Adverse events related to virtual care

CPSP
CANADIAN PAEDIATRIC SURVEILLANCE PROGRAM

PROTOCOL

Principal investigators

Ellen Goldbloom, MD, FRCPC, Virtual Care Medical Lead, Deputy Chief Medical Information Officer, Ambulatory Care Medical Director, Paediatric Endocrinologist, Children's Hospital of Eastern Ontario (CHEO), Assistant Professor, Department of Paediatrics, University of Ottawa, Clinical Investigator, CHEO Research Institute

Shelley Vanderhout, RD, PhD, Postdoctoral Fellow, Canadian Institutes of Health Research, Health Systems Impact

Co-investigators

Imaan Bayoumi, MD, MSc, FRCFP, Family Physician, Queen's Family Health Team, Assistant Professor, Department of Family Medicine, Queen's University

Jill Chorney, PhD, RPsych, Psychologist and Advance Practice Leader - Behaviour Change, Mental Health and Addictions, IWK Health Centre, Associate Professor, Department of Psychiatry, Dalhousie University

Megan Cooney, MD, Paediatrics and Adolescent Medicine, Assistant Professor, Paediatrics and Child Health, University of Manitoba, Shared Health Manitoba

David Creery, MD, MSc, FRCPC, MHSc, CHE, Medical Director, Patient Safety and Family Partnership, Paediatric Intensive Care Physician, CHEO, Associate Professor, Department of Paediatrics, University of Ottawa, Clinical Investigator, CHEO Research Institute

Janet Curran, PhD, RN, Research Chair, Quality and Patient Safety, Professor, School of Nursing, Dalhousie University

Tammie Dewan, MD, MSc, FRCPC, Clinical Assistant Professor, Department of Paediatrics, University of Calgary, Consultant Paediatrician, Paediatric Medicine and Complex Care, Clinician Investigator, Alberta Children's Hospital

Olivier Drouin, MD, MSc, MPH, FRCPC, Paediatrician, Division of General Paediatrics, CHU Sainte-Justine, Clinical Associate Professor, Department of Paediatrics, Faculty of Medicine and Department of Social and Preventive Medicine, Université de Montréal

Gary Garber, MD, FRCPC, FACP, FIDSA, CCPE, Director, Safe Medical Care Research, Canadian Medical Protective Association, Professor, Department of Medicine and School of Public Health and Epidemiology, University of Ottawa

Sarah Hall, MD, FRCPC, CCPE, Deputy Head, Professional Affairs, Department of Paediatrics, University of Calgary, Clinical Associate Professor, Department of Paediatrics, University of Calgary, Medical Lead, Virtual Health, Alberta Health Services

Michael Hill, MD, FRCPC, Community Paediatrician, Paediatric and Teen Health Network

Brenden Hursh, MD, MHSc, FRCPC, Clinical Assistant Professor, Paediatric Endocrinology, BC Children's Hospital and University of British Columbia

Sara Jassemi, MD, FRCPC, Clinical Assistant Professor, Adolescent Health and Medicine, BC Children's Hospital and the University of British Columbia

Kristopher Kang, MD, FRCPC, Consultant Paediatrician, Inpatient Units and Child Protection Service Unit, BC Children's Hospital

Jim King, MD, MSc, FRCPC, Chief Medical Information Officer, Consultant Paediatrician, CHEO, Professor, Department of Paediatrics, University of Ottawa, Clinical Investigator, CHEO Research Institute

Patricia Li, MD, MSc, FRCPC, General Paediatrician, Montreal Children's Hospital, Consultant Paediatrician, CLSC Parc-Extension, Scientist, Research Institute of the McGill University Health Centre, Associate Professor, Department of Paediatrics, McGill University

Julia Orkin, MD, MSc, FRCPC, Medical Officer, Integrated Community Partnerships, Consultant Paediatrician, The Hospital for Sick Children, Assistant Professor, Department of Paediatrics, University of Toronto

Dawn Pickering, Family Leader, CHEO Research Institute

Phillippe Robaey, MD, PhD, FRCPC, CHEO, Professor of Psychiatry, University of Ottawa

Daniel Rosenfield, MD, FRCPC, Staff Physician, Paediatric Emergency Medicine, Lead, Virtual Care, Paediatric Emergency Medicine, The Hospital for Sick Children, Assistant Professor, University of Toronto

Anne Rowan-Legg, MD, FRCPC, Consultant Paediatrician, CHEO, Associate Professor, Department of Paediatrics, University of Ottawa, Clinical Investigator, CHEO Research Institute

Sumeet Sadana, MD, FRCPC, Consultant Paediatrician, Capital KidZ Medical Centre, Queensway Carleton Hospital, Clinical Lecturer, University of Ottawa

Holden Sheffield, MD, FRCPC, Chief of Paediatrics, Qikiqtani General Hospital

Sam Wong, MD, Consultant Paediatrician, Stanton Territorial Hospital, Clinical Professor in Paediatrics, University of Alberta, Hospital Paediatrician, Stollery Children's Hospital

Kelley Zwicker, MSc, MD, FRCPC, Assistant Professor, Division of Community Paediatrics, University of Ottawa, Consulting Paediatrician, Ottawa Medical Group, Queensway Carleton Hospital, and CHEO, Clinical Investigator, CHEO Research Institute

Collaborators

Kim Courtney, Child Life Specialist, CHEO, Family Lead Coordinator, CHEO Research Institute

Christine Kouri, Equity, Diversity, Inclusion, and Indigeneity, CHEO

Alex Petiquan, MD, CHEO Indigenous Circle Member

Martha Pinheiro-Maltez, RN, Quality and Safety, CHEO

Cecile Rousseau, MD, Professor and Canada Research Chair, Division of Social and Cultural Psychiatry, McGill University, Virtual Care Evaluation Group, CHEO/CHEO Research Institute

Susannah Taylor, PhD, Policy Analyst, Health Canada

Background

The COVID-19 pandemic has led to the rapid adoption and prioritization of virtual health care delivery, often as a substitute for in-person medical visits (1, 2). In 2021, Solutions for Patient Safety, a network of more than 145 paediatric hospitals across North America, recognized this shift to virtual care across its network (3). In Canada, enhanced electronic health infrastructure development and updated remuneration schedules facilitated this shift, with a focus on synchronous (real-time) telemedicine. Virtual care offers benefits to patients and families, including improved access and convenience, increased patient and caregiver satisfaction, cost savings, and an opportunity to receive flexible, culturally-sensitive care (4). Virtual care may also facilitate improved patient-centred care by allowing a visual assessment of a child's home environment (5). Virtual care also supported access to care during a global pandemic when in-person services were reduced (6). Moreover, many patients, families, and providers have voiced that virtual care should continue post-pandemic and optimization of virtual care should align with national health care priorities (7, 8).

Although often perceived as an ideal substitute for in-person care, there are limitations to virtual care provision, including, but not limited to, the lack of a physical examination, inability to discern non-verbal cues, inability to always ensure privacy, connectivity issues, and inequitable access. These limitations can impact the quality of virtual health care delivery and result in adverse events (AEs) (9). Asynchronous (10) virtual care delivery (e.g., email, secure messaging), while efficient, convenient, and often effective (11, 12), lacks components of real-time care, thus creating the potential for AEs. Health systems have experienced barriers to implementing virtual care such as inadequate infrastructure and remuneration, and, importantly, a lack of evidence-based guidance regarding the appropriate clinical contexts for in-person versus virtual care (8).

While virtual care can be used in diverse clinical settings, there are patients for whom the standard of care cannot be met in a solely virtual environment (13). Whether these patients can be categorized into salient groups is unclear. Virtual care has been evaluated in specific clinical areas such as paediatric diabetes (14), paediatric asthma (15) and emergency medicine (16). Most literature to date has focused on the individual experiences of patients, families/caregivers, and providers (17, 18). However, the impact of virtual care on paediatric health outcomes remains largely unknown and there is a paucity of evidence regarding its equity, quality, safety, and cost-effectiveness. Importantly, a systematic evaluation of adverse outcomes related to virtual care is lacking, possibly due to

a lack of validated evaluation tools, consistent terminology, and user-friendly evaluative frameworks, making comparisons difficult and data challenging to appraise.

Though there are benefits to providing virtual care, it is unknown whether virtual care leads to adverse medical outcomes that would not occur if care was delivered in person. A coordinated and comprehensive evaluation of virtual care has not yet been performed. Surveillance is an appropriate methodology for collecting data on AEs suspected to be related to virtual care and will provide timely and detailed empiric data on unintended impacts of virtual care. Further, this study has the potential to generate information that will help paediatricians, public health authorities, and health care systems make evidence-informed decisions to guide care delivery recommendations and programs for children and adolescents receiving care virtually.

Methods

Using the established Canadian Paediatric Surveillance Program (CPSP) methodology, approximately 2800 paediatricians and paediatric subspecialists will be surveyed monthly and asked to report new cases of children and youth presenting in the previous month with an AE **suspected to be related to** care being provided virtually. Paediatricians who identify cases will be asked to complete a detailed questionnaire. Because causality is difficult to determine, the virtual care "suspected to be related" to the AE is the instance of care that preceded the AE, and may have led to it.

To ensure appropriate local follow-up and continuous quality improvement, participants will be advised to also report the AE locally through their usual safety reporting system. Those who report a case will also be informed that reporting AEs through this study will not lead to regulatory, legal, or punitive actions and will be viewed solely with a quality improvement lens. AE data will be used in aggregate form to preclude any possible linkage to any specific individual (e.g., patient, parent, health care provider).

Case definition

Report any patient less than 18 years of age (up to their 18th birthday) presenting with a new adverse event (AE) associated with harm that the reporting physician suspects is related to virtual care.

As defined in the Canadian Virtual Care Lexicon (26), the execution of virtual care may be:

Synchronous: Use of technology to enable individuals or care teams to provide patient care in live/real time (e.g., phone, video)

Asynchronous: Use of technology to enable individuals or care teams to interact with the patient through methods that do not require real time interactions (e.g., electronic or voice messaging, patient toolkits, patient review of personal health records)

Inclusion criteria

Report ONLY the following types of AEs suspected to be related to virtual care:

Misdiagnosis: The limitations of virtual care in patient assessment results in incorrect, missed, or delayed diagnosis.

Emergency without the ability to respond: The virtual care provider identifies an emergency clinical or social situation but is not able to provide timely emergency care.

Examples of AEs are provided below to help illustrate the case definition. This list is not comprehensive and participants are encouraged to report ANY events that they feel satisfy the case definition.

Misdiagnosis:

- Lack of physical examination during virtual assessment led to:
  - Unrecognized weight loss and deterioration in patient with eating disorder, requiring hospitalization
  - Delayed diagnosis of brain tumor in patient with precocious puberty
  - Late presentation to emergency department with bilateral acute otitis media and mastoiditis in patient thought to have upper respiratory tract infection on initial virtual assessment
  - Late presentation to the emergency department requiring hospitalization and exchange transfusion for a neonate with hyperbilirubinemia not detected on initial virtual assessment
  - Late presentation of traumatic brain injury from child maltreatment in an infant with bruising, which would have triggered evaluation for maltreatment during virtual assessment for colic
- Inability to speak with adolescent in private virtually led to:
  - Late diagnosis of sexually transmitted infection and ultimately pelvic inflammatory disease
  - Lack of full disclosure of symptoms of depression and late diagnosis requiring hospitalization

Emergency without the ability to respond:

- Active suicidal ideation during virtual assessment necessitating hospital admission but inability to connect with caregivers, followed by presentation to the emergency department with acetaminophen overdose requiring treatment
- Acute clinical deterioration (e.g., hypotension, decreased level of consciousness due to progression of sepsis) recognized during virtual care encounter with no possibility of providing supportive care (and the planned virtual care delayed the patient/family seeking in-person acute care)

Exclusion criteria

- AEs not deemed to be related to virtual care
- Near miss: A patient safety incident that did not reach the patient and therefore no harm resulted
- No-harm incident: A patient safety incident that reached the patient but no discernible harm resulted
- Event due to connectivity issues that interfered with patient care but did not result in harm
- AEs related to breach of privacy

Objectives

1) Understand the burden and nature of recognized AEs suspected to be related to the provision of virtual care in the Canadian paediatric population
2) Describe the types of recognized AEs suspected to be related to virtual care
3) Describe any association between clinical and sociodemographic characteristics and the likelihood of an AE related to virtual care, if one exists
4) Increase awareness of AEs related to virtual care and promote reporting to existing institutional systems to enable continuous quality improvement

Duration

December 2022 to November 2024

Expected number of cases

To date, there have been no studies that have reported incidence rates or prevalence rates for AEs related to virtual care. Since patient safety considerations are largely absent from evaluative virtual care literature (25), predicting the expected number of cases is difficult. However, based on our clinically-informed estimate, we expect a maximum of 100 cases per year.

Study limitations

The CPSP methodology relies on participants accurately identifying AEs that are suspected to be related to a virtual care encounter. This study will not capture unrecognized AEs nor AEs not recognized as being related to virtual care. AEs will be reported by participants based on the suspicion they are related to virtual care; however, the determination of causation may not be possible. This study is collecting data on AEs causing harm that are recognized by paediatricians/subspecialists who are CPSP participants and not those recognized by patients, families/caregivers, or other health care providers. In addition, acknowledging that the CPSP is a voluntary reporting system, it is understood that not all recognized cases will be reported.

Given these limitations, minimum incidence cannot be estimated, and this study may not be able to describe the full range of AEs related to care provided virtually.

Ethical approval

- Health Canada and the Public Health Agency of Canada Research Ethics Board
- CHEO Research Ethics Board

Analysis and publication

For objectives 1 and 2, data will be analyzed using descriptive statistics. Descriptive summaries of patient demographic characteristics, including service setting of virtual care, will be performed. Dichotomous variables will be summarized using percentages, normally distributed continuous variables will be summarized using means and standard deviations, and continuous variables that are not normally distributed will be summarized using medians and ranges. For

objective 3, multivariable logistic regression will be used to determine the relationship between clinical and sociodemographic characteristics and risk of AEs, where odds ratios and 95% confidence intervals will be calculated. Data analysis will be completed using R software, no later than six months after the completion of the study.

Knowledge translation

The results of the study will contribute to the evidence base on paediatric virtual care and will help inform guidelines outlining the safe and effective use of virtual care in paediatric practice. Specifically, study results will help inform when and for whom virtual care is not an adequate replacement for in-person care.

Annual and final reports will be published in the CPSP Results and will be circulated to all participants. Completed study results will be presented at national and international scientific meetings and submitted for publication in scientific peer-reviewed journals with a broad paediatric provider audience.

The research team will work with the Canadian Paediatric Society to translate results into resources that will support paediatric care providers.

A patient/family representative is a co-investigator to help ensure the study is co-designed to capture details important to patient-centred care. In addition to this partnership, the research team is working closely with existing Canadian youth and caregiver/family advisory councils to promote results to help raise awareness for the evidence behind decisions that guide the modality of care provision, in addition to patient/family preference.

References

1. Kim JW, Lame M, Szalay L, Lefchak B, Johnsson B, Gogia K, et al. Telemedicine Surge for Pediatric Patients in Response to the COVID-19 Pandemic in New York City. Telemed J E Health. 2021 Oct;27(10):1105–10
2. Howie F, Kreofsky BL, Ravi A, Lokken T, Hoff MD, Fang JL. Rapid Rise of Pediatric Telehealth During COVID-19 in a Large Multispecialty Health System. Telemed J E Health. 2022 Jan;28(1):3–10
3. Children's Hospitals' Solutions for Patient Safety. Children’s Hospitals Working Together to Eliminate Harm [Internet]. c2022 [cited 2022 Aug 12]. Available from: https://www.solutionsforpatientsafety.org/
4. Brophy PD. Overview on the Challenges and Benefits of Using Telehealth Tools in a Pediatric Population. Adv Chronic Kidney Dis. 2017 Jan;24(1): 17–21
5. Curfman A, McSwain SD, Chuo J, Yeager-McSwain B, Schinasi DA, Marcin J, et al. Pediatric Telehealth in the COVID-19 Pandemic Era and Beyond. Pediatrics. 2021 Sep;148(3):e2020047795
6. McGillion MH, Parlow J, Borges FK, Marcucci M, Jacka M, Adili A, et al. Post-discharge after surgery Virtual Care with Remote Automated Monitoring-1 (PVC-RAM-1) technology versus standard care: randomised controlled trial. BMJ. 2021 Sep 30;374:n2209

7. Government of Ontario. Ontario Health Teams: Digital Health Playbook. Toronto: Government of Ontario, 2022:141. Available from: https://health.gov.on.ca/en/pro/programs/connectedcare/oht/docs/dig_health_playbook_en.pdf
8. Canadian Medical Association. Virtual Care in Canada: Discussion Paper [Internet]. Ottawa: CMA, 2019. [cited 2022 Aug 12]. Available from: https://www.cma.ca/virtual-care-canada-discussion-paper
9. Balmuri N, Onel KB. Glitches in the utilization of telehealth in pediatric rheumatology patients during the COVID-19 pandemic. Pediatric Rheumatology. 2020 Oct 15;18(1):78
10. Digital Health Canada - Virtual Care Resources [Internet]. [cited 2022 Mar 1]. Available from: https://www.digitalhealthcanadamembers.com/Virtual-Care-Resources
11. de Jong CC, Ros WJ, Schrijvers G. The effects on health behavior and health outcomes of Internet-based asynchronous communication between health providers and patients with a chronic condition: a systematic review. J Med Internet Res. 2014 Jan 16;16(1):e19
12. Chung S, Panattoni L, Chi J, Palaniappan L. Can Secure Patient-Provider Messaging Improve Diabetes Care? Diabetes Care. 2017 Aug 14;40(10):1342–8
13. College of Physicians and Surgeons of Ontario - Home [Internet]. [cited 2022 Aug 12]. Available from: https://www.cpso.on.ca/
14. Fung A, Irvine M, Ayub A, Ziabakhsh S, Amed S, Hursh BE. Evaluation of telephone and virtual visits for routine pediatric diabetes care during the COVID-19 pandemic. J Clin Transl Endocrinol. 2020 Dec;22:100238
15. Papadopoulos NG, Custovic A, Deschildre A, Mathioudakis AG, Phipatanakul W, Wong G, et al. Impact of COVID-19 on Pediatric Asthma: Practice Adjustments and Disease Burden. J Allergy Clin Immunol Pract. 2020 Sep;8(8):2592-9.e3
16. Reid S, Bhatt M, Zemek R, Tse S. Virtual care in the pediatric emergency department: a new way of doing business? CJEM. 2021 Jan;23(1):80–4
17. Burke BL, Hall RW. Section on Telehealth Care. Telemedicine: Pediatric Applications. Pediatrics. 2015 Jul;136(1):e293-308
18. Young K, Gupta A, Palacios R. Impact of Telemedicine in Pediatric Postoperative Care. Telemed J E Health. 2019 Nov;25(11):1083–9
19. Shaker MS, Oppenheimer J, Grayson M, Stukus D, Hartog N, Hsieh EWY, et al. COVID-19: Pandemic Contingency Planning for the Allergy and Immunology Clinic. J Allergy Clin Immunol Pract. 2020 May;8(5):1477-88.e5
20. Mack DP, Chan ES, Shaker M, Abrams EM, Wang J, Fleischer DM, et al. Novel Approaches to Food Allergy Management During COVID-19 Inspire Long-Term Change. J Allergy Clin Immunol Pract. 2020 Oct;8(9):2851–7
21. Chuo J, Macy ML, Lorch SA. Strategies for Evaluating Telehealth. Pediatrics. 2020 Nov 1;146(5):e20201781

22. Reeves JJ, Ayers JW, Longhurst CA. Telehealth in the COVID-19 Era: A Balancing Act to Avoid Harm. Journal of Medical Internet Research. 2021 Feb 1;23(2):e24785

23. Kramer GM, Luxton DD. Telemental Health for Children and Adolescents: An Overview of Legal, Regulatory, and Risk Management Issues. J Child Adolesc Psychopharmacol. 2016 Apr;26(3):198–203

24. Sharma A, Feuer V, Stuart BK, Folk JB, Doan BT, Kulkarni CA, et al. Home-Based Telemental Health: A Proposed Privacy and Safety Protocol and Tool. J Child Adolesc Psychopharmacol. 2021 Sep;31(7):464–74

25. McLean S, Sheikh A, Cresswell K, Nurmatov U, Mukherjee M, Hemmi A, et al. The impact of telehealthcare on the quality and safety of care: a systematic overview. PLoS One. 2013;8(8):e71238

26. CHIEF Executive Forum. Virtual Care in Canada: Lexicon. Digital Health Canada. c2022. Available from: https://digitalhealthcanada.com/wp-content/uploads/2022/06/Virtual-Care-National-Lexicon-v-JAN2521.pdf