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ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Intermittent Catheters for Chronic Urinary Retention: A Health Technology Assessment

KEY MESSAGES

What Is This Health Technology Assessment About?

People who cannot empty their bladder on their own may develop chronic urinary retention. If not managed, this condition can lead to serious health problems. Urine that remains in the bladder for too long increases the risk of developing urinary tract infection, bladder damage, and kidney disease. To prevent such problems, children and adults with chronic urinary retention learn to insert a tube, called a catheter, into their body to drain the bladder. This process is called "intermittent" catheterization because people insert and remove the catheter as needed, typically about five times a day.

Catheters come in several types, either prelubricated or noncoated (these need to be lubricated manually). All are sold as "single use" but, due to cost, many people clean and reuse noncoated catheters multiple times (for example, using one per day or one per week). A year's supply in Ontario can range from about $558, for people who reuse noncoated catheters (using one per day), to about $12,800 for people who use a new hydrophilic catheter each time they empty their bladder. About 33,000 people in Ontario use intermittent catheters as a result of spinal cord injury, multiple sclerosis, stroke, spina bifida or for other reasons. Only a fraction have their supplies covered through various government programs.

This health technology assessment looked at the effectiveness, safety, and cost-effectiveness of different types of intermittent catheter for the management of chronic urinary retention. It also looked at the budget impact of publicly funding intermittent catheters in Ontario and the preferences and values of people who use intermittent catheters.

What Did This Health Technology Assessment Find?

The overall evidence from studies we reviewed did not consistently show significant differences in the safety or effectiveness of various types of intermittent catheter. In addition, the evidence is considered to be low quality. Therefore, we cannot confidently say whether a specific type of catheter is better at reducing people's risk of complications such as urinary tract infection. In interviews with 34 Ontario adults and parents of children with chronic urinary retention, we learned that many people struggle with the ongoing cost of catheters. Almost all said they would prefer not to reuse catheters sold as "single use" but could not afford the cost of using them as single use. Among types of catheter, there are large differences in costs but not much measurable difference in terms of their impact on people's quality of life. Therefore, the lowest-cost catheter—multiple-use noncoated, which people clean and reuse—is the most likely to be cost-effective. We estimated that publicly funding multiple-use noncoated catheters in Ontario, assuming people reuse one per day, would cost about $93 million over the next 5 years.

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This report was developed by a multidisciplinary team from Health Quality Ontario. The clinical epidemiologist was Lucia Cheng; the health economist was Sean Tiggelaar; the patient engagement specialists were Samanthika Ekanayake, Sunita Kheterpal, and David Wells; and the medical librarian was Melissa Walter.

The medical editor was Amy Zierler. Others involved in the development and production of this report were Tanveer Singh, Merissa Mohamed, Kellee Kaulback, Ana Laing, Claude Soulodre, Kara Cowan, Sarah McDowell, Vivian Ng, Andrée Mitchell, Amy Lang, Nancy Sikich, and Irfan Dhalla.

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

Citation

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ABSTRACT

Background

People with chronic urinary retention typically require intermittent catheterization. This review evaluates the effectiveness, safety, patient preference, cost-effectiveness, and budget impact of different types of intermittent catheter (IC). Specifically, we compared prelubricated catheters (hydrophilic, gel reservoir) and noncoated catheters, as well as their single use versus reuse (multiple use).

Methods

We performed a systematic literature search and included randomized controlled trials, cohort, and case-control studies that examined any type of single-use versus multiple-use IC, hydrophilic single-use versus noncoated single-use, or gel reservoir single-use versus noncoated single-use. The outcomes of interest were symptomatic urinary tract infection (UTI), hematuria, other serious adverse events, and patient satisfaction. The quality of the body of evidence was examined according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group criteria. We also completed an economic evaluation, using the perspective of the Ontario Ministry of Health and Long-Term Care, to determine the cost-effectiveness of various intermittent catheters used in Ontario. We determined the budget impact of fully and partially funding various intermittent catheters for outpatients with chronic urinary retention. To understand patient experiences with intermittent catheterization, we interviewed 34 adults and parents of children affected by chronic urinary retention.

Results

We found 14 randomized controlled trials that met the inclusion criteria. When comparing any type of single-use or multiple-use IC, we found no difference in UTI (RR = 0.98, 95% CI 0.70–1.39), hematuria, or serious adverse events, and inconclusive evidence on patient satisfaction.

Our meta-analysis of studies on people living in the community showed that hydrophilic ICs may result in fewer UTIs than single-use noncoated ICs, but given the nature of the studies, we were uncertain about this conclusion.

The nature of the available evidence also did not allow us to make definitive conclusions regarding whether one type of catheter was likely to result in less hematuria, fewer serious adverse events, or greater patient satisfaction.

Our economic evaluation found that owing to small differences in quality-adjusted life-years and moderate to large incremental cost differences, the lowest-cost ICs—noncoated multiple-use (using one catheter per week or one catheter per day)—have the highest probability of being cost-effective. In a subpopulation of those clinically advised not to reuse ICs, single-use noncoated ICs have the highest probability of being cost-effective. As current funding is limited in the outpatient setting, publicly funding noncoated multiple-use catheters (one per day) would result in a total additional cost of $93 million over the first 5 years. People who use ICs reported that the high ongoing cost of purchasing catheters was a financial burden. Almost all said they would prefer not to reuse catheters sold as “single use” but could not afford to do so.

Conclusions

Given the overall low quality of evidence in available studies, we are uncertain whether any specific type of IC (coated or noncoated, single- or multiple-use) significantly reduces symptomatic UTI, hematuria, or other serious adverse clinical events, or whether a specific type improves patient satisfaction. Therefore, the lowest-cost IC is likely the most cost-effective.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

OBJECTIVE

This health technology assessment looked at the effectiveness, safety, and cost-effectiveness of using intermittent catheters to manage chronic urinary retention. It also looked at the budget impact of publicly funding intermittent catheters, as well as patient preferences and values with regard to using intermittent catheters to manage chronic urinary retention.

BACKGROUND

Health Condition

Urinary retention is the inability to voluntarily empty the bladder completely, resulting in the build-up of residual urine in the bladder. This may lead to complications such as urinary incontinence, bladder damage, kidney disease, and urinary tract infections (UTI).[1] Urinary retention can be acute or chronic. People with acute urinary retention cannot urinate even with a full bladder. Acute urinary retention only lasts a short time, can cause discomfort and pain, and is a life-threatening medical condition requiring immediate treatment.[2] Chronic urinary retention can be long-lasting; it is characterized by the painless retention associated with an increased volume of residual urine.[3] Individuals with chronic urinary retention may not be aware of their condition until other problems develop, such as urinary incontinence or UTI.[2] The preferred method of managing chronic urinary retention, intermittent catheterization, is the focus of this health technology assessment.

Clinical Need and Target Population

Chronic urinary retention can occur in a broad set of medical conditions with neurological and non-neurological causes.[3] As a result, it is difficult to accurately estimate the affected population. The most common conditions, described below, are not a comprehensive list, but from these we can roughly estimate that about 33,000 people in Ontario live with chronic urinary retention.

Neurogenic bladder (urinary retention caused by impaired nerve function) typically results from spinal cord injury, spina bifida (a condition that results when the vertebrae do not form properly around the spinal cord during fetal development), multiple sclerosis, stroke, and Parkinson disease. In Ontario, an estimated 33,140 people live with spinal cord injury and around 600 new spinal cord injuries occur every year,[4] and approximately 70% to 84% of individuals with spinal cord injury have some degree of bladder dysfunction.[5] As of 2010, about 3,500 Ontarians live with spina bifida.[6] Approximately 95% of children with spina bifida have some aspects of bladder and bowel dysfunction, and it is estimated that 65% require intermittent catheterization.[7,8] Multiple sclerosis affects close to 23,000 Ontarians,[6] and 50% to 80% of people with multiple sclerosis report symptoms of bladder dysfunction or urinary incontinence.[9] As of 2010, about 94,000 Ontarians live with stroke, and about 15% have urinary tract dysfunction.[5,6,10] An estimated 28,200 Ontarians live with Parkinsonism, and 37% to 72% may have bladder symptoms.[5,6,10] However, only a small proportion of those with urinary symptoms require intermittent catheterization.

Chronic urinary retention can have non-neurological origins as well. A proportion of older men and women have an underactive bladder (idiopathic detrusor underactivity) and may require intermittent catheterization to manage their bladder function. Benign prostatic hyperplasia, a condition common in older men, can also cause chronic urinary retention as the enlarged prostate can block the flow of urine;[2,11] however, the need for intermittent catheterization is

relatively infrequent in this group, in large part due to the availability of other effective treatments.

Current Treatment Options

Intermittent catheterization is the first line of recommended treatment for people with chronic urinary retention.[3,5,11] This is a procedure that people can do at home, in which a tube (catheter) is inserted into the urethra or a surgically created opening (stoma) in the abdomen to drain the bladder. The catheter is immediately removed after the urine has drained. A person with complete urinary retention typically self-catheterizes 4 to 6 times per day to empty the bladder.[9,12]

An alternative method is indwelling catheterization. Indwelling catheters, also known as Foley catheters, remain in the bladder once inserted, either via the urethra or the abdomen (suprapubic catheterization). This type of catheter is commonly used in hospitals and is recommended only for less than 30 days' use.[13] People with indwelling catheters must wear a drainage bag.

Various studies have demonstrated the advantages of intermittent over indwelling catheterization, including a lower risk of urinary tract infections, greater patient autonomy, fewer barriers to intimacy and sexual activity, and improved quality of life.[1,14] Chronic use of indwelling catheters is also associated with complications including urethral trauma, renal failure, and sepsis.[3] In preparing this health technology assessment, we conducted a separate systematic search to identify relevant systematic reviews that compared intermittent and indwelling catheterization in patients requiring long-term bladder management. Appendix 1 presents technical notes on this systematic search and quality ratings for the two systematic reviews we included. One published in 1999 by Shekelle et al[15] examined adults and adolescents with neurogenic bladder due to spinal cord dysfunction. The review identified six cohort studies and reported consistent results that people using intermittent catheterization had fewer infections than those with indwelling catheters. The reviewers commented that no randomized controlled trials (RCTs) were identified because "healthcare providers consider intermittent catheterization so superior to the alternatives that randomization would be unethical."[15] The systematic review conducted by Pannek and Bertschy[16] in 2011 examined urological management in pregnant women with spinal cord injury. The reviewers identified a number of case reports, case series and prospective cohort studies, and reported that UTIs were more common in women with indwelling catheters (100%, 18 out of 18 women) than in those using intermittent catheterization (38.5%, 5 out of 13 women).[16] Two other systematic reviews in 2012 and 2013 attempted to identify randomized or quasi-randomized controlled trials comparing intermittent and indwelling catheterization in populations requiring long-term catheterization; neither review was able to identify any eligible trials.[17,18]

Guidelines around the world recommend intermittent catheterization for people with bladder-emptying dysfunction, especially those in the community setting.[3] The best practice toolkit from the Registered Nurses' Association of Ontario links to guidelines developed by Quality Improvement Scotland in 2004, stating "intermittent catheterization is the preferred alternative to indwelling catheterization for individuals in whom bladder emptying is incomplete."[19] The National Institute for Health and Care Excellence (NICE) in the United Kingdom,[20] the European Association of Urology Nurses,[21] the Centers for Disease Control in the United States,[22] and the American Urological Association[23] have made the same recommendation. Appendix 2 presents a summary of potentially relevant recommendations from selected guidelines on indwelling versus intermittent catheterization in bladder management.

Due to the overwhelming evidence of the benefits of intermittent catheterization over indwelling catheterization for people with chronic urinary retention, this health technology assessment focuses on intermittent catheterization only and compares the different types of intermittent catheters.

Health Technology Under Review

Types of Intermittent Catheters by Coating

Several materials and methods are available for intermittent catheters. To reduce friction and discomfort during insertion and removal, catheters can be coated with a hydrophilic polymer or prelubricated with a gel (this type is known as gel reservoir), or they can be noncoated, which requires the user to apply additional lubricant.

Because of their coated nature, hydrophilic and gel reservoir catheters must be discarded after each use.[11] Hydrophilic catheters, the most common type of coated intermittent catheter, have an outer layer of a polymer called polyvinylpyrrolidone bound to the surface of the catheter.[12] Upon exposure to water, the catheter surface becomes slippery, which replaces the need for an additional water-soluble lubricant. The lubrication remains throughout the entire length of the urethra.[1] The hydrophilic coating can be either pre-activated (ready to use) or activated by adding water at the time of use.[24] Prelubricated gel reservoir catheters are nonhydrophilic in nature but are packaged with a gel lubricant. The user does not apply additional lubricant, thus minimizing contact with the catheter itself during catheterization.

With noncoated intermittent catheters, users typically apply a separate lubricant before insertion. Noncoated catheters are made of a variety of materials including polyvinyl chloride (PVC), PVC-free material, silicone, rubber latex, and Teflon.[12]

PVC noncoated catheters are more prevalent in the United States, whereas coated hydrophilic catheters are more widely used in Europe by both adult and pediatric populations.[25]

Other Variations of Intermittent Catheters

Intermittent catheters can vary in other features as well. Catheters may have a straight tip (Nelaton catheter), curved and tapered tip (Tiemann or Coudé catheter), or an introducer tip which protects the catheter as it bypasses the part of the urethra that is colonized with bacteria. Catheters can also vary in rigidity, and some have an additional protective sleeve and gripper for easier handling. Catheters come in varying diameters and lengths to accommodate users of different ages and gender. Some manufacturers also offer compact versions which extend like a telescope when used. Compact catheters are easier to carry and more discreet: the female versions are smaller than a pen, and the male version is less than half the size of a standard catheter.[26] Another type, “closed-system” catheters, are pre-connected to a urine collection bag. Typically, these catheters are hydrophilic or prelubricated with gel and come in single-use sets to minimize the user’s contact with the catheter and the exposure to urine. In this health technology assessment, we assumed that catheters allowing for a touchless procedure or packaged in a closed-system are prelubricated with gel unless they are specified as having a hydrophilic coating.

In addition to variations in catheters, the technique used for intermittent catheterization can also vary depending on the available toilet facility and supplies. Catheterization can be performed using a sterile technique (i.e., using sterile catheters, gloves, and other supplies) or clean

technique (i.e., clean gloves or hands). An individual may use a sterile single-use catheter with either the sterile or clean technique or reuse a catheter with the clean technique.

Single Use and Reuse of Intermittent Catheters

Although hospitals and long-term care facilities use a new sterile catheter for every catheterization, the reuse of intermittent catheters in the home setting is common in some countries and remains controversial.[21] Reasons for reuse are mainly related to costs and environmental concerns, and reuse is less common in countries that reimburse people for single-use catheters.[27] In Canada, reusing noncoated catheters (i.e., one catheter per day or up to a week) is a common practice,[1] as it is in other countries too (e.g., Australia and the United States.[27] A 2008 survey of Canadians with spinal cord injury revealed that just over half of the surveyed users of noncoated catheters (53%, n = 191) used their catheter only once. Thirty percent (n = 108) of noncoated catheter users reused their catheters more than 9 times. Furthermore, 46% (n = 34) of the sampled hydrophilic catheter users clean and reuse the catheter, even though hydrophilic catheters are only intended for single use.[28]

Reuse of intermittent catheters is an off-label practice, and there are safety concerns that reusing catheters intended for single use can increase the risk of bacterial contamination.[27] Manufacturers place warning labels on the packaging, typically with the word “sterile” and a “do not reuse” symbol, and caution that reuse may cause infection and harm.

This health technology assessment will consider the multiple use of catheters as a comparator to reflect the real-world use of this technology. We use the term *multiple-use* to describe intermittent catheters that people clean and reuse, by choice or necessity.

Guidelines for Intermittent Catheterization

The safest type and application of intermittent catheters (prelubricated or noncoated, single- or multiple-use) remains uncertain. Practice guidelines vary across countries. A patient education brochure created by the Canadian Urological Association indicates that an intermittent catheter can be reused in the home setting for up to a week or until physical damage is noticed; it does not specify the type of intermittent catheter that can be reused.[29] The Canadian Nurse Continence Advisors gives similar instructions.[30] The best practice toolkit from the Registered Nurses’ Association of Ontario links to guidelines developed by Quality Improvement Scotland in 2004, which do not indicate a preference over single-use prelubricated catheters or reused catheters.[19] However, in the United Kingdom, because of regulatory changes on the use of single-use products,[31] guidelines from NICE recommend single-use catheters in primary and community settings.[20] Appendix 3 presents a non-exhaustive list of guideline recommendations and patient education materials on intermittent catheterization practices.

Regulatory Information

Intermittent catheters are Class II devices, which include all devices that penetrate the body through an orifice.[32] Intermittent catheters are licensed for use by Health Canada. Of the 34 intermittent catheter licences in Canada, about 21 are for hydrophilic catheters, involving five or more different manufacturers.

Health Canada’s approved indications are not always specific with regard to the single use of noncoated intermittent catheters.

Manufacturers place warning labels on the packaging, typically with the word “sterile” and a “do not reuse” symbol, and caution that reuse may cause infection and harm.

Ontario Context

A number of federal and provincial programs are in place to support specific groups of people with the costs of their catheter supplies, which can range from $18 to $1,067 per month. Examples include the Ontario Disability Support Program (ODSP, Ministry of Community and Social Services), Workplace Safety and Insurance Board, Veterans Affairs Canada (Disability Benefits), Easter Seals Ontario (for children ages 3 to 18 years), and the Non-insured Health Benefits Program (for First Nations and Inuit). In addition, some people may also be covered by private workplace insurance. Since Ontario’s Assistive Devices Program does not cover urinary catheters, the ODSP is the primary source of funding for adult users in Ontario requiring long-term intermittent catheterization. However, many employed Ontarians who seek income support through ODSP find that they are ineligible and must pay for their catheters out of pocket. The high costs may encourage the improper cleaning and reuse of sterile catheters that are labeled as single-use.

In 2006, the Medical Advisory Secretariat of the Ministry of Health and Long-Term Care in Ontario compared the effectiveness of hydrophilic and nonhydrophilic intermittent catheters with regard to rates of urinary tract infections (UTI) and quality of life.[1] There was insufficient evidence at the time: the five identified randomized controlled trials reported conflicting results with study design limitations.

To better understand the various types of intermittent catheters in the context of current clinical practice in Ontario, this health technology assessment will first compare the safety and effectiveness of single-use and multiple-use catheters, and then examine specific types of single-use catheters. Our target population is people living in the community (i.e., people who are not hospitalized), based on advice from Ontario clinical experts (Blayne Welk, MD, and Dean Elterman, MD, email communication, November 16, 2017), as people living in the community have the greatest funding needs related to intermittent catheters.

CLINICAL EVIDENCE

Research Questions

- What are the effectiveness and safety of any type of single-use intermittent catheter (IC) compared to multiple-use ICs in the outpatient setting?
- Among single-use ICs, what are the effectiveness and safety of hydrophilic ICs compared to gel reservoir ICs or noncoated ICs in the outpatient setting?
- Among single-use ICs, what are the effectiveness and safety of gel reservoir ICs compared to noncoated ICs in inpatient settings (i.e., inpatient and long-term care facilities), given that studies in the outpatient setting are unavailable?

Note: Whenever possible, we gathered evidence that directly examines intermittent catheters in an outpatient setting; if such evidence was unavailable, we included studies conducted in other settings such as inpatient or long-term care.

Methods

We developed the research questions in consultation with patients, health care providers, clinical experts, and other health system stakeholders.

Clinical Literature Search

We performed a literature search on October 13, 2017, to retrieve studies published from January 1, 1990, to the search date. We used the Ovid interface in the following databases: MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Health Technology Assessment Database, and National Health Service Economic Evaluation Database (NHS EED). We used the EBSCOhost interface to search the Cumulative Index to Nursing & Allied Health Literature (CINAHL).

Medical librarians developed the search strategy using controlled vocabulary (i.e., Medical Subject Headings) and relevant keywords. The final search strategy was peer reviewed using the PRESS Checklist.[33] We created database auto-alerts in MEDLINE, Embase, and CINAHL and monitored them for the duration of the assessment period.

We performed targeted grey literature searching of health technology assessment agency sites and clinical trial registries. See Appendix 4 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. We also examined reference lists for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications

- Studies published between January 1, 1990, and October 13, 2017. The publication period was chosen on advice from an Ontario clinical expert that data prior to 1990 are unlikely relevant to today's catheter material (Blayne Welk, MD, email communication, October 3, 2017)
- Studies in auto-alert updates until February 2018
- Randomized controlled trials (RCTs), randomized crossover studies, cohort and case-control studies that directly compared different types of intermittent catheters
- Study participants of all ages requiring long-term use of intermittent catheters (> 28 days)
- Studies that directly examined intermittent catheters in an outpatient setting; if such evidence was unavailable, we included studies conducted in inpatient settings such as inpatient or long-term care

Exclusion Criteria

- Studies with no comparison between different types of intermittent catheters
- Populations involving indwelling and suprapubic catheterization
- Populations in inpatient settings and long-term care facilities, unless evidence from home and community-dwelling populations was unavailable
- Cross-sectional studies, noncomparative studies, case studies, case series, editorials, commentaries, and review articles
- Animal and in vitro studies

Outcomes of Interest

Symptomatic urinary tract infections (UTIs) and urethral trauma (hematuria) are the most common complications of intermittent catheterization, and thus are the primary outcome variables for this review.[11] We used the definitions of UTI provided in each included study; however, we recognize that definitions vary across studies and do not necessarily conform to the Infectious Diseases Society of America 2009 Consensus Statement, which provides the most up-to-date and comprehensive definition of catheter-associated UTI.[34] We separated measures of hematuria into microscopic and gross hematuria. Microscopic hematuria is determined by the presence of blood cells in urine samples observed by microscope, and gross hematuria (also called macroscopic hematuria or urethral bleeding) refers to visible blood in the urine. Other serious adverse events related to intermittent catheterization, including stricture formation, the creation of false passage, bladder stones, epididymitis/orchitis, drug-resistant UTI, bacteremia, and urosepsis are secondary outcomes of interest. Patient preference and satisfaction are also reported. Bacteriuria (bacteria in the urine) in the absence of clinical symptom is not an outcome of interest since this indicator has minimal clinical impact.[35]

Data Extraction

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

- Study characteristics (i.e., citation information, study type, setting, population, intervention, comparator, study duration, and geographical location)

- Population (i.e., number enrolled and completed, reasons for drop out, inclusion and exclusion criteria, baseline demographic characteristics)
- Methods (i.e., type of catheter, coating, brand, and usage)
- Outcomes (i.e., outcomes measured, outcome definition, unit of measurement, upper and lower limits [for scales], and time points at which the outcome was assessed)
- Risk of bias (i.e., randomization sequence generation, allocation concealment, blinding, reporting of missing data, reporting of outcomes, and conflict of interest)

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

Statistical Analysis

We performed a quantitative synthesis of the individual studies using Review Manager, version 5.3.[36]

Summary measures were expressed as the risk ratio for dichotomous data and mean difference for continuous data using the Mantel-Haenszel method. Statistical heterogeneity was assessed using the I^2 statistic in accordance with the Cochrane Handbook for Systematic Reviews of Interventions: low heterogeneity (0%–40%), moderate (30%–60%), substantial (50%–90%), and considerable (75%–100%).[37] Results were pooled using a random-effects model if studies were heterogeneous. Graphs of the forest plots were also examined. A *P* value of .05 or less was considered statistically significant for the overall effect estimate.

Where appropriate (based on clinical, methodological, and statistical heterogeneity), we conducted subgroup and sensitivity analyses for the following:

- Types of single-use ICs such as hydrophilic versus noncoated
- Adult (18 years and older) versus children (under 18 years of age)
- Neurogenic versus non-neurogenic bladder
- Urethral versus non-urethral intermittent catheterization

Critical Appraisal of Evidence

We assessed risk of bias in randomized controlled trials using the Cochrane Risk of Bias tool.[38] Risk of bias in nonrandomized controlled trials was assessed by the Newcastle-Ottawa Assessment Scale.[39] Appendix 5 presents the critical appraisal of included studies.

We evaluated the quality of the body of evidence for each outcome according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Handbook.[40] The body of evidence was assessed based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The quality score reflects our assessment of the reliability of the evidence.

Expert Consultation

We sought expert feedback on intermittent catheterization for populations with chronic bladder dysfunction. The consultation included urologists, a nurse educator, researchers, and health economists. The role of the expert advisors was to contextualize the evidence, teach us about the technology, provide context for intermittent catheterization in Ontario, and advise on the scope and methods guiding the clinical evidence review of the health technology assessment.

Results

Literature Search

The literature search yielded 544 citations published between January 1, 1990, and October 13, 2017, after removing duplicates. Fourteen studies (all randomized controlled trials including five randomized crossover studies) met the inclusion criteria. We found six potentially relevant systematic reviews[11,15,41-44] and one potentially relevant health technology assessment.[1] However, they did not fully meet the inclusion criteria to address our research questions (e.g., examined ICs in all settings, compared only hydrophilic and nonhydrophilic ICs, or only compared single-use and multiple-use ICs) and were thus excluded. One potentially relevant systematic review was withdrawn from publication.[24] We hand-searched the reference lists of the included studies and the systematic reviews, along with health technology assessment websites and other sources, to identify additional relevant studies. See Appendix 6 for a list of studies excluded after full-text review.

Figure 1 presents the flow diagram for the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).

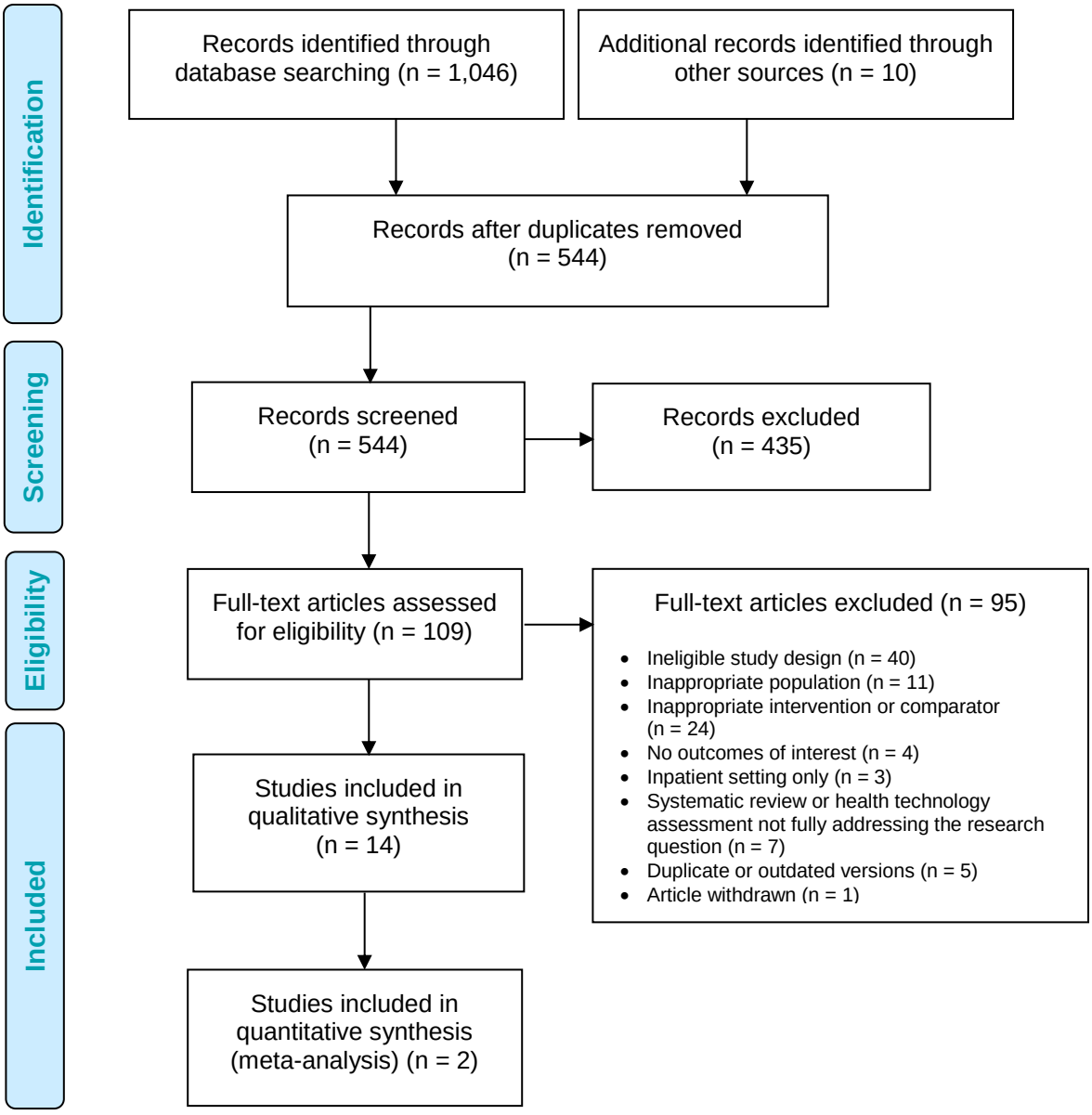

Figure 1: PRISMA Flow Diagram—Clinical Search Strategy

Source: Adapted from Moher et al.[45]

Characteristics of Included Studies

Fourteen randomized controlled trials were included,[7,25,46-57] five of which had a crossover design.[7,47,48,50,56] No eligible cohort and case-control studies were identified. Eight studies involved adults with neurogenic bladder, with varying proportions of participants with spinal cord injury.[49,51-57] Three of the eight studies had male participants only.[51,54,55] Four other studies examined children with neurogenic bladder due to spina bifida or myelomeningocele (the most serious form of spina bifida).[7,25,47,50] Two additional studies examined elderly men; one study involved participants with prostate enlargement,[48] and the other examined a mixed group with unspecified origins of urinary retention.[46] Seven studies took place in outpatient community settings.[7,25,47,48,50-52] Two studies examined inpatients who transitioned into outpatient settings

during the study period.[53,54] We included four studies in inpatient settings (rehabilitation hospital)[49,55-57] and one study in a long-term care facility[46] to obtain evidence on gel reservoir ICs and noncoated ICs that were reused up to a week. Studies were conducted in North America and Europe. The length of follow-up varied across studies, from 4.5 days to 1 year.

Seven studies compared a type of single-use IC with multiple-use noncoated ICs.[7,46-51] Four studies compared hydrophilic with single-use noncoated ICs,[25,52-54] and two studies compared gel reservoir with single-use noncoated ICs.[56,57] One additional study had a three-way comparison involving hydrophilic, gel reservoir, and single-use noncoated ICs.[55]

Thirteen studies reported data on UTI, although the definition and outcome measures of UTI varied across studies.[25,46-57] Some studies reported additional clinical outcomes and adverse events including hematuria,[25,47,48,51,53-56] stricture formation,[25,54] false passage,[25] and epididymitis.[48,51] A number of studies also reported patient preferences using various questionnaires that are not standardized or validated.[7,25,47,48,53-56] Table 1 presents the characteristics of the included studies.

Table 1: Characteristics of Included Studies

Author, Year	Study Design	Sample Size (Intervention/Control), Population, Country, Setting	Intervention	Control	Relevant Outcomes	Follow-Up
Single-use vs. multiple-use intermittent catheters						
Chick et al, 2013[7]	Randomized crossover	N = 51 (in both groups) Children with spina bifida[a] Alberta, Canada Community setting	Hydrophilic (brand name: SpeediCath)	Noncoated PVC, reuse up to 1–2 days[b]	Patient preference	1 year (6 months × 2 arms)
Duffy et al, 1995[46]	Randomized controlled trial	N = 80 (42/38) Older male in nursing home (mean age 72 years) United States Long-term care setting	Single-use noncoated Sterile technique: used sterile equipment, kept sterile field, cleaned meatus	Noncoated, reuse up to a week Clean technique: washed with mild soap and running water, dried on a clean, lint-free towel, and stored at the bedside in a clean, dry container	UTI data collected at day 15 (N = 80)	90 days
Kiddoo et al, 2015[47]	Randomized crossover	N = 66 (in both groups) Children with spina bifida[a] Alberta, Canada Community setting	Hydrophilic (brand name: SpeediCath); catheterize at least 3 times daily	Noncoated PVC, reuse daily at least 5 times/day Washed with soap and water, air dried after each use	UTI, hematuria, patient preference	48 weeks (24 weeks × 2 arms)
Pachler and Frimodt-Moller, 1999[48]	Randomized crossover	N = 43 (in both groups) Older males with prostate enlargement Denmark Community setting	Hydrophilic (brand name: LoFric); catheterized a mean of 3.8 times/day	Noncoated PVC (brand name: Mentor) with added gel lubricant; reuse daily; catheterized mean (range) of 4.0 (2–8) times/day After each use, rinse under lukewarm water and left to dry on a clean towel	UTI, hematuria, epididymitis/ orchitis, patient preference	6 weeks (3 weeks × 2 arms)
Prieto-Fingerhut et al, 1997[49]	Randomized controlled trial	N = 29 (14/15) Hospitalized males and females with spinal cord injury United States Inpatient setting (rehabilitation hospital)	Gel reservoir (brand name: O'Neil), plastic catheter in closed sterile system; catheterized every 4–6 hours by nursing staff	Noncoated rubber, clean after each use, used for 1 week then discarded; catheterized every 4–6 hours by nursing staff	UTI	3 months

Author, Year	Study Design	Sample Size (Intervention/Control), Population, Country, Setting	Intervention	Control	Relevant Outcomes	Follow-Up
Schlager et al, 2001[50]	Randomized crossover	N = 10 (in both groups) Children with neurogenic bladder (myelomeningocele) United States Community setting	Single-use noncoated (brand name: Mentor), plastic; catheterized 4 times/day	Multiple-use noncoated (brand name: Mentor), plastic; catheterized 4 times/day; catheter discarded after being reused 5 times[b]	UTI	8 months (4 months × 2 arms)
Vapnek et al, 2003[51]	Randomized controlled trial	N = 62 (31/31) Males with neurogenic bladder United States Community setting	Hydrophilic (brand name: LoFric)	Noncoated PVC, reuse daily for 4–5 times/day	UTI, hematuria, epididymitis	1 year
Hydrophilic vs. single-use noncoated intermittent catheters						
Cardenas and Hoffman, 2009[52]	Randomized controlled trial	N = 56 (28/28) Adults with spinal cord injury United States Community setting	Hydrophilic (brand name: LoFric)	Single-use noncoated	UTI	1 year
Cardenas et al, 2011[53]	Randomized controlled trial	N = 224 (108/116) Adults with acute spinal cord injury and with neurogenic bladder North America Mixed setting: everyone started in inpatient (acute care or rehab), moved to outpatient during study	Hydrophilic (brand name: SpeediCath)	Single-use noncoated PVC (brand name: Conveen) Used with gel supplied in individual-use sterile sachets.	UTI, hematuria, patient preference	6 months

Author, Year	Study Design	Sample Size (Intervention/Control), Population, Country, Setting	Intervention	Control	Relevant Outcomes	Follow-Up
DeFoor et al, 2017[25]	Randomized controlled trial	N = 78 (37/41) Children with neurogenic bladder (i.e., myelomeningocele, spina bifida) United States Community setting	Hydrophilic (brand name: LoFric)	Single-use noncoated (brand name: Coloplast Self-Cath), also supplied standard sterile, greaseless, water-soluble lubricant	UTI, hematuria, stricture, false passage, patient preference	1 year
De Ridder et al, 2005[54]	Randomized controlled trial	N = 123 (61/62) Adult males with neurogenic bladder (recent spinal cord injury) Europe multicentre Mixed setting: everyone started in inpatient (acute care or rehab), moved to outpatient during study	Hydrophilic (brand name: SpeediCath), ready to use	Single-use noncoated, lubricated manually with a water-soluble lubricant gel	UTI, hematuria, stricture, patient preference	1 year
Sarica et al, 2010[55]	Randomized controlled trial	N = 25 (in all groups)[c] Hospitalized spinal cord injury (male adults older than 18 years) Turkey Inpatient setting (rehabilitation hospital)	Arm 1: single-use noncoated Arm 2: hydrophilic (Rüsch FloCath hydrophilic catheter, in which water was added 30 seconds prior to use) Arm 3: gel reservoir		UTI, hematuria, patient preference	18 weeks (6 weeks × 3 arms)
Gel reservoir vs. single-use noncoated intermittent catheters						
Giannantoni et al, 2001[56]	Randomized crossover	N = 18 (in both groups) Hospitalized spinal cord injury patients (male and female) Italy Inpatient setting (rehabilitation hospital)	Gel reservoir	Single-use noncoated	UTI, patient preference	14 weeks (7 weeks × 2 arms)

Author, Year	Study Design	Sample Size (Intervention/Control), Population, Country, Setting	Intervention	Control	Relevant Outcomes	Follow-Up
Quigley and Riggin, 1993[57]	Randomized controlled trial	N = 30 (16/14) Adults with neurogenic bladder (stroke and spinal cord injury patients) United States Inpatient setting (rehabilitation hospital)	Gel reservoir (closed system)	Single-use noncoated	UTI	4.5 days (108 hours)
Sarica et al, 2010[55]	Randomized controlled trial	N = 25 (in all groups)[c] Hospitalized spinal cord injury (male adults older than 18 years old) Turkey Inpatient setting (rehabilitation hospital)	Arm 1: single-use noncoated Arm 2: hydrophilic (Rüsch Flocath hydrophilic catheter, in which water was added 30 seconds prior to use) Arm 3: gel reservoir		UTI, hematuria, patient preference	18 weeks (6 weeks × 3 arms)

Abbreviations: PVC, polyvinyl chloride; UTI, urinary tract infection.
[a]The study population examined by Chick et al[7] is a subset of the population examined by Kiddoo et al.[47]
[b]For the purpose of analysis, we treated the reuse as approximately 1 catheter per day.
[c]The study was a randomized controlled trial with a crossover element: each participant went through all 3 arms in a randomized order.

Urinary Tract Infection

Thirteen of 14 studies measured UTI (Table 2).[25,46-57] The definitions of UTI varied across studies but mostly consisted of laboratory proof of bacterial presence in the urine along with at least one clinical symptom. Studies reported different measures of UTI, such as the number of patients with one or more UTIs, average person-weeks of UTI, average number of UTI infections per patient per month, and total number of UTI infections. Due to the variety of outcome measures, we performed a meta-analysis using the most commonly reported measure: the number of patients with one or more UTIs. Studies that did not report the number of patients are not included in the meta-analysis, but their results are summarized in Table 2.

Any Type of Single-Use Catheter Versus Any Type of Multiple-Use Catheter

Six studies compared outcomes of using a type of single-use IC with a multiple-use IC.[46-51] Most studies did not find a difference in UTI between single-use versus multiple-use ICs. Pachler and Frimodt-Moller,[48] Schlager et al,[50] and Prieto-Fingerhut et al[49] reported equal or comparable numbers of patients with UTI in each group. Vapnek et al[51] did not find a statistically significant difference in the number of UTI infections per patient per month, and Duffy et al[46] did not find a significant difference in the incidence of UTI between the two groups.

Conversely, Kiddoo et al[47] reported significantly more person-weeks of UTI among people using hydrophilic catheters, compared to people who reused one catheter per day ($P < .001$). This finding suggests that people using hydrophilic catheters had worse UTI outcomes compared to people who reused one catheter per day. However, the authors noted that people using hydrophilic catheters may be more alert to UTI symptoms due to the change in their routine (they had previously used noncoated catheters), as there were no differences between the two groups regarding other indicators of UTI, such as white blood cells in the urine, fever, or treatment with antibiotics.[47] Overall, there does not seem to be a difference in UTI incidence between single-use and multiple-use ICs.

Four of the six studies reported the number of patients with UTI.[46,48-50] Of these, two studies[48,50] were not included in our meta-analysis on the basis of study design (crossover trial). Crossover trials can add bias to the pooled estimate due to potential carry-over effects. Since these crossover trials did not have a washout period and did not provide interim data before the treatment crossover, the study results measured after the crossover were not included in the meta-analysis. The pooled risk ratio demonstrated no significant difference in the rate of UTIs when single-use catheters were compared with multiple-use (RR = 0.98, 95% CI 0.70–1.39) (Figure 2).

Hydrophilic Versus Noncoated Catheters (Single-Use)

Five studies compared single-use hydrophilic with single-use noncoated IC.[25,52-55] In summary, some studies found a benefit in reducing UTI with hydrophilic IC, while other studies found no difference. Two studies conducted by Cardenas and colleagues[52,53] reported similar numbers of patients with UTI and no significant difference in UTI incidence. Conversely, De Ridder et al[54] reported a significantly greater number of patients with UTI in the single-use noncoated IC group, showing better outcome with the hydrophilic IC ($P = .02$). DeFoor et al[25] examined children with neurogenic bladder and found similar results comparing the number of UTI episodes per person-year ($P = .003$); however, hydrophilic ICs had no benefit in the subgroup who performed catheterization via abdominal wall stomas ($P = .4$). Sarica et al[55] reported one patient with UTI from the hydrophilic IC group and four patients from the noncoated group, but the difference was not statistically significant.

Four of the five studies reported the number of patients with UTI.[25,52,54,55] We did not include the study by Sarica et al[55] in the meta-analysis due to the heterogeneity in study design (three-arm comparison); the data were not available in a format that could be aggregated with other studies. The study by De Ridder et al[54] was conducted in a mixed setting (all participants started as inpatients but became outpatients during the study); as a result, we excluded that study from the main analysis but included it in the sensitivity analysis. Results from the two remaining studies[25,52] were aggregated to obtain a pooled risk ratio (Figure 3). The pooled estimate suggested the possibility of benefit, though the confidence interval was very wide (RR = 0.66, 95% CI 0.24–1.81). However, in the sensitivity analysis where we included the mixed-setting study, the pooled estimate was more precise and significant, indicating better outcomes for hydrophilic ICs (RR = 0.78, 95% CI 0.64–0.96) (Figure 4).

Gel Reservoir Versus Noncoated Catheters (Single-Use)

Three studies compared single-use gel reservoir ICs with single-use noncoated IC in an inpatient setting. Giannantoni et al[56] found that individuals using gel reservoir ICs had a significantly lower number of urinary tract infections compared to those using single-use noncoated IC (P = .03). Quigley and Riggin[57] reported zero patients with UTI in the gel reservoir IC group, and one patient in the single-use noncoated IC group. Sarica et al[55] reported one patient with UTI in the gel reservoir IC group and four patients in the noncoated group, but the difference was not statistically significant.

The study by Sarica et al[55] was methodologically different from the other studies, as it included a three-arm comparison, each group containing multiple interventions. Due to its methodological heterogeneity, this study was not included in the meta-analysis. The results from the two remaining studies could not be aggregated because they did not report a common outcome measure for UTI.

Table 3 presents the GRADE evidence profile for all studies that reported any measurement of UTI, and Table 4 presents the GRADE evidence profile for outpatient studies used in the meta-analysis (i.e., non-crossover trials that reported the number of outpatients with UTI).

Table 2: Urinary Tract Infection in Studies Comparing Types of Intermittent Catheters

Author, Year	Comparison	Definition	Outcomes
Any type of single-use vs. any type of multiple-use intermittent catheters			
Duffy et al, 1995[46]	Single-use (noncoated) vs. multiple-use (1/week)	Meeting 1 of 3 criteria: • Presence of > 100,000 colonies/mL of a single organism coupled with 1 or more signs or symptoms of UTI • Bacteriuria of a lesser colony count coupled with 1 or more symptoms or signs of UTI • Presence of 1 or more signs or symptoms of UTI coupled with > 10 white blood cells/high power field on urinalysis Signs and symptoms: fever, dysuria, urgency, frequency, costovertebral angle tenderness, altered mental status, change in activity level, abrupt onset of incontinence, hematuria, or cloudy, foul smelling urine containing mucus	Number of patients with 1 or more UTI measured at day 15: **Single-use noncoated**: n = 22 (52%) **Multiple-use (1/week):** n = 20 (53%) (*P* = NR) UTI incidence (number of UTI episodes/number of days at risk): **Single-use noncoated**: 0.013 UTI/day **Multiple-use (1/week)**: 0.011 UTI/day (*P* = NS)
Kiddoo et al, 2015[47]	Single-use (hydrophilic) vs. multiple-use (1/day)	Positive leukocytes plus fever, flank pain, increased incontinence, malaise, or cloudy or odorous urine requiring antibiotic treatment	Mean person-weeks of UTI: **Hydrophilic**: 3.42 ± 4.67 person-weeks **Multiple-use (1/day)**: 2.20 ± 3.23 person-weeks (*P* < .001)
Pachler and Frimodt-Moller, 1999[48]	Single-use (hydrophilic) vs. multiple-use (1/day)	Cystitis (significant bacteriuria and discomfort/suprapubic pain and/or fever)	Number of patients with cystitis: **Hydrophilic:** n = 1 (3.1%) **Multiple-use (1/day):** n = 1 (3.1%) (*P* = NR)
Prieto-Fingerhut et al, 1997[49]	Single-use (gel reservoir) vs. multiple-use (1/week)	Definition of UTI recommended by the National Institute on Disability and Rehabilitation Research: Bacteriuria (100 bacteria/mL of urine) with tissue invasion and resultant tissue response with signs and/ or symptoms	Number of patients with 1 or more UTI over 3-month follow-up; number of infections: **Gel reservoir:** n = 8 (57%); 11 symptomatic infections **Multiple-use (1/week):** n = 9 (60%); 12 symptomatic infections (*P* = NR)
Schlager et al, 2001[50]	Single-use (noncoated) vs. multiple-use (1/day)	Bacteriuria (≥ 10,000 colony forming units per milliliter of urine obtained by bladder catheterization) with fever, abdominal pain, change in continence pattern, or change in color, odor, or urine	Number of patients with 1 or more UTI over 4-month follow-up; number of infections: **Single-use noncoated**: n = 2 (20%); 2 infections in total (1/person) **Multiple-use (1/day):** n = 2 (20%); 2 infections in total (1/person) (*P* = NR)

Author, Year	Comparison	Definition	Outcomes
Vapnek et al, 2003[51]	Single-use (hydrophilic) vs. multiple-use (1/day)	Bacterial colony count of ≥ 100,000 colony forming units and at least 1 clinical symptom such as fever, chills, malodorous urine, increased spasticity or malaise; positive urine culture without clinical symptoms are not considered UTI	Mean number of UTI per patient per month: **Hydrophilic:** 0.13 ± 0.18 UTI/month **Multiple-use (1/day):** 0.14 ± 0.21 UTI/month (*P* = NS)
Hydrophilic vs. noncoated (single-use) intermittent catheters			
Cardenas and Hoffman, 2009[52]	Hydrophilic vs. single-use noncoated	≥ 100,000 colony forming units/mL plus at least 1 sign or symptom suggestive of UTI	Number of patients with 1 or more UTI over 1-year follow-up: **Hydrophilic:** n = 12 (54%) **Single-use noncoated:** n = 14 (61%) (*P* = NS) Mean total number of UTIs over 1-year follow-up: **Hydrophilic**: 1.18 ± 1.3 **Single-use noncoated**: 1.00 ± 1.0 (*P* = NS)
Cardenas et al, 2011[53]	Hydrophilic vs. single-use noncoated	Antibiotic treatment has been prescribed Bacteriuria ≥ 100 colony forming units/mL At least 1 of 7 UTI symptoms based on consensus guidelines (fever, autonomic dysreflexia [sweating, bradycardia, blood pressure elevation], increased spasticity, discomfort or pain over the kidney or ladder or during micturition, onset and/or increase in incontinence episodes, cloudy urine with increased odor, malaise, lethargy, or sense of unease) Dipstick test positive for leukocyte esterase	Symptomatic UTI incidence (total number of UTIs in the group/total number of months in the period): **Hydrophilic:** 0.198 UTI/month **Single-use noncoated:** 0.218 UTI/month (*P* = NS)
De Ridder et al, 2005[54]	Hydrophilic vs. single-use noncoated	A clinical infection with symptoms of UTI and for which treatment was prescribed	Number of patients with 1 or more UTI over 1-year follow-up: **Hydrophilic:** n = 39 (64%) **Single-use noncoated:** n = 51 (82%) (*P* = .02) Median number of UTI per 1,000 catheter days: **Hydrophilic**: 5.4 UTI/1,000 catheter days **Single-use noncoated**: 8.1 UTI/1,000 catheter days (*P* = NS)

Author, Year	Comparison	Definition	Outcomes
DeFoor et al, 2017[25]	Hydrophilic vs. single-use noncoated	Positive urine culture of > 50,000 colony forming units/mL of a single dominant organism associated with at least 1 of the following symptoms: fever, suprapubic pain, flank pain, worsening incontinence, malaise, cloudy/malodorous urine, and/or pain with urethral or stomal catheterization	Number of patients with 1 or more UTI over 1-year follow-up; UTI episodes per person-year: **Hydrophilic:** n = 2 (5%); 2 episodes of UTI per person-year **Single-use noncoated:** n = 7 (17%); 17 episodes of UTI per person-year (*P* = .003) Abdominal wall stomas subgroup: number of patients with 1 or more UTI: **Hydrophilic**: n = 2 out of 15 (13%); **Single-use noncoated**: n = 5 out of 15 (33%); (*P* = .4)
Sarica et al, 2010[55]	Hydrophilic vs. single-use noncoated	Bacterial colony count of ≥ 100,000 colony forming units and at least 1 clinical symptom, such as fever, chills, malodorous urine, increased spasticity, or malaise	Number of patients with 1 or more UTI over 6-week follow-up: **Hydrophilic:** n = 1 (4%) **Single-use noncoated**: n = 4 (16%) (*P* = NS)
Gel reservoir vs. noncoated (single-use) intermittent catheters			
Giannantoni et al, 2001[56]	Gel reservoir vs. single-use noncoated	Cloudy and odorous urine, onset of urinary incontinence, increased spasticity, autonomic dysreflexia, increased sweating and malaise or a sense of unease associated with pyuria, and significant bacteriuria	Number of UTI infections (not patients)[a]: **Gel reservoir**: 4 infections (7.4%) **Single-use noncoated**: 12 infections (22.2%) (*P* = .03)
Quigley and Riggin, 1993[57]	Gel reservoir vs. single-use noncoated	Onset of clinical signs and symptoms of urinary tract infection (i.e., fever, dysuria, costovertebral tenderness, suprapubic tenderness) after catheterization and in conjunction with colony counts of > 100,000 organisms per ml or visible organisms on gram smear of unspun fresh urine	Number of patients with 1 or more UTI over 4.5 days of follow-up: **Gel reservoir:** n = 0 **Single-use noncoated:** n = 1 (7%) (*P* = NR)[b]
Sarica et al, 2010[55]	Gel reservoir vs. single-use noncoated	Bacterial colony count of ≥ 100,000 colony forming units and at least 1 clinical symptom, such as fever, chills, malodorous urine, increased spasticity or malaise	Number of patients with 1 or more UTI over 6-week follow-up: **Gel reservoir**: n = 1 (4%) **Single-use noncoated**: n = 4 (16%) (*P* = NS)

Abbreviations: NR, not reported; NS, not significant; UTI, urinary tract infection; vs., versus.
[a]The original publication did not clearly report whether the UTI outcome reported was the number of UTI infections or the number of patients with UTI. Study author was emailed for clarification and we did not receive a reply. Based on the percentages given, we deemed that the UTI outcome reported was the number of infections, not individuals.
[b]We are aware that the data are different from those presented in the Cochrane systematic review conducted by Prieto et al[24] as well as the subsequent correction published by Christison et al.[58] On examining the original article, we deemed that only one patient from the single-use noncoated group was diagnosed with UTI within the study period; therefore, we did not count the extra case diagnosed after the end of study period. We also decided to use greater denominators according to the intent-to-treat principle, as follows: gel reservoir cases = 0 out of 16, single-use noncoated cases = 1 out of 14.

Figure 2: Risk Ratio for Urinary Tract Infection in Outpatient Setting Studies Comparing Single-Use Versus Multiple-Use Intermittent Catheters

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.
Data sources: Duffy et al, 1995[46]; Prieto-Fingerhut et al, 1997.[49]

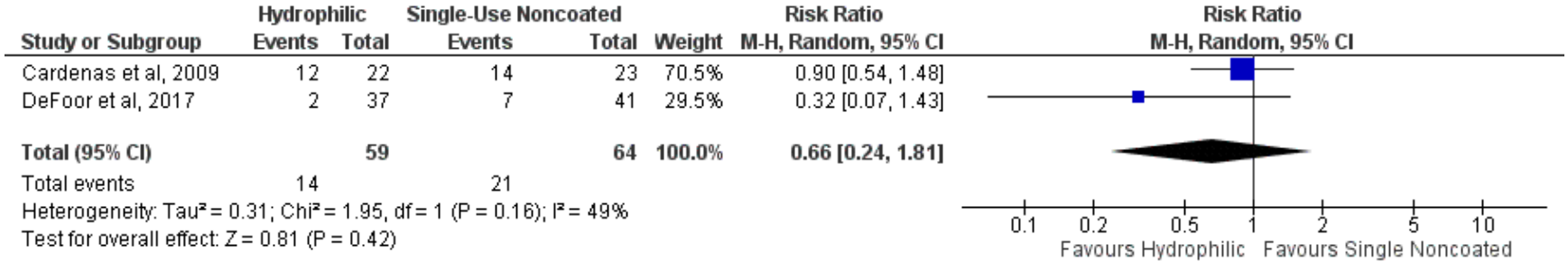

Figure 3: Risk Ratio for Urinary Tract Infection in Outpatient Setting Studies Comparing Hydrophilic Versus Noncoated Intermittent Catheters (Single-Use)

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.
Data sources: Cardenas et al, 2011[53]; DeFoor et al, 2017.[25]

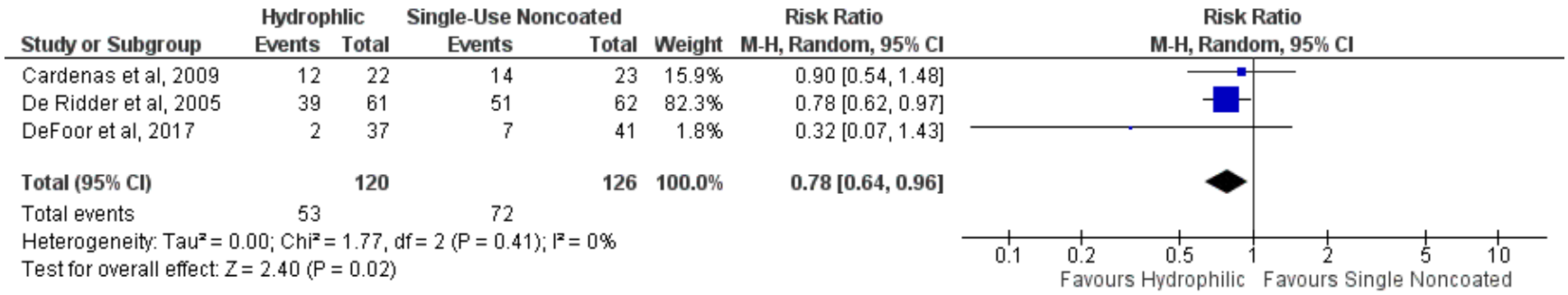

Figure 4: Risk Ratio for Urinary Tract Infection Comparing Hydrophilic Versus Noncoated Intermittent Catheters (Single-Use): Sensitivity Analysis Incorporating One Mixed-Setting Study

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.
Note: DeRidder et al[54] was a mixed-setting study.
Data sources: Cardenas et al, 2011[53]; De Ridder et al, 2005[54]; DeFoor et al, 2017.[25]

Table 3: GRADE Evidence Profile for Urinary Tract Infection (All Measurements in Narrative Data)

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Single-use vs. multiple-use intermittent catheters							
6 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	No other considerations	⊕⊕ Low
Hydrophilic vs. noncoated (single-use) intermittent catheters							
5 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	No other considerations	⊕⊕ Low
Gel reservoir vs. noncoated (single-use) intermittent catheters							
3 (RCTs)[c]	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[d]	Serious limitations (–1)[b]	Undetected	No other considerations	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; IC, intermittent catheter; RCT, randomized controlled trial; vs. versus.
[a]High attrition, potential bias with crossover study (no washout period).
[b]Small sample sizes and wide confidence interval.
[c]Sarica et al[55] is evaluated twice in both hydrophilic versus single-use noncoated ICs and gel reservoir versus single-use noncoated ICs.
[d]Adults from inpatient population (not outpatients, the population of interest).

Table 4: GRADE Evidence Profile for Urinary Tract Infection (Outpatient Studies Used in Meta-analysis Only)

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Single-use vs. multiple-use intermittent catheters							
2 (RCTs)	No serious limitations	No serious limitations	Serious limitations (–1)[a]	Serious limitations (–1)[b]	Undetected	No other considerations	⨁⨁ Low
Hydrophilic vs. noncoated (single-use) intermittent catheters							
2 (RCTs)	Serious limitations (–1)[c]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	No other considerations	⨁⨁ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial; vs, versus.
[a]The only two studies eligible for meta-analysis are from inpatient acute care and long-term care settings; there is a lack of data in the outpatient setting.
[b]Small sample sizes and wide confidence interval.
[c]High attrition and differential dropout between groups in DeFoor et al.[25]

Gross Hematuria

Seven of 14 studies reported gross (macroscopic) hematuria or visible bleeding to represent urethral trauma.[25,48,51,53-56] Studies used different terms such as urethral bleeding, macroscopic and gross hematuria to describe the same condition. Table 5 presents the data on gross hematuria.

Single-Use Versus Multiple-Use Catheters

Two studies reported visible bleeding in comparing a single-use IC with a multiple-use IC.[48,51] The number of individuals with gross hematuria was comparable between two groups in both studies. Vapnek et al[51] reported 1 person (3.2%) having gross hematuria from each group of the study, and Pachler and Frimodt-Moller[48] reported 2 patients (6.3%) with visible bleeding from each group of the study. We did not conduct a meta-analysis since Pachler and Frimodt-Moller[48] used a crossover design and did not provide data for the study period before the treatment crossover.

Hydrophilic Versus Noncoated Catheters (Single-Use)

Four studies compared visible bleeding in people using single-use hydrophilic versus single-use noncoated ICs, and most studies suggested no difference between the ICs.[25,53-55] De Ridder et al[54] did not find a statistically significant difference in the number of patients with urethral bleeding. DeFoor et al[25] found no hematuria in either group. Sarica et al[55] reported 1 patient with gross hematuria who used single-use noncoated IC and zero patients in the hydrophilic group. On the contrary, Cardenas et al[53] noted a significantly greater incidence of bleeding in the hydrophilic group compared to the group that reused catheters up to 1 day ($P = .05$). The authors postulated that this surprising finding was a result of technical inexperience of the medical staff at the beginning of the study, not a result of the hydrophilic IC.

We did not perform a meta-analysis for the comparison of gross hematuria between hydrophilic versus single-use noncoated ICs. Cardenas et al[53] and De Ridder et al[54] were conducted in mixed settings; DeFoor et al[25] reported zero events in both study arms, and the three-arm comparison in Sarica et al[55] was too methodologically different from the other studies to allow us to obtain a pooled estimate.

Gel Reservoir Versus Noncoated Catheters (Single-Use)

Two studies compared the incidence of visible bleeding in people using gel reservoir ICs and single-use noncoated ICs in an inpatient setting.[55,56] Giannantoni et al[56] reported 2 cases (11%) of urethral bleeding in the single-use noncoated IC group, and zero cases in the hydrophilic IC group (*P* value not reported). Sarica et al[55] reported 1 patient (4%) with urethral bleeding who used single-use noncoated ICs, and zero patients in the gel reservoir group (*P* value not reported). We did not conduct a meta-analysis due to methodological heterogeneity (crossover design and three-arm RCT).

Table 6 presents the GRADE evidence profile for gross hematuria.

Table 5: Gross Hematuria in Studies Comparing Types of Intermittent Catheters

Author, Year	Comparison	Definition/Terms Used	Outcomes
Single-use vs. multiple-use intermittent catheters			
Vapnek et al, 2003[51]	Single-use (hydrophilic) vs. multiple-use (1/day)	Gross hematuria	**Hydrophilic**: n = 1 (3.2%) **Multiple-use (1/day)**: n = 1 (3.2%) (*P* = NR)
Pachler and Frimodt-Moller, 1999[48]	Single-use (hydrophilic) vs. multiple-use (1/day)	Bleeding	**Hydrophilic:** n = 2 (6.3%) **Multiple-use (1/day):** n = 2 (6.3%) (*P* = NR)
Hydrophilic vs. noncoated (single-use) intermittent catheters			
Cardenas et al, 2011[53]	Single-use hydrophilic vs. single-use noncoated	Urethral bleeding	**Hydrophilic**: n = 14 (13%) **Single-use noncoated**: n = 6 (5.2%) (*P* = .05)[a]
De Ridder et al, 2005[54]	Single-use hydrophilic vs. single-use noncoated	Urethral bleeding	**Hydrophilic**: n = 38 (69%) **Single-use noncoated**: n = 32 (54%) (*P* = NS)
DeFoor et al, 2017[25]	Single-use hydrophilic vs. single-use noncoated	Gross hematuria	**Hydrophilic**: n = 0 **Single-use noncoated**: n = 0 (*P* = NR)
Sarica et al, 2010[55]	Single-use hydrophilic vs. single-use noncoated	Gross hematuria	**Single-use noncoated**: n = 1 (4%) Not reported in hydrophilic group (*P* = NR)
Gel reservoir vs. noncoated (single-use) intermittent catheters			
Giannantoni et al, 2001[56]	Single-use gel reservoir vs. single-use noncoated	Urethral bleeding	**Gel reservoir**: n = 0 **Single-use noncoated**: n = 2 (11%) (*P* = NR)
Sarica et al, 2010[55]	Single-use gel reservoir vs. single-use noncoated	Gross hematuria	**Single-use noncoated**: n = 1 (4%) Not reported in gel reservoir groups (*P* = NR)

Abbreviations: NR, not reported; NS, not significant.
[a]We are aware that the data are different from those presented in the Cochrane systematic review conducted by Prieto et al[24] as well as the subsequent correction published by Christison et al.[58] On examining the original article, we decided to use greater denominators according to the intent-to-treat principle, as follows: hydrophilic cases = 14 out of 108, and single-use noncoated cases = 6 out of 116.

Table 6: GRADE Evidence Profile for Gross Hematuria

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Single-use vs. multiple-use intermittent catheters							
2 (RCTs)	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[b]	Serious limitations (–1)[c]	Undetected	No other considerations	⊕ Very low
Hydrophilic vs. noncoated (single-use) intermittent catheters							
4 (RCTs)[d]	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[e]	No serious limitations	Undetected	No other considerations	⊕⊕ Low
Gel reservoir vs. noncoated (single-use) intermittent catheters							
2 (RCT)[d]	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[f]	Serious limitations (–1)[c]	Undetected	No other considerations	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; IC, intermittent catheter; RCT, randomized controlled trial; vs., versus.
[a]High attrition, potential bias with crossover study (no washout period).
[b]Lack of data on adult females and children.
[c]Low number of events, wide confidence intervals.
[d]Sarica et al[55] is evaluated twice in the comparison of hydrophilic versus single-use noncoated ICs and gel reservoir versus single-use noncoated ICs.
[e]Data from mostly inpatient and mixed settings.
[f]Data from inpatient setting only; lack of data on outpatients (population of interest).

Microscopic Hematuria

Five of 14 studies measured microscopic hematuria, or the presence of red blood cells (erythrocytes) in urine.[47,51,53-55] Microscopic hematuria was assessed using urine dipsticks or microscopy. Studies reported varying details of the definition and different measures of microscopic hematuria, including the number of patients with hematuria, person-weeks of hematuria, and percentage of positive tests. Other studies only reported the statistical difference between the groups. Since no common measure was reported, we did not conduct a meta-analysis. Table 7 presents the results for microscopic hematuria in five studies.

Single-Use Versus Multiple-Use Catheters

Two studies compared a type of single-use IC with a reused IC.[47,51] Both studies reported no significant difference in microscopic hematuria between the types of IC. Kiddoo et al[47] compared users of single-use hydrophilic ICs and people who reused noncoated ICs, and found no difference in person-weeks of hematuria (2.64 ± 4.65 person-weeks and 3.15 ± 4.90 person-weeks, respectively). Vapnek et al[51] reported the number of patients with hematuria, and found no difference between the hydrophilic group (n = 8, 27%) and the multiple-use group (n = 11, 36%). Since no common measure was reported, we did not conduct a meta-analysis.

Hydrophilic Versus Noncoated Catheters (Single-Use)

Three studies compared single-use hydrophilic versus single-use noncoated ICs.[53-55] Two of the three studies showed significant results favouring hydrophilic ICs. In 2011, Cardenas et al[53] found a significantly higher proportion of positive tests for hematuria in individuals using single-use noncoated ICs, thus indicating a better outcome for those using hydrophilic ICs ($P < .0001$). Sarica et al[55] found similar results showing significantly less hematuria among people using hydrophilic ICs than those using single-use noncoated IC ($P < .05$). Conversely, De Ridder et al[54] reported no significant difference in hematuria between the two groups. Since minimal data were provided in two of the studies, we did not have sufficient data to obtain a pooled estimate. The definitions of microscopic hematuria were not clearly reported in the studies.

Gel Reservoir Versus Noncoated Catheters (Single-Use)

In an inpatient setting, Sarica et al[55] found significantly less microscopic hematuria with gel reservoir ICs when compared to single-use noncoated ICs ($P < .05$).

Table 8 presents the GRADE evidence profile for microscopic hematuria.

Table 7: Microscopic Hematuria in Studies Comparing Types of Intermittent Catheters

Author, Year	Comparison	Definition	Outcomes
Single-use vs. multiple-use intermittent catheters			
Kiddoo et al, 2015[47]	Single-use (hydrophilic) vs. multiple-use (1/day)	≥ 10 cells/µl Assessed using urine dipsticks	Mean person-weeks of hematuria: **Hydrophilic**: 2.64 ± 4.65 person-weeks **Multiple-use (1/day)**: Mean 3.15 ± 4.90 person-weeks (*P* = NS)
Vapnek et al, 2003[51]	Single-use (hydrophilic) vs. multiple-use (1/day)	None: number of RBCs/high power field = 0 Mild: number of RBCs/high power field = 1–5 Moderate: number of RBCs/high power field = 5–50 Heavy: number of RBCs/high power field > 50 Assessed using urine dipsticks and microscopic analysis	Number of patients with some degree of microscopic hematuria (mild, moderate, or heavy) **Hydrophilic**: n = 8 (27%) **Multiple-use (1/day)**: n = 11 (36%) (*P* = NS)
Hydrophilic vs. noncoated (single-use) intermittent catheters			
Cardenas et al, 2011[53]	Hydrophilic vs. single-use noncoated	Presence of erythrocytes Assessed using urine dipsticks	Proportion of positive tests (%): **Hydrophilic**: 23% **Single-use noncoated**: 34% (*P* < .0001)
De Ridder et al, 2005[54]	Hydrophilic vs. single-use noncoated	None provided Assessed using microbiologic analysis	No difference in hematuria between 2 groups (*P* = NR)
Sarica et al, 2010[55]	Hydrophilic vs. single-use noncoated	Number of erythrocytes in the urine sediment Assessed using microscopic analysis	There was significantly less microscopic hematuria with hydrophilic ICs compared with PVC [single-use noncoated] catheter use (*P* < .05)
Gel reservoir vs. noncoated (single-use) intermittent catheters			
Sarica et al, 2010[55]	Gel reservoir vs. single-use noncoated	Number of erythrocytes in the urine sediment Assessed suing microscopic analysis	There was significantly less microscopic hematuria with gel reservoir ICs compared with PVC [single-use noncoated] catheter use (*P* < .05)

Abbreviations: IC, intermittent catheter; NR, not reported; NS, not significant; PVC, polyvinyl chloride; RBC, red blood cells.

Table 8: GRADE Evidence Profile for Microscopic Hematuria

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Single-use vs. multiple-use intermittent catheters							
2 (RCTs)	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[b]	No serious limitations	Undetected	No other considerations	⨁⨁ Low
Hydrophilic vs. noncoated (single-use) intermittent catheters							
3 (RCTs)[c]	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[d]	Serious limitations (–1)[e]	Undetected	No other considerations	⨁ Very low
Gel reservoir vs. noncoated (single-use) intermittent catheters							
1 (RCT)[c]	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[d]	Serious limitations (–1)[e]	Undetected	No other considerations	⨁ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; IC, intermittent catheterization; RCT, randomized controlled trial; vs. versus.
[a]High attrition, potential bias with crossover study (no washout period).
[b]Neurogenic bladder population only; missing adult women.
[c]Sarica et al[55] is evaluated twice in the comparison of hydrophilic versus single-use noncoated ICs and gel reservoir versus single-use noncoated ICs.
[d]Studies are conducted in mixed settings or inpatient setting only.
[e]Minimal data provided to evaluate the precision of estimates.

Serious Adverse Events

Four studies reported data on more serious adverse events including stricture,[25,54] creation of false passage,[25] bladder stones,[51] and epididymitis.[48,51] Data on drug-resistant UTI were not reported. DeFoor et al[25] reported zero events for stricture formation and false passage in both hydrophilic and single-use noncoated IC groups. De Ridder et al[54] reported 1 case of stricture formation in the single-use noncoated IC group versus zero events in the group using hydrophilic ICs. Vapnek et al[51] found 1 case of bladder stone in the group that reused catheters up to a day, but the authors speculated this was unrelated to the catheter. Pachler and Frimodt-Moller[48] reported zero cases of epididymitis in both single-use hydrophilic and multiple-use noncoated IC groups. Vapnek et al[51] reported 1 case of epididymitis in each of the same two groups. Overall, due to short follow-up time, studies reported very low numbers of serious adverse events regardless of the IC assignment. Due to the small number of studies and events reported, we did not conduct a meta-analysis for these outcomes. Table 9 presents all studies that reported data on serious adverse events.

Table 10 presents the GRADE evidence profile for serious adverse events.

Table 9: Serious Adverse Events in Studies Comparing Types of Intermittent Catheters

Author, Year	Comparison	Number of Patients Reported
Stricture formation		
DeFoor et al, 2017[25]	Hydrophilic vs. single-use noncoated	**Hydrophilic:** n = 0 **Single-use noncoated:** n = 0
De Ridder et al, 2005[54]	Hydrophilic vs. single-use noncoated	**Hydrophilic:** n = 0 **Single-use noncoated:** n = 1 (1.7%)
Creation of false passage		
DeFoor et al, 2017[25]	Hydrophilic vs. single-use noncoated	**Hydrophilic:** n = 0 **Single-use noncoated:** n = 0
Bladder stones		
Vapnek et al, 2003[51]	Single-use (hydrophilic) vs. multiple-use (per day)	**Hydrophilic:** n = 0 **Multiple-use (1/day):** n = 1 (3.2%) but authors speculated it was unrelated to the type of catheter used
Epididymitis/orchitis		
Pachler and Frimodt-Moller, 1999[48]	Single-use (hydrophilic) vs. multiple-use (per day)	**Hydrophilic:** n = 0 **Multiple-use (1/day)**: n = 0
Vapnek et al, 2003[51]	Single-use (hydrophilic) vs. multiple-use (per day)	**Hydrophilic:** n = 1 (3.2%) **Multiple-use (1/day):** n = 1 (3.2%)
Drug-resistant UTI		
None reported		

Abbreviations: UTI, urinary tract infection.

Table 10: GRADE Evidence Profile for Serious Adverse Events

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
4 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	No other considerations	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a]High attrition and differential withdrawal between groups.
[b]Low number of events, wide confidence intervals.

Patient Preference

Eight of 14 studies reported measures of patient satisfaction, often involving convenience, comfort, ease of handling, and pain during insertion and removal of the catheter.[7,25,47,48,53-56] The format of the questionnaires varied across studies and none had been validated previously. Some studies used visual analog scales for scoring, while others used point systems. Results were also presented in various ways, such as average scores, the percentage of users who rated their experience as "acceptable," or the number of patients who reported difficulty in handling the catheter. Due to differences in questionnaire format and measurement, we did not conduct a meta-analysis but summarize the results in Table 11.

Single-Use Versus Multiple-Use Catheters

Three studies compared user and caregiver experiences with single-use and multiple-use ICs. In two studies[7,47] involving the same population of children with spina bifida, children using hydrophilic ICs and noncoated multiple-use ICs were asked about convenience, comfort, ease of handling, overall satisfaction, and whether they would continue using the catheter after the study. Kiddoo et al[47] reported that, on all five domains, users of multiple-use ICs rated their satisfaction as highly as or higher than children who used the single-use hydrophilic ICs. Specifically, users of multiple-use noncoated IC reported higher overall satisfaction than users of hydrophilic ICs ($P < .05$); there was no significant difference between types of catheters in terms of comfort and convenience; and few users of hydrophilic ICs reported "handling" as acceptable or were interested in "continued use." Studying the same population, Chick et al[7] provided a more in-depth analysis and reported the initial difficulty experienced by some children in handling the hydrophilic catheter. Some found it too slippery, and successful adaption to handling the IC depended on the children's psychomotor skills—the ability to hold and guide the catheter during insertion. However, after the children got used to the slipperiness of the hydrophilic IC, parents were more assured by using this type of catheter, as they could pack fewer supplies and felt less need to oversee the child's routine. The elimination of the lubricating step also saved time in the washroom. Families preferred the sterile (hydrophilic) IC especially for outings without good toilet facilities.

In a randomized crossover study examining an older male population with prostate enlargement, Pachler and Frimodt-Moller[48] reported no significant difference in users' experience of the hydrophilic and noncoated multiple-use ICs. There was no difference in ease of handling, pain or, more specifically, a burning sensation during the insertion and removal of the catheter.

Hydrophilic Versus Noncoated Catheters (Single-Use)

Four studies that compared single-use hydrophilic with single-use noncoated ICs reported data on patient preference.[25,53-55] Cardenas et al[53] reported a significantly higher overall satisfaction in the hydrophilic group compared to the single-use noncoated group ($P = .007$). The group using hydrophilic ICs scored higher levels of satisfaction in all parameters, including preparation of the catheter, ease of insertion, comfort during insertion and withdrawal, and disposal. However, it is unclear whether each parameter-specific score was significantly different between the two groups. De Ridder et al[54] also reported a higher proportion of patients who were satisfied with hydrophilic ICs with regard to the overall catheterization procedure and the introduction and withdrawal of the catheter, although the difference was not statistically significant. Sarica et al[55] also reported higher satisfaction with the hydrophilic IC, but the difference was not statistically significant.

In contrast, the pediatric population studied by DeFoor et al[25] reported more difficulty using the hydrophilic IC compared to a single-use noncoated catheter. More children experienced difficulty in handling (P = .02), difficulty in passing the catheter (P = .06), and urethral pain (P = .06) with the hydrophilic IC. As the study progressed, users of hydrophilic ICs reported a decrease in discomfort, although the improvement over time was not statistically significant (P = .06).

Gel Reservoir Versus Single-Use Noncoated Catheters

Two studies that examined gel reservoir ICs versus single-use noncoated ICs in an inpatient setting reported data on user preferences.[55,56] Giannantoni et al[56] reported greater satisfaction among those using gel reservoir ICs compared to those using single-use noncoated ICs (P = .022). Gel reservoir IC users also reported significantly higher satisfaction during insertion (P = .00007) and extraction (P = .004), and in terms of comfort (P = .00002) and ease of handling (P = .000004). Sarica et al[55] also reported significantly higher satisfaction with gel reservoir ICs compared to both hydrophilic and single-use noncoated ICs (P < .05).

Table 12 presents the GRADE evidence profile for patient preferences.

Table 11: Patient Preferences in Studies Comparing Types of Intermittent Catheters

Author, Year	Comparison	Questionnaire Format	Outcomes
Single-use vs. multiple-use intermittent catheters			
Chick et al, 2013[7]	Single-use (hydrophilic) vs. multiple-use (1/day)	• Five questions asking about convenience, comfort, ease of handling, overall satisfaction, and whether participant would continue using the product • Two options for each question: acceptable or unacceptable • Comments and follow-up questions about users' experience are analyzed qualitatively for themes	Multiple-use catheter was rated as highly as or higher than the single-use hydrophilic product on all five questions addressing convenience, comfort, handling, satisfaction, and the continuation of catheter after study No significant difference between catheters with regard to comfort and convenience; fewer participants in the hydrophilic group reported "handling" as acceptable or were interested in "continued use" Some reported initial difficulty in handling the hydrophilic catheter; some found it too "slimy" or slippery Took a while to get used to the slipperiness, but once the users successfully adapted to manipulating the hydrophilic IC, the elimination of the lubricating step saved time in the washroom With single-use catheters, users are required to pack fewer supplies Parents of self-catheterizing children were more reassured by the use of hydrophilic catheter, feeling less need to oversee the child's routine
Kiddoo et al, 2015[47]	Single-use (hydrophilic) vs. multiple-use (1/day)	• Five questions asking about the convenience, comfort, ease of handling, overall satisfaction, and whether user would continue using the product • Two options to each of the five questions: acceptable or unacceptable • Sixth question asked how satisfied they are with the catheter, with three options: very satisfied, somewhat satisfied, not satisfied	**Overall satisfaction** (Percentage of patients who reported feeling IC was acceptable): Hydrophilic 72.9% vs. multiple-use (1/day) 87.5% (favoured; *P* < .05) **Convenience**: Hydrophilic 81.6% vs. multiple-use (1/day) 81.3% (*P* = NS) **Comfort**: Hydrophilic 87.5% vs. multiple-use (1/day) 95.7% (*P* = NS) **Ease of handling**: Hydrophilic 59.2% vs. multiple-use (1/day) 95.8% (favoured; *P* < .05) **Would continue using the product**: Hydrophilic n = 26 (57%) vs. multiple-use (1/day) n = 41 (92%) (*P* = NR) If children overcame the slipperiness issue of hydrophilic catheters, the families were pleased. Families approve of the portability of the package and preferred the sterile product for outings without good toilet facilities. Parents were more confident the child was being catheterized safely when using single-use catheters.

Author, Year	Comparison	Questionnaire Format	Outcomes
Pachler and Frimodt-Moller, 1999[48]	Single-use (hydrophilic) vs. multiple-use (1/day)	• Six questions about the following domains: problems in introducing the catheter, burning sensation when introducing the catheter, pain when introducing the catheter, burning sensation or pain after removal of the catheter, handling of catheter before introduction, handling of catheter after use • Each question had three options in terms of difficulty (easy, tolerable, troublesome)	No significant difference in responses about the patients' use of the hydrophilic or multiple-use catheters in any of the domains (pain, burning sensation, and ease of handling when introducing or removing the catheter)
Hydrophilic vs. nonhydrophilic (single-use) intermittent catheters			
Cardenas et al, 2011[53]	Hydrophilic vs. single-use noncoated	• 10 questions about the following domains: learning to catheterize, preparation of catheter in usual surroundings, preparation of catheter outside usual surroundings, ease of insertion, comfort during insertion, comfort during withdrawal, disposal, catheterization procedure in usual surroundings, catheterization procedure outside usual surroundings, and overall satisfaction • Each question used a 10-point scale: 0 = worst outcome (i.e., very difficult/severe discomfort/ very dissatisfied); 10 = best outcome (very easy/ no discomfort/satisfied) • Results presented as a mean score for each group	Summary: there was a tendency in favour of hydrophilic catheter for all parameters. **Overall satisfaction** (mean score ± SD): Hydrophilic (favoured): 9.3 ± 1.4 vs. single-use noncoated: 8.6 ± 1.3 (*P* = .007) **Learning to catheterize**: Hydrophilic 9 ± 1.6 vs. single-use noncoated 8.7 ± 1.8 (*P* = NR) **Prep of catheter in usual surroundings**: Hydrophilic 8.9 ± 1.4 vs. single-use noncoated 8.5 ± 1.8 (*P* = NR) **Prep of catheter outside usual surroundings**: Hydrophilic 7.6 ± 2.8 vs. single-use noncoated 6.8 ± 2.7 (*P* = NR) **Ease of insertion**: Hydrophilic 9.2 ± 1.6 vs. single-use noncoated 8.6 ± 1.6 (*P* = NR) **Comfort during insertion**: Hydrophilic 9.3 ± 1.2 vs. single-use noncoated 8.9 ± 1.4 (*P* = NR) **Comfort during withdrawal**: Hydrophilic 9.4 ± 1.1 vs. single-use noncoated 9.0 ± 1.5 (*P* = NR) **Disposal**: Hydrophilic 9 ± 1.4 vs. single-use noncoated 8.8 ± 1.7 (*P* = NR) **Catheterization procedure in usual surroundings**: Hydrophilic 9.3 ± 1.1 vs. single-use noncoated 8.8 ± 1.5 (*P* = NR) **Catheterization procedure outside usual surroundings**: Hydrophilic 7.7 ± 2.7 vs. single-use noncoated 6.8 ± 2.7 (*P* = NR)

Author, Year	Comparison	Questionnaire Format	Outcomes
De Ridder et al, 2005[54]	Hydrophilic vs. single-use noncoated	• Four questions about catheter introduction, withdrawal, time spent, and satisfaction with catheter • 4-point scale	Number and percentage of patients who were very satisfied with the catheter after 6 and 12 months: • At 6 months: hydrophilic n = 10 (33%) vs. single-use noncoated n = 6 (15.4%) (*P* = NS) • At 12 months: hydrophilic n = 9 (36%) vs. single-use noncoated n = 7 (21.9%) (P = NS) More patients/care providers in hydrophilic group found the overall procedure, introduction, and withdrawal of the catheter very easy or easy compared to the PVC group, but the differences were not significant (*P* = NS). The time needed to perform the catheterizations was similar in both groups (*P* = NR).
DeFoor et al, 2017[25]	Hydrophilic vs. single-use noncoated	• 10 questions about discomfort with catheterization, ease of opening the packaging, pain with catheterization, embarrassment about catheterization, convenience of using catheter, difficulty handling catheter, difficulty inserting catheter, and concern for UTI complications • Each question was scored 0–10: 0 = no discomfort, 10 = maximal discomfort	Hydrophilic users reported more issues: **Difficulty in handling**: hydrophilic n = 4 vs. single-use noncoated n = 0 (*P* = .02, favouring single-use noncoated) **Difficulty passing catheter**: hydrophilic n = 3 vs. single-use noncoated n = 0 (*P* = .06) **Urethral pain**: hydrophilic n = 3 vs. single-use noncoated n = 0 (*P* = .06) However, towards the end of the study, most hydrophilic catheter users would continue to use hydrophilic catheters; mean score at end of study: 2.5 (0 = continue hydrophilic, 10 = back to uncoated), a significant improvement compared to a mean score of 5.3 at baseline (*P* = .04). Compared to baseline, hydrophilic catheter users reported a decrease in discomfort with catheterization process at the end of the study, but this was not a significant decrease (*P* = .06); all other survey questions were unchanged for the hydrophilic group from baseline to end of study. Mean score remained consistent for single-use noncoated catheter throughout the study.
Sarica et al, 2010[55]	Hydrophilic vs. single-use noncoated	• Visual analog scale using a 10-cm line oriented vertically, from not satisfied at all (bottom) to very satisfied (top) • Five additional questions about satisfaction during the bladder emptying period, ease of handling, extracting, overall satisfaction, and comfort; each question was scored between 0 (not satisfied at all) and 4 (very satisfied)	Users of hydrophilic ICs had higher patient satisfaction score using a visual analog scale, but the difference is not statistically significant (*P* = NR). Exact data points cannot be extracted from graph.

Author, Year	Comparison	Questionnaire Format	Outcomes
Gel reservoir vs. noncoated (single-use) intermittent catheters			
Giannantoni et al, 2001[56]	Gel reservoir vs. single-use noncoated	• Visual analogue scales to evaluate overall satisfaction and five subcategories (learning, inserting, extracting, comfort and handling ease) • The lower the score, the higher the satisfaction	**Overall satisfaction** (mean score ± SD): Gel reservoir 2.33 ± 1.06 (favoured) vs. single-use noncoated 4.72 ± 2.13 (*P* = .022) **Learning**: Gel reservoir 1.1 ± 2.7 vs. single-use noncoated 1.1 ± 2.7 (*P* = .16) **Inserting**: Gel reservoir 3.6 ± 3.7 (favoured) vs. single-use noncoated 6.7 ± 3.4 (*P* = .00007) **Extracting**: Gel reservoir 3.0 ± 3.0 (favoured) vs. single-use noncoated 5.0 ± 3.4 (*P* = .004) **Comfort**: Gel reservoir 2.5 ± 3.1 (favoured) vs. single-use noncoated 5.8 ± 3.9 (*P* = .00002) **Handling ease**: Gel reservoir 1.4 ± 2.3 (favoured) vs. single-use noncoated 5.0 ± 3.4 (*P* = .000004)
Sarica et al, 2010[55]	Hydrophilic vs. single-use noncoated vs. gel reservoir	• Visual analog scale using a 10-cm line oriented vertically, from not satisfied at all (bottom) to very satisfied (top) • Five additional questions about satisfaction during the bladder emptying period, ease of handling, extracting, overall satisfaction, and comfort; each question was scored between 0 (not satisfied at all) and 4 (very satisfied)	Gel reservoir ICs had a significantly higher visual analog scale score (*P* < .05) indicating higher satisfaction. Gel reservoir ICs also scored significantly higher in questions about emptying period satisfaction, ease of handling, and comfort. (*P* < .05) Exact data points cannot be extracted from graph provided by authors.

Abbreviations: IC, intermittent catheter; NR, not reported; NS, not significant; PVC, polyvinyl chloride; SD, standard deviation; UTI, urinary tract infection; vs., versus.

Table 12: GRADE Evidence Profile for Patient Preference

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Single-use vs. multiple-use intermittent catheters							
3 (RCTs)	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[b]	No serious limitations	Undetected	No other considerations	⊕⊕ Low
Hydrophilic vs. noncoated (single-use) intermittent catheters							
4 (RCTs)	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[c]	No serious limitations	Undetected	No other considerations	⊕⊕ Low
Gel reservoir vs. noncoated (single-use) intermittent catheters							
2 (RCT)[d]	Serious limitations (–1)[a]	No serious limitations	Serious limitations (–1)[c]	No serious limitations	Undetected	No other considerations	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial; vs. versus.
[a]High attrition, differential withdrawal; no blinding, may influence patient satisfaction data.
[b]Only included children and the elderly; lack of data on adults (especially those with neurogenic bladder).
[c]Most data from mixed or inpatient setting.
[d]Sarica et al[55] is evaluated twice in the comparison of hydrophilic versus single-use noncoated ICs and gel reservoir versus single-use noncoated ICs.

Discussion

We included 14 studies in this clinical evidence review examining the effectiveness and safety of intermittent catheterization for chronic urinary retention. Although the main research questions are focused on the outpatient setting, we included 7 studies in inpatient settings when outpatient studies were unavailable. Given the overall low quality of the evidence, we are uncertain whether a specific type of intermittent catheter (coated or noncoated) or a particular method of use (single- or multiple-use) substantially improves patient satisfaction or reduces symptomatic urinary tract infection, hematuria, or other serious adverse clinical events.

Quality of Evidence

Several factors contributed to the low quality of evidence. Most studies had small sample sizes and differential withdrawal between groups. Only two of the 14 studies enrolled more than 100 participants, and only one study had over 100 participants completing the trial. Studies were underpowered: of the four studies[47,52-54] that included statistical power calculations, none was able to obtain the sufficient sample size. The duration of follow-up also varied: as short as 4.5 days in one study, up to 1 year in another. Considering that the population of interest requires ongoing use of intermittent catheters, the follow-up period is likely insufficient to capture more serious adverse events that may arise from long-term usage. Although studies with longer follow-up have been published, none met the inclusion criteria for this review (e.g., they were noncomparative, lacking a control group, or an ineligible observational study type). High dropout was also common in the studies we reviewed, especially those examining people with recent spinal cord injury. As individuals recovered from their injury, their bladder management plans also changed and some no longer required intermittent catheterization.

There are inherent methodological challenges in studying intermittent catheterization. Since various types of IC require different routines of care (e.g., participants must manually apply a lubricant to noncoated ICs), it is virtually impossible to blind the study arms. As a result, participants may be more aware of their symptoms when using a new type of catheter, increasing the reporting of UTI symptoms. The lack of participant blinding may also introduce pre-existing biases that influence self-reported satisfaction data. In addition, potential carryover effects may be present in crossover studies, since washout periods are not feasible for these individuals who depend on intermittent catheterization to maintain normal bladder function.

Various factors contributed to the heterogeneity across studies. Although the Infectious Diseases Society of America (IDSA) 2009 Consensus Statement served as the most up-to-date and comprehensive definition of catheter-associated UTI,[34] older studies varied in their definitions of symptomatic UTI, specifically in the threshold levels of bacteriuria and sets of clinical symptoms. Furthermore, studies reported different outcome measures of UTI, making it difficult to aggregate data. Similarly, we could not aggregate data on user satisfaction due to the variety of nonstandardized, nonvalidated questionnaires used, as well as the variety of scoring systems and ways of presenting results.

The extent of reporting also varied across studies. In some studies, we could not find information on the setting, type of catheters used in the control group, and extent of IC reuse. Some studies also did not provide the original questionnaires used in assessing patient preferences.

Other Strengths and Limitations

The generalizability of the results of our review may be limited. Quite a few studies were conducted in male-only populations, and the rest of the studies had unbalanced gender distributions. Although the higher proportion of men reflects the demographics of spinal cord injury and prostate enlargement, we cannot be certain whether the results are applicable to women. Furthermore, we could not extract clinical outcomes data stratified by sex and catheter type. Although females represent a minority of the population with spinal cord injuries, future studies should strive to address their unique concerns since females have an inherently higher risk of UTI regardless of the choice of intermittent catheters.[52,59]

Owing to a lack of studies in outpatient settings, we included inpatient studies to understand the safety and effectiveness of gel reservoir ICs compared with noncoated ICs reused up to one week. However, rates of UTI may differ across settings. As seen in Cardenas et al,[53] people living in the community had a lower risk of UTI than inpatients did; this may be because of their improved health status as outpatients or because inpatients are more closely monitored, making it more likely that a UTI will be detected.

In terms of strengths, this report is, to our knowledge, the first review to focus on evidence from outpatient settings for people with either neurological or non-neurological origins of urinary retention. In addition, we found a number of studies conducted in a pediatric population and have highlighted a specific challenge experienced by children when manipulating hydrophilic catheters.

Other Reviews

Several published systematic reviews have addressed certain aspects of our research questions but did not fully meet our inclusion criteria, primarily as they were not specific to the outpatient setting. Here we briefly summarize the findings of these systematic reviews and discuss them in the context of this health technology assessment.

A systematic review conducted in 2007 by Getliffe et al[41] compared single-use and multiple-use ICs. The reviewers found high risk of bias in the study designs and inconclusive evidence on the incidence of UTIs.[41] Our review identified more studies conducted after this systematic review. Similarly, we found that the overall evidence showed no difference between single- and multiple-use ICs, and we made similar observations on the variation in study methods and problems with attrition and imprecision.

In a systematic review and cost-effectiveness analysis published in 2013, Bermingham et al[11] found that individuals using hydrophilic and gel reservoir ICs were significantly less likely to report UTIs compared to those using single-use noncoated ICs, in all settings. However, there was no difference when UTI outcomes were measured as mean monthly UTIs or total UTIs at 1 year.[24] The authors concluded that the type of catheter seemed to make little difference to the risk of symptomatic UTI.[11]

A 2013 systematic review by Li et al[42] compared hydrophilic and nonhydrophilic IC with regard to UTI and hematuria in spinal cord injury patients in all settings. The reviewers reported significantly lower incidences of UTI and hematuria in the hydrophilic group compared to the nonhydrophilic group.[42] However, we believe there may have been errors in the reviewers' data extraction, which may have skewed the pooled estimates and subsequent interpretations.

The systematic review and meta-analysis by Rognoni and Tarricone[43] in 2017 reported a decreased risk of UTI associated with hydrophilic ICs compared to nonhydrophilic ICs in all settings but (similar to our results) no significant difference for gross hematuria. Our sensitivity analysis incorporating mixed-setting studies showed similar results for UTI, although we were unable to find significant differences in the outpatient setting.

A systematic review published in 2017 by Shamout et al[44] examined different types of ICs in adults with neurogenic bladder in all settings. The reviewers did not conduct a meta-analysis and reported that results in the literature were inconsistent with regard to UTI and hematuria, both gross and microscopic. Although the authors concluded that hydrophilic ICs tended to decrease the incidence of UTI and hematuria and improve patient satisfaction compared to nonhydrophilic IC, they also commented that overall the evidence remained insufficient for clinical decision-making. The authors also found gel reservoir ICs showed significantly better results in terms of patient satisfaction, although only two studies were available. Similar to this review, we also found low-quality evidence favouring gel reservoir ICs over noncoated single-use ICs in terms of improving the incidence of UTI and hematuria.

Ongoing Studies

From ClinicalTrials.gov, an international prospective registry of clinical trials, we identified two relevant registered clinical trials which have been published as conference abstracts but not as full-length studies. The first trial (ID: NCT01404481) was a randomized crossover study completed in 2013 comparing single-use noncoated with multiple-use noncoated ICs.[60] The abstract of the trial reported no statistical difference in symptomatic UTI between the single-use and multiple-use IC groups. We emailed the investigators regarding the publication of this trial, and we did not receive a reply by time of writing. The second study (ID: NCT02129738) was a prospective trial completed in March 2017 comparing hydrophilic with multiple-use noncoated ICs.[61] No study results have yet been posted.

According to PROSPERO, an international prospective registry of systematic reviews, two systematic reviews related to intermittent catheterization are ongoing. One systematic review (ID: CRD42017056301) is evaluating the effectiveness of ICs in patients with neurogenic bladder, with quality of life as the primary outcome. This systematic review will compare ICs to other methods of bladder emptying such as indwelling catheterization, use of diapers, and other non-invasive methods. The other ongoing systematic review (ID: CRD42017081087) is qualitatively analyzing psychosocial, socioeconomic, and medical themes around bladder management and catheterization in individuals with spinal cord injury. Types of bladder management will include intermittent, indwelling, and suprapubic catheterization. There are currently no ongoing systematic reviews that specifically compare different types of ICs in terms of reuse or coating.

Conclusions

The overall low quality of evidence from published studies on the effectiveness and safety of intermittent catheters used to manage chronic urinary retention creates a high degree of uncertainty in the study results. Therefore, we are uncertain whether any specific type of intermittent catheters—coated or noncoated, single- or multiple-use—significantly reduces symptomatic urinary tract infections, hematuria, or other serious adverse clinical events, or improves patient satisfaction. The quality of the evidence is low due to heterogeneity across studies, varying definitions of UTI, attrition, small sample sizes, failure to achieve statistical power (in studies that reported calculation), and short durations of follow-up.

When comparing single-use ICs (hydrophilic, gel reservoir, or noncoated) with the multiple use of noncoated ICs (any extent of reuse):

- We did not find a difference in the incidence of urinary tract infection, microscopic hematuria, or gross hematuria (low/very low quality)
- We did not find a difference in serious adverse events (bladder stones and epididymitis/orchitis) (low quality)
- We found inconclusive findings on preference/satisfaction: older males showed no preference for single-use or multiple-use ICs; children may favour hydrophilic ICs after overcoming initial challenges in handling this type of catheter (low quality)

When comparing single-use hydrophilic ICs with single-use noncoated ICs:

- We did not find a difference in reducing the incidence of urinary tract infection based on studies in the outpatient setting (low quality)
- We found reduced microscopic hematuria favouring hydrophilic ICs (very low quality)
- We did not find a difference in hematuria or serious adverse events (stricture formation and creation of false passage) (low quality)
- We found inconclusive findings on patient preferences: adults are more satisfied with hydrophilic ICs, and children may favour hydrophilic ICs after overcoming initial challenges in handling (low quality)

When comparing single-use gel reservoir ICs with single-use noncoated ICs, we found:

- Inconclusive findings, potentially favouring gel reservoir ICs in reducing the incidence of urinary tract infection (very low quality)
- Reduced microscopic hematuria favouring gel reservoir ICs (very low quality)
- Reduced gross hematuria favouring gel reservoir ICs (very low quality)
- Higher user satisfaction favouring gel reservoir ICs (low quality)

ECONOMIC EVIDENCE

Research Question

What is the cost-effectiveness of intermittent catheterization for patients with long-term usage (> 28 days) of intermittent catheters (i.e., single-use hydrophilic, single-use gel reservoir, single-use noncoated, and multiple-use noncoated)?

Methods

Economic Literature Search

We performed an economic literature search on October 16, 2017, for studies published from January 1, 1990, to the search date. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic and costing filter applied.[62]

We created database auto-alerts in MEDLINE, Embase, and CINAHL and monitored them for the duration of the assessment period. We also performed a targeted grey literature search of health technology assessment agency websites, clinical trial registries, and the Tufts Cost-Effectiveness Analysis Registry. See the clinical evidence literature search, p. 15, for further details on methods used. See Appendix 4 for the literature search strategies, including all search terms.

Literature Screening

A single reviewer reviewed titles and abstracts, and, for those studies likely to meet the eligibility criteria, we obtained full-text articles and performed a further assessment for eligibility.

Inclusion Criteria

- English-language full-text publications
- Studies on the long-term usage (> 28 days) of intermittent catheterization (IC)
- Cost-utility, cost-effectiveness, or cost-benefit studies

Exclusion Criteria

- Narrative reviews, letters/editorials, case reports, commentaries, abstracts, posters, unpublished studies, cost estimate studies
- Studies on indwelling and suprapubic catheterization

Outcomes of Interest

- Costs
- Quality-adjusted life-years (QALYs)
- Incremental cost and incremental effectiveness
- Incremental cost-effectiveness ratio (ICER)

Data Extraction

We extracted relevant data on the following:

- Source (i.e., first author, country, year)
- Population
- Interventions and comparator
- Outcomes (i.e., health outcomes, costs, and incremental cost-effectiveness ratio)

Study Applicability

We determined the usefulness of each identified study for decision-making by applying a modified quality appraisal checklist for economic evaluations that was originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom to inform development of NICE's clinical guidelines.[63] We modified the wording of the questions to remove references to guidelines and to make it Ontario-specific. A summary of the number of studies judged to be directly applicable, partially applicable, or not applicable to the research question is presented.

Results

Literature Search

The literature search yielded 117 citations published between January 1, 1990, and October 16, 2017, after removing duplicates. We excluded a total of 106 articles based on information in the title and abstract. We then obtained the full texts of 11 potentially relevant articles for further assessment. Six studies met the inclusion criteria. We also hand-searched the reference lists of the included studies but did not find any additional studies. Figure 5 presents the flow diagram for the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).

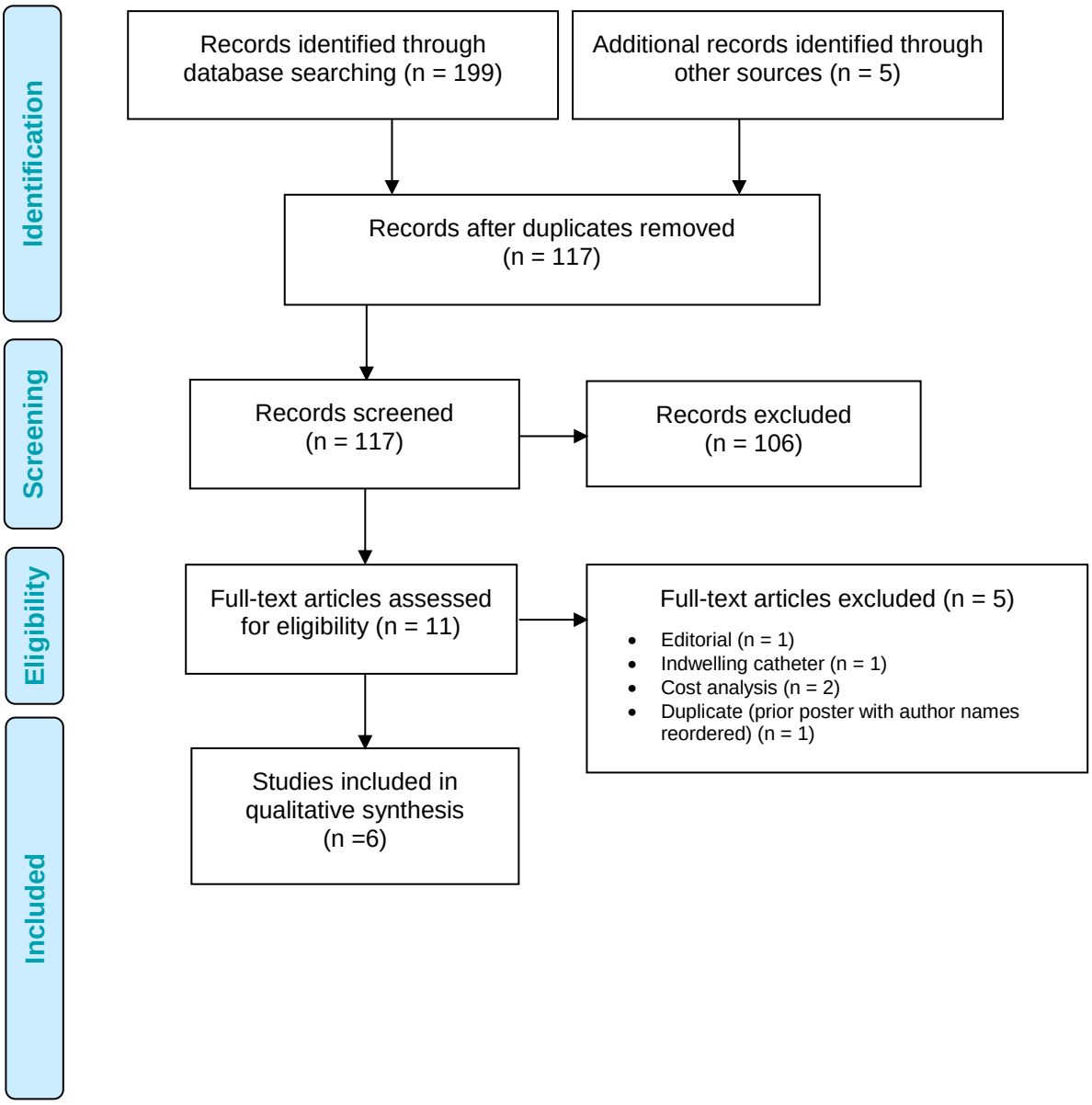

Figure 5: PRISMA Flow Diagram—Economic Search Strategy

Source: Adapted from Moher et al.[45]

Review of Included Economic Studies

A summary of the six included studies with decision analytic models is provided in Table 13.

Bermingham et al[11] conducted a cost-utility analysis that compared the following single- and multiple-use ICs in a population with neurogenic bladder due to spinal cord injury: single-use hydrophilic, single-use gel reservoir, sterile noncoated, clean noncoated (used for up to one day), clean noncoated (used for up to one week). The authors developed a Markov model to compare costs and QALYs over a lifetime horizon from the UK National Health Service (NHS) perspective. The model's parameters were defined primarily from their systematic literature review and meta-analysis, which combined results from randomized controlled trials and randomized crossover trials of long-term intermittent self-catheterization in the community or primary care setting. The ICER (2009/2010 GBP) was evaluated under two scenarios, including and excluding clean noncoated catheters (used up to one day and one week). When clean noncoated ICs were included, there was an 89.2% probability of clean noncoated (one per week) ICs being cost-effective at a £20,000 per QALY threshold. When clean noncoated ICs were excluded, single-use gel reservoir ICs were cost-effective compared with single-use hydrophilic ICs, with an ICER of £3,071 per QALY gained; and gel reservoir ICs had an 84.6% probability of being cost-effective at a £20,000 per QALY threshold. The results were robust in sensitivity analyses that evaluated changes in urethral complications and urinary tract infection (UTI) rates. However, a sensitivity analysis found that clean noncoated ICs ceased to be the most cost-effective option once patients used at least two clean noncoated ICs per day.

Clark et al[64] evaluated the cost-effectiveness of single-use hydrophilic ICs compared to sterile noncoated catheters in a population with both chronic urinary retention and spinal cord injury. A Markov model was constructed using a lifetime horizon and a UK NHS perspective, with the primary outcomes being cost per QALY, cost per life-year gained, and cost per UTI event avoided (2011 GBP). The study differed from the Bermingham et al[11] study by including long-term sequelae of UTIs (i.e., progressive kidney impairment and failure) in their model. The study also evaluated different settings through three scenarios that calculated UTI event rates using either hospital records, long-term community data, or combined hospital and long-term community data. When comparing single-use hydrophilic to noncoated ICs, the ICER was £6,100 per QALY gained, £3,300 per life-year gained, and £79 per UTI event avoided.

Rognoni and Tarricone[65] carried out a cost-effectiveness analysis of single-use hydrophilic versus single-use noncoated ICs, in patients with spinal cord injury who used intermittent catheterization in a community setting (with a sensitivity analysis for hospital and hospital-plus-community settings). The Markov model used a lifetime horizon under an Italian health care service perspective and included outcomes such as life-years and QALYs gained. The analysis replicated Bermingham et al's focus on short-term consequences of UTIs and hematuria,[11] but also included other infections and inflammations relevant to practising intermittent catheterization (i.e., epididymitis/orchitis, urethritis, prostatitis, strictures, false passage, and bladder stones). Health care resource utilization was derived from an e-survey sent to a group of urologists and neuro-urologists (N = 25). The study reported that the ICER (2015 Euros) of single-use hydrophilic ICs compared with noncoated ICs was €24,405 per QALY gained and €20,761 per life-year gained.

Watanabe et al[66] examined the cost-effectiveness, from a Japanese payer perspective, of single-use hydrophilic versus noncoated ICs in inpatients with spinal cord injury and chronic urinary retention. The Markov model was adapted from Clark et al[64] and adjusted to include Japanese data (UTI risk, age of spinal cord injury onset, costs, and mortality), collected from

clinician surveys, published literature, and national statistics. A lifetime horizon was used to evaluate the cost per QALY gained, cost per life-year gained, and cost per pyuria event (elevated white blood cells in the urine). The ICER (2014 JPY and USD) of single-use hydrophilic ICs compared with noncoated ICs was ¥3,826,351 per QALY gained (US$31,405/QALY gained) and ¥1,639,562 per life-year gained (US$13,550/QALY gained), which fell within the Japanese societal willingness-to-pay threshold. Sensitivity analyses found that monthly hydrophilic catheter costs, UTI risk with noncoated catheter use, and reduction of UTI rate with single-use hydrophilic catheters had a significant impact on the ICER. The probability of single-use hydrophilic ICs catheters being cost-effective was over 50% at a threshold of ¥4 million per QALY gained (US$33,057/QALY gained).

Truzzi et al[67] conducted a cost-effectiveness analysis to compare costs and effects of single-use hydrophilic and noncoated intermittent catheters in a mixed (inpatient/outpatient) Brazilian population with spinal cord injury. The lifetime Markov model was adapted from Clark et al,[64] using the perspective of the Brazilian public health care system. The authors expanded on the model from Clark et al[64] and added health states for first- and second-line antibiotic–resistant UTIs. Both a primary and secondary analysis was run: the primary analysis modeled all possible adverse events (i.e., UTIs, bladder stones, kidney stones, urethral injury, and urosepsis), while the secondary analysis only modeled UTIs. The primary analysis found single-use hydrophilic ICs compared to noncoated ICs had an ICER of R$57,432 per life-year gained and R$122,300 per QALY gained (2016 Brazilian real). The secondary analysis indicated that over the target population's lifetime, UTIs were reduced by 6% when patients used single-use hydrophilic ICs, for an additional cost of R$31,240. Sensitivity analyses determined the results were robust to variations in the lubrication type (reusable tube vs. single-use satchels), bacterial resistance levels, and the UTI rate.

Håkansson et al[68] used a cost-effectiveness analysis from the perspective of the US health care system to compare single-use hydrophilic and noncoated ICs in an inpatient population with spinal cord injury and chronic urinary retention. The Markov model focused on short-term outcomes, but unlike Bermingham et al,[11] it included dedicated health states for epididymitis, strictures, and bladder stones. The study based its IC costs on Medicare Healthcare Common Procedure Coding System codes that did not distinguish between catheter types. Therefore, catheter costs were assumed equal, except that noncoated ICs cost an additional $0.13 per catheter to account for external lubricant. The model's base case analysis, carried over a lifetime horizon, found single-use hydrophilic IC dominated noncoated ICs, with cost savings of $10,184 per patient (2015 USD) and gains of 0.55 QALYs per patient (avoiding, on average, 16 UTIs per person). Sensitivity analyses found the model results for single-use hydrophilic ICs remained cost saving, except when the cost of single-use hydrophilic ICs increased to $2.84, which resulted in an ICER of $40,421 per QALY gained.

Table 13: Results of Economic Literature Review—Summary

Name, Year, Location	Study Design and Perspective	Population	Intervention/ Comparator	Results		
				Health Outcomes	Mean Costs	Cost-Effectiveness
Bermingham et al, 2013,[11] United Kingdom	• Type of economic analysis: CUA • Study design: Markov model • Perspective: UK NHS • Time horizon: lifetime • Discount rate: 3.5%	• Patients with neurogenic bladder due to spinal cord injury • Mean age of 40 years • 80% male • Children were not included • Setting: mixed	• With multi-use noncoated catheters: *Comparator:* clean noncoated (1/week) *Interventions:* hydrophilic (single-use), gel reservoir (single-use), sterile noncoated (single-use), clean noncoated (1/day) • Excluding clean noncoated catheters: *Comparator:* hydrophilic (single-use) *Interventions* (all single-use): gel reservoir, sterile noncoated	• Total QALYs • Clean noncoated (1/week): 11.929 • Clean noncoated (1/day): 11.780 • Hydrophilic: 12.003 • Gel reservoir: 12.450 • Sterile noncoated: 11.880	• Currency: 2009-10 UK£ • Clean noncoated (1/week): £11,879 • Clean noncoated (1/day): £17,741 • Hydrophilic: £38,875 • Gel reservoir: £40,248 • Sterile noncoated: £43,594	• Two scenarios with and without multi-use noncoated catheters • *Scenario 1 with multi-use:* 89.2% probability clean noncoated (1/week) is CE at £20,000 threshold • *Scenario 2 without multi-use:* ICER: Gel reservoir vs. hydrophilic = £3,071/QALY gained 84.6% probability gel reservoir CE at £20,000 threshold
Clark et al, 2016,[64] United Kingdom	• Type of economic analysis: CEA/CUA • Study design: Markov model • Perspective: UK NHS • Time horizon: lifetime • Discount rate: 3.5%	• Patients with chronic urinary retention and a spinal cord injury • Mean age of 36 years • 80% male • Setting: inpatient, outpatient, mixed	• *Intervention:* hydrophilic catheter • *Comparator:* noncoated catheter	• Total QALYs Noncoated: 6.58 (95% CI 5.87–7.30) Hydrophilic-coated: 6.92 (95% CI 6.21–7.67) • Total LYG Noncoated: 14.75 (95% CI 13.96–15.53) Hydrophilic-coated: 15.39 (95% CI 14.47– 16.21) • UTI events Noncoated: 169.98 (95% CI 142.15–198.73) Hydrophilic-coated: 143.49 (95% CI 112.39–176.87)	• Currency: 2011 UK£ • Noncoated: £59,000 (95% CI 54,900–64,100) • Hydrophilic-coated: £61,100 (95% CI 57,700–65,600)	• ICER compared hydrophilic with noncoated • £6,100 per QALY gained • £3,300 per LYG • £79 per UTI event avoided

Name, Year, Location	Study Design and Perspective	Population	Intervention/ Comparator	Results		
				Health Outcomes	Mean Costs	Cost-Effectiveness
Håkansson et al, 2016,[68] United States	• Type of economic analysis: CEA/CUA • Study design: Markov model • Perspective: US health care system • Time horizon: lifetime • Discount rate: 3.0%	• Intermittent catheter users • Mean age of 40 years • 60% male • Setting: inpatient	• *Intervention:* hydrophilic catheter • *Comparator:* noncoated catheter	• Total QALYs Noncoated: 16.63 Hydrophilic-coated: 17.18 • Number of complication events Noncoated: 97.84 Hydrophilic-coated: 79.82	• Currency: 2015 USD • Noncoated: $85,341 • Hydrophilic-coated: $75,158	• Hydrophilic dominated noncoated catheters
Rognoni and Tarricone,[65] 2016, Italy	• Type of economic analysis: CEA/CUA • Study design: Markov model • Perspective: Italian health care service • Time horizon: lifetime • Discount rate: 3.5%	• Patients with spinal cord injury performing intermittent urinary catheterization in the home setting • Mean age of 40 years • 80% male • Setting: inpatient, outpatient, mixed	• *Intervention:* hydrophilic catheters • *Comparator:* noncoated catheters (single-use)	• Total QALYs Noncoated: 14.332 Hydrophilic-coated: 15.170 • Total LYG Noncoated: 17.299 Hydrophilic-coated: 18.284	• Currency: 2015 Euros (€) • Noncoated: €62,457 • Hydrophilic-coated: €82,915	• ICER compared hydrophilic with noncoated • €24,405 per QALY gained • €20,761 per LYG
Truzzi et al, 2017,[67] Brazil	• Type of economic analysis: CEA/CUA • Study design: Markov model • Perspective: Brazilian public health care system • Time horizon: lifetime • Discount rate: 5.0%	• Patients with spinal cord injury • Adapted population by Clark et al,[64] with 80% males and a mean age of 36 years old • Setting: mixed	• *Intervention:* hydrophilic catheters • *Comparator:* noncoated catheters	• Total LYG Noncoated: 5.689 Hydrophilic-coated: 6.233 • Total QALYs Noncoated: 2.550 Hydrophilic-coated: 2.805 • UTI events Noncoated: 54.73 Hydrophilic-coated: 51.53	• Currency: 2016 Brazilian reais (BRL) • Noncoated: 17,255 BRL • Hydrophilic-coated: 48,476 BRL	• ICER compared hydrophilic with noncoated • 122,330 BRL per QALY gained • 57,432 BRL per LYG

Name, Year, Location	Study Design and Perspective	Population	Intervention/ Comparator	Results		
				Health Outcomes	Mean Costs	Cost-Effectiveness
Watanabe et al, 2015,[66] Japan	• Type of economic analysis: CEA/CUA • Study design: Markov model • Perspective: Japanese payers • Time horizon: lifetime • Discount rate: 2.0%	• Patients with a spinal cord injury suffering from chronic urinary retention • Mean age of 57 years • 80% male • Setting: inpatient	• *Intervention:* hydrophilic catheters • *Comparator:* noncoated catheters	• Total QALYs Noncoated: 3.872 Hydrophilic-coated: 4.206 • Total LYG Noncoated: 9.233 Hydrophilic-coated: 10.014 • Total pyuria[a] events Noncoated: 64.63 Hydrophilic-coated: 56.25	• Currency: 2014 Yen (¥) • Noncoated: ¥5,112,621 • Hydrophilic-coated: ¥6,392,507	• ICER compared hydrophilic with noncoated • ¥3,826,351 per QALY gained • ¥1,639,562 per LYG • ¥152,731 per pyuria event

Abbreviations: CE, cost-effective; CEA, cost-effectiveness analysis; CI, confidence interval; CUA, cost-utility analysis; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHS, National Health Service; PSA, probabilistic sensitivity analysis; QALY, quality-adjusted life years; UK, United Kingdom; US, United States; UTI, urinary tract infection.

[a]Pyuria = elevated white blood cells in the urine.

Applicability of the Included Studies

The results of the applicability checklist for economic evaluations applied to the included articles are presented in Appendix 7. All six were deemed partially applicable to the research question, primarily due to an absence of studies relevant to the Ontario health care setting. Furthermore, other factors limited applicability for some studies: they did not conduct an analysis specific to the outpatient setting,[11,66-68] they lacked a systematic literature review,[64,66,68] or they did not evaluate all comparators of interest (i.e., intermittent catheters currently being used in Ontario).[64-68]

Discussion

The economic evidence review identified six studies with differing methodological approaches to evaluating the cost-effectiveness of various intermittent catheters. Overall, findings were consistent across studies, but given their differing settings, cost inputs, and UTI rates, the studies have limited relevance to the Ontario context.

The full mix of catheters currently being used in Ontario was not evaluated in all studies. In the five studies specifically comparing single-use hydrophilic and single-use noncoated intermittent catheters, all five determined hydrophilic catheters were the cost-effective device.[64-68] Only one study evaluated additional types of catheters, such as single-use gel reservoir and multiple-use noncoated; that study found that either single-use gel reservoir or multiple-use noncoated ICs (one per week) were cost-effective, depending on whether multiple-use ICs were included in the analysis.[11] However, both this and the other five studies were modeled from international contexts and are thus not representative of costs specific to the Ontario context.

Across the studies, the health economic models varied in their focus on short- or long-term health outcomes. Studies evaluating long-term outcomes classified their model around the patient's renal function, as they assumed complications of long-term intermittent catheterization, such as UTIs, would lead to progressive renal dysfunction. Other decision-modeling studies did not include long-term sequelae of complications like UTIs, but instead focused on acute complications of intermittent catheterization. The decision not to model long-term outcomes was driven by a 2007 NICE guideline on treating urinary tract infection in children.[69] This guideline concluded that it was not possible to estimate the true risk of renal failure from childhood UTIs; this guideline was updated in 2017 but continues to state that there is a lack of high-quality studies that would inform an estimate of the risk of childhood UTI leading to renal damage or established renal failure.[69] Additionally, the models used differing simulated outcomes, with hematuria, strictures, epididymitis, false passages, and bladder stones being evaluated variously across the studies.

With all six studies simulating a population with spinal cord injury (Håkansson et al[68] included a broader population with neurogenic bladder), the generalizability of the studies is limited to a select population of intermittent catheter users.[11,64-68] Several other limitations are specific to their methods and evidence base. Most evidence driving these models came from inpatient and rehabilitation settings, where risk of UTIs and other infections is higher than in community settings. The models were also limited by the available published evidence, which was reported in one analysis to have GRADE scores of low to very low.[11]

Conclusions

This economic literature review identified six economic evaluations modeling either short- or long-term complications owing to the long-term use of intermittent catheters. In five of the six

studies, only hydrophilic and single-use noncoated intermittent catheters were compared. The cost-effectiveness findings from those five studies ranged from hydrophilic catheters dominating single-use noncoated intermittent catheters to ICERs of up to $31,000 USD per QALY gained. In the remaining study, multiple-use noncoated and gel reservoir intermittent catheters were evaluated alongside hydrophilic catheters. There was an 89% probability of multiple-use noncoated catheters (reused for up to 1 week) being cost-effective at a £20,000 threshold.

The applicability of these studies to the Ontario context was limited owing to an absence of studies using Ontario-specific costs and to modeling that did not incorporate the perspective of the Ontario Ministry of Health and Long-Term Care. Two studies evaluated the cost-effectiveness of intermittent catheters used in an outpatient setting (i.e., patients in a community-dwelling or home setting conducting self-care), our population of interest in this health technology assessment; however, those studies used a different modeling technique from the model used in this health technology assessment.[64,65] To evaluate the cost-effectiveness of various types of intermittent catheter in Ontario, a model with Canadian inputs and effect estimates specific to the outpatient setting was needed to inform decision-making.

PRIMARY ECONOMIC EVALUATION

The published economic evaluations identified in the literature review studied various types of intermittent catheter; however, only one UK study[11] compared all intermittent catheters (ICs) currently being used in Canada (i.e., single-use hydrophilic, single-use gel reservoir, single-use noncoated, and multiple-use noncoated). As no study evaluated all intermittent catheters of interest from a Canadian perspective, we conducted a primary economic evaluation.

Research Question

Within the context of the Ontario Ministry of Health and Long-term Care, what is the cost-effectiveness of single-use hydrophilic and multiple-use noncoated intermittent catheters (i.e., reused for one day or one week) compared to single-use noncoated intermittent catheters, for use by people (including children and adults) living in the community with chronic urinary retention owing to spinal cord injury?

Methods

The information presented in this report follows the reporting standards set out by the Consolidated Health Economic Evaluation Reporting Standards Statement.[70]

Type of Analysis

Given the availability of utility data and the prior cost-utility analyses identified in the literature, we performed a cost-utility analysis comparing the costs and quality-adjusted life-years (QALYs) of intermittent catheters.

We conducted a reference case analysis and sensitivity analyses. Our reference case analysis adhered to the Canadian Agency for Drugs and Technologies in Health (CADTH) guidelines when appropriate and represents the analysis with the most likely set of input parameters and model assumptions.[71] Our sensitivity analyses explored how the results are affected by varying input parameters and model assumptions.

Target Population

People with bladder dysfunction comprise a heterogeneous population with various health conditions, such as spinal cord injury, multiple sclerosis, stroke, Parkinson disease, and benign prostate hyperplasia. Given this diversity and the differences among these groups, we chose one group as the model's target population: people with chronic urinary retention due to a spinal cord injury. Most of the clinical effectiveness literature is conducted in people with neurogenic bladder due to spinal cord injury, and utility data are available for this population.

We restricted our model to outpatients, defined as people with a spinal cord injury living in a community-dwelling or home setting and conducting self-care. If data from an outpatient setting were unavailable, we used clinical estimates from an inpatient setting.

The model population was on average 42 years old, the average age at which spinal cord injuries occurs, and they were 80% male and 20% female.[72] These population characteristics were based on the clinical trials used to inform clinical and state transition parameters of the model.[46,48,51-56,73,74] We also compared these population characteristics to Canadian spinal cord

injury data and determined that our hypothetical target cohort reasonably represented Canadians with spinal cord injury who perform intermittent catheterization.[4,75]

Perspective

We conducted this analysis from the perspective of the Ontario Ministry of Health and Long-Term Care.

Interventions

Currently in Ontario, there is no standard or accepted best type of intermittent catheter for managing chronic urinary retention; therefore, people use a variety of catheters such as hydrophilic, gel reservoir, and noncoated. Hydrophilic catheters have a polymer coating (polyvinylpyrrolidone) which upon exposure to water creates a lubricated surface to allow insertion of the catheter;[1] gel reservoir catheters are packaged with a water-based lubricant; and noncoated catheters require users to manually apply lubrication. As described in the Background section of this report (Current Treatment Options), we did not include indwelling/Foley catheters in this analysis, due to overwhelming evidence of the benefit of intermittent over indwelling catheters for self-catheterization in the outpatient setting.

We conducted evaluations for single-use hydrophilic ICs and multiple-use noncoated ICs (reuse of one IC for one day and for one week), compared with single-use noncoated ICs. After consulting with a manufacturer and considering the cost-effectiveness literature, we excluded single-use gel reservoir ICs from the reference case and analyzed them in a scenario analysis; this type of IC has low use in Ontario and available estimates are driven by a single-centre crossover study of 18 patients.[64] Table 14 summarizes the interventions evaluated in the reference case of our economic model.

Table 14: Summary of the Reference Case

Interventions	Data Source	Comparators	Patient Population	Outcomes
Single-use hydrophilic IC	Outpatient	Single-use noncoated IC	Long-term users of ICs with a spinal cord injury	• Costs • QALYs • ICERs
Multiple-use noncoated IC (1/day)	Outpatient			
Multiple-use noncoated IC (1/week)	Inpatient			

Abbreviations: IC, intermittent catheter; ICERs, incremental cost-effectiveness ratios; QALYs, quality-adjusted life-years.

Discounting and Time Horizon

We simulated the reference case over 5 years and ran sensitivity analyses at time horizons of 1 year and a lifetime. A lifetime horizon was not used for the reference case because the reference case focuses on short-term consequences of complications such as UTIs and hematuria, and because long-term clinical data on outpatients are lacking.

As per Canadian guidelines for economic evaluations, after the model's first year an annual discount rate of 1.5% was applied to costs and QALYs.[71] We explored different discount rates of 0%, 3%, and 5% in the sensitivity analyses.

Main Assumptions

To simplify our analysis, we made the following assumptions:

- People cannot switch between intermittent catheters
- Intermittent catheters of the same type from different manufacturers have the same efficacy and complication rate
- Where outpatient data were unavailable, mixed or inpatient data could represent outpatient data
- Antibiotic resistance is fixed over the model duration
- Complications such as strictures and false passage are equal between IC types
- Multiple-use ICs remain functional for their allotted duration (i.e., day use and week use)
- Each IC type can be used by any individual with a spinal cord injury
- The risk of a symptomatic UTI progressing to a more severe state is calculated from the cumulative probability of someone with a symptomatic UTI developing any of the more severe complications; there are no transitions between the first-line antibiotic–resistant, multidrug–resistant, and bacteremia health states

Model Structure

We adapted and altered a previously published Markov model from Bermingham et al,[11] to estimate the incremental cost per QALY of various intermittent catheters. Our model followed a cohort for 5 years, using a cycle length of 1 month. Given the acute conditions studied, we assumed all costs and utility gains/loses occurred within the month cycle. Each simulated cohort was assigned an intermittent catheter and its unique input parameters (e.g., probabilities, costs), which impacted the accumulation of costs and QALYs throughout the 5-year simulation.

The model included six health states:

- **No symptomatic UTI**: Individuals without a symptomatic UTI but at risk for complications (i.e., gross hematuria and bladder stones)
- **Symptomatic UTI**: Individuals with a symptomatic UTI who were diagnosed and prescribed a first-line antibiotic by a family physician or general practitioner
- **UTI resistant to first-line antibiotics**: Individuals with a UTI resistant to first-line antibiotics who were diagnosed and prescribed a second-line antibiotic by a family physician or general practitioner
- **Multidrug–resistant UTI**: Individuals with a multidrug–resistant UTI who are on their third line of treatment after receiving at least two prior antibiotic treatments, and are admitted to the hospital for treatment
- **Catheter-associated bacteremia**: Individuals with catheter-associated bacteremia, defined as bacteria reaching one's bloodstream due to a catheter-associated UTI, who are hospitalized because of a previously failed antibiotic therapy
- **Death**: An absorbing state for general mortality in a population with spinal cord injury, as well as for disease-specific mortality from the "multidrug–resistant UTI" and "catheter-associated bacteremia" health states

The cohort began in the "no symptomatic UTI" health state, and people could remain there or transition to the "symptomatic UTI" health state in the following cycle. In the "no symptomatic UTI" health state, people also had a risk of developing bladder stones or gross hematuria,

catheter-associated complications that result in additional costs and disutilities. People with a symptomatic UTI either resolved their UTI after their initial treatment (and returned to the "no symptomatic UTI" health state), or their UTI progressed and they transitioned to one of three temporary health states: "UTI resistant to first-line antibiotics," "multidrug–resistant UTI," or "catheter-associated bacteremia." As noted in our assumptions, the risk of the UTI progressing was derived from the cumulative probability of someone with a symptomatic UTI developing more severe complications; therefore, people moved to the state of their highest final acuity and did not transition between the three temporary health states. In the case of people entering "UTI resistant to first-line antibiotics," individuals were successfully treated by second-line therapy and transitioned back to "no symptomatic UTI" in the following cycle. In every health state, the population had a risk of mortality specific to a population with spinal cord injury; however, both the "multidrug–resistant UTI" and "catheter-associated bacteremia" health states had excess risk of mortality beyond this base rate, given the severity of these complications. If patients did not die as a result of having a multidrug–resistant UTI or catheter-associated bacteremia, their condition was resolved, and they returned to the "no symptomatic UTI" health state. Figure 6 presents a diagram of these transitions in our Markov model.

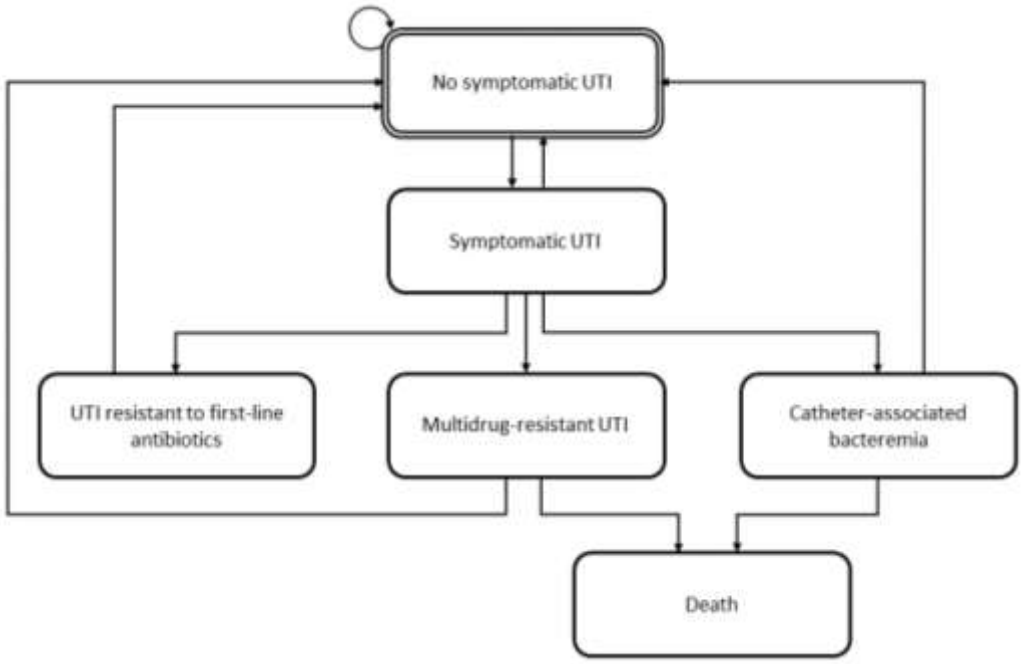

Figure 6: Model Structure

Abbreviation: UTI, urinary tract infection.

Notes: This model structure was adapted from Bermingham et al, 2013.[11]
All health states had a probability of moving to the death state, derived by multiplying the sex-adjusted mortality ratio for spinal cord injury by the age-specific general mortality.

Clinical Outcomes and Utility Parameters

We extracted clinical outcomes and utility parameters from various sources. The details of the model parameters are explained below.

Clinical Outcomes

To calculate transitional probabilities for each intermittent catheter, we conducted a meta-analysis using Review Manager version 5.3.[36] Data for the meta-analysis were taken from literature in the clinical evidence review of this health technology assessment. The meta-analysis evaluated the rates of symptomatic UTIs and gross hematuria in an outpatient and mixed inpatient/outpatient setting (Appendix 8). All intermittent catheters or interventions were compared to a common comparator, single-use noncoated ICs. In cases where no outpatient data were available for a specific IC, we used inpatient data.[46,56,57]

Given the variety of UTI outcome measures presented in the literature, we performed a meta-analysis and calculated risk ratios using the most commonly reported measure: the number of patients with a UTI (Appendix 9). While it is possible for someone to have more than one UTI during the study period, we were unable to ascertain the number of UTIs per patient, as most of the included studies did not provide individual-level data.

For gross hematuria, we used the number of patients with gross hematuria to calculate risk ratios. We were unable to aggregate data for microscopic hematuria, as no two studies had a common comparator and outcome measure. Table 15 presents the catheter-specific transitional probabilities derived from our meta-analysis.

Table 15: Monthly Transitional Probabilities by Intermittent Catheter

Model Parameters	Estimate[a]	95% CI	Source
Bladder stones			
Single-use noncoated	0.001200	NR	Truzzi et al, 2017[67]; Perrouin-Verbe et al,1995[76]; Chai et al, 1995[77]
Single-use hydrophilic	0.001080	NA	Expert opinion
Single-use gel reservoir	0.001200	NA	Assume equal to single-use noncoated IC
Multiple-use noncoated (1/day)	0.001200	NA	Assume equal to single-use noncoated IC
Multiple-use noncoated (1/week)	0.001200	NA	Assume equal to single-use noncoated IC
Gross hematuria			
Single-use noncoated	0.004396	NR	DeFoor et al, 2017[25]; Giannantoni et al, 2001[56]
Single-use hydrophilic	0.003957	NA	Expert opinion
Single-use gel reservoir	0.000881	0.000044–0.016991	Appendix 9, Meta-analysis
Multiple-use noncoated (1/day)	0.004615	NA	Expert opinion
Multiple-use noncoated (1/week)	0.005053	NA	Expert opinion
Symptomatic UTI			
Single-use noncoated	0.194802	NR	Woodbury et al, 2008[28]
Single-use hydrophilic	0.133246	0.050671–0.324408	Appendix 9, Meta-analysis
Single-use gel reservoir	0.060900	0.002164–0.765312	Appendix 9, Meta-analysis
Multiple-use noncoated (1/day)	0.194802	0.036163–0.713543	Appendix 9, Meta-analysis
Multiple-use noncoated (1/week)	0.194802	0.133246–0.282154	Appendix 9, Meta-analysis

Abbreviations: CI, confidence interval; IC, intermittent catheter; NA, not applicable, NR, not reported; UTI, urinary tract infection.
[a] Monthly transitional probabilities were calculated from rates using the methodology described in Briggs et al, 2006.[78]

Other transitional probabilities for each catheter type were derived from past cost-effectiveness analyses and assumptions provided by clinical experts. For bladder stones, we took estimates from Truzzi et al[67] and, after expert consultation (Blayne Welk, MD, November 2017) , we assumed single-use hydrophilic ICs would have a 10% lower rate of bladder stones than single-use noncoated ICs (Table 15). Due to a lack of published literature on gross hematuria rates for each catheter type, we used expert consultation (Blayne Welk, MD, November 2017) to estimate risk ratios (RRs) for single-use hydrophilic ICs (RR = 0.90), multiple-use noncoated ICs (one per day) (RR = 1.05), and multiple-use noncoated ICs (one per week) (RR = 1.15), compared to single-use noncoated ICs. Non–IC-specific transitional probabilities for first-line drug resistance were derived from Canadian rates of ciprofloxacin resistance to Escherichia coli.[79] Rates of multidrug–resistant UTIs and bacteremia were derived from the cost-effectiveness analysis by Bermingham et al[11] (Table 16).

Table 16: Monthly Transitional Probabilities for All Intermittent Catheters

Model Parameters	Estimate	95% CI	Source
UTI resistant to first-line antibiotics	0.191000	0.171623–0.210377	Karlowsky et al, 2011[79]
Multidrug–resistant UTI	0.070000	0.051000–0.092000	Bermingham et al, 2013[11]; Rognoni and Tarricone, 2017[65]; Dow et al, 2004[80]; Waites et al, 2000[81]; Mylotte et al, 2000[82]
Catheter-associated bacteremia	0.036000	0.034000–0.038000	Bermingham et al, 2013[11]; Rognoni and Tarricone, 2017[65]; Saint, 2000[83]

Abbreviation: CI, confidence interval; UTI, urinary tract infection.

Monthly mortality rates due to multidrug–resistant UTI and catheter-associated bacteremia were derived from published literature (Table 17). Both conditions require hospitalization, with potentially high acuity and risk to life.

Table 17: Monthly Mortality Rates for All Intermittent Catheters

Model Parameters	Probability	95% CI	Source
Multidrug–resistant UTI	0.00219	0.00109–0.00435	Bermingham et al, 2013[11]; Rognoni and Tarricone, 2017[65]; Klevens et al, 2008[84]
Catheter-associated bacteremia	0.00665	0.00245–0.01761	Bermingham et al, 2013[11]; Rognoni and Tarricone, 2017[65]; Montgomerie et al, 1991[85]

Abbreviations: CI, confidence interval; UTI, urinary tract infection.

Baseline mortality was based on age-specific Ontario life tables and modified to represent a population with spinal cord injury.[86] To adjust the Ontario life tables, we used published sex-specific standardized mortality ratios, representing the increased risk of mortality in the general population compared to individuals with spinal cord injury. Specifically, we used a weighted average specific to spinal cord injury across sexes (80% male, 20% female) to derive a single standardized mortality ratio, which was multiplied by the age-specific Ontario mortality rate to derive the cohort's mortality (Table 18).

Table 18: Spinal Cord Injury Standardized Mortality Ratio

	Men		Women	
Category	**SMR**	**(95% CI)**	**SMR**	**(95% CI)**
Paraplegia unweighted	1.30	(0.9–1.8)	3.30	(1.5–6.3)
Paraplegia weighted[a]	**1.70 (1.02–2.7)**			

Abbreviations: CI, confidence interval; SMR, standardized mortality ratio.
Source: Lidal 2017.[87]
[a] Weighted values are calculated as a weighted average that represents a population with spinal cord injury, with 80% males and 20% females.

Health State Utilities

Health outcomes were quantified as quality-adjusted life-years (QALYs). We used both utilities and disutilities to determine the impact on quality of life of certain health states and complications (i.e., bladder stones and hematuria). Utility weights were derived from published economic evaluations.[11,64,65] We assumed there was no differential utility in using a certain type of intermittent catheter; therefore, utilities gains and losses occurred through transitions to health states and complications (Table 19).

Table 19: Health State Utilities and Disutilities Used in the Economic Model

Health State	Utilities	95% CI	Source
Utilities			
No symptomatic UTI	0.831	0.809–0.852	Bermingham et al, 2013[11]; Vogel et al, 2002[88]; Zebracki et al, 2010[89]
Symptomatic UTI	0.782	0.764–0.799	Bermingham et al, 2013;[11] Vogel et al, 2002[88]; Zebracki et al, 2010[89]
UTI resistant to first-line antibiotics	0.760	0.685–0.834	Bermingham et al, 2013[11]
Multidrug–resistant UTI	0.738	0.688–0.787	Bermingham et al, 2013[11]; Vogel et al, 2002[88]; Zebracki et al, 2010[89]
Catheter-associated bacteremia	0.716	0.645–0.786	Bermingham et al, 2013[11]
Disutilities			
Bladder stones	−0.050	NR	Clark et al, 2016[64]
Hematuria	−0.093	NR	Rognoni and Tarricone, 2017[65]

Abbreviations: CI, confidence interval; NR, not reported; UTI, urinary tract infection.

Cost Parameters

We obtained cost inputs for our model from Ontario and Canadian sources. Health state costs were primarily derived from the Ontario Case Costing Initiative (OCCI), where a primary diagnosis code was matched to the model's health state to calculate average inpatient hospital costs (Table 20).[90] For health states treated in the outpatient setting, such as symptomatic UTI and UTI resistant to first-line antibiotics, we used microcosting from various sources: laboratory fees from the Ontario Schedule of Benefits for Laboratory Services,[91] physician billing fees from

the Physician Schedule of Benefits,[92] and average online prices for medical equipment (Table 21).

All costs are reported in 2017 Canadian dollars (CAD). When 2017 costs were not available, the health care components of the Statistics Canada Consumer Price Index (CPI) was used to adjust all costs to 2017 CAD.[35]

Table 20: Health State Costs

Health State	Monthly Cost, $	Range, $[a]	Source
No symptomatic UTI	0.00		
Bladder stones	4,662.00	3,496.50–5,827.50	OCCI[90] – Code N210
Hematuria	341.00	255.75–426.25	OCCI[90] – Code R310
Symptomatic UTI	78.10	58.58–97.63	Table 21
UTI resistant to first-line antibiotics	136.03	102.02–170.03	Table 21
Multidrug–resistant UTI	6,286.00	4,714.50–7,857.50	OCCI[90] – Code N390
Catheter-associated bacteremia	16,538.00	12,403.50–20,672.50	OCCI[90] – Codes A4150, A4151, A4158

Abbreviations: OCCI, Ontario Case Costing Initiative; UTI, urinary tract infection.
[a] Minimum and maximum range values were derived as 25% of the mean and were used in one-way sensitivity analyses.

Table 21: Microcosting Health State Costs

Variable	Cost, $	Source
Symptomatic UTI		
Health care consultation	77.20	Physician Schedule of Benefits[92] – Code A005
Dipstick	0.90	Average online unit price[a]
UTI resistant to first-line antibiotics		
Health care consultation	77.20	Physician Schedule of Benefits[92] – Code A005
Urine culture	12.93	Laboratory Fee Guide[91] – Code L634[b]
Repeat consultation	45.90	Physician Schedule of Benefits[92] – Code A006

Abbreviation: UTI, urinary tract infection.
[a]Taken from EMRN.ca, CanMedDirect.ca, and MyWellCare.ca.
[b]Laboratory fees are calculated by multiplying the individual unit values for labour, materials, and supervision by $0.517.

The average unit cost by catheter type was calculated using prices from online distributors (Table 22). Boxed catheter prices were pooled and the cost per IC type was derived using costs from various brands, tip styles (i.e., Coudé or straight) and material (i.e., PVC or red rubber). For noncoated ICs, the cost of lubricant satchels was derived from the same online distributors and added to the average IC cost. Appendix 11 shows our detailed calculations. In estimating monthly costs, we assumed that patients void urine five times per day. For users of multiple-use noncoated ICs, monthly costs were adjusted for reuse up to a day or a week. Average IC unit costs were validated by consulting with a long-term care facility and a supplier of ICs in Ontario (Red Leaf Medical, December 2017; Extendicare, December 2017).

Table 22: Intermittent Catheter Costs

Intermittent Catheter	Unit Cost, $	Monthly Cost, $	Range, $[a]	Source
Single-use hydrophilic	7.02	1,067.70	800.78–1,334.63	Ontario long-term care facility; online distributors[b]
Single-use gel reservoir	4.86	739.31	554.48–924.14	Online distributors[c]
Single-use noncoated[b]	1.09	179.56	134.67–224.45	Online distributors[c]
Mutliple-use noncoated (1/day)[b]	1.09	46.51	34.88–58.13	Online distributors[c]
Mutliple-use noncoated (1/week)[b]	1.09	17.99	13.49–22.49	Online distributors[c]

[a] Minimum and maximum range values were derived as 25% of the mean and were used in one-way sensitivity analyses.
[b] Noncoated catheter monthly costs included the price of 3.5G satchels of lubricant.
[c] Derived from SciSupply.ca, RedLeafMedical.ca, and LifeSupply.ca and calculated as an average unit price across Canadian online suppliers.

Analysis

Reference Case

For the reference case, we determined the mean incremental cost and QALYs for each intervention. As more than two interventions were being compared, we calculated the incremental cost-effectiveness ratio (ICER) using sequential analysis.[71] Sequential analysis compares all the interventions—single-use hydrophilic, single-use noncoated, multiple-use noncoated (one per day), and multiple-use noncoated (one per week)—and ranks them by increasing cost. Incremental costs and QALYs for each intervention are calculated by comparing it with the next most costly comparator. If an intervention is dominated (i.e., more costly and less effective than at least one other intervention) or is subject to extended dominance, it is removed from the analysis, and all remaining interventions are recalculated until only undominated interventions remain. (Extended dominance occurs "when the ICER for a given intervention compared with a lower-cost alternative is higher than the ICER for the comparison of a higher-cost intervention with the same lower-cost alternative."[71])

Parameter uncertainty was accounted for in a probabilistic sensitivity analysis, which performed 10,000 Monte Carlo simulations using values for the input parameters drawn from distributions reflecting the underlying uncertainty of various parameters. These distributions around each estimate were specified using the mean and standard error, which was derived from 95% confidence intervals (Table 23). We used gamma distributions for cost inputs; log-normal distributions for relative risk, odds ratio, or hazard ratio inputs; and beta distributions for probability and utility inputs. Where variables did not have a 95% confidence interval, only the fixed estimate was used in the probabilistic sensitivity analysis (e.g., disutilities and transitional probabilities of bladder stones). We also present the impact of uncertainty and variability through a cost-effectiveness acceptability curve.

Table 23: Probabilistic Sensitivity Analysis Variable Distributions[a]

Treatment Effect				
Symptomatic UTI Intervention IC: Comparator IC	**Mean OR**	**Log OR Standard Error**	**Distribution**	**Source**
Hydrophilic: noncoated (single-use)	0.66	0.50511	Lognormal	See Appendix 9
Gel reservoir: noncoated (single-use)	0.29	1.62645	Lognormal	See Appendix 9
Multiple-use noncoated (1/day): single-use noncoated	1.00	0.88116	Lognormal	See Appendix 9
Multiple-use noncoated (1/week): single-use noncoated	1.00	0.21020	Lognormal	See Appendix 9
Parameter: Probabilities	**Mean Probability**	**Standard Error**	**Distribution**	**Source**
UTI resistant to first-line antibiotics	0.191	0.00969	Beta	Bermingham et al, 2013[11]
Multidrug–resistant UTI	0.070	0.01025	Beta	Bermingham et al, 2013[11]
Mortality	0.00219	0.00408	Beta	Klevens et al, 2008[84]
Catheter-associated bacteremia	0.036	0.00100	Beta	Bermingham et al, 2013[11]
Mortality	0.00665	0.01700	Beta	Montgomerie et al, 1991[85]
Utilities and Costs				
Parameter: Utilities	**Mean**	**Standard Error**	**Distribution**	**Source**
No symptomatic UTI	0.831	0.64975	Beta	Bermingham et al, 2013[11]
Symptomatic UTI	0.782	0.60800	Beta	Bermingham et al, 2013[11]
UTI resistant to first-line antibiotics	0.760	0.66275	Beta	Bermingham et al, 2013[11]
Multidrug–resistant UTI	0.738	0.61500	Beta	Bermingham et al, 2013[11]
Catheter-associated bacteremia	0.716	0.62475	Beta	Bermingham et al, 2013[11]
Parameter: Costs	**Mean, $**	**Standard Error, $[b]**	**Distribution**	**Source**
Bladder stones	4,662.00	582.75	Gamma	OCCI
Hematuria	341.00	42.63	Gamma	OCCI
Symptomatic UTI	78.10	9.76	Gamma	OCCI
UTI resistant to first-line antibiotics	136.03	17.00	Gamma	OCCI
Multidrug–resistant UTI	6,286.00	785.75	Gamma	OCCI
Catheter-associated bacteremia	16,538.00	2,067.25	Gamma	OCCI
Single-use hydrophilic IC	1,067.70	133.46	Gamma	Online distributors
Single-use gel reservoir IC	739.31	92.41	Gamma	Online distributors
Single-use noncoated IC	179.56	22.45	Gamma	Online distributors
Multiple-use noncoated (1/day) IC	46.51	5.81	Gamma	Online distributors
Multiple-use noncoated (1/week) IC	17.99	2.25	Gamma	Online distributors

Abbreviations: IC, intermittent catheter; OCCI, Ontario Case Costing Initiative; OR, odds ratio; UTI, urinary tract infection.
[a]Variables without a 95% confidence interval in the deterministic analysis were not assigned a distribution.
[b]To be conservative, a 25% variation around the mean was used to calculate the standard error.[71]

Deterministic Sensitivity Analyses

We conducted one-way deterministic sensitivity analyses to evaluate how sensitive our reference case results were to specific parameters. One-way sensitivity analyses varied specific model variables based on their 95% confidence intervals and examined the impact on the results. Sensitivity analyses were conducted on all parameters, include clinical event rates, utilities, and costs. Details of the results and parameters used are presented in a tornado diagram.

Scenario Analyses

In addition to the reference case, we also conducted several deterministic scenario analyses (Table 24). The first removed multiple-use ICs, so we could directly compare single-use hydrophilic ICs and single-use noncoated ICs. This scenario was incorporated given concerns raised in the paper by Bermingham et al,[11] which identified that although intermittent catheters are reused in practice, some manufacturers label ICs as "single use" and do not recommend multiple use. In Canada, there is no clear guidance on this matter, and the Canadian Urological Association does not explicitly state a catheter type preference in their guidelines, but they do have brochures on intermittent catheterization that discuss cleaning and reuse.[93]

In the second scenario analysis, an additional intervention was added to the reference case: single-use gel reservoir ICs. Due to a lack of outpatient data on this type of catheter, we based their clinical efficacy measures on inpatient data. The remaining scenario analyses include using efficacy data from a mixed setting (i.e., inpatient/outpatient), using alternative time horizons (i.e., 1 year and lifetime), and varying discount rates (i.e., 0%, 3.0%, and 5.0%).

Table 24: Summary of the Scenario Analyses

Analysis	Interventions, by IC Type	Data Source Setting	Comparators	Patient Population	Outcomes
Scenario 1	Single-use hydrophilic	Outpatient	Single-use noncoated	Long-term users of IC	Costs, QALYs, ICERs
Scenario 2	Single-use gel reservoir	Inpatient	Single-use noncoated	Long-term users of IC	Costs, QALYs, ICERs
	Single-use hydrophilic	Outpatient			
	Multiple-use noncoated (1/day)	Outpatient			
	Multiple-use noncoated (1/week)	Inpatient			

Abbreviations: IC, intermittent catheter; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

Generalizability

The findings of this economic analysis cannot be generalized to all patients with spinal cord injury. The findings may, however, be used to guide decision-making about the specific patient populations addressed in the trials investigated by Health Quality Ontario.

Expert Consultation

Throughout the development of this model, we solicited advice from economic, clinical, and methodological experts. The role of the expert advisors was to review the structure and inputs of

the economic model to confirm that the information we used reasonably reflects the Ontario clinical setting. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the consulted experts.

Results

Reference Case Analysis

In the sequential analysis for our reference case (Appendix 10), we found extended dominance (i.e., lower effectiveness and a higher ICER) between multiple-use noncoated ICs (one per day) and single-use noncoated ICs, and between single-use noncoated ICs and single-use hydrophilic ICs. This resulted in two undominated (i.e., neither strategy being dominated by or dominating the other) strategies: multiple-use noncoated ICs (one per week) and single-use hydrophilic ICs. We determined that the ICER of single-use hydrophilic ICs compared with multiple-use noncoated ICs was $3,689,159 per QALY gained. The probabilistic analysis produced similar results, with an ICER above $4 million for single-use hydrophilic ICs. Tables 25 and 26 present further details on these results.

Table 25: Reference Case Analysis Results Using a Deterministic Analysis

Strategy, by IC Type	Average Total Costs, $	Incremental Cost, $	Average Total Effects	Incremental Effect	ICER, $
Multiple-use noncoated (1/week)	9,265.05		3.918163		
Single-use hydrophilic	67,343.49	58,078.44	3.933906	0.015743	3,689,159

Abbreviations: IC, intermittent catheter; ICER, incremental cost-effectiveness ratio.

Table 26: Reference Case Analysis Results Using a Probabilistic Analysis

Strategy, by IC Type	Average Total Costs, $ (95% CI)	Incremental Cost, $ (95% CI)	Average Total Effects (95% CI)	Incremental Effect (95% CI)	ICER, $/QALY Gained
Multiple-use noncoated (1/week)	8,668 (6,431–11,245)		3.9220 (3.895–3.939)		
Single-use hydrophilic	67,754 (53,279–84, 174)	59,285 (44,437–75,490)	3.9352 (3.893–3.959)	0.0132 (−0.0266 to 0.0444)	4,462,998

Abbreviations: CI, confidence interval; IC, intermittent catheter; ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life-year.

Sensitivity Analysis

The results of the one-way sensitivity analyses are presented through a tornado diagram in Figure 7a and 7b, comparing the two undominated interventions: single-use hydrophilic ICs and multiple-use noncoated ICs (one per week). When the monthly probability of having a symptomatic UTI among people using one noncoated IC per week was assumed to be 0.1332 (the lower limit of the 95% CI of the reference case parameter), the incremental cost became $60,125, while the incremental effectiveness was 0.000383, resulting in an ICER of

$156,985,138 per QALY gained. However, when the upper limit of the 95% CI was used (i.e., 0.2822), the ICER decreased to 1,606,891 per QALY gained.
Figures 7a and 7b do not show results of varying the monthly probability of having a symptomatic UTI with use of single-use hydrophilic ICs because the resulting ICER was negative. When the probability was 0.050671, the ICER was $1,372,232 per QALY gained, and the incremental cost and effectiveness were $54,784 and 0.039924, respectively. However, when the probability was 0.324408, single-use hydrophilic ICs were dominated, with an ICER of −$2,401,638 per QALY gained and an incremental cost and effectiveness of $63,841 and −0.026582, respectively. Our reference case results remained robust when other parameters were varied.

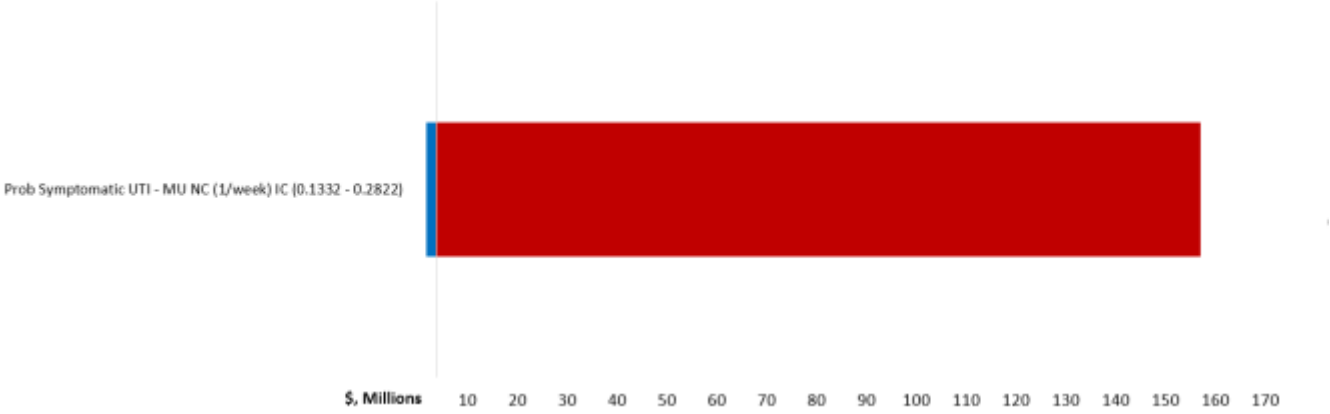

Figure 7a: One-Way Sensitivity Analysis: Single-Use Hydrophilic Versus Multiple-Use Noncoated (One per Week) Intermittent Catheters

Abbreviations: IC, intermittent catheter; MU, multiple-use; NC, noncoated; Prob, probability; UTI, urinary tract infection.
Note: X-axis represents the range of ICERs when reference case values are varied (ranges shown in parentheses). Vertical line represents the ICER for single-use hydrophilic intermittent catheters ($3,689,219 per QALY gained).

Figure 7b: One-Way Sensitivity Analysis: Single-Use Hydrophilic Versus Multiple-Use Noncoated (One per Week) Intermittent Catheters

Abbreviations: IC, intermittent catheter; Prob, probability; QALY, quality-adjusted life-years; UTI, urinary tract infection.
Note: X-axis represents the range of ICERs when reference case values are varied (ranges shown in parentheses). Vertical line represents the ICER for single-use hydrophilic intermittent catheters ($3,689,219 per QALY gained).

Figure 8 depicts the cost-effectiveness acceptability curve, which captures parameter uncertainty in estimates and lists the probability of certain ICs being cost-effective across a range of willingness-to-pay amounts. As four types of ICs are compared in this figure, cost-effectiveness is determined by the highest net monetary benefit, calculated as the incremental benefit multiplied by the willingness-to-pay amount and subtracted by the incremental cost. At a willingness-to-pay amount of $100,000 per QALY, there was a 59.3% chance multiple-use noncoated ICs (one per week) were cost-effective. At the same willingness-to-pay amount, there was a 40.6% chance multiple-use noncoated ICs (one per day) were cost-effective, and a 0% chance either single-use hydrophilic or single-use noncoated ICs were cost-effective.

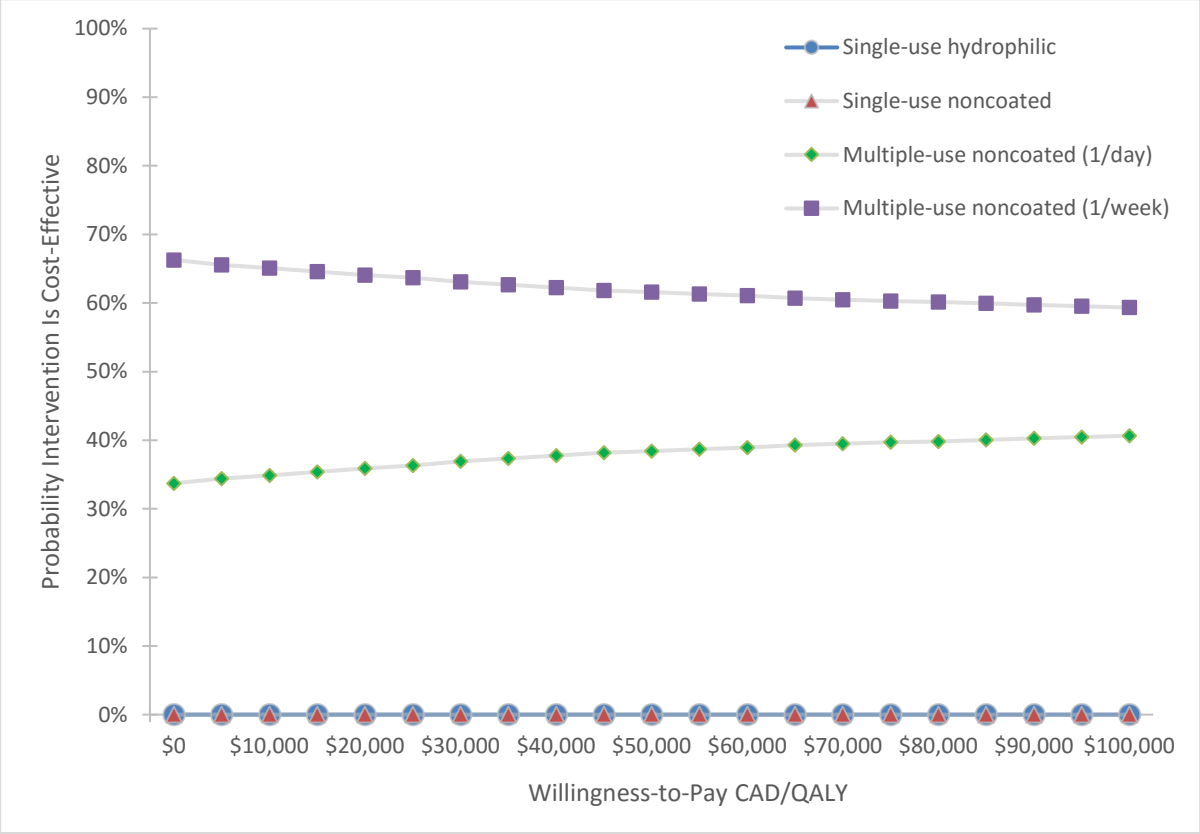

Figure 8: Cost-Effectiveness Acceptability Curve for Intermittent Catheters, by Catheter Type

Abbreviations: QALY, Quality-adjusted life-year.

Scenario Analyses

As shown in Table 27, all the various deterministic scenario analyses resulted in ICERs of more than $260,000 per QALY.

Excluding multiple-use noncoated catheters from the analysis (scenario 1) led to an ICER of more than $3.1 million per QALY for single-use hydrophilic catheters compared with single-use noncoated ICs. Figure 9 presents a cost-effectiveness acceptability curve for the same scenario; across all willingness-to-pay amounts, single-use noncoated ICs had a 100% probability of being cost-effective compared to hydrophilic ICs.

When single-use gel reservoir ICs were included (scenario 2), the ICER for that catheter type compared to multiple-use noncoated ICs (one per week) was about $960,000 per QALY. In scenario 3, transitional probabilities were taken from a mixed inpatient/outpatient setting, resulting in ICERs of $265,000 per QALY, $2.1 million per QALY, and $4.2 million per QALY for multiple-use noncoated ICs (one per day), single-use noncoated ICs, and single-use hydrophilic ICs, respectively. Varying the time horizon (scenarios 4 and 5) led to single-use hydrophilic ICs being undominated compared to multiple-use noncoated ICs (one per week), with ICERs over $2.5 million per QALY. Not shown in Table 27, using discount rates of 0%, 3.0%, and 5.0% as scenario analyses, led to ICERs similar to the reference case, and multiple-use noncoated ICs (one per week) remained the cost-effective therapy (Appendix 12).

Table 27: Deterministic Scenario Analyses Results

Strategy	Average Total Costs, $	Incremental Cost, $[a]	Average Total Effects	Incremental Effect[b]	ICER, $
Scenario 1: Excluding multiple-use noncoated ICs					
Single-use noncoated	18,524		3.918352		
Single-use hydrophilic	67,343	48,818	3.933906	0.015554	3,138,676
Scenario 2: Including single-use gel reservoir ICs					
Multiple-use noncoated (1/week)	9,265		3.918163		
Multiple-use noncoated (1/day)	10,896	1,630	3.918289	0.000126	Extended dominance
Single-use noncoated	18,525	9,259	3.918352	0.000189	Extended dominance
Single-use gel reservoir	45,616	36,351	3.956008	0.037845	960,516
Single-use hydrophilic	67,343	58,078	3.933906	0.015743	Dominated
Scenario 3: Transitional probabilities from mixed (inpatient and outpatient) setting					
Multiple-use noncoated (1/week)	9,812		3.914193		
Multiple-use noncoated (1/day)	10,896	1,084	3.918289	0.004096	264,604
Single-use noncoated	18,525	8,713	3.918352	0.004159	2,094,934
Single-use hydrophilic	68,133	58,321	3.928108	0.013915	4,191,267
Scenario 4: One-year time horizon					
Multiple-use noncoated (1/week)	1,791		0.813052		
Multiple-use noncoated (1/day)	2,129	338	0.813079	0.000027	Extended dominance
Single-use noncoated	3,711	1,920	0.813092	0.00004	Extended dominance
Single-use hydrophilic	13,862	12,071	0.815996	0.002944	4,100,357
Scenario 5: Lifetime horizon					
Multiple-use noncoated (1/week)	35,187		14.688182		
Multiple-use noncoated (1/day)	41,300	6,113	14.688652	0.00047	Extended dominance
Single-use noncoated	69,902	34,715	14.688888	0.000706	Extended dominance
Single-use hydrophilic	253,145	217,957	14.766068	0.077886	2,798,412

Abbreviations: IC, intermittent catheter; ICER = incremental cost effectiveness ratio.
[a]Incremental cost = strategy average cost − average cost of multiple-use noncoated (1/week) ICs.
[b]Incremental effect = strategy average effect − average effect of multiple-use noncoated (1/week) ICs.

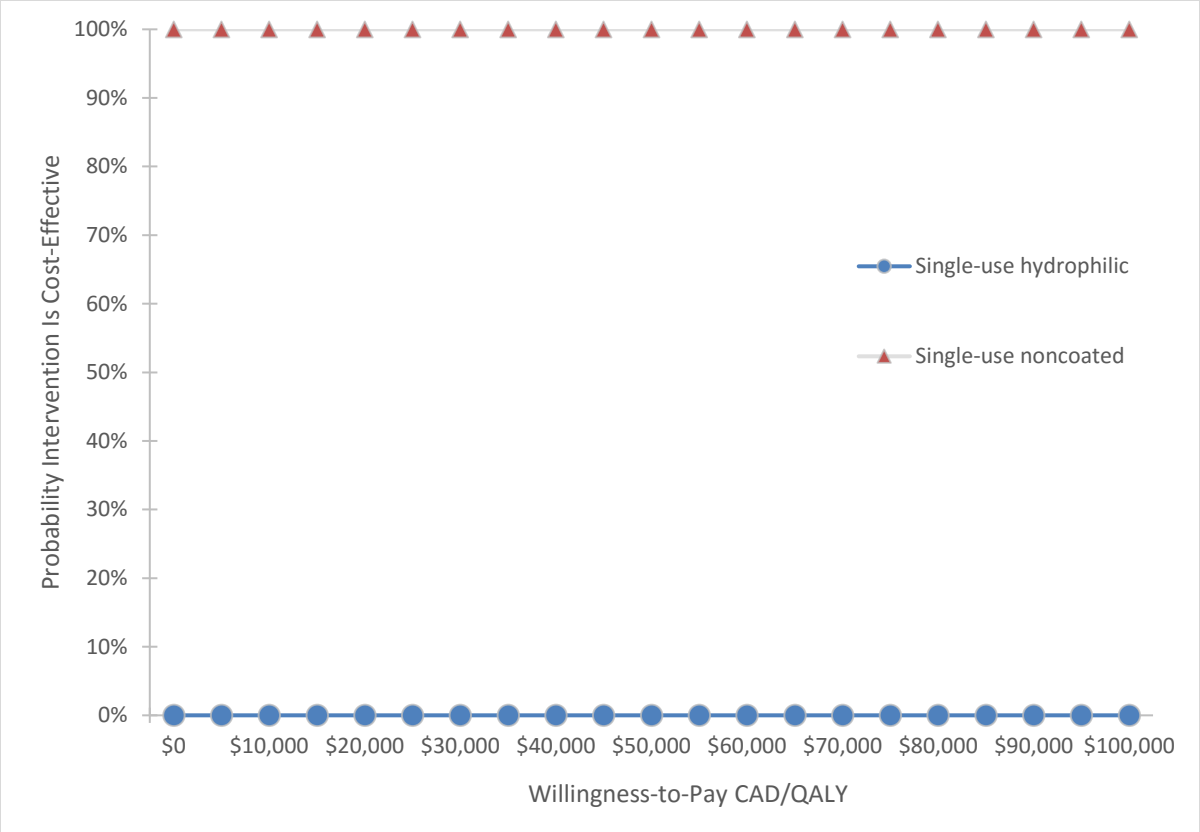

Figure 9: Cost-Effectiveness Acceptability Curve for Single-Use Intermittent Catheters

Abbreviations: CAD, Canadian dollar; QALY, Quality-adjusted life-year.

Discussion

This study evaluated the cost-effectiveness of various types of intermittent catheters in an outpatient population with spinal cord injury and chronic urinary retention. As several types of intermittent catheters are available in Ontario and there is no current treatment standard, we conducted a sequential analysis to compare all interventions: single-use hydrophilic, single-use noncoated, multiple-use noncoated (one per day and one per week). Based on the model results, extended dominance (i.e., lower effectiveness and a higher ICER) was found for single-use noncoated and multiple-use noncoated ICs (one per day). In our comparison of the two remaining types, single-use hydrophilic ICs had an ICER greater than $3.5 million per QALY gained (approximately $4.4 million per QALY in a probabilistic sensitivity analysis) compared to multiple-use noncoated (one per week). These high ICERs were driven by marginal differences in QALYs but large relative increases in costs across catheter types. Due to the marginal incremental QALY differences, the lowest-cost intervention, multiple-use noncoated ICs (one per week), likely provides the best value for money. This conclusion was reinforced by the cost-effectiveness acceptability curve, as 59.3% of model iterations indicated one-per-week noncoated ICs were cost-effective at a willingness-to-pay amount of $100,000 per QALY, and single-use hydrophilic ICs were not cost-effective at any willingness-to-pay amount. These results remained robust (i.e., high ICERs for single-use hydrophilic ICs) in various one-way sensitivity analyses, such as variations in complications relative to each type of catheter. Similar to results from Bermingham et al,[11] our modelling study found a marginal increase in QALYs across certain catheter types. This marginal increase can be explained by the primary

event, urinary tract infections, being an acute condition. Patients did not remain in a given UTI health state longer than one cycle; this resulted in very small differences when we compared the QALY gain from being in the “no symptomatic UTI” health state to that of the “symptomatic UTI” health state. In addition, relative UTI rates among catheter types were not large enough to create large differences in QALYs and were therefore another factor driving the large reported ICERs. These results are consistent with the clinical evidence review of this health technology assessment, which found that, given the overall low quality of evidence, we are uncertain whether one type of intermittent catheter significantly improves patient satisfaction or reduces symptomatic UTIs, hematuria, or other serious adverse events compared with another type.

We conducted a scenario analysis to consider patients for whom cleaning and reusing ICs would not be recommended. Single-use noncoated ICs would likely provide the best value for money for this population. This is because single-use hydrophilic ICs had an ICER of about $3 million per QALY gained in this direct comparison, and single-use noncoated had a 100% probability of being cost-effective, as shown on the cost-effectiveness acceptability curve, at every willingness-to-pay amount.

In a similar economic modelling study, Bermingham et al[11] evaluated the cost-effectiveness of various catheter types (based on data from a mixed setting) on a population with neurogenic bladder due to spinal cord injury. The authors determined multiple-use noncoated ICs (one per week) were cost-effective compared to single-use hydrophilic ICs, which had an ICER of £359,946 per QALY gained. Though large, this ICER is smaller than the ICER we report here, primarily due to differences in the costs of the catheters and the different settings from which inputs were derived (i.e., outpatient compared to mixed). In the Bermingham model, the unit price was relatively equal between catheter types, with an average hydrophilic IC costing £1.28 and a noncoated IC costing £1.19. In the Canadian setting, cost differences were more pronounced: average unit costs for hydrophilic and noncoated ICs were $7.02 and $1.09, respectively.

Alternative cost-utility models in the literature evaluated long-term sequelae of UTIs by incorporating long-term renal function and using a lifetime horizon.[64,66,67] Based on expert consultation (Blayne Welk, MD, November 2017) and a recent report from the National Institute for Health and Care Excellence (NICE), we did not incorporate long-term renal function in our model. The NICE report found that it was not possible to estimate the true risk of renal failure or renal damage as a result of childhood UTIs.[69] The limited literature on the relative severity of renal damage associated with different catheter types also contributed to our decision not to include long-term renal function. In addition, we selected a shorter, 5-year time horizon for our reference case because the literature informing relative risks of UTI rates by IC type were from studies with short durations. If we had taken a lifetime horizon, we would have had to assume the risks remained constant over a lifetime.

In late February 2018 (after we had conducted the systematic literature review), a cost-utility analysis was published comparing single-use hydrophilic to single-use noncoated ICs from the perspective of the Ontario Ministry of Health and Long-Term Care.[94] The authors conducted a Markov model evaluating the long-term sequelae of UTIs and their impact on renal function. Unlike past economic evaluations, the authors used an unpublished study that derived patient preferences indicating hydrophilic ICs provide distinct utility gains over noncoated ICs (derived from a time trade-off methodology and used in conjunction with a generic preference-based measure). Over a lifetime horizon, hydrophilic ICs were found to have a 0.72 QALY gain and an incremental cost of $48,016 compared to single-use noncoated ICs, leading to an ICER of $66,634 per QALY gained. The study also conducted scenario analyses that incorporated

additional utility gains from using compact single-use hydrophilic ICs and ICs not containing phthalates. Our study differs from this recent publication in that we did not evaluate long-term sequelae of UTIs. As described above, this decision was informed by expert consultation and a NICE report identifying that it was not possible to estimate the true risk of renal failure or damage as a result of childhood UTIs (i.e., a correlation between childhood UTIs and renal failure or damage later in life was not found).[69] Another key difference between studies is the average unit cost of catheters: the February 2018 publication found online unit costs of $3.77 for hydrophilic and $1.07 for noncoated ICs, versus costs in our model of $7.02 and $1.09. The authors also used a weighted average calculated from commercially available sales volumes of the three hydrophilic and uncoated ICs with the highest sales in Canada in 2017; in contrast, we used average costs for each type of catheter and validated them by consultation with a long-term care facility and a Canadian distributor of intermittent catheters.

Our primary economic evaluation had several strengths. Where possible, our model included Canadian data, such as baseline UTI rates and estimates of drug resistance for UTIs.[28,79] The baseline UTI rate was taken from a Canadian survey conducted in a population with spinal cord injury who were performing intermittent catheterization in an outpatient setting.[28] Although Canadian specific, the UTI rate was higher than previous models using data from inpatient settings. This high UTI rate suggests our results are conservative for multiple-use noncoated ICs (one per week), especially considering others have stated UTI incidence in the hospital setting is nearly three-fold higher than in the community setting.[64] An additional strength is the use of outpatient data to inform clinical effect estimates, where possible; these data will more accurately reflect current practice in Canada, where people who use intermittent catheterization do so primarily as outpatients.

Our analysis also has limitations. As highlighted in the clinical evidence review, the quality of the evidence was limited, and there were few outpatient studies for each catheter type that could inform each health outcome in our model. Due to this limitation, we used mixed or inpatient data where clinical estimates could not be derived from outpatient data (i.e., UTI rates for multiple-use noncoated ICs [one per week]). Another limitation was the inability to accurately reflect the complex, dynamic nature of antimicrobial resistance, which had to be simplified through a fixed estimate. Resistance rates could be higher, as the target population has frequent UTIs which can increase their exposure to hospital settings and antimicrobial agents.[95] Additionally, we could not stratify results for male and female populations due to a lack of outpatient data on UTI rates and the effectiveness of ICs stratified by sex. Although sensitivity analyses were conducted around UTI rates by catheter type, future research should explore how a higher UTI rate in women might impact IC cost-effectiveness.[59] Hematuria costs in our model were derived from an ambulatory setting, not an inpatient setting; although these costs were small, they were similar to costs reported in another cost-utility analysis,[65] and our study did not identify hematuria costs as a cost driver of the ICER. Finally, our model could not incorporate patient preferences regarding certain catheter types due to an absence of published utility data reflecting those options. Furthermore, as identified in the clinical evidence review of this health technology assessment, the available literature is inconclusive on overall patient preferences.

Conclusions

Our economic analysis indicates that two types of intermittent catheters used by an outpatient population with spinal cord injury were not cost-effective: single-use noncoated and single-use hydrophilic catheters. Given the marginal differences in total QALYs across catheter types, the lowest-cost intervention—multiple-use noncoated catheters (one per week)—had the highest probability of being cost-effective when compared with multiple-use noncoated (one per day),

single-use noncoated, and single-use hydrophilic catheters. Where it may not be feasible for some patients to clean and reuse catheters, single-use noncoated catheters have the highest probability of being cost-effective.

BUDGET IMPACT ANALYSIS

We conducted a budget impact analysis from the perspective of the Ontario Ministry of Health and Long-Term Care to determine the estimated cost burden of publicly funding intermittent catheters over the next 5 years. All costs are reported in 2017 Canadian dollars.

Research Question

What is the potential 5-year budget impact to the Ontario Ministry of Health and Long-Term Care of publicly funding one of the following types of intermittent catheters (ICs) for people with chronic urinary retention in the outpatient setting:

- Multiple-use noncoated (one per week)
- Multiple-use noncoated (one per day)
- Single-use noncoated
- Single-use hydrophilic
- Single-use gel reservoir

Methods

Analytic Framework

We estimated the budget impact of ICs using the cost difference between two scenarios: current public funding through the Incontinence Supplies Grant Program administered by Easter Seals Ontario (the current scenario) and the anticipated practice of publicly funding a selected type of catheter (the new scenario). The Easter Seals incontinence supplies grant is a provincial program, designed for children and youth ages 3 to 18 years with chronic disabilities that result in irreversible incontinence or retention problems lasting longer than 6 months. Easter Seals offers a Level A grant, which provides funding of up to $400 per year. Other sources of government funding for outpatients were explored, but were not incorporated for the following reasons:

- The Assisted Devices Program does not cover urinary catheters
- Local Health Integration Networks pay for intermittent catheters during a brief patient training program for patients, who must then upon completion fund their own incontinence supplies
- The Ontario Disability Support Program of the Ministry of Community and Social Services provides funding for incontinence supplies for eligible adults, but the program does not track information specific to funding of intermittent catheters, and catheters were expected to represent a small proportion of the overall funding for incontinence supplies which is dominated by adult briefs

Key Assumptions

- Multiple-use ICs remain functional for their allotted duration (i.e., use for one day or one week)
- Each catheter type can be used by anyone in the target population
- The target population conducts intermittent catheterization in the outpatient setting

Target Population

The target population for the analysis was all Ontarians with urinary retention requiring long-term use of ICs (> 28 days). This expands on the population of people with spinal cord injury used in our primary economic evaluation, to provide a cost estimate representative of all people requiring ICs in Ontario. After expert consultation (Dean Elterman, MD, and Blayne Welk, MD, December 2017), we included people with the following conditions: spinal cord injury, spina bifida, stroke, non-neurogenic urinary retention due to benign prostate hyperplasia, multiple sclerosis, and Parkinson disease (Table 28).

Table 28: Epidemiological Inputs Used to Derive the Target Population

Estimate	Value	Source
Ontario population (2016 Census)	13,448,494	Statistics Canada, 2017[96]
Prevalence		
Spinal cord injury	33,140	Spinal Cord Injury Ontario
Spina bifida	3,469	Ontario Brain Institute
Stroke	94,174	Ontario Brain Institute
Benign prostate hyperplasia[a]	1,253,076	Verhamme et al, 2002[97]
Multiple sclerosis	22,760	Ontario Brain Institute
Parkinson disease	28,191	Ontario Brain Institute
Incidence		
Spinal cord injury	600	Spinal Cord Injury Ontario
Spina bifida	27	Ontario Brain Institute
Stroke	12,749	Ontario Brain Institute
Benign prostate hyperplasia	0	Assume mortality and incidence are equivalent
Multiple sclerosis	1,830	Ontario Brain Institute
Parkinson disease	3,726	Ontario Brain Institute
Long-term intermittent catheter users (%)[b]		
Spinal cord injury	55%	Woodbury et al, 2008[28]
Spina bifida	66%	Verhoef et al, 2005[8]
Stroke	1%	Kong and Young, 2000[98]
Benign prostate hyperplasia[c]	5%	Expert opinion[d]
Multiple sclerosis	11%	Mahajan et al, 2013[99]
Parkinson disease	9%	Campos-Sousa et al, 2003[100]

[a] Calculated using the Ontario 2016 census in males aged 50 years and older.
[b] In cases where the percentage of long-term intermittent catheter users was not available, we used literature on the percentage of individuals with urinary/bladder retention, and we assumed all patients with retention were eligible for long-term intermittent catheterization.
[c] 5% of individuals with both benign prostatic hyperplasia and urinary retention (i.e., 10% of individuals with benign prostatic hyperplasia[101]) were assumed to be long-term intermittent catheter users.
[d] Email communication, Blayne Welk, MD, March 2018.

We estimated the total target population of intermittent catheter users in Ontario (including both children and adults) to be 32,764 individuals for our 5-year analysis (Table 29). In addition to the prevalence, incidence, and proportion of IC users presented in Table 28, we accounted for annual disease-specific mortality rates (Appendix 13). Target population estimates of the current

scenario were derived from consultation with the Ministry of Health and Long-Term Care and the Easter Seals Incontinence Supplies Grant Program; additionally, an annual growth rate of 1% was assumed beyond year 1 for the current scenario. More than 5,000 children and youth are enrolled in the Easter Seals grant, but only about 200 are estimated to be using grant funds for catheters (the majority of funds are used to buy diapers, pull-ups, attends, liners, and swimmers).

Table 29: Estimated Target Population of Intermittent Catheter Users in Ontario

Year	Current Scenario[a]	New Scenario[b]
Year 1	200	32,764
Year 2	202	33,126
Year 3	204	33,485
Year 4	206	33,841
Year 5	208	34,193

[a] The population in the current scenario was derived from data obtained from the Easter Seals Incontinence Supplies Grant Program, and we assumed 1% annual growth beyond year 1.
[b] The first year of the new scenario was calculated as the prevalence for each subpopulation multiplied by their respective percentage of long-term intermittent catheter users.

Costs

We used device-specific costs for each type of catheter. We did not include the costs of complications associated with catheter use (disease-associated costs) as we assumed they would be equivalent in the current and new scenarios. Under the current Easter Seals grant program, recipients can apply grant money to the catheter of their choice. Therefore, when comparing costs by IC type between the current and new scenarios, we assumed the same type of catheter was being used and the patient populations in the two scenarios would have equal disease-associated costs.

Table 30 presents average per-patient costs per year. All costs are Ontario-specific and expressed in 2017 Canadian dollars. We assumed that people using single-use catheters would use 5 devices per day. Costs for the current scenario were obtained from Easter Seals and based on 2016 data.

Table 30: Yearly Intermittent Catheter Costs per Patient

Intermittent Catheter	Unit Cost, $[a]	Yearly Cost per Patient, $[b]
Single-use hydrophilic	7.02	12,812.41
Single-use gel reservoir	4.86	8,871.74
Single-use noncoated	1.09	2,154.74
Multiple-use noncoated (1/day)	1.09	558.12
Multiple-use noncoated (1/week)	1.09	215.88

[a] Unit costs for noncoated catheters did not include lubricant costs; however, they are calculated in yearly costs.
[b] For single-use catheters, yearly costs were calculated as individual catheter cost multiplied by 5 uses per day, multiplied by 30.4167 days, multiplied by 12 months.

Analysis

We conducted a reference case analysis and scenario analyses. Our reference case analysis compared the current scenario to a new scenario of 100% funding for each IC. As the current funding through the Easter Seals Incontinence Supply Grant Program is specific to people 3 to 18 years old, all new scenarios represent a significantly larger, all-ages population.

In scenario analyses we explored:

- The variability in budget impact if cost-sharing strategies were implemented, with partial government funding of 25%, 50%, and 75%
- The impact a cost-sharing program would have on patients (the yearly cost each patient would need to cover in each partial-funding scenario)
- The impact of extending the Easter Seal grant program to patients of all ages

As noted, this budget impact analysis only evaluated device-specific costs, as the current funding scenario was a grant-based program that allows people to buy the IC of their choice. Therefore, when comparing full or partial funding for a specific type of catheter, we assumed the comparator, the current funding scenario, applied to that same IC, thus negating any disease-associated costs. Alternatively, disease-associated costs could be evaluated across the current market share by IC type in Ontario, but due to a lack of real-world evidence on market share, we excluded this approach. Consultation with manufacturers did provide a preliminary estimate of the market share based on sales volumes. However, sales volumes cannot account for the percentage of noncoated IC sales representing multiple-use IC users and therefore a market share analysis would underestimate the population using noncoated catheters.

We assumed an adoption rate of 100% from year 1. This patient population requires intermittent catheterization every day, and there are no alternative clinically recommended treatment strategies. An adoption rate of 100% would likely reflect reality, especially as private insurers may be expected to remove their coverage for ICs if provincial funding were in place.

Results

Results of the reference case analysis are shown in Table 31. In the current scenario, where ICs are funded only for people 3 to 18 years old, the total cost per year ranged from $80,000 in year 1 to $83,248 in year 5. Over the 5-year period, the total cost was estimated at just over $400,000. In the new scenario with 100% funding for each type of IC, the 5-year total costs were $36.14 million for multiple-use noncoated (one per week), $93.43 million for multiple-use noncoated (one per day), $360.72 million for single-use noncoated, $1.48 billion for single-use gel reservoir, and $2.14 billion for single-use hydrophilic catheters.

Table 32 presents estimates of the net budget impact of the new scenario, compared to the current scenario, at different funding levels of 25%, 50%, 75%, and 100% for each IC type. The highest net budget impact was for single-use hydrophilic ICs, with 5-year total costs of over $535.82 million if 25% of the cost were publicly funded. The total budget impact for the various cost-sharing strategies is presented in Appendix 14.

Table 33 provides the patient perspective for a partial funding program, showing the average yearly out-of-pocket cost per patient at the various levels of public funding. Annual patient expenses would range from $54 to $162 for multiple-use noncoated ICs (one per week), $140 to $419 for multiple-use noncoated ICs (one per day), $539 to $1,616 for single-use noncoated

ICs, $2,218 to $6,654 for single-use gel reservoir ICs, and $3,203 to $9,609 for single-use hydrophilic ICs.

We also analyzed a scenario in which the current Easter Seals Urinary Incontinence Grant Program was expanded to all ages. Table 34 describes the results of this analysis. The total net cost per year ranged from $13.02 million in year 1 to $13.68 million in year 5. Over the 5-year period, the total net costs were estimated at $66.56 million.

Table 31: Reference Case Results—Total Costs of Publicly Funding Intermittent Catheters in Current and New Scenarios

Strategy	Total Cost per Year, $					5-Year Total
	Year 1	Year 2	Year 3	Year 4	Year 5	
Current Scenario	80,000	80,800	81,608	82,424	83,248	408,080
New Scenario by Catheter Type						
Multiple-use noncoated (1/week)	7,073,189	7,151,295	7,228,736	7,305,518	7,381,642	36,140,381
Mutliple-use noncoated (1/day)	18,286,495	18,488,423	18,688,634	18,887,139	19,083,946	93,434,637
Single-use noncoated	70,598,835	71,378,420	72,151,379	72,917,747	73,677,561	360,723,944
Single-use gel reservoir	290,677,691	293,887,489	297,070,003	300,225,384	303,353,778	1,485,214,344
Single-use hydrophilic	419,791,444	424,426,977	429,023,106	433,580,049	438,098,019	2,144,919,596

Table 32: Net Budget Impact of Full and Cost-Shared Public Funding of Intermittent Catheters, New Scenario Compared to Current Scenario

	Net Budget Impact, $					
Strategy by Catheter Type	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**5-Year Total**
Multiple-use noncoated (1/week)						
25% funding	1,688,297	1,707,024	1,725,576	1,743,955	1,762,162	8,627,015
50% funding	3,456,595	3,494,847	3,532,760	3,570,335	3,607,573	17,662,110
75% funding	5,224,892	5,282,671	5,339,944	5,396,714	5,452,983	26,697,205
100% funding	6,993,189	7,070,495	7,147,128	7,223,094	7,298,394	35,732,300
Multiple-use noncoated (1/day)						
25% funding	4,491,624	4,541,306	4,590,551	4,639,361	4,687,738	22,950,579
50% funding	9,063,247	9,163,411	9,262,709	9,361,145	9,458,725	46,309,238
75% funding	13,634,871	13,785,517	13,934,868	14,082,930	14,229,711	69,667,897
100% funding	18,206,495	18,407,623	18,607,026	18,804,715	19,000,697	93,026,556
Single-use noncoated						
25% funding	17,569,709	17,763,805	17,956,237	18,147,013	18,336,142	89,772,906
50% funding	35,219,418	35,608,410	35,994,082	36,376,450	36,755,532	179,953,891
75% funding	52,869,126	53,453,015	54,031,926	54,605,886	55,174,923	270,134,877
100% funding	70,518,835	71,297,620	72,069,771	72,835,323	73,594,313	360,315,863
Single-use gel reservoir						
25% funding	72,589,423	73,391,072	74,185,893	74,973,922	75,755,196	370,895,506
50% funding	145,258,845	146,862,944	148,453,394	150,030,268	151,593,641	742,199,092
75% funding	217,928,268	220,334,817	222,720,895	225,086,614	227,432,085	1,113,502,678
100% funding	290,597,691	293,806,689	296,988,395	300,142,959	303,270,530	1,484,806,264
Single-use hydrophilic						
25% funding	104,867,861	106,025,944	107,174,169	108,312,588	109,441,256	535,821,818
50% funding	209,815,722	212,132,688	214,429,945	216,707,600	218,965,761	1,072,051,717
75% funding	314,763,583	318,239,432	321,685,722	325,102,613	328,490,266	1,608,281,616
100% funding	419,711,444	424,346,177	428,941,498	433,497,625	438,014,771	2,144,511,515

Table 33: Average Yearly Patient Costs for Intermittent Catheters in a Cost-Sharing Funding Model

Cost-Sharing Strategy by Catheter Type	Patient's Average Yearly Cost, $[a]	Patient's 5-Year Total Cost, $
Multiple-use noncoated (1/week)		
25% funding	162	810
50% funding	108	540
75% funding	54	270
Multiple-use noncoated (1/day)		
25% funding	419	2,093
50% funding	279	1,395
75% funding	140	698
Single-use noncoated		
25% funding	1,616	8,080
50% funding	1,077	5,387
75% funding	539	2,693
Single-use gel reservoir		
25% funding	6,654	33,269
50% funding	4,436	22,179
75% funding	2,218	11,090
Single-use hydrophilic		
25% funding	9,609	48,047
50% funding	6,406	32,031
75% funding	3,203	16,016

[a]Assumes costs remain constant for 5 years.

Table 34: Scenario Analysis – Expanding Easter Seals Funding Program

Strategy	Total Cost per Year, $					5-Year Total
	Year 1	Year 2	Year 3	Year 4	Year 5	
Current scenario	80,000	80,800	81,608	82,424	83,248	408,080
Expanded program[a]	13,105,780	13,250,500	13,393,990	13,536,257	13,677,307	66,963,833
Net budget impact	13,025,780	13,169,700	13,312,382	13,453,833	13,594,058	66,555,753

[a]Expanding the Easter Seals program was calculated by multiplying the grant per person in the current program ($400) by the target population.

Limitations

One limitation to our budget impact analysis is the possibility that an unknown percentage of the target population, such as people disabled by a stroke or people with multiple sclerosis receiving end-of-life care, may be receiving intermittent catheterization outside an outpatient setting. Therefore, it may be that long-term care facilities or hospitals would absorb some of the estimated costs. This study was also limited by a lack of data indicating the number of patients advised not to reuse intermittent catheters by their clinicians. The estimated size of this subpopulation is unknown, but it would result in higher total costs compared with some of our estimates, in which all patients are assumed to reuse noncoated intermittent catheters. An additional limitation is the sparse literature on the estimated percentage of specific populations using long-term intermittent catheterization (i.e., people with multiple sclerosis, Parkinson disease, or spinal cord injury). In cases where the proportion could not be estimated from the literature, we assumed all patients with urinary retention were intermittent catheter users. As well, the costs of the current scenario are likely underestimated, due to a lack of data or a low utilization in programs that could be measured. Finally, the overall budget impact of publicly funding intermittent catheters may be underestimated because we used catheter costs based on information from online suppliers, not traditional brick-and-mortar businesses where prices may be higher.

Discussion

When interpreting the results of this budget impact analysis alongside our primary economic evaluation, it is important to remember that the results of the primary economic evaluation are specific to a population with spinal cord injury, which is a subset of the population evaluated in the budget impact analysis.

In the reference case analysis, with 100% funding for each type of catheter, the annual budget impact was significantly higher than the current scenario, owing to the large increase in the number of IC users who would receive public funding (200 people in the current scenario and 32,764 for the new scenario in year 1). The baseline population is low because the Easter Seals Incontinence Supply Grant Program, our data source for the current scenario, applies only to children and youth 3 to 18 years old and because relatively few people use this funding for intermittent catheters. Looking at annual costs per patient, we found that multiple-use noncoated ICs (one per week), at $215 per person, would cost less than the $400 currently granted through the Easter Seals program. Given feedback from the program, we did not consider one-per-week multiple-use catheters in our conclusions.

Given the large differences between the current and new scenarios, we analyzed various cost-sharing scenarios. The 5-year net budget impact for the multiple-use noncoated ICs (one per day) compared to the current Easter Seals grant program was $22.9 million at 25% funding, $46.3 million at 50% funding, $69.6 million at 75% funding, and $93.0 million at 100% funding. If multiple-use ICs were excluded, the least costly device would be single-use noncoated ICs, with a 5-year net budget impact compared to the current Easter Seals grant program of $89.7 million, $179.9 million, $270.1 million, and $360.3 million for 25%, 50%, 75%, and 100% funding, respectively.

We also evaluated an alternative strategy of expanding the Easter Seals program to all ages (5-year net budget impact of $66.5 million). If, hypothetically, only one type of IC was funded through this expanded program, in the first year alone this funding would cover 72% of multiple-

use noncoated ICs (one per day), 19% of single-use noncoated ICs, 5% of single-use gel reservoir ICs, or 3% of single-use hydrophilic ICs.

Although the cost estimates for the new scenarios were large, the costs of ICs could theoretically be reduced. Under the current structure of the Easter Seals program, patients purchase their own ICs from manufacturers and distributors. However, if central purchasing was used, costs could theoretically be reduced through bulk purchasing. The potential to reduce IC costs is reinforced by international differences in the price of hydrophilic ICs; in Ontario, the average cost is $7, while other economic evaluations have estimated hydrophilic ICs at £1.28 in the United Kingdom,[11] €1.70 in Italy,[43] and R$4.99 in Brazil.[67]

We set uptake rates for ICs at 100% because all patients with chronic urinary retention must catheterize. Therefore, patients who need ICs are expected to receive or apply for funding within the year. We excluded a phased uptake over time owing to equity concerns and the expectation that private insurers would remove coverage in the event that ICs are fully publicly funded.

Rognoni et al[65] conducted a budget impact analysis comparing single-use hydrophilic ICs to single-use noncoated ICs from an Italian public payer perspective. Unit costs were significantly lower at €0.25 for noncoated ICs and €1.70 for hydrophilic ICs. The budget impact also differed as it accounted for both disease-associated and device-specific costs, and it used current and potential future market shares of single-use hydrophilic and noncoated ICs. The total 5-year budget impact, with an 89% market share for hydrophilic ICs and 11% for noncoated, was €857 million (IC device cost = €425 million). Although this is less than our estimates for full funding of hydrophilic ICs over 5 years ($2.1 billion), it is important to note the substantially higher costs of hydrophilic ICs in the Canadian market, which is a key driver of the total budget impact.

Conclusions

Our budget impact analysis indicates that publicly funding intermittent catheters for outpatient use in Ontario over the next 5 years would result in net spending that varies by type of catheter. Noncoated catheters that people can clean and reuse (one per day) would result in the lowest cost to fully fund intermittent catheters, at a cost of $93.0 million over 5 years. Single-use catheters would cost $360.3 million (for noncoated), $1.4 billion (gel reservoir), or $2.1 billion (hydrophilic). In an attempt to limit the overall budget impact, while still providing patients with a degree of support, we also analyzed several cost-sharing strategies in which 25%, 50%, and 75% of catheter costs would be publicly funded. Finally, expanding the current Easter Seals Incontinence Supplies Grant Program to all ages would cost an additional $66.5 million over the next 5 years.

PATIENT PREFERENCES AND VALUES

Objective

The objective of this analysis was to explore the underlying values, needs, impacts, and preferences of those who have lived experience with intermittent catheters due to chronic urinary retention caused by various health conditions.

Background

Patient, caregiver, and public engagement provides a unique source of information about people's experiences of a health condition and the health technologies or interventions used to manage or treat that health condition. This information includes the impact of the condition and its treatment on the patient, the patient's family and other caregivers, and the patient's personal environment. Engagement also provides insights into how a health condition is managed by the province's health system.

Information shared by people with lived experience can also identify gaps or limitations in published research (e.g., sometimes typical outcome measures do not reflect what is important to those with lived experience).[102-104] Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies or interventions.

Because the needs, priorities, preferences, and values of those with lived experience in Ontario are not often adequately explored in published literature, we contact and speak directly with people who live with a given health condition, including those who may have experience with the intervention we are exploring.

Intermittent catheters are used by people living with neurogenic bladder, spinal cord injury, multiple sclerosis, spina bifida and hydrocephalus, bladder cancer, prostate cancer, Parkinson disease, stroke, cerebral palsy, and other conditions. People can begin using intermittent catheters at any age and usually continue to do so over their lifetime. As estimated in our budget impact analysis in this report, approximately 33,000 people in Ontario rely on intermittent catheterization.

We spoke with adults and parents of children who have lived experience using intermittent catheters to manage chronic urinary retention. Gaining an understanding of the day-to-day experience of managing chronic urinary retention, including people's experience with intermittent catheters, helps us assess the potential value of this technology from the perspective of patients and caregivers.

Methods

Engagement Plan

The engagement plan for this health technology assessment focused on examining the experiences of people with chronic urinary retention and those of their caregivers, including their experience with using intermittent catheters. We engaged people face-to-face and via phone interviews.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people affected by chronic urinary retention. Our main task in interviewing was to understand what people told us and to gain an understanding of the story behind their experiences.[105] The sensitive nature of exploring people's experiences of a health condition and their quality of life are other factors that supported our choice of an interview methodology.

Participant Recruitment

We used an approach called purposive sampling,[106-109] which involves actively reaching out to patients, families, and caregivers with direct experience of the health condition and health technology or intervention being reviewed. We approached 90 organizations and health clinics involved in direct care, care coordination, or support for people with spinal cord injury, multiple sclerosis, spina bifida and hydrocephalus, stroke, bladder cancer, prostate cancer, cerebral palsy, and Parkinson disease, to spread the word about this engagement opportunity across Ontario.

Inclusion Criteria

We sought to speak with people and their caregivers who have been actively managing chronic urinary retention by using intermittent catheters for more than 28 days.

Exclusion Criteria

We did not set specific exclusion criteria.

Participants

We conducted interviews with 34 people in person or by telephone.

Those interviewed included adults with chronic urinary retention and parents of children (ages ranged from less than 2 to 12 years) with chronic urinary retention. No children were interviewed for this project.

All participants had direct experience with intermittent catheterization. They had been using intermittent catheters between 2 and 50 years. Many had experimented with single-use and multiple-use catheters as well as different types of catheters including hydrophilic catheters.

Approach

At the beginning of the interview, we explained the role of Health Quality Ontario, the purpose of the health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a printed letter of information (Appendix 15). We obtained participants' verbal consent before starting the interview. With participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 20 to 90 minutes. Interviews were loosely structured 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.[110] Questions focused on the impact of chronic urinary retention on patients' and families' quality of life, their experiences with treatment options, and

their perceptions of the benefits or limitations of using intermittent catheterization to manage their condition. See Appendix 16 for our interview guide.

Data Extraction and Analysis

We used a modified version of a grounded-theory methodology to analyze interview transcripts. The grounded-theory approach allowed us to organize and compare information on experiences across participants. This method consisted of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.[111,112] We used the qualitative data analysis software program NVivo (QSR International, Doncaster, Victoria, Australia) to identify and interpret patterns in interview data. The patterns we identified then allowed us to highlight the impact of chronic urinary retention and intermittent catheterization on the patients, family members, and caregivers we interviewed.

Results

Lived Experience of People Using Intermittent Catheters

During the interviews, people with chronic urinary retention and their family members emphasized the daily burden and stress of managing their condition. People with chronic urinary retention who use intermittent catheters must remember to have catheters with them at all times to regularly empty their bladders and avoid potentially grave health consequences. Participants emphasized that while self-catheterization becomes routine, the fear of urinary tract infections remains.

Diagnosis

As noted above, people can develop chronic urinary retention as a result of having various neurological and non-neurological conditions. Depending on their underlying condition, patients and families received varying levels of education about the importance of intermittent self-catheterization and the techniques involved. People who required an extensive hospital stay and rehabilitation, such as those with spinal cord injury, explained that nurses took the time to ensure their patients were comfortable with intermittent self-catheterization prior to discharge.

> *We were in a hospital, and the doctor suggested that I do this [self-catheterization], and I said okay. And they came right up there and showed me some catheters and gave me some samples to try. After that, they made three home calls. A nurse came in and showed me what to do and helped me to do it … I had three home visits for training … It was done very well and quickly.*
>
> *It was pretty intensive training by the nurses because obviously when people can get independent doing their own catheters in hospital it saves nursing time.*

However, people who were prescribed intermittent self-catheterization as outpatients, including those with multiple sclerosis and bladder cancer, often encountered a steep curve in learning to self-catheterize and manage their chronic urinary retention.

> *It was terrible … She [nurse] tried to teach me how to self-cath while lying down. Apparently, she's never actually taught a mobile patient how to self-cath. So she used a technique that would be used for somebody that would be kept in a bed … As a woman it's pretty much impossible to catheterize yourself while you're lying on a bed … That was a complete bust. I ended up with the indwelling [catheter]. Then I had another nurse*

> *from a different company come out who didn't seem nervous about the whole process. She taught me how to do it standing over the toilet, which is easy-peasy.*

For children with chronic urinary retention, it was usually their parents' responsibility to catheterize them. Most parents reported significant emotional distress as they learned to insert catheters at different stages of their child's development.

> *The first time I did his catheter I cried. He was a newborn and I couldn't go home until I could do it. I remember I was getting irritated because the nurses were late for doing his catheter. So I just shut the door, and I just did it. I bawled myself, but I did it. It was horrid. Nobody wants to have to do that to their infant. But I did it. It was tough … Then when he was older and I had to start doing it again, I thought how am I going to do this? Because it's not as easy when they're a baby. You just can't hold them down.*

Parents also had to decide when to teach their children to self-catheterize and how to do so. Given that intermittent self-catheterization requires hand dexterity, teaching children how to self-catheterize posed significant challenges.

> *The hospital actually did not have any training for a five-year-old. They advised me that it should be an organic process and I said, well, there's developmental issues. She doesn't even know what right from left is … A five-year-old can't read. A five-year-old doesn't understand … I ended up having to develop my own games ... So it's a huge, huge challenge to teach a five-year-old how to do this ... She had to know what hand washing was … There were so many precursors to just even learning the technique before you could even start.*

Day-to-Day Impact of Using Intermittent Catheters

Though events around the diagnosis of chronic urinary retention and management with intermittent catheterization were different for each person, those interviewed commonly reported the overwhelming impact it had in their daily lives. Most referred to their quality of life in terms of the significant challenges they faced and changes that needed to be made to manage their chronic urinary retention. The descriptions of this impact fell into two categories: social and emotional.

Social Impact

Adults and parents of children using intermittent catheterization commonly reported its social impact. No matter the age they began using intermittent catheters, most interviewees spoke of adjustments they had to make in social settings.

> *If I'm going on a plane, I watch my fluid intake. I do it [catheterize] before I board a plane and as soon as I get off the plane. My life revolves around catheters on some days.*

Parents reported that a particularly challenging time for their children was transitioning through school. Parents would often need to educate teachers and administrators about chronic urinary retention and how their children would manage it. For younger children, parents often had to seek extra support to manage their child's condition effectively in school. It required more responsibility by teachers, school nurses, and day care workers.

> *I needed to train the daycare workers … Me and my husband were trained, and we would do it all in the home, and then when she had to go to childcare for me to go back*

> *to work, we had to now rely on a third party to do that service for her because she was still an infant,...,They needed to learn all about infection and how to store the supplies,…,They basically needed one of those tables, a bed that could lift up, because you can't be lifting up a child with all these union rules and everything. So that was really stressful for us and we were still using the ones [catheters] with the lubricant because we didn't know [about hydrophilic catheters] and then it got so bad that the school couldn't provide the service.*

For some children, managing chronic urinary retention through intermittent catheterization meant a disruption in class to make sure they went to the washroom every couple of hours. Keeping their supplies clean and sterile was also a significant challenge in public school bathrooms.

> *I started doing self-catheterisation when I was about seven or eight. I would go to the nurse's station at school during recess and I would catheterize. They had a little area for me with my supplies, and every week I would take them home and my mum would boil them and we'd bring them back on Monday ... With high school though, I didn't have that opportunity but I carried a purse so I could keep my stuff in my purse and go to the bathroom when I had the opportunity to, between classes … But I can tell you that I didn't use a clean method, really. There was no gauze involved. It was quick and fast because that's the time I had.*

> *Catheters at school is a nightmare. He usually uses the teachers' bathroom because he's scared to death to go into the regular bathrooms, and there's no garbage disposals … It's tough going through school doing catheters.*

Parents felt extra stress if their children weren't independent enough to self-catheterize and required their help. In this case, children were also limited in the number of activities they could take part in and the amount of time they could spend with their friends.

> *If someone called in sick I would have to leave work and go to the school and do it [catheterize child]. So it just became very necessary for her to learn the techniques herself. She started learning at age five.*

> *When he was young, it was a big impact because I had to reroute my whole life. If we went anywhere I had to worry about catheters. It wasn't easy to go on a trip. It was tough. Now that he's a little older, it's a little bit easier because he does his catheters himself now.*

Additionally, some adults mentioned that since a bladder infection caused by their condition could creep up on them, it was difficult to make travel plans.

> *We kind of joke and say it's like living with a time bomb because you try to make plans to go away or do something and, when the bladder infection hits, he gets really sick so you really can't go anywhere, but that's just the nature of the beast, really.*

Emotional Impact

Most participants reported the emotional impact of having chronic urinary retention and using intermittent catheters. Adults and parents felt limited in their ability to travel and take part in

"normal" day-to-day activities. This emotional burden also had a large impact on parents, caregivers and families.

> *I mean the stress was enormous, to the point that I wasn't travelling or going anywhere. Or I would just not drink any water or any food, just to dry myself out which never happens … The stress was just terrible and prevented me from many activities. That was the biggest thing.*

> *I lost like three jobs since everything went boom in 2013 and, you know, I'm so expensive. If we don't end up divorced, I'll be shocked; my husband is so tired of paying for stuff. I'm trying to get back to work because I'm not eligible for disability. But it's a lot of work to get back to work … You end up sort of begging for help, which is so uncomfortable. I hate it.*

> *How would we ever leave the house? ... Basically she has to be catheterized every three hours. So, for the first few years it was like, okay, well, we can go out for an hour, as long as we're back for the catheter. Our life was completely consumed around the catheter … It was a very stressful thing.*

Both adults and parents of children using intermittent catheters consistently expressed the fear and anxiety they felt around developing a urinary tract infection (UTI).

> *I still do have stress, like if she sleeps in. Say we did the catheter at 11 p.m. and it's now 9 a.m. I'm like, ooh, I will wake her up. I will have to wake her up because she can't have the urine in her bladder that long. I don't want it sitting there making an infection. So there's always that infection worry all the time.*

> *My biggest worries were the UTI and my wife [my caregiver] gets over stressed about it and then I worry about her condition because she does have a bad heart and that just increases the worry for me.*

> *When I get an infection, it affects my multiple sclerosis. When I get an infection anywhere in my body, I almost have to be admitted to hospital. Because if I get a fever, then my whole body stiffens up and it affects me in a terrible, terrible, terrible way.*

> *At first when I started using the intermittent catheters, I followed the doctors and the clinical nurse and everyone's recommendation to reuse it. As a result I ended up in the hospital with sepsis and a bad kidney infection and whatnot. I almost died. I was in ICU [intensive care unit] … Never will I go there again … I could have lost my life due to the infection.*

Parents also spoke of their contrasting desires to keep their children healthy by ensuring they self-catheterized regularly, but also wanting to allow them independence to take control of their bladder management.

> *We still need assistance in the school for her to remind her when to go, because I don't fully trust her to remember to go every three hours … I worry about her ability to just manage. It's a lot for one person to manage.*

> *It's a lot for a child to remember to put the catheter, cleanly, wash it out. Like, forget it. You know, like, try to teach an eight-year-old to wash a catheter after they've gone to the bathroom? We're lucky if they washed their hands.*

Use of Intermittent Catheters

Almost all interviewees reported that having the ability to self-catheterize provided them with a sense of control over their condition and significantly improved their quality of life. Those who were able to afford hydrophilic catheters reported that the benefits were even more numerous and impactful compared to using regular catheters that required them to apply a lubricating gel.

Overall, the benefits of intermittent catheters fell into three general categories: social, emotional, and medical and safety benefits.

Social Benefits

Most people described social benefits such as the ability to comfortably travel and participate in regular day-to-day activities given their ability to self-catheterize, especially if they had access to hydrophilic intermittent catheters.

> *Ever since I started catheterizing, I have not had this sense of anxiousness around whether I was going to be able to get to a bathroom or not … I just had a whole different level of freedom to be able to go and do the things I want to do and to be out in public and go to a movie, go to a play, go to a concert and not be worried about sitting next to the aisle so that, you know, if I have to get out of here, I have to get out of here, right now.*

> *When you're in an airport or if you're at school and you have to go to a field trip at the beach or on a picnic or whatever these people do at school, I'd have to basically go on the field trip with her. But if we'd have these closed-bag catheters [hydrophilic catheters] it doesn't matter because if you're in the woods or whatever, going for a walk, or if the bathroom is particularly dirty, like those public bathrooms, you don't have to be worrying about being on the toilet or sitting or putting paper down or whatever. You can do this standing up and it was just a game changer … She can take violin lessons. She can go on field trips. She can have a sleepover … With these closed-bag systems and all these different options, it just makes life way more liveable.*

> *He can go camping and use these things [hydrophilic catheters]. We've gone camping where the regular catheter is a little bit more difficult to use. These ones, they're discreet, they can bend and they can go in your pocket, so he doesn't have to be embarrassed walking down the hallway with a long catheter in his hand … They're a lot more convenient.*

> *It [hydrophilic catheters] actually improved the quality of my life because before I had to have all the stuff that I had to carry around and you don't feel comfortable going when you're visiting family or friends or even if you're in a restaurant or you're in a public bathroom and you're taking all that time. And I've had people pound on the door even when I'm using the [catheter] and I'll say, "I'll be out in a minute." They say, "I got to go, got to go." I said, "Well, there's two other stalls." They said, "Well, they're full." I said, "Okay, I'll hurry up."*

For those that had to pay out-of-pocket for hydrophilic catheters, they would use them sparingly—only when they traveled or went out in public.

> *The unlubricated ones I buy, if I'm at home, and I'll use those at home with the lubrication, and then I save the [hydrophilic] ones for when I'm out, or going on vacation, or whatever because they're just that much easier to use.*

> *When I'm travelling or when I go out, I take with me the [hydrophilic catheters] … It's sterile and it is already lubricated. And they work very well, but they're quite expensive. So I use them for emergencies. I always have one or two in my coat when I go out.*

Emotional Benefits

Many people reported that the ability to self-catheterize restored a sense of normalcy to their lives.

> *At least with a self-catheterization I'm in control. If I'm in retention I can relieve myself.*

> *The catheters are great. They work—at least for people with my condition, they work very well. It really restores a normal life.*

Furthermore, parents whose children had access to hydrophilic catheters described feeling less stress, fear, and anxiety. Having access to hydrophilic catheters was "life-changing" for both the parents and their children as children were able to easily use hydrophilic catheters. Parents reported their increased comfort in allowing their child to grow and manage their chronic urinary retention more independently as a result of hydrophilic catheters.

> *It was night and day once she learnt … She no longer needed to be lying down and someone doing this for her. She didn't have to depend on anyone to go to the bathroom. She could just go to the bathroom herself and she would carry them in her little purse … Now she uses the little lipstick ones because she's self-conscious and she doesn't want, you know, to be advertised. She doesn't want to be carrying these bulky supplies all the time. She puts a little couple in her pocket for emergencies and she can be very discrete about it and those little ones are amazing for her. She loves them now. I'm not living on standby … It makes a huge difference, these products.*

Medical and Safety Benefits

Beyond the social and emotional benefits of using intermittent catheters, both adults and parents of children with chronic urinary retention reported the perceived added medical and safety benefits of hydrophilic catheters and using catheters as single-use only. Most people perceived a significant decrease in the number of urinary tract infections they developed and the number of related hospitalizations they experienced as a direct result of using hydrophilic catheters or using catheters as single-use only.

> *It's [the hydrophilic catheter] easier and it minimises another step of contamination. So that really, really made a difference because she was literally getting an infection every two weeks and she does have kidney damage as a result of those infections … It was night and day once she learnt how to do this and how to use the hydrophilic catheters. The infections totally decreased … If we didn't have these catheters she would be sick. She'd be having kidney infections … She can actually have a chance at living a normal life and participating and she can be a contributing member of society … We've taken*

her off her prophylactic antibiotics. She was on antibiotics every day for eight years. And now she's been off for about six months.

He was on basic catheters before, and he had tons and tons and tons of infections. So one of the doctors suggested [hydrophilic catheters] and it was like night and day. It didn't hurt him and he loved the catheters. They were easy for children. They had these little pouches. You just have to squeeze it and all the fluid goes into the catheter.

That's what they said [to reuse catheters] during this training, to store them in a vinegar solution and to use them for one day, and then switch to another one. But a couple of years ago I started getting more bladder infections. I've had them on and off anyway, but I started getting more. And I was really tired, so I found a somewhat less expensive source of catheters … I started using them only once because actually when you look at these things on the package, it always says "single use". It hasn't completely prevented infections. I still have them sometimes, but their frequency has gone down quite a lot.

When I first started and got my supplies from CCAC [community care access centre], they sent me five [catheters] to use. And I had to wash those catheters over and over and over and over and over again. First thing the doctor said, "Never reuse a catheter." … And ever since I stopped reusing catheters, my infections went away.

Barriers to Using Intermittent Catheters

Although adults and parents of children with chronic urinary retention reported substantial quality of life improvements as a result of intermittent catheters, they also reported important barriers to using intermittent catheters as single-use only and to more widespread use of hydrophilic intermittent catheters. The barriers can be described in two major categories: financial and other.

Financial Barriers

Adults and parents of children with chronic urinary retention consistently reported that, in general, cost was the greatest barrier to using intermittent catheters. Many people did not qualify for disability insurance and had to pay out-of-pocket for their catheter needs.

If I can't get disability insurance…because I have a risk of renal failure … I can't get a lot of disability insurance and other important things covered, so why am I still paying out of the pocket for a medical service that's causing me a lot of grief financially?

Financially it's been rough because I'm 47 years old and my mum still helps me pay for my supplies. And I work full time. You know, there's a lot of people out there, right now, who are struggling to pay for their catheters and it's through no fault of their own. They're trying to make a living. They're trying to work and not be on ODSP [Ontario Disability Support Program] but once they get out into the working world, then maybe they don't have the opportunity to have private insurance because not all companies offer that. And if you try to get insurance on your own and say that you have spina bifida, forget it; it won't happen because you have a predetermined condition and that's what health insurance companies call it and you will be disqualified.

Many participants reported that they used catheters sparingly to save on cost. Adults and parents of children with chronic urinary retention spoke often of the compromises they made to afford intermittent catheters, such as reusing catheters throughout the week, choosing to "dry"

themselves out to avoid urinating, and in some cases, choosing not to eat to save that money to pay for catheters instead.

> *Each month you make a choice. Am I going to eat this month or am I going to be able to go to the bathroom? That's basically what it comes down to. Which is more important, going to the bathroom or paying my rent or paying for groceries? … The reason we have to catheterize is because we don't have control of our systems and if you have a bladder like mine, that spasms, you'll have leaks all the time so you're not going to want to go out in public.*

> *People can't afford them. It's just plain and simple. People are barely making ends meet because they're on disability, and then have to pay for catheters, and they have to come out of your eating budget because it has to be done. It just drives me insane.*

> *There's a lot of us that can't afford them. So a lot of people, what they do is recycle the catheters and end up costing more in hospital visits than being able to stay at home.*

Some of those interviewed expressed their gratitude that they had private insurance or workplace injury compensation to purchase hydrophilic catheters or to use catheters as single-use only. However, many participants described how disability insurance and incontinence grants still weren't enough to cover the high ongoing cost of intermittent catheters.

> *Thankfully I work full time … And I have really good benefits, thank God, because the amount it would cost me out of pocket would just be horrendous.*

> *When you are on a fixed income, you have to pay rent, eat, if you have a vehicle, you have to pay for the vehicle and gas. And then you have to buy GU [genitourinary] supplies. You don't get that much on a fixed income, especially if you are on disability. I really don't know how these people survive. I am lucky. I have a pension, plus my disability.*

> *You can apply for an incontinence grant for children. And they have to be older than three, which is in and of itself kind of crazy because a lot of babies need to be catheterized and that's the most typical need. And then, once they're over three, though, they're eligible for this. But it's only about $200 or $300, and that's for the whole year.*

Most interviewees acknowledged that, for many families and individuals, the cost of catheters was simply prohibitive. Some parents expressed the emotional pain, fear, and frustration at not being able to provide the care they felt their child required.

> *Does my child not deserve the best catheter there is out there that's going to cause the less damage in his urethra? It'd be one thing if he were doing it for short-term, but he's got to do this the rest of his life. I think people deserve to have something that's good quality … I know they're [hydrophilic catheters] very expensive, and I worry that one day the benefits will max out, or we won't have them anymore, and I don't know what I will do then.*

> *I'm always very stressed … I really, really worry about when she turns 18 or when she's off our insurance. We're like, oh, we're just going to have to work forever because how is she ever going to afford, you know, $10,000 of supplies like this? That is a big worry and we need to have this mountain of cash. I need to have just $15,000 lying around at any*

> *given time, just in case something happens with the insurance or something, you know? Because she needs this to live.*

Families that purchased catheters out-of-pocket consistently described the financial impact this had on their quality of life and their future.

> *He's catheterized three times a day … We're looking at 100 catheters a month and when they range from $5 to $8 a catheter … our line of credit is almost maxed, just on medical supplies, but I really believe that they [hydrophilic catheters] make a difference. Our urologist that we had before, he thinks we're wasting our money … We've used our savings, it's gone, just on intermittent catheters. You know, when I retired we had plans, well … that's my only source of income now, is our line of credit.*

> *We've got three kids, three young kids for whom sports cost a lot of money. This [catheters] costs more than any sport will ever cost. It's part of our expenses now. It's just rolled into our mortgage basically at this point. It means that what my husband brings home doesn't go as far towards our family because we have this huge expense just to be able to go to the bathroom, which I feel is a right more than it is a privilege. And there's just no help for it unless you have some sort of help from your employer with really good insurance.*

Other Barriers

While cost was the greatest barrier to using intermittent catheters (especially hydrophilic catheters) mentioned by most people, a number of people also spoke about the lack of information they received regarding different types of intermittent catheters.

> *I think there's a lot of people around who use one catheter all their life … This new stuff on the market, you don't know what's, kind of, new because nobody keeps you up to speed on this stuff.*

> *Maybe it's an ethical reason or whatever in the hospital. They don't really tell you what's out there, but I'm a true believer in saying that the actual supplies you use make a huge, huge difference in your health trajectory. Just for ease of use … You need different types of catheters.*

For adults and children with limited hand function and dexterity, manipulating a catheter was challenging. Those who manually applied a gel coat to the catheter described it as "a pain in the neck". Most described the compact hydrophilic catheters to be easiest to use to alleviate hand dexterity issues and to reduce the number of steps in the catheterization process.

> *A lot of the catheter stuff, you almost need hand function to properly use them, right? You need to be able to pinch your thumb to your finger to open the packages and stuff like that … He has very limited hand activity, so it's really difficult when you have to finagle it in order to make it work for him. So that's a process.*

> *Not everyone is capable of self-catheterization. You have to have a lot of hand control and some people with spina bifida don't have much hand control, especially if hydrocephalus is involved and they may just not be mature enough to do the procedure on their own. And myself, I have no feeling in that area. So for me it's just a memory path that I have.*

> *The [hydrophilic catheters] are fantastic. I mean the whole thing that you don't have to think about lubricating it, right? It's all lubricated … [For people with multiple sclerosis] holding something firmly in our hand is not always possible, but with those [hydrophilic] ones … they're easy to hold and easy to apply.*

> *How's she going to hold this lubricant and how's she going to even understand any of this at age five … She found that [hydrophilic catheters] could be used for her level of dexterity for her hands. She just squeezes it, it lubricates it and it was long enough for her little hands to handle … So those [hydrophilic catheters] were a lifesaver.*

Some of those interviewed who lived in northern or rural areas mentioned that ordering catheters was sometimes a challenge. Pharmacies would ask them for a minimum order amount which would be quite costly.

> *We live in [a northern city] … [The pharmacy] said in order for them to get them [intermittent catheters] up here they have to guarantee so many cases that they're going to purchase … [My husband] is the only one in the city that uses them. This is why they want $700 to $800 a case because they have to bring in so many in order to get a half decent discount from Toronto.*

Discussion

Extensive outreach for this health technology assessment yielded interviews with 34 patients and caregivers. We interviewed adults and parents of children with chronic urinary retention. Those with experience using hydrophilic catheters were able to compare it with usual care, such as single-use or multiple-use noncoated intermittent catheters.

Those interviewed were tremendously supportive of intermittent catheters, especially single-use catheters and hydrophilic catheters, and the many benefits they provide for the management of chronic urinary retention. Both adults and parents of children with chronic urinary retention reported the great impact that the condition had on their daily activities and quality of life. They emphasized the positive outcomes of self-catheterization, including social, emotional, and perceived medical and safety benefits.

Participants also reported experiencing a number of equity issues related to using intermittent catheters, including barriers associated with cost, geography, and access to information about different types of catheters. If people were paying out-of-pocket for catheters, most could not afford the hydrophilic catheters. Almost all those interviewed said they would use catheters as indicated on the packaging, "single-use only," if they could afford to.

Most participants stated their concern with developing urinary tract infections due to catheter reuse or contamination associated with the numerous steps involved in using noncoated catheters. Those who transitioned from reusing catheters to single-use catheters or from noncoated catheters to hydrophilic catheters perceived a reduction in urinary tract infections and related hospitalizations.

Every person interviewed expressed that intermittent catheters were an essential part of managing their chronic urinary retention. All those who had experience with hydrophilic intermittent catheters compared them favourably with other options.

Conclusions

Adults and parents of children with chronic urinary retention reported positive experiences with intermittent catheters, especially the prelubricated hydrophilic catheters. All those interviewed felt that intermittent catheters provide significant social, emotional, and medical and safety benefits in managing their chronic urinary retention.

The high ongoing cost of using intermittent catheters was perceived as the greatest barrier to using this technology in general, and in particular to avoiding reuse of catheters and to using hydrophilic catheters.

CONCLUSIONS OF THE HEALTH TECHNOLOGY ASSESSMENT

We examined the effectiveness, safety, patient preference, cost-effectiveness, and budget impact of several types of intermittent catheters used to manage chronic urinary retention. Overall, the quality of clinical evidence, from 14 randomized controlled trials, was low. As a result, we are uncertain whether any specific type of catheter—coated or noncoated, single- or multiple-use—significantly reduces symptomatic urinary tract infection (UTI), hematuria, or other serious adverse clinical events, or improves patient satisfaction.

We identified six economic evaluations that modelled complications of long-term use of intermittent catheters. Their applicability to Ontario was limited, however, and we therefore conducted our own economic analysis, creating a model with Canadian inputs and effect estimates to inform provincial decision-making.

Our economic analysis indicates that two types of intermittent catheter used by an outpatient population with spinal cord injury—single-use noncoated and single-use hydrophilic—were not cost-effective at commonly used decision-maker or societal willingness-to-pay amounts. Differences in total quality-adjusted life-years across catheter types were marginal. The lowest-cost intervention—multiple-use noncoated catheters (one per day or one per week)—had the highest probability of being cost-effective compared with the other three types we included. Where it is not feasible for some patients to clean and reuse catheters, single-use noncoated catheters have the highest probability of being cost-effective.

Our budget impact analysis considered five types of intermittent catheter and found that publicly funding intermittent catheters for outpatient use in Ontario would result in net spending that varies widely by catheter type. Noncoated catheters that people can clean and reuse would result in the lowest costs over the next 5 years; specifically, it would cost $93.0 million for one-per-day multiple-use noncoated. Single-use catheters would cost either $360.3 million (for noncoated), $1.4 billion (for gel reservoir), or $2.1 billion (for hydrophilic). In an attempt to limit the overall budget impact while still providing patients with a degree of support, we also analyzed several cost-sharing strategies in which 25%, 50%, and 75% of catheter costs would be publicly funded. Finally, expanding the existing Incontinence Supplies Grant Program (now restricted to children and youth aged 3 to 18 years) to make this support available to people of all ages would cost an additional $66.5 million over its current funding, over the next 5 years.

We interviewed 34 adults and parents of children with chronic urinary retention. All participants reported that intermittent catheters provide important social, emotional, medical, and safety benefits. All those who had experience with using prelubricated hydrophilic catheters compared them favourably with other options. At the same time, many interviewees reported that the high ongoing cost of purchasing catheters was a significant financial burden on their household. Almost all said they would prefer not to reuse catheters sold as “single use” but could not afford the cost of using them as single use.

ABBREVIATIONS

AMSTAR	A Measurement Tool to Assess Systematic Reviews
CI	Confidence interval
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
IC	Intermittent catheter
ICER	Incremental cost-effectiveness ratio
IDSA	Infectious Diseases Society of America
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
ODSP	Ontario Disability Support Program
OR	Odds ratio
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
PVC	Polyvinyl chloride
QALY	Quality-adjusted life-year
RCT	Randomized controlled trial
RR	Relative risk
UTI	Urinary tract infection

GLOSSARY

Bacteremia	The presence of bacteria in the blood.
Bladder stones	Hard masses of minerals in the bladder.
Cost-effectiveness acceptability curve	Shows the probability that an intervention is cost-effective at various willingness-to-pay amounts.
Crossover trial	A method of comparing two treatments in which participants, upon completing one treatment, are switched to the other treatment.
Deterministic analysis	A type of analysis that changes the variables to determine whether the final answer will change. The analysis is done by first setting values for each factor, and then substituting other possible values for one (in a one-way sensitivity analysis) or more (in a multi-way sensitivity analysis) factors to test how these changes affect the result.
Disutility	A decrease in utility (quality of life) owing to a particular symptom or complication.
Drug resistance	A reduction in the effectiveness of a medication; used in the context of microorganisms and viruses that have developed the ability to withstand the effects of a medication. When an organism or virus is resistant to more than one drug, it is said to be multidrug resistant.
Epididymitis/ orchitis	An inflammation of the epididymis, the cord-like structure along the back of the testis.
False passage	Occurs when a catheter is placed into an area outside the opening of the urethra; commonly occurs when there is an obstruction in the urethra.
Incremental cost-effectiveness ratio (ICER)	Determines “a unit of benefit” for an intervention by dividing the incremental cost by the effectiveness. The incremental cost is the difference between the cost of the treatment under study and an alternative treatment. The effectiveness is usually measured as additional years of life or as “quality-adjusted life years.”
Markov model	A type of modelling that measures the health state of a patient over the course of treatment. A patient may stay in one health state or move from one health state to another, depending on the effect of the treatment and the progression of the disease.
Monte Carlo simulation	Determines the uncertainty in an economic model by running many trials of the model. In each trial, random numbers are assigned wherever values are uncertain to see how the model result changes.
Off-label	The use of a medication or medical device for a condition other than that for which it has been officially approved.

Probabilistic analysis	A type of analysis where the value of one or more unknown factors is estimated through the use of a technique that determines the most likely value or range of values for that factor. For instance, the Monte Carlo simulation will run a scenario many times using randomly assigned numbers where the value of a particular factor is unknown. The simulation indicates which outcomes are most common, and therefore most probable.
Quality-adjusted life-year (QALY)	A measurement that takes into account both the number of years gained by a patient from a procedure and the quality of those extra years (considering such factors as ability to function and freedom from pain). The QALY is commonly used as an outcome measure in cost–utility analyses.
Sequential analysis	A statistical method in which data are evaluated as they are collected, and further data collection is stopped once an answer of the desired accuracy is obtained. Participants are randomly allocated in pairs, with one receiving treatment and one in the control group, and each pair is then compared.
Stricture formation	The abnormal narrowing of a duct.
Urosepsis	A severe urinary tract infection.
Utility	The perceived benefit (value) placed on a treatment by a person or by society.
Washout period	The stage in a clinical trial when treatment is withdrawn so that its effects disappear. An effective washout period is essential in crossover trials.
Willingness-to-pay	The valuation of health benefit in monetary terms; often used in cost–benefit analyses.

APPENDICES

Appendix 1: Systematic Search of Systematic Reviews Comparing Indwelling and Intermittent Catheterization

Methods

Research Question: What is the risk of urinary tract infection associated with indwelling catheterization compared to that of intermittent catheterization for individuals requiring long-term bladder management?

Inclusion Criteria

- Long-term bladder management (> 28 days)
- Systematic reviews
- Compares indwelling with intermittent catheterization
- English and full-text publication

Exclusion Criteria

- Short-term catheterization (< 28 days)

Outcome

- Urinary tract infection as defined by the individual systematic review

Literature Search Strategies

Search date: October 10, 2017
Databases searched: All Ovid MEDLINE, Embase

Ovid
Embase <1980 to 2017 Week 41>, All Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 (intermittent adj5 catheter*).ti,ab,kf. (8298)
2 (indwelling adj5 catheter*).ti,ab,kf. (18650)
3 1 and 2 (1186)
4 Meta Analysis.pt. (91502)
5 Meta-Analysis/ or Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (287145)
6 (((systematic* or methodologic*) adj3 (review* or overview*)) or pooled analysis or published studies or published literature or hand search* or handsearch* or medline or pubmed or embase or cochrane or cinahl or data synthes* or data extraction* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab. (593760)
7 (meta analy* or metaanaly* or health technolog* assess*).mp. (386726)
8 or/4-7 (795432)
9 8 use ppez (347333)
10 3 and 9 (25)
11 (intermittent adj5 catheter*).tw,kw. (8333)
12 (indwelling adj5 catheter*).tw,kw. (18808)
13 11 and 12 (1190)

14 Meta Analysis/ or "Meta Analysis (Topic)"/ or Biomedical Technology Assessment/ (281234)
15 (((systematic* or methodologic*) adj3 (review* or overview*)) or pooled analysis or published studies or published literature or hand search* or handsearch* or medline or pubmed or embase or cochrane or cinahl or data synthes* or data extraction* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab. (593760)
16 (meta analy* or metaanaly* or health technolog* assess*).mp. (386726)
17 or/14-16 (794311)
18 17 use emez (448099)
19 13 and 18 (35)
20 10 or 19 (60)
21 limit 20 to english language (60)
22 remove duplicates from 21 (36)

Results: Indwelling Versus Intermittent Catheterization

The literature search yielded 35 citations after removing duplicates. Two eligible systematic reviews were identified. Figure A1 presents the flow diagram for the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).

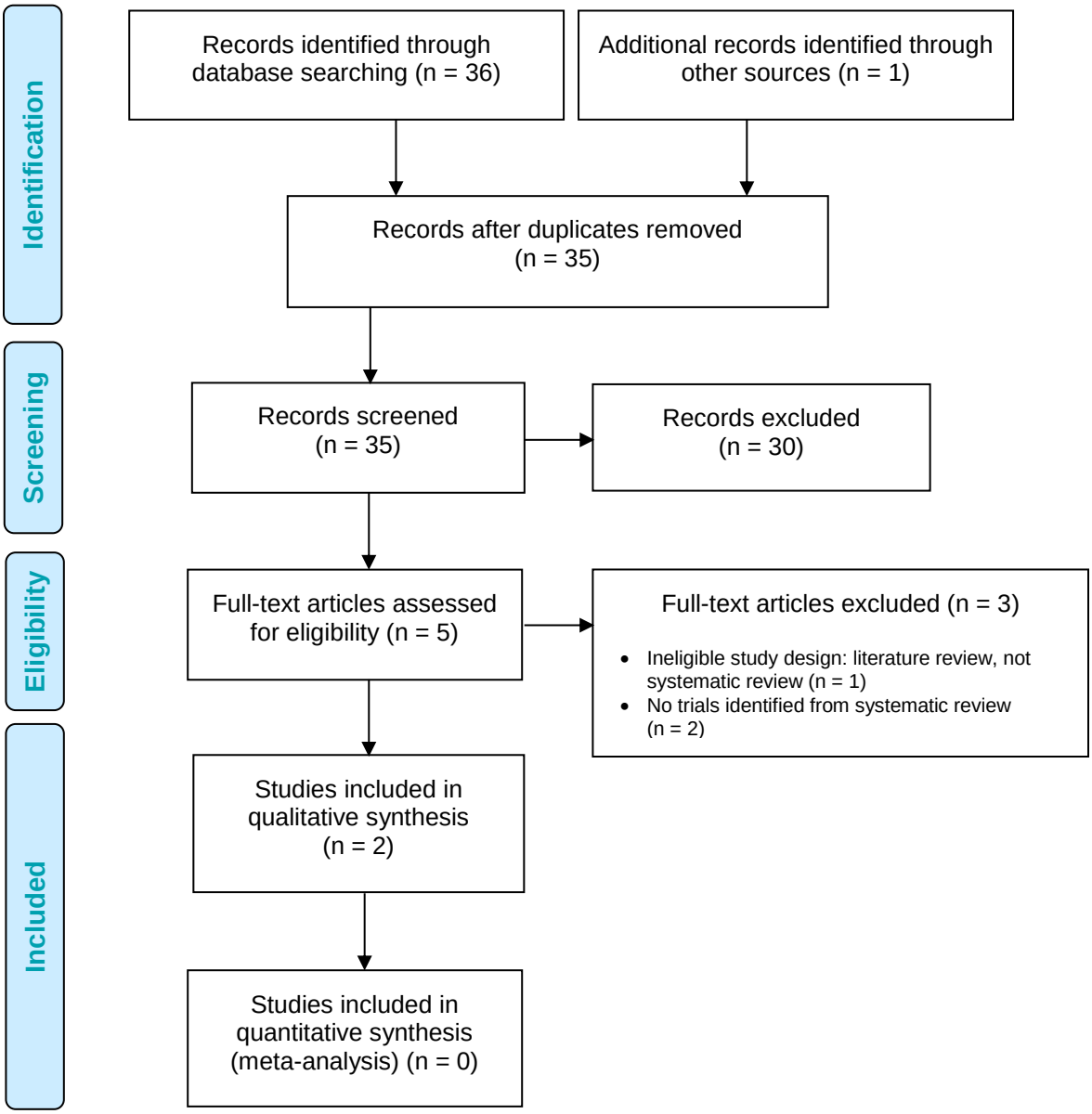

Figure A1: PRISMA Flow Diagram: Indwelling Versus Intermittent Catheterization

Source: Adapted from Moher et al.[45]

Table A1: AMSTAR 2 Rating of Included Systematic Reviews: Indwelling Versus Intermittent Catheterization

Author, Year	AMSTAR 2 Rating[a]	(1) Inclusion Criteria Addressed PICO	(2) Established A Priori Protocol	(3) Explained Study Design Selection	(4) Adequate Search Strategy	(5) Duplicate Study Selection	(6) Duplicate Data Extraction	(7) Listed Excluded Studies	(8) Provided Characteristics of Studies
Shekelle et al, 1999[15]	Moderate	✓	✗ (No explicit statement)	✗	✓	✓	✗	✓	✓
Pannek and Bertschy, 2011[16]	Low	✓	✗ (No explicit statement)	✗	Partial ✓	✓	✗	✗	Partial ✓

Author, Year	AMSTAR 2 Rating[a]	(9) Assessed Scientific Quality	(10) Reported Sources of Funding	(11) Methods to Combine Appropriate	(12) Assessed Meta-analyzed Studies	(13) Considered Quality in Report	(14) Discussed Heterogeneity	(15) Assessed Publication Bias	(16) Stated Conflict of Interest
Shekelle et al, 1999[15]	Moderate	✓	✗	No meta-analysis conducted	No meta-analysis conducted	✓	✓	✗	✗
Pannek and Bertschy, 2011[16]	Low	✗	✗	No meta-analysis conducted	No meta-analysis conducted	✓	✓	✗	✓

Abbreviations: AMSTAR, A Measurement Tool to Assess Systematic Reviews; PICO, population, intervention, comparator, outcomes.
[a]There are four ratings for the overall confidence in the results of the review: high, moderate, low, and critically low. Details of AMSTAR 2 rating are described in Shea et al.[113] AMSTAR 2 was used instead of AMSTAR because the newer version was optimized to assess systematic reviews that included nonrandomized studies.

Table A2: Selected Excluded Studies: Indwelling Versus Intermittent Catheterization

Citation	Primary Reason for Exclusion
Zambon JP, Cintra CC, Bezerra A, Bicudo MC, Wroclawski ER. What is the best choice for chronic urinary retention: indwelling catheter or clean intermittent catheterization. Einstein. 2009;7(4):520-4.	Not systematic review (literature review)
Jamison J, Maguire S, McCann J. Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders. Cochrane Database Syst Rev (Online). 2011;12:CD004375.	No trials identified from search
Niel-Weise BS, van den Broek PJ, da Silva EM, Silva LA. Urinary catheter policies for long-term bladder drainage. Cochrane Database Syst Rev (Online). 2012;8:CD004201.	No trials identified from search
Kidd EA, Stewart F, Kassis NC, Hom E, Omar MI. Urethral (indwelling or intermittent) or suprapubic routes for short-term catheterisation in hospitalised adults. Cochrane Database Syst Rev. 2015;12:CD004203.	Short-term catheterization
Moola S, Konno R. A systematic review of the management of short-term indwelling urethral catheters to prevent urinary tract infections. JBI Libr Syst Rev. 2010;8(17):695-729.	Short-term catheterization
Ercole FF, Macieira TGR, Wenceslau LCC, Martins AR, Campos CC, Chianca TCM. Integrative review: evidences on the practice of intermittent/indwelling urinary catheterization. Revista Latino-Americana de Enfermagem. 2013;21(1):459-68.	Not systematic review (integrative review)

Appendix 2: Guideline Recommendations on Indwelling Versus Intermittent Catheterization

Table A3: Guideline Recommendations on Indwelling Versus Intermittent Catheterization in Managing Bladder Dysfunction (Non-exhaustive List)

Author, Year, Title	Recommendation Excerpts
American Urological Association, 2014[23] Catheter-Associated Urinary Tract Infections: Definitions and Significance in the Urologic Patient	• Clean intermittent catheterization is widely advocated as an effective bladder management strategy for acute care patients with incomplete bladder emptying and/or urinary retention due to idiopathic or neurogenic bladder dysfunction. • Clean intermittent catheterization is preferred in spinal cord injury patients and in children with myelomeningocele and neurogenic bladder because clean intermittent catheterization may reduce the risk of urinary tract deterioration and urethral trauma in these patients over the long term.
Blok et al (European Association of Urology), 2015[114] Guidelines on Neuro-Urology	• Intermittent catheterisation—whenever possible aseptic technique—should be used as a standard treatment for patients who are unable to empty their bladder. • Indwelling transurethral catheterisation and, to a lesser extent, suprapubic cystostomy are associated with a range of complications as well as an enhanced risk for urinary tract infection. Both procedures should therefore be avoided when possible.
Consortium for Spinal Cord Medicine, 2006[115] Bladder Management for Adults with Spinal Cord Injury: A Clinical Practice Guideline for Health-Care Providers	• Intermittent catheterization provides a method of emptying the neurogenic bladder without leaving an indwelling catheter and lessens the frequency of long-term complications such as hydronephrosis, bladder and renal calculi, and autonomic dysreflexia encountered with other methods of neurogenic bladder management. • Indwelling catheterization is often used by individuals with chronic SCI [spinal cord injury] who are unable to perform intermittent catheterization or reflex voiding, have uncontrollable urinary incontinence, have difficulty wearing continence devices, or have an acute medical condition warranting catheterization, or by those who prefer indwelling catheterization because it offers greater expediency and compatibility with their lifestyle.
Geng et al (European Association of Urology Nurses), 2012[21] Catheterisation Indwelling Catheters in Adults – Urethral and Suprapubic	• Intermittent catheterisation is preferable to indwelling urethral or suprapubic catheters in patients with bladder emptying dysfunction. • Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient.
Gould et al (Centers for Disease Control), 2009[22] Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009	• Consider alternatives to chronic indwelling catheters, such as intermittent catheterization, in spinal cord injury patients. Intermittent catheterization is preferable to indwelling urethral or suprapubic catheters in patients with bladder emptying dysfunction. Consider intermittent catheterization in children with myelomeningocele and neurogenic bladder to reduce the risk of urinary tract deterioration. • Studies of patients with neurogenic bladder most consistently found a decreased risk of catheter-associated urinary tract infections with intermittent catheterization.

Author, Year, Title	Recommendation Excerpts
National Collaborating Centre for Women's and Children's Health (Commissioned by the National Institute for Health and Care Excellence), 2013[116] Urinary Incontinence in Women: the Management of Urinary Incontinence in Women	• Intermittent catheterisation is preferred to indwelling catheterisation. This recommendation was informed by a systematic review of risk factors for urinary tract infection, in adults with spinal cord dysfunction. • Intermittent catheterisation is associated with reduced risk of urinary tract infection compared with indwelling catheterisation.
National Institute for Health and Care Excellence (NICE), 2015[117] The Management of Lower Urinary Tract Symptoms in Men	• Offer intermittent bladder catheterisation before indwelling urethral or suprapubic catheterisation to men with voiding lower urinary tract symptoms that cannot be corrected by less invasive measures. • Consider offering self- or carer-administered intermittent urethral catheterisation before offering indwelling catheterisation for men with chronic urinary retention. • Consider offering intermittent or indwelling catheterisation before offering surgery in men with chronic urinary retention. • Offer intermittent bladder catheterisation before indwelling urethral or suprapubic catheterisation to men with voiding lower urinary tract symptoms that cannot be corrected by less invasive measures. • Intermittent catheterisation releases a patient from having a continuous indwelling catheter which in many patients is better tolerated with an improvement in quality of life and reduced morbidity.
National Institute for Health and Care Excellence (NICE), 2003[20] Infection: Prevention and Control of Healthcare-Associated Infections in Primary and Community Care	• The highest incidence of healthcare-associated infection is associated with indwelling urethral catheterisation. • Indwelling urinary catheters should be used only after alternative methods of management have been considered. • Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient.
Quality Improvement Scotland, 2004[19] Urinary Catheterization and Catheter Care – Best Practice Statement 2004[a]	• When catheterisation is being discussed as a treatment option, intermittent catheterisation is always considered as the first option rather than indwelling catheterisation, providing this is a safe and acceptable alternative for the individual and carer(s). • Intermittent self-catheterisation is the preferred alternative to indwelling catheters for individuals in whom bladder emptying is incomplete, providing they have the dexterity, ability and desire to manage the procedure. • Intermittent self-catheterisation allows the patient to gain control of their bladder and gives them the opportunity to become self caring. This helps the patient to achieve a more positive body image. Intermittent catheterisation has a reduced incidence of infection compared with indwelling catheters.
Tenke et al (European Society for Infection in Urology), 2008[118] European and Asian Guidelines on Management and Prevention of Catheter-Associated Urinary Tract Infections	• As indwelling urethral catheters are prone to cause symptomatic infection, clinicians should always consider alternatives. In appropriate patients, suprapubic catheters, condom drainage systems or intermittent catheterisation are preferable to indwelling urethral catheterisation. • The presence of an indwelling urethral catheter allows continuous access of organisms into the urinary bladder. Multivariate analyses have emphasised that the duration of catheterisation is the most important risk factor in the development of catheter-associated bacteriuria. The patient with a long-term indwelling catheter is at high risk of morbidity due to this procedure. Bacteriuria with at least one strain is universal, whilst most patients are infected with two or more strains.

[a]The best practice toolkit from the Registered Nurses' Association of Ontario links to this guideline.

Appendix 3: Guideline Recommendations on Intermittent Catheterization Practices

Table A4: Recommendations From Guidelines and Patient Education Materials on Intermittent Catheterization Practices (Non-exhaustive List)

Author, Year, Title	Recommendation Excerpts
American Urological Association, 2014[23] Catheter-Associated Urinary Tract Infections: Definitions and Significance in the Urologic Patient	• Hydrophilic-coated catheters may be preferable to standard noncoated catheters because of their low friction, and such catheters are associated with a lesser degree of urethral inflammatory response when compared to standard noncoated catheters. • Because the hydrophilic catheter theoretically causes less trauma upon insertion, performing clean intermittent catheterization with these catheters may also decrease the incidence of urinary tract infections, microscopic hematuria/urethral trauma, and urethral strictures.
Canadian Urological Association, 2014[29] Clean Intermittent Self-Catheterization for Women	• Generally, a catheter can be reused and cleaned for about a week or so unless it becomes rough, cracked or damaged. • Immediately after using a catheter, wash it with warm, soapy water and rinse it thoroughly, inside and out. Liquid hand and dish soap is effective and safe. Allow it to air dry on a clean surface or towel. Store the catheter in a dry, paper towel or clean plastic bag.
Gould et al (Centers for Disease Control), 2009[22] Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009	• Hydrophilic catheters might be preferable to standard catheters for patients requiring intermittent catheterization. Very low-quality evidence suggested a benefit of hydrophilic catheters over standard non-hydrophilic catheters in specific populations undergoing clean intermittent catheterization. Differences in catheter-associated urinary tract infection outcomes were limited to one study of spinal cord injury patients and one study of patients receiving intravesical immunochemoprophylaxis for bladder cancer, while multiple other studies found no significant differences.
Health Protection Surveillance Centre (Ireland), 2011[119] Guidelines for the Prevention of Catheter-associated Urinary Tract Infection	• Most catheters used for intermittent catheterisation are single-use. However, some catheters used for intermittent catheterisation are designed to be cleaned and reused. • The manufacturer's instructions for cleaning and storage of these catheters should be followed. • While many guidelines continue to recommend aseptic technique and sterile equipment for intermittent catheterisation in the healthcare setting, a clean technique is recommended for self-intermittent catheterisation
Hill et al, 2013[120] Best Practices for the Treatment and Prevention of Urinary Tract Infection in the Spinal Cord Injured Population: the Alberta Context	• At present, there is no gold standard for cleaning reusable PVC catheters for intermittent catheterization, but the practice typically recommended by clinicians in Alberta is to clean them thoroughly with liquid dish soap, air dry and store them in a clean plastic bag or container. • In Alberta, an individual's choice of sterile or clean method depends on a number of factors, one of which is the availability of funding to purchase the products. Alberta Aids to Daily Living (AADL) is a provincially funded program that provides financial assistance to Albertans with a long-term disability, chronic illness or terminal illness to buy medical equipment and supplies. AADL covers the cost of one sterile polyvinyl chloride (PVC) type catheter per day. Users are directed to wash the catheter and store it for up to 4 subsequent catheterizations. Individuals with spinal cord injury and some healthcare professionals have raised questions about whether the risk of urinary tract infection is increased when catheters are reused.
National Institute for Health and Care Excellence (NICE), 2003[20] Infection: Prevention and Control of Healthcare-Associated Infections in Primary and Community Care	• Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self-catheterisation. • Intermittent self-catheterisation is a clean procedure. A lubricant for single-patient use is required for non-lubricated catheters. An appropriate lubricant from a single-use container should be used during catheter insertion to minimise urethral trauma and infection.

Author, Year, Title	Recommendation Excerpts
National Institutes of Health (United States), 2007[121] Clean Intermittent Self-Catheterization (CISC): Procedure for Women	• When you are at home, use clean equipment and clean technique. Sterile equipment is used when you are in the hospital and is sometimes needed for people with recurrent or chronic urinary tract infections. • A clean self-intermittent catheter may be reused for up to 2 to 4 weeks. To control odor and remove thick mucous deposits, you may want to soak the catheter in a white vinegar solution once a week. Discard catheters when they become discolored, hard, brittle, no longer drain, or become too soft to insert. In some cases, if you are prone to infection, your doctor may want you to sterilize the catheter after each use by boiling it in water for 20 minutes. After it cools, store it in a clean, dry, secure location.
Quality Improvement Scotland, 2004[19] Urinary Catheterization and Catheter Care – Best Practice Statement 2004[a]	• Catheters for intermittent use can either be single use pre-lubricated catheters or PVC reusable catheters which after use can be washed in warm soapy water, rinsed thoroughly and then left in a clean area to air dry and stored in a clean dry receptacle. • These catheters can be used for approximately 1 week before being discarded.
Skelly et al (Canadian Nurse Continence Advisors), 2016[30] Intermittent Self-Catheterization: A Guide for Men and Women	• Wash all catheters well with soap and water after each use. • Wash the catheter by hand using liquid detergent under warm running water. Soap and rub the catheter for 10 seconds, then rinse well. • Place the catheter on a clean cloth to air dry. • When the catheter is dry, put it in a clean dry container for the next use. • Catheters that are not being used again should be thrown away. • Plastic catheters that are being used again should be thrown away when the plastic looks cloudy. This is about once a week.
Wound, Ostomy and Continence Nurses Society, 2016[122] Care and Management of Patients With Urinary Catheters: A Clinical Resource Guide	• No single technique for insertion or type of catheter material has been determined to be the best for intermittent catheterization, because these choices depend on the anatomical, social, and economic factors for each patient. • In the acute care setting, aseptic technique and sterile equipment is recommended for intermittent catheterization. • In the non-acute care setting, clean technique is an acceptable and practical alternative to sterile technique for patients needing long-term intermittent catheterization. • Using a clean “no-touch” technique for intermittent catheterization reduces microbial contamination of the catheter but has not been proven superior to the sterile technique. • Data are insufficient to determine whether the incidence of urinary tract infection is affected by a specific type of catheter or technique, use of single (sterile) or multiple-use (clean) catheters, or the method of cleaning multiple-use catheters. • Only standard PVC catheters can be reused after washing with soap and water. Multi-use catheters can be washed with soap and water, air-dried, stored in a clean, sealed plastic bag or container; and may be reused for up to four subsequent catheterizations. • Procedures shown to reduce bacterial contamination of reused catheters (e.g., rinsing with water after use, air-drying and keeping the catheter dry until reuse; microwaving; soaking in hydrogen peroxide, bleach, or betadine) have not been proven to prevent catheter-associated bacteriuria or catheter-associated urinary tract infection. • Hydrophilic catheters may reduce friction on insertion and are associated with increased patient satisfaction. However, current data are insufficient to support the routine use of hydrophilic catheters to reduce catheter-associated bacteriuria or catheter-associated urinary tract infection.

Abbreviations: PVC, polyvinyl chloride.
[a]The best practice toolkit from the Registered Nurses’ Association of Ontario links to this guideline.

Appendix 4: Literature Search Strategies

Clinical Evidence Search

Search date: October 13, 2017
Databases searched: All Ovid MEDLINE, Embase, Cochrane Database of Systematic Reviews, Health Technology Assessment Database, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, CINAHL

Ovid
Database: EBM Reviews - Cochrane Central Register of Controlled Trials <September 2017>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 11, 2017>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2017 Week 41>, All Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 exp Urinary Catheterization/ (23276)
2 Urinary Catheters/ (4546)
3 (urinary or urethra* or bladder).ti,ab,kf. (938753)
4 self catheter*.ti,ab,kf. (3325)
5 or/1-4 (947172)
6 ((sterile or "single use" or "one time use" or disposable*) adj4 catheter*).ti,ab,kf. (1726)
7 5 and 6 (501)
8 ((coated or coating or hydrogel* or gel or gels or lubricant* or prelubricate* or lubricate*) adj4 catheter*).ti,ab,kf. (2520)
9 (hydrophilic and catheter*).ti,ab,kf. (1318)
10 or/8-9 (3516)
11 5 and 10 (1084)
12 (flocath* or lofric* or easicath* or easycath* or speedicath* or magic3 or aquacath* or urocath).ti,ab,kf. (103)
13 (silky and catheter*).ti,ab,kf. (3)
14 or/11-13 (1125)
15 7 or 14 (1558)
16 exp Animals/ not Humans/ (14866296)
17 15 not 16 (1295)
18 Case Reports/ or Comment.pt. or Editorial.pt. or Letter.pt. or Congresses.pt. (5045935)
19 17 not 18 (1252)
20 limit 19 to english language [Limit not valid in CDSR; records were retained] (1029)
21 limit 20 to yr="1990 -Current" (908)
22 21 use ppez,coch,cctr,clhta,cleed (539)
23 bladder catheterization/ (5805)
24 exp urinary catheterization/ (23276)
25 exp urological catheter/ (10205)
26 intermittent catheterization/ (2990)
27 (urinary or urethra* or bladder).tw,kw. (940928)
28 self catheter*.tw,kw. (3357)
29 or/23-28 (952737)
30 ((sterile or "single use" or "one time use" or disposable*) adj4 catheter*).tw,kw,dv. (1802)
31 29 and 30 (547)

32 ((coated or coating or hydrogel* or gel or gels or lubricant* or prelubricate* or lubricate*) adj4 catheter*).tw,kw,dv. (2555)
33 (hydrophilic and catheter*).tw,kw,dv. (1361)
34 or/32-33 (3588)
35 29 and 34 (1136)
36 (flocath* or lofric* or easicath* or easycath* or speedicath* or magic3 or aquacath* or urocath).tw,kw,dv. (120)
37 (silky and catheter*).tw,kw,dv. (3)
38 or/35-37 (1180)
39 31 or 38 (1647)
40 (exp animal/ or nonhuman/) not exp human/ (10556733)
41 39 not 40 (1509)
42 Case Report/ or Comment/ or Editorial/ or Letter/ or conference abstract.pt. (9575005)
43 41 not 42 (1272)
44 limit 43 to english language [Limit not valid in CDSR; records were retained] (1051)
45 limit 44 to yr="1990 -Current" (932)
46 45 use emez (359)
47 22 or 46 (898)
48 47 use ppez (413)
49 47 use coch (1)
50 47 use cctr (117)
51 47 use clhta (2)
52 47 use cleed (6)
53 47 use emez (359)
54 remove duplicates from 47 (508)

CINAHL

#	Query	Results
S1	(MH "Urinary Catheterization+")	2,695
S2	(MH "Catheters, Urinary")	1,522
S3	(urinary OR urethra* OR bladder)	54,080
S4	self catheter*	368
S5	S1 OR S2 OR S3 OR S4	54,130
S6	((sterile OR "single use" OR "one time use" OR disposable*) N4 catheter*)	133
S7	S5 AND S6	47
S8	((coated OR coating OR hydrogel* OR gel OR gels OR lubricant* OR prelubricate* OR lubricate*) N4 catheter*)	228
S9	(hydrophilic AND catheter*)	93
S10	S8 OR S9	286
S11	S5 AND S10	132

S12	(flocath* OR lofric* OR easicath* OR easycath* OR speedicath* OR magic3 OR aquacath* OR urocath)	16
S13	(silky AND catheter*)	0
S14	S11 OR S12 OR S13	139
S15	S7 OR S14	175
S16	(MH "Vertebrates+") NOT (MH "Human")	140,676
S17	S15 NOT S16	174
S18	PT (Case Study OR Commentary OR Editorial OR Letter OR Proceedings)	818,258
S19	S17 NOT S18	160
S20	S17 NOT S18 Limiters - Published Date: 19900101-; English Language	148

Economic Evidence Search

Economic Evaluation and Cost-Effectiveness Search
Search date: October 16, 2017
Databases searched: All Ovid MEDLINE, Embase, Cochrane Database of Systematic Reviews, Health Technology Assessment Database, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, CINAHL

Ovid
Database: EBM Reviews - Cochrane Central Register of Controlled Trials <September 2017>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 11, 2017>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2017 Week 41>, All Ovid MEDLINE(R) <1946 to Present> Search Strategy:
---
1 exp Urinary Catheterization/ (23277)
2 Urinary Catheters/ (4546)
3 (urinary or urethra* or bladder).ti,ab,kf. (938904)
4 self catheter*.ti,ab,kf. (3325)
5 or/1-4 (947323)
6 ((sterile or "single use" or "one time use" or disposable*) adj4 catheter*).ti,ab,kf. (1726)
7 5 and 6 (501)
8 ((coated or coating or hydrogel* or gel or gels or lubricant* or prelubricate* or lubricate*) adj4 catheter*).ti,ab,kf. (2520)
9 (hydrophilic and catheter*).ti,ab,kf. (1318)
10 or/8-9 (3516)
11 5 and 10 (1084)
12 (flocath* or lofric* or easicath* or easycath* or speedicath* or magic3 or aquacath* or urocath).ti,ab,kf. (103)
13 (silky and catheter*).ti,ab,kf. (3)
14 or/7,11-13 (1558)

15 economics/ (254424)
16 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (788851)
17 economics.fs. (415535)
18 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (786991)
19 exp "costs and cost analysis"/ (555561)
20 (cost or costs or costing or costly).ti. (241085)
21 cost effective*.ti,ab,kf. (282262)
22 (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. (183118)
23 models, economic/ (11321)
24 markov chains/ or monte carlo method/ (74472)
25 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (36446)
26 (markov or markow or monte carlo).ti,ab,kf. (116819)
27 quality-adjusted life years/ (34578)
28 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (59543)
29 ((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (96806)
30 or/15-29 (2347934)
31 14 and 30 (215)
32 limit 14 to english language [Limit not valid in CDSR; records were retained] (1318)
33 limit 32 to yr="1990 -Current" (1178)
34 limit 31 to english language [Limit not valid in CDSR; records were retained] (191)
35 limit 34 to yr="1990 -Current" (184)
36 33 use cleed (6)
37 35 use ppez,coch,cctr,clhta (84)
38 36 or 37 (90)
39 bladder catheterization/ (5805)
40 exp urinary catheterization/ (23277)
41 exp urological catheter/ (10205)
42 intermittent catheterization/ (2990)
43 (urinary or urethra* or bladder).tw,kw. (941076)
44 self catheter*.tw,kw. (3357)
45 or/39-44 (952885)
46 ((sterile or "single use" or single-use or "one time use" or disposable*) adj4 catheter*).tw,kw,dv. (1802)
47 45 and 46 (547)
48 ((coated or coating or hydrogel* or gel or gels or lubricant* or prelubricate* or lubricate*) adj4 catheter*).tw,kw,dv. (2555)
49 (hydrophilic and catheter*).tw,kw,dv. (1361)
50 or/48-49 (3588)
51 45 and 50 (1136)
52 (flocath* or lofric* or easicath* or easycath* or speedicath* or magic3 or aquacath* or urocath).tw,kw,dv. (120)
53 (silky and catheter*).tw,kw,dv. (3)
54 or/47,51-53 (1647)
55 Economics/ (254424)
56 Health Economics/ or Pharmacoeconomics/ or Drug Cost/ or Drug Formulary/ (129183)
57 Economic Aspect/ or exp Economic Evaluation/ (425536)

58 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw,kw. (811301)
59 exp "Cost"/ (555561)
60 (cost or costs or costing or costly).ti. (241085)
61 cost effective*.tw,kw. (293126)
62 (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. (184247)
63 Monte Carlo Method/ (60229)
64 (decision adj1 (tree* or analy* or model*)).tw,kw. (40150)
65 (markov or markow or monte carlo).tw,kw. (121764)
66 Quality-Adjusted Life Years/ (34578)
67 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw,kw. (63301)
68 ((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw,kw. (116043)
69 or/55-68 (1988601)
70 54 and 69 (247)
71 limit 70 to english language [Limit not valid in CDSR; records were retained] (224)
72 limit 71 to yr="1990 -Current" (217)
73 72 use emez (91)
74 38 or 73 (181)
75 74 use ppez (66)
76 74 use coch (0)
77 74 use cctr (18)
78 74 use clhta (0)
79 74 use cleed (6)
80 74 use emez (91)
81 remove duplicates from 74 (113)

CINAHL

#	Query	Results
S1	(MH "Urinary Catheterization+")	2,695
S2	(MH "Catheters, Urinary")	1,522
S3	(urinary OR urethra* OR bladder)	54,096
S4	self catheter*	369
S5	S1 OR S2 OR S3 OR S4	54,146
S6	((sterile OR "single use" OR "one time use" OR disposable*) N4 catheter*)	134
S7	S5 AND S6	48
S8	((coated OR coating OR hydrogel* OR gel OR gels OR lubricant* OR prelubricate* OR lubricate*) N4 catheter*)	228
S9	(hydrophilic AND catheter*)	93
S10	S8 OR S9	286

S11	S5 AND S10	132
S12	(flocath* OR lofric* OR easicath* OR easycath* OR speedicath* OR magic3 OR aquacath* OR urocath)	16
S13	(silky AND catheter*)	0
S14	S11 OR S12 OR S13	139
S15	S7 OR S14	176
S16	(MH "Economics")	11,473
S17	(MH "Economic Aspects of Illness")	7,037
S18	(MH "Economic Value of Life")	525
S19	MH "Economics, Dental"	113
S20	MH "Economics, Pharmaceutical"	1,813
S21	MW "ec"	146,262
S22	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*)	225,780
S23	(MH "Costs and Cost Analysis+")	88,234
S24	TI cost*	41,591
S25	(cost effective*)	30,513
S26	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*))	21,186
S27	(decision N1 (tree* or analy* or model*))	5,518
S28	(markov or markow or monte carlo)	3,684
S29	(MH "Quality-Adjusted Life Years")	2,942
S30	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs)	6,999
S31	((adjusted N1 (quality or life)) or (willing* N2 pay) or sensitivity analys?s)	13,025
S32	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31	302,382
S33	S15 AND S32	29
S34	S15 AND S32 Limiters - Published Date: 19900101-; English Language	28

Grey Literature Search

Performed: September 25–October 13, 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, Sick Kids Paediatric Economic Database Evaluation (PEDE)

Keywords used: catheter, catheters, catheterization, catheterisation, hydrophilic, hydrogel, hydrogels, intermittent, urinary, urethral, bladder

Results (included in PRISMA): 5
Ongoing clinical trials: 27 (ClinicalTrials.gov)

Appendix 5: Critical Appraisal of Clinical Evidence

Table A5: Risk of Bias[a] Among Randomized Controlled Trials (Cochrane Risk-of-Bias Tool)

Author, Year	Random Sequence Generation	Allocation Concealment	Blinding of Participants and Personnel	Incomplete Outcome Data	Selective Reporting	Other Bias
Cardenas and Hoffman, 2009[52]	Unclear[b]	Unclear[c]	Low	Low	Unclear[d]	Low
Cardenas et al, 2011[53]	Low	Low	Low	High[e]	Unclear[d]	Unclear[f]
Chick et al, 2013[7]	Unclear[b]	Unclear[c]	High[g]	High[h]	Unclear[d,i]	Low
De Ridder et al, 2005[54]	Low	Low	High[g]	High[j]	Unclear[d]	Unclear[f]
DeFoor et al, 2017[25]	Unclear[b]	Unclear[c]	High[g]	High[k,l]	Unclear[d]	Unclear[f]
Duffy et al, 1995[46]	Unclear[b]	Unclear[c]	Low	High[m]	Unclear[d]	Low
Giannantoni et al, 2001[56]	Unclear[b]	Unclear[c]	Low	Low	Unclear[d]	Low
Kiddoo et al, 2015[47]	Unclear[b]	Unclear[c]	High[g]	High[n]	Unclear[d]	Low
Pachler and Frimodt-Moller, 1999[48]	Unclear[b]	Unclear[c]	High[g]	Low	Unclear[d]	Low
Prieto-Fingerhut et al, 1997[49]	Unclear[b]	Unclear[c]	Low	Low	High[o]	Unclear[f]
Quigley and Riggin, 1993[57]	Unclear[b]	Low	Low	Low	Unclear[d]	High[p]
Sarica et al, 2010[55]	Low	Unclear[c]	High[g]	High[q]	Unclear[d]	Low
Schlager et al, 2001[50]	Unclear[b]	Unclear[c]	Low	Low	High[r]	Unclear[f]
Vapnek et al, 2003[51]	Unclear[b]	Low	Low	High[k]	Unclear[d]	Unclear[f]

[a]Possible risk of bias levels: low, high, and unclear.
[b]Authors did not specify how the randomization was generated.
[c]Authors did not provide details on allocation concealment.
[d]No protocol described, but authors clearly stated outcomes and analysis method in the paper.
[e]High dropout: 110 of 224 (48%) did not complete study.
[f]Industry sponsored.
[g]No blinding, may influence patient satisfaction data.
[h]High dropout: 31 of 51 (61%) participants did not have complete data.
[i]Data points cannot be extracted as they are shown in graphical form.
[j]High dropout: 66 of 123 (54%) did not complete study.
[k]Differential withdrawal between groups.
[l]High attrition: 23 of 78 (29%) did not complete the study.
[m]High dropout: 43 of 82 (52%) lost to follow-up at 90 days.
[n]High dropout: 21 of 66 (32%) did not complete the study; had to discard the incomplete data for those who only completed one arm.
[o]Lack of details on a priori outcomes of interest and plan of analysis.
[p]At risk of selection bias: limited recruitment, selection criteria too strict; at risk of measurement error: urine collection conflicted with standard operating procedure for weekly urine sample.
[q]High dropout: 15 of 25 participants (60%) did not complete study; 9 participants were not approved of assigned catheter (n = 2 did not approve gel lubricated catheter; n = 5 did not approve PVC catheter; n = 2 did not approve hydrophilic).
[r]Lack of details on a priori outcomes of interest and plan of analysis.

Appendix 6: Selected Excluded Studies

For transparency, we provide this list of related studies that readers might expect to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary Reason for Exclusion
Bagi P, Hannibalsen J, Permild R, Stilling S, Looms DK. Safety of a new compact male intermittent catheter: randomized, cross-over, single-blind study in healthy male volunteers. Urol Int. 2011;86(2):179-84.	Inappropriate population: healthy volunteer
Bakke A, Vollset SE, Hoisaeter PA, Irgens LM. Physical complications in patients treated with clean intermittent catheterization. Scandinavian journal of urology and nephrology. 1993;27(1):55-61.	Noncomparative study; unclear sample sizes when data were briefly described post hoc as hydrophilic versus single-use noncoated groups.
Bermingham SL, Hodgkinson S, Wright S, Hayter E, Spinks J, Pellowe C. Intermittent self catheterisation with hydrophilic, gel reservoir, and noncoated catheters: a systematic review and cost effectiveness analysis. BMJ. 2013;346:e8639.	SR looked at all settings Hand-searched the reference list for eligible primary studies
Biering-Sorensen F, Hansen HV, Nielsen PN, Looms D. Residual urine after intermittent catheterization in females using two different catheters. Scand J Urol Nephrol. 2007;41(4):341-5.	Compared catheter length, and inappropriate comparator (mixture of hydrophilic and noncoated)
Biering-Sorensen F, Nielsen K, Vest Hansen H. Urethral epithelial cells on the surface on hydrophilic catheters after intermittent catheterization: cross-over study with two catheters. Spinal Cord. 1999;37(4):299-300.	Compared 2 hydrophilic ICs
Bjerklund Johansen T, Hultling C, Madersbacher H, Del Popolo G, Amarenco G. A novel product for intermittent catheterisation: its impact on compliance with daily life-international multicentre study. Eur Urol. 2007;52(1):213-20.	"Non-interventional" and can't compare before vs. after (data aren't presented as comparing the different types of ICs), mixed control
Boucher A, Cloutier J, Lebel S, Hamel M, Lamontagne P, Bolduc S. Hydrophilic-coated catheter appreciation study in a pediatric population. Can Urol Assoc J. 2010;4(6):e150-4.	Ineligible study type: not cohort (lack comparator); mixed control (unclear single or multiple-use noncoated)
Charbonneau-Smith R. No-touch catheterization and infection rates in a select spinal cord injured population. Rehab Nurs. 1993;18(5):296-9, 305.	Ineligible study type: not cohort (prospective intervention group, retrospective control group)
Chartier-Kastler E, Amarenco G, Lindbo L, Soljanik I, Andersen HL, Bagi P, et al. A prospective, randomized, crossover, multicenter study comparing quality of life using compact versus standard catheters for intermittent self-catheterization. J Urol. 2013;190(3):942-7.	Compared catheter length
Chartier-Kastler E, Lauge I, Ruffion A, Goossens D, Charvier K, Biering-Sorensen F. Safety of a new compact catheter for men with neurogenic bladder dysfunction: a randomised, crossover and open-labelled study. Spinal Cord. 2011;49(7):844-50.	Compared catheter length; 2 hydrophilic groups
Cindolo L, Palmieri EA, Autorino R, Salzano L, Altieri V. Standard versus hydrophilic catheterization in the adjuvant treatment of patients with superficial bladder cancer. Urol Int. 2004;73(1):19-22.	Inappropriate intervention: in this case IC is not used for bladder emptying but as drug delivery, thus only used on weekly/monthly basis
Cooper FP, Alexander CE, Sinha S, Omar MI. Policies for replacing long-term indwelling urinary catheters in adults. Cochrane Database Syst Rev. 2016;7:CD011115.	Inappropriate population: indwelling only
Costa JA, Menier M, Doran TJ, Kohler TS. Catheter length preference in wheelchair-using men who perform routine clean intermittent catheterization. Spinal Cord. 2013;51(10):772-5.	Compared length of ICs
Day RA, Moore KN, Albers MK. A pilot study comparing two methods of intermittent catheterization: limitations and challenges. Urol Nurs. 2003;23(2):143-7, 58.	No outcome of interest: asymptomatic bacteriuria only
Denys P, Previnaire JG, Aegerter P, De Seze M, Karsenty G, Amarenco G. Intermittent self-catheterization habits and opinion on aseptic VaPro catheter in French neurogenic bladder population. Spinal Cord. 2012;50(11):853-8.	Compared 2 hydrophilic ICs
Diokno AC, Mitchell BA, Nash AJ, Kimbrough JA. Patient satisfaction and the LoFric catheter for clean intermittent catheterization. J Urol. 1995;153(2):349-51.	Unclear setting; unclear control group consisted of patients' old catheters, lacking further description
Domurath B, Kutzenberger J, Kurze I, Knoth HS. Clinical evaluation of a newly developed catheter (SpeediCath Compact Male) in men with spinal cord injury: residual urine and user evaluation. Spinal Cord. 2011;49(7):817-21.	Intervention of interest was catheter length, not coating/reuse

Citation	Primary Reason for Exclusion
Fader M, Moore KN, Cottenden AM, Pettersson L, Brooks R, Malone-Lee J. Coated catheters for intermittent catheterization: smooth or sticky? BJU Int. 2001;88(4):373-7.	Compared 4 different hydrophilic ICs
Faleiros F, Toledo C, Gomide MFS, Faleiros RG, Käppler C. Right to health care and materials required for intermittent catheterization: a comparison between Germany and Brazil. Qual Prim Care. 2015;23(3):127-33.	Noncomparative and no outcome of interests
Getliffe K, Fader M, Allen C, Pinar K, Moore KN. Current evidence on intermittent catheterization: sterile single-use catheters or clean reused catheters and the incidence of UTI. J Wound Ostomy Continence Nurs. 2007;34(3):289-96.	SR looked at all settings Hand-searched the reference list for eligible primary studies.
Gucuk A, Tuygun C, Burgu B, Ozturk U, Dede O, Imamoglu A. The short-term efficacy of dilatation therapy combined with steroid after internal urethrotomy in the management of urethral stenoses. J Endourol. 2010;24(6):1017-21.	Inappropriate population/ intervention: short-term dilation; inappropriate comparator
Håkansson MA, Neovius K, Norrback M, Svensson J, Lundqvist T. Health care utilization and complications rates among users of hydrophilic-coated catheters. Urol Nurs. 2015;35(5):239-47.	Lacked valid comparator
Hansen RB, Biering-Sorensen F, Kristensen JK. Bladder emptying over a period of 10-45 years after a traumatic spinal cord injury. Spinal Cord. 2004;42(11):631-7.	Inappropriate comparison
Hellstrom P, Tammela T, Lukkarinen, Kontturi M. Efficacy and safety of clean intermittent catheterization in adults. Eur Urol. 1991;20(2):117-21.	No comparator (all hydrophilic, did not compare different types of ICs)
Jahn P, Beutner K, Langer G. Types of indwelling urinary catheters for long-term bladder drainage in adults. Cochrane Database Syst Rev (Online). 2012;10:CD004997.	Inappropriate population: indwelling only
Jahn P, Preuss M, Kernig A, Seifert-Huhmer A, Langer G. Types of indwelling urinary catheters for long-term bladder drainage in adults. Cochrane Database Syst Rev. 2007;(3) (no pagination)(CD004997).	Inappropriate population: indwelling only
Jaquet A, Eiskjaer J, Steffensen K, Laursen BS. Coping with clean intermittent catherization - experiences from a patient perspective. Scand J Caring Sci. 2009;23(4):660-6.	Qualitative, noncomparative
Johansson K, Greis G, Johansson B, Grundtmann A, Pahlby Y, Torn S, et al. Evaluation of a new PVC-free catheter material for intermittent catheterization: a prospective, randomized, crossover study. Scand J Urol. 2013;47(1):33-7.	Inappropriate comparator (comparison of interest is PVC), both arms are hydrophilic
King RB, Carlson CE, Mervine J, Wu Y, Yarkony GM. Clean and sterile intermittent catheterization methods in hospitalized patients with spinal cord injury. Arch Phys Med Rehabil. 1992;73(9):798-802.	Inpatient setting; day-use data (have this in outpatient setting)
Krassioukov A, Cragg JJ, West C, Voss C, Krassioukov-Enns D. The good, the bad and the ugly of catheterization practices among elite athletes with spinal cord injury: a global perspective. Spinal Cord. 2015;53(1):78-82.	Ineligible study type: cross-sectional; unclear type of single-use catheters
Kuhn W, Rist M, Zaech GA. Intermittent urethral self-catheterisation: long term results (bacteriological evolution, continence, acceptance, complications). Paraplegia. 1991;29(4):222-32.	Noncomparative, did not compare different types of ICs
Li L, Ye W, Ruan H, Yang B, Zhang S. Impact of hydrophilic catheters on urinary tract infections in people with spinal cord injury: systematic review and meta-analysis of randomized controlled trials. Arch Phys Med Rehabil. 2013;94(4):782-7.	SR looked at spinal cord injury population only, and looked at all settings Hand-searched the reference list for eligible primary studies
Lindehall B, Abrahamsson K, Hjalmas K, Jodal U, Olsson I, Sillen U. Complications of clean intermittent catheterization in boys and young males with neurogenic bladder dysfunction. J Urol. 2004;172(4 II):1686-8.	Did not separate the intervention and control group in the beginning
Litherland AT, Schiotz HA. Patient-perceived discomfort with two coated urinary catheters. Br J Nurs. 2007;16(5):284-7.	Inappropriate comparator (hydrophilic only)
Lockwood C, Page T, Conroy-Hiller T, Florence Z. Management of short-term indwelling urethral catheters to prevent urinary tract infections. Int J Evid Based Healthc. 2004;2(8):271-91.	Short-term indwelling; outdated SR
Lucas EJ, Baxter C, Singh C, Mohamed AZ, Li B, Zhang J, et al. Comparison of the microbiological milieu of patients randomized to either hydrophilic or conventional PVC catheters for clean intermittent catheterization. J Pediatr Urol. 2016;12(3):172.e1-.e8.	Mixed comparator: noncoated, both single and multiple-use; the only relevant outcome (patient satisfaction) cannot be extracted based on the graph given (no data point)
Mazzo A, Pecci GL, Fumincelli L, Neves RC, Dos Santos RC, Cassini MF, et al. Intermittent urethral catheterisation: the reality of the lubricants and catheters in the clinical practice of a Brazilian service. J Clin Nurs. 2016;25(21-22):3382-90.	Noncomparative/descriptive

Citation	Primary Reason for Exclusion
Mistry S, Goldfarb D, Roth DR. Use of hydrophilic-coated urethral catheters in management of acute urinary retention. Urology. 2007;70(1):25-7.	Inappropriate population, comparator and outcome
Moola S, Konno R. A systematic review of the management of short-term indwelling urethral catheters to prevent urinary tract infections. JBI Library of Systematic Reviews. 2010;8(17):695-729.	Inappropriate population/ intervention: short-term indwelling
Moore KN, Burt J, Voaklander DC. Intermittent catheterization in the rehabilitation setting: a comparison of clean and sterile technique. Clin Rehabil. 2006;20(6):461-8.	Inappropriate comparison (sterile vs. clean technique) both using single-use; inpatient setting
Moore KN, Kelm M, Sinclair O, Cadrain G. Bacteriuria in intermittent catheterization users: the effect of sterile versus clean reused catheters. Rehab Nurs. 1993;18(5):306-9.	No outcome of interest: only asymptomatic bacteriuria
Pascoe G, Clovis S. Evaluation of two coated catheters in intermittent self-catheterization. Br J Nurs. 2001;10(5):325-9.	Inappropriate comparator: compared 2 single-use coated ICs
Perrouin-Verbe B, Labat JJ, Richard I, Mauduyt de la Greve I, Buzelin JM, Mathe JF. Clean intermittent catheterisation from the acute period in spinal cord injury patients: long term evaluation of urethral and genital tolerance. Paraplegia. 1995;33(11):619-24.	No comparator; did not compare different types of IC and no pre-intervention data
Prasad A, Cevallos ME, Riosa S, Darouiche RO, Trautner BW. A bacterial interference strategy for prevention of UTI in persons practicing intermittent catheterization. Spinal Cord. 2009;47(7):565-9.	Inappropriate intervention and comparator
Rew M, Lake H. A survey of short- and long-term pre-lubricated intermittent catheters. Br J Nurs. 2013;22(18 SUPPL.):S12-S8.	Noncomparative: everybody used prelubricated catheter, no information on older catheter
Rijal A, Little B, McPhee S, Meddings RN. Bladder outflow problems in females. NMCJ. 2013;15(1):46-9.	Inappropriate comparator and study design
Rognoni C, Tarricone R. Intermittent catheterisation with hydrophilic and non-hydrophilic urinary catheters: systematic literature review and meta-analyses. BMC Urol. 2017;17(1):4.	SR looked at all settings Hand-searched the reference list for eligible primary studies
Sekiguchi Y, Yao Y, Ohko Y, Tanaka K, Ishido T, Fujishima A, et al. Self-sterilizing catheters with titanium dioxide photocatalyst thin films for clean intermittent catheterization: basis and study of clinical use. Int J Urol. 2007;14(5):426-30.	Inappropriate intervention
Shamout S, Biardeau X, Corcos J, Campeau L. Outcome comparison of different approaches to self-intermittent catheterization in neurogenic patients: a systematic review. Spinal Cord. 2017;55(7):629-43.	SR looked at neurogenic population only, and looked at all settings Hand-searched the reference list for eligible primary studies
Shekelle PG, Morton SC, Clark KA, Pathak M, Vickrey BG. Systematic review of risk factors for urinary tract infection in adults with spinal cord dysfunction. J Spinal Cord Med. 1999;22(4):258-72.	SR looked at all settings Hand-searched the reference list for eligible primary studies
Singh S, Sharma S, Sen R, Garg P, Airon R. Comparative evaluation of commonly used catheters through histopathological changes induced in bladder urothelium. Urol Int. 1994;53(3):155-7.	Inappropriate population and outcome
Spinu A, Onose G, Daia C, Pantu C, Anghelescu A, Onose L, et al. Intermittent catheterization in the management of post spinal cord injury (SCI) neurogenic bladder using new hydrophilic, with lubrication in close circuit devices--our own preliminary results. J Med Life. 2012;5(1):21-8.	Inpatient; nonhydrophilic group: unknown whether single-use or multiple-use
Stensballe J, Looms D, Nielsen PN, Tvede M. Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: a prospective, randomised, participant-blinded, crossover study of three different types of catheters. Eur Urol. 2005;48(6):978-83.	Healthy volunteers
Sutherland RS, Kogan BA, Baskin LS, Mevorach RA. Clean intermittent catheterization in boys using the LoFric catheter. J Urol. 1996;156(6):2041-3.	Unknown setting and unknown control (whether single-use or reuse)
Taskinen S, Fagerholm R, Ruutu M. Patient experience with hydrophilic catheters used in clean intermittent catheterization. J Pediatr Urol. 2008;4(5):367-71.	Inappropriate comparator (different brands of hydrophilic IC)
Tenke P, Mezei T, Bode I, Koves B. Catheter-associated urinary tract infections. Eur Urol, Suppl. 2017;16(4):138-43.	Inappropriate population: indwelling only
Vaidyananthan S, Soni BM, Brown E, Sett P, Krishnan KR, Bingley J, et al. Effect of intermittent urethral catheterization and oxybutynin bladder instillation on urinary continence status and quality of life in a selected group of spinal cord injury patients with neuropathic bladder dysfunction. Spinal Cord. 1998;36(6):409-14.	Inappropriate intervention: intervention was IC in general, did not test different types of IC

Citation	Primary Reason for Exclusion
Vaidyanathan S, Soni BM, Dundas S, Krishnan KR. Urethral cytology in spinal cord injury patients performing intermittent catheterisation. Paraplegia. 1994;32(7):493-500.	Inappropriate outcome: urethral inflammation by examining urethral cell sample, not urine sample
Van Hala S, Nelson VS, Hurvitz EA, Panzi A, Bloom DA, Ward MJ. Bladder management in patients with pediatric onset neurogenic bladders. J Spinal Cord Med. 1997;20(4):410-5.	Ineligible study type: cross-sectional
Waller L, Jonsson O, Norlen L, Sullivan L. Clean intermittent catheterization in spinal cord injury patients: long-term followup of a hydrophilic low friction technique. J Urol. 1995;153(2):345-8.	No comparator arm: all participants used hydrophilic; no baseline data so can't compare before vs. after
Waller L, Telander M, Sullivan L. The importance of osmolality in hydrophilic urethral catheters: a crossover study. Spinal Cord. 1997;35(4):229-33.	Compared 2 hydrophilic ICs
Witjes JA, Popolo GD, Marberger M, Jonsson O, Kaps HP, Chapple CR. A multicenter, double-blind, randomized, parallel group study comparing polyvinyl chloride and polyvinyl chloride-free catheter materials. J Urol. 2009;182(6):2794-8.	Compared 2 hydrophilic ICs
Woodbury MG, Hayes KC, Askes HK. Intermittent catheterization practices following spinal cord injury: a national survey. Can J Urol. 2008;15(3): 4065-71.	Ineligible study type: cross-sectional; hydrophilic contains mixture of single-use and multiple-use
Wyndaele JJ, De Ridder D, Everaert K, Heilporn A, Congard-Chassol B. Evaluation of the use of Urocath-Gel catheters for intermittent self-catheterization by male patients using conventional catheters for a long time. Spinal Cord. 2000;38(2):97-9.	Ineligible study type: not cohort (lack comparator); mixed setting (some inpatient and some outpatient setting); mixed control (single- and multiple-use noncoated)
Yoshida M, Igawa Y, Higashimura S, Suzuki M, Niimi A, Sanada H. Translation and reliability and validity testing of a Japanese version of the intermittent self-catheterization questionnaire among disposable and reusable catheter users. Neurourol Urodyn. 2017;36(5):1356-62.	Ineligible study type: a part of validation study, not an eligible observational study

Abbreviations: IC, intermittent catheter; SR, systematic review.

Appendix 7: Results of Applicability Checklist for Studies Included in Economic Literature Review

Table A6: Assessment of the Applicability of Studies Assessing the Cost-Effectiveness of Long-Term Intermittent Catheterization

Objective: To assess the cost-effectiveness of long-term use of intermittent catheters					
Author, Year	**Is the study population similar to the question?**	**Are the interventions similar to the question?**	**Is the health care system in which the study was conducted sufficiently similar to the current Ontario context?**	**Were the perspectives clearly stated and what were they?**	**Are estimates of relative treatment effect from the best available source?**
Bermingham et al, 2013[11]	Partly, long-term IC use (base case = spinal cord injury patients) in the community and primary care setting	Yes, more extensive: hydrophilic, gel coated, sterile noncoated, clean noncoated (daily), clean noncoated (weekly)	No, it is the UK health system	Yes (UK NHS perspective)	Yes, a systematic literature search was used to collect RCTs or RCoTs
Clark et al, 2016[64]	Partly, adults with spinal cord injury in the hospital or community setting	Yes, single-use hydrophilic and noncoated catheters	No, it is the UK health system	Yes (UK NHS perspective)	No systematic literature search; estimates are primarily from uncontrolled observational research studies
Watanabe et al, 2015[66]	Partly, patients with spinal cord injury (care setting not specified)	Yes, single-use hydrophilic and noncoated catheters	No, it is the Japanese health system	Yes (Japanese payer perspective)	No systematic literature search; estimates from local Japanese survey and RCT data where applicable
Håkansson et al, 2016[68]	Partly, users of intermittent catheterization (care setting not specified)	Yes, single-use hydrophilic and noncoated catheters	No, it is the US health system	Yes (US payer perspective)	No systematic literature search; estimates primarily from uncontrolled observation research studies
Rognoni and Tarricone, 2017[65]	Yes, patients with spinal cord injury in the outpatient setting (i.e., their home)	Yes, single-use hydrophilic and noncoated catheters	No, it is the Italian health system	Yes (Italian health care service perspective)	Yes, a systematic literature search was used to collect RCTs or RCoTs
Truzzi et al, 2017[67]	Partly, patients with spinal cord injury (care setting not specified)	Yes, single-use hydrophilic and noncoated catheters	No, it is the Brazilian health system	Yes (Brazilian public health care system perspective)	Yes, a systematic literature search was used to collect RCTs, meta-analyses, and observational studies

Author, Year	Are all future costs and outcomes discounted? (If yes, at what rate?)	Is the value of health effects expressed in terms of quality-adjusted life-years?	Are costs and outcomes from other sectors fully and appropriately measured and valued?	Overall judgement (directly applicable/partially applicable/ not applicable)
Bermingham et al, 2013[11]	Yes (costs and QALYs discounted at 3.5%)	Yes (well explained)	No (a societal perspective is not used)	Partially applicable
Clark et al, 2016[64]	Yes (costs and QALYs discounted at 3.5%)	Yes	No (a societal perspective is not used)	Partially applicable
Watanabe et al, 2015[66]	Yes (cost and QALYs discounted at 2%)	Yes	No (a societal perspective is not used)	Partially applicable
Håkansson et al, 2016[68]	Yes (cost and QALYs discounted at 3.5%)	Yes	No (a societal perspective is not used)	Partially applicable
Rognoni and Tarricone, 2017[65]	Yes (cost and QALYs discounted at 3.5%)	Yes	No (a societal perspective is not used)	Partially applicable
Truzzi et al, 2017[67]	Yes (cost and QALYs discounted at 5%)	Yes	No (a societal perspective is not used)	Partially applicable

Abbreviation: NHS, National Health Service; RCT, randomized controlled trial; RCoT, randomized crossover trial; UK, United Kingdom; US, United States.
Note: Response options for all items were “yes,” “partially,” “no,” “unclear,” and “NA” (not applicable).

Appendix 8: Mixed-Setting Treatment Effects

Table A7: Monthly Transitional Probabilities by Type of Intermittent Catheter

Model Parameters	Estimate	95% CI	Source
Gross hematuria			
Single-use noncoated	0.004396	NR	DeFoor et al, 2017[25]; Giannantoni et al, 2001[56]
Single-use hydrophilic	0.048014	0.024910–0.090896	Meta-analysis
Single-use gel reservoir	0.006209	0.000311–0.114093	Meta-analysis
Multiple-use noncoated (1/day)	0.004615	NA	Expert opinion
Multiple-use noncoated (1/week)	0.005053	NA	Expert opinion
Symptomatic UTI			
Single-use noncoated	0.194802	NR	Woodbury et al, 2008[28]
Single-use hydrophilic	0.155491	0.129482–0.187793	Meta-analysis
Single-use gel reservoir	0.060900	0.002164–0.765312	Meta-analysis
Multiple-use noncoated (1/day)	0.194802	0.036163–0.713543	Meta-analysis
Multiple-use noncoated (1/week)	0.212060	0.133246–0.282154	Meta-analysis

Abbreviations: CI, confidence interval; NA, not applicable; NR, not reported; UTI, urinary tract infection.

Appendix 9: Meta-analysis Summary Measures

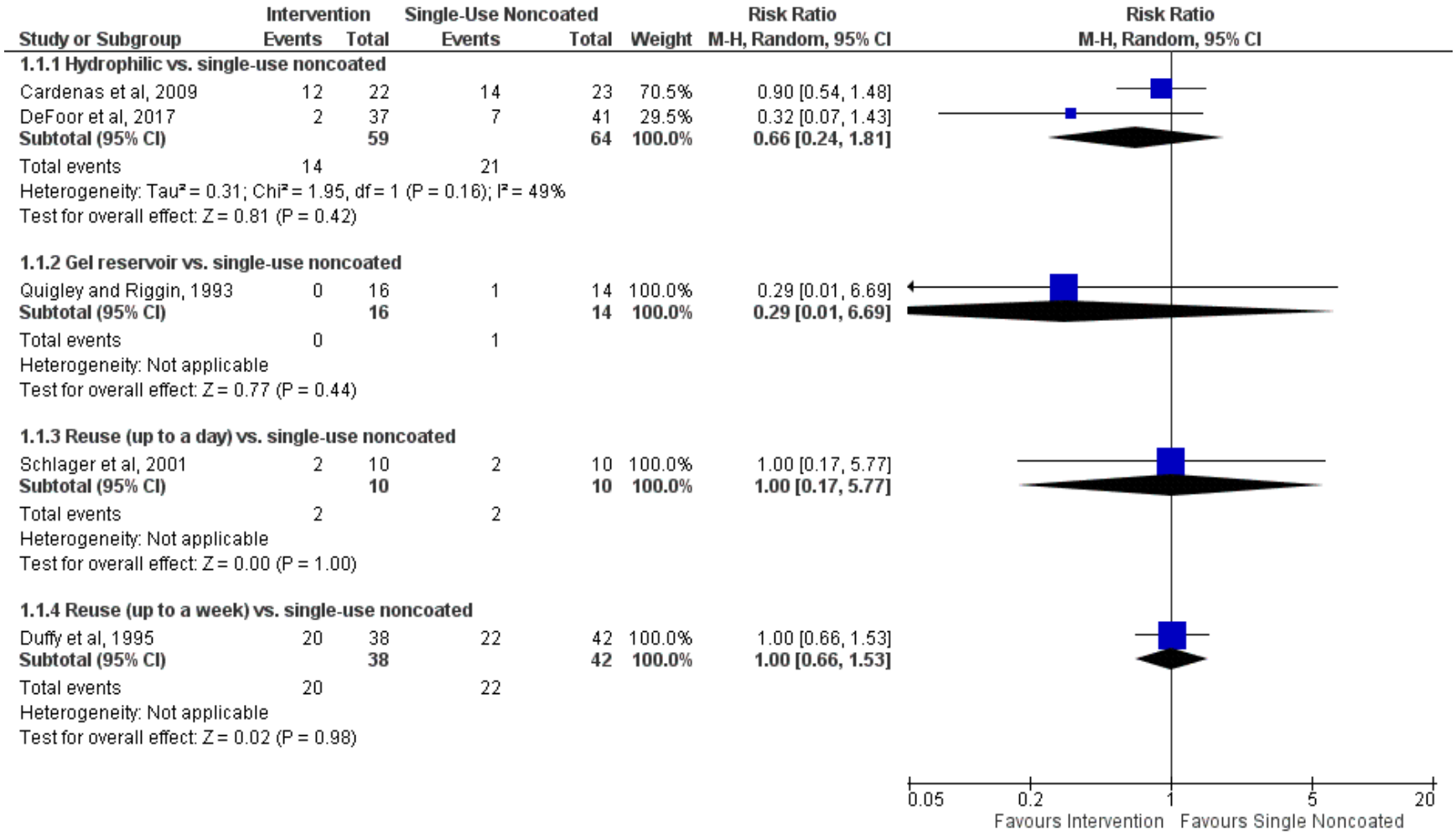

Figure A2: Risk Ratio for Urinary Tract Infection in Studies Comparing Any Type of Intermittent Catheter With Single-Use Noncoated, Outpatient Setting Studies Only

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.

Data sources: Cardenas et al, 2009[52]; DeFoor et al, 2017[25]; Quigley and Riggin, 1993[57]; Schlager et al, 2001[50]; Duffy et al, 1995.[46]

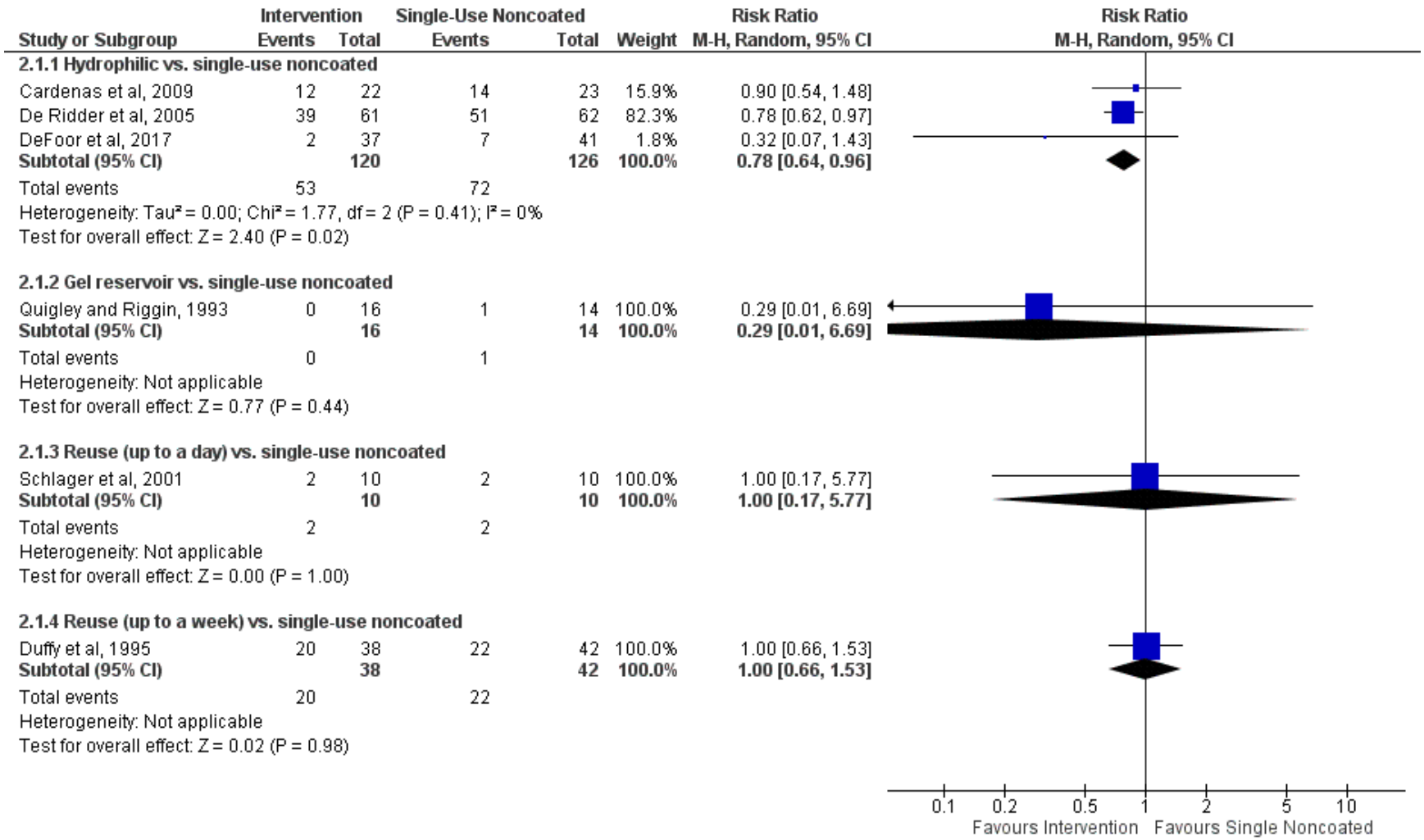

Figure A3: Risk Ratio for Urinary Tract Infection in Studies Comparing Any Type of Intermittent Catheter With Single-Use Noncoated, Including Mixed-Setting Studies

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.

Data sources: Cardenas et al, 2009[52]; De Ridder et al, 2005[54]; DeFoor et al, 2017[25]; Quigley and Riggin, 1993[57]; Schlager et al[50]; Duffy et al, 1995.[46]

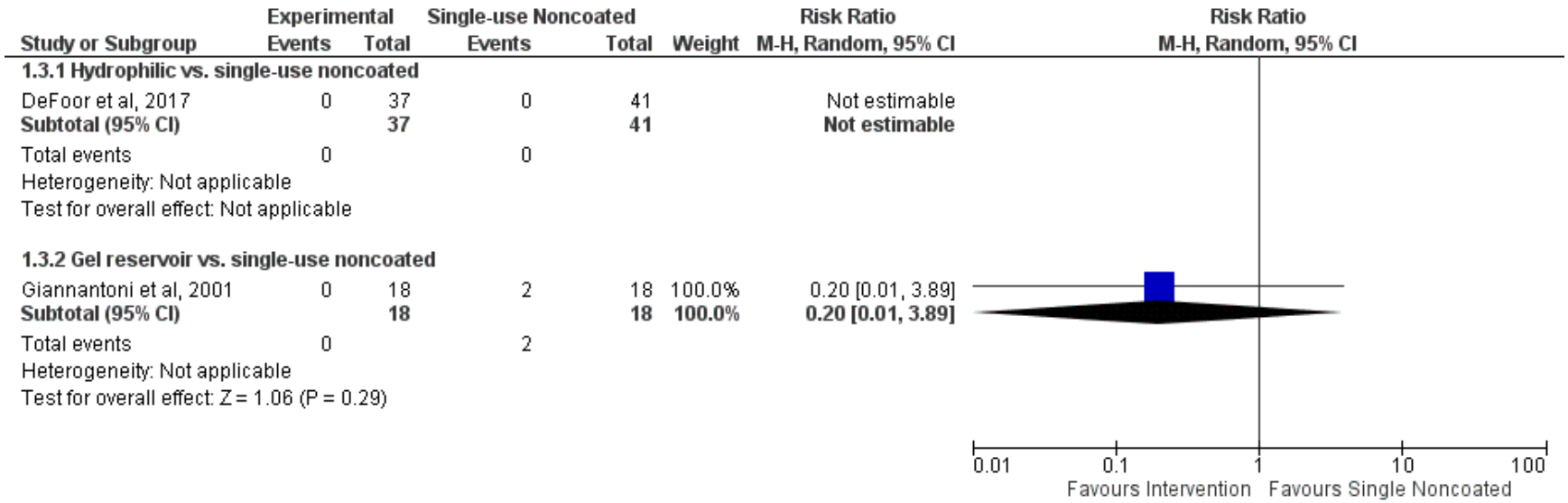

Figure A4: Risk Ratio for Gross Hematuria in Studies Comparing Any Type of Intermittent Catheter With Single-Use Noncoated, Outpatient Setting Studies Only

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.

Data sources: DeFoor et al, 2017[25]; Giannantoni et al, 2001.[56]

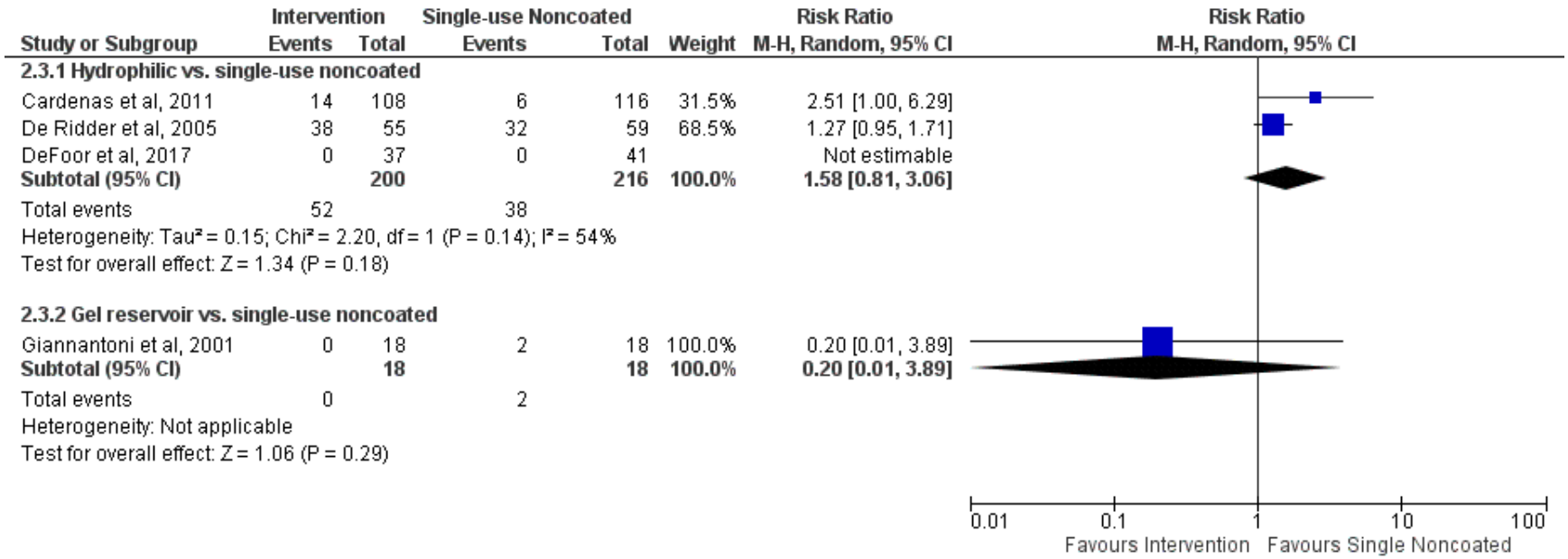

Figure A5: Risk Ratio for Gross Hematuria in Studies Comparing Any Type of Intermittent Catheter With Single-Use Noncoated, Including Mixed-Setting Studies

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel test.

Data sources: Cardenas et al, 2009[52]; De Ridder et al, 2005[54]; DeFoor et al, 2017[25]; Giannantoni et al, 2001.[56]

Appendix 10: Primary Economic Evaluation, Deterministic Sequential Analysis

Table A8: Reference Case Analysis—Sequential Analysis Step 1

Strategy	Average Total Costs, $	Incremental Cost, $	Average Total Effects	Incremental Effect	ICER, $	Dominated Status
Multiple-use noncoated IC (1/week)	9,265.05		3.918163			
Multiple-use noncoated IC (1/day)	10,895.50	1,630.45	3.918289	0.000126	12,940,079	Not dominated
Single-use noncoated IC	18,524.51	7,629.01	3.918352	0.000063	121,095,396	Extended dominance
Single-use hydrophilic IC	67,343.49	48,818.98	3.933906	0.015554	3,138,676	Not dominated

Abbreviations: IC, intermittent catheter; ICER, incremental cost-effectiveness ratio.

Table A9: Reference Case Analysis—Sequential Analysis Step 2

Strategy	Average Total Costs, $	Incremental Cost, $	Average Total Effects	Incremental Effect	ICER, $	Dominated Status
Multiple-use noncoated IC (1/week)	9,265.05		3.918163			
Multiple-use noncoated IC (1/day)	10,895.50	1,630.45	3.918289	0.000126	12,940,079	Extended dominance
Single-use hydrophilic IC	67,343.49	56,447.99	3.933906	0.015617	3,614,522	Not dominated

Abbreviations: IC, intermittent catheter; ICER, incremental cost-effectiveness ratio.

Table A10: Reference Case Analysis—Sequential Analysis Step 3

Strategy	Average Total Costs, $	Incremental Cost, $	Average Total Effects	Incremental Effect	ICER, $	Dominated Status
Multiple-use noncoated IC (1/week)	9,265.05		3.918163			
Single-use hydrophilic IC	67,343.49	58,078.44	3.933906	0.015743	3,689,159	Not dominated

Abbreviations: IC, intermittent catheter; ICER, incremental cost-effectiveness ratio.

Appendix 11: Primary Economic Evaluation, Intermittent Catheter Costs

Table A11: Intermittent Catheter Online Costs by Catheter Type

Model Parameters	Cost per Catheter, $[a]	Source
Hydrophilic		
Extendicare (long-term care provider)	7.08	Extendicare[b]
Red Leaf Medical	7.00	Red Leaf Medical, average cost[c]
SciSupply – LoFric Classic	5.96	https://www.scisupply.ca/products/lofric-classic
SciSupply – LoFric Primo	6.91	https://www.scisupply.ca/products/lofric-primo-2
SciSupply – SpeediCath Compact	4.95	https://www.scisupply.ca/products/coloplast-speedicath-compact-male
SciSupply – LoFric Origo Coudé Tip	10.23	https://www.scisupply.ca/products/lofric-origo-3
Gel reservoir		
Red Leaf Medical	5.00	Red Leaf Medical, average cost[c]
SciSupply – Manfred Sauer – IQ-Cath Gel	5.18	https://www.scisupply.ca/products/manfred-sauer-iq-cath-gel ready-to-use
SciSupply – Hollister Advance	4.40	https://www.scisupply.ca/products/hollister-advance
Noncoated		
Red Leaf Medical	1.00	Red Leaf Medical, average cost[c]
LifeSupply – Robinson/Nelaton PVC	0.57	https://www.lifesupply.ca/all-purpose-rob-nel-pvc-10fr-bx-100-rus-238500100/
LifeSupply – Cure Straight Tip	0.70	https://www.lifesupply.ca/cure-m16-bx-30-cure-male-intermittent-catheter-16fr-16-straight-tip/
SciSupply – Convatec GentleCath Straight PVC	0.50	https://www.scisupply.ca/products/convatec-gentlecath-straight-tip-pvc-catheter
SciSupply – Cure Straight	1.07	https://www.scisupply.ca/products/cure-catheter-straight-tip
SciSupply – Coloplast Self-Cath Straight	1.49	https://www.scisupply.ca/products/coloplast-self-cath-male-straight-tip?sku=904
SciSupply – Rüsch Easy Cath Coudé Tip	2.32	https://www.scisupply.ca/products/rusch-easy-cath-coude-tip
Lubricant		
LifeSupply – Muko 3.5G Satchel Lubricant Jelly	0.09	https://www.lifesupply.ca/lubricant-jelly-muko-3-5g-source-brand-100-box-sm1322n/
LifeSupply – Lubricating Gel 3G Satchel	0.08	https://www.lifesupply.ca/lubricating-gel 3gr-packets
SciSupply – Medpro Lubricating Gel Tube (142g)	0.09	https://www.scisupply.ca/products/medpro-lubricating-gel

[a] Costs as of December 2017.
[b] Email communication, Extendicare, December 2017.
[c] Email communication, Red Leaf Medical, December 2017.

Appendix 12: Primary Economic Evaluation, Deterministic Scenario Analyses

Table A12: Deterministic Scenario Analyses—Varying Discount Rates

Strategy	Average Total Costs, $	Incremental Cost, $[a]	Average Total Effects	Incremental Effect[b]	ICER, $
Scenario 1: Discount rate of 0%					
Multiple-use noncoated (1/week)	9,619		4.065321		
Multiple-use noncoated (1/day)	11,311	1,692	4.065452	0.000131	Extended dominance
Single-use noncoated	19,226	9,607	4.065517	0.000196	Extended dominance
Single-use hydrophilic	69,878	60,259	4.081678	0.016357	3,683,984
Scenario 2: Discount rate of 3%					
Multiple-use noncoated (1/week)	8,933		3.780082		
Multiple-use noncoated 1/day)	10,506	1,573	3.780204	0.000122	Extended dominance
Single-use noncoated	17,866	8,933	3.780265	0.000183	Extended dominance
Single-use hydrophilic	64,965	56,032	3.795249	0.015167	3,694,365
Scenario 3: Discount rate of 5%					
Multiple-use noncoated (1/week)	8,521		3.60886		
Multiple-use noncoated (1/day)	10,023	1,502	3.608977	0.000117	Extended dominance
Single-use noncoated	17,049	8,528	3.609035	0.000175	Extended dominance
Single-use hydrophilic	62,016	53,495	3.623314	0.014454	3,701,079

Abbreviations: ICER, incremental cost-effectiveness ratio.

[a]Incremental cost = strategy average cost − average cost of multiple-use noncoated catheter (1/week).

[b]Incremental effect = strategy average effect − average effect of multiple-use noncoated catheter (1/week).

Appendix 13: Mortality Rates for Subpopulations of Intermittent Catheter Users

Table A13: Mortality Rates Used in the Budget Impact Analysis

Model Parameters	Estimated Mortality Rate	Source
Ontario	4.6 per 1,000	Statistics Canada
Spinal cord injury	SMR = 1.7	Lidal et al, 2007[87]
Spina bifida	4.6 per 1,000	Assume Ontario rate
Stroke	90.6 per 100,000	Statistics Canada
Benign prostatic hyperplasia	0	Assume mortality and incidence are equivalent
Multiple sclerosis	4.6 per 1,000	Assume Ontario rate
Parkinson disease	200 per 100,000	Jones et al, 2012[123]

Abbreviations: SMR, standardized mortality ratio.

Appendix 14: Total Budget Impact With Cost Sharing

Table A14: Total Budget Impact of Full and Cost-Shared Public Funding of Intermittent Catheters in New Scenario

	Total Budget Impact, $					
Strategy	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year Total
Multiple-use noncoated (1/week)						
25% funding	1,768,297	1,787,824	1,807,184	1,826,379	1,845,411	9,035,095
50% funding	3,536,595	3,575,647	3,614,368	3,652,759	3,690,821	18,070,190
75% funding	5,304,892	5,363,471	5,421,552	5,479,138	5,536,232	27,105,286
100% funding	7,073,189	7,151,295	7,228,736	7,305,518	7,381,642	36,140,381
Multiple-use noncoated (1/day)						
25% funding	4,571,624	4,622,106	4,672,159	4,721,785	4,770,986	23,358,659
50% funding	9,143,247	9,244,211	9,344,317	9,443,569	9,541,973	46,717,318
75% funding	13,714,871	13,866,317	14,016,476	14,165,354	14,312,959	70,075,978
100% funding	18,286,495	18,488,423	18,688,634	18,887,139	19,083,946	93,434,637
Single-use noncoated						
25% funding	17,649,709	17,844,605	18,037,845	18,229,437	18,419,390	90,180,986
50% funding	35,299,418	35,689,210	36,075,690	36,458,874	36,838,781	180,361,972
75% funding	52,949,126	53,533,815	54,113,534	54,688,311	55,258,171	270,542,958
100% funding	70,598,835	71,378,420	72,151,379	72,917,747	73,677,561	360,723,944
Single-use gel reservoir						
25% funding	72,669,423	73,471,872	74,267,501	75,056,346	75,838,444	371,303,586
50% funding	145,338,845	146,943,744	148,535,002	150,112,692	151,676,889	742,607,172
75% funding	218,008,268	220,415,617	222,802,503	225,169,038	227,515,333	1,113,910,758
100% funding	290,677,691	293,887,489	297,070,003	300,225,384	303,353,778	1,485,214,344
Single-use hydrophilic						
25% funding	104,947,861	106,106,744	107,255,777	108,395,012	109,524,505	536,229,899
50% funding	209,895,722	212,213,488	214,511,553	216,790,025	219,049,010	1,072,459,798
75% funding	314,843,583	318,320,232	321,767,330	325,185,037	328,573,514	1,608,689,697
100% funding	419,791,444	424,426,977	429,023,106	433,580,049	438,098,019	2,144,919,596

Appendix 15: Call for Participation

ATTENTION

CALL FOR PARTICIPATION FROM HEALTH QUALITY ONTARIO

REVIEW OF INTERMITTENT CATHETERS

WHO IS HEALTH QUALITY ONTARIO?

Health Quality Ontario is a provincial agency ensuring our health care system delivers high quality care, a positive patient and caregiver experience and responsible use of health care dollars. This includes evaluating the effectiveness of health care technologies and services through a review called **health technology assessments (HTAs)**.

WHAT IS THE OPPORTUNITY?

Health Quality Ontario is currently reviewing **intermittent catheters** for people with **bladder-emptying problems due to various health conditions**. The purpose is to understand whether this program should be more broadly funded in Ontario. A key part of this review is to make sure the lived experiences of individuals and caregivers that use intermittent catheters are taken into account.

WHO ARE WE LOOKING FOR?

We are looking to speak to individuals and their families that may have had experience with using intermittent catheters.

WHY GET INVOLVED?

This review will result in a recommendation to the Ministry of Health and Long-Term Care about the public funding of intermittent catheters. The views, values, and experiences of individuals and caregivers using intermittent catheters are of vital importance to this review.

WHAT WE NEED FROM YOU

- **20-40 minutes of your time for a phone or in-person interview to share your story**
- **Permission to audio (not video) record the interview, if possible**

We are hoping to conduct interviews through the end of **February 2018**. If you are interested in participating, please don't hesitate to reach out to us at HQO:

Appendix 16: Interview Guide

Interview for Intermittent Catheter HTA

Introduction

- Explain HQO purpose, HTA process, and purpose of interview
- History of chronic urinary retention diagnosis and various treatments (general only)

Lived Experience

- Day-to-day routine
- What is the impact of chronic urinary retention and intermittent self-catheterization on person and family? Adverse events?
- What is the impact on parent if child has chronic urinary retention (if applicable)?

Therapies

- What current therapies/treatments are used and their impact?
- Experience with different intermittent catheters, past versus present. Experience with hydrophilic intermittent catheters?
- Is accessibility to therapies/treatments an issue? Are you able to take advantage of all potential therapies?
- Expectations of current therapies?

Intermittent Catheters

- Information surrounding intermittent catheters?
- Day-to-day routine? Were you taught to reuse catheters/are you reusing catheters?
- Experience with urinary tract infections?
- Any equity issues in regard to treatment options? Barriers/challenges? Cost, access, safety, inconveniences? Health literacy (i.e., training to be comfortable)?
- Decision-making in choosing intermittent catheter type for use? Was it difficult to weigh potential benefits and risks when deciding on which catheter to go with? How to choose for your child, if applicable?
- Result, impact, change in quality of life (if applicable)?

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About Health Quality Ontario

Health Quality Ontario is the provincial lead on the quality of health care. We help nurses, doctors and other health care professionals working hard on the frontlines be more effective in what they do – by providing objective advice and data, and by supporting them and government in improving health care for the people of Ontario.

We focus on making health care more effective, efficient and affordable through a legislative mandate of:

- Reporting to the public, organizations, government and health care providers on how the health system is performing,
- Finding the best evidence of what works, and
- Translating this evidence into clinical standards; recommendations to health care professionals and funders; and tools that health care providers can easily put into practice to make improvements.

Health Quality Ontario is governed by a 12-member Board of Directors with a broad range of expertise – doctors, nurses, patients and from other segments of health care – and appointed by the Minister of Health and Long-Term Care.

In everything it does, Health Quality Ontario brings together those with first-hand experience to hear their experiences and views of how to make them better. We partner with patients, residents, families and caregivers to be full participants in designing our programs and services, to ensure they are aligned to their needs and priorities. We work collaboratively with organizations across the province to encourage the spread of innovative and proven programs to support high quality care, while also saving money and eliminating redundancy. And, we work with clinicians on the frontlines to use their collective wisdom and experience to bring about positive change in areas important to Ontario – such as addressing the challenges of hallway health care and mental health.

> For example, 29 Ontario hospitals participated in a pilot program last year that reduced infections due to surgery by 18% – which in turn reduces the number of patients returning to hospital after surgery and alleviating some of the challenges faced in hallway health care. This program enabled surgeons to see their surgical data and how they perform in relation to each other and to 700 other hospitals worldwide. We then helped them identify and action improvements to care. Forty-six hospitals across Ontario are now part of this program, covering 80% of hospital surgeries.
>
> Health Quality Ontario also develops quality standards for health conditions that demonstrate unnecessary gaps and variations in care across the province, such as in major depression or schizophrenia. Quality standards are based on the best evidence and provide recommendations to government, organizations and clinicians. They also include a guide for patients to help them ask informed questions about their care.
>
> In addition, Health Quality Ontario's health technology assessments use evidence to assess the effectiveness and value for money of new technologies and procedures, and incorporate the views and preferences of patients, to make recommendations to government on whether they should be funded.

> Each year, we also help hospitals, long-term care homes, home care and primary care organizations across the system create and report on the progress of their annual Quality Improvement Plans, which is their public commitment on their priorities to improve health care quality.

Health Quality Ontario is committed to supporting the development of a quality health care system based on six fundamental dimensions: efficient, timely, safe, effective, patient-centred and equitable.

Our goal is to challenge the status quo and to focus on long-lasting pragmatic solutions that improve the health of Ontarians, enhance their experience of care, reduce health care costs, and support the well-being of health care providers. A quality health system results in Ontarians leading healthier and more productive lives, and a vibrant society in which everyone benefits.

Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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