

Position Paper

October 2020

Intermittent Urinary Catheterization Supplies Recommendations to the Ontario Government

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This position paper is a **call to action** for the Ontario government to review public coverage for **intermittent urinary catheterization supplies** in order to address important **patient safety and potential liability risks** associated with individuals having to **reuse single-use catheters for financial reasons**.

Introduction

Intermittent Urinary Catheterization

When an individual has a condition that prevents them from being able to empty their bladder on their own, they may develop chronic urinary retention. If not managed, this can lead to serious health problems. Urine that remains in the bladder for too long increases the risk of developing urinary tract infections, bladder damage, and kidney disease.¹

Treatment for chronic urinary retention is to either use an indwelling catheter which remains in the bladder for up to 30 days with the patient needing to wear a drain bag or using catheters intermittently with the catheter being inserted into the body to drain the bladder as needed, typically five times a day.¹

There is compelling evidence for 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

In Ontario, an estimated 33,000 people rely on intermittent catheterization for their daily life.¹ These individuals are living with a wide range of conditions such as a spinal cord injury, multiple sclerosis, spina bifida, bladder cancer, prostate cancer, cerebral palsy, multiple sclerosis and Parkinson's disease.

Having the ability to self-catheterize provides individuals with a sense of control over their condition and significantly improves quality of life.¹

All intermittent urinary catheters are sold "sterile" and for "single use only" but, due to cost, many people clean and reuse uncoated catheters multiple times (for example, using one per day or one per week).¹

Clinicians are then put into a difficult situation, wanting to provide information to patients about how to clean intermittent catheters despite the catheters being intended to be used one time and then discarded.

Intermittent Urinary Catheters – Need for the Right Product for the Right Patient

People can begin using intermittent catheters at any age and usually continue to do so over their lifetime.

Having a wide selection of intermittent catheters is important as the same catheter is not the right option for every patient. Catheter flexibility, diameter, material, size, lubrication and hygienic properties are characteristics that factor into patient preference.² Users of intermittent catheters have varying needs due to gender, age, dexterity, condition. For example, patients with impaired dexterity or motor skills benefit from a catheter that can be easily gripped and manipulated.² Children who need to catheterize will obviously need a choice of catheters different than adults.

The vast majority of patients initially rely on a recommendation from a healthcare provider to select an intermittent catheter with one of the first discussions being the difference between coated and uncoated catheters.

Each individual's financial situation is also a factor in selecting the right catheter for the patient. Provincial support programs vary across the country and not all provinces, including Ontario, provide adequate reimbursement coverage.

OPPORTUNITY WITH SUPPLY CHAIN MODERNIZATION TO IMPROVE PUBLIC COVERAGE

We understand one of the primary drivers for reusing a single-use intermittent catheter is financial due to inadequate public coverage.

The Ontario government is moving ahead with a bold initiative to modernize the supply chain. For the healthcare sector, this means modernizing the supply chain to optimize procurement practices, achieve greater value and improve care for patients.³

There is an opportunity with supply chain modernization to review the current support programs available for intermittent catheters and create a new program that could not only improve patient care but also improve value by taking into consideration the following:

- Chronic urinary retention can either be managed by indwelling or intermittent catheterization;
- Various studies have demonstrated the advantages of

Coated Catheters (Single-Use, Sterile)

To reduce friction and discomfort during insertion and removal, catheters can be coated with a hydrophilic polymer or pre-lubricated with a gel (known as a gel reservoir).¹ **Hydrophilic catheters** are the most common type of coated intermittent catheter. Upon exposure to water, the catheter surface becomes slippery, which replaces the need for an additional water-soluble lubricant. **Pre-lubricated gel reservoir catheters** do not require the application of additional lubricant.

Uncoated Catheters (Single-Use, Sterile)

With **uncoated catheters**, users typically apply a separate lubricant before insertion. Uncoated catheters are made from a variety of materials including PVC, PVC-free material, silicone, rubber latex, and Teflon

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. Chronic use of indwelling catheters is also associated with complications including urethral trauma, renal failure, and sepsis.¹

- Adherence to intermittent catheterization can be negatively affected by such factors as frequency of complications e.g. urinary tract infections (UTIs);²
- Global crisis of antibiotic resistance has targeted UTIs as a critical area to reduce and carefully target antibiotic use;⁴
- Guidelines recommend that individuals be offered a choice among different intermittent catheter products with the reasoning being that someone who has participated in the selection of and is satisfied with the features of his or her system is more likely to achieve successful catheterization and adhere to recommended frequency;²
- Hydrophilic catheters have a significantly lower incidence of UTIs vs other catheters⁵

Ontario Public Coverage for Intermittent Urinary Catheters

Recommendations

In light of the known patient safety and potential liability risks associated with reusing intermittent catheters and new outcomes data for hydrophilic catheters, we strongly encourage the government to adopt a value-based approach for public coverage.

We are providing the government with the following recommendations on how to embark on this important work.



RECOMMENDATION
#1

Funding Coverage to Prevent Reusing Single-Use Intermittent Catheters

- For patient safety and potential liability risks, reusing single-use intermittent urinary catheters should not be recommended and should not be incorporated into any financial analysis for public coverage.
- Provincial programs to fund intermittent catheters should be established to provide enough coverage necessary to prevent patients from needing to reuse single-use catheters for financial reasons.



RECOMMENDATION
#2

Consistency of Choice Across the Health System

- Provincial governments should have a public program for intermittent catheters aligned with the selection of catheters in other sectors (e.g. acute, rehabilitation) to ensure patients can continue to use the same catheter as they move through the system if it is working best for them.
- Provincial programs to fund intermittent catheters should be centralized to deliver supply chain excellence across the ecosystem providing patients with what they need, when and where they need it and for government to have visibility to assess value for money.



RECOMMENDATION
#3

Collaborative Approach to Building a Public Coverage Model

- Provincial government programs should be developed in collaboration with patients and clinicians in order to determine the right product for the right patient at the right time according to updated Canadian clinical recommendations from both the nursing and physician community.
 - Nursing Guidelines: A single-use, pre-lubricated catheter should be recommended for patients, especially those with repeated, symptomatic UTIs.⁶
 - Canadian Urological Association Best Practice: Whenever possible hydrophilic-coated or pre-lubricated catheters should be proposed to the patient as the first treatment option because they appear to lower the risk of UTI, may result in less urethral trauma and have higher convenience and ease of use compared to conventional uncoated catheters.⁷

Appendix

REUSING SINGLE-USE INTERMITTENT URINARY CATHETERS – CALL TO ACTION FOR FUNDING REVIEW

There has been a long-standing debate in the clinical community about the reuse of catheters and the link to urinary tract infections (UTIs).

A 2014 Cochrane review comparing single vs multiple-use catheters and urinary tract infections stated, “There is still no convincing evidence that the incidence of UTI is affected by use of aseptic or clean technique, coated or uncoated catheters, single (sterile) or multiple-use (clean) catheters.”⁸

These findings may have had a strong influence on Canadian healthcare providers and government suggesting that the reuse of catheters is an acceptable practice, given the gaps in funding which prevent many patients from affording the indicated utilization of these single-use sterile medical devices.

IMPORTANT UPDATE

The Cochrane review has since been discredited and withdrawn from publication.

An independent appraisal of the data and analysis identified crucial discrepancies in the data extraction and analyses within the review.

Using corrected data, there is a **trend to favouring single versus multiple-use catheters and a significantly lower incidence of UTIs using hydrophilic versus other catheters.**⁵

The reuse of intermittent catheters poses both a safety risk for patients as well as a potential liability risk for clinicians if they promote the off-label use of these products.

Patient Safety Risks with Reusing Single-Use Intermittent Urinary Catheters

A single-use medical device is designed, manufactured and approved for sale by Health Canada to be used once on a single patient and then to be discarded.

Single-use devices are not designed, manufactured or approved for sale to be cleaned for reuse.

Of particular concern is the reuse of critical, single-use devices (e.g. urinary catheters) as by definition these types of devices penetrate the skin (or sterile tissue), and directly contact blood and or body fluids, and can enter normally sterile cavities, which can present a high risk of infection if the medical device is contaminated with any organisms.⁹

Intermittent urinary catheters intended for single use are packaged individually in sterile packaging.

In contrast to reusable devices, manufacturers of single-use devices, including manufacturers of intermittent catheters, do not provide instructions for proper cleaning and sterilization.¹⁰

There is insufficient evidence-based research on how best one could safely and effectively clean single-use intermittent catheters yet there are a number of documents and clinical guidance continuing to provide instructions to patients about this practice.

Patient adherence to a cleaning method cannot be predicted and this further amplifies the risk of complications and their burden on the healthcare system.¹¹

Potential Liability Risk Associated with Recommending the Reuse of Single-Use Intermittent Catheters

A healthcare professional (HCP) recommending reusing a device (e.g. single-use intermittent catheter) against the original equipment manufacturers’ instructions is promoting off-label use which can pose a potential liability risk for HCP’s.

The Canadian Medical Protective Association (CMPA) has provided guidance for physicians about how to minimize the risk of liability when considering using medications or medical devices off-label:¹²

- Determine if the proposed use of the medication or device constitutes an off-label use.
- **Consider if there is sufficient support from the medical literature (e.g. guidelines from medical specialty organizations) for the off-label use of the medication or product. Is the use in keeping with the present standards of practice?**
- Document the rationale for using the medication or device off-label.
- Obtain a detailed history from patients and examine them to determine if they have a condition that would place them at increased risk of potential side-effects from the off-label use of the drug or device.
- Obtain and document patients’ consent after an appropriate discussion of the potential risks and benefits, and after a discussion about the medication or device being used in an off-label fashion.
- Document any questions asked by patients and the answers provided.

- Carefully monitor patients for side-effects during or following on an off-label treatment.

In light of the independent appraisal of the Cochrane review, there is now sufficient evidence **reusing intermittent catheters should not be the standard or acceptable form of practice.**

By continuing to promote this practice, it increases the potential risk of liability, particularly if the patient suffers from repeated urinary tract infections as a result of reusing their catheter.

Urinary Tract Infections – Known Complication and Concerns with Antibiotic Resistance

Urinary tract infection (UTI) is the most common complication of intermittent catheterization causing both physical and social discomfort and should not be taken lightly. Adults and parents of children using intermittent catheters have a fear and anxiety around developing a UTI¹ given the negative impact they can have on quality of life, and concerns with missed workdays or social events.

Lived experience from intermittent catheter users provides government with a critical perspective about why UTIs need to be taken seriously and why funding needs to be reviewed - here are just three examples of many:¹

- *He was on basic catheters before and he had tons of infections. So, one of the doctors suggested hydrophilic catheters and it was like night and day.*
- *The hydrophilic catheter is easier, and it minimizes 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. We've taken her off prophylactic antibiotics. She was on antibiotics every day for eight years.

- *When I first started and got my supplies from CCAC, they sent me five catheters to use. And I had to wash those catheters 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.*

In addition to the impact of UTIs on a patient's quality of life and associated cost of complications, another important consideration is the global crisis of antibiotic resistance with UTIs being referred to as the canary in the coal mine.⁴

UTIs are typically caused by bacteria living on or in our bodies and like many human infections require treatment with antibiotics. What's alarming the medical community now is that UTIs are becoming ever harder to treat with common antibiotics. If antibiotic resistance continues to grow, more people will need intravenous treatment for UTIs. We're also likely to see more complications, like kidney infections and sepsis, arising from ineffective treatment.⁴

Until evidence can confidently demonstrate that multiple use is as safe as single use of catheters, healthcare providers should advocate for single use of catheters, especially considering that catheter cleaning is a major issue because there is no standardized and universally accepted cleaning method that would be the pre-requisite for multiple-use catheters.⁵

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