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ONTARIO IC
WORKING GROUP

Spinal Cord Injury Ontario, Ontario SCI Alliance and Ontario IC Working Group

Response to

Ontario Health Technology Assessment - Intermittent Catheters for Chronic Urinary Retention: A Health Quality Ontario Report

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ONTARIO IC
WORKING GROUP

1) Who We Are

Spinal Cord Injury Ontario (SCIO)

SCIO provides services, support, knowledge, and advocacy with a vision that ensures people with SCI are living the life they choose in a fully inclusive Ontario. SCIO is the only organization in Ontario that supports people with a spinal cord injury from point of injury throughout their entire lifespan.

Ontario SCI Solutions Alliance

The Ontario SCI Alliance is a network of 70 organizations across the continuum of care in Ontario with 250 key provincial members, including strategic partners of researchers, service providers, policy makers, funders, and people with spinal cord injury, that addresses and resolves systemic barriers that impact the quality of life of people with SCI in Ontario.

Ontario IC Working Group

The Ontario IC Working Group is forum for interested Intermittent Catheter (IC) Users, clinicians, organizations, people with disabilities, and policymakers to advocate for appropriate, evidence-based access to ICs for Ontarians.

Together, we represent a unified voice on behalf of Ontarians to help eliminate barriers to accessing urinary catheters so that everyone who relies on them for basic life functions receives the type that is right for them.

2) Executive Summary

On September 24th, 2018, Health Quality Ontario (HQO) released its draft report on "Intermittent Catheters for Chronic Urinary Retention: A Health Technology Assessment." Below are the key findings from the report:

HQO Key Finding 1: Intermittent Catheter Cost: HQO recommends that the Government of Ontario only provide public funding for non-coated intermittent catheters for people with chronic urinary retention.

HQO Key Finding 2: Standards of Practice: HQO reports that there is no clear evidence at this time to conclusively prove that the use of Hydrophilic Catheters is better, safer or more cost effective than other types of catheters available to users.

HQO Key Finding 3: Intermittent Catheter Re-Use: Although the HQO report highlights a number of anecdotal references discouraging multiple catheters re-use, according to HQO's findings, there is no statistical evidence available to prove that re-using catheters for urinary retention results in a medical risk for users.

The HQO report states that the evidence base for hydrophilic catheters reducing urinary tract infections is inconclusive because the evidence is insufficient to conclusively make a decision on which catheter is more superior than another.

Our collective response to the HQO report offers multiple examples illustrating how its assessment of intermittent catheters is too narrow and does not reflect the "real world" impact on the affordability and re-use of ICs. Our submission focuses mainly on the inappropriate HQO decision regarding the re-use of catheters and on the strength of the evidence base.

Below are the key recommendations of Spinal Cord Injury Ontario, the Ontario SCI Alliance, and the Ontario IC Working Group, which it is hoped HQO will adopt in its report:

1. Publicly fund catheters for all permanent IC Users in Ontario based on a prescription by a medical expert and allow special circumstance.

2. Eliminate the re-use of catheters in community settings, mirroring single-use products in hospitals

3. Eliminate the piecemeal of inconsistent funding programs in Ontario based on income, age, and municipality.

3) Background

A significant population in Ontario requires intermittent catheters (IC) to manage their bladder, making catheter coverage an extremely important clinical need, health and safety issue, and quality of life factor. Given that an average individual needs to catheterize anywhere from 3-6 times a day and up to 200 times per month, provincial programs should cover nothing less than the appropriate usage for their bladder management to help maintain their independence.

I. Clinical Need

Intermittent catheterization is recommended as the most superior bladder management method for individuals with urinary retention due to neurogenic (e.g., spinal cord injury) or non-neurogenic (e.g., benign prostate hyperplasia/prostate enlargement) causes.

The estimated number of intermittent catheter users in Ontario ranges from 32,000 to 38,000. However, the total number of IC users remains uncertain. (See Uncertain Budget Impact for further information). The majority of IC users are people with spinal cord injuries or spinal bifida who often start catheterization at a young age, use it permanently over their life span, and are continuously at risk of developing urinary complications, often at a very high cost to the medical system.

II. Health and Safety

Currently, ICs are only approved for single usage by Health Canada. Yet the vast majority of catheter users continue to *re-use* them owing to poor access and poor financial coverage for medical supplies. This is a deeply troubling trend given that there is substantial clinical and anecdotal evidence indicating that catheter re-use not only increases complications, but also puts the IC user safety at risk. This should be eliminated as a standard of practice in the community, as it is in hospital settings.

According to a 2006 global health review of 27 industrialized countries conducted by the Ontario IC Working Group, Canada remains an outlier in terms of appropriate access to catheters and is one of the very few first-world countries to still recommend IC re-use.

Given that user safety is one factor that lies at the heart of this issue, there is significant benefit in providing coverage for and promoting the appropriate use of ICs. Appropriate coverage minimizes infections, unnecessary ER visits, hospitalizations, autonomic dysreflexia, secondary complications, re-constructive surgeries, and antibiotic resistance.

III. Quality of Life

IC Users want to live a full life. They work, play, go to school and support their families, as all citizens do. It is inappropriate to perceive these users as merely "patients." It is also inappropriate to assume that people only catheterize in hospitals and at home. Aside from research, acts of daily living need to be incorporated in the quality assessment of covering catheters and funding models. IC Users can't re-use their catheters in a clean, safe and efficient manner in public washrooms, in professional work environments, on the plane, on the train, and so on, like every other person who needs to use the

bathroom. As a result, re-use of catheters is insufficient for an everyday active person with a disability who uses catheters for their entire lifespan.

The health technology assessment conducted by Healthy Quality Ontario examines effectiveness and safety of intermittent catheters for urinary retention and compares any one type of single-use versus multiple-use IC, hydrophilic-coated single-use versus non-coated single-use IC, and gel reservoir single-use versus non-coated single-use IC.

Below are some shortcomings of the HQO report conclusions:

- This assessment does not take into account user best practice and professional medical opinion.
- The report inaccurately concludes that there is inconclusive evidence that suggests that one type of catheter is better than another in terms of health risks.
- The report highlights no difference in the outcomes of interest and presents inconclusive evidence on patient satisfaction, safety and effectiveness.
- The report ignores the user-engagement experience and misrepresents the community experience with respect to catheterization.

We offer challenges and alternatives to the HQO findings in Section 4.

4) Challenges with HQO Findings

I. IC User Preference and Values Not Taken Into Account

All IC Users interviewed for the HQO report conclusively stated that they preferred "single-use only" catheters as indicated on the packaging. Yet the report ignores this preference and recommends multiple-use non-coated catheters.

The interviews also document that some users require hydrophilic coated catheters because of their lifestyle or because they are not able to use other types of catheters due to their disability. Additionally, the majority of the IC Users would prefer hydrophilic coated catheters if they could access them.

The user interviews clearly show that re-use of catheters has significant negative consequences for the users. Several users spoke of how re-use of catheters negatively impacts the social determinates of health.

Please review additional quick facts and barriers from IC Users attached.

II. Incomplete Clinical Evidence

Apart from the sole reliance on RCTs, this group objects to the conclusions made on the basis of the studies that re-use vs. single-use studies are inconclusive. It is not reasonable to conclude that it is safe to re-use single-use catheters, especially when types of evidence are excluded which indicate safety problems (eg. Krassioukov 2014 and Saadat 2018). In light of these clear indications and the serious safety problems revealed in the user interviews, we find it unacceptable that re-use is recommended, especially since these catheters are approved for single use only.

Additionally, we disagree with the decision to exclude mixed- setting studies from the main analysis of uncoated vs hydrophilic coated catheters. The health effects from the coating of a catheter and increase ease or use should be considered as key factors in the final clinical evidence, particularly for those with limited hand dexterity.

The HQO recommendations completely neglect the findings from key research studies. One such study is Christison's "Intermittent Catheterization: The Devil is in the Details," published in the peer-reviewed *Journal of Neurotrauma.* Another is "Intermittent catheterization with hydrophilic and non-hydrophilic urinary catheters: systematic literature review and meta-analyses" by Rognoni and Tarricone published in *BMC Urology*. This study's conclusion favours single over multiple use of catheters and indicates significantly better outcomes for hydrophilic ICs compared to uncoated ICs.

III. IC Users Placed at Risk

When it comes to catheter re-use, there is a serious misalignment between HQO recommendations and Health Canada approvals, manufacturer labels, clinical guidelines, and provincial reimbursement programs. This puts user safety significantly and irresponsibly at risk.

The report recommends multiple-use of non-coated intermittent catheters. However, there are no non-coated ICs manufactured by industry for re-use, and product labels currently contain warnings that re-use of single-use products may create potential harm and/or infection to user.

The recommendation of re-using also does not take into account the myriad of complications that can result from the various methods available for washing and sterilizing catheters. To our knowledge, none of the available cleaning methods have been documented to be safe for the users in various public places, which further challenges the value and reliability of the HQO recommendation. Additionally, boiling, microwaving or using a variety of different substances to sterilize the catheter might lead to changing composition of the catheter itself, putting users at risk. It is the belief of our community that this is medically irresponsible, inappropriate and unethical.

IV. Underdeveloped Health Economic Evaluation

The health economic evaluation is based on overestimated catheter costs. The hydrophilic coated catheters are priced at $7. However, this is based on expensive specialty catheters and not the standard catheters that most hydrophilic users rely on and can be purchased online today for approximately half the price. In addition, it is reasonable to conclude that the prices will be driven down by increased competition and scale purchasing power under a public funding scheme. This applies to all types of catheters.

The health economic evaluation does not include any quality of life impact of different catheter types. Our community believes that this is in fact one of the most critical component of bladder management and should be carefully factored in the final analysis. The 34 interviews overwhelmingly document that the number and types of catheters play a massive role in people's everyday lives, and this clearly needs to be factored in. Additionally, the included health utility values do not take into consideration many long term complications such as reconstructive surgery.

Additionally, the IC Users' time required for cleaning/preparing and administrating catheters in multiple settings is also not factored into the cost effectiveness analysis.

The evaluation does not factor in long-term complications. This is surprising to us since these complications used to be the primary cause of mortality among people with spinal cord injuries – and continue to cause increased mortality and morbidity compared to the rest of the population. Also, the report has no mention of Autonomic Dysreflexia (AD), a serious life-threatening consequence from catheter misuse/over-use.

The new cost effectiveness study by *Welk et all* includes most of the mentioned limitations and should be included in the report.

We endorse the economic evaluation feedback provided by the Ontario SCI Alliance under the leadership of Dr. Brian Chan in a separate cover. Please review recommendations.

V. Uncertain Budget Impact

The budget impact plays a large role in HQO's recommendation. HQO's report weighs its recommendations heavily on budget impact, determining an accurate number of IC users in Ontario is important when conducting the economic modelling in the report. Thus far we have seen reports indicating that there are 32,800 people using IC's in Ontario (see below) other reports indicate that there are 38,000 – 40,000 people and the HQO report suggests that there are 34,000 IC users.

The range of IC users vary from 3-6 catheters per day, however, the average used by HQO is 5 catheters per day. Our community believes that the average is 4 catheters per day. These variables substantially impact the results of the economic modelling.

An important step in assessing the provincial budget impact is to understand the total number of full-time and occasional IC Users in Ontario, and the average number of catheters used per day.

Condition	Total population	IC requiring	IC users
SCI	33,140	55%	18,227
SB	3,500	66%	2,310
MS	23,000	11%	2,530
Stroke	94,000	1%	940
Parkinson	28,200	9%	2,538
BPH	1,253,076	1%	6,265,38
			32,810,38

5) Additional Factors to Consider

In addition to the above comments, the HQO report is also missing several important perspectives that are crucial for persons needing to use IC.

Access to Health and Health Care: Access to health and health care is a central human right. Article 25 in the UN Convention on the Rights of Persons with Disabilities requires that all governments secure that persons with a disability have access to the highest attainable standard of health without discrimination on the basis of disability. We believe that being forced to re-use catheters is in direct conflict with the highest attainable standard of health, and since we know of no other group being forced to re-use similar devices in Ontario today, we believe the recommendation to be discriminatory.

Range, Quality and Standard of Health Care: Article 25 additionally requires State Parties to a) provide persons with disabilities with the same range, quality and standard of free or affordable health care as provided to other persons and b) to provide those health services needed by persons with disabilities specifically because of their disabilities. We believe that the HQO recommendation to re-use catheters contrasts with both these elements, since IC Users would in effect be denied the health services they need and would therefore be forced to buy the catheters they need, which for many is not affordable.

Societal Ethical Values: We believe the recommendations to be out of tune with the societal ethical values around equal access to health and health care and dignity. The practical aspects of re-using catheters on a daily basis are not described in the report at all. It is not mentioned anywhere how much additional time it takes for a person with reduced hand dexterity due to a disability to clean 3-6 catheters per day. It is a tremendous burden to constantly carry around the medical supplies needed for preparing, cleaning and storing catheters and also to find a place that is private, appropriate and sufficiently clean to carry out all of the steps involved when catheterizing outside of the home setting.

When we fail to equip people with disabilities the tools to be self-reliant, we significantly increase PSW hours, which is an unfactored economical consequence in the HQO Report. The user interviews clearly show that this practical burden is a major barrier for participating in the labour market, gaining an education and living a normal family life. In addition, the constant fear of urinary tract infections and not being able to empty the bladder when needed further reduce quality of life. We think this standard of care is unacceptable not only from a health perspective but also from an ethical and social justice perspective.

Variability in Users and User Need: Since IC is the gold standard of bladder emptying, it is crucial to support users in adhering to this method. It is by definition burdensome to catheterize 3-6 times per day, and it is therefore critical that users have access to the type of catheter that fits with their specific physical, anatomical, and social needs. In recommending re-use the standard of care, HQO effectively removes all user choice and cements a practice for all for public funding, which the 34 interviews clearly demonstrate to be unacceptable. As a result, some users will unnecessarily switch to other and inferior techniques with more complications as a result. We therefore stress that access to catheters must be determined by the needs of the users and not by purely economic considerations.

Barriers to Catheters:

If you are on ODSP:

- Client needs to call their ODSP worker to receive a Mandatory Special Necessities Benefit Request Form (MSN Form) to apply for their supplies.
- Since the MSN form is not available online the client has to call their worker and wait until the form is mailed to them.
- Client needs to make an appointment with their family members and have them complete the form and mail original copy back to ODSP. This takes a lot of time and effort every three months.
- 100% funding for intermittent catheters is not guaranteed under ODSP for clients who use the benefits
- ODSP only approves intermittent catheter prescriptions three months at a time.

Client then needs to find their own supplier and connect them to their ODSP worker since ODSP will only pay the supplier directly and not the client.

- This process can often take weeks until the client get their supplies.
- If the client's health status is not deemed stable the client will have to re-submit another MSN form.

If you are 65 and are no longer eligible for ODSP:

- Client **may** be entitled to Extended Benefits through ODSP but has to arrange this with ODSP before they turn 65.
- The Extended Benefits program will pay for catheters but client has to reapply every 6 months.
- In order to apply for the Hardship Fund client must first have a preliminary phone interview and then if they qualify, an in-person interview where they have to present documentation including their income, assets, bank accounts, income tax statements, etc.
- Many IC users depend on charities to help them pay for intermittent catheters.

If you are not eligible for ODSP:

- Clients have to buy their intermittent catheters out of pocket.
- Clients have to buy their own private health benefits to help fund their intermittent catheters (if unemployed or without coverage.)
- Private insurance usually has a cap of how many intermittent catheters they will fund.
- Limited annual income forces many to choose between paying rent, buying food and being able to pee.
- Ontario has a 70% unemployment rate for people with disabilities and intermittent catheter costs drive people on social assistance.
- People with disabilities choose not to marry their spouses fearing that their joint income will exceed the threshold for social assistance eligibility.

OW Hardship Fund:

- OW hardship fund has started limiting the amount of funding for catheters.
- Client can also get their catheters funded through the City of Toronto (Hardship Fund) if they have low income but the hardship fund only provides coverage for client in the Toronto region and must re-apply every 6 months.

6) Conclusion

In conclusion, the HQO report doesn't consider many factors identified by the community associated with IC bladder management. It is disappointing that after conducting a systematic review, the report fails to reflect the reality of what people face every day.

We are disappointed that HQO didn't work closely with the many experts across Canada and around the world to help it reach effective and comprehensive conclusions. We hope to work collaboratively with HQO in the future to strengthen its process on health technology assessment. In particular we would like to understand why HQO's position on re-use is in contradiction with first world countries around the world.

It is unfortunate that we have to defend technologies like catheters and oppose the notion of re-use when there is a clear logical rationale for not inserting non-sterile products into our bodies. As but one example among tens of thousands, what parent would want to catheterize their own child with a re-used catheter?

7) Key Recommendations

1. Publicly fund catheters for all permanent IC Users in Ontario based on a prescription by a medical expert and allow special circumstance.

2. Eliminate the re-use of catheters in community settings.

3. Eliminate the piecemeal of inconsistent funding programs in Ontario based on income, age, and municipality.

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