Systematic Review of Urinary Incontinence and Overactive Bladder Cost-of-Illness Studies

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Abstract: *Context*: Within pelvic floor disorders, urinary incontinence (UI) and overactive bladder (OAB) are relevant health problems confronting the rapidly aging of modern society; this holds true also from an economic perspective.

Objective: Systematise all the international available evidence on the burden of disease because of UI and OAB on society.

Materials and Methods: A systematic search of Medline and Embase databases was conducted on June 30th, 2008, aimed at retrieving studies concerning the cost of UI and OAB, any time.

Results: Out of 161 abstracts retrieved, 25 studies were included in the review. Key findings emerged from the review process: (i) prevalence rates vary depending upon definitions used, populations studied, and methods employed, (ii) estimates of direct healthcare costs should take into account the hidden nature of incontinence since the most affected individuals do not seek treatment, (iii) biases may occur when estimating the burden of disease using claims data as these concern only people seeking care and treated for their symptoms, and (iv) direct costs of incontinence would likely be higher, if a greater proportion of patients with UI and/or OAB sought care. From an economic perspective, investing more resources in early diagnosis and initial treatment could potentially reduce the costs of treating late-stage disease and its consequences. This study illustrates also that healthcare systems never pursued clearly this direction: in OAB community-dwellers the cost of diagnosing and treating is less than the cost of treating its related consequences (e.g. skin irritations, urinary tract infections, falls), 29% and 48.4% of direct costs respectively. Whilst in UI community-dwellers, the cost of treating consequences is still high, being 18.2% of direct costs.

Conclusions: UI and OAB are associated with significant cost to the individual, institution and society. Understanding the magnitude of the impact of these pelvic floor disorders is important to health care providers, payers, and public policy-makers in establishing health care priorities, taking advantage of potential savings, and allocating scarce resources for its appropriate management.

Keywords: Systematic review, cost of illness, urinary incontinence, overactive bladder.

INTRODUCTION

Amongst pelvic floor disorders, urinary incontinence (UI) and overactive bladder (OAB) are two of the most important health problems confronting modern society. UI is a distressing and disabling condition, incurring significant financial burden on individuals, their families, and healthcare organisations [1, 2]. The three main types of UI symptoms are stress urinary incontinence (SUI), which is "involuntary leakage on effort or exertion"; urge urinary incontinence (UUI), defined as "involuntary leakage accompanied by or immediately preceded by urgency", and mixed urinary incontinence (MUI), which refers to "involuntary leakage associated with urgency and also exertion, effort, sneezing or coughing" [3]. UI affects adults of all ages, with an especially high prevalence among elderly women; incontinence is estimated to affect 17–55% of community-dwelling people and up to 50% of nursing home residents, making it one of the most prevalent chronic diseases [4-11]. Available figures most likely underestimate the true prevalence of UI for several reasons, including patient embarrassment, low rates of clinical detection, and lack of awareness of effective treatment options [12]: UI is often medically unrecognized, with only one-quarter to one-half of individuals seeking medical attention [10]. UI in older adults is a potentially life-threatening problem: potential consequences include significant functional decline, impaired quality of life, frailty, institutionalization, and death [13, 14]. OAB is also a common and disabling condition. In the 2002 ICS Standardization of Terminology report, OAB is defined as "urgency, with or without urge incontinence, usually with frequency and nocturia" [3]. Pure stress incontinence, induced by increased pressure in the abdomen due to effort or exertion, is generally not associated with urgency, frequency, or nocturia; therefore, it is out of the spectrum of OAB. The National Overactive Bladder Evaluation (NOBLE) Program [15] revealed an overall prevalence of OAB of 16.5%, with 16.9% of women and 16.0% of men affected and prevalence among patients of

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both sexes increasing with age; urge incontinence affects only a portion of the OAB population: 33% of patients have OAB with urge incontinence ("OAB wet"), while 66% have OAB without urge incontinence ("OAB dry").

Economic considerations have gained more prominence in health care decision making in recent years [16, 17], especially when dealing with diseases that impose high socioeconomic burdens, such as UI and OAB, whose incidence and prevalence seem to rapidly increase because of ageing populations. However, it is important to understand the magnitude of the economic burden of UI and OAB so to support policy-makers identifying the key cost drivers as well as paving the way to any further economic evaluation analysis aimed at assessing the potentials of innovative technology for treating the diseases. Cost of illness studies estimate the economic burden of diseases and should always be considered when allocative decisions are at stake [18]. The purpose of the present study was to conduct a systematic literature review [19] of UI and OAB cost of illness estimates internationally, and to summarize the best available evidence on the economic burden because of UI and OAB on society as a whole.

MATERIAL AND METHODOLOGY

A search of Medline was conducted on June 30th, 2008, aimed at retrieving studies concerning the cost of UI and OAB. The following strategy was used:

1. Urinary Incontinence/Economics
2. Urinary Bladder, Overactive/Economics
3. Urinary Incontinence/
4. Urinary Bladder, Overactive/
5. Health Care Costs/
6. Cost of Illness/
7. Health Expenditure/
8. Health Resources/Economics, Utilization
9. Sick Leave/Economics
10. 1 or [3 and (or 5-9)]
11. 2 or [4 and (or 5-9)]

/ = Medical Subject Headings (MeSH)

The search was limited to papers (i.e. editorials, letters and opinions were excluded) published in English with abstracts available, any time. The same search algorithm was used to retrieve papers in the Embase database and final results were then matched. References of the included papers were also examined in order to collect further relevant papers and to check the consistency with the databases searches performed. Once retrieved, papers were analysed to check whether relevant for the present study's purposes. The following criteria were used to keep or drop papers.

Inclusion criteria:

- UI or OAB as the main focus of the cost analysis; and
- Monetary estimate of direct and/or indirect costs; and
- Societal, third payer, service provider or patient's perspectives.

Exclusion criteria:

- Economic evaluations (e.g. cost-effectiveness analyses); or
- Faecal and urinary incontinence costs without distinctions; or
- Cost analysis concerning only some specific cost components (e.g. drug costs, specific intervention, management costs only); or
- Study population referring to a very specific and limited sub-group only (e.g. severely handicapped children); or
- Cost analysis referred in terms of resources consumption without any monetary evaluation (i.e. indirect costs expressed as number of lost work days); or
- Review articles without new data, already collected above.

When abstracts' data were not sufficient to determine paper's eligibility, full-text articles were retrieved and further screened. All potentially relevant papers were obtained and reviewed independently by two reviewers. Reference searching and author searches ensured literature saturation.

The following data were extracted for all included studies (18 items) [20]:

- Author(s);
- Target country(s);
- Publication year;
- Study population (UI/OAB, male, female; age);
- Setting of care (community/institutions, nursing homes, sub-acute care);
- Type/design of study (observational, retrospective, cross-sectional, longitudinal, prospective, modelling, expert panel, etc.);
- Sample size;
- Year of cost data;
- Data sources;
- Form of UI and OAB considered;
- Case definition/severity of UI and OAB;
- Perspective;
- Cost types;
- Costing methods (top-down, bottom-up);
- Method for estimating production losses (if present);
- Prevalence of UI and OAB according to case definition;
- Target population in the Country;
- Estimated societal, direct, and indirect costs (if present).

These 18 items were also used to assess the quality and completeness of each paper: articles with the presence,

Table 1. Characteristics of Papers Included in the Review and Quality Appraisal

	Authors	Country/ Countries	Publication Year	UI/OAB	Setting of Care	Type of Study	Form of UI or OAB	Case Definition of UI/OAB	Data Sources	Quality Appraisal
1	Ouslander *et al.* [31]	United States	1984	UI	Nursing home	Modelling	n.r.	n.r.	Nursing homes, medical supply companies, and a large laundry company databases; survey through questionnaires to licensed nurses and administrators in 16 facilities	**
2	Hu [21]	United States	1986	UI	Institutions/ Community	Modelling	All types of UI	n.a.	n.a.	***
3	Townsend [28]	United Kingdom	1988	UI	Institutions/ Community	Observational, retrospective	n.r.	n.r.	Harrow Health District database	*
4	Wagner *et al.* [1]	United States	1998	UI	Institutions/ Community	Modelling	All types of UI	n.r.	Published literature/National Hospital Ambulatory Medical Care Survey (NHAMCS)/National Hospital Discharge Survey (NHDS)	*****
5	Dowell *et al.* [23]	Australia	1999	UI	Community	Observational, prospective	All types of UI	Use of frequency-volume charts (voids/24 h, leaks/week) to determine UI severity	Dowell/Briant Incontinence Cost Index (DBICI) questionnaire to community-dwelling women undergoing conservative therapy	*
6	Tediosi *et al.* [26]	Italy	2000	UI	Community	Observational, cross-sectional, prospective	Stress UI and other types	UI as at least 1 episode in 1 year; Frequent UI as 7 or more episodes per week	Telephone interviews in 6 areas of Italy amongst patients of a network of GPs; INHS Tariffs as estimates for unit costs	***
7	Samuelsson *et al.* [27]	Sweden	2001	UI	Institutions/ Community	Observational, retrospective	All types of UI	Severe or more frequent UI with the use of aids	Central database of district of Jämtland	***
8	Wilson *et al.* [32]	United States	2001	UI	Institutions/ Community	Modelling/Expert panel	All types of UI	UI defined as at least 1 episode in 1 year	Agency for Health Policy and Research Clinical Practice Guidelines for Urinary Incontinence Management Average national Medicare reimbursement	***
9	Doran *et al.* [24]	Australia	2001	UI	Community	Modelling/Expert panel	All types of UI	n.r.	Women's Health Australia (WHA) project Dowell-Bryant Incontinence Cost Index (DBICI): Dowell C, Bryant C *et al.*, 1999	***
10	Langa *et al.* [33]	United States	2002	UI	Community	Observational, cross-sectional, prospective	All types of UI	UI as at least 1 episode in 1 year; UI not requiring pads, UI requiring pads	Asset and Health Dynamics among the Oldest Old (AHEAD) cohort of the Health and Retirement Study (HRS)	***

(Table 1) contd…..

	Authors	Country/ Countries	Publication Year	UI/OAB	Setting of Care	Type of Study	Form of UI or OAB	Case Definition of UI/OAB	Data Sources	Quality Appraisal
11	Kinchen *et al.* [34]	United States	2003	UI	Community	Observational, longitudinal, retrospective	Stress UI	n.r.	Medstat s MarketScan Commercial Claims and Encounters (CC&E) and the Medicare Supplemental and Coordination of Benefits (COB) databases	*
12	Birnbaum *et al.* [35]	United States	2003	UI	Community	Observational, retrospective	Stress UI	n.r.	Administrative dataset for beneficiaries of a large, national Fortune 100 company including over 100,000 women/published government statistics	*
13	Birnbaum *et al.* [36]	United States	2004	UI	Community	Observational, retrospective	Stress UI	n.r.	Administrative dataset for beneficiaries of a large, national Fortune 100 company including over 100,000 women/published government statistics	**
14a	Hu *et al.* [22]	United States	2004	UI	Institutions/ Community	Modelling	UI include OAB wet; OAB include UI urge	Daily UI	Published literature/National Hospital Discharge Survey	*****
14b	Hu *et al.* [22]	United States	2004	OAB	Institutions/ Community	Modelling	UI include OAB wet; OAB include UI urge	n.r.	National Overactive Bladder Evaluation (NOBLE) Program	****
15	Morris *et al.* [37]	United States	2005	UI	Sub-acute care	Observational, prospective	All types of UI or faecal	Incontinence defined as 2 or more episodes of leakage of either urine, faeces or both within a 48-hr period	Primary data form University of New SouthWales and the South Eastern Sydney Area Health Service	**
16	Kinchen *et al.* [38]	United States	2005	UI	Community	Observational, cross-sectional, retrospective	Stress UI	n.r.	Medicaid claims database (MarketScan Medicaid, Medstat, Inc.)	**
17	Papanicolaou *et al.* [16]	Europe (Germany, Spain, UK /Ireland)	2005	UI	Community	Observational, retrospective	All types of UI	UI defined as at least 1 episode in 1 year	Retrospectively data collection for information on resource use in the 12 months preceding enrolment; Unit costs through questionnaires to local researchers in all the countries participating in PURE (Prospective Urinary Incontinence REsearch)	**
18	Anger *et al.* [49]	United States	2006	UI	Institutions/ Community	Observational, retrospective	All types of UI	n.r.	Medicare claims data; 1999 to 2000 National Health and Nutrition Examination Survey	*

(Table 1) contd…..

	Authors	Country/ Countries	Publication Year	UI/OAB	Setting of Care	Type of Study	Form of UI or OAB	Case Definition of UI/OAB	Data Sources	Quality Appraisal
19	Subak *et al.* [39]	United States	2006	UI	Community	Observational, prospective	All types of UI	UI defined as 3 or more episodes per week for at least 3 months, seeking for treatment	Data collected by self-report questionnaires; National unit costs were estimated by a survey of 14 stores in 6 states (California, Florida, Colorado, Massachusetts, New Jersey, Washington) and one national Internet source in 2001	**
20	Subak *et al.* [40]	United States	2007	UI	Community	Observational, prospective	All types of UI	Weekly or daily UI (47% of these seeking treatment)	Reproductive Risks for Incontinence Study at Kaiser (RRISK); National unit costs estimated by a survey of 14 stores in 6 states (California, Florida, Colorado, Massachusetts, New Jersey, Washington) and one national Internet source in 2001	**
21	Hu *et al.* [41]	United States	2003	OAB	Institutions/ Community	Observational, retrospective	All types of OAB	> 8 micturitions in a 24-hour period	Survey of community-dwelling adults > 18 years in USA and a follow-up postal survey of all individuals with OAB (The National Overactive Bladder Evaluation Program - NOBLE); Previous published cost data on UI in nursing homes.	*****
22	Wu *et al.* [42]	United States	2005	OAB	Community	Observational, retrospective	All types of OAB	n.r.	Administrative claims database containing medical, work loss, and demographic information on employees, retirees, and their spouses and dependants of nine large self-insured companies in the United States (1999 – 2002)	*
23	Klotz *et al.* [25]	Germany	2006	OAB	Institutions/ Community	Modelling/Expert panel	All types of OAB	n.r.	Literature review using Medline, Embase, and German literature	***
24	Reeves *et al.* [29]	Europe (Germany, Italy, Spain, Sweden, UK)	2006	OAB	Community	Modelling/Expert panel	All types of OAB	n.r.	Review of published and unpublished literature	***
25	Prasopsanti *et al.* [30]	Thailand	2007	OAB	Community	Modelling/Expert panel	All types of OAB	n.r.	Epidemiology data were drawn from two 11 country Asian studies; costs estimated from a survey using a cost questionnaire and from unit costs of King Chulalongkorn Memorial Hospital	****

Legend:
UI: Urinary Incontinence
OAB: Overactive Bladder
n.r.: not reported
n.a.: not applicable
Appraisal ("n.r" based on Table 1 *and* 2 items):
******* : 0-1 n.r. (best)**
****** : 2-3 n.r.**
***** : 4-5 n.r.**
**** : 6-7 n.r.**
*** : > 7 n.r.**

exhaustive explanations and details for each of the items indicated above were deemed higher quality cost of illness studies (Table **1**).

For studies reporting details on direct healthcare cost components, data attributable to each of the following (or similar) categories were extracted:

- Diagnostics services;
- Pharmacological treatments (anticholinergic, tricyclic antidepressant, alpha-adrenergic agonist, estrogen, and combination estrogen plus alpha-adrenergic agonist medications);
- Specialist visits (e.g. urologic, gynaecologic, dermatologic);
- Behavioral/rehabilitation services (bladder training, scheduled toileting, pelvic muscle exercises);
- Surgical Treatments (retropubic urethropexy, needle bladder suspension, suprapubic sling, artificial sphincter, and periurethral injection procedures);
- Routine care (elsewhere defined also as UI or OAB management, includes the following resources: absorbent pads, skin care products, laundry, catheters, and nurse labour costs);
- Consequences (e.g. skin irritations, urinary tract infections – UTIs, falls).

RESULTS

The search strategy yielded 161 abstract of studies, of which 127 (79%) were not relevant because they did not meet eligibility criteria: abstracts were rejected because UI or OAB was not the main focus of the analyses (n. 69), or did not indicate monetary estimates of resources (n. 31), some being economic evaluations (n. 9), or had the analyses limited to specific cost components or to small populations subgroups (n.18). The remaining 34 (21%) were retrieved in full-text format. When full-text articles were screened, 25 (16%) studies were deemed relevant according to the inclusion and exclusion criteria and included in the review. The remaining 9 papers were rejected because presented faecal and urinary incontinence costs without distinctions (n. 2), concerned only to some specific cost components like drug costs or specific interventions (n. 4), concentrated on a very specific and limited sub-group (n. 3). The methodology, the aggregate and per capita cost estimates for the 25 relevant studies included is summarized in Tables **1-3**.

Studies from Australia (n.2) [23, 24], Germany (n.1) [25], Italy (n.1) [26], Sweden (n.1) [27], United Kingdom (n.1) [28], different countries from Europe (n.2) [16, 29], Thailand (n.1) [30], and the United States (n.16) [1, 21, 22, 31-42] were obtained. Non-US studies represented 36% (n.9) of the papers, while the remaining 64% (n.16) were US studies. Most of the studies (76%, n.19) focused exclusively on UI, while 20% (n.5) on OAB; only one study directly compared the two conditions in the same study. The prevalence of UI and OAB varied widely amongst studies, depending on the sub-age groups of population, the settings of care considered, and the case definition (e.g., episode within the past two weeks, episode within the last month): this specific point is key when comparing data from different studies. Amongst the retrieved studies, 20% (n.5) examined costs from the widest perspective possible, the societal perspective; 64% (n.16) used a less broad point of view, a third payer perspective (insurer's, national healthcare system's, employer's) – this perspective instead fails to catch non-healthcare costs (e.g. home help, transports) and the "production losses" (or "indirect costs") reflecting the economic value of consequences for which there is no direct monetary transfer ('e.g. absenteeism, decreased productivity, death); 32% (n.8) considered also the patient's perspective, which takes into account healthcare and non-healthcare costs borne by patient (e.g. out-of-pocket), while 8% (n.2) and 4% (n.1) used the service provider's, dealing with directs healthcare costs only, and informal caregiver's perspective respectively, taking into account healthcare and non-healthcare costs borne by the informal caregiver.

Four studies, all from United Stated, estimated the total national economic burden of the two conditions. Ten additional studies reported national estimates of direct costs only, whereas just one study estimated indirect costs on a national level. The remaining ten studies provided only per-capita results. All results are reported in the study's local currency at the time of the study: being the healthcare sector highly regulated by government in every developed country, the authors did not attempt to inflate or deflated costs that do not follow strict market mechanisms.

From these results, it emerges that the cost of both UI and OAB is considerable high in every country where this was fully investigated through a complete cost of illness study [1, 21, 22, 24, 25, 29, 30, 32, 41].

Urinary Incontinence Cost of Illness Evidence

The first comprehensive cost of illness study is a 1986 analysis that estimated the economic impact of UI with a third payer perspective of all types of UI in the US: USD 1.8 billion in nursing homes, USD 6.3 billion in the community (1984 costs) [21]. An update in **1998** [1] estimated the cost at USD 26.3 billion, or USD 3,565 per patient (**1995** costs), with direct costs accounting for >97% of the total – as expected, production losses were higher in community settings (4%) and much lower in institutional settings (1%). The costs of routine care, which included use of pads and reusable briefs as well as laundry, were estimated at USD 11.4 billion per year (46% and 40% in community and institutional setting respectively). In a later US study [32], the annual direct cost of UI of all types was estimated at USD 16.3 billion (1995 values) in those aged ≥15 years: USD 10.8 billion of which was incurred by those aged >65 years: these underlines a huge variability in study results concerning the burden of this disease. A more recent study [22], substantially confirmed Wilson's results, estimating the societal costs of UI at USD 19.5 billion (2000 values) – the authors explained the reasons for the 26% decrease between this estimate and their previous one [1], from USD 26.29 billion (1995 dollars) to USD 19.5 billion (2000 values). They identified four key factors: (i) use of more conservative UI prevalence data, (ii) reduction of the length of stay in hospitals, (iii) use of more precise information on the utilization of routine care products (e.g. people tended to

Table 2. Annual National Estimates of Total, Direct, or Indirect Costs for UI and OAB

	Authors	Perspective	Cost Types	Study Target Population	Target Population in the Country	UI/OAB	Year of Cost Data	Local Currency	Societal Costs			Direct Costs			Prod. Losses		
									National	Per Capita	Per Capita (Euro 2000)*	National	Per Capita	Per Capita (Euro 2000)*	National	Per Capita	Per Capita (Euro 2000)
1	Ouslander *et al.* [31]	Service provider	Direct healthcare	UI patients >70 years	600.000	UI	n.r.	USD		n.r.	n.r.	n.r.	1.000.000.000	1.667	1.817		n.r.	n.r.	n.r.
2	Hu [21]	Health care payer	Direct healthcare	UI patients >65 years	n.a.	UI	1984	USD		n.r.	n.r.	n.r.	8.100.000.000	n.a.	n.a.		n.r.	n.r.	n.r.
3	Townsend [28]	Health care payer	Direct healthcare	All UI patients	n.r.	UI	1986	GBP		n.r.	n.r.	n.r.	60.000.000	n.r.	n.r.		n.r.	n.r.	n.r.
4	Wagner *et al.* [1]	Societal	Direct and Production losses	UI patients >65 years	7.400.000	UI	1995	USD	26.292.400.000	3.565	3.886	25.588.000.000	3.458	3.769	704.400.000	95	104
5	Dowell *et al.* [23]	Health care payer/ Patient	Direct healthcare and non-healthcare	UI women treating UI in an ambul-atory setting	n.r.	UI	n.r.	AUD		n.r.	n.r.	n.r.	n.r.	880	558		n.r.	n.r.	n.r.
6	Tediosi *et al.* [26]	Health care payer/ Patient	Direct healthcare	UI women >40 years	1.380.000	UI	1998	Lire		n.r.	n.r.	n.r.	351.800.000.000	255.519	132		n.r.	n.r.	n.r.
7	Samuelsson *et al.* [27]	Health care payer	Direct healthcare	UI patients using aids in district of Jämtland	367.000	UI	1999	SK		n.r.	n.r.	n.r.	925.000.000	2.682	319		n.r.	n.r.	n.r.
8	Wilson *et al.* [32]	Health care payer	Direct healthcare	UI patients >15 years	19.800.000	UI	1995	USD		n.r.	n.r.	n.r.	16.300.000.000	823	897		n.r.	n.r.	n.r.
9	Doran *et al.* [24]	Health care payer/ Patient	Direct healthcare and non-healthcare	UI women >18 years	1.835.628 of which 742.348 (40%) help-seeking	UI	1998	AUD		n.r.	n.r.	n.r.	710.440.000	387	245		n.r.	n.r.	n.r.
10	Langa *et al.* [33]	Informal carer	Direct non-healthcare/Production losses	UI patients >70 years	4.100.000	UI	1998	USD		n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	6.900.000.000	1.683	1.834	

(Table 2) contd…..

									Societal Costs			Direct Costs			Prod. Losses		
	Authors	Perspective	Cost Types	Study Target Population	Target Population in the Country	UI/OAB	Year of Cost Data	Local Currency	National	Per Capita	Per Capita (Euro 2000)*	National	Per Capita	Per Capita (Euro 2000)*	National	Per Capita	Per Capita (Euro 2000)
11	Kinchen *et al.* [34]	Health care payer	Direct healthcare	UI women	n.r.	UI	1999	USD	n.r.	n.r.	n.r.	n.r.	1.382	1.506	n.r.	n.r.	n.r.
12	Birnbaum *et al.* [35]	Health care payer	Direct healthcare	UI women	n.r.	UI	2002	USD	n.r.	n.r.	n.r.	n.r.	3.300< 64y; 15.000 65y+	3.597< 64y; 16.350 65y+	n.r.	n.r.	n.r.
13	Birnbaum *et al.* [36]	Health care payer	Direct healthcare and production losses	UI women >18 years <64 years	n.r.	UI	1998	USD	n.r.	9.850	10.737	n.r.	5.642	6.150	n.r.	4.208	4.587
14a	Hu *et al.* [22]	Societal	Direct and Production losses	All UI patients	17.945.000	UI	2000	USD	19.540.240.000	1.089	1.187	18.987.840.000	1.058	1.153	552.500.000	31	34
14b	Hu *et al.* [22]	Societal	Direct and Production losses	All OAB patients	34.614.250	OAB	2000	USD	12.558.090.000	363	395	11.731.210.000	339	369	826.880.000	24	26
15	Morris *et al.* [37]	Service provider	Direct healthcare	All UI or faecal patients >65 years admitted in a sub-acute care setting	n.r.	UI	2003	AUD	n.r.	n.r.	n.r.	n.r.	383	243	n.r.	n.r.	n.r.
16	Kinchen *et al.* [38]	Health care payer	Direct healthcare	UI women (Medicaid population)	n.r.	UI	2002	USD	n.r.	n.r.	n.r.	n.r.	795	867	n.r.	n.r.	n.r.
17	Papanicolaou *et al.* [16]	Health care payer/ Patient	Direct healthcare	UI women >18 years seeking for treatment	n.r.	UI	2004	Euro	n.r.	n.r.	n.r.	n.r.	528	528	n.r.	n.r.	n.r.
18	Anger *et al.* [49]	Health care payer	Direct healthcare	UI women >65 years (Medicare)	6.800.000	UI	1998	USD	n.r.	n.r.	n.r.	234.400.000	n.r.	n.r.	n.r.	n.r.	n.r.
19	Subak *et al.* [39]	Patient	Direct healthcare	UI women >40 years	n.r.	UI	2005	USD	n.r.	n.r.	n.r.	n.r.	492	536	n.r.	n.r.	n.r.

(Table 2) contd…..

	Authors	Perspective	Cost Types	Study Target Population	Target Population in the Country	UI/OAB	Year of Cost Data	Local Currency	Societal Costs			Direct Costs			Prod. Losses		
									National	Per Capita	Per Capita (Euro 2000)*	National	Per Capita	Per Capita (Euro 2000)*	National	Per Capita	Per Capita (Euro 2000)
20	Subak *et al.* [40]	Patient	Direct healthcare	UI women >40 years <69 years	n.r.	UI	2005	USD	n.r.	n.r.	n.r.	n.r.	186	203	n.r.	n.r.	n.r.
21	Hu *et al.* [41]	Societal	Direct and Production losses	All OAB patients >18 years	34.506.285	OAB	2000	USD	12.021.700.000	348	380	11.180.470.000	324	353	841.240.000	24	27
22	Wu *et al.* [42]	Employer	Production losses	All OAB employees	n.r.	OAB	2002	USD	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	391	426
23	Klotz *et al.* [25]	Health care payer/ Patient	Direct healthcare	All OAB patients >40 years	6.481.000	OAB	n.r.	Euro	n.r.	n.r.	n.r.	3.979.150.000	614	614	n.r.	n.r.	n.r.
24	Reeves *et al.* [29]	Health care payer/ Patient	Direct healthcare	All OAB patients >40 years	20.200.000	OAB	2000	Euro	n.r.	n.r.	n.r.	4.200.000.000	208	208	n.r.	n.r.	n.r.
25	Prasopsanti *et al.* [30]	Societal	Direct and Production losses	All OAB patients >18 years	14.461.653	OAB	2005	USD	1.956.848.985	135	147	1.826.898.192	126	138	129.950.793	9	10

Legend:
UI: Urinary Incontinence.
OAB: Overactive Bladder.
n.r.: not reported.
n.a.: not applicable.
(*) OECD exchange rates – year 2000.

avoid costly undergarments whenever possible in favour of toilet paper or menstruation pads), (iv) better accounting for the varying length of stay resulting from staggered nursing home admissions [22]. Australian estimates of the direct costs of UI in community-dwelling women were at AUD 880 per woman per year (1998 values), covering only pads, laundry and treatment [23]. Pad costs accounted for most of the personal expenditures, and increased with age. Total costs were significantly correlated with the severity of leakage, but treatment cost showed poor correlation. Another Australian study [24] used the results of Dowell *et al*., along with literature on prevalence, to estimate the total costs of urinary incontinence in community-dwelling Australian women at AUD 710 million in 1998.

In Europe, an Italian study estimated the direct costs of UI in women *via* a cross-sectional study of 2,767 women aged ≥40 years [26]. The study estimated the annual cost (in Italian lira - L) of UI at L 351,850 billion (1998 values USD 1 = Euro 0.81 = L 1,539), but only considered pads and drug treatment; annual per case cost totalled Lire 256,000 (Euro 132). Another European study estimated the medical resource utilisation and cost of care for women seeking treatment for UI in an outpatient setting, three examples were taken from countries participating in the Prospective Urinary Incontinence Research (PURE) study (Germany, Spain, UK/Ireland) [16]. As expected, the authors found variations in medical resource use and cost of treatment between the three countries, reflective of the differences in the healthcare systems and in the management of care (i.e.

Table 3. UI and OAB Per Capita Estimates for Community-Dwelling and Institutionalized People (for Papers that Published Cost Details Only)

Disease	**Urinary Incontinence**												**Overactive Bladder**			
Annual Cost Per Case: Cost Categories/ Authors	**Wagner** *et al.* [1]		**Dowell** *et al.* [23]	**Wilson** *et al.* [32]		**Doran** *et al.* [24]	**Hu** *et al.* [22]		**Papanicolaou** *et al.* [16]				**Hu** *et al.* [22]		**Klotz** *et al.* [25]	**Prasopsanti** *et al.* [30]
Year of Data	**1995**	**1995**	**1999**	**1995**	**1995**	**1998**	**2000**	**2000**	**2004**	**2004**	**2004**	**2004**	**2000**	**2000**	**2006**	**2005**
Setting of Care	**Inst.**	**Comm.**	**Comm.**	**Inst.**	**Comm.**	**Comm.**	**Inst.**	**Comm.**	**Comm. (EU)**	**Comm. (GER)**	**Comm. (SPA)**	**Comm. (Uk/Ire)**	**Inst.**	**Comm.**	**Comm.**	**Comm.**
	USD	***USD***	***AUD***	***USD***	***USD***	***AUD***	***USD***	***USD***	***Euro***	***Euro***	***Euro***	***Euro***	***USD***	***USD***	***Euro***	***USD***
Direct healthcare costs per case	***9.871,8***	***2.338,8***	***871,4***	***6.876,3***	***565,8***	***383,3***	***5.635,4***	***803,7***	***528,4***	***537,2***	***673,0***	***375,0***	***5.639,4***	***244,9***	***427,2***	***98,0***
Diagnostics services	12,1	6,0	113,4	3,8	9,0	45,9	26,0	24,5	83,0	48,0	177,0	24,0	30,0	2,3		
Pharmacological treatments *	0,8	1,3	29,2		6,0	11,8	6,0	14,4	66,3	77,0	41,0	81,0	6,0	35,2	13,1	19,5
Specialist visits			198,7			80,3		82,1	106,3	56,0	162,0	101,0		22,4	100,2	
Behavioral/ Rehabilitation**	3,8	9,5	10,3	157,5	1,1	4,1		35,9	14,4	0,2	11,0	32,0		8,3		
Surgical Treatments***	38,9	97,1	98,3		54,3	38,6		134,4	79,3	95,0	103,0	40,0		16,5		
Routine care ^	4.018,6	1.130,7	421,5	3.537,5	447,7	202,6	5.475,0	79,2	179,0	261,0	179,0	97,0	5.475,0	46,0	105,5	28,1
Consequences^^	5.797,7	1.094,1		3.177,5	47,7		128,4	433,2					128,4	114,3	208,5	50,3
Direct non-healthcare costs per case	**n.r.**	**n.r.**	***9,2***	**n.r.**	**n.r.**	***3,7***	**n.r.**	**n.r.**	**n.r.**	**n.r.**	**n.r.**	**n.r.**	**n.r.**	**n.r.**	**n.r.**	***28,4***
Travel			9,2			3,7										28,4
Indirect costs per case	***95,4***	***95,4***	**n.r.**	**n.r.**	**n.r.**	**n.r.**	***0,0***	***32,5***	**n.r.**	**n.r.**	**n.r.**	**n.r.**	***0,0***	***24,7***	**n.r.**	***9,0***
Production losses	95,4	95,4					0,0	32,5					0,0	24,7		9,0
Societal costs per case	***9.967,2***	***2.434,3***	***880,6***	**n.r.**	**n.r.**	***387,0***	***5.635,4***	***836,2***	**n.r.**	**n.r.**	**n.r.**	**n.r.**	***5.639,4***	***269,7***	**n.r.**	***135,3***

Legend:
n.r.: not reported.
Inst: institutionalized people.
Comm: community-dwelling people.
(*) Anticholinergic, tricyclic antidepressant, alpha-adrenergic agonist, estrogen, and combination estrogen plus alpha-adrenergic agonist medications.
(**) Bladder training, scheduled toileting, pelvic muscle exercises.
(***) Retropubic urethropexy, needle bladder suspension, suprapubic sling, artificial sphincter, and periurethral injection procedures.
(^) Routine care, or elsewhere defined as UI/OAB management, includes the following resources: absorbent pads, skin care products, laundry, catheters, and nurse labour costs.
(^^) Skin irritations, urinary tract infections, falls.

specialists and/or GPs responsibility). Nevertheless, in all three countries most of the women had used protective pads, which more than half the patients paying for them out-of-pocket, despite potential healthcare reimbursement schemes. Mean total UI-related costs per year ranged from Euro 359 in the UK/Ireland for patients predominantly treated in the GP, setting to Euro 515 in Germany, and Euro 655 in Spain for patients treated by specialists and GPs [16] (Table **3**).

Overactive Bladder Cost of Illness Evidence

Concerning OAB, a US study [41], using prevalence data derived from the National Overactive Bladder Evaluation (NOBLE) Program, estimated the societal costs of OAB at USD 12 billion (2000 values). Direct cost for community-dwellers amounted at USD 8.3 billion, with women incurring the majority (USD 7.4 billion); direct costs for institutional residents were estimated at USD 2.85 billion, with routine care costs accounting for most of this (USD 2.8 billion). The

cost of productivity losses associated with OAB was small by comparison (USD 841 million). Another recent US cost study [22] compared the costs of urinary incontinence in general with those for OAB specifically. Total OAB costs, both in community and in institutions, were estimated at USD 12.6 billion, while for UI they were USD 19.5 billion (2000 values). The difference is partially explained by the fact that stress UI generates higher resource use and it is included in the general UI category. Also, patients with OAB may have urgency without actually experiencing incontinence.

In Europe, a paper estimated the annual direct costs of OAB in Germany from the perspective of third payer and patients [25]; the results revealed that 6.48 million adults over 40 years old were affected by OAB, totalling Euro 4 billion cost directly related to OAB. The authors concluded that OAB imposed a substantial economic burden in German health and nursing care, insurance, and on patients with OAB, compatible to those of other chronic diseases such as dementia or diabetes mellitus. Another study [29], estimated and compared the direct cost of OAB to the health care systems of five European countries (Germany, Italy, Spain, Sweden, and UK). The authors, through a health economic model, estimated that, in 2000, 20.2 million people over the age of 40 in the five countries would experience OAB; total cost for OAB to health care systems across all five European countries was estimated at Euro 4.2 billion in 2000, resulting in an average of Euro 208 per case. Approximately 70% of total resources were absorbed by the UUI subpopulation ("wet OAB") – 7 million people – these were assumed to consume all the cost of incontinence pads and co-morbidities. Average direct costs of UUI management (medical visits, incontinence pads, and drugs) and UUI-related co-morbidities management (UTIs, skin conditions, falls and fractures) ranged from Euro 269 (UK) to Euro 706 (Italy) per patient per year, demonstrating a large variability amongst countries; in this subgroup, the largest cost component was incontinence pads, accounting for an average of 63% of the annual per patient cost.

Aggregate Evidence

Table **4** below represents an attempt to summarize the impact of each cost category on the burden incurred either by UI or by OAB conditions: these estimates are taken from a subgroup of studies in literature reviewed so far (i.e. the studies contained in Table **3**), gathering analyses that calculated and showed comparable classification of cost categories.

As expected, routine care accounted for the highest percentage in UI costs, both in institutions and in community settings: values range from 63.1% (minimum value registered 40.7%, maximum 97.2%) in institutions, to 45.4% in community-dwelling people (min. 9.9%, max. 79.1%) of the direct healthcare costs – notable is the high variability of the results presented in Table **4**, which depends probably on the combined effects of case definition, methods applied, and different cost classifications. The second largest cost component was consequences costs (e.g., skin irritations, UTIs, falls), ranging from 35.7% (min. 2.3%, max. 58.7%) in institutions, to 18.2% in community-dwelling people (min. 0.0%, max. 53.9%) of the direct healthcare costs. As for community-dwelling people, also costs for specialist visits (12.3%) and for surgical treatment (11.1%) accounted for a large portion of direct healthcare costs. Direct non-healthcare costs and production losses are negligible when confronted with the other costs: 1% of the direct cost (healthcare plus non-healthcare) for travelling expenses, and 3.9% of societal costs (healthcare plus non-healthcare plus indirect costs) for community-dwelling people.

Table 4. UI and OAB Cost Categories Impact for Community-Dwelling and Institutionalized People

	Cost Categories (%) – UI *						***Cost Categories (%) – OAB *****					
	Institutions			***Community***			***Institutions***			***Community***		
Cost categories	*%*	*%*	*%*	*%*	*%*	*%*	*%*	*%*	*%*	*%*	*%*	*%*
Direct healthcare costs	*Min*	***Mean***	*Max*	*Min*	***Mean***	*Max*	*Min*	***Mean***	*Max*	*Min*	***Mean***	*Max*
Diagnostics services	*0,1%*	***0,2%***	*0,5%*	*0,3%*	***7,6%***	*15,7%*	*0,5%*	***0,5%***	*0,5%*	*0,0%*	***0,5%***	*0,9%*
Pharmacological treatments	*0,0%*	***0,1%***	*0,1%*	*0,1%*	***3,6%***	*12,6%*	*0,1%*	***0,1%***	*0,1%*	*3,1%*	***12,9%***	*20,0%*
Specialist visits	*n.r.*	***n.r.***	*n.r.*	*0,0%*	***12,3%***	*22,8%*	*n.r.*	***n.r.***	*n.r.*	*0,0%*	***10,4%***	*23,4%*
Behavioral/Rehabilitation	*0,0%*	***0,8%***	*2,3%*	*0,2%*	***1,7%***	*4,5%*	*n.r.*	***n.r.***	*n.r.*	*0,0%*	***1,7%***	*3,4%*
Surgical Treatments	*0,0%*	***0,1%***	*0,4%*	*4,2%*	***11,1%***	*16,7%*	*n.r.*	***n.r.***	*n.r.*	*0,0%*	***3,4%***	*6,7%*
Routine care	*40,7%*	***63,1%***	*97,2%*	*9,9%*	***45,4%***	*79,1%*	*97,1%*	***97,1%***	*97,2%*	*18,8%*	***22,7%***	*28,7%*
Consequences	*2,3%*	***35,7%***	*58,7%*	*0,0%*	***18,2%***	*53,9%*	*2,3%*	***2,3%***	*2,3%*	*46,7%*	***48,4%***	*51,3%*
Direct non-healthcare costs												
Travel	*n.r.*	***n.r.***	*n.r.*	*1,0%*	***1,0%***	*1,0%*	*n.r.*	***n.r.***	*n.r.*	*22,5%*	***22,5%***	*22,5%*
Indirect costs												
Production losses	*0,0%*	***0,5%***	*1,0%*	*3,9%*	***3,9%***	*3,9%*	*0,0%*	***0,0%***	*0,0%*	*6,6%*	***8,3%***	*9,2%*

Legend:
n.r.: not reported.
(*) References for UI studies (N.6): Wagner *et al.* [1]; Dowell *et al.* [23]; Wilson *et al.* [32]; Doran *et al.* [24]; Hu *et al.* [22]; Papanicolaou *et al.* [16].
(**) References for OAB studies (N.3): Hu *et al.* [22]; Klotz *et al.* [25]; Prasopsanti *et al.* [30].

The order of cost categories in institutions is quite similar when confronting UI and OAB conditions, being routine care the highest cost category, followed by consequences costs; nevertheless, these for OAB absorb only 2.3% of direct healthcare costs *vs* 35.7% for UI. Instead, different results are registered in OAB-affected community-dwelling people. For this group, consequences represent the major component (48.4% of direct non-healthcare costs), while routine care switched, for the first time, to the second place, with 22.7%; while the other percentages are quite compatible with community-dwelling UI cost of care, except for diagnostic services. Notably, production losses account for almost 10% of societal costs for OAB, while only 4% on average for UI.

DISCUSSION

Systematic reviews of the literature provide a means for dealing with the information mountain, by allowing large amounts of research information to be distilled into a manageable form, further presenting potentially defendable statements, as these are drawn on all relevant scientifically sound research, rather than on single studies [43]. The present systematic review process pointed out some relevant findings on the topic. First of all, prevalence rates of UI and OAB vary depending upon definitions used, populations studied, and methods employed: the exact number of individuals with OAB and/or UI remains elusive and caution is advised in interpreting these estimates [44]: a reliable range for daily incontinent episodes would lie between 5% and 12% in community-dwellers [4, 21, 41], whilst more than 50% of institutionalized persons would suffer from UI [6]; OAB, including "OAB wet", would instead affect 16%-17% of men and women [15, 41, 50]. This could primarily explain the large variability in the results presented in the papers collected (Table **4**), together with combined effects of case definition, methods applied, and different cost classifications.

Secondly, correct estimates of direct healthcare costs for incontinence must take into account the hidden nature of incontinence since the most affected individuals do not seek treatment [32]. Yarnell *et al*. found in a community survey of 1,060 Welsh women that half of those with urinary incontinence serious enough to interfere with their daily activities had not consulted a physician [45, 46]. Other authors report that only about a third of those affected actually seek medical help, because of lack of knowledge (on the part of the patient or the provider) about available treatments as well as patients' embarrassment about revealing their "lack of control" [47]. There is also a time lag of typically more than a year, and sometimes more than 3 years, between the onset of symptoms and seeking professional help [48]. Reasons for this behaviour relate more to attitudes than to the accessibility to care: Dutcher [44] well explains that many people and their caregivers fail to seek treatment, mistakenly believing effective treatment is nonexistent or that bladder problems are a normal part of aging. Many females cling to the stereotype that it is a normal effect of having children or a consequence of menopause. Some are embarrassed to seek treatment; others keep symptoms secret, fearing that they will be placed in a nursing home. Failure to seek treatment results in various coping strategies including reduced fluid intake, planning social activities around bathroom needs, decreased social contacts, and being reliant upon absorbent pads.

Thirdly, biases may occur if a study estimated the burden of disease using claims data: these assess only a fraction of incontinence expenditures, only people treated for their symptoms (seeking AND treated), thus recorded in a claim, which are usually the most expensive patients on a per-capita basis because treatment is an add-on cost to routine care [34-36, 38, 42, 49]. Community-dwelling women seeking for treatment would cost four times the cost of women not seeking for treatment in a reviewed Australian study: AUD 674 *vs* AUD 192 respectively (1998 values) [24]. In order to be fully representative of the phenomenon, studies would then need to account for two different subgroups of people: (i) people seeking treatment for their symptoms (also *via* claims databases), both in community and in institutions, and (ii) community-dwelling people who do not seek help for their symptoms, and instead develop coping strategies such as wearing protective pads, bought out-of-pocket.

Fourthly, a logical consequences of the peculiarities of these disabling conditions, is that the direct costs of incontinence would likely be higher, if a greater proportion of patients with UI and/or OAB sought care. However, this potential increase in economic costs would be at least partially offset by reductions in condition specific-related consequence costs, such as UTIs, falls, skin infections, and longer hospital stays. This offset depends on the degree to which UI and/or OAB causes these consequences – more research is needed to establish whether a causal pathway exists [41, 50].

From an economic perspective, investing more resources in early diagnosis and initial treatment could potentially reduce the costs of treating late-stage disease and its consequences. The evidence produced so far showed that healthcare systems never pursued clearly this direction, as, for example, in OAB community-dwellers the cost of diagnosing and treating is on average less than the cost of treating its related consequences: 29% of direct costs for diagnosis and treatment (summing up diagnostics, pharmacological treatments, specialist visits, behavioural-rehabilitation service, and surgical treatments) *vs* 48.4% for consequences (Table **4**); whilst in UI community-dwellers the latter is still high, being 18.2% of direct costs. Furthermore, potential savings would be accrued from improved productivity if patients are able to remain at work (especially for community-dwelling OAB).

Indeed, future research is needed to support the above mentioned issues, primarily aimed at establishing the underlying mechanisms that link UI and OAB with increased risks of UTIs, falls and injuries; from clarification of any such causal link would emerge important targets for the development of cost-effective and cost-saving measures for preventing and treating these conditions [50]. These themes are even more imperative and impelling when considering probable future trends: (i) treatments change over years *via* continuous technological innovations, resulting in the introduction of more and more costly and sophisticated drugs, surgery interventions and incontinence-related products; (ii) the age composition of countries changes over time, as population ages the prevalence of UI and OAB is

expected to grow, as well as the number of people suffering simultaneously from other co-morbid conditions, complicating more and more the overall picture of an incontinent person. All these issues put together would indicate the global need for better awareness at every level – patient's, caregiver's, physician's, decision- and policy-maker's – of these complex conditions, their correct evaluation and treatment.

CONCLUSIONS

Despite the limitations of existing research described above, it seems clear that, as prevalent health conditions, UI and OAB are associated with significant cost to the individual, institution and society. These involve suffering by afflicted patients and economic consequences affecting patients, care providers, and the public who pays for care. These costs are expected to rise dramatically with the rapidly expanding of older population, who is at higher risk of any form of incontinence. Understanding the magnitude of the impact of these pelvic floor disorders is important to health care providers, payers, and public policy-makers in establishing health care priorities, taking advantage of potential savings, and allocating scarce resources for its appropriate management.

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