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Impact of catheter material on health and environment

Clinical evidence Overcome challenges with Lentismed Education

For patients with a neurogenic bladder, such as those with a traumatic spinal cord injury, multiple sclerosis, and spina bifida, clean intermittent catheterization (CIC) is considered the gold standard in bladder management. It is generally accepted by organizations such as the National Institute for Health and Care Excellence (NICE) and the European Association of Urology that intermittent catheterization is recommended over the use of indwelling catheters, since it is associated with considerably fewer urinary tract infections (UTIs) and complications<sup>1</sup>.

Individual care plans help determine the appropriate frequency of catheterization based on urinary dysfunction, impact on quality of life, frequency volume charts, bladder functional capacity, and ultrasound examination of the bladder for residual urine<sup>2</sup>. A general rule for adults is to catheterize 4-5 times daily to ensure the bladder volume remains within 300-500 ml<sup>3</sup>. A disposable urinary catheter passes through the urethra on average 5 times a day, 150 times a month and 1825 times a year. In male population, in which the urethra is on average 21 centimetres long, this means that in a single catheterization 42 centimetres of tube will pass through the urethra, 210 cm in one day, 76.650 cm, or 766 meters of tube in one year.

Due to the high frequency of use of disposable catheters and the frequency of contact of the catheter with the urethra, it is necessary to carefully consider the choice of catheter material, as they may have a major impact on both the environment and health.

The most commonly used materials in catheter construction are silicone, polyvinyl chloride (PVC), and latex4. Historically, latex was the most commonly used catheter material, but due to concerns about allergic reactions, specifically

in the spina bifida population<sup>5</sup>, PVC and silicone catheters are much more common today.[4]

PVC would be very hard and brittle without additives and practically useless for technical use. Various plastic softeners are used in the industry to improve flexibility. Plasticizers such as di-2-ethylhexyl phthalate (DEHP) are often added. Environmental and health concerns about both PVC and DEHP and an increasing demand by the community for PVC-free materials have driven the development of alternative materials for catheters used in CIC<sup>6</sup>.

## Health impact

Phthalates can easily leach out of products and contaminate the external environment because they are not chemically bound to the plastic matrix or to other chemicals in formulations. Recent biomonitoring studies in the USA and Europe have detected relatively high levels of monoester metabolites of phthalates in the urine of the general population<sup>7</sup>.

Critically ill patients and neonates hospitalized in intensive care units may be exposed to significantly higher doses of phthalates that migrate from medical devices such as blood bags, catheters and nasogastric and intravenous tubes<sup>8</sup>. Considering that developing organisms are particularly vulnerable to the effects induced by phthalates, new-borns undergoing medical treatment in intensive care units may be at increased risk when compared with the general population.[7]

Phthalates act on the human body as hormone disruptors, meaning that they disrupt the balance of hormones in living organisms and can potentially cause the feminization of men.

<sup>1</sup> Krassjoukov A, Igawa Y, Averbeck MA, Madersbacher H, Llovd AJ, Bøgelund M, Thiruchelvam N, Gains in health utility associated with urinary catheter innovations. Med Devices. 2018; 1(11): 345-51.

<sup>2</sup> Moore KN. Fader M, Getliffe K. Long-term bladder management by intermittent catheterisation in adults and children. Cochrane Database Syst Rev. 2007; 17(4): CD006008.

<sup>3</sup> Prieto J, Murphy CL, Moore KN, Fader M. Intermittent catheterisation for long-term bladder management. Cochrane Database Syst Rev. 2017; 8(8): CD006008

<sup>4</sup> Sun AJ, Comiter CV, Elliott CS. The cost of a catheter; An environmental perspective on single use clean intermittent catheterization. Neurourol Urodyn. 2018; 37(7): 2204-8.

<sup>5</sup> Blumchen K, Bayer P, Buck D, et al. Effects of latex avoidance on latex sensitization, atopy and allergic diseases in patients with spina bifida, Allergy, 2010; 65: 1585-93.

<sup>6</sup> Johansson K, Greis G, Johansson B, Grundtmann A, Pahlby Y, Törn S, Axelberg H, Carlsson P. Evaluation of a new PVC-free catheter material for intermittent catheterization: a prospective, randomized, crossover study. Scand J Urol. 2013; 47(1): 33-7.

<sup>7</sup> Talsness CE, Andrade AJ, Kuriyama SN, Taylor JA, vom Saal FS. Components of plastic: experimental studies in animals and relevance for human health. Philos Trans R Soc Lond B Biol Sci. 2009; 364(1526): 2079-96.

<sup>8</sup> Dutta S. Haggerty DK, Rappolee DA, Ruden DM, Phthalate Exposure and Long-Term Epigenomic Consequences: A Review. Front Genet. 2020; 11(6): 405.

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In addition, their carcinogenicity has been proven, which manifests itself primarily in the form of malignant breast cancer and testicular cancer. Phthalates cause various abnormalities in testicular tissue and reduce fertility in men.[8]

There is a need for limiting the use of materials that contain DEHP, limiting repeated exposure and the development of toxicity as a consequence of inhalation and dermal exposure during production, processing and industrial end-use of preparations or materials containing DEHP<sup>9</sup>.

## **Enviromental impact**

Disposable products are under scrutiny for their environmental impact. Singleuse catheters may generate a large amount of waste and only in the US, up to 38 million kilograms or 206 million litres of waste are produced annually.[4]

The potential environmental waste generated by single-use medical devices is substantial. Therefore, the environmental aspect is a major concern and an important factor in the development of new products.

The current climate of environmental consciousness is ideal for making a lasting change in the practice of intermittent catheterization, which could reduce our "catheter footprint." To help achieve this goal, the use of biodegradable materials in catheter construction should be considered.[4]

Most common materials (PVC and silicone) for catheters either do not degrade at all or take nearly a century.[4] The incineration of PVC has an environmental impact, due to the formation of hydrochloric acid that can contribute to 'acid rain' unless it is effectively neutralized during the incineration process<sup>10</sup>. The use of biodegradable materials such as aluminium and polyurethane in catheter tubes and recyclable packaging should be considered.[4]

# 9 European Commission Joint Research Centre. European Union Risk Assessment Report. 2008. https://echa.europa.eu/documents/10162/e614617d-58e7-42d9-b7fb-d7bab8f26feb

## Primary catheter materials

Material	Relative prevalence	How long it takes to degrade	
PVC	Most common	Does not degrade	
Silicone	Common	Likely does not degrade significantly	
Latex	Less common 50-80 years		
Polyurethane	Less common Months or years		
Polyolefin	Less common Months to centuries (depends on additives)		

Name	Catheter material	Weight in package (gram)	Volume in package (ml)
ConvaTec GentleCath	PVC	8	25
Coloplast SpeediCath	polyurethane	9	15
Bard Clean-Cath	PVC	10	25
Coloplast Self-Cath	PVC	10	30
Cure Catheter	PVC	10	25
Bard All-Purpose	latex	12	40
Barg Magic 3	silicone	17	75
Lofric Primo	polyolefin- based elastomer	26	50
Hollister VaPro	PVC	28	125
Bard Touchles Plus unisex	PVC	62	375
Bard Magic3 Touchless	silicone	71	300

<sup>\*</sup> Sun, Comiter and Elliott, 2018 [4]

<sup>10</sup> Rowat SC. Incinerator toxic emissions: a brief summary of human health effects with a note on regulatory control. Med Hypotheses. 1999; 52(5): 389-96.

Polyurethane (PU) is a soft and elastic polymer containing urethane blocks. PU offers flexibility without the use of plasticizers, which provides the needed properties for intermittent catheters without having substances such as PVC and phthalates in them, which are undesirable in waste incineration<sup>11</sup>.

The catheter tube in LentisCath catheter is made of PU, a rarely used material, and can be decomposed, as some types of fungi and bacteria can biodegrade it. Harmful PVC is removed from all aspects of the catheter, including packaging, which is made of aluminium that does not leave toxic components in the soil and groundwater<sup>12</sup>.

#### Conclusion

Due to the high frequency of use of disposable catheters and the frequency of contact of the catheter with the urethra, we must carefully consider the choice of catheter material, as it can have an impact on the environment and health. The most commonly used PVC catheters are potentially hazardous to health and the environment due to the formation of hydrochloric acid, which can contribute to 'acid rain' unless it is effectively neutralized during the incineration process. PVC-free catheters from biodegradable materials such as polyure-thane in the catheter tube and aluminium in the recyclable packaging should be considered.



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<sup>11</sup> Nurses Specialized in Wound Ostomy and Continence Canada (NSWOCC). Clean Intermittent Urethral Catheterization in Adults. 2020 http://nswoc.ca/wp-content/uploads/2020/05/Clean-Intermittent-Urethral-Catheterization-Adults-for-Nurses-BPR-May2020-Ir-1.pdf

<sup>12</sup> Djordjevic LM, Bizic M, Stojanovic B, Bencic M, Korac G. Impact of Catheter Characteristic on Complications Associated with Clean Intermittent Catheterization: Review of the Literature and Our Experience. EC Nursing and Healthcare. 202; 175-82.