



# BMJ Open Quality Introducing an innovative model of acute paediatric mental health and addictions care to paediatric emergency departments: a protocol for a multicentre prospective cohort study

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## ABSTRACT

**Introduction** Children and youth with mental health and addiction crises are a vulnerable patient group that often are brought to the hospital for emergency department care. We propose to evaluate the effect of a novel, acute care bundle that standardises a patient-centred approach to care.

**Methods and analysis** Two paediatric emergency departments in Alberta, Canada are involved in this prospective, pragmatic, 29-month interventional quasi-experimental study. The acute care bundle comprises three components, applied when appropriate: (1) assessing self-harm risk at triage using the Ask Suicide-Screening Questionnaire (ASQ) to standardise the questions administered, enabling risk stratification; (2) use of the HEADS-ED (Home, Education, Activities/peers, Drug/alcohol, Suicidality, Emotions and behaviour, Discharge Resources) to focus mental health evaluations for those who screen high risk on the ASQ; and (3) implementation of a Choice And Partnership Approach to enable shared decision making in care following the emergency department visit. The overarching goal is to deliver the right care at the right place and time for the patients. The study design involves a longitudinal collection of data 12 months before and after the introduction of the bundle and the use of quality improvement strategies such as Plan-Do-Study-Act cycles during a 5-month run-in period to test and implement changes. The primary study end-point is child/youth well-being 1 month after the emergency department visit. Secondary outcomes include family functioning, child/youth well-being at 3 and 6 months, satisfaction with emergency department care, and health system outcomes (hospital admissions, length of emergency department stays, emergency department revisits).

**Ethics and dissemination** The study is registered at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and has received ethics and operational approvals from study sites. The results of the study will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement. Results will be shared broadly with key policy and decision makers and disseminated

in peer-reviewed academic journals and presentations at conferences.

**Trial registration number** NCT04292379.

## PROBLEM

Each year, over the past decade, visits to Canadian emergency departments (EDs) for child and youth mental healthcare have increased substantially.<sup>1</sup> Acute mental health crises can occur from a variety of unexpected or untreated concerns such as suicidal intentions, panic attacks, and aggressive behaviour.<sup>2-3</sup> Healthcare providers working in the paediatric ED play a vital role in assessing a child/youth's safety and well-being and referring children and youth to services for ongoing care,<sup>4-5</sup> and their approach to care should pinpoint risks, inform treatment, and consider family needs and preferences as part of a patient-centred approach. Yet, this approach to care has not been widely adopted in EDs. A previous study conducted by members of our team found that not all of Canada's paediatric EDs are resourced with a dedicated mental healthcare team, use validated tools to guide healthcare provider assessments or ensure that families are connected to follow-up care.<sup>6</sup> ED visits are often long and drawn-out,<sup>2</sup> and families have publicly stated that they do not feel their needs are met during visits.<sup>7</sup> Our team believes that these limitations have led to the provision of acute mental healthcare in Canada that lacks sufficient quality and efficiency.

The purpose of this study is to introduce a novel, acute mental healthcare bundle to ED-based care and evaluate its impact on children, youth, their families, and the impact on the healthcare resource use. The

bundle was developed in partnership with parents and youth (ie, patient partners) and leading emergency and mental healthcare experts. It comprises a set of evidence-informed practices—tools and approaches known to improve risk identification, support healthcare decision making and increase collaboration between families and healthcare providers—that will be used collectively to improve the quality of acute mental healthcare.<sup>8</sup> Quality improvement methods will be used during the study to promote successful bundle implementation.

## BACKGROUND

The novel bundle of acute mental healthcare has three areas of focus that relate to limitations in the existing approach to care in the ED:

### To improve risk assessment at triage and promote choice in care

A child/youth's ED visit begins with a nursing illness severity assessment, called triage. The assessment classifies visit urgency so the most seriously ill patients are seen first.<sup>9</sup> In Canada, child and youth concerns are categorised into five acuity levels using the Canadian Triage and Acuity Scale (CTAS) score. While the CTAS system is designed to prioritise significant mental health complaints and safety concerns, the system does not provide triage nurses with the specific questions needed to assess self-harm behaviour risks.<sup>10</sup> Thus, there remain an opportunity and a need to facilitate such assessments by triage nurses. Another perspective on the role of care provision in EDs has emerged from team-member patient partners who have highlighted the need for alternative, non-ED-based options. The latter is crucial to enable families to select the care location that is most suited to the needs of their child. Achieving this goal requires the healthcare system to prioritise a more family-centred model of care.

### To eliminate physician 'gatekeeping'

Following triage, physicians evaluate all patients, including those presenting with mental health concerns, for a host of potential medical aetiologies, a process often referred to as *medical clearance*. In many institutions this process is connected to determining the need for consultation by a mental healthcare provider, which places the physician as the gatekeeper for accessing mental healthcare. The process of medical clearance extends the duration of the ED visit<sup>11</sup> and increases healthcare system costs<sup>12</sup>; further, it rarely alters healthcare decision making.<sup>13</sup> This evaluation step is additionally problematic as ED physicians have limited mental health training and rarely use standardised tools to guide assessment.<sup>4,14</sup> This gatekeeper role has been shown to result in fewer than half of paediatric patients with mental health concerns being referred by the ED physician for evaluation by a mental healthcare provider in the ED.<sup>15</sup>

### To facilitate patient-centred follow-up care

Over 80% of children/youth who visit an ED with a mental health crisis are discharged to home. Though follow-up care is critical after a mental health crisis,<sup>4,15</sup> most ED physicians overseeing discharge planning may have limited familiarity with or access to follow-up care options.<sup>7</sup> As a result, families may receive no specific recommendations or be asked to organise care themselves. This is problematic because: (1) giving families the responsibility to organise follow-up care during a crisis may be overwhelming; (2) EDs are the point of first contact for families when they are most vulnerable; and (3) this approach does not ensure connection to care. Even when a recommendation for follow-up care is provided, children and youth often return to the ED within a few days.<sup>16</sup>

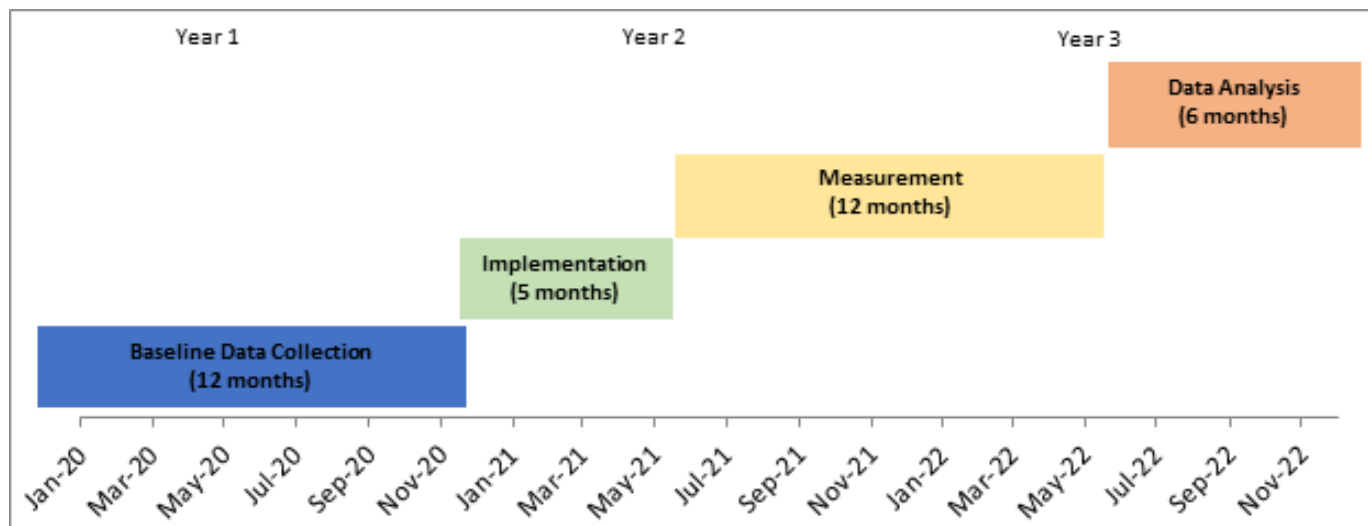
## METHODS

### Design and setting

We are conducting a prospective, pragmatic, 29-month interventional quasi-experimental study with an interrupted time series analysis.<sup>17,18</sup> The study has three phases: (1) *baseline*: no changes to clinical care occur and baseline data are collected longitudinally for 12 months; (2) *implementation*: the bundle of care is introduced to study sites using Plan-Do-Study-Act (PDSA) cycles conducted over a 5-month period<sup>19</sup> and (3) *measurement*: data are collected for 12 months after the conclusion of the PDSA cycles. With data being collected longitudinally before, during and after the introduction of the care bundle, we will be able to examine whether the intervention influenced the outcomes of interest relative to underlying secular trends.<sup>20,21</sup> An overview of the study timeline for key milestones is presented in [figure 1](#). The bundle will be implemented in two tertiary care paediatric EDs in the province of Alberta, Canada, the Stollery Children's Hospital (Edmonton) and Alberta Children's Hospital (Calgary). The study is supported by a clinical research network, Paediatric Emergency Research Canada, and a provincial funding agency, Alberta Innovates.

### Patient and public involvement

We used Amirav's adaptation of the International Association of Public Participation *Spectrum of Engagement* for health research and the Canadian Institutes of Health Research *Patient Engagement Framework* for an evidence-informed approach to patient engagement.<sup>22,23</sup> To date, patient partners have been involved in the conceptualisation, planning, design and implementation approaches developed for this study. This involvement occurred over a 2-year period (2017–2019). During this period, we held several in-person meetings and teleconferences for patient partners to discuss and prioritise bundle components (intervention refinement) and help select study outcomes and outcome measures. The study's primary outcome, change in child/youth well-being, was chosen by patient partners over other outcomes as it encompasses



**Figure 1** Study timeline for key milestones.

important impacts on comfort, health and happiness. Patient partners reviewed several measures of well-being and selected ones for the study that had items most relevant to mental health and were appropriate for patient self-report. Patient partners stated that when a child/youth is in crisis, so too is the family. Thus, we will measure both satisfaction with care and family functioning. Future involvement of patient partners will occur during bundle implementation (2021–2022) through participation in designing tests of change that introduce bundle components and the review of the results of these activities.

### Study population

Children and youth are eligible if they meet the following criteria at ED triage:

1. <18.0 years.
2. Chief complaint related to one of the following triage categories for a mental health and/or addiction concern: anxiety, bizarre behaviour, concern for patient's welfare, self-harm (eg, thoughts of self-harm, non-suicidal self-injury), depression/suicidal, homicidal behaviour, insomnia (eg, related to anxiety, worries, bizarre behaviours), disruptive behaviour, situational crisis or violent behaviour.

Children and youth who meet the following criteria will be excluded:

1. Brought to the ED by a police/peace officer;
2. Chief complaint related to one of the following triage categories: schizophrenia or delusional/psychotic disorders; behavioural syndromes or other medical concerns requiring medical clearance (eg, eating disorder, ingestion); significant self-harm requiring medical clearance (eg, suicide attempt, not just ideation).
3. Barriers to communication at triage (eg, language).
4. Previous study participation.

Ineligible children and youth will receive medical evaluation and treatment as clinically indicated focused on addressing underlying medical and physical safety concerns. The published literature suggests that <10% of

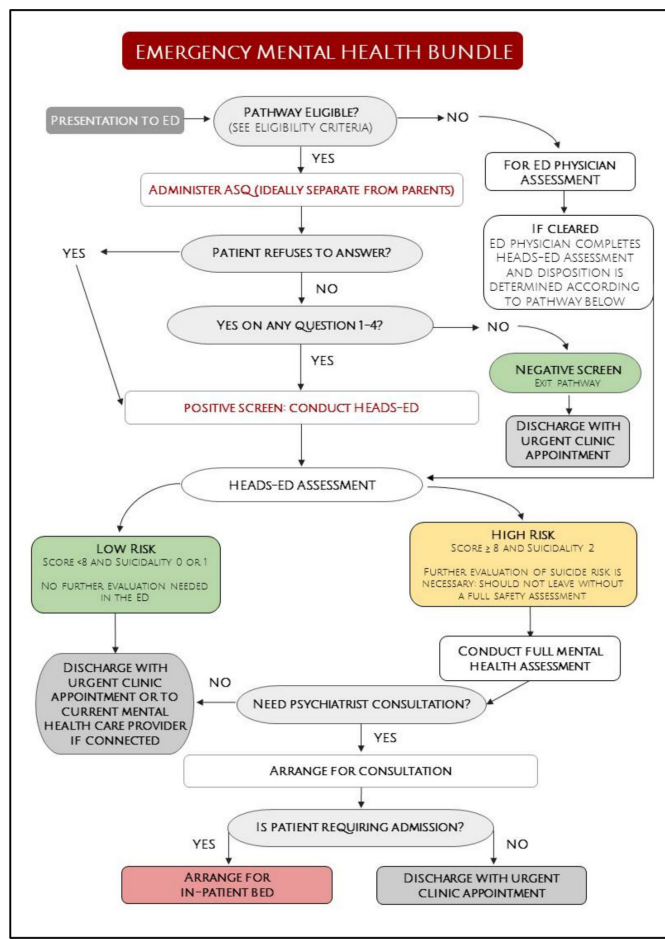
children and youth who seek mental healthcare in the ED will meet at least one of the exclusion criteria.<sup>2 3 24</sup>

### Study intervention

The acute mental healthcare bundle consists of three tools and approaches that will be introduced during (1) ED triage, (2) mental health assessment and (3) after discharge care (figure 2).

(1) To improve risk assessment at triage, triage nurses will screen for suicide risk using the Ask Suicide-Screening Questions (ASQ) tool. The ASQ consists of four yes/no questions, takes 20s to administer<sup>25</sup> and requires minimal training. It has been validated for children and youth,<sup>5 26–29</sup> and has excellent diagnostic test characteristics including a negative predictive value of 99.6% to detect suicide risk among those seeking emergency care.<sup>30</sup> Because healthcare providers differ in how they ask self-harm/suicide questions and patient responses are influenced by how questions are posed,<sup>31</sup> a standard approach to triage questioning will enhance the ability of nurses to rapidly and accurately identify patients at extremely low risk for self-harm.<sup>32</sup>

The ASQ will be administered at triage to all eligible children and youth. Those who answer 'Yes' or refuse to answer any question will be assessed as 'at-risk',<sup>5</sup> and their triage score will be classified as more urgent (eg, potential threat to life) than other concerns. These children and youth will receive a focused mental health assessment. Children and youth who reply 'No' to all questions will be considered 'low risk'. These children/youth and accompanying parents/caregivers will meet with a healthcare provider (eg, nurse, social worker or mental health team member) who will discuss the low-risk status and offer the family the option of a booked, urgent follow-up care appointment in a partnered mental health clinic. Appointment details will be provided prior to ED discharge and will include date, time, location and name of the healthcare provider with whom they will meet. Real-time scheduling (ie, access to a booking calendar)



**Figure 2** Acute mental healthcare bundle. ASQ, Ask Suicide-Screening Question; ED, emergency department.

will be used to ensure the availability of follow-up to occurs within 48 hours at a time agreeable to the family. Families that do not feel comfortable with the follow-up plan provided may opt to wait to see a physician in the ED and undergo further evaluation.

(2) In the care bundle, the physician's 'gatekeeper' role has been eliminated. Children and youth who screen 'at-risk' on the ASQ will not undergo medical clearance; following triage they will see a mental healthcare provider (eg, psychiatry nurse, counsellor) who will conduct a brief and focused mental health assessment using the HEADS-ED tool (Home, Education, Activities/peers, Drug/alcohol, Suicidality, Emotions and behaviour, Discharge Resources). The tool requires minimal training<sup>5</sup> and is endorsed for ED use as it can improve communication, expedite decision making and guide resource use.<sup>5 33–35</sup>

HEADS-ED use will enable the mental healthcare provider to assign scores and *action levels* to each of the HEADS-ED components: 0 (*no/minimal functional impairment, no action needed*), 1 (*moderate functional impairment, needs action but not immediate*) or 2 (*severe functional impairment, needs immediate action*).<sup>36</sup> The individual domain scores are then summed to generate a total score. Scores >8 or a 'suicidality' score of 2 will lead to consultation

with a psychiatrist as this score indicates high risk of harm and moderate-to-severe functional impairments in several domains. Total scores  $\leq 8$  with a 'suicidality' score of 0 or one will result in an urgent follow-up mental health clinic appointment as described previously, if agreed to by the family. A core principle of the bundle is that medical evaluation will be conducted by an ED physician if requested by a healthcare provider (eg, nurse, mental health worker, psychiatry) or if a concern emerges during the HEADS-ED assessment.

(3) To facilitate follow-up care after the ED visit, we will introduce the Choice And Partnership Approach (CAPA) to our urgent follow-up mental health clinic providers. CAPA is a system transformation model grounded in demand and capacity theory,<sup>37</sup> Lean,<sup>38 39</sup> and shared decision making<sup>40 41</sup> to identify inefficiencies in care and increase care capacity without increasing budgets to meet clinical demand.<sup>42</sup> In multiple countries, CAPA has reduced wait times to care, increased family engagement and service satisfaction, and reduced ED use.<sup>41 43 44</sup> This process uses full booking and referral systems to streamline schedules and enable clinics to provide 48 hours follow-up without having to increase resources.

The initial follow-up appointment in the partnered mental health clinic will be a *choice* appointment focused on understanding the main concern(s) and the child/youth/family's strengths, and joint goal setting and treatment planning. The appointment will conclude with a joint decision on what resources and services best match the family's context, needs and goals. A *partnership* appointment where the child/youth/family is matched with an appropriately skilled provider for care/therapy will be booked as necessary. This prioritising of choice promotes partnerships between a range of services for families—primary healthcare, school, social and community-based services. As a result, families will be directly connected to, and not required to self-advocate for, services.

### Bundle implementation

PDSA cycles will provide a structured, experiential learning approach to testing the changes needed to implement bundle improvements.<sup>19 45</sup> The value of using PDSA cycles instead of a planned, phased implementation approach alone is to (1) assure that bundle elements are implemented as intended with fidelity, and (2) ensure that changes result in the desired outcomes without significant unintended consequences. This is particularly important as the implementation of several bundle elements in a paediatric ED has not previously been performed. Each set of PDSA cycles will test the introduction of a bundle element and will consist of (1) planning the change based on change theory and previously collected data and making predication (Plan); (2) enacting the test of change and collecting the data (Do); (3) comparing the data with predictions (Study); (4) and identifying learnings to inform next steps (Act).<sup>46</sup> Over the 5-month implementation period, multiple cycles will occur, with successful changes on a small scale being

implemented on progressively larger scales with run or control charts being used to assess progress towards aims. By assessing the impact of changes in real time starting with small tests, challenges and unintended consequences can be addressed, and staff and patient engagement can be maximised.

### Study recruitment and enrolment

Potentially eligible youth and parents/caregivers of potentially eligible children will complete a consent to contact form either during (in-person) or after (via telephone) the ED visit. A member of the healthcare team will obtain this consent to ensure that patient and family confidentiality is maintained. If the form is completed via telephone, the employee will use contact information from the patient's electronic health record. The form asks the child/youth and a parent/caregiver to indicate if they consent to be contacted to discuss the study. Those who indicate 'No' will receive no further contact regarding the study unless an additional, eligible ED visit occurs. Those who indicate 'Yes' are asked to provide preferred contact information, and they will be contacted by a study research assistant who will use a standardised script to review study details, confirm eligibility and enrol the child/youth and parent/caregiver into the study if they confirm their desire to participate.

Enrolled participants are given two options regarding how to proceed with study participation: (1) the participant can provide verbal consent/assent on the telephone and complete baseline surveys during the same phone call; or (2) the project team can email secure study weblink to the participant so they can review, print and electronically sign the consent/assent form, and complete the baseline surveys online at their leisure. In compliance with local health information privacy laws, if verbal consent

is provided and baseline surveys are completed over the telephone, an additional step is taken after the phone call to email a secure study weblink to the participant where they can review, print and electronically sign the consent/assent form that grants the project team access to health information contained in their medical record related to the ED visit.

### Data collection

We will use REDCap, a secure web-based application,<sup>47</sup> to collect and store all collected outcome data. Table 1 outlines each outcome, its measurement time point and the data source. Youth and parents/caregivers will receive automated emails/text from REDCap that will include an embedded weblink that will take the recipient into REDCap where they will be able to complete follow-up reporting. Each email will contain a personalised REDCap link to report outcomes and experiences. Non-respondents will receive four reminders followed by a telephone call by a project team member who will complete the follow-up outcome measures with the study participant over the phone. Any non-respondents who cannot be contacted by phone will be considered lost to follow-up.

### Primary outcome

The primary outcome is the change in child/youth well-being, which will be measured as the difference between 1 month and baseline reports. Well-being will be measured with the Stirling Children's Well-being Scale (for children aged 8–13 years) and the Warwick-Edinburgh Mental Well-being Scale (for youths aged 13–17 years).<sup>48–50</sup> The Stirling Children's Well-being Scale asks children 12 questions about their emotional and personal well-being (5-point response scale, total possible score of

**Table 1** Overview of data collection

	Measurement Time-point				Source
	Baseline*	1 month post-ED visit	3 month post-ED visit	6 month post-ED visit	
<b>Patient-reported outcomes</b>					
Child well-being	√	√	√	√	Parent
Youth well-being	√	√	√	√	Youth
Family functioning	√	√			Parent
<b>Patient-reported experiences</b>					
Satisfaction with care	√				Parent and youth
<b>Health system outcomes</b>					
Hospital admissions for mental healthcare	√				Electronic medical record
Length of ED visit	√				Administrative data
ED re-visits		√			Electronic medical record
Deaths by suicide		√			Administrative data

\*Measured within 72 hours of the ED visit.  
ED, emergency department.



60 indicating highest level of well-being). The measure has excellent internal consistency (Cronbach's  $\alpha=0.85$ ) and good test-retest reliability ( $r=0.75$ ).<sup>48 51</sup> The Warwick-Edinburgh Mental Well-being Scale consists of 14 questions with five response categories (total possible score of 70 indicating highest level of well-being).<sup>52</sup> The scale is valid and reliable when used with youth with conditions requiring ED care<sup>52</sup> and has excellent internal consistency (Cronbach's  $\alpha=0.89$ ) and test-retest reliability ( $r=0.83$ ).<sup>53</sup>

### Secondary outcomes

1. The change in child/youth well-being from 1-month to 3-month reports and 1-month to 6-month reports as measured by the Stirling Children's Well-being Scale or Warwick-Edinburgh Mental Well-being Scale.
2. The change in family functioning, which will be measured as the difference between 1 month and baseline reports. Functioning will be measured using the Family Quality of Life Scale.<sup>54-56</sup> The measure is reliable (Cronbach's  $\alpha=0.88-0.94$ ) and consists of 25 items that measure family interaction, parenting, emotional well-being, physical/material well-being and disability-related support (5-point scale, total possible score of 125 indicating highest quality of life).
3. Satisfaction with acute mental healthcare, which will be measured 3 days after the initial ED visit for a mental health and/or addiction concern. Satisfaction will be measured using the Service Satisfaction Scale, a 15-item (parent/caregiver version) or 13-item (youth version) instrument for measuring global satisfaction with mental health services.<sup>57</sup> Items are scored on a 5-point response scale, with a total possible score of 60 (parent) or 50 (youth). The instrument's advantages include brevity, parallel youth and parent/caregiver forms, and robust development.<sup>57</sup>
4. Among study participants, the proportion of those admitted to a hospital for mental healthcare at the completion of the initial ED visit for a mental health and/or addiction concern. Admission is defined as admission to a hospital for a child/youth mental health service (in-patient psychiatry, mental health unit and so on). Data from the patient electronic medical record will be used.
5. Among participants, the duration of the initial ED visit. This is defined as the time between patient triage and discharge. Administrative data from each paediatric ED will be used.
6. Among study participants, the proportion of children/youth with an ED revisit within (a) 72 hours and (b) 30 days for a mental health and/or substance use disorder concern. Data from the patient electronic medical record will be used.

### Other outcomes

To assess for unintended consequences of the bundle, the balancing measure that we will monitor and report on is death by suicide among children/youth within 30 days of the initial ED visit as measured using provincial coroner's

data. Processes that will be studied during PDSA cycles include qualitative feedback from patients, families, and triage nurses on the ASQ screening process and feedback on the process of booking an appointment an urgent appointment or at a partnered mental health clinic.

### Data analysis

Each study site will be analysed independently. Before, during and after implementation, Statistical Process Control charts will be used to assess baseline stability of measures,<sup>58</sup> whether changes are resulting in improvement and whether improvements are sustained. We will use segmented regression to analyse trends in pre- and postimplementation periods, estimating effect size of the care model and accounting for underlying trends. For all outcomes, data will be inspected to determine appropriate regression models for analyses. We will censor data points during the 5-month implementation period. We will conduct stratified analyses to identify whether the bundle has a distributional impact on key child/youth features such as age, gender, sex and acuity of concern at the initial ED presentation. The gender-based analysis will also be considered when appropriate.<sup>59</sup> We will control for seasonality and other long-term trends using a model stratified by the calendar month or using more complex functions such as Fourier terms (eg, pairs of sine and cosine functions) or splines as appropriate.<sup>60</sup> Because we are using time series data, correlations between time points may violate regression assumption. If so, we will explore residual autocorrelation and use lagged variables.<sup>61 62</sup> Where residual autocorrelation remains, this will be adjusted for using methods such as Prais regression or autoregressive integrated moving average.<sup>63</sup>

## DISCUSSION

### Strengths and limitations of the study design

The study as designed presents both strengths and challenges to our team. In terms of partnerships, important strengths include having key clinical practice, healthcare administration and family/youth representatives as team members. The perspectives of these team members were considered in the design and development of this study, which has increased study relevance and feasibility. Family and youth representatives were involved in selecting the study's primary outcome and outcome measures. Healthcare providers (ie, frontline staff), healthcare decision makers, administrators, and patients and families will be involved in bundle implementation and evaluation, including reviewing results of PDSA cycles so that results can be translated back into clinical care to enhance the success of bundle implementation. Key challenges to the team relate to study set-up (completed) and enrolment (currently active). It required more time than anticipated to set up the study database in a manner that supports online recruitment and enrolment of various participants (youth consent or assent, parent consent) and the varying outcome measures. Testing the functionality of

the database required investment of human resources and funds and took 4 months longer than anticipated. Current challenges relate to enrolment and include families not being asked to consent to participate in the study during the ED visit thus requiring significant resources to obtain consent to contact after the visit. Identifying consistently available healthcare employees to complete consent to contact has been difficult. To protect patient and family confidentiality, it is required for a healthcare system employee to act as the intermediary and obtain consent to contact. However, given the high volume and demanding nature of their work, there are often insufficient resources to fully support the consent to contact process. Reaching families is often difficult and may require many attempts. This is most prominently a challenge in settings where the telephone used an unlisted telephone number that appears as 'unlisted caller ID' in participants' telephone call displays; some participants are reluctant to answer the telephone for an unlisted telephone number. Finally, the current COVID-19 pandemic has altered patient care in ED (eg, reduced volumes,<sup>64</sup> promotion of virtual care<sup>65</sup>), which will need to be accounted for in data analysis.

## IMPLICATIONS FOR CLINICAL PRACTICE

Current acute mental healthcare is fragmented, system-centred and limits access to mental health services. The bundle of care that we will evaluate has the potential to improve the care delivered by matching resources and services to need, eliminating healthcare inefficiencies, closing care gaps and promoting timeliness to specialised or community mental healthcare.

## ETHICS AND DISSEMINATION

The study received approval from the following committees: University of Calgary (REB19-0357) and University of Alberta (Pro00092862). Consent/assent will be obtained and documented for all children, youth and parents/guardians participating in the study. The results of the study will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement. Results will be disseminated via peer-reviewed, academic journals and presentations with local healthcare stakeholders. Results will also be made available for participating sites, the study funder, and for families seeking emergency mental healthcare using tailored communication products (eg, pamphlets, one-page reports).

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**Collaborators** Pediatric Emergency Research Canada (PERC).

**Contributors** AN and SF planned the project with major contributions from BW, ASS and AM regarding ED care management and processes; LMA, AC, LV and MS regarding mental healthcare management and processes; JT-F and TL regarding quality improvement and evaluation methods; KP regarding health research ethics and privacy processes; and patient partners who helped with study planning and design. AN and JT-F took the lead on revising the manuscript based on reviewer feedback. Pediatric Emergency Research Canada is a national research organisation supporting the study's conduct in the two paediatric emergency departments.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** No data are available. This is a protocol; no data are available at this time.

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