# **CADTH Horizon Scan**

# Shortages of Care and Medical Devices Affecting the Pediatric Patient Population

Sarah Jones Melissa Walter



# Key Messages

#### What Is the Issue?

- Shortage events, the phenomena when demand exceeds supply, can affect both medical care and medical devices. The COVID-19 pandemic caused a global shortage event, the consequences of which are still being experienced beyond the peak of the pandemic (e.g., the lack of pediatric pain medication available in fall 2022).
- Children are vulnerable to shortage events as they represent a small proportion of the overall population, have distinct needs, and the pediatric medical device market has historically offered a lack of options.

## What Are the Technologies?

- Technologies such as artificial intelligence (AI)-enabled devices, point
  of care testing, and virtual care options could contribute to alleviating
  shortages in pediatric care.
- Technologies such as 3D printing, alternative interventions such as tracheostomy during shortages of mechanical ventilators, and the reprocessing of single use devices such as ventilator tubes have been suggested in times of pediatric medical device shortages.
- Solutions to shortage events can take the form of novel devices, interventions, or policies; however, due to the complexity of this problem, a multipronged approach is likely needed.

# What Is the Potential Impact?

- Shortages can cause delayed intervention, which has health and financial costs. When cancer diagnoses and treatments are delayed, overall survival rates decrease. High-quality early intervention can change a child's developmental trajectory and improve outcomes for children, families, and communities.
- Finding solutions to shortages, particularly for children as they are already at risk for health inequities, is crucial to ensure good health care outcomes in the long-term.

#### What Else Should We Know?

- During a shortage event, alternative interventions may have different safety profiles or require different training than default practices.
- Equity should be a consideration when implementing technologies, interventions, and policies to address shortage events so that these solutions do not end up replicating or exacerbating existing inequities.



# **Purpose and Scope**

The purpose of this horizon scan is to present health care stakeholders in Canada with an overview of information related to shortages of medical devices and care for children. This report aims to provide an overview of the scope of the shortages and, in turn, some of the policies, technologies, and interventions that are currently being used or have the potential to address shortages of care and medical devices affecting children in Canada.

This report is not a systematic review and does not involve critical appraisal or include a detailed summary of study findings. It is not intended to provide recommendations for or against the use of any policy, technology, or intervention. For literature search, screening, and selection methods, refer to <a href="#">Appendix 1</a>.

Although shortages of pediatric medications have been reported (e.g., ketamine and antibiotics¹), drugs are not a focus of this report; however, the report does highlight information on new areas of research, such as 3-dimensional (3D)-printed tablets, that are within the scope of this report. Some health and human resources solutions, such as cross training among medical staff to address shortages of pediatric health care providers, are mentioned in this report; however, systemic issues, such as accelerated training programs for medical professionals, are outside of the scope of this report. It is important to note that larger systemic change is a part of the solution to care shortages.

# Background

Parents and caregivers in Canada have been experiencing shortages relating to the availability of health care for their children. Shortages of care (e.g., overcrowded pediatric emergency departments [EDs] or difficulty finding or accessing a health care provider for their child; shortages of over-the-counter pain medication; and shortages of medical devices, such as pediatric catheters, stents, and accessories for ventilators)<sup>2</sup> were reported across Canada during the fall of 2022. During the same period, children's hospitals were consistently operating above 100% capacity.<sup>3</sup> During the same time period, overcrowding was also experienced in general EDs.

The pediatric population of Canada represents about 21% of the total population.<sup>4</sup> However, children are not a monolith, from neonates to adolescents, the experiences, abilities, and health care needs of this group vary widely and can be affected by history and location, as well as political, economic, and social status. As children grow and change, they have unique developmental differences that require specific types of health care intervention that differ from adult care. Furthermore, children have much of their lifespan ahead of them. When we consider health care outcomes for children we must think in terms of decades of potential impacts. Ensuring high-quality, complete, and timely care for this population is crucial for good health care outcomes in the very long-term. Finally, it must be noted that structural inequities, such as systemic racism in the health care system, can cause children who are racialized to have worse health outcomes than their peers. Acknowledging and addressing this fact would also be transformational for pediatric health care.



Canada ranks 30th among 38 rich countries in the well-being of children and youth under age 18 according to a UNICEF report card from 2020.<sup>5</sup> This report found that Canada systematically underinvests in this population compared with other similar jurisdictions, investing 1.68% of Canada's gross domestic product toward policies and investments for children and youth, compared to up to 3.68% of gross domestic product by countries such as France, the UK, and Sweden.<sup>5</sup>

While pediatric health care is a stated priority for people living in Canada,<sup>6</sup> parents, caregivers, and health care providers are concerned about access to essential care, medicines, and health products like medical devices.<sup>7</sup> The COVID-19 pandemic has further contributed to these concerns about children's access to medical care and health resources.<sup>8</sup> This report provides an overview of:

- issues related to shortages and access to care for children
- the policies, technologies, and interventions that are currently being used or have the potential to address shortages of care for children
- issues related to access to medical devices for children
- the policies, technologies, and interventions that are currently being used or have the potential to address shortages of medical devices for children.

# Addressing Access to Care for Children

Access to medical care professionals is a well-documented issue for people living in Canada. Pediatrics is a specialized area of medicine that focuses on child and youth health. It requires additional training after medical school. There are also pediatric subspecialties; clinicians can specialize in a particular area of care, such as pediatric oncologists, neonatologists, or pediatric hematologists. Some areas in Canada are experiencing a shortage of physicians, specialists, and other health care providers. Due to their unique skills and training there are fewer clinicians who specialize in the treatment of children, which can exacerbate these access issues. As a result, children often wait longer for health care of all forms than adult patients do; including mental health interventions, surgeries, and primary care. As many as 1.5 million, or about 18%, of children in Canada are currently without a primary care provider.

This pediatric care shortage showed itself as more parents and caregivers turning to pediatric EDs for care in the absence of other options, which contributed to very high attendance at children's EDs in the fall of 2022.<sup>14,15</sup>

The COVID-19 pandemic has increased the pressure on the existing workforce.<sup>13</sup> For specialized areas like pediatrics, these care shortages affect an already small workforce and make it difficult for some people living in Canada to access care. These ongoing access issues are exacerbated when a shortage event, like the COVID-19 pandemic, occurs. Beginning in March 2020, health care resources were strategically redeployed to deal with COVID-19, leaving fewer resources and creating a backlog for regular health care



services. During the height of the pandemic when beds were in short supply, pediatric resources were often reallocated to adults (i.e., pediatric ED and intensive care unit beds were allocated to adults). This shortage event resulted in cascading effects for children, including surgical backlogs and longer wait times to see a specialist. This is crucial because delayed intervention leads to serious health and financial costs. For example, when certain cancers are discovered and treatment is started early, the overall survival rates increase. Another example is that for children with developmental needs, high-quality early intervention services can change a child's developmental trajectory and improve outcomes for children, families, and communities. These interventions are likely to be more effective and less costly when provided earlier in life rather than later. It is clear that backlogs and increased wait times lead to delays that can result in more serious harms.

Although this shortage of pediatric care is a complex problem, potential solutions that were present in the medical literature ranged from the use of technologies such as Al and virtual care to strategies for resource management and health and human resources within health care settings. This section outlines examples of how these technologies may contribute to addressing some of the care shortages that affect children, though this list of technologies is not exhaustive and is not a CADTH recommendation for or against these technologies.

#### Al and Automation

Retinopathy of prematurity (ROP) is the leading cause of childhood blindness in very low birth weight and very preterm infants. As more pediatric patients survive prematurity, there is a corresponding increasing need for assessments of ROP. However, fewer professionals are training to be neonatal ophthalmologists. This mismatch of needs and specialists has required health systems to consider technological alternatives. A deep learning algorithm has reportedly been developed and tested to diagnose ROP remotely, based on images. The algorithm was able to outperform 6 of 8 human experts. Combining this AI with telemedicine can help to address regional shortages of specialists.

In addition to ROP, AI has the potential to diagnose pediatric respiratory illnesses. One such technology that is early in its development is DeepBreath, a deep learning model that can be used to identify the audible signatures of acute respiratory illnesses (such as pneumonia and bronchiolitis) in children. Machine learning is also being used to advance the understanding of pediatric asthma. The value proposition of Alaided analysis is that it may contribute to the standardization and automation of the evaluation of breathing patterns in pediatric patients, which could result in increased throughput.

Robotics is an area that shows promise in pediatric pain management. Studies have shown that humanoid robot—based distraction therapy can have a modest effect on reducing distress for children undergoing IV insertion.<sup>21</sup> Medi is a 2 ft humanoid robot that teaches deep breathing to children to help them cope with fear and pain caused by IV insertions.<sup>22</sup> Children who were trained by Medi were able to tolerate more completed insertions compared to usual care even though the pain and fear experienced by the patient were about the same.<sup>22</sup> While these robots do not replace in-demand workers, a potential benefit is in the ability to save clinician time at the patient's bedside by addressing these common and understandable concerns so that the clinician can successfully attend to other patients.



While AI and automation show promise to address shortages of specialized pediatric health care workers, it is important to acknowledge the specific risks that AI might pose to the pediatric population. Children are vulnerable and ensuring AI health care is equitable and inclusive is of paramount importance.<sup>23</sup> A systematic review on the use of AI for the pediatric population determined that few studies found that direct patient outcomes were improved with its use and recommends further study to standardize outcomes and measures, as well as developing implementation standards for AI-enabled technologies.<sup>24</sup>

## Point of Care and At-Home Testing

Point of care testing (POCT) is medical diagnostic testing performed outside the clinical laboratory, at or near where a patient is receiving care, such as a rapid antigen COVID-19 test taken in a pharmacy. POCT is sometimes seen as an inferior alternative to more resource-intensive gold standard diagnostic tests that require laboratory access. However, with appropriate training and implementation, POCTs may have a role in pediatric EDs to save time and resources in times of resource constraint.<sup>25</sup> In addition to their in-hospital use, POCTs can be used in settings such as pharmacies and even at home.

In fall of 2022 and winter of 2023, a "triple-demic" of respiratory syncytial virus (RSV), influenza, and COVID-19 contributed to demand in children's EDs across Canada. At-home testing for respiratory conditions could play a role in alleviating some of the pressure on pediatric EDs as the ability to test at home might offer some reassurance to worried caregivers. While there is currently no rapid at-home test for all 3 respiratory viruses on the market in Canada, the FDA has approved an at-home test for RSV, influenza, and COVID-19. However, the cost and the processing time of this test might limit its possible uses; the test costs US\$169 and the specimens must be sent to a lab for processing, which may be an unacceptable delay for receiving results.<sup>26</sup> Further developments in at-home testing for respiratory conditions may help to determine if this type of technology leads to a meaningful reduction in the use of EDs.

#### **Virtual Care**

While there is some variability in how the term *virtual care* is used in the literature, the Women's College Hospital Institute for Health Systems Solutions and Virtual Care defines it as any interaction between patients, caregivers, and providers that occurs remotely, using any form of communication or information technology, with the aim of facilitating or maximizing the quality or effectiveness of patient care.<sup>27</sup> Virtual care has been deployed to help with many aspects of the care continuum — it has been proposed as a solution to a shortage of mental health care providers for youth and young adults,<sup>28-30</sup> and virtual care has also been used successfully to increase access to gender affirming care to pediatric patients who may live in regions without such services.<sup>31</sup> A systematic review found that mobile health technologies, such as the use of smartphones, tablets, and patient monitoring devices to communicate health information to the care team (asynchronous virtual care), have been shown to improve postoperative outcomes for pediatric patients and attendance at postoperative procedures, as well as reliably monitoring patients' pain.<sup>32</sup>

While there is some evidence that virtual care increases access to certain specialties, a lack of specialists cannot entirely be addressed through virtual access to a limited pool of care providers.



## **Health Human Resource Management**

The specialist workforce trained to treat the pediatric patient population is in decline and predicted to continue shrinking. 18,33 According to Canadian Institute for Health Information (CIHI) data from 2021, the workforce of pediatric specialists is as large as it has ever been; however, there are regions that have been disproportionately affected by pediatric workforce shortages in recent years, including Nova Scotia and the Northwest Territories.34 It should be noted that the total workforce number does not necessarily reflect full-time working physicians as it does not account for the increasing complexity of care that may require physician collaboration, reduced working hours, or physicians who pursue academic or other nonclinical work. Research on primary care and family care shortages has found that volume of patient contacts is decreasing over time and practice sizes are also shrinking. 35 Trends that affect access to primary care for the general and pediatric populations are the growing population, changing physician demographics, impending retirements, shifts away from comprehensive practice, and burnout across health care professionals.36 The COVID-19 pandemic has placed strains on the health care workforce and there is evidence that clinicians are reducing their hours and retiring early in response to burnout.<sup>37</sup> The literature describes many possible solutions for this potential shortage of trained pediatric staff, such as clinician cross training within an institution among adult and pediatric practitioners, 38,39 knowledge sharing among specialized practitioners like child psychologists, 40-42 telemedicine consultation for rural and remote areas, 43 primary care providers taking on specialist roles,44 and encouraging institutions to support clinicians who choose to work in pediatric specialties with added incentives. 45 Additional supports for the mental health of practising clinicians may also be helpful in addressing chronic clinician burnout.46

When sharing limited resources among all types of patients (i.e., cross training physicians to treat and manage both adult and pediatric patients, especially in a time of extreme resource strain like the COVID-19 pandemic), taking an equity approach to resource allocation is crucial. Developing shared resource allocation protocols ahead of time ensures that decision-making during times of crisis can run as smoothly as possible. This is of particular concern for special patient groups like pediatric patients who might pose unique challenges to traditional ways of assessing morbidity and mortality risk.<sup>47</sup>

# **Addressing Access to Medical Devices for Children**

The term *medical device*, as defined in Canada's Food and Drugs Act, covers a wide range of health or medical instruments used in "diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state." Medical devices is a broad category that includes items as diverse as wheelchairs, imaging modalities like MRI machines, as well as rapid COVID-19 tests. Both in Canada and internationally, for certain diseases, especially rare diseases, children have either no device options, inadequate options, or adult devices that are modified and used off-label with little or no safety or efficacy data for their use in pediatrics.<sup>48</sup> Pediatric patients often require specialized medical devices due to unique conditions and the fact that devices developed for the general population might be too large for their bodies.



Some experts suggest that access to medical devices that are purposely designed and developed for children and youth is vital to improving the quality and safety of children's health care delivery in Canada.<sup>3</sup>

Researchers have noted that children are disadvantaged in the realm of health technology assessment priority setting for a variety of systemic and practical reasons.<sup>49</sup> One of the reasons for this disadvantage is the difficulty in generating robust evidence for the treatment and management of children. Randomized controlled trials are considered the evidence gold standard; however, these types of studies have practical and ethical limitations in the pediatric population. When recruiting for clinical trials, there are often small numbers of potential subjects for childhood diseases and there is also a historical reticence to involve children in clinical research due to concerns about safety. As many jurisdictions use health technology assessment to allocate funding for medical devices and pharmaceuticals, these concerns have a direct effect on what medical technologies are available and accessible to the pediatric population.

The COVID-19 pandemic has revealed particular vulnerabilities in the medical device market.<sup>50</sup> An expert that we spoke to regarding Canadian medical device supply chains summed it up neatly as "less choice, more demand." (Ms. Claudette (Chloe) Brozuk, Provincial Health Services Authority, Victoria, BC: personal communication, Feb 21, 2023). This is not a problem specific to Canada — with global supply chain issues, medical device shortages are an problem for many regions.<sup>51</sup> A group of cardiologists in the EU note that pediatric patients are particularly vulnerable when devices are in short supply in part because there are often fewer or no alternatives to devices that are intended for children.<sup>52</sup> Apart from the additional strains placed on supply chains and the COVID-19 pandemic, pediatric medical devices have different market dynamics characterized by a lower volume of sales and reduced return on investment when compared to general medical devices.<sup>53</sup>

In response to increasing shortages of medical devices in Canada, a new medical device regulation was introduced in March 2, 2022, that attempts to ensure manufacturers and importers report shortages and discontinuations of medical products.<sup>54</sup> This information may then appear on the Health Canada—maintained *List of shortages and discontinuations*, which tracks information on actual and anticipated device shortages.<sup>2</sup> In the US, the FDA has started a similar program to push for increased authority to compel medical device manufacturers to report when there are shortages of critical medical devices.<sup>55</sup> These types of programs can be used for future planning for medical devices.

The shortages of some pediatric medical devices have many causes and possible solutions ranging from technical solutions like 3D printing to regulatory solutions that could change how devices enter the market.

# **3D Printing**

In Canada, guidance about bringing 3D-printed implantable medical devices to market acknowledges that this is a quickly changing field.<sup>56</sup> 3D-printed medical devices are potentially less reliant on international supply chains depending on the materials they use — polymers are generally available domestically while



other materials may not be. Another potential advantage of 3D-printed devices is that they can be made to correspond to a specific patient's measurements. This type of precision manufacturing can be particularly useful for children as this patient population is rarely 1 size fits all; consider neonates and children born preterm who are at risk for being born at a low birth weight (defined as less than 5 pounds) or a very low birth weight (defined as less than 2.5 pounds). 57,58 3D-printed medical devices that are already being explored for use in the pediatric patient population are stents, tubes, swabs, and airway support devices that could be created in much smaller sizes to suit the wide range of needs of this population. 57-61 Challenges like very small anatomy size and growth over time must be considered when 3D printing medical devices for this population. Follow-up and replacement of the device must be considered as part of the device implementation. 62

3D printing technology is also being used to create pharmaceutical tablets for pediatric patients, which has the potential to be used to address the problem of a shortage of pediatric drug formulations. There is evidence that 3D printing using the hot melt extrusion process manufactured mini tablets that fulfilled the requirements of the European Pharmacopoeia. It should be noted that children often use liquid or suspension formulations as many are unable to easily use tablet medications.

#### **Alternative Products and Procedures**

### **Extracorporeal Membrane Oxygenation**

When pediatric medical devices are in short supply, alternative solutions are sought. Sometimes an alternative procedure can be suggested, but the alternative may have a different safety or risk profile. For example, the removal of a neonatal venovenous cannula from the market in 2018 resulted in the nearly exclusive use of venoarterial extracorporeal membrane oxygenation (ECMO) for respiratory failure during the first half of 2021.<sup>64</sup> The involvement of the carotid artery in venoarterial ECMO may make it a riskier option than venovenous ECMO.<sup>64</sup>

#### Ventilation

When there is a lack of mechanical ventilators for pediatric patients, patients who would otherwise be treated with a mechanical ventilator are switched to a more invasive tracheostomy tube. <sup>55</sup> While a ventilator is a somewhat invasive medical device that requires the placement of an endotracheal and nasogastric tube, a tracheostomy is more invasive as it requires a surgical procedure with all of the risks that that entails. In the US, while shortages persist, the FDA recommends that health care centres reuse tracheostomy tubes after they are reprocessed and sterilized. <sup>65</sup>

#### **IV Locks**

In the US in 2018, Ablysinol was granted orphan drug designation by the FDA for the rare indication of treating hypertrophic obstructive cardiomyopathy. This designation allowed patent exclusivity which in turn prohibits other manufacturers from making and marketing dehydrated, sterile ethanol. The result was a shortage of ethanol in the US and a related price increase that required changes to certain common procedures such as the use of ethanol locks to keep IV lines clear of infection. <sup>66</sup> This shortage of ethanol locks has made it necessary to source new locking agents. Furthermore, there is concern that an ethanol



lock shortage and the related reliance on new locking agents may increase the rates of central line bloodstream infection (an adverse event) on an already vulnerable pediatric patient population.<sup>66</sup>

## **Sexually Transmitted Infection Testing**

Another area that has been affected by shortages is sexually transmitted infection testing.<sup>67</sup> This shortage may necessitate resource stewardship in terms of only testing groups that are at highest risk, as well as treating individuals who are symptomatic without a confirming test. This latter situation, while practical, is not recommended best practice for antibiotic stewardship.

### **Policy-Based Solutions**

Researchers and clinicians have suggested that new incentives for manufacturers of pediatric medical devices might help to curb supply shortages. In Canada, programs such as the Special Access Program allow medical professionals to access medical devices that have not been approved for use in Canada under special circumstances — such as in times of shortages. Other jurisdictions offer additional incentive programs for device manufacturers to help ensure access to medical products for rare diseases, sometimes referred to as orphan medical device programs. These types of programs help to ensure access to critical medical devices and often serve in-need patient populations. Health Canada is undertaking a plan to update the regulatory review of drugs and devices and, as part of that ongoing process, steps are being taken to formalize a preclinical meeting framework where medical device manufacturers will be able to receive advice and recommendations, especially on their investigational testing protocols.

While Canada has an orphan drug program, a similar program for devices might help ensure these technologies are still produced for the populations who need them — even when the devices are not profitable.

The European Medicines Agency (EMA) has recently developed a scientific advice pilot program for high-risk medical devices.<sup>71</sup> This type of program aims to help shepherd device manufacturers through the approval process. The pilot aims to take 10 devices that will be either those intended for the treatment of a rare condition or those meant for pediatric use.<sup>71</sup>

# **Final Remarks**

Medical device and care shortages are an ongoing concern for children in Canada. This report is not an exhaustive list nor endorsement of possible solutions to these events. Furthermore, this report did not consider systemic changes that may be related to human resources or infrastructure investments for health care needs.

The pediatric patient population is unique in the health care system and has some specific vulnerabilities as a result. Children make up a minority of the population and many systems are not designed with their



needs in mind. Pediatric patients are growing and developing over time, which means their bodies, as well as their mental and emotional capacities, are changing significantly. One result of this is that they may literally outgrow a medical device over time. In terms of quality of life, children also have the potential to live for many decades after a health care event, which must be factored into their treatment and health outcomes.

When considering technical or policy-based interventions to assist this patient population, these unique characteristics must be considered. Policy-based solutions that incentivize the development of medical devices for children are a potentially useful upstream solution, because, as it stands now, there are often few backup devices when shortages occur.

From a resource management perspective, both personnel and medical devices can be deployed in innovative ways to deal with shortage events. The solutions are many and varied and must consider the individual needs of patients and the full health care setting. For example, when alternative devices or procedures are offered, it is important to consider whether these alternatives have a similar safety profile. Some technologies mentioned in this report are in the early stages of development and it is possible that the uses of these technologies will change as more evidence becomes available.

While technologies such as virtual care and AI offer promise to addressing shortages affecting the pediatric population, it is crucial that these technologies are deployed thoughtfully with an equity framework in mind lest these new technologies reproduce and/or exacerbate existing inequalities and structural racism in health care. Policy-based solutions must ensure that safety and access are considered when pediatric medical devices are brought to market.



## References

- 1. Health Canada. Tier 3 drug shortages. 2023; <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/tier-3-shortages.html#wb-auto-4">https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/tier-3-shortages.html#wb-auto-4</a>. Accessed 2023 Jun 9.
- 2. Health Canada. Medical device shortages: List of shortages and discontinuations. 2023; <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/shortages/list.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/shortages/list.html</a>. Accessed 2023 Mar 21.
- National Strategy 2023. Healthy Futures For All: Advancing a Strategy for Child and Youth Health. Ottawa (ON): Children's
   Healthcare Canada; 2023 Feb: <a href="https://www.childrenshealthcarecanada.ca/en/child-health-advocacy/National-Strategy-2023.pdf">https://www.childrenshealthcarecanada.ca/en/child-health-advocacy/National-Strategy-2023.pdf</a>.
   Accessed 2023 Mar 29.
- 4. Statistics Canada. Population estimates on July 1st, by age and sex. 2022; <a href="https://www150.statcan.gc.ca/t1/tbl1/en/tv.action">https://www150.statcan.gc.ca/t1/tbl1/en/tv.action</a>?pid=1710000501. Accessed 2023 Feb 22.
- 5. Worlds Apart: Canadian Summary of UNICEF Report Card 16. Toronto (ON): UNICEF Canada; 2020: <a href="https://www.unicef.ca/sites/default/files/2020-08/UNICEF%20Report%20Card%2016%20Canadian%20Summary.pdf">https://www.unicef.ca/sites/default/files/2020-08/UNICEF%20Report%20Card%2016%20Canadian%20Summary.pdf</a>. Accessed 2023 Mar 29.
- 6. Denburg AE, Ungar WJ, Chen S, Hurley J, Abelson J. Does moral reasoning influence public values for health care priority setting?: A population-based randomized stated preference survey. *Health Policy*. 2020;124(6):647-658. PubMed
- 7. Canadians Agree: It's Time for All Levels of Government to Prioritize Children's Health. Ottawa (ON): Children's Healthcare Canada; 2023: <a href="https://www.childrenshealthcarecanada.ca/en/child-health-advocacy/resources/Canadians-Agree-Its-Time-for-All-Gov-to-Prioritize-Children's-Health.pdf">https://www.childrenshealthcarecanada.ca/en/child-health-advocacy/resources/Canadians-Agree-Its-Time-for-All-Gov-to-Prioritize-Children's-Health.pdf</a>. Accessed 2023 Feb 22.
- 8. Morray BH, Gordon BM, Crystal MA, et al. Resource Allocation and Decision Making for Pediatric and Congenital Cardiac Catheterization During the Novel Coronavirus SARS-CoV-2 (COVID-19) Pandemic: A U.S. Multi-Institutional Perspective. *J Invasive Cardiol.* 2020;32(5):E103-E109. PubMed
- 9. Statistics Canada. Health Fact Sheets Primary health care providers, 2019. 2020; <a href="https://www150.statcan.gc.ca/n1/pub/82-625-x/2020001/article/00004-eng.htm">https://www150.statcan.gc.ca/n1/pub/82-625-x/2020001/article/00004-eng.htm</a>. Accessed 2023 Mar 29.
- 10. Ontario College of Family Physicians. More Than 2.2 Million Ontarians Left Without a Family Doctor. 2023 Feb 9; <a href="https://www.ontariofamilyphysicians.ca/news-features/news/~287-More-Than-2-2-Million-Ontarians-Left-Without-a-Family-Doctor">https://www.ontariofamilyphysicians.ca/news-features/news/~287-More-Than-2-2-Million-Ontarians-Left-Without-a-Family-Doctor</a>. Accessed 2023 Mar 29.
- 11. Innovations Strengthening Primary Health Care Through Research (Inspire PHC). Primary Care Data Reports for Ontario Health Teams (OHTs). 2022; <a href="https://www.ontariohealthprofiles.ca/ontarioHealthTeam.php">https://www.ontariohealthprofiles.ca/ontarioHealthTeam.php</a>. Accessed 2023 Mar 29.
- 12. Roadmap to a Stable Physician Workforce Recommendations to stabilize the physician workforce in Nova Scotia. Dartmouth (NS): Doctors Nova Scotia; 2018: <a href="https://doctorsns.com/sites/default/files/2018-09/next-steps/Road-Map-to-a-Stable-Physician-Workforce\_0.pdf">https://doctorsns.com/sites/default/files/2018-09/next-steps/Road-Map-to-a-Stable-Physician-Workforce\_0.pdf</a>. Accessed 2023 Mar 29.
- 13. Make Kids Count A children's health action plan to ensure hospital capacity and provide timely access to care both in the immediate pandemic response and through recovery. Children's Health Coalition; 2021: <a href="https://www.chcontario.ca/wp-content/uploads/2022/04/Make-Kids-Count-Action-Plan-from-the-Childrens-Health-Coalition-2.pdf">https://www.chcontario.ca/wp-content/uploads/2022/04/Make-Kids-Count-Action-Plan-from-the-Childrens-Health-Coalition-2.pdf</a>. Accessed 2023 Mar 29.
- 14. Moylan A, Maconochie I. Demand, overcrowding and the pediatric emergency department. *CMAJ*. 2019;191(23):E625-E626. PubMed
- 15. Taylor B, Young M. Pediatric ED departmental complexity: a different approach to the concept of ED crowding. *CJEM*. 2022;24(3):318-324. PubMed
- 16. Hanna TP, King WD, Thibodeau S, et al. Mortality due to cancer treatment delay: systematic review and meta-analysis. *BMJ*. 2020;371:m4087. PubMed
- 17. Murphy K, Harrison E. The weight of waiting: the impact of delayed early intervention on parental self-efficacy. *British Journal of Special Education*. 2022;49(1):84-101.
- 18. Barrero-Castillero A, Corwin BK, VanderVeen DK, Wang JC. Workforce Shortage for Retinopathy of Prematurity Care and Emerging Role of Telehealth and Artificial Intelligence. *Pediatr Clin North Am.* 2020;67(4):725-733. PubMed



- 19. Heitmann J, Glangetas A, Doenz J, et al. DeepBreath-automated detection of respiratory pathology from lung auscultation in 572 pediatric outpatients across 5 countries. NPJ Digit Med. 2023;6(1):104. PubMed
- 20. Cilluffo G, Fasola S, Ferrante G, et al. Machine learning: A modern approach to pediatric asthma. *Pediatr Allergy Immunol.* 2022;33 Suppl 27(Suppl 27):34-37.
- 21. Ali S, Manaloor R, Ma K, et al. A randomized trial of robot-based distraction to reduce children's distress and pain during intravenous insertion in the emergency department. *CJEM*. 2021;23(1):85-93. PubMed
- 22. Lee-Krueger RCW, Pearson JR, Spencer A, Noel M, Bell-Graham L, Beran TN. Children's Pain During IV Induction: A Randomized-Controlled Trial With the MEDi(R) Robot. *J Pediatr Psychol.* 2021;46(8):991-1000. PubMed
- 23. Israni ST, Matheny ME, Matlow R, Whicher D. Equity, Inclusivity, and Innovative Digital Technologies to Improve Adolescent and Young Adult Health. *J Adolesc Health*. 2020;67(2S):S4-S6. PubMed
- 24. Adegboro CO, Choudhury A, Asan O, Kelly MM. Artificial Intelligence to Improve Health Outcomes in the NICU and PICU: A Systematic Review. *Hosp Pediatr.* 2022;12(1):93-110. PubMed
- 25. Rasti R, Brannstrom J, Martensson A, et al. Point-of-care testing in a high-income country paediatric emergency department: a qualitative study in Sweden. *BMJ Open.* 2021;11(11):e054234. PubMed
- 26. U.S. Food & Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test Available without a Prescription That Also Detects Flu and RSV. 2022 May 16; <a href="https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-available-without-prescription-also">https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-available-without-prescription-also</a>. Accessed 2023 Mar 3.
- 27. Nayakarathna R, Neilson H, MacDougall D, Cowling T. Virtual Care Use in Primary Care or Specialty Care Settings. Can J Health Technol. 2022;2(8). https://www.cadth.ca/sites/default/files/pdf/htis/2022/RC1444-Virtual-Care.pdf. Accessed 2023 Mar 07.
- 28. Wang S, Ungvari GS, Xiang YT. The shortage of child and adolescent psychiatrists in China. *Asian J Psychiatr.* 2023;81:103404. PubMed
- 29. Hoffmann JA, Attridge MM, Carroll MS, Simon NE, Beck AF, Alpern ER. Association of Youth Suicides and County-Level Mental Health Professional Shortage Areas in the US. *JAMA Pediatr.* 2023;177(1):71-80. PubMed
- 30. Hollinsaid NL, Price MA, Hatzenbuehler ML. Transgender-Specific Adolescent Mental Health Provider Availability is Substantially Lower in States with More Restrictive Policies. *J Clin Child Adolesc Psychol.* 2022:1-12. PubMed
- 31. Russell MR, Rogers RL, Rosenthal SM, Lee JY. Increasing Access to Care for Transgender/Gender Diverse Youth Using Telehealth: A Quality Improvement Project. *Telemed J E Health*. 2022;28(6):847-857. PubMed
- 32. Nguyen N, Leveille E, Guadagno E, Kalisya LM, Poenaru D. Use of mobile health technologies for postoperative care in paediatric surgery: A systematic review. *J Telemed Telecare*. 2022;28(5):331-341. PubMed
- 33. Russo MW, Fix OK, Koteish AA, et al. Modeling the Hepatology Workforce in the United States: A Predicted Critical Shortage. Hepatology. 2020;72(4):1444-1454. PubMed
- 34. Canadian Institute for Health Information. Physicians per 100,000 Population, by Specialty [indicator]. 2022; <a href="https://www.cihi.ca/en/indicators/physicians-per-100000-population-by-specialty">https://www.cihi.ca/en/indicators/physicians-per-100000-population-by-specialty</a>. Accessed 2023 Mar 30.
- 35. Rudoler D, Peterson S, Stock D, et al. Changes over time in patient visits and continuity of care among graduating cohorts of family physicians in 4 Canadian provinces. *CMAJ*. 2022;194(48):E1639-E1646. PubMed
- 36. Mangin D, Premji K, Bayoumi I, et al. Brief on Primary Care Part 2: Factors Affecting Primary Care Capacity in Ontario for Pandemic Response and Recovery. Science Briefs of the Ontario COVID-19 Science Advisory Table. 2022;3(68). https://covid19-sciencetable.ca/sciencebrief/brief-on-primary-care-part-2-factors-affecting-primary-care-capacity-in-ontario-for-pandemic response-and-recovery/. Accessed 2023 Apr 18.
- 37. CMA 2021 National Physician Health Survey. Ottawa (ON): Canadian Medical Association; 2022: <a href="https://www.cma.ca/sites/default/files/2022-08/NPHS\_final\_report\_EN.pdf">https://www.cma.ca/sites/default/files/2022-08/NPHS\_final\_report\_EN.pdf</a>. Accessed 2023 Mar 29.
- 38. Knotts CM, Prange EJ, Orminski K, Thompson S, Richmond BK. The Provision of Acute Pediatric Surgical Care by Adult Acute Care General Surgeons: Is There a Learning Curve? *Am Surg.* 2020;86(12):1640-1646. PubMed



- 39. Alabbas A, Kirpalani A, Morgan C, et al. Canadian Association of Paediatric Nephrologists COVID-19 Rapid Response: Guidelines for Management of Acute Kidney Injury in Children. Can J Kidney Health Dis. 2021;8:2054358121990135. PubMed
- 40. Bettencourt AF, Ferro RA, Williams JL, et al. Pediatric Primary Care Provider Comfort with Mental Health Practices: A Needs Assessment of Regions with Shortages of Treatment Access. *Acad Psychiatry.* 2021;45(4):429-434. PubMed
- 41. Sullivan K, George P, Horowitz K. Addressing National Workforce Shortages by Funding Child Psychiatry Access Programs. *Pediatrics*. 2021;147(1):01.
- 42. Urquhart PD, Holland AJA. Supply and demand: an audit of specialty paediatric surgical outreach. *ANZ J Surg.* 2021;91(7-8):1337-1341. PubMed
- 43. Schmitz GR. Addressing Shortages in Pediatric Emergency Care-The Evolution of Health Care Access. *JAMA Netw Open.* 2021;4(5):e2110115. PubMed
- 44. Wilson JM, Schwartz AM, Farley KX, Devito DP, Fletcher ND. Doing Our Part to Conserve Resources: Determining Whether All Personal Protective Equipment Is Mandatory for Closed Reduction and Percutaneous Pinning of Supracondylar Humeral Fractures. *J Bone Joint Surg Am.* 2020;102(13):e66. PubMed
- 45. Keller DM, Davis MM, Freed GL. Access to pediatric subspecialty care for children and youth: possible shortages and potential solutions. *Pediatr Res.* 2020;87(7):1151-1152. PubMed
- 46. Pospos S, Young IT, Downs N, et al. Web-Based Tools and Mobile Applications To Mitigate Burnout, Depression, and Suicidality Among Healthcare Students and Professionals: a Systematic Review. *Acad Psychiatry*. 2018;42(1):109-120. PubMed
- 47. Lemmon ME, Truog RD, Ubel PA. Allocating Resources Across the Life Span During COVID-19-Integrating Neonates and Children Into Crisis Standards of Care Protocols. *JAMA Pediatr.* 2021;175(4):347-348. PubMed
- 48. Espinoza JC. The Scarcity of Approved Pediatric High-Risk Medical Devices. JAMA Netw Open. 2021;4(6):e2112760. PubMed
- 49. Denburg AE, Giacomini M, Ungar WJ, Abelson J. 'The problem is small enough, the problem is big enough': a qualitative study of health technology assessment and public policy on drug funding decisions for children. *Int J Equity Health*. 2020;19(1):45. <u>PubMed</u>
- 50. Beleche T, Kuecken M, Sassi A, Toran K, Galloway E, Henry T. Characteristics Of Medical Device Shortages In The US, 2006–20. Health Aff (Millwood). 2022;41(12):1790-1794. PubMed
- 51. Goldschmidt K, Stasko K. The downstream effects of the COVID-19 pandemic: The supply chain failure, a wicked problem. *J Pediatr Nurs*. 2022;65:29-32. PubMed
- 52. European Society of Cardiology. European cardiologists call for urgent action to prevent medical device shortages. 2022 Dec 7; <a href="https://www.escardio.org/The-ESC/Press-Office/Press-releases/european-cardiologists-call-for-urgent-action-to-prevent-medical-device-shortage">https://www.escardio.org/The-ESC/Press-Office/Press-releases/european-cardiologists-call-for-urgent-action-to-prevent-medical-device-shortage</a>. Accessed 2023 Feb 22.
- 53. Melvin T, Kenny D, Gewillig M, Fraser AG. Orphan Medical Devices and Pediatric Cardiology What Interventionists in Europe Need to Know, and What Needs to be Done. *Pediatr Cardiol.* 2023;44(2):271-279. PubMed
- 54. Government of Canada. Medical device shortages: Overview. 2023; <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/shortages.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/shortages.html</a>. Accessed 2023 Feb 22.
- 55. Lim D. Covid-19 supply chain fallout's latest victim: Pediatric tracheotomy patients. Politico Pro 2022 Nov 9; <a href="https://subscriber.politicopro.com/article/2022/11/covid-19-supply-chain-fallouts-latest-victim-pediatric-tracheotomy-patients-00066004">https://subscriber.politicopro.com/article/2022/11/covid-19-supply-chain-fallouts-latest-victim-pediatric-tracheotomy-patients-00066004</a>.
  Accessed 2023 Feb 22.
- 56. Guidance Document Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing. Ottawa (ON): Health Canada; 2019: <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/3d-licensing-requirements/document.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/3d-licensing-requirements/document.html</a>. Accessed 2023 Feb 24.
- 57. Ramaraju H, Landry AM, Sashidharan S, et al. Clinical grade manufacture of 3D printed patient specific biodegradable devices for pediatric airway support. *Biomaterials*. 2022;289:121702. PubMed
- 58. Starosolski Z, Admane P, Dunn J, Kaziny B, Huisman T, Annapragada A. Design of 3D-Printed Nasopharyngeal Swabs for Children is Enabled by Radiologic Imaging. *AJNR Am J Neuroradiol*. 2020;41(12):2345-2347. PubMed



- 59. Carter CB, Gallardo FF, Jr., Colburn HE, Schlieder DW. Novel Digital Workflow for Nasoalveolar Molding and Postoperative Nasal Stent for Infants With Cleft Lip and Palate. Cleft Palate Craniofac J. 2022:10556656221095393. PubMed
- 60. Bellia-Munzon G, Cieri P, Toselli L, et al. Resorbable airway splint, stents, and 3D reconstruction and printing of the airway in tracheobronchomalacia. Semin Pediatr Surg. 2021;30(3):151063. PubMed
- 61. He DL, Wang HE, Jiao Y, et al. Successful Resolution of Nutcracker Syndrome with 3d Printed Peek Extravascular Stent in an Adolescent Boy. *Acta Clin Croat*. 2022;61(1):138-144. PubMed
- 62. Francoisse CA, Sescleifer AM, King WT, Lin AY. Three-dimensional printing in medicine: a systematic review of pediatric applications. *Pediatr Res.* 2021;89(3):415-425. PubMed
- 63. Krause J, Muller L, Sarwinska D, Seidlitz A, Sznitowska M, Weitschies W. 3D Printing of Mini Tablets for Pediatric Use. *Pharmaceuticals (Basel)*. 2021;14(2):11. PubMed
- 64. Hatch LD, Bridges BC, Chapman RL, Danko ME, Schumacher RE, Patrick SW. Trends in Neonatal Extracorporeal Membrane Oxygenation During a Venovenous Cannula Shortage. *Pediatr Crit Care Med.* 2023;24(3):245-250. PubMed
- 65. U.S. Food & Drug Administration. Device Shortage List. 2023; <a href="https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency">https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency</a>. Accessed 2023 Mar 02.
- 66. Talathi S, Mezoff E, Galloway D, Rahhal R. Anticipated impact of recent ethanol lock shortage and price increase on practice among pediatric intestinal rehabilitation programs across the United States. JPEN J Parenter Enteral Nutr. 2022;46(2):319-323. PubMed
- 67. Haamid FW, Bonny AE, Holland-Hall C. Protecting Adolescents During a Sexually Transmitted Infection Testing Shortage: An Additional Challenge During a Global Pandemic. *JAMA Pediatr.* 2021;175(7):667-668. PubMed
- 68. U.S. Food & Drug Administration. Medical products for rare diseases and conditions. 2023; <a href="https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions">https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions</a>. Accessed 2023 Mar 07.
- 69. Ministry of Health, Labour and Welfare of Japan. Overview of Orphan Drug/Medical Device Designation System. 2023; <a href="https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/orphan\_drug.html">https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/orphan\_drug.html</a>. Accessed 2023 Mar 07.
- 70. Health Canada. Improving the regulatory review of drugs and devices. 2020; <a href="https://www.canada.ca/en/health-canada/">https://www.canada.ca/en/health-canada/</a> corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices.html Accessed 2023 Mar 07.
- 71. European Medicines Agency. EMA pilots scientific advice for certain high-risk medical devices. 2023; <a href="https://www.ema.europa.eu/en/news/ema-pilots-scientific-advice-certain-high-risk-medical-devices">https://www.ema.europa.eu/en/news/ema-pilots-scientific-advice-certain-high-risk-medical-devices</a>. Accessed 2023 Mar 02.
- 72. Ozer EM, Lester JC. Innovative Digital Technologies to Improve Adolescent and Young Adult Health. *J Adolesc Health*. 2020;67(2S):S3. PubMed



# **Appendix 1: Methods**

## **Literature Search Strategy**

An information specialist conducted a literature search on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were pediatrics and shortages or potential solutions to shortages, including 3D printing, home tests, and artificial intelligence/smart devices. Retrieval was limited to the human population. The search was completed on January 31, 2023 and limited to English-language documents published since January 1, 2020.

## **Study Selection**

One author screened the literature search results in Endnote and the same author reviewed the full text of all potentially relevant publications. Articles that described policies, technologies, and interventions that are currently being used or have the potential to address shortages of care or devices for pediatric patients were included as information sources for this horizon scan. This project used CADTH's definition of health technologies which focuses on those medical devices and interventions that are patient-facing and that are intended to have a direct impact on patient outcomes.

## **Expert Consultation**

For this report, CADTH interviewed 2 individuals with expertise relating to medical supply chains in Canada.

#### **Peer Review**

A draft version of this bulletin was reviewed by 1 clinical expert who specializes in pediatric emergency medicine.



Authors: Sarah Jones, Melissa Walter

Acknowledgement: Dr. Samina Ali, MDCM, FRCPC(PEM) Research Director, Pediatric Emergency Medicine, University of Alberta

ISSN: 2563-6596

**Disclaimer:** The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up to date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein are those of CADTH and do not necessarily represent the views of Canada's federal, provincial, or territorial governments or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian *Copyright Act* and other national and international laws and agreements. Users are permitted to make copies of this document for non-commercial purposes only, provided it is not modified when reproduced and appropriate credit is given to CADTH and its licensors.

**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to Requests @ CADTH.ca.