b>3. PERSPECTIVE</b>	<ul style="list-style-type: none"> <li>• Explicitly stated</li> <li>• Appropriate</li> <li>• Costs and outcomes appropriate for perspective</li> </ul>
<b>4. ANALYTIC MODEL</b>	<ul style="list-style-type: none"> <li>• Explicit (spreadsheet, tree, Markov process)</li> <li>• Strategies, intermediate and terminal states described</li> <li>• Includes reasonable alternative strategies</li> </ul>
<b>5. PROBABILITIES</b>	<ul style="list-style-type: none"> <li>• Source of data</li> <li>• Quality of data</li> </ul>
<b>6. COSTS</b>	<ul style="list-style-type: none"> <li>• Appropriate measure (cost, charge; direct, indirect costs)</li> <li>• Source of data</li> <li>• Quality of data</li> </ul>
<b>7. OUTCOME MEASURE</b>	<ul style="list-style-type: none"> <li>• Explicitly stated</li> <li>• Appropriate</li> <li>• [Utility measure (source of data, appropriate methods)]</li> </ul>
<b>8. INCREMENTAL ANALYSIS</b>	<ul style="list-style-type: none"> <li>• Done</li> <li>• Appropriate “basecase”</li> <li>• Appropriate summary measure</li> </ul>
<b>9. SENSITIVITY ANALYSES</b>	<ul style="list-style-type: none"> <li>• Done</li> <li>• Appropriate range</li> <li>• Appropriate variables</li> </ul>
<b>10. DISCOUNTING (WHEN APPROPRIATE)</b>	



**Figure 4 : Costs of QALYs gained with 5 different treatments for incontinence in female patients (means and standard errors) [95].**

by a factor of 2.75 when the percentage reduction in symptoms doubled (from 25% to 50%).

In summary, selection of an effectiveness measure after surgical intervention is often difficult and controversial. For benign disease, life years or QALYs may not be sensitive to a reasonable safe intervention. In the short-term, utility may be negatively affected by surgery and recovery. In longer-term analyses, these effects will be diluted by time and may be negligible. Nevertheless, QALYs are the current gold standard [1, 2]. Researchers are encouraged to use QALYs, but they may find it very worthwhile to add other outcome measures, such as disease-specific quality of life measures that are more sensitive to treatment.

## VI. SUMMARY

Urinary incontinence continues to be a costly illness that affects personal resources, medical treatment, and quality of life, as evidenced from quantitative estimates from middle to high-income countries. The magnitude of urinary incontinence costs is quite comparable to other illnesses afflicting the female population, such as breast cancer, osteoporosis and arthritis. Most studies focus on the direct costs of the illness, which are relatively easier to quantify than indirect costs, such as productivity loss. Among the direct costs, personal care (routine care costs) took an overwhelming share of total direct costs. It was found that there is a strong correlation between the economic status of the country and the amount of incontinence pads used.

In recent years, a special effort has been made to follow up treatment cost analysis, both in terms of the effect of new medication on the treatment of urge incontinence and procedures on treating stress incontinence. A number of studies have examined the patterns of treatment among the managed care system.

More quantitative analysis has been carried out to study health related cost consequences due to urinary incontinence. This is a more challenging task. Through direct survey and multivariate analysis, more reliable estimates are now available.

Finally, cost-effectiveness analyses and cost-utility analyses of alternative treatment protocols have been studied, but in limited quantity, and largely under quasi-experimental design. More studies are needed using randomized trials.

## VII. FUTURE RESEARCH PRIORITIES

Since the last review, more studies have been published on the costs of urinary incontinence among community dwelling residents, the detailed costs estimate of routine care, cost consequences of urinary incontinence, and the costs of OAB (which overlaps the subset of urinary incontinence – urge and mixed condition). The estimation of costs of urinary incontinence has been expanded beyond the US in the last few years, and in countries such as Australia, France, Germany, The Netherlands, Italy and the UK urinary incontinence continues to be a significant illness affecting personal resource use in the health care system and quality of life. However, there is still a need to know more about these costs in low-income countries. One of the reasons for the paucity of these cost studies in low-income countries is that this topic has not been widely recognized either due to cultural differences or differences in economic status. In addition, most of the available data only exists from high-income countries. To encourage low-income countries to engage these cost estimates, it would be useful to explore findings for these types of study in the future.

We have identified the following priority areas for research on the economics of incontinence:

1. direct medical costs of urinary incontinence
2. productivity loss and indirect intangible costs of incontinence
3. routine care costs
4. effect of incontinence on institutionalization and hospitalization
5. costs of incontinence for the population under 65 years
6. cost variation by type of urinary incontinence
7. costs of treating incontinence in different health care systems
8. the sensitivity of utilities and willingness to pay in economic evaluations
9. national differences in the costs of incontinence and funding of care
10. cost implication of disease progression and remission in incontinence and OAB

To facilitate economic research, it is imperative to establish validated and accepted outcome measures of symptom severity as well as measures for symptom

improvement following therapy. We need to define when a treatment works and what is a clinically significant change.

These research priority areas should not be viewed as mutually exclusive. For instance, there are costs associated with urinary incontinence whether or not a person is treated. If a person is treated and becomes continent, direct treatment costs are incurred but the cost consequences of indirect costs and intangible costs are avoided. In contrast, if a person does not seek medical attention, then the direct medical costs will be minimal but the indirect and intangible costs will be increased. In addition, such people will likely contribute to an underreporting of the prevalence of urinary incontinence. There has been no research on the different types of costs associated with urinary incontinence with respect to national and cultural differences. Clearly, it will depend on people's knowledge of incontinence and their willingness to seek medical advice for it based on severity and cultural conditioning. Understanding the costs and cost-effectiveness as well as effectiveness of intervention will help to guide health policy.

Another area that has not been explored is the effect of remission and recurrence in terms of the cost impact and how prevention programs may be cost-effective. For example, patients with OAB may be continent because they are using coping strategies to deal with their frequency and urgency, but if they decompensate then incontinence ensues. Hence, an understanding of costs related to prevention of decompensation would be of value.

Cost analyses are necessary to help health policy planners determine how to allocate resources. For such analyses to be meaningful, it is necessary to abstract data only from studies that are tightly focused, and to keep references to these data within the context of the original work. Generalizations or extrapolations that do not relate directly to each aspect of a survey will be misleading. To date, most analyses have not been so stringent because data are lacking. Such information is urgently needed to allow meaningful interpretation.

It should be emphasized that research on costs should be carried out in the developing world as well as in more developed countries outside of the US. Data from the US, such as they exist, will help to guide such endeavors.

This committee wishes to encourage inclusion of the following in future incontinence studies:

- Direct and indirect measurement of patient preferences (utilities)
- Economic evaluation preferably cost-effectiveness analysis (especially cost-utility analysis)

In order to facilitate economic studies regarding the cost of incontinence treatment, each country should gather data regarding the costs of the available treatments and investigations and publish average figures, which could be employed in economic studies. The actual cost of visits to each type of continence clinician should be obtained from the cost of doing business rather than relying on charges. Policy guidelines should be based not only on evidence-based medicine but also on cost-effectiveness.

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