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Study Design

Implementation of a Sudden Cardiac Death Risk Prediction Tool in Clinical Practice Through Electronic Health Records (INSERT-HCM Study Design)

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ABSTRACT

Sudden cardiac death is a leading cause of mortality in children with hypertrophic cardiomyopathy (HCM). The PRecIsion Medicine in CardiomYopathy consortium developed a validated tool (PRIMaCY) for sudden cardiac death risk prediction to help with implantable cardioverter defibrillator shared decision-making, as recommended by clinical practice guidelines. The Implementing a Sudden Cardiac Death Risk Assessment Tool in Childhood HCM (INSERT-HCM) study aims to implement PRIMaCY into electronic health records (EHRs) and assess implementation determinants and outcomes.

INSERT-HCM is a prospective, multicentre, hybrid type-3 mixed-methods implementation study of an EHR-embedded risk calculator across Canadian pediatric hospitals. The Active Implementation Framework will inform a staged implementation process, with

RÉSUMÉ

La mort subite cardiaque est une des principales causes de mortalité chez les enfants atteints de cardiomyopathie hypertrophique (CMH). Le consortium PRecIsion Medicine in CardiomYopathy a développé un outil validé (PRIMaCY) pour la prédiction du risque de mort subite cardiaque afin d'aider à la prise de décision partagée concernant l'utilisation des défibrillateurs cardioverteurs implantables, conformément aux recommandations par les lignes directrices de pratique clinique. L'étude INSERT-HCM (Implementing a Sudden Cardiac Death Risk Assessment Tool in Childhood HCM) vise à intégrer PRIMaCY dans les dossiers de santé électroniques (DSE) et à évaluer les déterminants et les impacts de sa mise en œuvre.

L'étude INSERT-HCM est une étude d'implémentation prospective, multicentrique, hybride de type 3, fondée sur des méthodes mixtes,

Hypertrophic cardiomyopathy (HCM) is a predominantly genetic cardiac disorder that affects 1 in 2500 children.[1] Sudden cardiac death (SCD) is the leading cause of mortality in children with HCM.[2-4] The 10- and 15-year event-free survival rates in childhood HCM are 86% and 62%, respectively.[2,3,5] ICDs are implanted transvenously or surgically in patients who have survived life-threatening events (secondary prevention), and in those who have not yet suffered an event but are deemed to be at high risk for the occurrence of an event (primary prevention). Imprecise and subjective means of evaluating risk hampers the timely insertion of primary prevention ICDs in at-risk patients, resulting in the unfortunate loss of young lives.[4] Further, most patients who receive primary prevention ICDs do not need them and are exposed to an unnecessary risk of ICD complications.[6-8]

The PRecIsion Medicine in CardiomyopathY (PRIMaCY) international consortium of 20 centres across Canada, the US, and Australia published the first fully validated SCD risk-prediction model for pediatric HCM that incorporates multiple evidence-based risk factors and calculates an individualized 5-year sudden-death risk score for each patient.[4]

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organization-based implementation teams facilitating the implementation technical installation and implementation process. PRIMaCY will be installed as a user-tested EHR-integrated tool and implemented in practice using an organization and provider-focused strategy at participating hospitals. Technical installation and implementation strategies will be optimized for each healthcare setting. The Implementation Outcomes Taxonomy will inform implementation outcomes. Back-end EHR data will assess tool adoption, penetration, and fidelity. The Consolidated Framework for Implementation Research will assess implementation determinants (facilitators and barriers), and sustainability in clinical practice will be explored.

INSERT-HCM will inform best practices for implementing an evidence-based digital health solution within hospital EHRs and clinical workflows to improve guideline-directed care. Developing an effective implementation strategy will inform the future dissemination of EHR-integrated digital health tools to the broader scientific and clinical community.

qui se concentre sur l'intégration d'un calculateur de risque au sein des DSE dans les hôpitaux pédiatriques canadiens. Le cadre d'implémentation active guidera un processus de mise en œuvre par étapes, avec des équipes d'implémentation basées dans les organisations facilitant l'installation technique et le processus d'implémentation. PRIMaCY sera installé en tant qu'outil intégré au DSE et testé par les utilisateurs, puis déployé dans la pratique au moyen d'une stratégie axée sur l'organisation et les prestataires dans les hôpitaux participants. Les stratégies d'installation technique et de mise en œuvre seront optimisées pour chaque établissement de santé. La taxonomie des résultats de la mise en œuvre renseignera sur les résultats de l'implémentation. Les données issues du système de gestion des DSE permettront d'évaluer l'adoption, la pénétration et la fidélité de l'outil. Un cadre consolidé pour la recherche sur cette mise en œuvre permettra d'évaluer les déterminants de l'implémentation (facilitateurs et obstacles) et sa durabilité dans la pratique clinique sera étudiée.

L'étude INSERT-HCM fournira des informations sur les meilleures pratiques pour l'implémentation d'une solution de santé numérique fondée sur des données probantes dans les DSE des hôpitaux et les flux de travail cliniques afin d'améliorer les soins axés sur les lignes directrices. L'élaboration d'une stratégie d'implémentation efficace contribuera à la diffusion future des outils de santé numérique intégrés au DSE auprès de la communauté scientifique et clinique au sens large.

This prediction model ensures that all risk factors are considered based on their relative weight and unique combination for each patient. The 2024 American College of Cardiology & American Heart Association clinical practice guidelines and the 2024 Canadian Cardiovascular Society clinical practice update recommend that PRIMaCY be used clinically to calculate and predict individual SCD risk in eligible pediatric HCM patients.[9,10]

The guidelines also emphasize using this prediction to guide a shared decision-making dialogue about ICD between patients and their care team with full disclosure of all options, discussion of the risks and benefits of those options, and engagement of patients so they can express their goals and risk tolerance.

Traditional methods of disseminating practice guidelines through publications have modest or inconsistent effects on healthcare delivery and outcomes.[11,12] The adoption of practice guidelines is improved when they are available to healthcare providers within clinical workflows.[13,14] When PRIMaCY was first delivered to healthcare providers as a Web-based calculator in October 2021 with its computational interface hosted with Shiny applications accessed via primacycalculator.com, uptake was immediate and sustained, with 452 users from 41 countries (287 from North America) within the first 5 months of launch (unpublished data via Google web analytics).[15] However, a Web-based application remains outside clinical workflows and lacks accessibility at the point of care, automation, documentation, and data retention. We evaluated user experience through a survey of cardiomyopathy specialists across North American centres. The responses indicated that 89% of respondents used the tool, of which 100% found it clinically useful. However, only 52% used it regularly; 88% reported that the major barrier to regular use was lack of integration into the electronic health record (EHR; unpublished 2022 survey data). For clinical decision-support tools such as risk-prediction models that use advanced statistical methods, integration into interoperable EHRs can facilitate their adoption. This situation has led to growing efforts toward automated extraction of risk variables using natural language processing and automated measurements of echocardiographic variables so that these variables are accessible and available for calculating risk.[16-18] However, current SCD risk-prediction tools have not been integrated into EHRs.

Implementing new technology requires a multifaceted implementation strategy involving the assessment of organizational readiness, resources, and supportive functions, stakeholder communication, engagement, and training, and availability of user-friendly tools.[19,20] Implementation-science methods have the potential to inform the effective implementation of new technology into clinical practice through stakeholder engagement, iterative adaptation, and continuous evaluation.

The objective of the **I**mplemen**n**ting a **S**udden Cardiac D**e**ath **R**isk Assessment **T**ool in Childhood **HCM** (INSERT-HCM) study is to implement PRIMaCY into clinical workflows within hospital EHRs of Canadian pediatric hospitals to facilitate the delivery of evidence-informed practice at point-of-care and assess implementation outcomes and determinant factors. We hypothesize that an implementation science-informed process will achieve effective and sustainable implementation of PRIMaCY within organizations and facilitate positive practice change. This article describes the design, objectives, and proposed methodologies for the INSERT-HCM study.

Methods

The overarching aim is to use an evidence-based implementation approach to support the effective and sustainable

implementation of PRIMaCY across healthcare settings in Canada. The study objectives are as follows: (i) to implement PRIMaCY into hospital EHRs using an organization and provider-focused implementation approach; and (ii) assess implementation determinants and outcomes to improve implementation effectiveness. The implementation outcomes taxonomy will guide the evaluation of implementation effectiveness.[21]

Study design

This multi-centre hybrid type 3 mixed-methods implementation study will explore implementation outcomes.[22,23] Implementation of PRIMaCY will be informed by the Active Implementation Frameworks (AIF), a process framework comprised of implementation stages, implementation drivers, implementation teams, and improvement cycles.[24] Implementation procedures will follow the 4 stages of the AIF implementation process—exploration, installation, initial implementation, and full implementation. The components of the framework and their application to PRIMaCY implementation are outlined in Table 1.

The study will be conducted across 4 tertiary-care pediatric hospitals in Canada—The Hospital for Sick Children (SickKids), in Toronto, Children's Hospital of Eastern Ontario (CHEO), in Ottawa, Stollery Children's Hospital, in Edmonton, and BC Children's Hospital, in Vancouver. All participating sites have specialty cardiomyopathy clinics that follow eligible HCM patients. Patients eligible for PRIMaCY use are HCM patients aged < 18 years who are phenotype-positive, who do not have a secondary etiology for HCM (ie, syndromic, endocrine, hypertension, neuromuscular, structural heart defects), and who do not have a preexisting ICD. In addition, all sites have interoperable EHR systems, including Epic Systems at 3 sites and Oracle Cerner at one site. Participating sites reflect diversity in geography, size, and structure, allowing us to explore implementation effectiveness and barriers and facilitators across organizations and providers to establish external validity. The study duration is 3 years. Research ethics board approval will be obtained at each participating institution. Informed consent will be obtained from hospital staff invited to participate in implementation teams.

Implementation stages

Stage 1—exploration. As a foundational step to plan for organizational implementation and build conditions necessary for effective and sustainable practice change, the factors associated with early readiness to implement an EHR-compatible version of PRIMaCY were assessed and guided by the Hexagon Tool.[25] Study sites were selected based on their capacity and readiness to implement the core components of the intervention, which are as follows: (i) an interoperable EHR; (ii) an EHR-compatible model of PRIMaCY; (iii) compatibility of the innovation with clinical practice workflows; and (iv) willingness of site investigators to implement PRIMaCY. The path to EHR integration at each site will be explored through consultation with technical field experts comprising institutional information technologists, technical developers, EHR vendors, and industry providers. Resources will be budgeted for all participating sites, including compensation for information technology efforts.

Stage 2—installation

Implementation teams. To prepare the infrastructure and workflow to integrate PRIMaCY, implementation teams will be established at each implementing organization to explore the competency, organizational, leadership drivers, and organizational functions needed to support the implementation. Hospital staff including information technologists, healthcare providers, and research staff, will be recruited to site implementation teams to plan and execute site-specific implementation.[26] This process includes facilitating technical integration of PRIMaCY into EHRs, training healthcare providers in tool use, and liaising with hospital administration and healthcare providers to provide ongoing support and troubleshoot issues as they arise.

EHR-compatible model. A critical organizational driver is a PRIMaCY model that can be integrated within EHRs. We will explore the direct integration of PRIMaCY within EHR tools and external EHR application programming interfaces. Although technically compatible with integration, challenges may be associated with direct integration as PRIMaCY is an advanced statistical model using competing risk, calculated using the programming language R, and will require upgrades to system capabilities such as Epic's Cognitive Computing platform.[27] Alternatives include external applications compatible with EHR integration using the Substitutable Medical Applications Reusable Technologies on Fast Healthcare Interoperability Resources workflow (also known as SMART on Fast Healthcare Interoperatbility Resources

Table 1. Implementation stages (Active Implementation Framework)

Stage 1	Stage 2	Stage 3	Stage 4
Exploration	Installation	Initial implementation	Full implementation
Assess organizational need, fit, resources, evidence for innovation, readiness and capacity for implementation	1. Establish site implementation teams	1. Launch EHR-integrated PRIMaCY at each site	1. Establish that PRIMaCY is fully implemented into usual clinical practice.
	2. Integrate PRIMaCY into EHR	2. Regular implementation team meetings and PDSA cycles	2. Sustainment Measurement System survey
	3. Test usability of PRIMaCY within clinical workflows	3. Assess implementation outcomes, barriers and facilitators (CFIR-based interviews)	

CFIR, Consolidated Framework for Implementation Research; EHR, electronic health record; PDSA, plan, do, study, act; PRIMaCY, PRecIsion Medicine in CardiomYopathy.

[FHIR]). Given that different healthcare settings have different capabilities, we will explore whether using SMART on FHIR applications for medical calculators is a feasible alternative, wherein PRIMaCY can be developed as part of an existing application that is marketed already in EHR marketplaces (ie, Epic Showroom, Cerner/Oracle Health Marketplace, Kansas City, MO). To address potential security concerns with third-party applications, these applications leverage OAuth 2.0, a standard protocol for secure authorization by a third-party application to access information in the hospital EHR.[28-30] Computation occurs on a virtual private server hosting the application where calculator inputs are sent, and results are returned to the hospital network hosting the EHR. FHIR resources pull patient data for autofill capabilities using Logical Observation Identifiers Names or Codes (LOINC), while remaining within the hospital network so personal health information does not exit hospital firewalls. The first installation of an EHR-integrated application will be performed at the lead site (SickKids Hospital). This experience will guide installation at the remaining participating sites with customization for each healthcare setting.

Usability testing. A subset of healthcare providers (physicians, nurse practitioners) who are expected to use the tool in assessing pediatric HCM patients will be recruited for usability testing. Usability testing will ensure that provider needs regarding accessibility, usability, and acceptability of the EHR interface for the tool and its placement within clinical workflows are met. Considering that the tool's components will have simple interfaces and navigation, one round of usability testing with up to 4 end-users is planned.[31] Usability testing will involve observing end-users completing the PRIMaCY tasks in the EHR. Participants will verbalize their thoughts regarding navigation, the user interface, and other challenges while interacting with PRIMaCY (think-aloud technique).[32,33] This process is integral to understanding the end-user experience and will highlight potential barriers to adoption that can inform its subsequent implementation.[26] Questions asked at the end of the session will ascertain what participants liked and disliked, and why, their opinion on ease of use, functionality in the context of typical practice workflow, and suggestions for improvements. Testing sessions will be video-recorded, transcribed verbatim, and deidentified, and content analysis will be conducted to identify emerging themes.[34] Insights will inform modifications that improve PRIMaCY usability.

Stage 3—initial implementation. Initial implementation represents the "go-live" phase of the EHR-embedded version of PRIMaCY at the participating sites. Site implementation teams will disseminate information about the PRIMaCY launch to relevant stakeholders and will provide organizational onsite support for technical and clinical workflow issues. Implementation outcomes will be captured as described in a subsequent section. These data will be collected and shared regularly at implementation team meetings to address challenges through plan, do, study, and act cycles.[35] Qualitative field notes also will be captured to identify implementation barriers and facilitators. Data from the lead site's implementation will inform implementation at the other sites and actively establish best practices toward effective implementation protocols. Twelve months of follow-up is planned to assess implementation outcomes and identify and address barriers and facilitators.

Stage 4—full implementation. Full implementation will be achieved once the model is considered embedded in usual organization and provider practice. A sustainment survey will ascertain the extent to which PRIMaCY can be maintained within the organization's ongoing, stable operations. Site implementation teams will build internal capacity and ensure resources and infrastructure are in place beyond the study period to support operational sustainability. At this stage, site implementation teams will hand off to organizational quality-management teams for ongoing monitoring of quality and sustainability.

Implementation outcomes, barriers, and facilitators

Implementation outcomes defined using the Implementation Outcomes taxonomy will be measured to evaluate implementation effectiveness.[21] Mixed methods will enable a thorough evaluation of implementation outcomes, as described in Table 2.

Provider-level outcomes. Patient health records will be screened to identify outpatients eligible for tool use, and back-end EHR logs will be exported and reviewed monthly during the initial implementation stage to determine how many providers used the tool (adoption), for how many eligible patients the tool was used (penetration), and how often the tool is used as intended (fidelity; Table 2). These data will be summarized and presented at monthly implementation team meetings and will inform plan, do, study, and act cycles to address challenges in adoption, penetration, and fidelity of tool use.

Organization-level outcomes. The Consolidated Framework for Implementation Research (CFIR), an established implementation determinant framework, will guide the assessment of implementation effectiveness across different hospital settings.[36,37] CFIR-based interviews with site implementation teams, administered at the end of implementation, will capture determinant factors that hindered or facilitated implementation per 5 domains—intervention characteristics, inner setting, outer setting, characteristics of individuals, and process. Organizational staff interviews performed as part of the study will be audio-recorded to ensure data accuracy before analysis is performed. At an organizational level, sustainability, ie, the extent to which a newly implemented practice is maintained or institutionalized within a service setting's ongoing stable operations, will be assessed using the Sustainment Measurement System Scale (SMSS).[38] SMSS will be administered to implementation team participants as a survey and adapted for relevance to the healthcare setting for assessing domains of sustainability and exploring prominent contextual factors that may impact the future sustainability of PRIMaCY within the organizational structure and clinical workflow. Implementation processes and milestones will be tracked using the Stages of Implementation Completion tool to track the time needed to complete the different processes that span the initial engagement stage to achieve full organizational competency.[39,40] Sites will be deemed to have

Table 2. Implementation outcome measures and operational definitions

Implementation outcomes	Operational definitions	Data source
Healthcare provider level*		
Adoption	% of eligible healthcare providers using PRIMaCY. Eligible healthcare provider is defined as a cardiomyopathy or electrophysiology physician or nurse practitioner who is in the clinical circle of care for pediatric HCM patients.	EHR back-end user logs & clinic encounter chart reviews
Penetration	% of eligible patients in whom PRIMaCY is used. Eligible patient is defined as a pediatric patient aged < 18 years who is phenotype-positive for HCM that is considered primary, ie, not due to secondary causes.	EHR clinic encounter chart reviews
Fidelity	% of patients in whom PRIMaCY is used as intended, ie, in the right patient at the right time defined as use in an eligible patient without a preexisting ICD and prior to a sudden cardiac death event, as well as inclusion of the PRIMaCY risk score in the clinic encounter within the EHR.	EHR clinic encounter chart reviews
Organization level		
Stages of implementation completion	Time to stage completion, proportion of activities completed within a stage, and site progress toward full implementation	Administrative data tracked using the Stages of Implementation Completion tool
Implementation costs	Infrastructure, resources, and personnel costs for implementation.	Administrative data tracked using the Stages of Implementation Completion tool
Sustainability	Extent to which PRIMaCY can be maintained within the organization's ongoing, stable operations	Sustainment Considerations Survey

EHR, electronic health record; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter defibrillator; PRIMaCY, PRecIsion Medicine in CardiomYopathy.

*Data source may vary by site.

achieved competency after they demonstrate consistent adoption, penetration, and fidelity in tool use by site providers. Direct costs of PRIMaCY EHR integration, including service and personnel time, will be measured as a factor influencing implementation effectiveness.

Analysis

Data will be analyzed using a convergent parallel mixed-methods design, giving equal weight to the quantitative and qualitative data. Provider and healthcare-system factors associated with adoption, penetration, and fidelity will be analyzed using a Cox proportional hazards model. CFIR interview data will be analyzed using the rapid-analysis method.[41] After notes are finalized, coders will independently assign a rating to all CFIR constructs within each interview to reflect valence (positive or negative influence) and strength (score of −2, −1, 0, 1, 2); discrepancies will be resolved through consensus. Regression models will be used to identify factors associated with implementation effectiveness in organization and healthcare provider users as described in Table 2. Implementation cost and resource requirements will be assessed at each site. The SMSS will provide subscales and global scores for sustainability. The global measure represents the average of 4 individual forms of sustainment that together assess the degree to which a new program is sustained, ie, the project continues to operate as intended, to deliver services to its intended population, to deliver services that are evidence-based, and to periodically measure the fidelity of the services delivered. A multivariable linear regression model will be used to identify predictors of the global sustainability score, including site program adoption, penetration, and implementation costs.[42] All statistical tests will be 2-tailed, and statistical significance will be defined as P-values < 0.05. Content analysis will be used for qualitative interviews from usability testing to identify insights for modifications that improve PRIMaCY usability, which is expected to reduce the chances of implementation failure. The planned analysis will inform an evidence-supported strategy for effectively implementing an EHR-integrated version of PRIMaCY.

Discussion

The INSERT-HCM study bridges the gap between developing a decision-support tool and its clinical implementation via EHR integration. The study will be conducted across sites that are diverse in geography, size, and structure, to identify implementation barriers and facilitators across different hospital systems. Effective PRIMaCY implementation will enable an evidence-based, patient-centred approach to SCD prevention in childhood HCM and provide a roadmap for making digital health solutions accessible within healthcare systems. Promoting the adoption of PRIMaCY for childhood HCM SCD risk assessment aligns with clinical practice guidelines. This approach is expected to result in a reduction in sudden death events, improved appropriate ICD use, and a reduction in unnecessary ICD implantations, which will contribute to healthcare cost savings and enhance lifetime productivity gains from lives saved.

Canada has invested in healthcare interoperability to improve the efficiency, quality, and accessibility of healthcare services for patients and providers.[43] Although hospitals have upgraded to interoperable EHRs capable of integrating new technologies, very few have successfully implemented digital

decision tools applicable across diverse healthcare systems. Published accounts of the clinical implementation of EHR-embedded predictive models relate to domains with a high disease burden in inpatient settings, whereas outpatient conditions remain underrepresented.[44] PRIMaCY is primarily an outpatient tool used in pediatric-onset HCM, a rare disorder. INSERT-HCM will generate insights into the necessary organizational conditions and processes to implement a tool for a specialized clinical service in a rare pediatric condition, which we hope will have broader applicability to other outpatient decision-support tools. Future research will assess the impact of PRIMaCY adoption on provider and patient experience in ICD shared decision-making.

Ethics Statement

The study described adheres to the relevant ethical guidelines. Research ethics board approval will be obtained at each participating institution. Informed consent will be obtained from hospital staff invited to participate in implementation teams.

Patient Consent

Research ethics board approval for waiver of patient consent was obtained as patient data will be collected retrospectively after completion of clinic visits (SickKids REB number1000080799).

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Disclosures

S.M. is a consultant for Bristol Myers Squibb, Tenaya Therapeutics, and Rocket Pharmaceuticals. The other authors have no conflicts to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2024.10.002.