Health Quality Ontario

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# ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

## Electronic Monitoring Systems to Assess Urinary Incontinence: A Health Technology Assessment

### KEY MESSAGES

#### *What Is This Health Technology Assessment About?*

Urinary incontinence is the accidental leakage of urine. Assessing and managing incontinence is an important part of health care for people living in a long-term care home or geriatric inpatient setting. We evaluated the effectiveness and cost of using an electronic monitoring system to assess urinary incontinence and the impact this may have on the management of urinary incontinence. We also interviewed people who have urinary incontinence to learn more about their experiences.

#### *What Did This Health Technology Assessment Find?*

We are uncertain whether electronic monitoring systems to assess urinary continence improve incontinence care because the quality of evidence is very low. We estimated that publicly funding an electronic monitoring system for people living in long-term care homes who are eligible to use this technology for urinary incontinence assessment would cost $6.4 million in the first year and $1.6 million in each subsequent year.



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## HEALTH TECHNOLOGY ASSESSMENT AT HEALTH QUALITY ONTARIO

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The statements, conclusions, and views expressed in this report do not necessarily represent the views of the consulted experts.

**Citation**

TBD

## ABSTRACT

### Background

Urinary incontinence is involuntary leakage of urine and can affect people of all ages. Incidence rises as people age, often because of reduced mobility or conditions affecting the nervous system, such as dementia and stroke. Urinary incontinence can be a distressing condition and can harm a person's physical, financial, social, and emotional well-being. People with urinary incontinence are susceptible to skin irritation, pressure sores, and urinary tract infections. Urinary incontinence is also associated with an increased risk of falls in older adults.

This health technology assessment examined the effectiveness of, budget impact of, and patient values and preferences about electronic monitoring systems to assess urinary incontinence for residents of long-term care homes or geriatric hospital inpatients with complex conditions.

### Methods

A clinical evidence review of the published clinical literature was conducted to June 9, 2017. Critical appraisal of the clinical evidence included assessment of risk of bias and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria to reflect the certainty of the evidence.

We calculated the funding required for an electronic urinary incontinence monitoring system in the first year of implementation (when facilities would buy the systems) and in subsequent years.

We interviewed six people with urinary incontinence and two caregivers, who described ways urinary incontinence affected daily life.

### Results

We included one observational study in the clinical review. Most of the 31 participants in the observational study were female (78%) and required high levels of care, primarily because of cognitive impairment. The quality of evidence for all outcomes was very low owing to potential risk of bias and indirectness. We are consequently uncertain about how electronic monitoring systems affect management of urinary incontinence.

For patients living in long-term care homes who are eligible for the technology, we estimated that an electronic monitoring system to assess urinary incontinence would cost $6.4 million in the first year of implementation and $1.6 million in subsequent years.

Patients said urinary incontinence reduced their independence and social life and adversely affected their quality of life. Incontinence made them embarrassed and reduced their self-esteem. Several respondents mentioned how expensive supplies to manage incontinence were.

### Conclusions

The effectiveness of using the electronic monitoring system to assess urinary incontinence is uncertain because of the very low quality of the evidence. Introducing electronic monitoring systems would result in incremental costs, and there would be savings only if the systems substantially reduced incontinence.

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## OBJECTIVE

This health technology assessment examined the clinical effectiveness, the budget impact, and the patient values and preferences related to electronic monitoring systems that assess urinary incontinence.

## BACKGROUND

### Health Condition

Urinary incontinence is defined as involuntary leakage of urine.[1,2] The three main types of incontinence are stress, urge, and mixed. Stress urinary incontinence is leakage associated with exertion, sneezing, or coughing when pelvic floor muscles supporting the urethra weaken. It represents 50% of cases of incontinence. Urge urinary incontinence is leakage immediately preceded by or associated with a sudden desire to void because of an overactive bladder. It represents 14% of cases. Mixed urinary incontinence is characterized by the combination of stress and urge urinary incontinence and represents 32% of cases. Other types of incontinence include overflow incontinence caused by either poor bladder contraction or blockage of the urethra and functional incontinence caused by medications or health problems that make it difficult to reach the toilet.

Urinary incontinence can be a distressing condition and can harm a person's physical, financial, social, and emotional well-being.[3] People with urinary incontinence are susceptible to skin irritation, pressure sores, and urinary tract infections.[4] Urinary incontinence is also associated with an increased risk of falls in older adults.[5,6]

### Clinical Need and Target Population

Urinary incontinence can affect people of all ages but often increases with age, immobility, or conditions that affect the nervous system such as dementia or stroke. In 2014, an estimated 3.5 million Canadians (10%) experienced some form of urinary incontinence.[1] The prevalence by age and sex in Canada in 2014 is estimated as follows:

- 65 to 74 years: women 130,000 (9.8%) and men 78,000 (6.4%)
- 75 to 84 years: women 143,000 (16.6%) and men 79,000 (11.6%)
- ≥ 85 years: women 75,000 (22.3%) and men 34,000 (18.7%)[1]

Although urinary incontinence can affect both men and women of any age, there is a higher prevalence in older women.[7]

Management of urinary incontinence can require a considerable amount of time for caregivers in the home and staff in long-term care (LTC) homes (i.e., LTC residences or nursing homes). It also accounts for a substantial proportion of a facility's or a patient's budget when the total cost for pad use, skin care, and laundry are taken into account. Each year, the cost of supplies and nursing care to support a person with incontinence living in LTC homes can range from $4,000 to $14,000.[1] Effective management of urinary incontinence can improve people's health and quality of life.[4]

## Current Methods to Assess Urinary Incontinence

Ontario's Long-Term Care Homes Act of 2007 requires all LTC homes in Ontario to have a continence care and bowel management program to provide residents with a continence assessment and to create an individualized care plan to promote and manage continence.

Bladder continence assessment should be undertaken using a clinically appropriate instrument to help determine the following:

- Causes (e.g., recurrent urinary tract infections)
- Incontinence patterns (e.g., daytime or nighttime urinary incontinence, constipation)
- Type of incontinence (e.g., stress, urge, overflow, or functional)
- Medications that affect bladder control (e.g., diuretics)
- Potential to restore continence (e.g., prompted voiding, bedside commode, incontinence product)
- Type and frequency of physical assistance necessary to facilitate toilet visits[8]

A voiding record that documents the amount of urine voided and incontinence episodes should also be completed over a 7-day period to establish the person's voiding pattern and to monitor trends.[8] This usually involves asking patients or their caregivers about their voiding patterns or manually checking their clothes or any incontinence aids every 1 to 3 hours for episodes of urinary incontinence. The record identifies the person's care needs, and the information is used to develop a urinary continence care plan. Monitoring and re-evaluating the bladder continence assessment at least every quarter is also considered part of standard or usual care.

The *Best Practice Guideline on Promoting Continence Using Prompted Voiding* by the Registered Nurses' Association of Ontario[9] recommends that a prompted voiding schedule should be based on the client's toileting needs and on a 3-day voiding record.

## Health Technology Under Review

Electronic monitoring systems have been developed to assess urinary incontinence in real time without having to rely on manual recording processes. These systems include disposable sensor briefs, which can electronically track a person's voiding pattern. The systems operate over the Internet, and data are automatically transmitted to a private, secure server. Over a 72-hour assessment period, systems track voiding patterns and urine volume and convert these data into reports that staff can access via the web portal. Staff can use these reports to individualize toileting times, to adjust care routines, and to select appropriate incontinence products.

## Regulatory Information

Two electronic monitoring systems for urinary incontinence have been approved by Health Canada as Class II devices.[10] The Smart Incontinence Monitor (SIM) electronic monitoring system by Simavita Limited (Sydney, Australia) was licensed in February 2015. TENA Identifi by SCA Personal Care (Oakville, ON) was licensed in November 2013.

## Ontario Context

In Ontario, approximately 417,000 (3.1%) persons have urinary incontinence, of which approximately 272,000 272,865 (3.9%) are women and 144,000 (2.1%) are men.[1] According to the manufacturer of TENA Identifi, the system is currently being used in Ontario and Quebec by some LTC homes.

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# CLINICAL EVIDENCE

## Research Question

What is the effectiveness of an electronic monitoring system in the management of urinary incontinence among adults in long-term care (LTC) or inpatients with complex conditions in hospital geriatric departments?

## Methods

We developed the research question in consultation with people with urinary incontinence, health care providers, clinical experts, and other health system stakeholders.

### *Clinical Literature Search*

We performed a literature search on June 9, 2017, to retrieve studies published from inception to the search date. We used the Ovid interface in the following databases: MEDLINE, Embase, Cochrane Database of Systematic Reviews, Health Technology Assessment, Cochrane Central Register of Controlled Trials, and National Health Service Economic Evaluation Database (NHSEED); and we used the EBSCOhost interface to search the Cumulative Index to Nursing & Allied Health Literature (CINAHL).

Medical librarians developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. The final search strategy was peer reviewed using the PRESS Checklist.[11] We created database auto-alerts in MEDLINE, Embase, and CINAHL and monitored them for the duration of the health technology assessment.

We performed targeted grey literature searches of health technology assessment agency sites and clinical trial registries. See Appendix 1 for Literature Search Strategies, including all search terms.

### *Literature Screening*

A single reviewer conducted an initial screening of titles and abstracts using DistillerSR management software, and then obtained the full text of studies that appeared eligible for the review according to the inclusion criteria. The author then examined the full-text articles and selected studies that were eligible for inclusion.

### *Inclusion Criteria*

- English-language full-text publications
- Randomized controlled trials, observational studies, systematic reviews, meta-analyses
- Studies that compared electronic monitoring systems to assess urinary incontinence with standard or usual care
- Studies published from inception to June 9, 2017
- Studies that included people 50 years of age or older
- Studies that included residents of LTC homes, nursing facilities, or hospital units with complex geriatric in-patients

### *Exclusion Criteria*

- Animal and in vitro studies
- Abstracts, letters, editorials, case reports, or commentaries
- Studies with inadequate, incomplete, or duplicated data
- Acute care settings such as emergency departments

### *Outcomes of Interest*

Any of the following outcomes of interest reported in the included studies were synthesized in the report. The outcomes of interest were categorized into resource use outcomes and quality of care outcomes.

Resource use outcomes included the following:

- Change in number of pads used
- Change in time for construction of continence care plan following assessment
- Change in health care aide's or personal support worker's time spent in continence care

Quality of urinary incontinence care outcomes included the following:

- Change in proportion of residents with pad leakage episodes
- Change in quality of life (measured with validated scales)
- Change in activities of daily living (measured with validated scales)
- Change in number of wet checks at night, reduction in number of residents on "timed toileting schedules"

### *Data Extraction*

We extracted relevant data on study characteristics and risk-of-bias items using a data form to collect information about:

- Source (i.e., citation information, contact details, study type)
- Methods (i.e., study design, study duration, reporting of outcomes, and whether the study compared two or more groups)
- Outcomes (i.e., outcomes measured, number of participants for each outcome, number of participants missing for each outcome, outcome definition and source of information, unit of measurement, upper and lower limits [for scales])

### *Statistical Analysis*

Depending on the outcomes collected, dichotomous variables were reported as percentages while continuous variables were reported as mean ± standard deviation or as median (interquartile range). Statistical significance of $P < .05$ was considered significant. We did not perform the meta-analysis of the results we had planned *a priori*, as we identified only one study that met our inclusion criteria.

### *Critical Appraisal of Evidence*

Risk of bias was assessed using the modified ROBINS-I checklist.[12] The quality of the body of evidence for each outcome was evaluated according to GRADE.[13] The body of evidence was assessed on the basis of the following considerations: risk of bias, indirectness, imprecision, and publication bias. The level of quality reflects our certainty about the evidence.

### *Expert Consultation*

In May 2017, we consulted experts on appropriate use of an electronic monitoring system to assess urinary incontinence. Consultants included nursing managers and directors specializing in care of people with urinary continence. The role of the expert advisors was to contextualize the evidence and provide advice on electronic monitoring of urinary incontinence.

## Results

The literature search yielded 764 citations published from inception to June 9, 2017, after removing duplicates. We reviewed titles and abstracts to identify potentially relevant articles. We obtained full texts for eight of these articles for further assessment. One observational study met the inclusion criteria.[14] We searched the reference list of the included study, along with health technology assessment websites and other sources, to identify additional relevant studies. We found none. Figure 1 presents the flow diagram for the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA).[15]

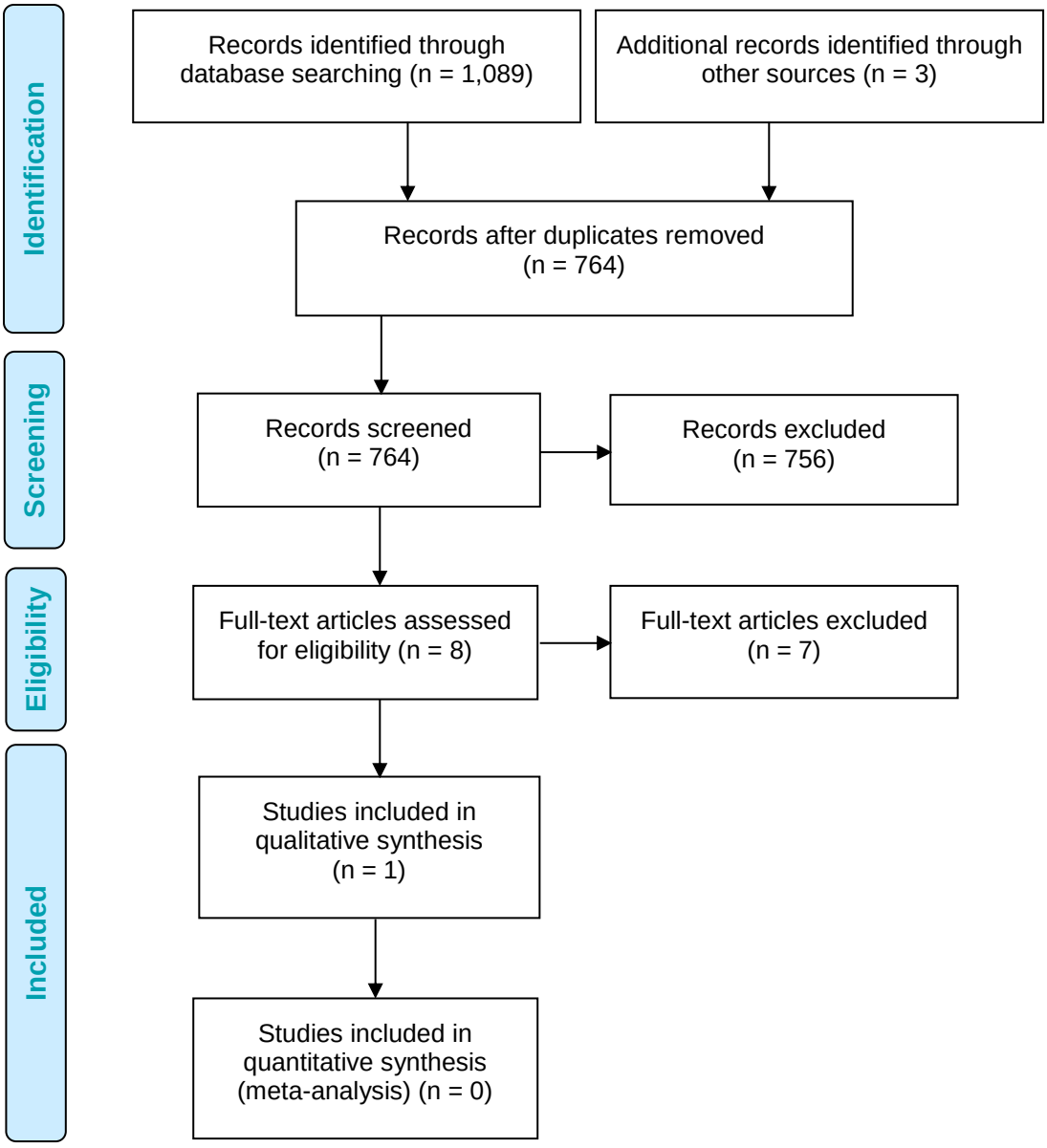


**Figure 1: PRISMA Flow Diagram for the Clinical Search Strategy**

Abbreviation: PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.
*Source: Adapted from Moher et al.*[15]

We identified one observational study that used a pre- and post-intervention repeated measures design (Table 1).[14] The SIM electronic monitoring system was used to assess urinary incontinence. The study reported outcomes from 31 participants living in LTC homes, with an average age of 81 ± 8 years. Most participants were female (78%). All participants required high levels of care, primarily owing to cognitive impairment.

**Table 1: Study Characteristics of Included Study**

| Author, Year | Objective | Study Design and Methods | Description of Intervention |
|---|---|---|---|
| Yu et al, 2014[14] | To explore effects of an electronic monitoring system for urinary incontinence assessment and a concurrent staff training program about incontinence care planning for older people living in nursing homes. How the electronic monitoring system and staff training affected adherence of nursing staff to care plans was also evaluated | Non-randomized study with outcome measures assessed before (pre) and after (post) the electronic urinary incontinence system | Baseline data were collected using an electronic monitoring system to record voiding events for study participants during a 72-hour urinary incontinence assessment (T1). Data collected from T1 were used to develop continence care plans. Outcomes of the intervention were evaluated after 2 weeks (T2). The treatment intervention also included staff training. Before data collection, care staff were trained to ensure they had relevant knowledge and skill to use the electronic monitoring system, including manual data entry, reading signal data from the system, and undertaking urinary incontinence care |

Six outcomes were measured before and after the intervention (Table 2). Investigators reported substantial improvement in urinary incontinence except for the percentage of successful toilet visits. The number of times a participant was offered assistance to use the toilet increased from an average of two times to five or six times in 24 hours. The volume of urine voided into continence aids was also reduced. The number of successful toilet visits, defined as visits where voiding occurred, increased. Finally, staff increased their adherence to incontinence care plans.

**Table 2: Incontinence Care Outcomes Measured Before and After Implementation of an Electronic Monitoring System**

| Outcome | Results | | |
|---|---|---|---|
| | Pre-intervention | Post-intervention | *P* Value |
| Incontinence void (weight of urine voided into continence aid, mg) | Mean 2.07 (SD 1523)[a] | Mean 1.53 (SD 1795)[a] | .015 |
| Number of prescribed toilet visits in care plan (in 72 hours) | Median 18 (IQR 6) | Median 15 (IQR 3) | .015 |
| Number of actual toilet visits (in 72 hours) | Median 6 (IQR 5) | Median 16 (IQR 6) | < .001 |
| Number of successful toilet visits (in 72 hours) | Median 3 (IQR 5) | Median 8 (IQR 9) | .011 |
| % of successful toilet visits[b] | 50% (SE 8.98%) | 50% (SE 31.7%) | 1.000 |
| % compliance by nursing staff with care plan prescription | 33.3 (SD 42.9)[a] | 106.7 (SD 31.7) | .033 |

Abbreviations: IQR = interquartile range; NA = not applicable; SD = standard deviation; SE = standard error; SIM, Smart Incontinence Monitor.
[a]Analytic errors, ±SD covers implausible values.
[b]SEs and *P* value were computed by authors of this report.
*Source: Yu et al.[14]*

The overall quality of the body of evidence for all six outcomes was assessed as very low (Appendix 2, Table A1). There was a potential for indirectness because surrogate outcomes were reported, and risk of bias because of selection bias as well as analytic errors in the statistical analysis undertaken by the study authors, for which the quality of the body of evidence was downgraded (Appendix 2, Table A2).

## Discussion

Incontinence assessment is a critical component of care in LTC homes. Manual assessment of urinary incontinence can be labour-intensive, intrusive, and inconsistent in the way the assessment is done. Generic incontinence care plans can lead to mistimed toilet visits that do not reflect the toileting patterns and needs of the resident.

An electronic monitoring system to assess urinary incontinence has been suggested as a way of addressing these limitations and improving person-centred care. We identified one study that attempted to evaluate the effectiveness of an electronic monitoring system.[14] A similar study was published previously, which investigated the impact of electronic alerts that were sent to care staff when a resident was incontinent.[16] However, this technology required staff to manually enter the electronic alerts, unlike the study by Yu and colleagues included in this health technology assessment, where electronic alerts indicating that the resident had voided were automatically uploaded to the Internet.[14]

The single observational study included in this review has important limitations. First, because care staff were required to manually record data for some outcomes (such as the time of toilet visits and the rate of success in using the toilet), data entry errors are possible. Second, as part of the intervention, staff were provided with additional training on incontinence assessment and care. Therefore, improvements in incontinence care might not have been entirely attributable to the electronic monitoring system alone. Third, important patient outcomes, such as skin infection rates and quality of life, were not assessed. As a result, there is considerable uncertainty with regard to the incremental effectiveness of electronic monitoring systems over standard care and also over best practice care.

### *Ongoing Studies*

Two ongoing studies with potential relevance to this review were identified. One is a prospective, non-randomized controlled study with a mixed methods design with qualitative and quantitative components (NCT02511314).[17] The second is a prospective clinical trial that compares a standard manual toileting protocol (e.g., "check and change" strategy) with toileting patterns recorded by the TENA Identifi system that identify incontinence patterns and events. Researchers are assessing whether such data differentially improve a care planning strategy, nursing effort, product use, or wet-time for urinary incontinence (NCT03209570).[18] Both studies are expected to be completed in 2018.

## Conclusions

We are uncertain if using electronic monitoring systems to assess incontinence improves management of incontinence compared with manual assessments of incontinence for people living in LTC homes or geriatric hospital in-patients requiring complex care.

# ECONOMIC EVIDENCE

## Research Question

What is the published literature on the cost-effectiveness of an electronic monitoring system to assess urinary incontinence versus standard care (routine practices and procedures of nursing homes or long-term care [LTC] facilities) in patients with urinary incontinence?

## Methods

### *Literature Search*

We performed an economic literature search on June 12, 2017, for studies published from inception to the search date. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic filter applied.

We created database auto-alerts in MEDLINE, Embase, and CINAHL and monitored them for the duration of the health technology assessment. We performed targeted grey literature searches of health technology assessment agency sites, clinical trial registries, and Tufts Cost-Effectiveness Analysis Registry. See Clinical Evidence, Literature Search, above, for methods used and Appendix 1 for literature search strategies, including all search terms.

### *Literature Screening*

A single reviewer examined titles and abstracts. For those studies likely to meet the eligibility criteria, we obtained full-text articles and further assessed eligibility. Citation flow and reasons for exclusions of full-text articles were reported according to the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) statement.

### *Inclusion Criteria*

- English-language full-text publications
- Studies that compared electronic monitoring systems to assess urinary incontinence with standard or usual care
- Studies published from inception to June 12, 2017
- Studies that included people 50 years of age or older
- Studies that included residents of LTC homes, nursing facilities, or geriatric hospital in-patients requiring complex care
- Cost-utility analyses, cost-effectiveness analysis, cost-benefit analyses, or cost-minimization analyses

### *Exclusion Criteria*

- Economic reviews
- Abstracts, letters, editorials, case reports, or commentaries
- Studies with inadequate, incomplete, or duplicated data
- Acute care settings such as emergency departments

### *Outcomes of Interest*

- Cost
- Quality-adjusted life-years (QALYs)
- Incremental cost and incremental effectiveness
- Cost per QALY gained

### *Data Extraction*

We extracted relevant data on the following:

- Source (i.e., name, location, year)
- Population and comparator
- Interventions
- Outcomes (i.e., health outcomes, costs, and incremental cost-effectiveness ratios [ICERs])

We contacted authors of the studies to provide clarification as needed.

### *Study Applicability*

We determined the usefulness of each identified study for decision-making by applying a modified applicability checklist for economic evaluations that was originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom. The original checklist is used to inform development of clinical guidelines by NICE.[19] We retained questions from the NICE checklist related to study applicability and modified the wording of the questions to remove references to guidelines and to make guidelines Ontario-specific. The number of studies judged to be directly applicable, partially applicable, or not applicable to the research question is summarized.

## Results

### *Literature Search*

The literature search yielded 50 articles published from inception to June 12, 2017, after removing duplicates. We excluded all 50 articles on the basis of information in the title and abstract. Figure 2 presents the flow diagram for PRISMA.

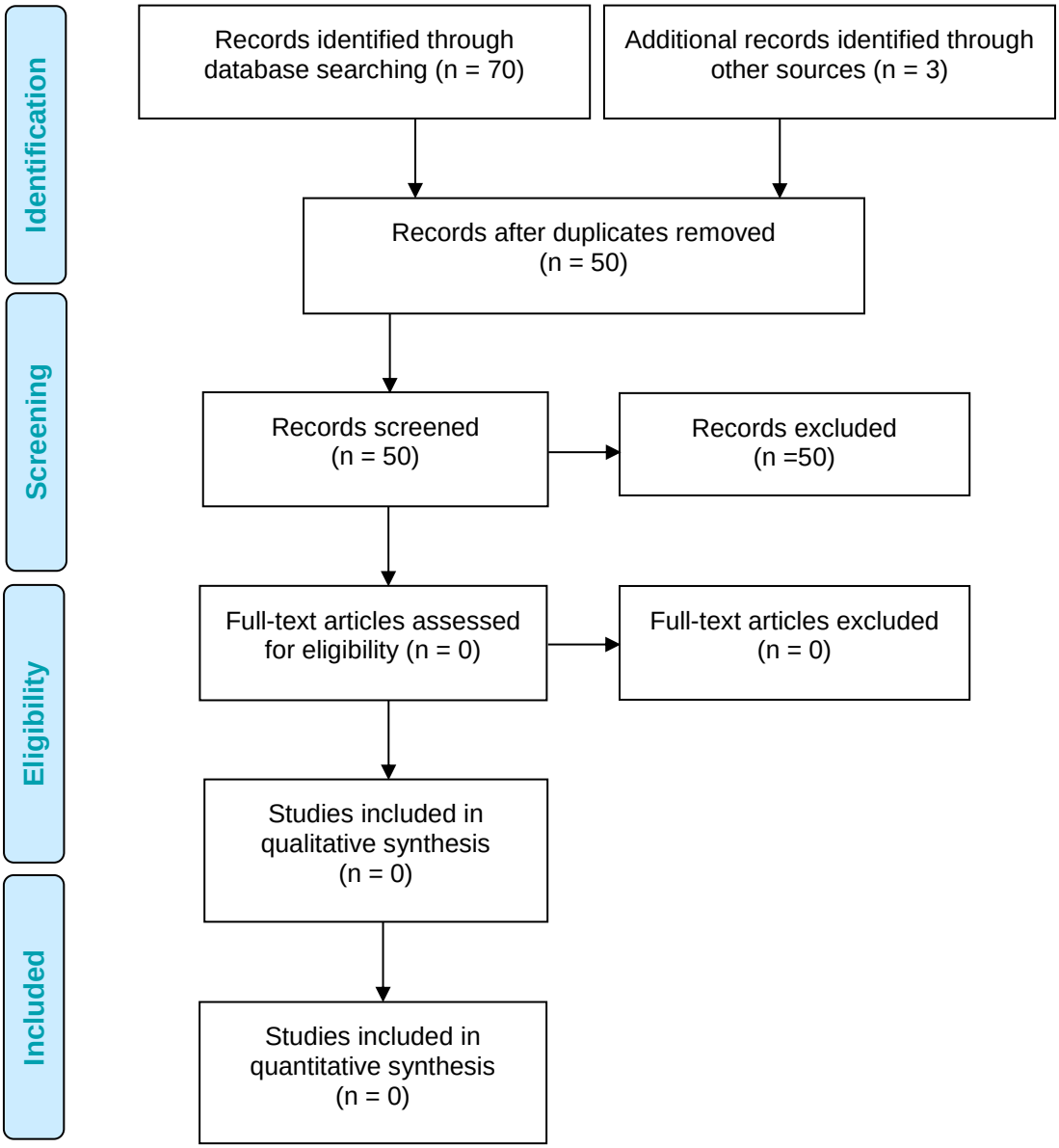


**Figure 2: PRISMA Flow Diagram for the Economic Evidence Review**

Abbreviation: PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.
*Source: Adapted from Moher et al.*[15]

### *Review of Included Economic Studies*

We did not identify any economic studies on the effect of an electronic monitoring system on resource use or on management of incontinence care among people with urinary incontinence.

## Conclusions

We did not identify any cost-effectiveness or cost-utility studies of an electronic monitoring system to assess urinary incontinence.

## PRIMARY ECONOMIC EVALUATION

In theory, there is a need for cost-effectiveness studies on electronic monitoring systems that assess urinary incontinence because no information is available on this topic in the literature. However, the clinical evidence review revealed very low-quality evidence (and therefore considerable uncertainty about how using an electronic monitoring system to assess urinary incontinence will affect management of urinary incontinence and resource use). Therefore, we did not conduct a primary economic evaluation for this topic.

## BUDGET IMPACT ANALYSIS

We conducted a budget impact analysis from the perspective of the Ontario Ministry of Health and Long-Term Care to estimate the cost burden of publicly funding an electronic monitoring system to assess urinary incontinence for the next 5 years (2017–2021). All costs were reported in 2017 Canadian dollars.

### Research Question

What is the 5-year affordability of publicly funding an electronic monitoring system to assess urinary incontinence from the perspective of the Ontario Ministry of Health and Long-Term Care?

### Methods

We conducted a reference case analysis and a scenario analysis. Our reference case analysis represents the analysis with the most likely set of input parameters and model assumptions. In the scenario analysis we explore how results are affected by varying input parameters and model assumptions.

#### *Target Population*

The target population was adults with urinary incontinence who were eligible for an electronic monitoring system (adults who are incontinent and require incontinence briefs) and living in LTC homes (LTC residences or nursing homes) in Ontario.

Patients in hospital geriatric care departments could also be using electronic monitoring systems to assess urinary incontinence. However, we do not have detailed information on this population. We did not include these people in our analysis.

#### Methods for Calculating the Target Population

Figure 3 explains how we estimated the numbers of adults with urinary incontinence who are eligible for an electronic monitoring system and who live in LTC homes in Ontario.

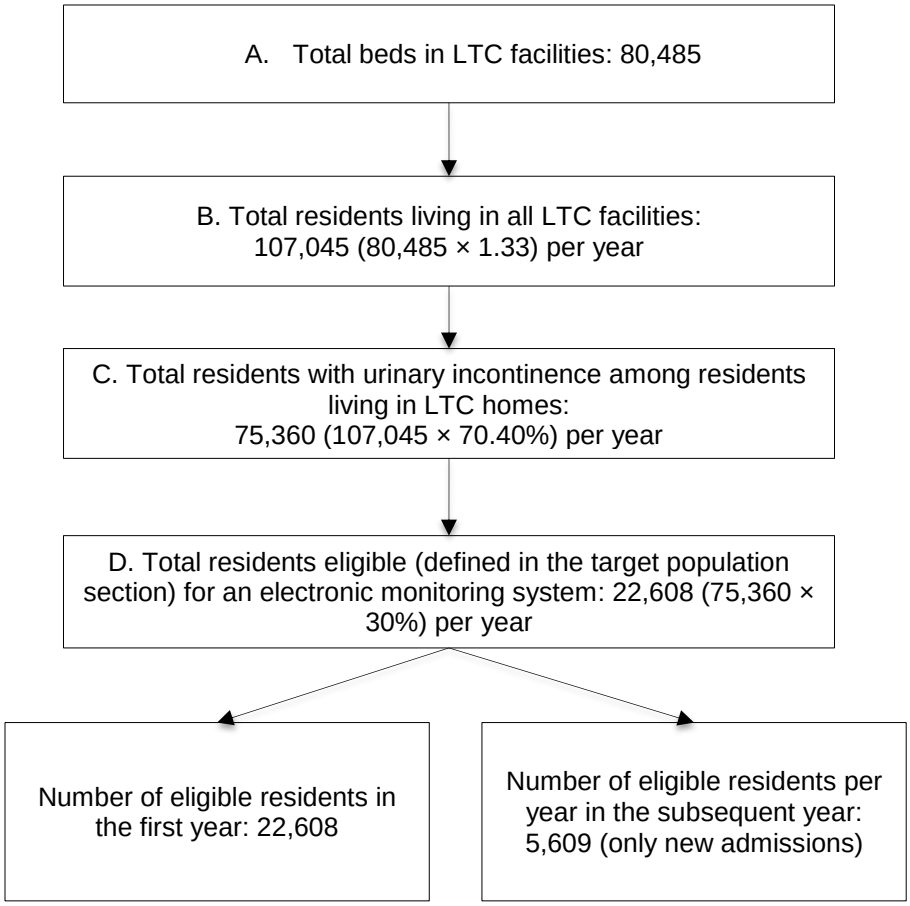


**Figure 3: Estimation of Adults With Urinary Incontinence who Were Eligible for Electronic Monitoring System and Lived in LTC Homes in Ontario**

Abbreviation: LTC, long-term care.

Details of each step in the calculation are explained below.

### *Number of Beds in LTC Homes*

In all LTC homes in the 14 local health integrated networks (LHINs) in Ontario (according to www.thehealthline.ca[2]), there are roughly 80,485 beds.

### *Total Residents Living in all LTC Homes*

The number of residents living in an LTC facility in Ontario depends on the number of beds available and on the number of current and new residents an LTC facility can receive each year. Assuming an LTC facility has full occupancy (this assumption was based on the long waiting lists for LTC homes in Ontario),[20] the maximum number of residents living in an LTC facility is calculated using the following formula:

> *Total number of residents in an LTC facility yearly = number of beds in an LTC facility × (1 + new admission rate)*

Based on input from a clinical expert as well as data from one LHIN, we used a new admission rate of 33% in our reference case, with a range of 19% to 82%.

The total number of beds in all facilities in the 14 LHINs was 80,485. We adjusted for the admission rate of new residents of 33%. The total number of residents living in all LTC homes in Ontario each year was thus estimated to be 107,045 residents (range 95,777–146,483) (Table 3).

For simplicity, we conservatively assumed that numbers of beds in all LTC homes in Ontario would remain constant. We also assumed that the yearly admission rate of new residents would remain the same across LTC homes over the next 5 years.

### *Total Residents With Urinary Incontinence Among Residents in LTC Homes*

Based on data from the Canadian Institute for Health Information (CIHI),[21] an estimated 70.4% of residents living in LTC homes in Ontario would experience urinary incontinence episodes. Table 3 shows the number of LTC residents with urinary incontinence in Ontario.

### *Total Residents Eligible for Electronic Monitoring Systems*

Approximately 30% to 50% of people with urinary incontinence were eligible for an electronic monitoring system.[22] We conservatively assumed that 30% of residents with urinary incontinence who live in LTC homes in Ontario would be eligible for an electronic monitoring system to assess urinary incontinence for all scenarios (Table 3).

**Table 3: Residents With Urinary Incontinence Expected to Receive Assessments Using Electronic Monitoring System in Ontario**

| Variables | Reference Case |
|---|---|
| Total beds in LTC homes | 80,485 |
| New admission rates (%) | 33 |
| Total residents living in LTC homes | 107,045 |
| People with UI living in LTC homes (%) | 70.4 |
| Number of people with UI living in LTC homes | 75,360 |
| People eligible for electronic monitoring system for UI treatment (%) | 30 |
| Potential people receiving electronic monitoring system for UI treatment in LTC homes | 22,608 |

Abbreviations: LTC, long-term care; UI, urinary incontinence.

## Expected Assessments of Urinary Incontinence Using Electronic Monitoring System

In general, after a person is initially assessed with an electronic monitoring system, he or she does not receive a second assessment (expert opinion, July 21, 2017). In the reference case analysis, we assumed that each LTC resident with urinary incontinence who is eligible to use an electronic monitoring system would receive one assessment. The total number of assessments would therefore equal the number of eligible residents with urinary incontinence living in all LTC homes in Ontario. Table 4 shows the estimated number of assessments that would use an electronic monitoring system during the first year of implementation and in subsequent years in all LTC homes in Ontario.

**Table 4: People to Receive Assessments Using Electronic Monitoring in all Ontario LTC Homes**

| Year of Implementing Electronic Monitoring System | People to Receive Assessments (Reference case) |
|---|---|
| First year[a] | 22,608 |
| Subsequent years[b] | 5,609 |

Abbreviation: LTC, long-term care; UI, urinary incontinence.
[a]In first year of implementation, number of assessments equals number of people with urinary incontinence eligible for assessment using electronic monitoring system.
[b]As people do not generally receive a second assessment, number of new assessments would decrease in subsequent years. Therefore, in subsequent years, the number of new assessments equals numbers of newly admitted patients.

### *Health Care Resources*

Health care resources for an electronic monitoring system to assess urinary incontinence were obtained from the manufacturers of this technology. Nursing time (including time for developing individual care plans for people with urinary incontinence and time for assisting them with toileting) was established through expert consultation. An electronic monitoring system uses disposable sensor briefs and a data logger, which can electronically track a person's voiding episodes, toileting times, and volumes in real time and convert the patterns into a visual report. The electronic monitoring system operates over the Internet, and data are automatically transmitted to a private, secure server, which staff can access to generate reports via a web portal.

### *Canadian Costs*

The costs of using an electronic monitoring system were supplied by the manufacturer of one system. Costs of standard care were taken from published literature[1] or from expert consultation. All costs used were Canada-specific and were expressed in 2017 Canadian dollars.

We calculated the budget impact by estimating the number of patients who would be assessed using an electronic monitoring system in all LTC homes in Ontario, both for the first year and for subsequent years if it were publicly funded. Cost details are provided in Table 5.

## Cost of Assessment Using an Electronic Monitoring System

The price of an assessment consists of costs of the device and materials. Each person with urinary incontinence who is eligible for electronic monitoring would need approximately 12 disposable sensor briefs for 72 hours. Each LTC facility of roughly 100 beds would require two loggers, through which data for each patient would be captured and transmitted. Detailed costs are described in Table 5.[13,23]

**Table 5: Costs of an Electronic Monitoring System[a]**

| Resource Items | Cost | Source |
|---|---|---|
| 12 Sensor Wear products (includes cost of graphed assessment report)<br>10–12 disposable sensor briefs are used over 72 hours per person **(A)** | $280.00 | Manufacturer[b] |
| Cost of integrated services per LTC home[c] | $500.00 | Manufacturer[b] |
| Cost of integrated services per patient[d] **(B)** | $3.76 | Manufacturer[b] |
| Total cost of device and material per person over 72-hour period **(C = A + B)** | $283.76 | Calculation |
| Time to develop care plan per person | 15 min | Expert opinion |
| Hourly cost of nursing time | $32.00 | MOHLTC[13] and expert opinion |
| Cost of developing care plan per patient[e] **(D)** | $8.00 | Calculation |
| Total cost per person over 72-hour assessment[f] **(C+D)** | $291.76 | Calculation |

Abbreviation: LTC, Long-term care; MOHLTC, Ministry of Health and Long-Term Care.
[a] Costs of assessment of urinary incontinence using electronic monitoring systems available in Ontario.
[b]Cost data were provided by the manufacturer in the submission for the review of the technology.
[c]Each LTC home with 100 beds would need two loggers for transmitting patterns of toilet visits, volume, and voiding. Information on use of data loggers and charging unit, set up, access to the web portal of the electronic monitoring system, and start-up package was provided by manufacturers' representatives, industry reports and analysis, and device hotline and support.
[d]Each year a 100-bed LTC home would receive an average of 133 patients. Cost of integrated services per person would be $500 divided by 133 patients.
[e]This cost was calculated by dividing 60 minutes of nursing time by 15 minutes of service and multiplying the product by the hourly cost of nursing time.
[f]This cost was calculated by adding the cost of the device of the technology to the cost of a nurse making an individual care plan after the assessment.

After a person with urinary incontinence is assessed with an electronic monitoring system, the person would be assisted with toileting according to their individual care plan. As the quality of clinical evidence is very low, it is unclear whether an electronic monitoring system is more effective than standard care to improve the management of incontinence care. Therefore, in the reference case analysis, we conservatively assumed that there was no additional benefit from an electronic monitoring system versus standard care. The resource use of an electronic monitoring system is presented in Table 6. Costs incurred by people with urinary incontinence after being assessed by an electronic monitoring system were calculated by adding the daily

cost of a personal support worker's time to assist at each toileting visit to the cost of incontinence supplies after assessment (Table 6).

## Costs of Standard Care

According to the Canadian Continence Foundation, the cost of supplies and nursing care to support a person with incontinence living in an LTC home can range from $4,000 to $14,000 each year.[1] Resource use before and after using an electronic monitoring system, estimated for the reference case analysis, is presented in Table 6.

**Table 6: Resource Use and Costs During 72-Hour Assessment Before and After Implementation of Electronic Monitoring System—Reference Case**

| Resource Items | Without Electronic Monitoring System (Pre-assessment) | Remarks | With Electronic Monitoring System (Post-assessment) | Remarks |
|---|---|---|---|---|
| Daily visits to toilets | 6 visits | 6–8 visits Expert opinion and Yu et al[14] | 6 visits | 5–6 visits Yu et al[14] |
| PSW time per toilet visit[a] | 15 min | Expert opinion | 15 min | Expert opinion |
| Number of PSWs accompanying patient per toilet visit | 1 | Expert opinion | 1 | Expert opinion |
| Daily cost of incontinence supplies[b] | $5.75 | Calculation | $5.75 | Calculation |
| Hourly cost of PSW[c] | $24 | MOHLTC[24] and expert opinion | $24 | MOHLTC[24] and expert opinion |
| Total daily cost of PSW accompanying patient per toilet visit[d] | $36 | Calculation | $36 | Calculation |
| Length of patient stay in LTC facility[e] | 244.55 d/y | Calculation | 244.55 d/y | Calculation |
| Cost per person of electronic monitoring system | -- | -- | $291.76 | Calculation |
| Total annual cost of supplies, PSW time, and device per patient | $10,284[f] | Calculation | $10,576[g] | Calculation |

Abbreviation: LTC, long-term care; MOHLTC, Ministry of Health and Long-Term Care; PSW, personal support worker.

[a]It took 15 minutes for nurse to accompany person with urinary incontinence to toilet.

[b]The Canadian Urinary Continence Association calculated daily cost of incontinence supplies for pre-assessment from a yearly cost of incontinence supplies ranging from $1,400 to $2,100 per person receiving home care. The Economic Analysis and Evaluation Unit of the MOHLTC suggested that when budget impact is analyzed for LTC homes, $2,100 for cost of incontinence supplies should be applied. Daily cost of incontinence supplies after assessment was calculated from daily cost of incontinence supplies before assessment and adjusted for change in incontinence void.

[c]Hourly wage for PSW includes 21% benefits (expert opinion).

[d]Cost was calculated with the following formula: numbers of toilet visits per day × PSW time per toilet visit × hourly cost per PSW.

[e]Each LTC facility was assumed to have 33% new admissions per year. Therefore, each resident living in an LTC facility would stay 67% of year in an LTC home or 67% × 365 days = 244.55 days.

[f]Cost was calculated by the following formula: Number of PSW × Number of days person would stay in an LTC home each year × Total daily cost of PSW accompanying patient to toilet + Number of days person would stay in an LTC home each year × Daily cost of incontinence supplies per patient.

[g]Cost was calculated by the following formula: Number of PSW × Number of days a person would stay in an LTC home yearly × Total daily cost of PSW accompanying a patient to toilet + Number of days person would stay in an LTC home yearly × Daily cost of incontinence supplies per patient++ Cost of electronic monitoring system per person with urinary incontinence.

Table 7 presents the yearly cost incurred by a person with urinary incontinence who was assessed using an electronic monitoring system versus standard care in the first year and subsequent years for the reference case analysis.

**Table 7: Average Yearly Cost for People With Urinary Incontinence—Reference Case**

| Strategies | Yearly Costs After Implementation, $ | |
|---|---|---|
| | First Year | Subsequent Years |
| Electronic monitoring system[a] | 10,576 | 10,284 |
| Standard care[b] | 10,284 | 10,284 |

[a]Cost data were provided by manufacturer of an electronic monitoring system to assess urinary incontinence. People using this technology were each assessed only once; therefore, the cost was incurred in the first year only.
[b]The Canadian Urinary Continence Association's estimate of costs included incontinence supplies and nursing care.

In scenario analysis, we assumed that there were more benefits with an electronic monitoring system to assess urinary incontinence than with standard care (i.e., fewer prescribed toilet visits and less personal support worker's [PSW] time).

Scenario analyses presented in Table 8 include the resource use and costs in standard care and for a 72-hour electronic monitoring system assessment.

**Table 8. Resource Use and Costs Without and With an Electronic Monitoring System—Scenario Analysis**

| Resource Items | Without Electronic Monitoring System (Pre-assessment) | Remarks | With Electronic Monitoring System (Post-assessment) | Remarks |
|---|---|---|---|---|
| Daily visits to toilets | 6 visits | 6–8 visits Expert opinion and Yu et al[14] | 5.5 visits | 5–6 visits Yu et al[14] |
| PSW time per toilet visit[a] | 15 min | Expert opinion | 15 min | Expert opinion |
| Number of PSWs accompanying patient per toilet visit | 1 | Expert opinion | 1 | Expert opinion |
| Daily cost of incontinence supplies[b] | $5.75 | Calculation | $4.71 | Calculation |
| Hourly cost of PSW[c] | $24 | MOHLTC[24] and expert opinion | $24 | MOHLTC[24] and expert opinion |
| Total daily cost of PSW accompanying patient per toilet visit[d] | $36.30 | Calculation | $33.28 | Calculation |
| Length of patient stay in LTC facility[e] | 244.55 d/y | Calculation | 244.55 d/y | Calculation |
| Cost per person of electronic monitoring system | -- | -- | $291.76 | Calculation |
| Total annual cost of supplies, PSW time and device per patient | $10,284[f] | Calculation | $9,582[g] | Calculation |

Abbreviation: LTC, long-term care; MOHLTC, Ministry of Health and Long-Term Care; PSW, personal support worker.

[a]It took 15 minutes for nurses to accompany person with urinary incontinence to toilet.

[b]The Canadian Urinary Continence Association calculated daily cost of incontinence supplies for pre-assessment from a yearly cost of incontinence supplies ranging from $1,400 to $2,100 per person receiving home care. The Economic Analysis and Evaluation Unit of the MOHLTC suggested that when budget impact is analyzed for LTC homes, $2,100 for cost of incontinence supplies should be applied. Daily cost of incontinence supplies after assessment was calculated from daily cost of incontinence supplies before assessment and adjusted for change in incontinence void.

[c]Hourly wage for PSW includes 21% benefits (expert opinion).

[d]Cost was calculated with the following formula: Numbers of toilet visits per day × PSW time per toilet visit × hourly cost per PSW.

[e]Each LTC facility was assumed to have 33% new admissions per year. Therefore, each resident living in an LTC facility would stay 67% of year in an LTC home or 67% x 365 days = 244.55 days.

[f]Cost was calculated by the following formula: Number of PSW × Number of days person would stay in an LTC home yearly × Total daily cost of PSW accompanying patient to toilet + Number of days person would stay in an LTC home yearly × Daily cost of incontinence supplies per patient.

[g]Cost was calculated by the following formula: number of PSW × Number of days a person will stay in an LTC home yearly × Total daily cost of PSW accompanying patient to toilet + Number of days person would stay in an LTC home yearly × Daily cost of incontinence supplies per patient + Cost of electronic monitoring system per person with urinary incontinence.

The yearly average cost for a person with urinary incontinence using an electronic monitoring system and standard care for the scenario analysis is presented in Table 9.

**Table 9: Average Yearly Cost for People With Urinary Incontinence Using an Electronic Monitoring System—Scenario Analysis**

| Strategies | Yearly Costs After Implementation, $ | |
|---|---|---|
| | First Year | Subsequent Years |
| Electronic monitoring system[a] | 9,582 | 9,290 |
| Standard care[b] | 10,284 | 10,284 |

[a]Cost data were provided by manufacturer of an electronic monitoring system to assess urinary incontinence. People using this technology were each assessed only once; therefore, the cost was incurred in the first year only.
[b]The Canadian Urinary Incontinence Association's estimate of costs included incontinence supplies and nursing care.

### *Analysis*

In the reference case analysis, we calculated the budget required to fund an electronic monitoring system (e.g., cost of the device) under the assumption that there was no additional benefit to incontinence management with an electronic monitoring system compared with standard care. We also calculated the net budget impact as the difference between the cost of using an electronic monitoring system versus cost of standard care, and the potential savings of reduced time needed from personal support workers.

The detailed calculation of net budget impact is presented below, where N = number of all people with urinary incontinence eligible for an electronic monitoring system.

> **Net budget impact in the first year** = (N × yearly cost per person for one assessment using the electronic monitoring system during the first year) – (N × yearly cost per person in standard care)
>
> **Net budget impact in subsequent years** = (N of newly admitted eligible patients × yearly cost per person of one assessment during first year using the electronic monitoring system) + (N of patients remaining at LTC homes after first year of using the electronic monitoring system × yearly cost per person in subsequent years with electronic monitoring system) – (N of all eligible patients × yearly cost per person in standard care)

### *Expert Consultation*

We consulted with experts on electronic monitoring systems between June and August 2017. The role of the expert advisors was to provide advice on research questions, review methods, and review results and to contextualize the evidence on the effectiveness and safety of an electronic monitoring system for urinary incontinence. However, the statements, conclusions, and views expressed in this report do not necessarily represent views of the experts we consulted.

## Results

### *Reference Case Analysis*

If no additional benefits accrue from an electronic monitoring system to assess urinary incontinence compared with standard care, we estimated that the budget required to publicly fund electronic monitoring systems to assess urinary incontinence for people who live in LTC

homes in Ontario who are eligible to receive treatment for urinary incontinence would be $6,415,208 for the first year and $1,591,743 for subsequent years.

Costs of labour, incontinence supplies, nursing time to develop an individual care plan, and the device are summarized as the expected net budget impact for the first year of implementing the system and subsequent years (Table 10). Implementing an electronic monitoring system to assess urinary incontinence in LTC homes would require an additional $6,596,072 for the first year of implementation and $1,636,619 for subsequent years.

**Table 10: Budget Impact of Adopting Electronic Monitoring System to Assess Urinary Incontinence in Ontario—Reference Case**

| Strategy | Yearly Cost After Implementation, $[a] | |
|---|---|---|
| | First Year | Subsequent Years |
| **Electronic monitoring system to assess urinary incontinence** | | |
| Yearly labour cost | 200,694,188 | 200,694,188 |
| Yearly cost of incontinence supplies | 31,809,336 | 31,809,336 |
| Yearly cost to develop an individual care plan | 180,863 | 44,876 |
| Yearly cost of the device | 6,415,208 | 1,591,743 |
| *Total yearly cost of an electronic monitoring system* | *239,099,595* | *234,140,143* |
| **Standard care** | | |
| Yearly labour cost | 200,694,188 | 200,694,188 |
| Yearly cost of incontinence supplies | 31,809,336 | 31,809,336 |
| *Total yearly cost of standard care* | *232,503,524* | *232,503,524* |
| **Net budget impact** | **6,596,072** | **1,636,619** |

[a]Numbers might appear inexact owing to rounding.

## *Scenario Analysis*

Assuming benefits (i.e., reduced toilet visits with personal support worker) of an electronic monitoring system would last for more than a year after assessment, the expected net budget impact for the first year of publicly funding the system and subsequent years is presented in Table 11. Using an electronic monitoring system to assess urinary incontinence in LTC homes would potentially reduce costs to the health care system assuming incontinence management would be better.

**Table 11: Budget Impact of Adopting Electronic Monitoring System to Assess Urinary Incontinence in Ontario Assuming Clinical Benefits—Scenario Analysis**

| Strategy | Yearly Cost After Implementation, $[a] | |
|---|---|---|
| | First Year | Subsequent Years |
| **Electronic monitoring system to assess urinary incontinence** | | |
| Yearly labour cost | 183,969,672 | 183,969,672 |
| Yearly cost of incontinence supplies | 26,062,532 | 26,062,532 |
| Yearly cost to develop an individual care plan | 180,863 | 44,876 |
| Yearly cost of the device | 6,415,208 | 1,591,743 |
| *Total yearly cost of electronic monitoring system* | *216,628,276* | *211,668,823* |
| **Standard care** | | |
| Yearly labour cost | 200,694,188 | 200,694,188 |
| Yearly cost of incontinence supplies | 31,809,336 | 31,809,336 |
| *Total yearly cost of standard care* | *232,503,524* | *232,503,524* |
| **Net budget impact** | **(15,875,248)** | **(20,834,700)** |

[a]Numbers might appear inexact owing to rounding.

### *Limitations*

The budget required to fund an electronic monitoring system was calculated only for people with urinary incontinence who live in LTC homes (nursing homes and LTC residences) who were eligible. We were unable to calculate the budget required to fund this technology for people with urinary incontinence who are eligible to receive this treatment and require complex geriatric care in hospitals. As a result, the findings of this analysis could underestimate the actual budget to publicly fund this technology.

## Discussion

Our analysis was based on the conservative assumption that 30% of people in LTC homes in Ontario would be eligible for an electronic monitoring system. This value is conservative in terms of use, and is likely to underestimate the direct costs of this technology to the health care system. Our calculations were based on the clinical outcomes of Yu et al,[14] which were limited by a short follow-up and by studying a single nursing home located outside Canada.

The scenario analysis showed that using an electronic monitoring system could potentially reduce costs to the Ontario health care system, largely through savings in personal support workers' time if using an electronic monitoring system improved the management of incontinence care. This savings is unlikely to have a direct budget impact, but instead could help improve efficiency in facilities through reallocation of human resources. However, given the uncertainty about how electronic monitoring systems would affect incontinence management, there is little confidence in this scenario analysis.

Not all people with urinary incontinence reside in an LTC home. If this technology were used by people receiving home care and improved management of urinary incontinence, potential

benefits might be realized for this population as well. However, we did not find any evidence to support its use for people receiving home care, and therefore the budget impact to publicly fund electronic monitoring systems for home care is unknown.

## Conclusions

If an electronic monitoring system to assess urinary incontinence is publicly funded in Ontario for people with urinary incontinence who live in LTC homes, it would cost the health care system $6.4 million for the first year and $1.6 million in subsequent years for the procurement of the device. It would potentially reduce costs to the health care system if the clinical evidence shows greater effectiveness than standard care on managing incontinence, mostly by reducing time required from personal support workers.

## PATIENT, CAREGIVER, AND PUBLIC ENGAGEMENT

### Objective

This analysis explored how urinary incontinence affects those who have lived experience with the condition. We focused on assessment with electronic monitoring systems for urinary incontinence.

### Background

Public and patient engagement explores the lived experience of a person with a health condition, including the impact the condition and its treatment has on the patient, the patient's family or other caregivers, and the patient's personal environment. Public and patient engagement intends to increase awareness and build appreciation for the needs, priorities, and preferences of the person at the centre of a treatment program. Insights gained through public and patient engagement provide an in-depth picture of lived experience, through an intimate look at the values that underpin the experience.

Lived experience is a unique source of evidence about the personal impact of a health condition and how that condition is managed, including what it is like to navigate the health care system with that condition, and how technologies might or might not make a difference in people's lives. Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcome measures that do not reflect what is important to those with lived experience).[25-27] Lived experience can also provide information or perspectives on the implications of technologies and treatments for ethical and social values. Because the needs, priorities, preferences, and values of those with lived experience in Ontario are not often adequately explored by published literature, Health Quality Ontario makes an effort to reach out to, and directly speak with, people who live with the health condition, including those who have experience with the intervention in question.

Urinary incontinence is distressing for patients and their families, and it has a substantial effect on their quality of life. Urinary incontinence mostly affects older adults. To understand how urinary incontinence affects quality of life, we heard from both people who have urinary incontinence and their families. The people we spoke to were managing urinary incontinence using various methods (including incontinence protection products); however, none of the participants had used an electronic monitoring system to assess urinary incontinence. Nevertheless, gaining an understanding of the day-to-day experience of managing urinary incontinence helps us place the potential value of this technology into context from the perspective of patients and caregivers.

### Methods

#### *Engagement Plan*

Engagement as a concept captures a range of efforts to involve the public and patients in various domains and stages of decision-making.[28] Rowe and Frewer[29] outline three types of engagement: communication, consultation, and participation. Communication constitutes a one-way transfer of information from the sponsor to the individual, while participation involves the sponsor and individual collaborating through real-time dialogue. Consultation, on the other hand, refers to the sponsor's seeking out and soliciting information (for example, experiential

input) from the public, patients, and caregivers affected by the technology or intervention in question.[30]

The engagement plan for this health technology assessment was consultation. Within this type of engagement, the study design focused on interviews to examine the lived experience of patients and family members who have experience with urinary incontinence.

The qualitative interview was selected as an appropriate method because it allowed Health Quality Ontario staff to deeply explore the meaning of central themes in the lived experience of participants and their family members. We engaged people face-to-face and via phone interviews. Our main task in interviewing is to understand what people tell us and gain an understanding of the story behind their experiences.[31] Interviews are particularly useful for getting the story behind a participant's experiences, which was the objective in this portion of the health technology assessment. The sensitive nature of quality-of-life issues is another reason to use interviews for this project.

### *Participant Recruitment*

We used an approach called purposive sampling,[32-35] which involves actively reaching out to patients, families, and caregivers with direct experience of the health condition and health technology or intervention being reviewed. Staff from the Patient, Caregiver, and Public Engagement team at Health Quality Ontario contacted more than 40 long-term care (LTC) facilities, nursing homes, and complex geriatric care departments in hospitals and rehabilitation centres across the province. Twenty-four facilities agreed to share our recruitment information with their residents.

This outreach resulted in connections with two family members who were interested in participating in this review. We also conducted in-person recruitment with people who reside at an LTC facility in Toronto that specializes in LTC and inpatient community health services. Unfortunately, several people who reside at this facility and have urinary incontinence were unable to participate in the interviews, as they either were unable to express themselves or did not feel comfortable sharing their experiences. This in-person recruitment resulted in six interviews. We were unable to recruit any people who had experience with using electronic monitoring systems, and we learned that many care facilities do not use an electronic monitoring system for urinary assessment because of cost constraints.

### *Inclusion Criteria*

We sought to speak with people who had experienced urinary incontinence and their family members. They were not required to have direct experience with electronic monitoring systems.

### *Exclusion Criteria*

No exclusion criteria were set.

### *Participants*

We conducted six interviews with people with urinary incontinence and two interviews with family members. Two interviews were conducted over the phone, while six interviews were conducted in person at a facility in Toronto that specializes in LTC and inpatient community health services.

### *Approach*

At the outset of the interviews, Patient, Caregiver, and Public Engagement staff at Health Quality Ontario explained the purpose of health technology assessments (including the role of Health Quality Ontario and the Ontario Health Technology Advisory Committee), risks to participants, and protection of personal health information. These attributes were explained to participants verbally and through a letter of information (Appendix 3). Verbal consent was then obtained from participants before commencing interviews. With the consent of these participants, interviews were audio recorded, except when consent to audio recording was not given, in which case written notes were taken.

Interviews lasted 20 to 30 minutes. They were semistructured and consisted of a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement in Health Technology Assessment.[36] Questions focused on how urinary incontinence affected the quality of life for both patients and families, the lived experience with urinary incontinence, and methods of managing urinary incontinence, as well as patients' values, preferences, and expectations regarding incontinence protection products. In addition, we also sought their views on their experience (if any) with electronic monitoring systems. See Appendix 4 for our interview guide.

### *Data Extraction and Analysis*

We used a modified version of a grounded-theory methodology to analyze interview transcripts, because it captured and allowed for elements of the lived experience to be assigned themes and compared among participants. The inductive nature of grounded theory follows an iterative process of eliciting, documenting, and analyzing responses while simultaneously collecting and analyzing data using a constant comparative approach.[37,38] We used the qualitative data analysis software NVivo (QSR International) to identify and interpret patterns in interviews. The patterns we identified then allowed us to highlight how health conditions and treatments affected patients and their family members.

## Results

### *Health Conditions Leading to Urinary Incontinence*

Patients' length of experience with urinary incontinence varied from a few months to more than 10 years. For example, some people had first experienced urinary incontinence during childhood; others first experienced it during their later years. Patients and family members reported that various health conditions led to urinary incontinence including Alzheimer's disease, dementia, stroke, injuries, cancer, or surgeries, and that those conditions had eventually led them to be admitted to care facilities. Complications of urinary incontinence together with other health conditions caused serious challenges for patients as well as for their family members.

> *It happened when I collapsed with my back. Then, you know, I was numb from the waist down, so that caused the incontinence.…*
>
> *So the dementia added another layer of complication. He became more uncertain about when he had to go, and he couldn't always explain it. At this point, in 2017, I would say he is incontinent, but not because of lack of control, but because he just doesn't know whether he has to go or not. The amazing thing about him is that he will look at me earnestly. When I ask, "Do you have to go to the washroom?" … he'll say, "I don't know."*

> *I didn't really identify it; I just thought I had to pee a lot, and I didn't really know why, … and I'd be surprised when I took down my pull-ups and they'd be wet, because I didn't expect them to be.…*

### *Quality of Life for Patients*

While the consequences of urinary incontinence were unique to each person, almost everyone shared how urinary incontinence changed their own or their family members' quality of life. This included serious adjustments to their daily routine including restricting food and fluid intake, limits on places they visited, frequent toilet visits, and less engagement in social activities.

### *Social and Physical Impacts*

Participants spoke about their lives before urinary incontinence as being fairly active and independent and then shared how their lifestyles were forced to change following the onset of urinary incontinence. Many shared that urinary incontinence led to fewer established social interactions and added a burden to activities they enjoyed before diagnosis.

> *Well, not just that, it's the walking too. Also I like to dance and I like to ride my bicycle and yeah, it's going to affect my life. I think I'm going to be saddled in the house.*

> *I need to know where bathrooms are. I usually shop in the same places, and I know where the bathrooms are. But yes, I need to know where they are. Well, when I go to a new mall or store—I'm visually impaired, so I don't go to new places unless somebody is with me.…*

### *Emotional Impacts*

Almost everyone shared their constant struggle with as well as the stress of managing urinary incontinence. Feelings of shame and embarrassment were common among respondents. Loss of body control, and especially being incontinent in public, was seen as a loss of dignity. This caused emotional stress and damaged respondents' self-esteem, sometimes leading to social isolation.

> *It depends. You know, it affects every part of [life], because I no longer have control when I move, or sneeze, or cough, or laugh.… Well, before I could just simply go out and not be affected by stress incontinence. And … sometimes it's very undignified.*

> *I don't like any of this stuff. Who does? Especially when, you know, you've been independent all your life and then you've got to rely on people to look after you when you wet yourself.*

> *I went one time to the grocery store. Thank God, it was my daughter-in-law that took me. And while I was reaching for something, one of the bags broke … in the grocery store.… And I said, "That's it; I will never, never—never." And I never did. Had I not been able to get back to going normal, I would never have left my room.*

Some family members shared how their loved ones kept their urinary incontinence secret because they considered it to be a private topic and assumed there was a taboo surrounding an open discussion of such an issue. Such feelings inhibited them from seeking support from medical professionals or the staff at LTC homes. As a result, family members had to intervene and advocate on their behalf for them to receive the care and support that they required.

> *So she was getting worse; she was wearing, like, two pairs of underwear because she would leak.… So I let the nurse know.… It was sad to see my mother, you know, take one step further into the whole disease. [S]he was at the stage for eventually not having control over her bladder and her bowels. [It's] a sad thing.*

**Quality of Life for Family Members**

Family caregivers described how caring for a person with urinary incontinence requires great attention. It requires making adjustments to the routine, in particular when people with urinary incontinence are away from their home and in public.

> *It was just part of life. With being a caregiver, this is all part of the whole business. You have to keep adjusting all the time, and this was a major part of it. It's amazing what you look back on and you think, "My gosh, how did I do that?"*

> *I would take him in the women's [washroom]; this might be some humour. I insisted we go into women's washrooms always because I wasn't willing to deal with urinals, myself, in the men's. He would swish in the wheelchair, and if there was a woman at the sink, you know, doing her hair or washing her hands, we'd always get a funny look as we—and he would salute as we swished into the disability cubicle. We kept the door shut and we're very … as discreet as we could be.*

Interviews with family members also indicated challenges they faced because they lacked knowledge of how to look after someone with urinary incontinence. A lack of advice and information about managing the condition increased the workload and compromised the quality of life for family members.

> *Middle of the night was the hard time because I was on my own. You know, when I had to change the bed. It took me a long time to discover disposable pads. I didn't know they existed. And they were such a blessing. When one of the pharmacists mentioned, "Why aren't you using these?" And I said, "What? They exist? Let me at them." So we find out about these things as caregivers just by accident and by talking with each other, mostly, … and people have to say, "Oh, didn't you know?" And I don't know what the answer to that is because it's a whole new world you move into, of course.*

### *Managing Urinary Incontinence*

Patients reported that they have used a variety of measures to manage urinary incontinence. Use of incontinence protection products was most common, while use of bedpans, commodes, and catheters was also reported. Although none of the people enjoyed wearing incontinence aids, pull-up briefs were the most preferred product. Bedpans and catheters were the least preferred products.

> *[Pull-up briefs are] easy for me right now to step into them.… Yes, I didn't like them, and I wanted to look forward to wearing my panties again, but that hasn't happened; I'm still on them.*

> *A bedpan [was used] when I'm sick. I didn't like the bedpan, hard to get on the bedpan. Can't hold it in until the bedpan is placed.*
> *There was [a catheter] in the beginning after surgery. I hated it; … it hurts to put it in and pull it out, and it's uncomfortable to go anywhere. It's a terrible procedure, I think.*

> *I got a commode—I rented it for $50 a month, and I had it right beside my bed, so if I got the urge, I could make it, but I usually never made it in time.*

### *Patient Preferences for Incontinence Products*

Various urinary incontinence products, including adult diapers, pull-up diapers, pads, briefs, and liners were used by those who participated in the interviews. When participants considered what incontinence products would be most suitable, factors included absorbency, size, comfort, cost, quality, and ability to protect skin. While effective protection against leaks was important when choosing a product, bulkiness of the product was crucial, as these people worried that wearing such products would be visible to others.

> *She's just a tiny lady, so it was a kind of product that was small enough for her; … the first [product she had tried] was a little bulky, and she was then aware that she wasn't wearing underwear and that kind of made her sad. So we were able to find a smaller one that fit better and then … she didn't get the feeling that she was wearing a diaper. [S]he was more [receptive] to wearing that one. … It was important that she had something that … would still protect her and her clothing.*

> *They were soft, and with the smaller size, it didn't feel like a diaper.… I guess with modern technology they're able to make or use products that are thinner but still absorb as much.*

> *When they were able to find the right size and with a thinner material, she … felt like nobody could see it through her clothes.*

### *Benefits of Incontinence Protection Products*

Both patients and family members thought that incontinence protection products helped them and their loved ones to regain at least some of their independence and a degree of freedom. Wearing incontinence products gave them the sense of protection when being away from home or from LTC homes and reduced the burden of toilet route planning.

> *I [thought wearing incontinence products] was very important for her because she didn't feel like she was losing her dignity. Because she was a woman that was very prim and proper, … and that kind of thing was very important to her.*

Several participants spoke of the health benefits of using incontinence protection products. These included protection against skin irritation or sores, as well as reducing concerns about odour.

> *Urinary incontinence just goes on. I know they use briefs, and it's been a marvelous product so far. It does seem to be protecting him down there. He doesn't seem to have any bedsores or any chafing or wetness that is causing trouble.… I mean, of course he's sore, but it's nothing like what it was when I had him at home. I was using baby powder and the wet wipes—not in that order—to keep him as dry as possible.*

### *Challenges With Managing Urinary Incontinence*

Patients and family members were asked about the challenges they experienced when managing urinary incontinence. Despite the fact that incontinence aids are designed to absorb

liquid fully and protect skin, in some cases these products were not meeting all expectations of patients.

### *Social Challenges*

Some patients thought that wearing incontinence products was humiliating, particularly if products were visible to others. Further, several participants were vocal about how dependence on others for their self-care reduced their freedom and privacy.

> *When it was up my back with—like I've been wearing my long jacket … because I think, "Oh, people will know I've got the pad on." So I've been wearing this long jacket.… Well, it's embarrassing and you don't want people to see it on you.*

> *The uncomfortableness. Like I feel I have a rash, you know, on my legs. I've been putting stuff on it. It's just embarrassing, too, you know. But now I'm going to be getting up on the walker so I don't want to look abnormal, and that's why I went to the smaller pad. But I don't know. Can you still tell if I'm wearing one? I'm wearing the wrong jacket, but can you tell that I'm wearing one?*

### *Challenges in Long-Term Care Facilities*

Overall, patients and family members appreciated the care and support that they received from staff at LTC homes; however, several interviewees shared their frustration over the challenges they faced during their stays. Not being able to make decisions about their self-care routine was commonly highlighted. According to some people, it took longer to get assistance from staff during meal times or at night when fewer staff are available.

> *I think [I wait] 10 to 15 minutes. Does that sound right? I think it's average.… Then you wet yourself and you wet the bed.… Well, sometimes somebody comes with a flashlight in the middle of the night.*

The lack of privacy and the lack of power to make decisions regarding their care or toileting times, together with the lack of individualized care plans was worrisome, while the sex of personal support workers was also a concern for some people. It is clear from interviews that there are some unmet needs of the patients especially with regard to care routines.

> *Been independent all my life. Oh, yeah. I find it embarrassing, especially when you have men nurses. And there's a few here. Four or five men nurses.… I don't request them. They just change your nurse every day or every two days.… You know, you've been independent all your life, and then you've got to rely on people to look after you when you wet yourself.*

> *Of course, they try to get them onto a routine as much as possible. But this is why he is parked on the toilet for an hour every morning. They pretty much got him going at that time. It's still erratic, as I say. He might go in the afternoon, and you can only find out when you smell him and think, "Oh, oh. Something's happened." And I have to run and get someone.*

A few people shared it was embarrassing for them to request staff support for a "false alarm," which would waste time for staff; however, the worry of incontinence left them with no alternative.

> *Yes, because I did know it was coming, I just couldn't do anything about it. And that was very off … I'd just break air or something and I was sure I had gone to the bathroom.… But lots of times … Oh, I felt bad, you know, making them come if I didn't have a problem. But they never made me feel bad.… Yeah, I'd go, "Gee, I'm sorry," you know, that kind of thing.*

### *Financial Barriers*

Nearly all participants stated that the cost of incontinence protection products is their biggest barrier to managing urinary incontinence. Some people acknowledged that they have financial support from their family; however, several respondents felt the lack of a publicly funded system to cover the cost of incontinence protection products. A lack of financial resources also led some people to compromise the quality of the products they purchased or to delay changing times, both of which reduced their quality of life and health.

> *I don't like having to wear a sanitary napkin. I'm down to the smaller ones now, but it's expensive, too. I've used a smaller one. I've been using bigger ones. I mean it's quite costly.*

> *They're expensive—very expensive. Because my daughter's paying for them, and my son. Yeah, my children pay for my extra expenses, … and I wouldn't have been able to pay for that if my kids hadn't paid for it. So they've been paying for my extra stuff.*

### *Views on Electronic Monitoring System to Assess Urinary Incontinence*

None of the patients or family members had heard of an incontinence product with electronic sensors that can detect and record urination patterns. When information was presented to participants about these systems during interviews, many stated that they were interested in learning more about the products.

> *Well, I can tell you I have fascinated the staff on his floor. They said, "What? A sensor in the briefs? Really? How would it work?" And I'm curious too. Would the sensor be manually moved from brief to brief or do the briefs come with them built in? I'm fascinated that such a technology can exist. And they're all mulling this over, too, the ones I talked with.*

> *That sounds like magic to me. It's just amazing. But it sounds very good. I don't know if it would fit that profile as well simply because of the complication of the codeine he's getting. But I know that's—I'm sure you'll work on that, too. Maybe it'll work better on new residents when you're trying to figure out right away what is the right routine for this person.*

## Discussion

Six people with urinary incontinence and two family caregivers participated in interviews. The findings of the patient engagement review revealed the substantial burden and challenges experienced by people with urinary incontinence and their families regardless of how long they had had the condition. Various health conditions led people to develop urinary incontinence and eventually to be admitted to LTC homes. They revealed that urinary incontinence greatly affected their day-to-day function, and in particular limited their independence and social interactions. The emotional consequences of urine incontinence were substantial: many lived with the fear of being embarrassed and reported losing self-esteem. Several measures were

used by people to manage incontinence. Urine incontinence protection products, such as disposable briefs, ranked at the top. When people selected the most appropriate product, they considered several factors, including absorbency, size, comfort, cost, quality, and ability to protect skin.

Many patients believed that urinary incontinence protection products help them manage the social and emotional effects of incontinence by supporting regained independence and a certain degree of freedom. Financial challenges were the most significant barrier people faced, and many were concerned about the lack of financial support to cover their costs. None of the participants was aware of disposable briefs with electronic sensors that can detect and record urination patterns. Many were interested in learning more about the product.

## Conclusion

Patients with urinary incontinence face serious emotional, social and physical challenges that affect their families as well. Respondents reported the condition limits their independence, sense of freedom, social interactions, and ability to engage in day-to-day activities. Patients use various measures to manage incontinence, and incontinence protection products, such as disposable briefs, were ranked at the top. None of the patients or families we interviewed were aware of a disposable product with electronic sensors that can detect and record urination patterns. We do not know how people would see the benefits or challenges of using an electronic monitoring system to assess urinary incontinence, what expectations they would have for the product, or how its use would affect people with urinary incontinence and their families.

## OVERALL CONCLUSIONS

It is uncertain if the use of an electronic monitoring system to assess incontinence improves the management of incontinence compared with manual assessments of incontinence for people living in a LTC home, nursing facilities, or hospital units with complex geriatric in-patients

We did not identify any cost-effectiveness or cost–utility studies of an electronic monitoring system to assess urinary incontinence. If an electronic monitoring system to assess urinary incontinence is publicly funded in Ontario for people with urinary incontinence who live in LTC homes, it would cost the health care system $6.4 million for the first year and $1.6 million in subsequent years. It would potentially reduce costs to the health care system if the clinical evidence shows greater effectiveness than standard care on the management of urinary incontinence, mostly by reducing time required from personal support workers.

People with urinary incontinence face emotional, social, and physical challenges that affect their families as well. Respondents reported the condition limits their independence, sense of freedom, social interactions, and ability to engage in day-to-day activities. Many LTC homes do not use an electronic monitoring system to assess urinary incontinence because of its cost. None of the people or families we interviewed were aware of a disposable product with electronic sensors that can detect and record urination patterns. We do not know how people with urinary incontinence would see the benefits or challenges of using the electronic monitoring system to assess their incontinence patterns, what expectations they would have for the product, or how its use would affect people with urinary incontinence and their families.

## ABBREVIATIONS

| | |
|---|---|
| **GRADE** | Grading of Recommendations Assessment, Development, and Evaluation |
| **ICER** | Incremental cost-effectiveness ratio |
| **IQR** | Interquartile range |
| **LHIN** | Local Health Integrated Network |
| **LTC** | Long-term care |
| **NICE** | National Institute for Health and Care Excellence |
| **PRISMA** | Preferred Reporting Items for Systematic reviews and Meta-analyses |
| **QALY** | Quality-adjusted life-year |

## GLOSSARY

| | |
|---|---|
| **Disposable sensor briefs** | A single-use undergarment with an electronic sensor designed to monitor and track the wearer's voiding patterns and volume. The information from the censor assists continence care professionals in making informed decisions about a person's incontinence management needs. |
| **Observational study** | A study in which the researcher is unable to control how subjects are assigned to groups or which treatments each group receives. Generally, investigators observe real-world changes in health status in relation to changes in other patient characteristics. |

# APPENDICES

## Appendix 1: Literature Search Strategies

### *Clinical Evidence Search*

**Search date:** June 9, 2017
**Databases searched:** All Ovid MEDLINE, Embase, Cochrane Database of Systematic Reviews, CRD Health Technology Assessment Database, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, CINAHL

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <April 2017>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to May 31, 2017>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2017 Week 23>, All Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---

1 exp urinary incontinence/ (94858)
2 Incontinence pads/ (1933)
3 Absorbent pads/ (224)
4 Diapers, Adult/ (120)
5 (incontinen* or continence or diaper* or voiding or urination or micturition or toileting).ti,ab,kf. (175868)
6 or/1-5 (204263)
7 Monitoring, Physiologic/is (10244)
8 telemetry/ (24206)
9 Telemedicine/ (34016)
10 Monitoring, Ambulatory/ (17809)
11 Biosensing Techniques/ (51065)
12 Clinical Alarms/ (1383)
13 Electronics, Medical/ (6650)
14 Remote Sensing Technology/ (7208)
15 Diagnosis, Computer-Assisted/ (58879)
16 Computer Systems/ (36383)
17 or/7-16 (237767)
18 6 and 17 (618)
19 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) adj6 (sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms)).ti,ab,kf. (607)
20 ((urinary or urine) adj5 ((sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms) adj3 (electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth))).ti,ab,kf. (41)
21 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) and ((electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth) adj5 (system or systems or management or device* or technolog* or assessment*))).ti,ab,kf. (286)
22 (TENA or Simavita or Simpad or SenseUrine).ti,ab,kf. (112)
23 or/18-22 (1537)
24 exp Animals/ not Humans/ (14493416)
25 23 not 24 (1087)

26 adolescent/ or exp child/ or exp infant/ or (child or children or childhood or teen* or adolescen* or juvenile or youth or young people or young person* or pediatric* or paediatric*).ti. (6772709)
27 exp adult/ or (adult* or elder* or geriatric*).ti,ab. (14648239)
28 26 not 27 (3796347)
29 25 not 28 (943)
30 limit 29 to english language [Limit not valid in CDSR; records were retained] (847)
31 30 use ppez,coch,cctr,clhta,cleed (476)
32 urine incontinence/ (39625)
33 mixed incontinence/ (1522)
34 stress incontinence/ (30148)
35 urge incontinence/ (6742)
36 urine incontinence device/ (10)
37 incontinence aid/ (36)
38 diaper/ (1422)
39 adult diaper/ (120)
40 (incontinen* or continence or diaper* or voiding or urination or micturition or toileting).tw,kw. (177662)
41 or/32-40 (195026)
42 physiologic monitoring/ (56165)
43 telemedicine/ (34016)
44 telehealth/ (20642)
45 urological monitoring device/ (9)
46 telemonitoring/ (1955)
47 alarm monitor/ (776)
48 alarm monitoring/ (748)
49 medical electronics/ (6649)
50 remote sensing/ (5330)
51 wireless communication/ (3537)
52 electronic sensor/ (1817)
53 or/42-52 (110667)
54 41 and 53 (320)
55 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) adj6 (sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms)).tw,kw,dv. (642)
56 ((urinary or urine) adj5 ((sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms) adj3 (electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth))).tw,kw,dv. (44)
57 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) and ((electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth) adj5 (system or systems or management or device* or technolog* or assessment*))).tw,kw,dv. (336)
58 (TENA or Simavita or Simpad or SenseUrine).tw,kw,dv. (121)
59 or/54-58 (1356)
60 (exp animal/ or nonhuman/) not exp human/ (10145147)
61 59 not 60 (1204)
62 exp juvenile/ or (child or children or childhood or teen* or adolescen* or juvenile or youth or young people or young person* or pediatric* or paediatric*).ti. (4223915)
63 exp adult/ or (adult* or elder* or geriatric*).ti,ab. (14648239)
64 62 not 63 (2760873)
65 61 not 64 (1071)
66 limit 65 to english language [Limit not valid in CDSR; records were retained] (956)

67 66 use emez (448)
68 31 or 67 (924)
69 68 use ppez (424)
70 68 use coch (0)
71 68 use cctr (51)
72 68 use clhta (0)
73 68 use cleed (1)
74 68 use emez (448)
75 remove duplicates from 68 (660)

**EBSCOhost CINAHL**

| # | Query | Results |
|---|---|---|
| S1 | (MH "Urinary Incontinence+") | 9,015 |
| S2 | (MH "Incontinence Aids") | 873 |
| S3 | (MH "Toileting") | 464 |
| S4 | (MH "Diapers") | 291 |
| S5 | TI(incontinen* or continence or diaper* or voiding or urination or micturition or toileting) | 9,333 |
| S6 | AB(incontinen* or continence or diaper* or voiding or urination or micturition or toileting) | 9,620 |
| S7 | S1 OR S2 OR S3 OR S4 OR S5 OR S6 | 18,491 |
| S8 | (MH "Monitoring, Physiologic") | 15,858 |
| S9 | (MH "Telemetry") | 1,522 |
| S10 | (MH "Telemedicine") | 6,804 |
| S11 | (MH "Biosensing Techniques") | 240 |
| S12 | (MH "Equipment Alarm Systems") | 592 |
| S13 | (MH "Wearable Sensors") | 349 |
| S14 | (MH "Diagnosis, Computer Assisted") | 3,366 |
| S15 | (MH "Computer Systems") | 1,625 |
| S16 | (MH "Therapy, Computer Assisted") | 4,622 |
| S17 | S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 | 33,543 |
| S18 | S7 AND S17 | 62 |
| S19 | ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) N6 (sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms)) | 56 |
| S20 | ((urinary or urine) and ((sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms) N3 (electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth))) | 31 |
| S21 | ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) and ((electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth) N5 (system or systems or management or device* or technolog* or assessment*))) | 45 |
| S22 | (TENA or Simavita or Simpad or SenseUrine) | 17 |
| S23 | S18 OR S19 OR S20 OR S21 OR S22 | 189 |
| S24 | (MH "Vertebrates+") NOT (MH "Human") | 135,083 |
| S25 | S23 NOT S24 | 189 |
| S26 | (MH "Adolescence+") OR (MH "Child+") OR (child or children or childhood or teen* or adolescen* or juvenile or youth or young people or young person* or pediatric* or paediatric*) | 863,466 |

| | | |
|---|---|---|
| S27 | (MH "Adult+") OR (adult* or elder* or geriatric*) | 1,408,067 |
| S28 | S26 NOT S27 | 542,105 |
| S29 | S25 NOT S28 | 170 |
| S30 | S25 NOT S28 Limiters - English Language | 165 |

**Grey Literature**

Performed on: March 16-21, 2017

Websites searched:
HTA Database Canadian Repository, Alberta Health Technologies Decision Process reviews, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), McGill University Health Centre Health Technology Assessment Unit, National Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Australian Government Medical Services Advisory Committee, Centers for Medicare & Medicaid Services Technology Assessments, Institute for Clinical and Economic Review, Ireland Health Information and Quality Authority Health Technology Assessments, Washington State Health Care Authority Health Technology Reviews, ClinicalTrials.gov

Keywords used:

Incontinence, continence, urination, diaper, diapers, voiding, micturition, toileting, urinary, urine

Results: 3

## *Economic Evidence Search*

**Search date:** June 12, 2017
**Databases searched:** All Ovid MEDLINE, Embase, Cochrane Database of Systematic Reviews, CRD Health Technology Assessment Database, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, CINAHL

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <April 2017>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 9, 2017>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2017 Week 24>, All Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 exp urinary incontinence/ (95001)
2 Incontinence pads/ (1936)
3 Absorbent pads/ (226)
4 Diapers, Adult/ (121)
5 (incontinen* or continence or diaper* or voiding or urination or micturition or toileting).ti,ab,kf. (176158)
6 or/1-5 (204601)
7 Monitoring, Physiologic/is (10244)
8 telemetry/ (24231)

9 Telemedicine/ (34118)
10 Monitoring, Ambulatory/ (17823)
11 Biosensing Techniques/ (51156)
12 Clinical Alarms/ (1388)
13 Electronics, Medical/ (6654)
14 Remote Sensing Technology/ (7233)
15 Diagnosis, Computer-Assisted/ (58926)
16 Computer Systems/ (36407)
17 or/7-16 (238095)
18 6 and 17 (618)
19 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) adj6 (sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms)).ti,ab,kf. (607)
20 ((urinary or urine) adj5 ((sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms) adj3 (electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth))).ti,ab,kf. (41)
21 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) and ((electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth) adj5 (system or systems or management or device* or technolog* or assessment*))).ti,ab,kf. (289)
22 (TENA or Simavita or Simpad or SenseUrine).ti,ab,kf. (112)
23 or/18-22 (1540)
24 economics/ (252084)
25 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (770735)
26 economics.fs. (401378)
27 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (752140)
28 exp "costs and cost analysis"/ (538440)
29 (cost or costs or costing or costly).ti. (232101)
30 cost effective*.ti,ab,kf. (268578)
31 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab. (174331)
32 models, economic/ (10609)
33 markov chains/ or monte carlo method/ (69659)
34 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (34636)
35 (markov or markow or monte carlo).ti,ab,kf. (110522)
36 quality-adjusted life years/ (32618)
37 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (55815)
38 ((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (90384)
39 or/24-38 (2264550)
40 23 and 39 (74)
41 40 use ppez,coch,cctr,clhta (31)
42 23 use cleed (1)
43 41 or 42 (32)
44 limit 43 to english language [Limit not valid in CDSR; records were retained] (27)
45 urine incontinence/ (39712)
46 mixed incontinence/ (1528)
47 stress incontinence/ (30183)
48 urge incontinence/ (6755)
49 urine incontinence device/ (10)

50 incontinence aid/ (36)
51 diaper/ (1423)
52 adult diaper/ (121)
53 (incontinen* or continence or diaper* or voiding or urination or micturition or toileting).tw,kw. (177958)
54 or/45-53 (195359)
55 physiologic monitoring/ (56215)
56 telemedicine/ (34118)
57 telehealth/ (20681)
58 urological monitoring device/ (9)
59 telemonitoring/ (1964)
60 alarm monitor/ (781)
61 alarm monitoring/ (749)
62 medical electronics/ (6653)
63 remote sensing/ (5354)
64 wireless communication/ (3563)
65 electronic sensor/ (1821)
66 or/55-65 (110895)
67 54 and 66 (320)
68 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) adj6 (sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms)).tw,kw,dv. (642)
69 ((urinary or urine) adj5 ((sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms) adj3 (electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth))).tw,kw,dv. (44)
70 ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) and ((electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth) adj5 (system or systems or management or device* or technolog* or assessment*))).tw,kw,dv. (339)
71 (TENA or Simavita or Simpad or SenseUrine).tw,kw,dv. (121)
72 or/67-71 (1359)
73 Economics/ (252084)
74 Health Economics/ or Pharmacoeconomics/ or Drug Cost/ or Drug Formulary/ (126344)
75 Economic Aspect/ or exp Economic Evaluation/ (414033)
76 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw,kw. (776233)
77 exp "Cost"/ (538440)
78 (cost or costs or costing or costly).ti. (232101)
79 cost effective*.tw,kw. (279310)
80 (cost* adj2 (util* or efficac* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab. (175402)
81 Monte Carlo Method/ (56576)
82 (decision adj1 (tree* or analy* or model*)).tw,kw. (38325)
83 (markov or markow or monte carlo).tw,kw. (115417)
84 Quality-Adjusted Life Years/ (32618)
85 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw,kw. (59557)
86 ((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw,kw. (109486)
87 or/73-86 (1914567)
88 72 and 87 (128)
89 88 use emez (34)
90 limit 89 to english language [Limit not valid in CDSR; records were retained] (31)

91 44 or 90 (58)
92 91 use ppez (24)
93 91 use emez (31)
94 91 use cctr (2)
95 91 use coch (0)
96 91 use clhta (0)
97 91 use cleed (1)
98 remove duplicates from 91 (42)

**EBSCOhost CINAHL**

| # | Query | Results |
|---|---|---|
| S1 | (MH "Urinary Incontinence+") | 9,016 |
| S2 | (MH "Incontinence Aids") | 873 |
| S3 | (MH "Toileting") | 464 |
| S4 | (MH "Diapers") | 291 |
| S5 | TI(incontinen* or continence or diaper* or voiding or urination or micturition or toileting) | 9,334 |
| S6 | AB(incontinen* or continence or diaper* or voiding or urination or micturition or toileting) | 9,620 |
| S7 | S1 OR S2 OR S3 OR S4 OR S5 OR S6 | 18,492 |
| S8 | (MH "Monitoring, Physiologic") | 15,859 |
| S9 | (MH "Telemetry") | 1,522 |
| S10 | (MH "Telemedicine") | 6,805 |
| S11 | (MH "Biosensing Techniques") | 240 |
| S12 | (MH "Equipment Alarm Systems") | 592 |
| S13 | (MH "Wearable Sensors") | 349 |
| S14 | (MH "Diagnosis, Computer Assisted") | 3,366 |
| S15 | (MH "Computer Systems") | 1,625 |
| S16 | (MH "Therapy, Computer Assisted") | 4,622 |
| S17 | S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 | 33,545 |
| S18 | S7 AND S17 | 62 |
| S19 | ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) N6 (sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms)) | 56 |

| | | |
|---|---|---|
| S20 | ((urinary or urine) and ((sensor or sensors or monitor* or telemonitor* or tracker* or tracking or detector* or logger* or logging or alarm or alarms) N3 (electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth))) | 31 |
| S21 | ((incontinen* or continence or diaper* or voiding or urination or micturition or toileting) and ((electronic* or smart or intelligent or Internet or wireless* or mobile or Bluetooth) N5 (system or systems or management or device* or technolog* or assessment*))) | 45 |
| S22 | (TENA or Simavita or Simpad or SenseUrine) | 17 |
| S23 | S18 OR S19 OR S20 OR S21 OR S22 | 189 |
| S24 | (MH "Economics") | 11,245 |
| S25 | (MH "Economic Aspects of Illness") | 6,787 |
| S26 | (MH "Economic Value of Life") | 520 |
| S27 | MH "Economics, Dental" | 108 |
| S28 | MH "Economics, Pharmaceutical" | 1,789 |
| S29 | MW "ec" | 143,318 |
| S30 | (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*) | 220,496 |
| S31 | (MH "Costs and Cost Analysis+") | 86,016 |
| S32 | TI cost* | 40,594 |
| S33 | (cost effective*) | 29,455 |
| S34 | AB (cost* N2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)) | 20,340 |
| S35 | (decision N1 (tree* or analy* or model*)) | 5,325 |
| S36 | (markov or markow or monte carlo) | 3,480 |
| S37 | (MH "Quality-Adjusted Life Years") | 2,721 |
| S38 | (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs) | 6,599 |
| S39 | ((adjusted N1 (quality or life)) or (willing* N2 pay) or sensitivity analys?s) | 12,371 |
| S40 | S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 | 294,862 |
| S41 | S23 AND S40 | 12 |
| S42 | S23 AND S40<br>Narrow by Language: - english | 12 |

**Grey Literature**

Performed on: May 16-21, 2017; June 12, 2017.

Websites searched:
HTA Database Canadian Repository, Alberta Health Technologies Decision Process reviews, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), McGill University Health Centre Health Technology Assessment Unit, National Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Australian Government Medical Services Advisory Committee, Centers for Medicare & Medicaid Services Technology Assessments, Institute for Clinical and Economic Review, Ireland Health Information and Quality Authority Health Technology Assessments, Washington State Health Care Authority Health Technology Reviews, ClinicalTrials.gov, Tufts Cost-Effectiveness Analysis Registry.

Keywords used:

Incontinence, continence, urination, diaper, diapers, voiding, micturition, toileting, urinary, urine.

Results: 3

## Appendix 2: Critical Appraisal of Clinical Evidence

**Table A1: GRADE Evidence Profile for Comparison of Standard Care and Electronic Monitoring to Assess Urinary Incontinence**

| Number of Studies (Design) | Risk of Bias[a] | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| **Incontinence void (weight of urine voided into incontinence aid)** | | | | | | | |
| 1 (observational) | Very serious limitations (−2)[a] | Not applicable | Serious limitations (−1)[b] | No serious limitations | Undetected | None | ⊕ Very Low |
| **Number of prescribed toilet visits in care plan** | | | | | | | |
| 1 (observational) | Very serious limitations (−2)[a] | Not applicable | Serious limitations (−1)[b] | No serious limitations | Undetected | None | ⊕ Very Low |
| **Number of actual toilet visits** | | | | | | | |
| 1 (observational) | Very serious limitations (−2)[a] | Not applicable | Serious limitations (−1)[b] | No serious limitations | Undetected | None | ⊕ Very Low |
| **Number of successful toilet visits** | | | | | | | |
| 1 (observational) | Very serious limitations (−2)[a] | Not applicable | Serious limitations (−1)[b] | No serious limitations | Undetected | None | ⊕ Very Low |
| **Percentage of successful toilet visits** | | | | | | | |
| 1 (observational) | Very serious limitations (−2)[a] | Not applicable | Serious limitations (−1)[b] | No serious limitations | Undetected | None | ⊕ Very Low |
| **Compliance with care plan prescription** | | | | | | | |
| 1 (observational) | Very serious limitations (−2)[a] | Not applicable | Serious limitations (−1)[b] | No serious limitations | Undetected | None | ⊕ Very Low |

Abbreviation: GRADE, Grading of Recommendations Assessment, Development, and Evaluation.

[a]Study was downgraded for risk of bias because there was a possibility of selection bias and analytic errors.

[b]Authors of the primary study used a combination of an electronic monitoring system plus education as intervention, whereas we were interested in an electronic monitoring system alone. We were also more interested in important patient outcomes (such as falls, skin breakdown, and quality of life), but authors reported surrogate outcomes (such as number of successful toilet visits).

**Table A2: Risk of Bias[a] for Comparison of Standard Care and Electronic Monitoring to Assess Urinary Incontinence**

| Author, Year | Confounding | Selection Bias | Measurement Bias | Reporting Bias | Missing Data | Other Bias |
|---|---|---|---|---|---|---|
| Yu, 2014[14] | N | Y | N | N | N | Y[b] |

Abbreviations: Y, Yes; N, No.

[a]Risk of bias assessed through modified ROBINS-I checklist.[12]

[b]Bias from analytic errors.

## Appendix 3: Call for Participation From Health Quality Ontario

Ontario
Health Quality Ontario

**LETTER OF INFORMATION**

Health Quality Ontario is conducting a review of **Electronic Monitoring of Urine Incontinence**. The purpose is to understand whether this technology should be funded in Ontario.

An important part of this review involves speaking to patients and caregivers of those who have experience of urine incontinence and who may or may not have used urine incontinence monitoring. We are looking to speak with people with urine incontinence and who are residing in either long-term care homes, nursing homes or complex geriatric care in hospitals or rehabilitation centres. Our goal is to make sure the experiences of people with urine incontinence and their caregivers are considered in the funding recommendations for this technology.

### WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 30-50 minutes of your time for a phone or in-person interview
- ✓ Permission to audio- (not video-) record the interview

### WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Health Quality Ontario staff. The interview will likely last 30-50 minutes. It will be held in a private location or over the telephone. With your permission, the interview will be audio-taped. The interviewer will ask you questions about your or your loved one's condition and your perspectives about treatment options in Ontario.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

### CONFIDENTIALITY

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After the project completion, the records will be destroyed.

### RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experience.

### IF YOU ARE INTERESTED, PLEASE CONTACT

## Appendix 4: Interview Guide

1) Can you give me a little bit of information about your/ your loved ones journey of having urine incontinence, when was diagnosis, are there any other health conditions that were diagnosed as well?

2) What methods were used to manage the urine incontinence in the past, what's used now? Were they accessible and affordable?

3) Were there any other products used?

4) Did you notice a difference from the previous method to the current one?

5) Was an electronic monitoring system used to create a voiding pattern? Was it manual?

6) What is the impact of urine incontinence in your life?

7) We are trying to include diverse perspectives within Ontario. Do you feel that you are part of a group or community that is not served well by our health system

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# About Health Quality Ontario

Health Quality Ontario is the provincial advisor on the quality of health care. We are motivated by a single-minded purpose: **Better health for all Ontarians.**

## Who We Are.

We are a scientifically rigorous group with diverse areas of expertise. We strive for complete objectivity, and look at things from a vantage point that allows us to see the forest and the trees. We work in partnership with health care providers and organizations across the system, and engage with patients themselves, to help initiate substantial and sustainable change to the province's complex health system.

## What We Do.

We define the meaning of quality as it pertains to health care, and provide strategic advice so all the parts of the system can improve. We also analyze virtually all aspects of Ontario's health care. This includes looking at the overall health of Ontarians, how well different areas of the system are working together, and most importantly, patient experience. We then produce comprehensive, objective reports based on data, facts and the voice of patients, caregivers and those who work each day in the health system. As well, we make recommendations on how to improve care using the best evidence. Finally, we support large scale quality improvements by working with our partners to facilitate ways for health care providers to learn from each other and share innovative approaches.

## Why It Matters.

We recognize that, as a system, we have much to be proud of, but also that it often falls short of being the best it can be. Plus certain vulnerable segments of the population are not receiving acceptable levels of attention. Our intent at Health Quality Ontario is to continuously improve the quality of health care in this province regardless of who you are or where you live. We are driven by the desire to make the system better, and by the inarguable fact that better has no limit.

**About the Ontario Health Technology Advisory Committee (OHTAC)**

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