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Behavioural Interventions for Urinary Incontinence in Community-Dwelling Seniors

An Evidence-Based Analysis

October 2008



Medical Advisory Secretariat Ministry of Health and Long-Term Care

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The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series.*

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

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If you are aware of any current additional evidence to inform an existing evidence-based analysis, please contact the Medical Advisory Secretariat: <u>MASinfo.moh@ontario.ca</u>. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit <u>http://www.health.gov.on.ca/english/providers/program/ohtac/public engage overview.html.</u>

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Abbreviations

CCAC	Community Care Access Centre
CI	Confidence interval
CNS	Clinical nurse specialist
HTA	Health technology assessment
HR	Hazard ratio
ICS	International Continence Society
IIQ	Incontinence impact questionnaire
I-QOL	Incontinence Quality of Life (questionnaire)
LTC	Long-term care
MWES	Mean weighted effect size
NCA	Nurse continence advisor
NS	Not statistically significant
OR	Odds ratio
PFMT	Pelvic floor muscle training
PVR	Postvoid residual
RCT	Randomized controlled trial
RR	Relative risk
SD	Standard deviation
SE	Standard error
TVT	Tension-free vaginal tape
UI	Urinary incontinence
WMD	Weighted mean difference

Executive Summary

In early August 2007, the Medical Advisory Secretariat began work on the Aging in the Community project, an evidence-based review of the literature surrounding healthy aging in the community. The Health System Strategy Division at the Ministry of Health and Long-Term Care subsequently asked the secretariat to provide an evidentiary platform for the ministry's newly released Aging at Home Strategy.

After a broad literature review and consultation with experts, the secretariat identified 4 key areas that strongly predict an elderly person's transition from independent community living to a long-term care home. Evidence-based analyses have been prepared for each of these 4 areas: falls and fall-related injuries, urinary incontinence, dementia, and social isolation. For the first area, falls and fall-related injuries, an economic model is described in a separate report.

Please visit the Medical Advisory Secretariat Web site, <u>http://www.health.gov.on.ca/english/providers/</u> program/mas/mas_about.html, to review these titles within the Aging in the Community series.

- 1. Aging in the Community: Summary of Evidence-Based Analyses
- 2. Prevention of Falls and Fall-Related Injuries in Community-Dwelling Seniors: An Evidence-Based Analysis
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- 4. Caregiver- and Patient-Directed Interventions for Dementia: An Evidence-Based Analysis
- 5. Social Isolation in Community-Dwelling Seniors: An Evidence-Based Analysis
- 6. The Falls/Fractures Economic Model in Ontario Residents Aged 65 Years and Over (FEMOR)

Objective

To assess the effectiveness of behavioural interventions for the treatment and management of urinary incontinence (UI) in community-dwelling seniors.

Clinical Need: Target Population and Condition

Urinary incontinence defined as "the complaint of any involuntary leakage of urine" was identified as 1 of the key predictors in a senior's transition from independent community living to admission to a long-term care (LTC) home. Urinary incontinence is a health problem that affects a substantial proportion of Ontario's community-dwelling seniors (and indirectly affects caregivers), impacting their health, functioning, well-being and quality of life. Based on Canadian studies, prevalence estimates range from 9% to 30% for senior men and nearly double from 19% to 55% for senior women. The direct and indirect costs associated with UI are substantial. It is estimated that the total annual costs in Canada are

\$1.5 billion (Cdn), and that each year a senior living at home will spend \$1,000 to \$1,500 on incontinence supplies.

Interventions to treat and manage UI can be classified into broad categories which include lifestyle modification, behavioural techniques, medications, devices (e.g., continence pessaries), surgical interventions and adjunctive measures (e.g., absorbent products).

The focus of this review is behavioural interventions, since they are commonly the first line of treatment considered in seniors given that they are the least invasive options with no reported side effects, do not limit future treatment options, and can be applied in combination with other therapies. In addition, many seniors would not be ideal candidates for other types of interventions involving more risk, such as surgical measures.

Note: It is recognized that the terms "senior" and "elderly" carry a range of meanings for different audiences; this report generally uses the former, but the terms are treated here as essentially interchangeable.

Description of Technology/Therapy

Behavioural interventions can be divided into 2 categories according to the target population: caregiverdependent techniques and patient-directed techniques. Caregiver-dependent techniques (also known as toileting assistance) are targeted at medically complex, frail individuals living at home with the assistance of a caregiver, who tends to be a family member. These seniors may also have cognitive deficits and/or motor deficits. A health care professional trains the senior's caregiver to deliver an intervention such as prompted voiding, habit retraining, or timed voiding. The health care professional who trains the caregiver is commonly a nurse or a nurse with advanced training in the management of UI, such as a nurse continence advisor (NCA) or a clinical nurse specialist (CNS).

The second category of behavioural interventions consists of patient-directed techniques targeted towards mobile, motivated seniors. Seniors in this population are cognitively able, free from any major physical deficits, and motivated to regain and/or improve their continence. A nurse or a nurse with advanced training in UI management, such as an NCA or CNS, delivers the patient-directed techniques. These are often provided as multicomponent interventions including a combination of bladder training techniques, pelvic floor muscle training (PFMT), education on bladder control strategies, and self-monitoring. Pelvic floor muscle training, defined as a program of repeated pelvic floor muscle contractions taught and supervised by a health care professional, may be employed as part of a multicomponent intervention or in isolation.

Education is a large component of both caregiver-dependent and patient-directed behavioural interventions, and patient and/or caregiver involvement as well as continued practice strongly affect the success of treatment. Incontinence products, which include a large variety of pads and devices for effective containment of urine, may be used in conjunction with behavioural techniques at any point in the patient's management.

Evidence-Based Analysis Methods

A comprehensive search strategy was used to identify systematic reviews and randomized controlled trials that examined the effectiveness, safety, and cost-effectiveness of caregiver-dependent and patient-directed behavioural interventions for the treatment of UI in community-dwelling seniors (see Appendix 1).

Research Questions

- 1. Are caregiver-dependent behavioural interventions effective in improving UI in medically complex, frail community-dwelling seniors with/without cognitive deficits and/or motor deficits?
- 2. Are patient-directed behavioural interventions effective in improving UI in mobile, motivated community-dwelling seniors?
- 3. Are behavioural interventions delivered by NCAs or CNSs in a clinic setting effective in improving incontinence outcomes in community-dwelling seniors?

Assessment of Quality of Evidence

The quality of the evidence was assessed as high, moderate, low, or very low according to the GRADE methodology and GRADE Working Group. As per GRADE the following definitions apply:

High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the
	estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in
	the estimate of effect and is likely to change the estimate.
Very low	Any estimate of effect is very uncertain.

Summary of Findings

Executive Summary Table 1 summarizes the results of the analysis.

The available evidence was limited by considerable variation in study populations and in the type and severity of UI for studies examining both caregiver-directed and patient-directed interventions. The UI literature frequently is limited to reporting subjective outcome measures such as patient observations and symptoms. The primary outcome of interest, admission to a LTC home, was not reported in the UI literature. The number of eligible studies was low, and there were limited data on long-term follow-up.

Intervention	Target Population	Interventions	Conclusions	GRADE quality of the evidence
1. Caregiver- dependent techniques (toileting assistance)	Medically complex, frail individuals at home with/without cognitive deficits and/or motor deficits Delivered by informal caregivers who are trained by a nurse or a nurse with specialized UI training (NCA/CNS)	 Prompted voiding Habit retraining Timed voiding 	There is no evidence of effectiveness for habit retraining (n=1 study) and timed voiding (n=1 study). Prompted voiding may be effective, but effectiveness is difficult to substantiate because of an inadequately powered study (n=1 study). Resource implications and caregiver burden (usually on an informal caregiver) should be considered	Low
2. Patient- directed techniques	Mobile, motivated seniors Delivered by a nurse or a nurse with specialized UI training (NCA/CNS)	Multicomponent behavioural interventions Include a combination of • Bladder training • PFMT (with or without biofeedback) • Bladder control strategies • Education • Self-monitoring	Significant reduction in the mean number of incontinent episodes per week (n=5 studies, WMD 3.63, 95% CI, 2.07–5.19) Significant improvement in patient's perception of UI (n=3 studies, OR 4.15, 95% CI, 2.70–6.37) Suggestive beneficial impact on patient's health-related quality of life	Moderate
		PFMT alone	Significant reduction in the mean number of incontinent episodes per week (n=1 study, WMD 10.50, 95% CI, 4.30– 16.70)	Moderate
3. Behavioural interventions led by an NCA/CNS in a clinic setting	Community-dwelling seniors	Behavioural interventions led by NCA/CNS	Overall, effective in improving incontinence outcomes (n=3 RCTs + 1 Ontario-based before/after study)	Moderate

Executive Summary Table 1: Summary of Evidence on Behavioural Interventions for the Treatment of Urinary Incontinence in Community-Dwelling Seniors

*CI refers to confidence interval; CNS, clinical nurse specialist; NCA, nurse continence advisor; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; WMD, weighted mean difference; UI, urinary incontinence.

Economic Analysis

A budget impact analysis was conducted to forecast costs for caregiver-dependent and patient-directed multicomponent behavioural techniques delivered by NCAs, and PFMT alone delivered by physiotherapists. All costs are reported in 2008 Canadian dollars. Based on epidemiological data, published medical literature and clinical expert opinion, the annual cost of caregiver-dependent behavioural techniques was estimated to be \$9.2 M, while the annual costs of patient-directed behavioural techniques delivered by either an NCA or physiotherapist were estimated to be \$25.5 M and \$36.1 M, respectively. Estimates will vary if the underlying assumptions are changed.

Currently, the province of Ontario absorbs the cost of NCAs (available through the 42 Community Care Access Centres across the province) in the home setting. The 2007 *Incontinence Care in the Community Report* estimated that the total cost being absorbed by the public system of providing continence care in the home is \$19.5 M in Ontario. This cost estimate included resources such as personnel, communication with physicians, record keeping and product costs. Clinic costs were not included in this estimation because currently these come out of the global budget of the respective hospital and very few continence clinics actually exist in the province. The budget impact analysis factored in a cost for the clinic setting, assuming that the public system would absorb the cost with this new model of community care.

Considerations for Ontario Health System

An expert panel on aging in the community met on 3 occasions from January to May 2008, and in part, discussed treatment of UI in seniors in Ontario with a focus on caregiver-dependent and patient-directed behavioural interventions. In particular, the panel discussed how treatment for UI is made available to seniors in Ontario and who provides the service. Some of the major themes arising from the discussions included:

- Services/interventions that currently exist in Ontario offering behavioural interventions to treat UI are not consistent. There is a lack of consistency in how seniors access services for treatment of UI, who manages patients and what treatment patients receive.
- > Help-seeking behaviours are important to consider when designing optimal service delivery methods.
- There is considerable social stigma associated with UI and therefore there is a need for public education and an awareness campaign.
- > The cost of incontinent supplies and the availability of NCAs were highlighted.

Conclusions

There is moderate-quality evidence that the following interventions are effective in improving UI in mobile motivated seniors:

- Multicomponent behavioural interventions including a combination of bladder training techniques, PFMT (with or without biofeedback), education on bladder control strategies and self-monitoring techniques.
- Pelvic floor muscle training alone.

There is moderate quality evidence that when behavioural interventions are led by NCAs or CNSs in a clinic setting, they are effective in improving UI in seniors.

There is limited low-quality evidence that prompted voiding may be effective in medically complex, frail seniors with motivated caregivers.

There is insufficient evidence for the following interventions in medically complex, frail seniors with motivated caregivers:

- ▹ habit retraining, and
- timed voiding.

In early August 2007, the Medical Advisory Secretariat began work on the Aging in the Community project, an evidence-based review of the literature surrounding healthy aging in the community. The Health System Strategy Division at the Ministry of Health and Long-Term Care subsequently asked the secretariat to provide an evidentiary platform for the ministry's newly released Aging at Home Strategy.

After a broad literature review and consultation with experts, the secretariat identified 4 key areas that strongly predict an elderly person's transition from independent community living to a long-term care home. Evidence-based analyses have been prepared for each of these 4 areas: falls and fall-related injuries, urinary incontinence, dementia, and social isolation. For the first area, falls and fall-related injuries, an economic model is described in a separate report.

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Objective

To assess the effectiveness of behavioural interventions for the treatment and management of urinary incontinence (UI) in community-dwelling seniors.

Clinical Need: Target Population and Condition

Urinary Incontinence Identified as a Predictor of Long-Term Care Home Admission

Urinary incontinence, defined as "the complaint of any involuntary leakage of urine," (1) was identified as 1 of the key predictors in a senior's transition from independent community living to admission to a

long-term care (LTC) home. For caregivers, UI is often a major driver in the decision to institutionalize elderly family members and is often cited as the "tipping point."

Several large recent cohort studies have examined UI as a possible predictor of LTC home admission. Studies followed cohorts of community-dwelling seniors and determined the number of seniors with UI who were admitted to LTC homes by the end of follow-up. Study characteristics are presented in Table 1. Figure 1 pools the results from 4 of the studies that investigated UI as a predictor of LTC home admission. Based on the pooled results, it appears that UI is a predictor of LTC home admission. However, it is important to note that the estimates presented in Figure 1 are not adjusted for age, sex, or other chronic conditions that may also be important factors in influencing LTC home admission. As noted in Table 1, when Banaszak-Holl et al. (2) adjusted the hazard ratio for disability, which was defined as requiring assistance with activities of daily living,¹ they found that UI was not a predictor of LTC home admission even when the results stratified by sex, and found that UI was a predictor of LTC home admission even when the results were adjusted for age, dementia, cardiovascular disease, and renal disease.

¹ Activities of Daily Living (ADL) are basic but important general tasks required for day-to-day living such as bathing, dressing, grooming, eating, and toileting.

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Study, Year	Location	Sample	Cohort Follow- Up (years)	Number Placed in LTC Home With UI by the End of Follow-Up (%)	Number Not Placed in LTC Home With UI by the End of Follow-Up (%)	Statistical Results
Andel et al., 2007 (4)	United States (Florida)	1,943 community- dwelling older adults (≥ 65 y)	4	319/726 (44)	377/1217 (31)	Overall <i>P</i> < .001 Without dementia <i>P</i> < .001 With dementia <i>P</i> > .05
Banaszak- Holl et al., 2004 (AHEAD study) (2)	United States (national sample)	6,676 community- dwelling older adults (≥ 70 y)	6.6	284/1,092 (26)	1,061/5,584 (19)	Univariate HR 1.7 (95% Cl, 1.5–1.9; $P < .001$) Adjusted HR without disability 1.2 (95% Cl, 1.1–1.4; $P < .001$) Adjusted HR with disability 1.0 (95% Cl, 0.9–1.2; $P < .001$)
Nuotio et al., 2003 (6)	Finland	775 community- dwelling older adults (≥ 60 y)	13	26/127 (20.5)	52/570 (9.1)	For men, unadjusted $P =$.006, age-adjusted RR 2.96 (95% Cl, 1.33–6.61, P = .008) For women, unadjusted P = .125, age-adjusted RR 1.37 (95% Cl, 0.84– 2.22, $P =$.206)
Lachs et al., 2002 (3)	United States (Connecticut)	2,812 community- dwelling older adults (≥ 65 y)	9	468/955 (49.4)	744/1852 (40.5)	<i>P</i> < .001
Thom et al., 1997 (5)	United States (Northern California)	5,986 HMO members (≥65 y)	9	Not reported	Not reported	Adjusted RR for women 2.0 (95% Cl, 1.7–2.4) Adjusted RR for men 3.2 (95% Cl, 2.7–3.8) (adjusted for age, cardiovascular disease, dementia, heart disease, renal disease)

Table 1: Studies Reporting Urinary Incontinence as a Possible Predictor of Long-Term Care Home Admission*

*AHEAD refers to Asset and Health Dynamics Among the Oldest Old Study; CI, confidence interval; HMO, Health Maintenance Organization; LTC, long-term care; HR, hazard ratio; RR, relative risk; UI, urinary incontinence.

Figure 1: Pooled Unadjusted Results From Studies Examining Urinary Incontinence as a Predictor of Long-term Care Home Admission*

Study or sub-category	Diagnosed with UI n/N	No UI n/N	RR (random) 95% Cl	Weight %	RR (random) 95% Cl
Lachs	468/955	744/1852	-	33.33	1.22 [1.12, 1.33]
Nuotio	26/127	52/570		- 7.29	2.24 [1.46, 3.45]
Banaskzak-Holl	284/1092	1061/5584	-	29.92	1.37 [1.22, 1.53]
Andel	319/726	377/1217	-	29.47	1.42 [1.26, 1.60]
Total (95% CI)	2900	9223	•	100.00	1.38 [1.21, 1.57]
Total events: 1097 (Diagno	osed with UI), 2234 (No UI)				and the second se
Test for heterogeneity: Ch	hi ² = 11.04, df = 3 (P = 0.01), l ² = 7	2.8%			
Test for overall effect: Z =	= 4.91 (P < 0.00001)				
7			0.1 0.2 0.5 1 2	5 10	

*CI refers to confidence interval; RR, relative risk; UI, urinary incontinence.

†Results become more complex when adjusted for activities of daily living (ADLs), sex, age, chronic disease.

Reasons for admission to LTC are complex, as is evidenced by the studies investigating UI as a predictor of LTC home admission. According to unadjusted univariate analysis, UI is a significant predictor of LTC home admission (Figure 1). However, when UI data are adjusted for activities of daily living, chronic conditions (such as dementia and cardiovascular disease), age, and sex, the strength of UI as a predictor of LTC home admission is less clear.

Morrison et al. (7) used data from the Thom et al. (5) study to calculate the fraction of LTC home admissions attributable to UI. The authors determined that 10% of all admissions for men and 6% of all admissions for women were attributable solely to UI. By extrapolating data to the population of the United States in 2000, the annualized cost of LTC home admissions due to UI was estimated at \$6 billion. (7)

Urinary Incontinence in Seniors

There is a large amount of literature on the prevalence, diagnosis, treatment, and management of incontinence. Incontinence can span a person's lifetime, and it has many causes and various classifications.

Urinary incontinence affects a substantial proportion of Ontario's community-dwelling seniors, impacting their health, functioning, and well-being. It can also have potentially devastating effects on quality of life, which encompasses physical, psychological, sexual, and social domains. It impacts upon caregivers, and as mentioned, it is often a major driver in the decision to institutionalize elderly people. The situation has the potential to be psychologically difficult for all parties involved because of feelings of humiliation and guilt. (8;9)

Note: It is recognized that the terms "senior" and "elderly" carry a range of meanings for different audiences; this report generally uses the former, but the terms are treated here as essentially interchangeable.

Causes of Urinary Incontinence

Urinary incontinence may occur as a result of different functional abnormalities of the lower urinary tract or as a result of other illnesses. Normal continence is maintained through the neurologically mediated coordination between bladder, urethra, urethral sphincter, and pelvic floor. Incontinence occurs when

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there is a breakdown in the relationship between the above components, either due to physical damage or nerve dysfunction. Additional causes of UI include but are not limited to adverse drug effects, cognitive impairment, and physical/mobility impairment. (9)

Seniors are especially predisposed to developing UI because of changes in bladder physiology that occur as a part of the aging process. (9) This predisposition, coupled with pathologic, physiologic, or pharmacologic factors, explains why the elderly are so likely to become incontinent. Urinary incontinence should not, however, be considered a normal part of the aging process. (10) A key distinction in etiology of UI between younger and older individuals is the frequent role of conditions outside the lower urinary tract in precipitating or aggravating symptoms. Some of these multifactorial influences may include mobility limitations, chronic illnesses, medications, and cognitive impairment. (10;11)

Complications associated with UI include skin breakdown, pressure ulcers, urinary tract infections, and psychosocial consequences such as shame, isolation, and depression. (10)

Types of Urinary Incontinence

As mentioned, several physiological mechanisms and changes can result in different types of UI. Urinary incontinence may also be transient in nature. The transient causes of UI can be described by the mnemonic DIAPERS: delirium, infection, atrophic urethritis/vaginitis, pharmaceuticals, excess urine output, restricted mobility, stool impaction. (9) Once transient causes of UI have been addressed, the established causes of UI can then be targeted.

Dysfunction of the bladder wall muscle (detrusor overactivity) may result in urge UI, and poor functioning of the bladder outlet (urethra, sphincters, pelvic floor muscles) may result in stress UI. Detrusor underactivity may result in overflow UI. (9;10) The major types of UI and their characteristics are listed below.

- > Stress UI is involuntary urine leakage on effort or exertion, or on sneezing or coughing.
- Urge UI is involuntary urine leakage accompanied by or immediately preceded by a sudden compelling desire to pass urine, a desire that is difficult to defer.
- Mixed UI is a combination of stress and urge incontinence. It is involuntary urine leakage associated with urgency and also with exertion, effort, sneezing, or coughing.

Other types of incontinence include

- > Overflow UI is the constant leaking or dribbling from a full bladder.
- Functional UI denotes incontinence related to causes outside of the urinary system. For example, UI may be exacerbated by functional factors such as physical barriers to the toilet, a lack of mobility, a degree of unwillingness to comply, and medication. This type of UI may be managed by addressing these functional factors.

Prevalence of Urinary Incontinence

Estimates for the prevalence of UI are inconsistent because of issues with underreporting, social stigma, and variation in definitions and measurement tools. Many patients are also never screened for UI and are too embarrassed to tell their physicians about this problem. Prevalence of UI increases with age, institutionalization, failing mental powers, and loss of mobility. (8;12)

For people aged 65 years and older, prevalence estimates derived from Canadian studies range from 9% to 30% for men and from 19% to 55% for women (Table 2). Thus, the prevalence of UI in senior women is nearly double that of senior men. The survey by Herschorn et al. (13) also collected information on severity. Only about 25% of respondents indicated that their incontinence resulted in "moderate to severe

interference with everyday life," and approximately one-quarter of the people who reported having any bladder problem indicated that they had consulted a health care provider regarding their condition.

Study, Year	Prevalence
Irwin et al., 2006 (14)	men 10.4%, women 19.3% (≥ 60 years)
EPIC Study	
Canadian Community Health Survey, 2003 (CCHS) (15)	10.7%
	(≥ 65 years)
Ostbye et al., 2004 (16)	men 9%, women 19%
	(≥ 65 years)
The Canadian Study of Health and Aging (CSHA)	
Herschorn et al., 2008 (13)	men 30%, women 55%, combined
	21.8%
The Canadian Urinary Bladder Survey (CUBS)	(≥ 65 years)

Table 2: Recent Canadian Surveys on Prevalence of Urinary Incontinence

Swanson et al. (17) published results of an Ontario survey of 606 community-dwelling women aged 45 years and older in 2 family practice clinics in Hamilton. The survey was not limited to seniors but provided useful information on prevalence in Ontario and on help-seeking behaviour. They found that UI was reported by 51.3% of women, of whom 35.7% perceived it as a problem. Roughly one-third of incontinent women had discussed urine loss with their physician, and among these, 70% felt satisfied with their physician's responses.

In their 2007 report on UI, the Agency for Healthcare Research and Quality (18) in the United States presented pooled UI prevalence estimates in seniors 65 years and older. Using a broad definition of UI that included various frequencies (monthly, weekly, daily) and levels of severity, the prevalence of UI was estimated to be 45.1% for women and 20.5% for men. The prevalence of daily UI in women was 17% and in men was 9%. The prevalence of severe UI, defined as UI resulting in wet clothes or severe enough for the person to seek treatment, was 9% in women and 4% in men.

Given the high prevalence of UI among community-dwelling seniors, the direct and indirect costs associated with UI are substantial. Herschorn et al. (13) reported that the total annual costs of UI in Canada were estimated at \$1.5 billion. The Canadian Continence Foundation (8) estimates that each year a senior living at home will spend \$1,000 to \$1,500 on incontinence supplies.

Treatment and Management of Urinary Incontinence

Early and effective treatment of UI is reported to be important for restoring both physical function and emotional well-being. (10) In most seniors, the type of UI can be diagnosed by history, physical examination, and postvoid residual (PVR) urine volume measurement. (10) This initial assessment is an essential part of managing UI, since it allows health care professionals and patients to discuss patient expectations, determine treatment preferences, and identify realistic outcomes that would reflect a meaningful improvement in the patient's quality of life. (8) An individual's progress and expectations can then be continually reviewed throughout the treatment process.

Patients with UI are treated and managed by a variety of health care professionals including family

physicians, nurses, nurses with specialized training in UI such as a nurse continence advisor² (NCA) or clinical nurse specialist³ (CNS), physiotherapists, urologists, or gynecologists. There may also be an opportunity to improve health care professionals' awareness and knowledge on UI. A recent survey of Canadian family physicians reported that only 46% of physicians clearly understood incontinence, and just 38% had an organized plan for incontinence problems. (19) Almost half reported that they usually referred patients with incontinence. (19)

Interventions to treat and manage UI can be classified into broad categories including lifestyle modification, behavioural techniques, medications, devices (e.g., continence pessaries), surgical interventions, and adjunctive measures (e.g., absorbent products). The Medical Advisory Secretariat previously conducted 2 reviews on surgical interventions to treat UI: *Sacral Nerve Stimulation for the Management of Urge Incontinence, Urgency-Frequency, Urinary Retention and Fecal Incontinence* and *Midurethral Slings for Women with Stress Urinary Incontinence*. (20;21) Although the reviews were not conducted for an exclusively senior population, the evidence indicated that both of the surgical interventions were effective at treating and managing UI in select patient populations.

The focus of the current review was on behavioural interventions since they are commonly the first line of treatment for UI in seniors. (22-24) Behavioural interventions are the least invasive options, have no reported side effects, do not limit future treatment options, and can be applied in combination with other therapies. (23;24) Further, many seniors would not be ideal candidates for other types of interventions involving more risk, such as surgical treatment.

Behavioural Interventions for the Treatment of Urinary Incontinence

Behavioural interventions can be divided into 2 categories according to the target population: caregiverdependent techniques and patient-directed techniques (Table 3).

Caregiver-dependent techniques (also known as toileting assistance) are targeted at medically complex, frail individuals living at home with the assistance of a caregiver, who tends to be a family member. The elderly person may also have cognitive deficits and/or motor deficits. The Canadian Continence Foundation (8) defines frail elderly persons as "those who depend on others for the activities of daily living or who are at high risk of becoming dependent." Caregiver-dependent techniques are delivered by the senior's caregiver, who is trained by a health care professional to deliver a prompted voiding, habit retraining or timed voiding intervention. The health care professional who trains the caregiver is commonly a nurse or a nurse with advanced training in the management of UI, such as an NCA or CNS.

Prompted voiding is a caregiver-dependent technique that is "...used to teach people with or without cognitive impairment to initiate their own toileting through requests for help and positive reinforcement from carers when they do this." (25) The Registered Nurses' Association of Ontario (26) published best practice guidelines on prompted voiding in 2005 which were developed through a process of consensus and based on the literature. In North America, prompted voiding is mainly used in institutional settings although it can also be applied to community-dwelling seniors.

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² A nurse continence advisor (NCA) is a nurse certified with specialized training in conservative methods of managing incontinence.

³ A clinical nurse specialist (CNS) is an advanced practice nurse with graduate preparation (master's or doctorate) and advanced training in continence care.

Habit retraining is another caregiver-dependent technique that involves "the identification of a person's natural voiding pattern and the development of an individualized toileting schedule which pre-empts involuntary bladder emptying." (27) Like prompted voiding, habit retraining is mostly employed in LTC home settings, but it can also be applied to the frail elderly community-dwelling population.

Timed voiding involves voiding on a fixed schedule, typically every 2 to 4 hours. This interval remains fixed for the duration of the intervention. It is also mainly used in institutional settings. (28)

All 3 caregiver-dependent techniques can be labour intensive and require motivation by caregivers to carry out the intervention.

The second category of behavioural interventions is referred to as patient-directed techniques which target mobile and motivated seniors. This population of seniors is cognitively able without any major physical deficits and is motivated to regain and/or improve their continence. A nurse or a nurse with advanced training in UI management, such as an NCA or CNS, delivers the patient-directed techniques which are often provided as multicomponent interventions including a combination of bladder training techniques, pelvic floor muscle training (PFMT), education on bladder control strategies and fluid management, and self-monitoring. The principal aim of bladder training is to increase the interval between voids either though a mandatory or self-adjustable schedule. (29) Pelvic floor muscle training, defined as a program of repeated pelvic floor muscle (PFM) contractions taught and supervised by a health care professional, may be delivered by a physiotherapist. A PFMT program may be prescribed to increase strength, endurance, and coordination of muscle activity, or to suppress urge, or a combination of these. Strength training decreases the frequency of UI with time, and skill training immediately reduces the amount of leakage. The training may or may not include biofeedback. (30;31)

Education is a large component of both caregiver-dependent and patient-directed behavioural interventions and patient and/or caregiver involvement as well as continued practice heavily impact treatment success. The use of incontinence products, which includes a large variety of pads and devices for effective containment of urine, may be used in conjunction with behavioural techniques at any point in the patient's management. (10;23)

Table 3: Characteristics of Behavioural Interventions for the Treatment and Management of Urinary Incontinence

Intervention	Target Population	Interventions
1. Caregiver- dependent techniques	Medically complex, frail individuals at home with/without cognitive deficits and/or motor	Delivered by family caregivers who are trained by nurse or a nurse specializing in UI (NCA/CNS)
(toileting	deficits	Includes
assistance)		habit retraining
,		timed voiding
2. Patient-directed techniques	Patient-directed Mobile, motivated seniors chniques A) Multicomponent Interventions Delivered by a nurse or a nurse spec (NCA/CNS) Includes a combination of bladder training techniques PFMT (with or without biofeedba education on bladder control stra self-monitoring	
		 B) Pelvic floor muscle training (PFMT) alone Delivered by a nurse, a nurse specializing in UI (NCA/CNS) or a physiotherapist a program of repeated PFM contraction taught and supervised by a health care professional (with or without biofeedback)

*CNS refers to clinical nurse specialist; NCA, nurse continence advisor; PFMT, pelvic floor muscle training.

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Evidence-Based Analysis of Effectiveness

Objective

To assess the effectiveness of behavioural interventions for the treatment and management of UI in community-dwelling seniors.

Research Questions

- 1. Are caregiver-dependent behavioural interventions effective in improving UI in medically complex, frail community-dwelling seniors with/without cognitive deficits and/or motor deficits?
- 2. Are patient-directed behavioural interventions effective in improving UI in mobile motivated community-dwelling seniors?
- 3. Are behavioural interventions delivered by an NCA or CNS in a clinic setting effective in improving incontinence outcomes in community-dwelling seniors?

Methods

Inclusion Criteria

- English language (January 2000–September 2007);
- population of community-dwelling seniors (majority of study participants aged 65 years and older) with any type of UI;
- randomized controlled trial (RCT), quasi-experimental design, or systematic review/meta-analysis; and
- studies comparing behavioural interventions (caregiver-dependent techniques and patient-directed techniques) or PFMT alone or interventions led by an NCA or CNS versus usual care.

Exclusion Criteria

- studies reporting only fecal incontinence or acute incontinence (e.g., temporary incontinence as a result of surgery);
- > abstracts, non-peer-reviewed reports, nonsystematic reviews, case reports;
- studies with special populations (e.g., patients undergoing liver transplantation, patients with multiple sclerosis, patients with bladder cancer); or
- \blacktriangleright studies that lack a control group or studies with a small sample size (N<10).

Outcomes of Interest

- admission to LTC home;
- improvement/cure in incontinence symptoms, and
 - measures of patient observations and symptoms, or
 - change in incontinent episodes measured though bladder diaries; or
- > quality of life.

Note: Given the shortage of appropriate evidence in this area, the inclusion/exclusion criteria were less rigorously applied to existing systematic reviews. For example, the results of a systematic review on

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prompted voiding were presented although not all studies included in the review were conducted in community-dwelling seniors (some studies were conducted in LTC home residents). Although existing reviews did not always limit themselves to studies that satisfied our criteria, it was deemed important to highlight the results of existing systematic reviews due to the shortage of relevant evidence in this area. The conclusions of this report are, however, based on studies that met all eligibility criteria.

Method of Review

A search of electronic databases (OVID MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, The Cochrane Library, and the International Agency for Health Technology Assessment/Centre for Reviews and Dissemination [INAHTA/CRD] database) was undertaken to identify evidence published between January 1, 2000, and September 23, 2007. The search strategy is detailed in Appendix 1.

Studies meeting the inclusion criteria were selected from the search results. Data on the study characteristics, patient characteristics, primary and secondary treatment outcomes, and adverse events were extracted. Reference lists of selected articles were also checked for relevant studies.

Assessment of Quality of Evidence

The quality rating assigned to individual studies was determined using the Medical Advisory Secretariat's adaptation of a hierarchy proposed by Goodman. (32)

The overall quality of the evidence was examined according to the GRADE Working Group criteria. (33;34)

Quality refers to criteria such as the adequacy of allocation concealment, blinding, and follow-up.

Consistency refers to the similarity of estimates of effect across studies. If there is important unexplained inconsistency in the results, confidence in the estimate of effect for that outcome decreases. Differences in the direction of effect, the size of the differences in effect, and the significance of the differences guide the decision about whether important inconsistency exists.

Directness refers to the extent to which the interventions and outcome measures are similar to those of interest.

As stated by the GRADE Working Group, the following definitions were used in grading the quality of the evidence.

High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain.

Results of Evidence-Based Analysis

The search identified 722 articles published from January 1, 2000, to September 23, 2007. Of the 722 citations identified, 9 existing reviews and 15 studies met the inclusion criteria. The present review included four existing reviews and 3 RCTs on caregiver-dependent techniques; 4 existing reviews and 8 RCTs on patient-directed techniques; and 1 existing review, 3 RCTs, and 1 Ontario-based quasi-experimental before/after study on the role of the NCA/CNS in delivering behavioural interventions in a clinic setting. Table 4 lists the level of evidence of individual studies and the number of studies identified.

Table 4: Quality of Evidence of Included Studies*

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT,*systematic reviews of RCT	1	 4– caregiver-dependent techniques 4 – patient-directed techniques 1 – role of the NCA/CNS
Large RCT unpublished but reported to an international scientific meeting	1(g)	
Small RCT	2	 3 – caregiver-dependent techniques 8 – patient-directed techniques 3 – role of the NCA/CNS
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	1 – role of the NCA/CNS
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	0
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

*CNS refers to clinical nurse specialist; NCA, nurse continence advisor; g, grey literature; RCT, randomized controlled trial.

†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (32) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meetings.

The results will be presented in 3 sections:

- 1. Caregiver-dependent techniques
- 2. Patient-directed techniques
- 3. The role of the NCA/CNS in delivering behavioural interventions in a clinic setting

Summary of Existing Evidence

The Agency for Healthcare Research and Quality (18) in the United States recently published a wideranging evidence-based report on UI. The objective of the report was to assess the prevalence of and risk factors for urinary and fecal incontinence in adults in LTC settings and in the community; to assess the effectiveness of diagnostic methods to identify adults at risk and patients with incontinence; and to review the effectiveness of clinical interventions to reduce the risk of incontinence. There were 1,077 articles eligible for the analysis. Given that this report did not focus specifically on community-dwelling seniors, it was not directly included in the Medical Advisory Secretariat analysis; however, relevant information was incorporated when appropriate.

Section 1 – Caregiver-Dependent Behavioural Techniques

Summary of Existing Evidence

Four existing systematic reviews on caregiver-dependent techniques were included in the analysis (Table 5). Three existing Cochrane reviews focused on specific caregiver-dependent techniques, (25;27;28) and a review by Fonda et al. (11) included studies on all caregiver-dependent techniques. Overall, the majority of studies that were included in these existing reviews were conducted in LTC home residents, which limited the generalizability of their findings to the population of interest, community-dwelling seniors. Although the existing reviews did not limit themselves to studies that satisfied the inclusion criteria of community-dwelling seniors (the reviews included some studies conducted in LTC home residents), they provided relevant information regarding caregiver-dependent techniques, and given the scarcity of evidence in this area, they were included in the Medical Advisory Secretariat's review.

Systematic Review, Year	Intervention	Number of Studies Included in Roview	Results and Conclusions	Comments
Eustice et al., 2000 Updated in 2006 Cochrane review (25)	Prompted voiding	9 RCTs or quasi- randomized trials	Clear conclusions on effectiveness are difficult to make based on the limited evidence available; however, there is suggestive evidence of short-term benefit. Prompted voiding is resource-intensive, but size of resource implications is pat clear	Majority of study participants were women Majority of studies were conducted in nursing home setting, One study was conducted in homebound seniors with full-time caregiver
Ostaszkiewicz et al., 2004 Cochrane review (27)	Habit retraining	3 RCTs or quasi- randomized trials	Clear conclusions regarding the effectiveness are difficult to make based on the limited evidence available.	Small number of eligible studies Majority of study participants were women One study was conducted in a nursing home setting, Two studies were conducted in a community setting
Ostaszkiewicz et al., 2005 Cochrane review (28)	Timed voiding	2 RCTs	The quality of the studies was "modest" according to the authors, and did not permit them to confidently make conclusions regarding the effectiveness of timed voiding	Small number of eligible studies and old publication dates Both studies included older women predominantly with cognitive and physical impairments Both studies were conducted in nursing home setting

Table 5: Existing Systematic Reviews on Caregiver-Dependent Techniques for Urinary Incontinence*

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Fonda et al., 2006	All caregiver- dependent	Included the above-mentioned	Prompted voiding is effective for the short-term treatment	Majority of studies were conducted in nursing
Report by the International Continence Society (11)	techniques in frail seniors	systematic reviews and any recent studies	of UI in nursing home residents and home-care clients if caregivers comply with intervention.	home setting.
('')			Unable to determine the treatment effect of habit retraining	
			Unable to determine the treatment effect of timed voiding	

*RCT refers to randomized controlled trial.

Overall, the 3 Cochrane reviews that focused on specific caregiver-dependent techniques found that clear conclusions regarding the effectiveness of prompted voiding, habit retraining, and timed voiding were difficult to make based on the limited evidence available. Eustice et al. (25) also concluded that there was evidence suggestive of short-term benefit of prompted voiding. The review by Fonda et al. (11) concluded that prompted voiding was effective for the short-term treatment of UI in nursing home residents and home-care clients if caregivers were compliant with the intervention. They also stated that it was not possible for them to determine the treatment effect of habit retraining and timed voiding.

Systematic Review by the Medical Advisory Secretariat

Three RCTs examining the effectiveness of caregiver-dependent techniques met the inclusion criteria. (35-37) Details of the studies are outlined in Table 6 below. All 3 studies focused on different caregiver-dependent interventions. Caregivers were typically trained by nurses.

Overall, clear conclusions regarding the effectiveness of caregiver-dependent techniques to treat UI in medically complex, frail community-dwelling seniors are difficult to make, based on the limited evidence available and the heterogeneity between studies. Inadequate evidence indicates that prompted voiding may be effective in improving UI in this population, but its effectiveness is difficult to substantiate due to an inadequately powered study (small sample size, high risk of type II error). To date, the majority of studies on prompted voiding have been conducted in institutional settings and not in community-dwelling seniors. With interventions delivered by caregivers, it is important to consider the associated resource implications and caregiver burden. (25)

Study, Year	Intervention	Study Design and Methods	Results	Limitations
Jirovec et al., 2001 (35)	Timed voiding	RCT 118 memory-impaired seniors living in the community with UI and having the assistance of a caregiver 6 months duration Outcome: Change in incontinence calculated as the percentage of time the patient was incontinent	Treatment group had significantly reduced incontinence from baseline (Z = -1.83, P < .05) but no significant difference between groups	No intention-to- treat analysis, allocation concealment unclear, no justification provided for sample size
Engberg et al., 2002 (36)	Prompted voiding	RCT (crossover) 19 cognitively impaired homebound seniors aged 60 years and older with UI and a full-time caregiver 8 weeks duration Outcome: change in incontinence frequency	Treatment group reduced daily incontinent episodes by 47% (SD 39.2) compared with 27% (SD 26.1) in the control group, but this difference was not statistically significant (P = .19)	Study not adequately powered to detect a difference (risk of type II error), allocation concealment unclear
Colling et al., 2003 (37)	Habit retraining "Pattern Urge Response Toileting" (PURT)	RCT (delayed control group) 106 community-dwelling, caregiver-dependent non- demented elderly persons ≥55 yrs with urge or mixed UI 6 weeks duration Outcome: change in incontinence frequency	Treatment group had fewer daily incontinent episodes (4.0, SD 2.6) than control group (3.4 SD 2.6), but this difference was not statistically significant (<i>P</i> = .23)	Allocation concealment unclear, difficulty in recruiting an appropriate sample, patient/ caregiver study retention problematic

Table 6: Studies on Caregiver-dependent Techniques for Urinary Incontinence*

*RCT refers to randomized controlled trial; SD, standard deviation; UI, urinary incontinence.

Section 2 – Patient-Directed Behavioural Techniques

Summary of Existing Evidence

Four existing systematic reviews on patient-directed behavioural techniques for the treatment of UI in community-dwelling seniors were identified (Table 7). One review focused on bladder training, (29) 1 review included all behavioural techniques as well as drug therapy in the elderly, (38) and 2 reviews focused on PFMT alone. (30;31) Although the existing reviews did not limit to studies that satisfied the age inclusion criteria of greater than 65 years (the reviews included some studies conducted in younger populations), they provided relevant information regarding patient-directed techniques, and given the scarcity of evidence in this area, they were included in Medical Advisory Secretariat's review.

Systematic Review, Year	Intervention	Number of Studies Included in Review	Results and Conclusions	Comments
Wallace et al., 2004 Updated in 2006 Cochrane review	Bladder training	12 studies; 8 studies provided usable data	Clear conclusions regarding the effectiveness of bladder training are difficult to make based on the limited evidence available.	Not limited to seniors Only 2 of 12 studies where majority of population >65 y
(29)			Compared with no bladder training, point estimates of effect favoured bladder training; however, CI were wide and no statistically significant differences were found.	
Teunissen et al., 2004 (38)	Behavioural therapy and drug therapy in community-	4 before-after studies 4 RCTs	Behaviour therapy, including PFMT, is effective in reducing urinary leakage (5 studies).	Not limited to RCT evidence
	based seniors		There is insufficient high-quality evidence to make conclusions regarding drug therapy in seniors.	
Choi et al., 2007 (30)	PFMT versus no treatment	12 studies	Studies heterogeneous in terms of types of incontinence, eligible ages, duration of PFMT.	Only 5 of 12 studies where majority of population >65 y
			 PFMT is effective in reducing Incontinent episodes (MWES -0.68; 95% CI, -0.91 to -0.46); Urine leakage amount (MWES -1.48; 95% CI, -2.58 to -0.38); and Perceived severity (NS) (MWES -1.66; 95% CI, -3.59 to 0.27). 	Included studies with multicomponent behavioural interventions and not just PFMT alone
Hay-Smith et al., 2006 Cochrane review (31)	PFMT alone versus no treatment	13 studies; 6 studies contributed data to the analysis	 Considerable variation among studies in inclusion criteria, interventions and outcome measures Patient perceived cure more likely after PFMT than control Fewer incontinent episodes with PFMT than control May be improved condition-specific quality of life with PFMT compared with control Treatment adherence likely to impact size and direction of treatment effect, but difficult to measure No serious adverse effects reported Final conclusion: PFMT is better than no treatment for women with stress, urge, or mined the 	Excluded trials where PFMT was combined with another conservative therapy (to be examined in future reviews) Only 3 of 13 studies where majority of population >65 y Did not pool estimates of effect

Table 7: Existing Systematic Reviews on Patient-Directed Behavioural Techniques for the Treatment of Urinary Incontinence*

*CI refers to confidence interval(s); MWES, mean weighted effect size; NS, not significant; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; UI, urinary incontinence.

The review by Wallace et al. (29) on bladder training did not limit itself to studies conducted in the elderly population, and only 2 out of the 12 studies that were included in their review were conducted in community-dwelling seniors, thus limiting the generalizability of the findings. Nonetheless, Wallace et al. reported that although point estimates of effectiveness favoured bladder training when the authors compared seniors in the bladder training group with controls, these differences were not statistically

significant, and therefore clear conclusions regarding the effectiveness of bladder training could not be drawn.

The review by Teunissen et al. (38) included both behavioural therapies and drug therapies for the treatment of UI in community-dwelling seniors. They concluded that behaviour therapy, including PFMT, was effective in improving UI outcomes, and that it appeared to be more effective than drug therapy in seniors.

The systematic reviews by Choi et al. (30) and Hay-Smith et al. (31) examined the effectiveness of PFMT compared with no treatment for the management of UI. In order to be included in the systematic review, studies had to include PFMT by a health care professional on a repeated basis. Only a limited number of studies included in the reviews were conducted in community-dwelling elderly women, thus limiting the generalizability of the findings. The review by Choi et al. (30) included studies with multicomponent behavioural interventions and not just PFMT alone, whereas the Cochrane review (31) excluded studies where PFMT was combined with another conservative therapy. Overall, both systematic reviews concluded that for women with all types of UI, PFMT was more effective in managing and treating UI than no treatment.

Systematic Review by the Medical Advisory Secretariat

Part A – Multicomponent Behavioural Interventions

Six RCTs examining the effectiveness of multicomponent patient-directed behavioural interventions met the inclusion criteria. Details of the studies are outlined in Table 8 below. Studies were classified as multicomponent if the intervention included a combination of bladder training techniques, PFMT (with or without biofeedback), education on bladder control strategies, and self-monitoring techniques.

Study, Year	Intervention	Study	Methods	Outcomes	Limitations
Johnson et al., 2005 (39)	PFMT, bladder control strategies and self-monitoring	Secondary analysis of RCT	131 community-dwelling women aged ≥55 y Urge or urge-predominant incontinence	Nocturia outcomes	Randomization and allocation concealment unclear, sample size not justified
			8 weeks duration, clinic setting		
Burgio et al., 2002 (40)	PFMT + biofeedback and bladder control strategies	RCT	22 ambulatory, non- demented, community- dwelling women aged ≥55 y Urge or mixed UI (urge	Mean reduction in incontinence	Allocation concealment unclear
	C		predominant pattern)	Bladder capacity	
			8 weeks duration, clinic setting		
Goode et al., 2002 (41;42)	PFMT + biofeedback and bladder control	RCT	197 ambulatory, non- demented, community- dwelling women aged ≥55 y	Incontinent episodes	No intention-to- treat analysis, allocation
	strategies		Urge or mixed UI (urge	Voiding	concealment
			predominant pattern)	nequency	size not justified
			8 weeks duration, clinic setting	Bladder capacity	

Table 8: Studies on Multicomponent Patient-Directed Behavioural Techniques for Urinary Incontinence*

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Dougherty et al., 2002 (43)	PFMT + biofeedback, bladder training and self-monitoring	RCT	218 community-dwelling rural women aged ≥55 y with stress, urge or mixed UI 6 months duration, patient's home	Incontinent episodes Severity of urine loss	Allocation concealment unclear, sample size not justified
Subak et al., 2002 (44)	"Low-intensity" program consisting of bladder training and development of individualized voiding schedules and instructions on PFMT	RCT	152 women aged >55 y Urge, stress, or mixed UI 6 weeks duration, clinic setting	Incontinent episodes	No intention-to- treat analysis, allocation concealment unclear
McFall et al., 2000 (45)	Group educational approach consisting of bladder training, managing urge to urinate, PFMT, and group support	RCT (delayed control group)	145 community-dwelling, literate women aged >65 y with self-reported UI and no cognitive, visual, or hearing impairment 12 weeks duration, clinic setting	Incontinent episodes	No intention-to- treat analysis, randomization and allocation concealment not reported, no justification for sample size

*PFMT refers to pelvic floor muscle training; RCT, randomized controlled trial; UI; urinary incontinence.

All study participants were elderly women, the sample size ranged from 131 to 222, interventions were typically delivered by nurses, and the duration of the intervention ranged from 6 weeks to 6 months. Although the inclusion criteria for age in most studies was listed as greater than 55 years of age, the mean age of participants in each study was greater than 65 years and thus satisfied the Medical Advisory Secretariat's criteria.

Five studies used information collected from bladder diaries to report on changes in incontinent episodes following treatment. (40;41;43-45) As shown in Figure 2, multicomponent patient-directed behavioural interventions resulted in significantly fewer incontinent episodes posttreatment compared with controls (n=5 studies; weighted mean difference [WMD] 3.63; 95% CI, 2.07–5.19).

Figure 2: Total Incontinent Episodes per Week (Posttreatment)*

Review: UI Comparison: 01 Multicomponent Behavioural Interventions (Patient-directed) Outcome: 04 Total Incontinent Episodes per Week (Post-treatment)								
Study or sub-category	Ν	Treatment Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% Cl	Weight %	WMD (fixed) 95% Cl	Year
Burgio	110	6.00(10.70)	65	6.70(11.40)		20.82	-0.70 [-4.12, 2.72]	2002
Dougherty	94	7.00(13.30)	84	12.60(13.30) -	I	15.87	-5.60 [-9.51, -1.69]	2002
Goode	63	2.80(4.69)	62	8.19(11.62) .	_	25.05	-5.39 [-8.51, -2.27]	2002
McFall	49	3.60(7.20)	59	5.90(8.50)		27.73	-2.30 [-5.26, 0.66]	2002
Subak	66	5.20(6.80)	57	11.00(17.40)		10.53	-5.80 [-10.61, -0.99]	2002
Total (95% CI)	382 eity: Chi² = 6.58. df :	= 4 (P = 0.16) ² = 30.2	327		•	100.00	-3.63 [-5.19, -2.07]	
Test for overall effe	ect: $Z = 4.57$ (P < 0.0	00001)	. /0					
				-10	-5 0	5 10		
				Favo	ours treatment Favou	rs control		

*CI refers to confidence interval; SD, standard deviation; WMD, weighted mean difference. †Note that studies reporting daily incontinent episodes were converted to weekly estimates.

Three studies reported on the subjective measure of patients' perception of improvement in UI. (40;41;44) As shown in Figure 3, a meta-analysis of multicomponent patient-directed behavioural interventions resulted in a significant improvement in patients' perception of UI when compared with the control group (n=3 studies, odds ratio [OR], 4.15; 95% CI, 2.70–6.37).

Review: Compatison: Outcome:	Review: UI Comparison: 01 Multicomponent Behavioural Interventions (Patient-directed) Outcome: 06 Patient's Perception of Improvement in UI - All studies								
Study or sub-category	Treatment	Control n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl	Year			
Burgio	79/110	31/65		- 53.81	2.80 [1.47, 5.30]	2002			
Goode	47/58	23/52		22.54	5.39 [2.29, 12.66]	2002			
Subak	39/66	11/57		23.66	6.04 [2.66, 13.72]	2002			
Total (95% Cl) Total events 1	234 65 (Treatment), 65 (Control)	174	•	100.00	4.15 [2.70, 6.37]				
Test for overall	effect: $Z = 6.48$ (P < 0.00001	= 23.9%							
			0.1 0.2 0.5 1 2	5 10					
			Favours control Favours treat	tment					

Figure 3: Patients' Perception of Improvement in Urinary Incontinence

*CI refers to confidence interval; OR, odds ratio.

†Improvement was defined as self-reported improvement or no restriction in daily activities.

Quality of life was assessed in 3 out of the 6 studies. Dougherty et al. (43) reported that the intervention group reported significantly better quality of life as assessed by the Incontinence Impact Questionnaire than controls (P = .0025). Burgio et al. (40) found that the intervention had statistically significant effects on quality of life as measured by the Incontinence Impact Questionnaire (all 4 questionnaire subscales P < .001). McFall et al. (45;46) reported that the intervention affected condition-specific quality of life and self-management but did not affect general health-related quality of life as measured with the Medical Outcomes Study Short Form-36. Overall, multicomponent patient-directed behavioural interventions appear to beneficially affect quality of life.

There were several limitations of the studies included in the analysis. Although all study participants were women, there was variation in their method of diagnosis and type of UI. There was also variation in the components of the behavioural interventions so that not all studies incorporated the same mix of elements. The use of different outcome measures also hampered comparisons between studies, and none of the studies addressed compliance, which is likely to be an important factor in behavioural interventions. Lastly, the control group was not always usual care. For example, the control groups in the studies by Burgio et al. (40) and Goode et al. (41) consisted of a self-help pamphlet. This could be considered another approach to behavioural techniques; however, it was regarded as usual care for the purposes of this review.

Part B – Pelvic Floor Muscle Training Alone

The Medical Advisory Secretariat review included two older RCTs that had been included in the previously described systematic reviews by Choi et al. (30) and Hay-Smith et al. (31) and that focused on PFMT alone. Although the inclusion criteria for age in the studies was listed as greater than 55 years or 60 years, the mean age of participants in each study was greater than 65 years and thus satisfied the secretariat's criteria. Details of the 2 RCTs are presented in Table 9.

Study, Year	Intervention	Study Design	Methods	Outcome	Results	Limitations
Burns et al., 1993 (47)	PFMT + Biofeedback, PFMT alone	RCT	135 cognitively intact community- dwelling women aged >55 y with predominant stress UI 8 weeks duration	Total incontinent episodes per week	Both the PFMT + biofeedback and the PFMT alone treatment groups had significantly fewer weekly incontinent episodes posttreatment than the control group (WMD 10.50; 95% Cl, 4.30– 16.70) The 2 treatment groups had similar impacts on mild, moderate, and severe urine-loss groups	No intention- to-treat analysis, randomization and allocation concealment not reported, sample size not justified
Miller et al., 1998 (48)	PFMT – basic and digital palpation to teach PFMT Taught "The Knack" method (intentionally contract the PFM before and during a cough)	RCT	27 community- dwelling women >60 y with self- reported stress UI 1 week duration	Urine leakage on the Paper Towel Test	Urine leakage was similar in both groups without The Knack, but when Group 1 used The Knack, subjects leaked 98.1% less than subjects in Group 2 who had not yet learned The Knack (<i>P</i> = .293).	Intention-to- treat analysis not stated, allocation concealment not reported, baseline data not reported, sample size not justified

Table 9: Studies on PFMT	Interventions for	Urinary	/ Incontinence*
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*PFM indicates pelvic floor muscles; PFMT, pelvic floor muscle training; RCT, randomized controlled trial, WMD, weighted mean difference; UI, urinary incontinence.

Burns et al. (47) reported that women in the treatment groups receiving either PFMT with biofeedback or PFMT alone had significantly fewer weekly incontinent episodes posttreatment than the control group (WMD for treatment groups combined, 10.50; 95% CI, 4.30–16.70). The 2 treatment groups also had similar impacts on mild, moderate, and severe urine loss groups. Miller et al. (48) reported a different outcome, which was urine leakage on the paper towel test, after participants were taught "The Knack" method (i.e., intentionally contracting the PFM before and during a cough). They found that urine leakage without The Knack was similar in both groups, but that when participants used The Knack, they leaked less than participants who had not yet learned the method; however, this difference was not statistically significant (P = .293).

The major limitation of this section was that few studies examined PFMT alone. Most recent trials examined the effectiveness of PFMT as 1 element of a multicomponent intervention. Studies also varied in outcome measures and according to parameters of PFMT. There were no long-term data on adherence. A study by Bo et al. (49) examined PFMT adherence after 15 years but was not limited to the elderly population. They found that women's adherence to training after 15 years was low and that there was no difference in the continence status of women who had received PFMT versus those who had not.

Overall, PFMT alone resulted in an improvement in incontinence outcomes.

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Section 3 – Role of Nurse Continence Advisor or Clinical Nurse Specialist in Delivering Behavioural Interventions in a Clinic Setting

Summary of Existing Evidence

One existing systematic review on the role of the nurse in continence care by Du Moulin et al. (50) was identified (Table 10). The review was limited to RCTs that compared the effectiveness of UI treatment by nurses with usual care or no treatment. In order to be included in the analysis, the intervention had to include a nurse playing an important role in the care for UI patients. Eleven RCTs met eligibility criteria. Studies varied in terms of the setting, age limits, and outcomes. The components of the interventions also varied across studies, but the majority of interventions included a combination of patient-directed behavioural treatment elements such as PFMT, bladder training, and education. Overall, the authors reported that the limited evidence indicated that treatment by nurses resulted in a decrease in incontinence. The major limitation of this review was that no set criteria were defined for the nurse's qualifications or the nurse's degree of specialized training in UI. The review included studies with nurses ranging from those with no specialized training in continence care to NCAs, nurse practitioners who were specially trained in UI management, and nurses instructed in treatment details by a urotherapist nurse. Another limitation was that there was ambiguity in the definition of usual care in the control groups.

Systematic Review, Year	Intervention	Number of Studies Included in Review	Results and Conclusions	Comments
Du Moulin et al., 2005 (50)	An intervention with a nurse playing an important role in patient care versus usual care or no treatment	11 RCTs	Variation among studies in age, inclusion criteria, outcomes, setting Variation in intervention components, but majority included a combination of treatment elements, of which most common included PFMT, bladder training, and patient education	Not limited to NCA/CNS (only 8/11 studies had nurses that were skilled or specially trained in managing UI)
	Not limited to seniors		 All studies reported a significantly greater reduction in incontinence episodes in the intervention group. However, most studies had follow-up periods less than 1 year. One of the 2 RCTs reporting on costs found a significant reduction in costs relating to treatment, but no formal cost-utility analysis was conducted 	No pooled estimate of effect Ambiguity in definition of usual care in control groups
			Overall Conclusion: There is limited evidence that treatment by nurses results in a decrease in incontinence.	
*CNS refers to	clinical nurse spe	cialist; NCA, nurs	se continence advisor; RCT, to randomized cont	rolled trial.

Table 10: Existing Systematic Review of the Role of the Nurse in Treating Urinary Incontinence*

Systematic Review by the Medical Advisory Secretariat

Given that no studies were identified that were conducted in an exclusively elderly population where the majority of study participants were older than 65 years, the scope of the review was broadened to include studies where the mean age of participants was greater than 60 years. The review was limited to studies with an NCA or CNS with advanced training in UI management who delivered behavioural techniques in a clinic setting. Three RCTs were identified (see Table 11). (51-53) One before/after study was also included in the analysis because it was conducted in Ontario, even though it did not satisfy RCT criteria. (54) It is further described below.

Study, Year	Intervention	Study Design	Methods Population	Outcome	Results	Limitations
Location						
Borrie et al., 2002 (51) Ontario, Canada	NCA	RCT	NCA sessions every 4 weeks for 6 months versus usual primary care 421 men and women, 50% of participants > 65 y	Incontinent episodes and pad use	Treatment group reported significantly fewer incontinent episodes (<i>P</i> = .001) and less pad usage (<i>P</i> = .021) than control group	Allocation concealment not adequate, no justification for sample size Potential for selection bias since subjects responded to active advertising
Moore et al., 2003 Australia (52)	NCA	RCT	NCA sessions weekly for 12 weeks versus outpatient urogynecology regimen (tertiary unit) 145 women, mean age 60 y	Incontinent episodes and pad use	No significant differences between groups, but changes from baseline showed highly significant reduction of incontinence (incontinent episodes, pad use) for both treatment regimens ($P < .01$). Caution – study not designed for an intragroup comparison Caution – comparison group not usual primary care NCA regimen was less expensive than the standard urogynecology regimen (median difference A\$87.30)	Allocation concealment not adequate, caution by authors of a high drop-out rate (24%)
Williams et al., 2005 (53) United Kingdom	Specially trained nurses	RCT	Continence service by specially trained nurses for 4 weeks over 8-week treatment period versus standard primary care 3,746 men and women, 53% of participants > 60 y	Urinary symptoms	Treatment group reported significantly less leakage (P = .002) and a greater overall improvement (at least 1 symptom alleviated) than control group $(P < .001)$ Cost-effectiveness analysis indicated that a nurse-led intervention could alleviate symptoms at a cost of £242 per symptom over a 3-month period Unclear if this represents value for money	Note that randomization was carried out by household, at a ratio of 4:1 in favour of the continence nurse

Table 11: Studies with Interventions for Urinary Incontinence Led by Nurse Continence Advisors *

*NCA refers to nurse continence advisor; RCT, randomized controlled trial.

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The RCTs differed in study parameters such as intervention duration and intensity as well as the outcomes reported. In the 3 RCTs, the behavioural interventions delivered by NCAs in a clinic setting were multicomponent patient-directed behavioural techniques targeted at a mobile elderly population. The study by Moore et al. (52) used a comparator group of tertiary care, unlike the other 2 RCTs where the comparator was standard primary care. This difference in comparison group may partly explain why no significant difference between treatment groups was reported by Moore et al. (52) Overall, results from the 3 RCTs indicate that behavioural interventions led by NCAs or CNSs in a clinic setting are effective in improving incontinence outcomes in community-dwelling seniors and may also have the potential to result in reduced costs to the healthcare system.

A recent before/after Ontario-based study entitled *IC3: Improving Continence Care in the Community* was also included in this review; it was a report for the Ontario Health Performance Initiative of the Ontario Ministry of Health and Long-Term Care. (54) The objective of the study was to implement and evaluate a new interdisciplinary model consisting of NCA continence clinics for integrating continence care in the community. Table 12 presents specific information on the study.

Intervention	Methods	Participants	Outcomes	Results
A new interdisciplinary model consisting of NCA Continence Clinics for integrating continence care in the community	Participants recruited from 2 CCACs (Hamilton- Wentworth and Grey Bruce) 3 NCA continence clinic sites established in each CCAC region 9-month duration 3 clinic visits Behavioural interventions included: behaviour modification related to lifestyle options, PFMT, bowel program, fluid intake, weight reduction, personal hygiene changes, and incontinence	N=122, 84% female, mean age 74.5 y Majority had RAI continence scores of frequently or occasionally incontinent (58%) Primary diagnosis: 60% urge UI, 17% stress UI, and 16% mixed UI	Goal Attainment Score Quality of life Cost	Continence Goal Attainment Score: Of the 94 clients who completed at least 1 follow-up visit, there was a significant improvement in Continence Goal Attainment Scores at discharge (mean change in score from baseline 27.74 (score increases if client is able to work on their goals), $P < .001$) Incontinence Quality of Life Score (IQOL): There was a significant improvement in IQOL score for patients who completed the program (mean change 20.51, $P < .001$) Cost: The estimated cost of providing continence care in a clinic setting versus home visiting per individual client for an initial assessment followed by 2 follow-up visits is substantially lower (\$120.83 per client in the clinic versus \$233.33 per client in the home visit – a cost difference of \$112.50). The major driver of this cost difference relates to the time involved in a home visit compared with a clinic visit. Dowell-Bryant Incontinence Cost Index (DBICI): Index measures personal costs related to incontinence. The mean annual cost of disposable products is reduced by 24% for each client who
	P. 20000 0010			regenierinprovoo nie or ner oonanonoo.

Table 12: Before/After IC3 Project – Improving Continence Care in the Community*

*CCAC refers to Community Care Access Centre; CNS, clinical nurse specialist; NCA, nurse continence advisor; RAI, resident assessment index; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; UI, urinary incontinence.

The IC3 report concluded that NCA continence clinics reduced the physical and financial burden of incontinence, and improved patients' quality of life. The report also concluded that the clinics decreased the cost of incontinence to the system by decreasing overall product use and making the most appropriate use of health human resources. A major limitation of this study was the low referral rate. A post hoc

analysis conducted by the authors indicated that those not referred to the clinics had more physical and cognitive impairments that limited their ability to manage themselves.

Summary of Findings of Literature Review

 Table 13: Summary of Evidence on Behavioural Interventions for the Treatment of Urinary

 Incontinence in Community-Dwelling Seniors

Intervention	Target Population	Interventions	Conclusions
Caregiver- dependent techniques	Medically complex, frail individuals at home with/without cognitive	Prompted voidingHabit retraining	There is no evidence of effectiveness for habit retraining and timed voiding. Prompted voiding may be effective,
(tolleting assistance)	deficits and/or motor deficits	Timed voiding	powered study, effectiveness is difficult to substantiate.
	Delivered by informal caregivers who are trained by NCA/CNS		Resource implications and caregiver burden (usually informal caregiver) should be considered.
Patient-directed techniques	Mobile, motivated seniors	Multicomponent behavioural Interventions	Significant reduction in the mean number of incontinent episodes per week (n=5 studies, WMD 3.63, 95%
	Delivered by NCA/CNS	 Includes a combination of: bladder training PFMT (with or without biofeedback) bladder control strategies 	Cl, 2.07–5.19) Significant improvement in patient's perception of UI (n=3 studies, OR 4.15, 95% Cl, 2.70–6.37)
		educationself-monitoring	Suggestive of beneficial impact on patient's health-related quality of life
		PFMT alone	Significant reduction in the mean number of incontinent episodes per week (n=1 study, WMD 10.50, 95% CI, 4.30–16.70)
Behavioural interventions led by an NCA/CNS in a clinic setting	Community-dwelling seniors	Behavioural interventions led by NCAs or CNSs	Overall, effective in improving incontinence outcomes (n=3 RCTs and 1 Ontario-based before/after study)

*CI refers to confidence interval; CNS, clinical nurse specialist; NCA, nurse continence advisor; OR, odds ratio; PFMT pelvic floor muscle training; RCT, randomized controlled trial; UI, urinary incontinence; WMD, weighted mean difference.

GRADE Quality of the Evidence

Table 14: Quality of Trials on Caregiver-Dependent Behavioural Techniques According to GRADE*

Intervention		No of Studies	Quality Assessment					Summary of Findings	Overall Quality
		(+ 4 existing reviews)	Design	Quality†	Consis- tency	Direct- ness	Other modifying factors		
	Prompted voiding	1	RCT High	Moderate‡	Yes	Yes	Sparse data Inadequately powered study	There is no evidence of effectiveness for habit retraining and timed	Low
Caregiver- dependent techniques	Habit retraining	1	RCT High	Moderate§	Yes	Yes	Sparse data	voiding. Prompted voiding may be effective but effectiveness is difficult to substantiate due to sparse data and an inadequately powered study	
	Timed voiding	1	RCT High	Moderate	Yes	Yes	Sparse data		

*RCT refers to randomized controlled trial.

†Blinding not possible owing to the nature of the intervention

‡Allocation concealment unclear

§Methods poorly described

Allocation concealment unclear and no intention-to-treat analysis

Limitations of the Evidence

For both caregiver-directed and patient-directed behavioural interventions, there was considerable variation in study populations and in the type and severity of participants' UI. Subjective outcome measures such as patient observations and symptoms are frequently reported in the UI literature. Information on anatomical and functional outcomes may be more difficult to collect in this population. Nevertheless, subjective outcomes provide valuable information on effectiveness in this area of study. (55) Although the primary outcome of interest was admission to an LTC home, this outcome was not reported in the UI literature. Also the number of eligible studies was low, and there were limited data on long-term follow-up. Owing to the nature of behavioural interventions; information on compliance and adherence would be important in assessing the effectiveness of interventions; however, the studies did not routinely collect this information. Lastly, it was not possible to capture data on behavioural interventions for UI in the Ontario Provincial Health Planning Database, which made it difficult to contextualize for the Ontario population in terms of assessing current access to treatment and the number of seniors currently seeking care for UI in Ontario.

Table 15: Quality of Trials on Patient-Directed Behavioural Techniques and the Role of the Nurse Continence Advisor / Clinical Nurse Specialist According to GRADE*

Intervention		No of Studies		Q	Summary of Findings	Overall Quality			
			Design	Quality†	Consis- tency	Directness	Other modifying factors		
Patient- directed Techniques	Multi- compo- nent	6 (+ 2 existing reviews)	RCT High	Moderate‡	Yes	Some uncertainty§	None	Significant reduction in the mean number of incontinent episodes per week (n=5 studies, WMD 3.63, 95% CI, 2.07–5.19)	Moderate
	PFMT Alone	2 (+ 2 existing reviews)	RCT High	Moderate§	Yes	Some uncertainty	None	No pooled estimate, because of heterogenous outcomes Overall, effective in improving incontinence outcomes (n=1 study, WMD 10.50, 95% CI, 4.30– 16.70)	Moderate
Behavioural interventions led by an NCA/CNS in a clinic setting		3 RCTs +1 before/ after Ontario study (+ 1 existing review)	RCT High	Moderate	Yes	Yes	None	No pooled estimate, because of heterogenous outcomes Overall, effective in improving incontinence	Moderate

*CI refers to confidence interval; CNS, clinical nurse specialist; NCA, nurse continence advisor RCT, randomized controlled trial; WMD, weighted mean difference. †Blinding not possible owing to the nature of the intervention

‡Not always intention-to-treat and in most studies, allocation concealment unclear

§Allocation concealment not adequate in 2 studies

Only included female participants

¶1 out of 3 studies conducted in Ontario population

Economic Analysis

Disclaimer: The Medical Advisory Secretariat uses a standardized costing methodology for all of its economic analyses of technologies. The main cost categories and the associated methods from the province's perspective are as follows:

Hospital: Ontario Case Costing Initiative cost data are used for all in-hospital stay costs for the designated International Classification of Diseases-10 (ICD-10) diagnosis codes and Canadian Classification of Health Interventions procedure codes. Adjustments may need to be made to ensure the relevant case mix group is reflective of the diagnosis and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis or procedure, the secretariat normally defaults to considering direct treatment costs only.

Non-hospital: These include physician services costs obtained from the Ontario Schedule of Benefits for physician fees, laboratory fees from the Ontario Laboratory Schedule of Fees, device costs from the perspective of local health care institutions, and drug costs from the Ontario Drug Benefit formulary list price.

Discounting: For all cost-effectiveness analyses, a discount rate of 5% is used as per the Canadian Agency for Drugs and Technologies in Health.

Downstream costs: All costs reported are based on assumptions of utilization, care patterns, funding, and other factors. These may or may not be realized by the system or individual institutions and are often based on evidence from the medical literature. In cases where a deviation from this standard is used, an explanation has been given as to the reasons, the assumptions and the revised approach. The economic analysis represents an estimate only, based on assumptions and costing methods that have been explicitly stated above. These estimates will change if different assumptions and costing methods are applied for the purpose of developing implementation plans for the technology.

Economic Analysis of Effective Behavioural Interventions for Urinary Incontinence

The Medical Advisory Secretariat systematic review demonstrated that caregiver-dependent and patientdirected (both multicomponent and single session) behavioural techniques were effective in reducing incontinence episodes in seniors living in the community. Therefore economic analysis to project total cost to implement program in the first year of implementation was calculated based on eligible seniors in the community and their respective caregivers who were willing to participate in behavioural technique sessions. Nurse continence advisors were considered as health care providers, while CNSs were excluded from this analysis as recommended by clinical expert opinion. Table 16 describes the cost to implement the program in the first year for these interventions.

Table 16: Cost to Implement Program (2008 Cdn \$)

Parameter	Unit Cost (\$)	Unit	Cost in the First Year (\$)	Population	N	Total Cost in the First Year (\$)
Caregiver-Dependent Behavioural Techniques*						
Nurse Continence Advisor	50.00	per hour	182.50	Frail, homebound, cognitively impaired willing to participate	50,521	9,220,119
Patient-Directed Behavioural Techniques						
Nurse Continence Advisor†	50.00	per hour	130.00	Mobile, independent seniors willing to participate	196,011	25,481,456
Physiotherapist‡	18.41	per session	184.10	Mobile, independent seniors willing to participate	196,011	36,085,662

*The intervention was administered in a home setting to 80% of patients and caregivers, and in a clinic setting to 20%. The intervention included 1 initial assessment (2 hour) + 2 follow-up sessions (1 hour each) with an NCA at home. (54) An occupational therapist might also have visited the home to scan for environmental/physical barriers; this was not factored into the analysis.

†The intervention was administered in a home setting to 20% of patients and in a clinic setting to 80%. The intervention consisted of a multi-component session with an NCA doing pelvic exercises, bladder training, etc., which included 1 initial assessment (1.25 hour) plus 2 follow-up sessions (30 minutes each). (54)

‡The single component included PFMT exercise with a trained physiotherapist providing 10 weekly instructional sessions. (54) Some clients may require follow-up visits a few years later for a refresher and some additional motivation and coaching; this was not factored into the analysis. Assumed a 20.5% (males) and 45.1% (females) prevalence of UI in seniors 65 years and older in Ontario (740,200 males and 945,500 females). (18) Assumed 4.5% of seniors over 65 are in an LTC setting and the remainder are in the community. (56) Assumed prevalence of eligible elders to be 50% for both caregiver-dependent and patient-directed techniques. (54) Assumed a participation rate of 18.3% for caregiver-dependent techniques. (54) Assumed a participation rate of 71% for patient-directed techniques. (54) Nurse continence advisor cost from IC3 report. (54) Physiotherapist cost from fee schedule. (57)

Note: This economic analysis was calculated for the first year after introduction of the interventions, from the perspective of the Ministry of Health and Long-Term Care, using prevalence data only. Prevalence estimates are for all levels of severity of UI (mild, moderate, severe) and all types of UI (stress, urge, mixed). Incidence and mortality rates were not factored in. Numbers may change based on population trends, rate of intervention uptake, trends in current programs in place in Ontario, and assumptions on costs. Number refers to patients likely to access these interventions in Ontario based on assumptions stated below from the literature. Resource consumption was confirmed by the expert panel.

Assumptions

There were several assumptions made to calculate the annual budget impact:

- assumed a 20.5% (males) and 45.1% (females) prevalence of UI in seniors over 65 years in Ontario (740,200 males and 945,500 females); (18)
- assumed 4.5% of seniors greater than 65 are in an LTC setting and the remainder are in the community; (56)
- assumed prevalence of eligible seniors to be 50% for both caregiver-dependent and patient-directed techniques; (54)
- ➤ assumed a participation rate of 18.3% for caregiver-dependent techniques; (37)

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- ▶ assumed a participation rate of 71% for patient-directed techniques; (54)
- assumed an NCA hourly cost of \$50.00; (54)
- ➤ assumed a physiotherapist hourly cost of \$18.41; (57)
- assumed for caregiver-dependent behavioural techniques to consist of 1 initial assessment (2 hour) plus 2 follow-up sessions (1 hour each) with an NCA 80% of patients plus caregivers at home and 20% in a clinic; (54)
- assumed for patient-directed behavioural techniques to consist of either a multicomponent session with an NCA doing pelvic exercises, bladder training, etc. – 1 initial assessment (1.25 hour) plus 2 follow-up sessions (30 minutes each) – 20% of patients at home and 80% in a clinic; (54) and
- assumed a single session to consist of PFMT exercise with a trained physiotherapist providing 10 weekly instructional sessions. (54)

Because of the assumptions and the limited data available in the literature, the potential for uncertainty exists. If and when new evidence is presented, these economic results may change, allowing for a more accurate analysis.

Current Expenditures in the Province of Ontario

Currently the province of Ontario absorbs the cost for an NCA (delivered through the 42 Community Care Access Centres [CCACs] across the province of Ontario) in the home setting. The 2007 Incontinence Care in the Community Report estimated that a total of 500,000 clients would be referred to these 42 CCACs, and of these, 33.5% of clients would suffer from incontinence. This proportion was estimated from the Hamilton and Grey-Bruce CCAC minimal data set database. At a prevalence of 50% being capable of self-management, the number of potential incontinent clients would be 83,750 in the province of Ontario. The estimated cost of providing continence assessments is \$233.33 per client in the home setting, the cost being absorbed by the public system. This cost estimate included resources such as personnel costs, physician communications, record keeping, and product costs. The total estimated expenditure in the province of Ontario is \$19,541,387. The clinic cost was not included in this estimation because currently the clinic cost comes out of the global budget of the respective hospital, and very few continence clinics exist in the province. The economic analysis factored in a cost for the clinic setting assuming that the public system would absorb the cost with this new model of community care. Our analysis predicted a cost impact of \$25,481,456 for patient-directed behavioural techniques administered by an NCA. If we compare this figure to the current expenditure in the province, the net impact of such a program is approximately \$5,940,069. Please note, however, that this is a rudimentary estimate since resource consumption varied between both analyses.

Existing Guidelines

Several guidelines exist regarding the treatment and management of UI. Most guidelines are broad in scope and are not limited to community-dwelling seniors. Following is a list of select guidelines that are most relevant to the research question. Many guidelines have also been developed for individual techniques (e.g., prompted voiding) and have not been included in the list below.

- Canadian Consensus Conference on Urinary Incontinence. Clinical Practice Guidelines for Adults, 2001 (23)
- United States Agency for Healthcare Policy and Research (AHCPR), 1996 (22)
- Society of Obstetricians and Gynecologists of Canada. Conservative Management of Urinary Incontinence, 2006 (24)

Ontario Health System Impact Analysis

Considerations and Implications

An expert panel on aging in the community met on 3 occasions from January to May 2008, and in part, discussed treatment of UI in seniors in Ontario with a focus on caregiver-dependent and patient-directed behavioural interventions. In particular, it was discussed how treatment for UI is made available to seniors in Ontario and who provides the service. Comments from the panel are reported below.

1. Services/interventions that currently exist in Ontario offering behavioural interventions to treat UI are not consistent. There is a lack of consistency in the following:

- ➢ How seniors access UI services:
 - Seniors who are CCAC clients can access treatment for UI through home care services. There may be some inefficiencies with this model of care, given that not all seniors require treatment for UI in the home, and some may be able to seek treatment in a clinic setting instead.
 - Seniors may refer themselves to NCA continence clinics or be referred by their general
 practitioner, though there are only a few clinics in the province. Currently, the NCA continence
 clinics are being run as outpatient hospital clinics with costs being absorbed by the hospital global
 budget.
- ➢ Who manages seniors with UI:
 - Seniors with UI are managed by general practitioners, physician specialists (gynecologists, urologists), NCAs through CCAC home visits, and physiotherapists.
 - There is also a lack of physician knowledge on UI. A survey of Canadian family physicians indicated that only 46% of physicians clearly understood incontinence, and just 38% had an organized plan for incontinence problems. Almost half reported that they usually referred patients with incontinence. (19)
- ▶ How patients with UI are assessed and managed:
 - There was general consensus that the assessment and management of older people could be greatly improved.

2. Help-seeking behaviours should be taken into account.

- Help-seeking behaviours of seniors with UI are influenced by diverse and complex personal and societal variables such as
 - a lack of knowledge about cause and treatment options,
 - the perception that UI is not a serious problem and misconceptions about normal aging, and
 - the belief that surgery is the only option. (58)

3. Social stigma is associated with UI, and there is a need for public education and an awareness campaign.

- Urinary incontinence has the stigma of a socially unacceptable condition because of public lack of knowledge, misconceptions, and intolerance. This leads to personal isolation, social embarrassment, and delays in seeking medical advice. Additional efforts should be made to improve awareness and decrease social stigma of UI.
- A good example of an organization that has made efforts to improve awareness and decrease social stigma is the Continence Foundation of Australia. The Foundation's objectives are wide-ranging and include raising awareness, encouraging help-seeking, destigmatizing UI, educating community and clinicians, promoting better management, encouraging development of accessible services and information, supporting the development of self-help groups, and facilitating and/or funding

continence-related research. The Canadian Continence Foundation shares many of the same objectives as the Continence Foundation of Australia; however, there is potential for the Foundation to take on a more active role.

4. Other issues were highlighted by the panel:

- Cost of incontinent supplies
 - Each year, an individual with incontinence living at home will spend an average of \$1,000 to \$1,500 on incontinence supplies. Incontinence supplies are not covered by the provincial public health plans, nor by most private insurance companies, meaning that the full cost of supplies is borne by the individual.
- > Health human resources and the availability of NCAs
 - Numbers of NCAs appear to be insufficient.
 - There are 100 NCAs trained in Ontario, but currently only 40 are working in this capacity.

The Canadian Continence Foundation also highlighted some additional policy issues relevant to UI in community-dwelling seniors in its 2007 report. (8) Some of the key points are outlined below. "Long wait times for care

- "Long wait times for care "If a patient overcomes their reticence and discusses their incontinence with their physician, they will often have to wait 6-9 months before they will see a specialist. Another 4-6 month wait is generally required to assess their incontinence, and if surgery is an option, patients can wait up to two years to receive the surgical treatment that they require.
- "Lack of availability of treatments and products
 "Many incontinence treatments (such as injectable bulking agents y)

"Many incontinence treatments (such as injectable bulking agents, which cost as much as \$2,000 Cdn) are not covered by public or private health plans, meaning that the patient will need to cover the full cost of the treatment.

"Lack of access to the newest medicines"

"Most of the drugs for overactive bladder (OAB) that are covered by provincial formularies are older and have negative side effects. Providing some relief to OAB sufferers are newer, more effective drugs. These are however, not covered on the public formularies, therefore if a person suffering from incontinence wants to use these newer, more effective treatments, they will have to pay for them out of their own pockets. As the prevalence of incontinence increases with age, it is often seniors living on fixed incomes who would want to take these medicines, but often lack the financial ability to do so."

Other Considerations

Although the scope of this review was limited to behavioural interventions for UI, the midurethral sling procedure is increasingly being used to treat women with stress UI. In February 2006, the Medical Advisory Secretariat completed a review entitled *Midurethral Slings for Women with Stress Urinary Incontinence*. (21) The analysis concluded, "The midurethral sling procedure is a minimally invasive procedure that is highly effective at reducing the symptoms associated with stress UI in women who have failed conservative treatments for stress UI." Based on the evidence, the Ontario Health Technology Advisory Committee recommended the expansion of the development of guidelines by Health Technology Utilization Guidelines of Ontario from the appropriate use of tension-free vaginal tape (TVT) to the appropriate use of midurethral slings, and that the introduction of a new Ontario Health Insurance Plan code specific to midurethral slings be explored.

Although a full systematic review on midurethral slings in senior women was not undertaken as part of this review, studies in elderly women suggest that age does not seem to be a significant factor for failure of midurethral sling procedures and that these procedures are associated with good clinical outcomes.

However, the risk of postoperative de novo urge incontinence as well as age-related morbidity may be increased. (59-65) Based on expert opinion, approximately 10% of senior women could potentially benefit from midurethral sling procedures.

Conclusions

There is moderate-quality evidence that the following interventions are effective in improving UI in mobile motivated seniors:

- multicomponent behavioural interventions including a combination of bladder training techniques, PFMT (with or without biofeedback), education on bladder control strategies, and self-monitoring; and
- pelvic floor muscle training alone.

There is moderate-quality evidence that when behavioural interventions are led by NCAs or CNSs in a clinic setting, they are effective in improving UI in seniors.

There is limited low-quality evidence that prompted voiding may be effective in medically complex, frail seniors with motivated caregivers.

There is insufficient evidence for the following interventions in medically complex, frail seniors with motivated caregivers:

- habit retraining, and
- timed voiding.

Glossary

Bladder diary: A document that records voiding times and voided volumes, incontinence episodes, pad usage and other information such as fluid intake, the degree of urgency, and the degree of incontinence.

Mixed urinary incontinence: Involuntary urine leakage associated with urgency and also with exertion, effort, sneezing, or coughing.

Nocturia: The complaint of having to wake at night 1 or more times to void.

Pelvic floor muscle training (PFMT): Repetitive selective voluntary contraction and relaxation of specific pelvic floor muscles.

Postvoid residual (PVR): The volume of urine left in the bladder immediately after voiding. This is usually diagnosed by bladder scan (ultrasound) or in-out catheterization. Abnormal volumes are variously defined by researchers as greater than a threshold that may range between 100 and 200 mL.

Stress urinary incontinence: Involuntary urine leakage on effort or exertion, or on sneezing or coughing.

Urge urinary incontinence: Involuntary urine leakage accompanied by or immediately preceded by a sudden compelling desire to pass urine, a desire that is difficult to defer.

Urinary incontinence: The complaint of any involuntary urinary leakage.

Appendix

Appendix 1: Literature Search

Search date: October 3, 2007

Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, CINAHL, Cochrane Library, INAHTA/NHS EED

Database: Ovid MEDLINE(R) <1996 to September Week 3 2007> Search Strategy:

- 1 exp Urinary Incontinence/ (9701)
- 2 (urin\$ adj3 incontinen\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (11248)
- 3 1 or 2 (11248)
- 4 exp Aged/ (749903)
- 5 (elder\$ or senior\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (71440)
- 6 4 or 5 (765611)
- 7 3 and 6 (4712)
- 8 limit 7 to (humans and english language and yr="2000 2007") (2863)
- 9 limit 8 to (controlled clinical trial or meta analysis or randomized controlled trial) (317)
- 10 (meta analy\$ or metaanaly\$ or pooled analysis or (systematic\$ adj2 review\$)).mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (54569)
- 11 exp Random Allocation/ or random\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (326025)
- 12 exp Double-Blind Method/ (48004)
- 13 exp Control Groups/ (493)
- 14 exp Placebos/ (8371)
- 15 RCT.mp. (1998)
- 16 or/9-15 (366984)
- 17 8 and 16 (506)

Database: EMBASE <1980 to 2007 Week 39> Search Strategy:

- 1 exp Urine Incontinence/ (12477)
- 2 (urin\$ adj3 incontinen\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (16445)
- 3 1 or 2 (16445)
- 4 Aged/ (906192)
- 5 (elder\$ or senior\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (115074)
- 6 4 or 5 (944496)

- 7 3 and 6 (5172)
- 8 limit 7 to (human and english language and yr="2000 2008") (2594)
- 9 Randomized Controlled Trial/ (149282)
- 10 exp Randomization/ (24000)
- 11 exp RANDOM SAMPLE/ (792)
- 12 (meta analy\$ or metaanaly\$ or pooled analysis or (systematic\$ adj2 review\$)).ti,mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (76601)
- 13 Double Blind Procedure/ (66657)
- 14 exp Triple Blind Procedure/ (8)
- 15 exp Control Group/ (1007)
- 16 exp PLACEBO/ (104532)
- 17 (random\$ or RCT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (386635)
- 18 or/9-17 (511379)
- 19 8 and 18 (481)

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to September Week 4 2007>

Search Strategy:

1 exp Urinary Incontinence/ (4189)

- 2 (urin\$ adj3 incontinen\$).mp. [mp=title, subject heading word, abstract, instrumentation] (4243)
- 3 1 or 2 (4590)
- 4 exp Aged/ (145207)
- 5 (elder\$ or senior\$).mp. [mp=title, subject heading word, abstract, instrumentation] (31642)
- 6 4 or 5 (152354)
- 7 3 and 6 (1655)
- 8 limit 7 to (english and yr="2000 2007") (929)
- 9 random\$.mp. or exp RANDOM ASSIGNMENT/ or exp RANDOM SAMPLE/ (60536)
- 10 RCT.mp. (736)
- 11 exp Meta Analysis/ (5696)
- 12 exp "Systematic Review"/ (3320)
- 13 (meta analy\$ or metaanaly\$ or pooled analysis or (systematic\$ adj2 review\$) or published studies or medline or embase or data synthesis or data extraction or cochrane).mp. (19960)
- 14 exp double-blind studies/ or exp single-blind studies/ or exp triple-blind studies/ (11524)
- 15 exp PLACEBOS/ (3799)
- 16 or/9-15 (78869)
- 17 8 and 16 (152)

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