CHAPTER 2

Committee 24

Economics of Incontinence

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CONTENTS

ABBREVIATIONS

AQoL Assessment of Quality of Life
ASHCN Australian Southern Health Care Network
BOA Basic Office Assessment
CCA Cost consequence analysis
CBA Cost benefit analysis
CEA Cost-effectiveness analysis
CI Confidence Interval
COI Cost of illness
CMA Cost minimization analysis
CUA Cost-utility analysis
DALY Disability Adjusted Life Year
DBICI Dowell-Bryant Incontinence Cost Index
DRG Diagnostic Related Group
EQ5D EuroQoL 5 dimension health status measure
FFR French Francs
GDP Gross Domestic Product
HIV/AIDS Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome
HRG Health Care Resource Group
HRQOL Health Related Quality of Life
HUI Health Utilities Index
IBS Irritable bowel syndrome
ICER Incremental Cost-effectiveness Ratio
IQR Interquartile Range (25%-75%)
MAU Multi-attribute utility
NIH National Institutes of Health
OAB Overactive Bladder
OR Odds Ratio
PTSD Post traumatic stress disorder.
QALY Quality Adjusted Life Year
QOL Quality of life
QWB Quality of Well-Being Index
SG Standard Gamble
TTO Time Tradeoff
TVT Tension free vaginal Tape
WTP Willingness to pay
UK United Kingdom
US United States
UTI Urinary tract infection
VAS Visual analog scale

Economics of Incontinence

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I. INTRODUCTION

Economics analyses inform decision makers about how to allocate resources to maximize societal well-being within a limited budget. Within the field of economics there are many specialized topics, such as banking, monetary policy, taxation, international trade, and public finance. During the past quarter century, health and medical services have become an increasingly important component in the economy. Currently, most industrialized counties spend between 7-14% of their gross domestic product on health-related services (Table 1). As a result, the application of economic knowledge and methodology to health care services is now a special field, called health economics or medical care economics. Health economics is the application of microeconomic principles, such as demand, supply, costs, and production, to health care practices and health care behavior both at provider and consumer levels. Often health economists are called upon to: (1) estimate the cost to treat an illness, (2) evaluate the economic consequences of not treating the illness (i.e., the excess burden of disease), and (3) compare the costs and benefits (or cost-effectiveness) of alternative treatments.

Economics can provide valuable information on how regulations, health insurance and health care financing affect the supply of health professionals, the processes of care and health outcomes. These topics may seem less directly relevant to clinicians studying incontinence. However, incontinence imposes very different costs on payers, providers and patients. These differences can lead to complex organizational arrangements that impact where patients get care, what services are covered by health insurance, and patient outcomes. For example, there is an association between public health insurance, regulations, and nursing home quality [1-5]. Given the prevalence of incontinence in nursing homes and the association between incontinence and nursing home admission, this type of economic research can be important for patients, clinicians and policy makers.

Why should clinicians read a chapter about "The Economics of Incontinence?"

As the average life span of the population of most developed countries is rapidly increasing, the prevalence of incontinence will continue to rise and the demand for incontinence services will increase. Unfortunately, national health care budgets will not rise in parallel. Furthermore, health care interventions are becoming increasingly sophisticated and costly, e.g., medicated cardiac stents, laparoscopic surgery, new medications, and all of these technological developments compete for the finite health care dollar.

As continence clinicians, if we are to justify increasing expenditure on our field of medicine, we must prove that our new treatments are not just more "effective" but more "cost-effective" than current treatments. This can only be demonstrated through rigorous economic studies of incontinence interventions, using a common yardstick such as the QALY (discussed later). If this is not done, patients may suffer because health providers and governments may refuse to pay for new or even existing "unproven" treatments and technologies.

Frequently economists are called upon to evaluate the value of new treatments. After identifying efficacious treatments, an important question is, "are the benefits worth the costs?" The answer may not be

straightforward, as both health conditions and their treatment cost money and impact quality of life, and there may be many alternative treatments available for any particular condition. The application of economics to medical practice does not necessarily mean that less can or should be spent. Instead, the underlying belief is that resources should be allocated to those treatments that maximize social welfare [6] (**Table 1**).

Table 1. Total expenditures on health as a percent of Gross Domestic Product (GDP)

	1990	1995	2000	2001
Australia	7.8	8.2	8.9	9.2
Austria	7.1	8.2	7.7	7.7
Belgium	7.4	8.6	8.6	9
Canada	9	9.2	9.2	9 .7
Czech Republic	5	7.3	7.1	7.3
Denmark	8.5	8.2	8.3	8.6
Finland	7.8	7.5	6.7	7
France	8.6	9.5	9.3	9.5
Germany	8.5	10.6	10.6	10.7
Greece	7.4	9.6	9.4	9.4
Hungary		7.5	6.7	6.8
Iceland	8	8.4	9.3	9.2
Ireland	6.1	6.8	6.4	6.5
Italy	8	7.4	8.2	8.4
Japan	5.9	6.8	7.7	8
Mexico	4.8	5.6	5.6	6
Netherlands	8	8.4	8.6	8.9
New Zealand	6.9	7.2	8	8.1
Norway	7.7	7.9	7.6	8
Poland	5.3	6	6	6.3
Portugal	6.2	8.3	9	9.2
Spain	6.7	7.6	7.5	7.5
Sweden	8.2	8.1	8.4	8.7
Switzerland	8.5	10	10.7	11.1
United Kingdom	6	7	7.3	7.6
United States	11.9	13.3	13.1	13.9

Source: OECD HEALTH DATA 2003 3rd ed.

This chapter is divided into eight sections, described below.

I. Introduction on the economics of incontinence.

II. Background information on economic methods and terminology. Cost is defined and we explain how the context can affect the interpretation of economic data.

III. Different types of economic analyses are described, including cost of illness, cost-effectiveness and cost-utility analysis.

IV. Description of outcome measures that are appropriate for economic analysis.

V. Review of how to do a cost-utility analysis.

VI. Synthesis of research on the economics of incontinence.

VII. Summary of current research.

VIII. Identification of future research priorities.

II. BACKGROUND

1. Defining and Measuring Costs

Outside of health, most items that we purchase daily have a readily observable cost. We know the price of coffee before we get it, know what kind of questions to ask, and know what we get for that price. In the coffee market (i.e., markets with perfect competition), the cost is determined by supply and demand, and the market self-regulates, requiring little or no outside regulation. This does not occur, however, in health care. Few people have the ability to study which treatment they should get, and those that do have no time when faced with an emergency. In emergencies, people rely on the system and treatment being provided, regardless of the provider.

Problems with the health care market has resulted in substantial regulation [7-9]. Although all countries regulate health care to some degree, they do so in very different ways (e.g., the regulatory environment within which health care is provided, insurance, limitations on the building of hospitals, and control over health care costs). 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

affect the cost. Health care systems, as a nation, province, or health plan, can limit the treatments for which they will pay or set limits on the prices. Pharmaceuticals are often regulated in this fashion, where access is limited or the government regulates the price [10].

Patients often observe very different "costs" for health care goods and services. Further variation arises because accounting systems often identify services and price them differently. These estimates are usually in the form of charges that are moderately correlated with economic costs, in the true economic sense. Cost is the amount to produce the good, whereas a charge represents the amount on a bill. Therefore, different accounting systems can yield very different cost estimates.

Most of the hospital accounting systems in the U.S. focus on billing and payments. The charges listed on the bill usually overstate costs and are rarely paid in full by the payer. In the U.S., researchers have developed imperfect methods for adjusting the charges with a hospital-specific ratio of costs to charges to better estimate costs [11]. Charges, however, are not always available. Integrated health care systems, including Canada and the U.K, do not routinely generate bills. For these systems, researchers have developed methods for generating pseudo-bills and cost estimates [12-14].

Many cost determination methods are used and most analyses include a combination of "gross costing" and "micro costing" [6]. Accounting and billing systems use micro-costing methods, whereby very detailed estimates of time and products (inputs) are combined with unit costs to estimate total costs. Micro-costing is extremely challenging to perform because a single inpatient stay or outpatient procedure might have hundreds or thousands of inputs. Even when there is just a single input, such as a pill of medication, the cost can vary by location or day. At the other end of the spectrum, gross cost methods identify a limited number of important characteristics such as the Health Care Resource Group (HRGs) in the U.K., Diagnosis Related Groups (DRGs) in the U.S or Australia, and length of stay. These characteristics can then be combined using different techniques to estimate total costs (**Figure 1**).

Accounting systems are limited in that they always report the health care payer's costs or charges. Since societal costs are usually of interest [6, 15], it is important to distinguish between and to include both provider-incurred costs and patient-incurred costs.

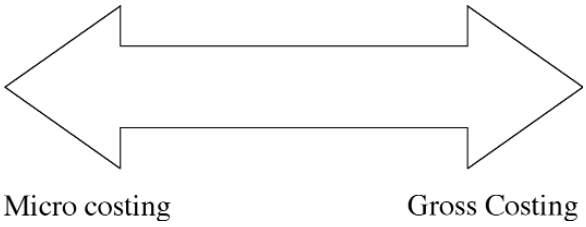


Figure 1. Methods for estimating direct health care costs.

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 incurred by individuals, and in 1995 the routine care costs in the U.S. represented at least 50% of the total cost of urinary incontinence [16, 17].

2. Categorizing Costs

There are different typologies or frameworks for categorizing costs. One that dates back to the 1950's involves separating direct, indirect and intangible costs [18]. Direct costs are the value of all goods, services and other resources used to treat or manage the condition. For incontinence, direct costs include diagnosis, treatment, and routine care. Routine care, which includes the use of absorbent pads, is one of the largest cost components. The direct costs also include costs of consequences caused by incontinence, and include fractures from falls [19], nursing home admissions [20], and urinary tract infections [21]. However, the causal link between incontinence and its consequences is less clear. Thus, caution needs to be used when attributing the cost of a consequence to incontinence.

Indirect costs are the value of lost productivity or lost employment due to morbidity and mortality. Incontinence is not associated with premature death, but it is associated with lost productivity for both early retirement and fewer hours of productive work. 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 and gender adjusted average wages or by using minimum wages (a human capital approach). Intangible costs are the third type of cost and are the monetary value of pain and suffering.

Most cost studies exclude both indirect and intangible costs for three reasons. First, most studies report costs from the point of view of the health sec-

tor. That is most studies are only concerned with the direct costs of providing treatment. However, when most costs associated with a health condition are borne by the patient, his/her family and society at large, the health sector study perspective is inadequate. Indeed, for these very reasons the recommendations state that the societal perspective, which includes all three types of costs, should be adopted [6]. Second, methods for estimating these costs, such as willingness to pay, are not well developed and there are limited data on these costs. Third, when comparing cost and outcomes, the indirect and intangible effects are often included in outcome measurement. Therefore, including indirect and intangible costs would lead to double counting when comparing costs and outcomes.

The potential overlap between indirect and intangible costs has led some economists to avoid this categorization framework and use a framework that is based upon who bears the cost. Costs can be evaluated from many different perspectives. The four most commonly used perspectives are (1) societal, (2) payer, (3) provider and (4) patient or consumer. Since the economic impact on society is significant, regardless of where the burden falls, it is helpful for policymakers to know the overall burden of incontinence on society. A societal perspective can also act as a benchmark to understand other perspectives. Therefore researchers should use a societal perspective [6, 15]. Maintaining the societal perspective facilitates comparisons of costs of various illnesses within a country or across countries.

Point of clarification:

Costs can be categorized by type (direct, indirect or intangible), or by perspective (i.e., who bears the cost). Cost of illness studies often use the former, whereas cost-utility, cost-benefit and cost-effectiveness analysis use the latter. Many economists prefer to categorize costs by perspective.

Payers, both the government and private insurance, incur financial expenses to care for patients. Therefore, these payers are interested in the financial impact of a disease so that future health care budgets or insurance premiums can be planned.

Providers, such as hospitals, managed care plans, and nursing homes, are interested in the costs for reimbursement and planning. Providers that receive retrospective reimbursement are interested in accurately recording the services and who will pay for those services. Providers in systems with capitated financing are interested in the cost associated with a particular illness, such as incontinence or dementia, so that they can be considered for their global health care budgeting.

Finally, patients often incur sizeable costs when paying for lost wages, routine care products, treatments, and long-term care. These costs vary considerably by country. In some countries, such as Sweden, health insurance covers routine care products. In the U.S., these products are not covered and they can be very expensive. In Australia, low-income patients are eligible to apply for a subsidy of their routine care products. In many countries, office visits, diagnostic testing, and treatment require a co-payment. There is also wide variability in the generosity of long term care benefits. In some countries, such as the U.S., the strict limits on long-term care results in patients paying for most or all of the care. Other countries, such as Japan, provide generous long-term benefits, reducing out of pocket costs for institutional residents. In Australia, low-income patients who have no private superannuation (pension fund) can receive fully funded long-term care, but the quality of facility available may be lower than in the private facilities**.** Finally, incontinence can affect an individual's productivity in the workforce and can contribute to the decision to retire, resulting in loss of productivity and wages.

3. CONTEXT

Economic analysis provides valuable information when the results are used in context. First, it is 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. It is also important to discount future costs to reflect time preferences – the desire to have money now rather than money in the future [6, 15]. There is controversy over the appropriate discount rate and therefore there is no international standard [22-24]. In recent years, most international studies have used 3% as a discount rate to reflect the preference for future values of money in current terms.

Second, costs borne in past years should be expressed in the current year's dollars. In many countries, past and future costs can be adjusted by the Consu-

mer Price Index or other appropriate indices for all urban consumers (e.g., 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). Most countries track inflation using relatively standardized methods, thereby providing a method for inflating past costs.

Caution is urged when past costs are inflated to present day values. General inflation is measured as the cost of a *consistent* set of goods over time. Consistency means that the goods must be of the same quality over time, and thus the costs observed five years ago can be observed today and will be observable again in the future. When these conditions are met then the inflation index is informative. However, medical goods change rapidly. Newer technologies with a different price and different quality replace older technologies. This makes it difficult to determine whether any changes in price is due to inflation or due to improved quality. In this case, just inflating costs from many years ago can be misleading.

In summary, defining and measuring costs in health care can be very difficult. Often there is large variability in costs. Given this uncertainty, analysts should use sensitivity analysis to investigate how different cost estimates can influence the results. This involves re-running the analysis with different input parameters. Nevertheless, the costs usually reflect institutional idiosyncrasies, and as we describe in the next section, explicitly describing these contextual issues is crucial for interpreting results.

III. TYPES OF ECONOMIC ANALYSIS

Economic evaluations provide information that decision makers can use to obtain the most "value" for the health care budget. Allocating resources in a transparent manner requires information on the alternative choices, and a set of economic tools exists to provide information that can be used in the decision-making process. A typology of economic analysis for health and medicine has emerged over the past few decades. This section reviews these studies

1. Cost of illness (COI)

COI studies involve enumerating all of the costs related to an illness or disease and then summing these costs together for a given population. The costs are annualized for a given year. Thus we talk about the cost of incontinence in a given year such as 1995 or 1999. A COI is a descriptive analysis and it provides a lot of information about how incontinence has affected a population. A COI analysis is only as good as its assumptions and only as complete as current knowledge allows. It is often very difficult to estimate accurate costs and to identify the many consequences of an illness. For example, medical co-morbidities associated with incontinence, such as depression or urinary tract infection, have large cost impacts but may not be included in the cost of incontinence analysis.

An important limitation with COIs is that the results provide little information to decision makers about how to allocate scarce resources for treating conditions. In a COI, usually there is no attempt to measure the "value" of the relevant treatments or health interventions. Cost-utility and cost benefit analysis, which we discuss next, can address this particular issue.

2. Cost minimization analysis (CMA)

CMA compares costs of alternative health care strategies assuming that the benefits of the alternatives are equivalent. When the two treatments are truly equivalent in their risks, outcome, and an individual's preference for them, then a cost minimization analysis is sufficient; the cheapest intervention is to be preferred. However, cost minimization studies are relatively rare because the assumption of equivalency is usually not warranted. Most new treatments provide some incremental benefit at an additional cost. This implies that decision makers must consider costs and benefits simultaneously. Unfortunately this is often not understood and health care providers under significant budgetary pressure resort to such analyses to choose the cheapest option even if it does not present the best cost to benefit ratio.

3. Cost consequence analysis (CCA)

CCA is a variation on the cost-minimization analysis framework, and it involves assessing whether a new treatment resulted in a greater decrease in health care utilization than another treatment. Thus costs of the intervention are compared to health care utilization, such as the cost per hospitalization averted. There is a naturally appealing rationale for conducting this analysis. If the new treatment were to reduce health

care utilization, then health care providers may have incentives to adopt it. Unfortunately, when examined in detail, this rationale boils down to an analysis of whether the new treatment saves money in comparison to the alternative treatment. Most studies of this type conclude that the new treatment offers some benefits over the alternative treatment but that it is more expensive than the alternative. This partly reflects the pricing of the new treatments. For-profit companies have to make profits and as such any new development that they introduce will likely cost more. However, it is essential for good business practice for any new therapy to "add value." Businesses understand this and try to have their pricing strategies conform to this axiom. Accordingly, a cost-utility or cost-benefit analysis provides many advantages over a cost consequence analysis.

4. Cost-effectiveness analysis (CEA)

CEA refers to the broad class of calculations where the effectiveness measure is a general health outcome. CEAs with narrowly focused health outcomes (e.g., depression symptoms or incontinence episodes) have well-accepted limitations. Most notably, the use of narrowly focused health outcomes will miss other important effects. For this reason, there has been widespread convergence on the use of quality adjusted life years (QALYs) as the preferred health outcome in cost-effectiveness analysis.

5. Cost-utility analysis (CUA)

CUA refers to a CEA when QALYs are used as the outcome measure. Gold et al. [6] and Drummond et al. [15] have published texts that discuss standard techniques for conducting a CUA. In health and medicine, the CUA is considered to be the gold standard. The British Medical Journal, the New England Journal of Medicine, and the Journal of the American Medical Association will only review CUAs. Since utilities capture all potential benefits of an intervention and allow comparisons with other health conditions, cost-utility analysis is a powerful research tool.

To date, there are minimal data on utilities in incontinence and no data on the effect of treatment or change in incontinence severity on preferences.

6. Cost benefit analysis (CBA)

refers to a CUA where the benefits are measured in dollars. When everything is measured in dollars, optimal choice can be easily found by addition and subtraction. However, it is difficult to measure benefits in dollars, and many researchers, policymakers and clinicians are averse to placing a dollar value on life. CBA is rarely done in health.

Point of clarification:

Many researchers use the terms CEA and CUA synonymously. At times, this can be confusing. The past decade has seen a widespread convergence on the use of quality adjusted life years (QALYs) as the preferred health outcome in cost-effectiveness analysis. Prior to that, the use of QALYs was less common and so CUA was used to identify studies that used QALYs. CEAs with more narrowly focused health outcomes (e.g., depression symptoms or incontinence episodes) have well-accepted limitations and are used less frequently.

7. Summary

COI and cost-minimization analyses are simple, yet limited economic tools. Most new treatments offer additional benefits at an additional cost. The CBA, CUA and CEA were designed to determine how much money it costs to obtain another unit of effectiveness. Although the CUA is the preferred method, there are many challenges with calculating a QALY. We will discuss these issues in more depth next because different methods for calculating QALYs can have a very profound effect on the interpretation of the CEA.

IV. HEALTH OUTCOMES FOR ECONOMIC ANALYSIS

There are a number of health outcomes that are used in economic evaluations. These include disease-specific outcomes, health status, health value (e.g., QALY) and mortality. Each is discussed in turn.

1. Incontinence specific outcomes

Cost-Effectiveness in Health and Medicine [6] recommends using QALYs as the effectiveness measure in the CEA. However, the panel also notes that analysts can use a clinical outcome measure. For incontinence, clinical outcome measures include 24-hour pad test, incontinence symptoms from a voiding diary, or urodynamics. These outcomes can be particularly attractive for clinicians because they often use these measures in clinical practice.

Clinical outcomes can be very valuable in identifying when a treatment is efficacious. However, using clinical outcomes in a CEA yields results that are limited in scope. A treatment might have improved a person's quality of life, but had little effect on the clinical outcome measure. In this case, the results would be biased. In addition, a CEA with a clinical outcome measure might not be comparable to another CEA with a different clinical outcome measure. A clear advantage of cost utility analysis is that QALYs can be generalized beyond incontinence. For this reason, the QALYs and CUAs are the gold standard.

2. Health Status and Quality of Life Measures

There are a number of frequently used and highly regarded health status measures. Examples include the SF-36, the Sickness Impact Profile and the Nottingham Health Profile. These questionnaires provide valuable information describing a person's current health state.

Instruments that assess how a person perceives or feels about their health state are called quality of life (QOL) measures. The World Health Organization Quality of Life (WHOQOL-Brèf) measure, for example, covers physical, psychological, social and environment life domains. However, most instruments used in health care only focus on health-related quality of life (HRQoL) and many are focused on a specific disease (i.e., a disease specific HRQoL measure).

Chapter 6 in this book reviews quality of life measures. These measures can be very useful for understanding the effects of a treatment. However, they are not useful in an economic analysis and at present they cannot be used to create QALYs. The exception is the SF-36 for which Brazier et al. [25] have created a rudimentary utility scoring system.

3. Health value

Although there are several ways of measuring the value of a health state, the most common are willingness to pay (WTP), the disability-adjusted life year (DALY) and the quality-adjusted life year (QALY). We discuss all three here, and devote most of the time discussing QALYs as they represent the current standard for measuring health value.

a) Willingness to Pay

A tradition in economics is to observe what people purchase with their limited income. This provides information on people's inherent preferences because they are willing to trade some money, which they could use for other things, to purchase a good. Implicit in this tradeoff is that the consumer is knowledgeable and the good being purchased is worth the money. This method is often not possible in health care because of the many idiosyncratic characteristics of the health care market. In particular, health insurance obscures what people would be willing to pay.

As an alternative methodology, researchers use survey methods to ask people what they would be willing to pay for a treatment. WTP involves surveying people about their intents and preferences. That this does not observe actual behavior and that survey response may have little correlation with behavior remain reasons why some economists dislike WTP. Many clinicians are averse to using a measure of benefits that is related to ability to pay. Economists, on the other hand, expect benefits to be positively correlated with income. The National Ocean and Atmospheric Administration panel, chaired by Arrow, concluded that a positive correlation between income and WTP should be used to test validity [26].

WTP can be used as a measure of benefit in a cost benefit analysis. Although WTP has been used in urinary incontinence [27], experts frequently prefer cost-effectiveness analysis (CEA) or cost-utility analysis (CUA) instead [6].

b) Disability adjusted life year (DALY)

The DALY brings together two estimates of losses caused by illness: losses in expected life-length due to premature mortality, and losses due to living with disability due to illness or injury [28]. As with the QALY, the DALY is a weighted measure from 0 to 1, where the weights are usually established by clinicians [28, 29].

To estimate the DALY of incontinence would require data on the prevalence of incontinence by incontinence type, gender, and severity, the incidence of incontinence, mortality rates by gender and age, disability weights, and discount rates (so all years lost can be converted into present value). To date, no one has estimated DALYs for incontinence.

c) Quality adjusted life years (QALYs)

QALYs denote the relationship between the value of a given health state and the length of time a person lives in that health state. The value of a given health

state is measured in 'utilities', where 'utilities' represent preferences for a given health state.

To understand utilities, consider the following. Most people would prefer to be healthy over a given time rather than suffer constant urinary or fecal incontinence. Utility measurement refers to valuing these preferences on a life-death scale with endpoints of 1.00 and 0.00, where 1.00 is perfect quality of life (best imaginable) and 0.00 is death equivalent quality of life. For example, the measured utility for urinary incontinence may be 0.60. If treatment improves this to 0.70, then the value of the treatment is 0.70 – 0.60 = 0.10. If this utility gain is maintained over time, say for 10 years, then the gain is 0.10 x 10 = 1.00 QALY. This is illustrated in Diagram 2, which compares two different treatments for incontinence. Clearly, Treatment B is to be preferred since it yields a greater number of utilities when compared with Treatment A. Because utilities fall on the life-death scale, they are (in theory) common across all health states and therefore can be used to compare the effect of interventions in different health fields, or different interventions within the same field. For example, the QALYs gained from treatment for incontinence could be compared with those gained from treatment for depression. Where treatment costs (including costs to the patient) are known, the treatment providing the lowest cost-per-QALY gained is preferred as this ensures society gains the greatest benefit from the health care dollar. (**Figure 2**)

Direct and indirect methods have been used to elicit utilities [30]. The most common direct elicitation methods for valuation include time trade off (TTO), standard gamble (SG), and the visual analog scale (VAS).

Time trade-off (TTO). A person with severe incontinence can have a treatment that will restore her to full health; but a side effect is she will live a shorter life. She is asked to choose how many years of her life she would be willing to 'give up' in order to be in full health. If, in her untreated condition, her life expectancy was 10 years and after the treatment this was 5 years she may reject the treatment. If after the treatment it was 9 years, she may accept it; if her life expectancy was 6 years, she may not. Her choices would continue back-and-forth like this until she indicated that she was indifferent to whether she had the treatment or not. If the point of indifference was that 8 years of full health was the equivalent of 10 years with severe incontinence, then the quality of life value for her current health state is 8/10 or 0.80.

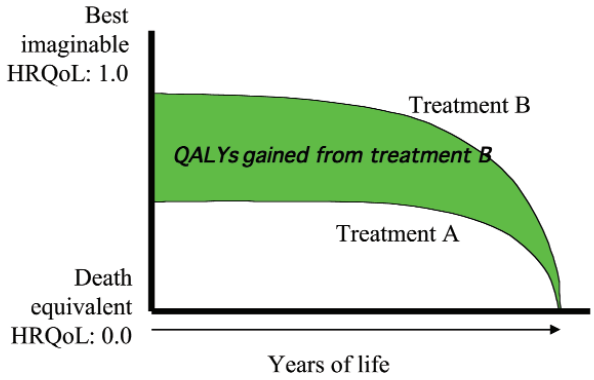


Figure 2. Understanding QALYs

Standard gamble (SG). A person with urinary incontinence is presented with a treatment option that has two possible outcomes: either full health for the remainder of his life, or death. He is free to choose either the treatment or to remain with lifelong urinary incontinence. If the probability of full health is 1.00 (i.e., his incontinence will be cured and there is no chance of death), then obviously he will choose to have the treatment. If the probability of full health is 0.90 and death 0.10, he may still choose the treatment. However there would be a point, for example at 0.80 for full health and 0.20 for death, where he is not clear as to whether he would want the treatment or would choose to remain in his current health state. This point of indifference is the 'value' or 'utility' of his health state.

Visual analog scale (VAS). The respondent is asked to consider an incontinent health state and then to rate this on a scale, where the endpoints are 0.00 (death equivalent) and 1.00 (full health equivalent). Unlike the TTO or SG, with the VAS there is no uncertainty: the respondent is not asked to 'trade' anything. Consequently many consider that VAS scores do not represent utilities because they provide a simple ranking of health states. Where VAS scores are used, a transformation is generally required, based on TTO or SG [31-33].

When measuring utilities, there is a question of who should provide the values. Gold et al. [6] recommend using utility values from the general population rather than values from patients themselves. The recommendation is based on the fact that health care is a publicly provided good and should reflect the values of the public. This remains one of the most debated recommendations, with many researchers believing that utilities from patients are more informative.

Instruments measuring utilities suitable for QALY calculation

Multi-attribute utility (MAU) instruments can be used instead of the direct elicitation methods. Simply, a MAU-instrument decomposes HRQoL into health domains (e.g., mobility and emotions), respondents provide estimates for each of the parts, which are then 'valued' and recomposed back into a utility.

There are seven MAU-instruments at the present time. Each is briefly described, in order of development. The descriptions are largely based on Hawthorne & Richardson [34, 35].

1. Rosser Index

The Rosser Index, designed for use in hospital settings, had two dimensions measuring disability and distress, and measured 29 health states. Values (magnitude estimation) were from a convenience sample of 70 respondents [36]. A revised version in the early 1990s was based on SG procedures and included discomfort as an additional dimension [36]. Administration requires a trained interviewer. The upper boundary is 1.00, and the lower boundary –1.49, which means that health states worse than death are permitted.

2. Quality of Well-Being Index (QWB)

The QWB has three dimensions (Mobility, Physical Activity, and Social Activity), with 3–5 levels each, and 27 illness symptoms. Combined, these provide an index of 'Well-life expectancy' with 43 functioning levels [37-39]. The QWB requires interview administration (15–35 minutes; training is required [40]), although a shorter version is available which takes about 15 minutes [41] and a self-report version is under development. The upper boundary is 1.00, and the lower boundary is 0.00 (death equivalent) and health states worse than death are not permitted.

3. Health Utilities Index (HUI)

The HUI uses 12 items that measure 8 domains (Vision, Hearing, Speech, Ambulation, Dexterity, Emotion, Cognition and Pain). The upper boundary is 1.00, and the lower boundary is –0.36, permitting health states worse than death.

4. 15D

The 15D was created in Finland. It has 15 items, measuring Mobility, Vision, Hearing, Breathing, Sleeping, Eating, Speech, Elimination, Usual Activities, Mental Function, Discomfort & Symptoms, Depression, Distress, Vitality and Sexual Function [42]. The upper boundary is 1.00, and the lower boundary is +0.11: death-equivalent and worse than death health states are not allowed.

5. EQ5D (also known as the EuroQol)

The EQ5D was developed by a team from 7 European countries [43, 44]. It has 5 items measuring Mobility, Self-care, Usual Activities, Pain/Discomfort and Anxiety/Depression. The upper boundary is 1.00, and the lower boundary is –0.59: it permits values worse than death.

6. Assessment of Quality of Life (AQoL)

The AQoL comprises 15 items, 12 of which compute the utility score [45, 46]. There are five dimensions: Illness (not used in utility computation), Independent Living, Social Relationships, Physical Senses and Psychological Well-being [46, 47]. The upper boundary is 1.00, and the lower boundary is –0.04; it permits health state values worse than death.

7. SF6D

Although two different algorithms have been published by for deriving preference-based values from the SF-36, only the second is described here [25, 48]. Whenever SF-36 raw scores are available, SF6D utilities can be computed. The SF6D measures physical functioning, bodily pain, mental health, physical role, emotional role, social functioning, and vitality. The endpoints for the SF6D are 1.00, and 0.30 for the worst possible health state; the SF6D does not allow death equivalent values.

4. Review of Utilities and Incontinence

After searching Medline and Econlit, 90 articles were identified with information on incontinence and utilities. Of these, 16 reported using multi-attribute utility instruments; 6 had no utility data, 2 reported global utility values, 2 reported mean or median scores and nothing else, 1 reported medians and IQRs, 1 reported EQ5D VAS, but nothing else. Two unpublished Australian databases (i.e., the 1998 South Australian Health Omnibus Survey and satisfaction with surgery for incontinence study) were included in this review.

Two studies used the HUI [49, 50]. Data on the AQoL and SF6F were collected by Hawthorne [51], and the 1998 South Australian Omnibus Health Survey. One study reported on the 15D [52] and EQ5D [53] each. These articles provide limited information on incontinence. Caveats include limited sample sizes, results specific to an individual country, and data along side clinical trials instead of random populations.

Before presenting data that compares incontinence to

other conditions, it should be noted that there was wide variation among those with incontinence. This can reflect incontinence severity as well as the effect of other co-morbid conditions. People with incontinence often have other health problems, and it is difficult to isolate the independent effect of incontinence in these situations.

Hawthorne et al used data from the 1998 South Australian Omnibus Health Survey and compared incontinence to other conditions. As is shown in Figure 3, fecal incontinence has a greater impact on quality of life than urinary incontinence. (**Figure 3**)

Clearly, these results show that obtaining more precise estimates of utility is important for future cost utility analyses. Prospective randomized controlled trials should collect utilities as part of the trial.

One questions is which MAU to use, or whether to use direct utility elicitation through a standard gamble or time trade off. Experts have yet to reach consensus on this and consensus is highly unlikely. Some researchers always use standard gambles or time tradeoffs because of their preferences for the theoretical axioms of utility and judgment and decision making. Others feel that these methods are not always practical.

When choosing among MAUs, issues about language availability might dictate the choice. Most MAUs are available in a wide range of languages and take little time for the patient to complete. When multiple MAUs are available, other empirical data can guide the decision. One issue is the instruments' ability to detect an effect. The SF6D, HUI, AQoL and HUI3 are relatively similar in their ability to detect small to moderate effects (based on Cohen's measure of effect size). Limited data with the 15D has indicated that it has less ability to detect a small or moderate effect. This remains an area of research and new data are likely to provide valuable insights on how to measure utilities with incontinence.

5. Summary

Of the many types of economic analyses, CUA is the gold standard in health care. The measurement of utilities, and other outcomes, was presented in this chapter. The utilities are then combined with information on mortality to identify QALYs, which remains the preferred outcome.

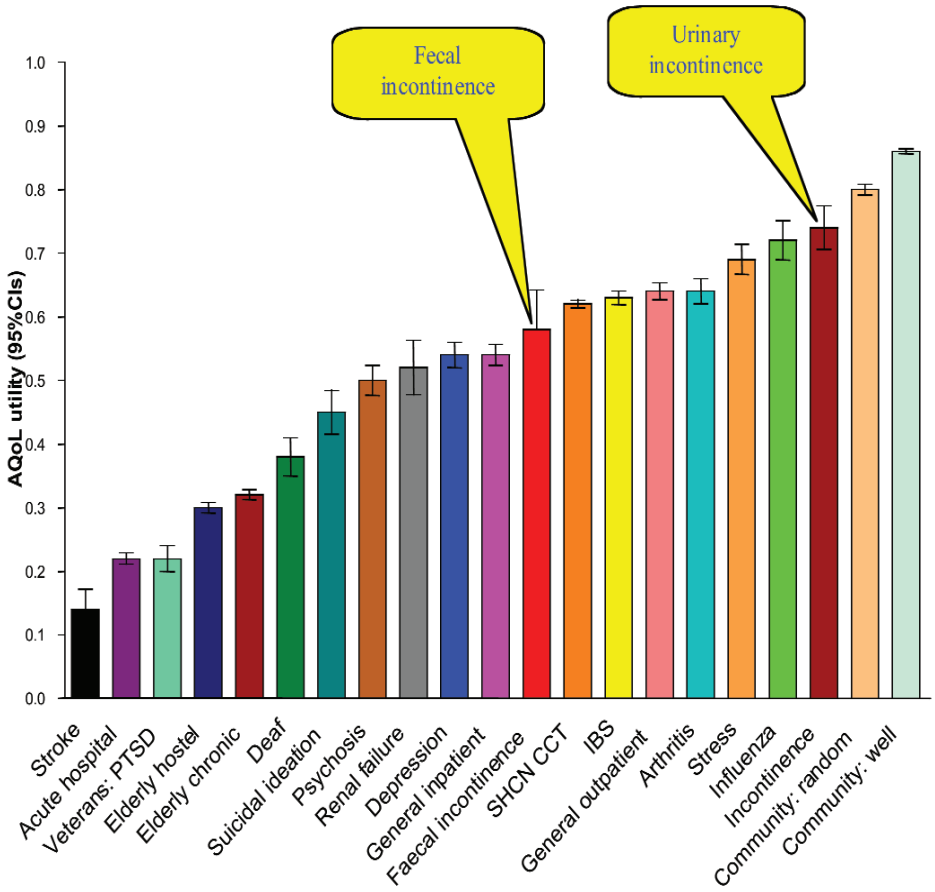


Figure 3. A comparison of incontinence to other conditions from Australia Source: Data from the 1998 South Australian Omnibus Health Survey PTSD= post traumatic stress disorder. SHCN = Australian Southern Health Care Network Controlled Trial of High Cost Inpatient users IBS = irritable bowel syndrome

Broad outcomes like QALYs and DALYs capture the effects of lost productivity, pain and suffering. When these outcome measures are used in a cost-effectiveness analysis, there is the potential for double-counting. Double counting happens when QALYs capture the impact of incontinence on work productivity, and the economic cost of decreased productivity is also included as a cost. Caution should be used to avoid double-counting. If there is reason to believe that the outcome measure captures the lost productivity or suffering, then these costs should be excluded.

There are many different methods for eliciting utilities or the value of a particular health state. Two direct elicitation methods, TTO and SG, remain favored by theoreticians. The VAS is a widely used direct elicitation method, but because it includes no uncertainty, there is doubt whether the values truly represent utilities. The collection of utilities using direct methods often requires interviewer administration and there are concerns that people do not understand what is being asked of them. A number of indirect MAU instruments were developed as alternatives to the TTO and SG. There are distinct differences between these instruments, which we briefly reviewed. The MAU instruments are not equivalent. Nor are they equivalent to the direct elicitation methods. Readers interested in more details should see Hawthorne & Richardson [34]. Nevertheless, it should be clear that the choice of methods could impact the results and interpretation of a cost-utility analysis.

One final note about collecting utilities is warranted. Many people with incontinence are not cognitively able to complete a MAU or go through a standard utility elicitation process. Some of the MAUs, such as the HUI3, have been validated for use with proxies. Although not always possible, if proxies are expected then proxies should be gathered for all cases, even those patients who complete the utility measure themselves, so that the method is applied in a standard fashion.

V. DO IT YOURSELF: CONDUCTING AN ECONOMIC ANALYSIS

Different economic analyses fulfill different aims and purposes. Although the existing COI studies on urinary incontinence in the US would obviate the need for another study, a study describing the costs of fecal incontinence would be helpful. Therefore, researchers and advocates should give careful consideration to the existing literature and their ultimate goals before departing on a study.

The cost utility analysis is frequently used and misused. Because it now represents the gold standard for medical decision making, the remainder of this section highlights key issues that must be addressed. These ten principles, summarized below, comprise an appropriate minimum standard for performing and reporting cost utility analyses. The principles were identified from guidelines established by the Panel on Cost-Effectiveness in Health and Medicine convened by the United States Public Health Service [6]. Each principle should be explicitly addressed in every CEA study.

1. Research Question: The research question must be clearly stated. All CUAs must compare at least two different health care strategies, and these strategies should include standard practices.

2. Time Frame: The period of time over which costs and benefits are measured should be long enough to capture the economic impact of an intervention and future health outcomes. Lifetime costs and benefits is the gold standard and should be use, but additional time spans can be considered in further analyses.

3. Perspective: The choice of perspective should be clear. Societal is the gold standard. Other perspectives, such as the payer or patient perspective, may be useful, and they can be presented with the societal perspective.

4. Probabilities: Probabilities are needed for each "chance" event, such as the chance of improvement or the chance of an adverse event. The best sources of probabilities come from meta-analyses of randomized clinical trials. Data from individual clinical trials may be useful and is preferred over observational studies or clinician judgment.

5. Costs: Units and unit costs should be described in detail. Information on the source (e.g., charges, payments) and year of the cost data should be presented. If the costs were inflated and/or converted from another currency, then this must be described.

6. Outcome Measure: Measures of effectiveness depend on the type and objectives of analysis. Quality adjusted life years are the gold standard; although other outcomes may also be informati-

ve. Utilities, which are needed to estimate QALYs, can be collected along side clinical trials; we describe common methods and instruments elsewhere in this chapter.

7. Analytic Model: Each intervention or program being assessed must be described and possible courses of events identified, including the expected course of disease, treatments, complications, and outcomes. This may be performed using a spreadsheet or decision tree.

8. Discounting: Since the value of both costs and benefits may decrease over time, discounting is used to calculate the present value of money and health states that will occur in the future. Future costs and utilities should be discounted to present value; 3 % per year is a recommended starting point.

9. Incremental Analysis: The purpose of a CUA is to describe the relative value of one health care strategy compared to another. An incremental cost-effectiveness ratio (ICER) is the incremental cost divided by the incremental effectiveness of intervention a compared to intervention b, and is calculated as follows.

$$\text{ICER} = \frac{\text{Average Cost}_{\text{intervention a}} - \text{Average Cost}_{\text{intervention b}}}{\text{Average Utility}_{\text{intervention a}} - \text{Average Utility}_{\text{intervention b}}}$$

Averages should be used rather than other measures of central tendency, such as medians, because it is important to include the effect of outliers. The leverage of the outliers should be tested in a sensitivity analysis.

Sensitivity Analysis: The sensitivity analysis fills two important goals. First, there is uncertainty with regard to costs and probabilities. The ICER needs to reflect this uncertainty, and a sensitivity analysis can provide information that is equivalent to confidence intervals. Second, policy makers and clinicians are very interested in boundaries where two treatments are equivalent—on one side, treatment

A is preferred whereas treatment B is preferred on the other side. Documenting these boundaries helps define the conditions under which a treatment is preferred. Researchers are developing innovative methods for conducting sensitivity analyses. Probabilistic models that use simulations are becoming more common, although they can be computationally complex.

VI. SYNTHESIS OF RECENT APPLIED RESEARCH

In this section we review the empirical research on the economics of urinary incontinence, overactive bladder, pelvic organ prolapse and fecal incontinence. We focus on research articles published in the last three years, and, when appropriate, we draw connections to older studies that were reviewed in a prior ICI report [54].

In the year 2000, the Swedish Council on Technology Assessment in Health Care reviewed the urinary incontinence literature and stated, "There are no economic studies addressing both the cost and effects of various methods for treating urinary incontinence [55, p 725]." Studies that compare costs and outcomes remain rare to this day. Most studies only describe costs.

1. Cost of illness

There have been two recent studies in the U.S. (see **Table 2**). The first was published by Wilson and colleagues in 2001 and estimated the costs of incontinence at US$16.3 billion (1995 dollars) [17]. In 2004, Hu et al. [56] estimated the cost at US$19.5 billion (2000 dollars). Wilson and colleagues [17] and Hu and colleagues [56] estimated costs for women and men over age 18. Both studies used a bottom-up estimation approach, which involves estimating an average annual cost and combining it with prevalence data. This approach is highly sensitive to the prevalence data, and small differences (<1%) can translate into differences of millions or billions of dollars for the U.S.

Figure 4 shows the breakdown of costs for community residents. Although the treatment costs are noteworthy, of particular interest are the large costs borne by patients to manage symptoms (routine care costs) and the very large consequence costs.

In 2000, the U.S. National Institutes of Health published a compendium of disease-specific costs of illness (http://ospp.od.nih.gov/pdf/table_1.pdf). Urinary incontinence is the most costly kidney or urology condition. Incontinence is relatively similar in magnitude to HIV/AIDS (US$13.2 billion in 1999), asthma (US$14 billion in 1996), and breast cancer (US$12.7 billion in 1990), which is a striking example of the large cost of urinary incontinence. **Table 3** identifies the direct costs associated with treatment and management of women's health problems.

Table 2. International comparison of urinary incontinence community treatment cost estimates

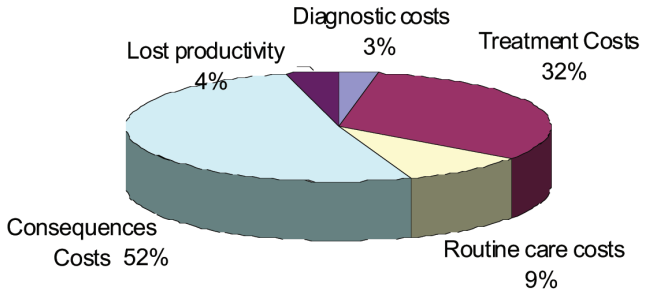
Country	Cost	Year of cost estimate	Notes	U.S. dollar equivalence (year)	US 2004 Dollars* (Millions)
Spain [59]	55,750 million Pesetas	1995	Restricted to direct treatment costs from the Spanish National Health System's perspective	131.765 (1995)	$514
Australia [57]	710 million Australian dollars	1998	Restricted to community-dwelling Australian women 18 years of age and older	1.535 (1998)	$526
Italy [60]	352 billion Lira	1997	Restricted to direct costs and the perspective of the national health care system.	1,527 (1997)	$266
France [61]	3 billion French Francs	1995	Restricted to direct treatment costs for women.	5.340 (1995)	$683
U.S. [56]	US$19.5 billion	2000	Societal costs for people over age	18 1 (2000)	$20,972
U.S. [17]	US$16.3 billion	1995	Societal costs for people over age 18	1 (1995)	$19,808

Inflated using the U.S. General Consumer Price Index.

Table 3. Direct Costs of Interventions and Disease Management for Prevalent Health Problems in Women

Disease	Adjusted* Direct Cost (US$ Billions)	Year of Estimate	US$ 2004 (Billions)	Ref.
SURGICAL THERAPY OR HOSPITALIZATION				
Stress urinary incontinence surgery	0.5	1991	0.7	[108]
Pelvic organ prolapse surgery+	1.0	1997	1.2	[100]
Breast neoplasms	1.1	1997	1.3	[109]
Gynecological neoplasms	1.8	1997	2.1	[109]
Osteoporosis/fractures	5.6	1997	6.5	[109]
Cardiovascular disease (women only)	28.4	1997	32.8	[109]
ANNUAL COST OF DISEASE MANAGEMENT				
Infertility	1.0	1987	1.6	NIH
Pelvic inflammatory disease & sequelae	1.9	1998	2.2	[110]
Gynecological neoplasms	2.4	1997	2.8	[109]
Breast neoplasms	2.6	1997	3.0	[109]
Breast cancer	6.6	1990	9.4	NIH
Urinary incontinence	10.3	1987	16.8	NIH
Osteoporosis/fractures	12.9	1997	14.9	[109]
Cardiovascular disease (women only)	60.4	1997	69.7	[109]

**Adjusted to 2004 dollars using the General Consumer Price Index, Bureau of Labor Statistics Data*



Source: Hu et al. [56]

Figure 4. The Cost of Incontinence among Community Residents

In recent years, UI cost of illness studies from Australia, Italy, and Spain were published. In Australia, Doran et al. [57] used the Dowell-Bryant Incontinence Cost Index (DBICI) [58] and prevalence data to estimate the cost of incontinence for community-dwelling Australian women 18 years of age and older. For 1998, they estimated that 1.83 million women had urinary incontinence for a total annual cost of AUD$710 million ($US 462 million in 1998 dollars). A majority (60%) of the costs were attributed to women over 40 years of age.

A study on economic costs of urinary incontinence in Spain estimated that total direct costs of UI in 1995 for those over 65 years old was 55.75 million Pesetas (US$ 423 million in 1995 dollars) [59]. This cost is only limited to the Spanish National Health System. Direct costs include diagnosis and medical evaluation, surgical, institutional patients care, sanitary towels, medicine, and other incontinent supplies. Among these, the cost of sanitary towels and institutional patient care accounts for 40% of total direct costs. In this study, these costs only reflect the amount paid by the public system; these totals do not including cost to the private individuals.

Tediosi and colleagues [60] conducted an analysis in Italy whereby they estimated the treatment costs in 1997 for the national health care system. The total cost (L351.85 billion, or US$ 231 in 1997 dollars) was relatively low in part because of they focus on the national health care system's treatment costs, which has rather limited benefits. The largest cost components were diapers and drugs.

Ballanger and Rischmann [61] 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 in 1995 dollars).

Table 2 provides a summary of the cost estimates for the countries discussed above. Caution should be used when directly comparing these studies because of differences in the age of the target population, perspective of the analysis and size of the population affected. As mentioned earlier, insurance benefits vary considerably by country. In Sweden, for instance, absorbent pads are provided free of charge to people with incontinence. Samuelsson and colleagues [62] estimated that this accounts for 0.5% of the country's health care expenditures and 0.05% of the gross national product. Therefore, when COI studies use the health care provider's perspective rather than the societal perspective, the results may not be comparable without further information on the health care systems

In the U.S., a large component of the cost of urinary incontinence is routine care, which is paid for by people with incontinence. Third-party payers do, however, cover routine care expenses for some institutionalized people and/or specific products. Recent comprehensive surveys of resource use for community-dwelling women with incontinence observed routine care costs between US$70-225 per year (<US$1 per day) [58, 63]. In the past, routine care costs in the community were estimated using the unit costs for incontinence briefs (US$0.75, 2003 dollars). Because briefs are so expensive and are not covered by health insurance, people with incontinence frequently use other products, such as panty liners (US$0.04; 2003 dollars) [56]. People with incontinence have adjusted their use of routine care products to match their preferences, given their budgets. Many people use the less expensive products, and use other coping mechanisms, such as mapping bathrooms in public places. People have also started buying in bulk at discount stores. Otherwise they can face much higher prices, depending on where they shop.

2. PREVENTION

The primary prevention of incontinence involves adopting health behaviors to minimize the chance of getting incontinence. Most frequently, this includes pelvic floor exercises. Lal [64] suggests that some women are choosing to have cesarean section because vaginal delivery increases the risk of incontinence. To date, there have been no economic analyses on the prevention of incontinence.

Secondary prevention is more common in nursing homes where the health professionals and staff members attempt to minimize the number of incontinent

episodes. Managing UI adds costs. Several studies have addressed costs of UI in nursing homes. Sowell et al. [65] did a time motion study on 24 incontinent residents in a Tennessee nursing facility to compare the costs of four products (disposable bed pads, disposable diapers, launderable absorbent pads, and linen service pads). All patients used a different product each day and all products were used every day for two 12-hour days. Reusable pads had the highest daily costs (US$1.84 per day) while disposable bed pads had the least cost (US$0.67 per day) in 1995 dollars.

In a randomized clinical trial comparing disposable diapers and reusable cloth products among 68 patients (34 used disposable products and 34 used cloth products) in a Pennsylvania nursing home [66, 67]. They found that disposable products had lower costs, ranging from US$0.44 to US$0.68 depending on the size of disposable pad. There were more changes per day for less absorbent reusable cloth diapers than for disposable diapers. At the end of the five-week trial, the skin condition greatly improved more for users of the disposable product compared to users of the reusable cloth [66].

A recent study by Schnelle and colleagues [68] tested an exercise and incontinence intervention on nursing home residents. The intervention involved supervised daily exercise, mobility and stretching exercises. The intervention group showed significant improvements in functional and incontinence outcomes when compared to the control group. There were also fewer acute problems, such as pressure ulcers and falls, but this effect was not statistically significant. They found no differences in utilization between the two groups. Although this intervention did not save money, it is unclear if it would be considered cost-effective given current guidelines. This limitation was noted in an accompanying editorial [69].

Frantz and colleagues [70] compared nursing homes that adopted an incontinence management program based on treatment guidelines from the U.S. Agency for Healthcare Research and Quality. The pre-post analysis found that the presence of wetness from incontinence and pressure ulcers declined after the management program. The program cost each facility US$573 per day, or US$9 (1998 dollars) per resident per day. However, this was not a randomized controlled trial, nor was there a control group, so it remains unclear whether the management program is related to the improved patient outcomes or whether it relates to something else that was not measured.

Several studies have evaluated the prevention of pressure ulcers, which are associated with incontinence since incontinence is a major risk factor for ulcers. Researchers in the UK, U.S., and Australia have studied ways to improve pressure ulcers including different washes [71, 72] and different pads [73]. Although the costs of the intervention are sometimes described, more formal economic analyses with larger samples are warranted. Mitigating the effect of incontinence is particularly important when the options for secondary prevention or treatment of the incontinence is not feasible or possible.

Although secondary prevention is common in nursing homes, research by O'Sullivan et al. [74] studied community dwelling women and found that treatment costs are associated with disease severity such that costs are higher for more serious cases. Mild incontinence patients often have little social or hygienic disability, so they can be in a "pre clinical" phase, and treating them is, to some extent, a form of secondary prevention. The natural history of incontinence is not well understood. If incontinence worsens over time, then treating people with mild to moderate incontinence would be cheaper than waiting until the incontinence becomes more severe to treat it.

3. TREATMENT

There are a limited number of studies that systematically compare costs and outcomes of urinary incontinence treatments. Most have focused on stress incontinence, while a few studies on urge incontinence and overactive bladder have been recently published. Cost-effectiveness analyses in incontinence have focused on strategies for nursing home management [75-78], comparison of surgical techniques for stress incontinence [79, 80], pharmacological therapy of urge incontinence and OAB [53], and diagnosis [81, 82].

Manca and colleagues conducted a cost-utility analysis alongside a multi-site randomized controlled trial comparing tension-free vaginal tape (TVT) to colposuspension [80]. They used the perspective of the UK health care system and modeled costs and utilities over six months. Although the surgical cost of tension-free vaginal tape is more expensive than colposuspension, participants randomized to the vaginal tape treatment had significantly lower hospital stays, recovery times, re-admission rates and office visits. Thus, the higher surgical cost of the tape was offset by lower health care costs within 6 months. For the short term, this provides strong evidence for health

care providers to use tension free vaginal tape when indicated instead of colposuspension. The sensitivity analysis indicated that the results were very robust to a number of input parameters. However, it remains unclear if the results would have been different if lifetime costs and benefits were assessed and if a societal perspective were taken. This depends on the long-term effectiveness of these treatments.

Several studies compared the cost of incontinence surgeries, supporting the finding that tension free vaginal tape is more costly than colposuspension. Quievy and colleagues [83] found greater than two-fold increase in hospitalization costs associated with the retropubic suspension (FFR 26,322 vs. FFR 10,958 for the TVT; year of cost is unknown). Reduced costs for the TVT technique were due to reduced operating time and postoperative stay. Walter et al. [84] compared women undergoing laparoscopic and open Burch retropubic urethropexy and found no s8ignificant differences in the hospital charges.

In a cost-effectiveness study in Canada comparing collagen injections to stress incontinence surgeries (retropubic suspension, transvaginal suspension, sling procedures), Oremus et al. [85] observed that the cost to cure an additional patient with surgery ranged from $1388 to $6814 (1998 Canadian dollars). These ratios were sensitive to changes in the mean number of injections for collagen patients and to a reduction in the length of hospital stay for surgery to 1 day. The analysis should be viewed with caution as it had a number of strong assumptions and important limitations, as noted by the authors. The outcome was cure, based on expert opinion; the analysis did not incorporate patient quality of life. The analysis also only considered the perspective of the health care system; costs to patients were excluded.

Weber and colleagues [81] compared the cost-effectiveness of preoperative testing strategies in women with stress incontinence symptoms who were candidates for primary surgical treatment. They used decision analysis to compare a basic office assessment (BOA) and urodynamic testing. Costs were calculated from U.S generalizable estimates. Incremental cost-effectiveness was defined as the cost in dollars per additional patient cured of incontinence. Urodynamics did not improve the effectiveness of treatment (both strategies resulted in a cure rate of 96% after initial and secondary treatments) and the mean cost of care (including initial and secondary treatments and outcomes) was similar for the two strategies ($5042 for BOA, $5046 for urodynamic testing). As expected, the reduced testing costs with BOA were balanced by increased costs for patients who failed the initial treatment. One additional cure of incontinence using the urodynamic strategy cost $3847

O'Brien [53] assessed the costs and benefits over one year associated with tolterodine for patients with urge incontinence who discontinued with oxybutynin. Tolterodine was associated with slightly higher costs and slightly higher benefits. The authors concluded that the cost-utility ratio of CAN$9982 per QALY was well within current standards to justify using tolterodine as a second line treatment after oxybutynin.

Moore et al. [86] undertook a randomized trial of conservative treatment by dedicated nurse continence advisors versus routine urogynaecology outpatient treatment. This proved to be a form of cost-minimization analysis because the cure rates for nurses and doctors were almost identical (65% cure on pad test for mild stress urge or mixed incontinence, 35% cure for moderate incontinence). Although the nurses spent more time with the patients (median 2.6 hrs versus median 1.5 hrs for doctors), their treatment regime was considerably cheaper (median $59.20, IQR 48.10-77.70 over 12 weeks) than that of the doctors (median $189.70, IQR 120.60-250.70). Cure rates were well maintained in both groups at a median of 3.5 years. The perspective was hospital payments to staff.

4. Consequences of Incontinence

A growing literature documents the consequences associated with incontinence. These studies usually involve cohort or cross-sectional studies, in which multivariate regression models are used to control for confounders. Causal relationships are suggested by these data and these findings are biologically plausible. However, caution is needed in interpreting results because causation cannot be conclusively determined.

The most frequently cited and most costly consequences of incontinence include admission to a nursing home or long-term care facility, injurious falls and fractures, and urinary tract infections (UTIs). Thom et al.'s [20] article on the risk of nursing admission associated with incontinence remains widely cited, and is supported by other research [87]. Thom et al. [20] analyzed medical records from a managed care organization in California and found that the risk of nursing home admission was 2 (95% CI 1.7-2.4) and 3.2 (95% CI 2.7-3.8) times higher for

women and men, respectively, with incontinence compared to those without that diagnosis.

Brown and colleagues [19] followed a cohort of women for an average of 3 years to determine whether incontinence was related to an elevated risk for falls and fractures. Urge incontinence was associated with higher-odds of falling (odds ratio = 1.26; 95% CI 1.14-1.40) and with non-spine nontraumatic fracture (relative hazard 1.34; 95% CI 1.06-1.69). They found that stress incontinence, however, was not an independent risk factor for falls and fractures. Wagner and colleagues [88] also found that people with overactive bladder (OAB) had a higher odds of having an injurious fall. The hypothesis is that urinary frequency, nocturia, and rushing to the bathroom to avoid urge incontinent episodes most likely increase the risk of falling, which then results in fractures.

Urinary incontinence has been cited as a risk factor for urinary tract infections (UTIs) [88-90], possibly due to the presence of wet undergarments that promote the colonization of bacteria. An alternative behavioral explanation exists, whereby people with incontinence manage their condition by drinking less fluids, putting them at higher risk for UTIs [91]. Foxman and colleagues [92] estimated that over 11 million women in the U.S. had at least one UTI treated with antibiotics per year, resulting in an annual cost of $1.6 billion. To the degree that incontinence and overactive bladder are causally related to UTIs, successfully managing and treating incontinence could save UTIs related morbidity and costs. In addition, preliminary data suggests that taking cranberry tables to prevent UTIs among people with urge incontinence may be more cost effective than placebo (no prevention) [93].

Researchers have observed an association between urinary incontinence and overactive bladder and greater health care costs. All else being equal, urinary incontinence adds a level of complexity to the treatment of other conditions, and health care costs for these patients are higher. This association has been found with short stay hospitalizations [88, 94, 95], outpatient geriatric evaluation and management [87], rehabilitation [87], and nursing home care [96, 97].

In addition to greater health care costs, caring for a person with incontinence can place a significant burden on their spouses and informal caregivers [98, 99]. Langa et al. [98] analyzed the U.S. Asset and Health Dynamics Study dataset and estimated the additional yearly cost of informal care at US$6 billion. Per person, this equals US$1,700 (1998 dollars) and US$4,000 for incontinent men who did not and did use pads, and US$700 and US$2,000 for women in these groups, respectively [98].

In summary, a small but growing area of research has found that urinary incontinence and overactive bladder are associated with important and costly consequence. The consequences may be rare, but they can have a large impact on costs, morbidity, quality of life and mortality. When evaluating the cost-effectiveness of treatments, these consequences should be taken into account.

5. Pelvic Organ Prolapse, Overactive Bladder and Fecal Incontinence

Pelvic organ prolapse is prevalent, affecting up to half of all women over 50 years of age, and is the most common indication for hysterectomy. Despite the high prevalence of and frequency of surgery for pelvic organ prolapse, there are minimal data on costs of medical care for this condition. One COI study estimated the annual direct cost of surgery for pelvic organ prolapse in the U.S. using national data [100]. Direct costs of pelvic organ prolapse surgery were US$1,012 million (1997 dollars; 95% CI US$775, US$1,251 million), including US$499 million (49%) for vaginal hysterectomy, US$279 million (28%) cystocele and rectocele repair, and US$135 million (13%) abdominal hysterectomy. Hospitalization accounted for a majority of the total cost (71%) with the remainder being physician services (29%). Twenty-one percent of pelvic organ prolapse operations included urinary incontinence procedures (US$218 million). The annual direct costs of operations for pelvic organ prolapse are substantial and similar to other surgical interventions for women (breast cancer, gynecologic cancer, urinary incontinence).

Although urinary incontinence and OAB have some overlapping clinical characteristics and symptoms, and some patients with OAB also have urge urinary incontinence, many experts believe the etiology is different. A recent study by Hu and colleagues [101] estimated the national costs of OAB in 2000 in the U.S. They estimated the cost at approximately US$12 billion. Their study focused predominantly on costs among community dwelling individuals, where the cost was estimated at US$9.2 billion. To date, there has been one cost-utility analysis for urge incontinence and OAB treatment (see O'Brien et al.'s [53] article above).

Fecal incontinence is less common that urinary incontinence, with estimates generally around 2-3% [102, 103] for older adults. The prevalence increases with age to over 10% for the oldest old, and the prevalence among older institutionalized individuals has been estimated at almost half [104-106]. We found no COI studies for fecal incontinence, and one limited study assessing the costs and effectiveness of sphincteroplasty versus sphincteroplasty plus POP or incontinence surgery [107]. More economic research on this condition is needed.

VII. SUMMARY

Incontinence places a large economic burden on society. Not only are patients and their immediate families the most adversely affected by incontinence, but also they often have to pay for all the costs of managing the illness. When medically necessary, most private insurance companies in industrialized countries will cover treatments. Yet, this sets up competing incentives. People with incontinence might seek treatment, whereas payers might seek to deny or delay such services. The paucity of research on the cost-utility of treatments might further hinder access to treatments as payers are disinclined to pay for treatments that are not cost-effective.

Economic analysis can help decision makers allocate limited resources. COI and cost-minimization analyses are simple, yet limited economic tools. Of the economic tools, CUA is the current gold standard. The CUA requires a person's preference of a health state (utility) in combination with information on mortality. Together these can be used to calculate quality adjusted life years, the preferred outcome for the CUA.

There are many different methods for eliciting utilities or the value of a particular health state. Two direct elicitation methods, TTO and SG, remain favored by theoreticians. The collection of utilities using direct methods often requires interviewer administration and there are concerns that many people do not understand what is being asked of them. A number of indirect MAU instruments were developed as alternatives to the TTO and SG. There are differences between these instruments and they should not be viewed as equivalent.

Despite the need for high-quality economic analysis in incontinence, surprisingly little has been done. Most of the new research published in the past few years has been COI studies. A few cost utility analyses have also been published in areas supported by corporations.

Although the data are very limited, the current data on the cost-effectiveness of incontinence treatment show that intervention is likely cost-effective when compared to no treatment [53, 79]. There is little or no evidence, however, to guide choice among treatment. The strongest evidence was for the use of tension free vaginal tape compared to colposuspension [80].

While more high quality studies are needed, researchers continue to publish incorrect claims. There have also been studies claiming that a treatment is cost-effective without any conducting a cost-effectiveness analysis.

VIII. FUTURE RESEARCH PRIORITIES

Since the last consultation, there have been considerable contributions in our understanding on the cost of urinary incontinence, particularly on overactive bladder symptoms and the quality of life assessment in urinary incontinence. However, there are still large gaps of research topics. These list of research priorities include:

1 More cost information from mid-to-lower income countries. To perform appropriate cost estimation requires systematic cost data, particularly, the overhead data. Because incontinence has a large economic effect on people with the condition, primary data should be collected.

2 Studies on the financing and reimbursement of incontinence treatment and how this affects patient outcomes. Different health care systems have different reimbursement methods that in turn affect the incentives of providers and economic burden on incontinent consumers. This is a particularly important area for nursing homes, where regulations and financial arrangements can have a large impact on quality of care.

3 More information on people's utility for incontinence and its treatments. These utilities can then be used to estimate QALYs.

4 A need to estimate Disability Adjusted Life Years for urinary incontinence. International organizations such as WHO and World Bank often use the magnitude of DALYs among different diseases as

one tool to guide resource allocation. DALYs can also be used for direct international comparisons on the burden of disease for a particular illness. An initial step would be to appoint a research committee to examine the data requirement and methodologies of estimating DALY for urinary incontinence. Understanding DALYs associated with incontinence would also draw international attention on the socio-economic burden of urinary incontinence.

5. There is a need for more carefully executed cost-utility studies on treating urinary incontinence. The clinical research community has widely recognized that randomized trial is a gold standard for cost/effectiveness studies. The edited books by Gold et al. [6] and Drummond et al. [15] should be used as the standard references when designing a cost-effectiveness measure. Studies should work to use a societal perspective and use QALYs so that the results can inform decision makers.

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