CADTH

CADTH HEALTH TECHNOLOGY ASSESSMENT

Remote Monitoring Programs for Cardiac Conditions — Project Protocol

Service Line: Health Technology Assessment
Issue: Volume 10, Issue 2a
Publication Date: October 2020
Report Length: 29 Pages

CADTH

Cite As: *Remote Monitoring Programs for Cardiac Conditions — Project Protocol*. Ottawa: CADTH; 2020 Sept. (CADTH health technology assessment — project protocol).

ISSN: 1927-0127 (online)

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.

CADTH

Table of Contents

Abbreviations

COPD	chronic obstructive pulmonary disease
HTA	health technology assessment
SPIDER	Sample, Phenomenon of Interest, Design, Evaluation, Research type

Introduction and Rationale

Remote monitoring (also known as remote patient monitoring or remote patient management) is a type of telehealth whereby health care is delivered to patients outside traditional settings by allowing health data to be exchanged between patients and health care providers using telecommunication technologies (e.g., video conferencing) or stand-alone devices (e.g., portable heart rate monitors).[1,2] Canada Health Infoway has defined remote monitoring as "the delivery of [health care] to patients outside of conventional settings enabled by a technological application or device."[1] The stated goals of using remote monitoring in clinical practice centre around promoting home-based self-management to improve patient outcomes or reduce health system usage.[3] Self-management strategies typically aim to improve diet and cholesterol levels, exercise levels, knowledge of the patient's health condition, confidence to stay at home, patient satisfaction, and quality of life. These outcomes are, in turn, theorized to lead to improved patient outcomes over time and to enable patients to continue living at home and in the community.[3]

At its core, remote monitoring relies on the use of telecommunication technology for the transmission of health data between patients and health care providers.[2] Examples of health data that may be transmitted include readings of physiological activity such as oxygen saturation levels and cardiac rhythm or patient observations such as mental status and medication intake. For example, for patients with hypertension, blood pressure readings could be transmitted to evaluate treatment effectiveness and adherence. For the purposes of this health technology assessment (HTA), CADTH considers a remote monitoring program to be a formal, organized offering from a health authority or health care organization that may employ a variety of technologies (e.g., video conferencing, blood pressure monitors, online portals) to collect and transmit patient data. This is in contrast to the one-off use of remote monitoring devices that may occur in a clinician's office.

Remote Monitoring for People With Cardiac Conditions

In Canada, the number of people with heart failure is increasing annually, with more than 600,000 people currently living with the condition and more than 50,000 new cases diagnosed each year.[4,5] An estimated 350,000 Canadians live with atrial fibrillation[6] and more than 5.4 million Canadians have hypertension.[7] While many Canadians with cardiovascular disease would benefit from cardiac rehabilitation, only an estimated 10% to 30% have access to these programs.[8,9]

Remote monitoring for people living with cardiac conditions has been proposed as a means of detecting health issues earlier, while also reducing the need for routine office visits, emergency department visits, and hospital admissions.[10,11] Remote monitoring also aims to help patients maintain independence and remain in the home or community, which may be particularly relevant for patients living in rural or remote communities.[9,10,12,13] For conditions like hypertension, dozens of home monitors are readily available to patients.[14] In the remote monitoring space, several companies have recently begun marketing low-cost, direct-to-consumer devices that have drawn media and health care provider attention, and that are capable of monitoring heart rate, heart rhythm, and blood pressure at home.[15-18] Large telehealth providers have also emerged to support care for cardiac patients.[19,20] However, there remains uncertainty and gaps in the evidence surrounding the use of remote monitoring.[21] Included in this uncertainty, because of its reliance on data and internet connections, remote monitoring raises concerns about patient privacy and data security.[9,13]

Based on a comparison of various program objectives and characteristics including duration,[3] remote monitoring programs for people with cardiac conditions tend to be of two general forms: programs that are without a pre-specified duration (e.g., ongoing monitoring) and programs that are of a pre-set duration (between four weeks to six months). Remote monitoring programs of a shorter duration are designed to help patients improve their self-management, with the goal that improvements will last beyond the duration of the program. Ongoing remote monitoring programs are also designed to support self-management and can have the additional objective of improving the continuity of care through improved communication between care providers and patients.

Program activities can vary widely within remote monitoring programs for people with cardiac conditions. In general, they include processes that collect and transmit patient data, which is then evaluated and triggers a form of intervention.[1] Data collection and transmission varies by what is collected, how it is collected (e.g., by a device or by the person living with a cardiac condition), how it is transmitted, and when (e.g., frequency) it is transmitted. The data, once received, can be evaluated by a health care provider or program staff, a third party, or an algorithm. Interventions vary in how they are provided and their scope, which can include medication adjustments, prompts to support a healthy diet, increased physical activity, and smoking cessation, or advice to seek in-person care.

The severity of patients' conditions is important when considering remote monitoring programs for people with cardiac conditions.[1] This may be because, for remote monitoring programs to reduce health care utilization and to offset the expense of operating remote monitoring programs, it may be important to enrol patients who are at moderate or high risk of emergency department visits or hospitalization rather than enrolling healthier patients.[1] Hence, many large-scale programs typically describe contact with health care services (e.g., one or more emergency department visits, and so forth) as eligibility criteria.[1,3]

Improved self-management of patients with chronic cardiac conditions through remote monitoring has been viewed as a means of reducing resource utilization across health care systems — including pre-hospital, emergency, acute care, and long-term care settings. These reductions in health care utilization are seen as both freeing up staff time (reducing pressures on health systems) and creating an opportunity for cost savings.[3]

Jurisdictions have expressed interest in an assessment of remote monitoring that explores the following patient groups: heart failure, atrial fibrillation, hypertension, and people eligible for cardiac rehabilitation.

Jurisdictions also expressed interest in an assessment of remote monitoring that includes rural, remote, and urban populations. CADTH Liaison Officers indicated the variability of cardiac care available to patients across the country depending on the type of community in which they live. Therefore, remote monitoring programs may also have different impacts on patients in rural, remote, or urban settings.

Remote Monitoring Programs in Canada

Remote monitoring takes on particular salience in a geographically large country such as Canada, as it enables the delivery of health care outside of health care institutions and thus to patients who live remotely or rurally. In Canada, the remote monitoring of cardiac conditions has been, or is being, studied in a number of projects and jurisdictions.[1,9,12,13,20,22,23] In 2018, the Newfoundland & Labrador Centre for Applied Health Research completed an environmental scan that identified remote monitoring programs for

chronic conditions in place across Canada and selected international jurisdictions to "inform the implementation and evaluation of [remote monitoring] for those living with chronic disease in remote and rural [Newfoundland and Labrador]."[3] The authors identified 22 remote monitoring programs (or initiatives) active in the previous five years, 11 of which were in Canada and enrolled people with cardiac conditions. Of these 11 Canadian remote monitoring programs, some of which enrol more than one type of patient group,:

- eight were available to people with heart failure
- two were open to people with hypertension and one for pulmonary hypertension
- one was for cardiac rehabilitation
- two were available to all people with chronic diseases
- one was open to all people in the province with a provincial health card.

These 11 remote monitoring programs were available to residents of British Columbia, Newfoundland and Labrador, New Brunswick, Ontario, Prince Edward Island, and Quebec. The scan also identified an additional 10 pilot remote monitoring programs or ongoing research studies from Canada. The environmental scan did not discuss barriers or facilitators to implementation, nor did it evaluate the remote monitoring programs identified.

The Need for a Health Technology Assessment

Based on jurisdictional feedback, the stage of diffusion of remote monitoring programs for people with cardiac conditions varies across the country. Some jurisdictions, such as New Brunswick, have well-established programs serving many different patient groups. Others, such as Manitoba and Saskatchewan, are just beginning to explore implementing remote monitoring programs for patients with cardiac conditions. As such, while there is broad interest in the topic, the needs of each jurisdiction vary greatly depending on the level of adoption of remote monitoring technologies. There is also uncertainty about which patients would benefit from participation in remote monitoring programs. Because of existing work, jurisdictions indicated additional assessment of remote monitoring programs for patients with implanted cardiac devices, such as implantable cardioverter-defibrillators, is not needed at this time.

The purpose of a CADTH HTA of this topic is to determine:

- how remote monitoring programs could be used in the management of heart failure, atrial fibrillation, hypertension (excluding hypertension caused by pregnancy), and chronic or acute cardiac rehabilitation
- the barriers and facilitators to implementing remote monitoring programs for people with cardiac conditions and how they can be effectively implemented
- the people living with these cardiac conditions for whom remote monitoring programs would be most suitable
- the lived experience of patients with cardiac conditions participating in remote monitoring programs and their caregivers
- the experience of health care practitioners responsible for patients participating in remote monitoring programs for patients with cardiac conditions.

Decision Problem

According to some jurisdictions, the implementation of remote monitoring technologies is not a question of if it will happen; rather, it is a question of when and how it will happen. Because of this (and the varied stages of diffusion), jurisdictions are faced with the problem of how best to implement remote monitoring programs for patients living in rural, remote, and urban settings. The driver behind this problem appears to be a need — from policy-makers, patients, and health care providers alike — to provide care to patients in their homes or communities, minimizing the need for patients to travel or be transported from their homes to the hospital. However, there is uncertainty about whether remote monitoring programs are safe, if they will have the desired impact on health system usage, about how to implement remote monitoring programs, and about which patients would benefit from them.

Objective(s)

The purpose of this HTA is to address the decision problem through a series of analyses, including a realist review of remote monitoring programs for cardiac conditions; a qualitative evidence synthesis of the perspectives and experiences of those participating in remote monitoring programs for cardiac conditions, including patients, caregivers, and health care providers; stakeholder consultations; and an analysis of ethical considerations. These analyses will be informed by the results of a CADTH environmental scan of remote monitoring programs for cardiac conditions in Canada.[24] As the HTA progresses, other considerations such as costs and the financial impact of implementing remote monitoring programs may be assessed if deemed relevant.

Deliverables

The following deliverable(s) are planned:

- a science report detailing all analyses conducted to inform the decision problem
- a recommendations report detailing all the recommendations and considerations to answer the decision problem.

Research Questions

The proposed HTA will address the decision problem by exploring the following research questions.

1. What aspects (e.g., duration and frequency of monitoring, what is monitored and how) of remote monitoring programs influence patient- and system-level outcomes, for whom, in what circumstances, to what extent, and why?

Perspectives and Experiences Review

2. For people living with a chronic cardiac condition or post-cardiac event, what are their expectations of, experiences with, and perspectives on remote monitoring programs?
3. What are their families' and care providers' expectations of, experiences with, and perspectives on remote monitoring programs?

4. How do people living with a chronic cardiac condition or post-cardiac event, their families, and their care providers experience and understand:
   - how to adopt and use remote monitoring technologies?
   - how remote monitoring programs move health care into peoples' places of residence? What is the impact of this shift on the families of people with a chronic cardiac condition or who are post-cardiac event?
   - the changes in roles and responsibilities that can accompany remote monitoring programs? What is the impact of this shift on the families of people with a chronic cardiac condition or who are post-cardiac event?
   - how and when remote monitoring programs are seen as "working" or as "not working"?

Ethics Analysis

5. What are the ethical issues related to remote monitoring programs?
6. How might these issues be addressed in rural, remote, and urban settings?

Methods

To inform the preparation of this protocol, a preliminary scoping review of the existing literature, including HTAs and evidence syntheses, was conducted. This protocol was written a priori, using appropriate reporting guidelines for guidance on clarity and completeness, and they will be followed throughout the study process. Any deviations from the protocol will be disclosed in the final report.

Realist Review

A realist review will be conducted. Realist reviews are appropriate for understanding the mechanisms by which interventions or programs affect outcomes and how those outcomes are dependent on the context in which they are delivered or implemented. Such interventions may be classified as "complex interventions" because of the number of and interactions between intervention components, the number of levels of the health care system targeted by the intervention, and the number and variability of outcomes.[25] Remote monitoring programs, having these characteristics, can be classified as complex interventions.

Using a realist mode of inquiry, this review will seek to answer the question: What aspects of remote monitoring programs work, for whom, in what circumstances, to what extent, and why?

The focus will be on explaining the relationship between the context in which remote monitoring programs have been implemented, the mechanisms by which they work (or don't), and the outcomes that are produced. The goal will be to inform decisions about how remote monitoring programs can be made to work most effectively. Results and conclusions will take the form of caveats and considerations for those involved in the delivery of remote monitoring programs, such as "'remember A," "beware of B," "take care of C," "D can result in both E and F," "G's and H's are likely to interpret I quite differently," "if you try J, make sure that K, L, and M have also been considered."[26]

A detailed protocol for the realist review will be developed and the HTA protocol will be a amended following active stakeholder engagement to focus the inquiry. While a deviation

from more typical clinical effectiveness reviews, the same broad steps will be followed and outlined in the protocol, including: clarifying the scope; searching for evidence; appraising studies and extracting data; synthesizing evidence and drawing conclusions. Steps will be described sequentially, although in practice will be overlapping and iterative, responding to results as they emerge. As appropriate, the protocol will be drafted ensuring attention is paid to elements described in the Realist And MEta-narrative Evidence Syntheses: Evolving Standards (RAMESES)[27] publication standards.

Perspectives and Experiences Review

This protocol provides a general overview of the methods to be used at each stage of this qualitative evidence synthesis and describes refinements and amendments that may be made during the conduct of this review. This emergent approach to protocol execution is consistent with the inductive principles of qualitative research and allows for the research — and specifically decisions on study selection, data collection, and analysis — to be responsive to the available qualitative literature. Subsequent refinements or amendments will be documented in the final report together with their rationale and updates will be made to the PROSPERO submission accordingly (registration: submitted; registration number not yet received [ID: 211271 October 2]).

The synthesis will be reported using Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) guidelines for reporting qualitative research syntheses.[28]

This protocol was informed by a limited scoping search of the existing qualitative literature on remote monitoring for cardiac conditions. This preliminary reading of the qualitative literature identified concepts, issues, and experiences that served as sensitizing concepts to help orient and develop research questions.

Research Questions: For people living with a chronic cardiac condition or post-cardiac event, what are their expectations of, experiences with, and perspectives on remote monitoring programs? What are their families' and care providers' expectations of, experiences with, and perspectives on remote monitoring programs?

Secondary Research Questions

To ensure the relevance of the analysis to this HTA, a set of secondary research questions will be used to guide and focus the analysis on particular features of the use of remote monitoring programs:

How do people living with a chronic cardiac condition or post-cardiac event, their families, and their care providers, experience and understand:

- how to adopt and use remote monitoring technologies?
- how remote monitoring programs move health care into peoples' places of residence? What is the impact of this shift on the families of people with a chronic cardiac condition or who are post-cardiac event?
- the changes in roles and responsibilities that can accompany remote monitoring programs? What is the impact of this shift on the families of people with a chronic cardiac condition or who are post-cardiac event?
- how and when remote monitoring programs are seen as "working" or as "not working"?

This set of secondary research questions reflect the initial sensitizing concepts and will be used to probe the data and the analysis, and may be further refined during data collection and analysis. Additionally, this review will attend to differences in experiences and understandings by type of cardiac condition and by characteristics of remote monitoring programs (e.g., setting, duration, program design).

Study Design

A qualitative evidence synthesis of primary qualitative research will be conducted to understand peoples' experiences with and perspectives on remote monitoring programs for chronic cardiac conditions and cardiac rehabilitation. Included publications will be synthesized using thematic synthesis.[29] As an approach, thematic synthesis facilitates the development of both descriptive and synthetic findings. Descriptive findings will present the ways in which remote monitoring has been understood and experienced by participants who have engaged with it. Synthetic findings, which move beyond description and present a new interpretation of published literature, will offer additional insight into the phenomena of remote monitoring programs. The primary goal of this review is to consider how remote monitoring plays out in the lives of those who engage with it, and its impact on their lives, their roles and social relations, and their health care.

Literature Search Methods

The search for literature exploring perspectives and experiences will be performed by an information specialist using a peer-reviewed search strategy according to the PRESS Peer Review of Electronic Search Strategies checklist (https://www.cadth.ca/resources/finding-evidence/press).[30] The complete search strategy is presented in Appendix 1.

Published literature will be identified by searching the following bibliographic databases: MEDLINE All (1946–) via Ovid, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCO, and Scopus. The search strategy will comprise both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts will include chronic cardiac conditions, cardiac rehabilitation, and remote monitoring.

Search filters will be applied to limit retrieval to qualitative studies. Retrieval will not be limited by publication date but will be limited to the English language.

The initial search was completed in the summer of 2020. Regular alerts will update the search until the publication of the final report.

Grey literature (literature that is not commercially published) will be identified by searching sources listed in relevant sections of the *Grey Matters: A Practical Tool For Searching Health-Related Grey Literature* checklist (https://www.cadth.ca/grey-matters),[31] which includes the websites of regulatory agencies, HTA agencies, clinical guideline repositories, systematic review repositories, patient-related groups, and professional associations. Google will be used to search for additional internet-based materials. These searches will be supplemented by reviewing bibliographies of key papers and through contacts with experts and industry, as appropriate. See Appendix 1 for more information on the grey literature search strategy.

Selection and Eligibility Criteria

Eligible publications will be primary English-language qualitative studies. For the purpose of this review, qualitative studies are those that use both qualitative data collection methods (e.g., documents, interviews, or participant observation) and qualitative data analysis methods (e.g., constant comparative method, content analysis). Studies that use surveys as a method of data collection will be excluded. Mixed-method studies will be excluded from the qualitative review because of the anticipated large volume of primary qualitative studies that will provide rich data to answer our research question.

Studies that have multiple publications using the same dataset will be included if they report on distinct research questions; duplicate publications using the same data with the same findings, will be reported. Table 1 describes the eligibility criteria to be used, built using the Sample, Phenomenon of Interest, Design, Evaluation, Research type (SPIDER) criteria for framing qualitative evidence synthesis research questions.[32]

Table 1: Selection Criteria Using SPIDER[32]

Sample	Adults persons living with a chronic cardiac condition (i.e., heart failure, hypertension, and atrial fibrillation) or post-cardiac event (i.e., heart attack, cardiac surgery, heart transplant, or angioplasty); persons who care for those living with a chronic cardiac condition or post-cardiac event (e.g., partners, family, health care providers)
Phenomena of interest	Remote monitoring programs for people living with a chronic cardiac condition or post-cardiac event that are delivered by health care systems (i.e., primary care clinics, specialist clinics, outpatient care, community health clinics, or long-term care facilities) and what they do, how they work, what it means for them to work and for whom they work, what is required for them to work; how people with chronic cardiac conditions engage with remote monitoring programs and what is required for them to do so? What are the consequences of doing so on their understanding of their condition, their self-management, their health care and home, and social relationships and changes in roles (impact on friends, family, shifts from family member to caregiver)?
Design	Qualitative studies of any design (e.g., phenomenology, grounded theory, qualitative description)
Evaluation	Expectations, experiences, understandings, social relations and perspectives of people living with a chronic cardiac condition or post-cardiac event and who have engaged with remote monitoring programs, and of those involved in their care
Research type	Primary qualitative studies using qualitative methods for both data collection and data analysis

SPIDER = Sample, Phenomenon of Interest, Design, Evaluation, Research type.

Publications reporting on programs monitoring people with hypertension associated with pregnancy will be excluded. Those reporting on remote monitoring programs that do not exclusively include people living with chronic cardiac conditions or post-cardiac events — that is, which include people living with cardiac conditions as well as those living with other chronic conditions (e.g., chronic obstructive pulmonary disease [COPD], diabetes) — will be included even if there is no separate reporting by cardiac conditions.

Publications that are case reports, editorials, or commentaries, or non–full-text publications (i.e., abstracts), will be excluded.

Screening and Selecting Studies for Inclusion

Title and abstract screening will involve two reviewers experienced with qualitative syntheses who will independently assess titles and abstracts of potentially eligible publications in DistillerSR.[33] At the first level of screening, reviewers will exclude citations based on title and abstract that are assessed as being not qualitative. At the second level of screening, they will assess citations for eligibility based on whether publications were about remote monitoring and about adults with chronic cardiac conditions. Two reviewers will then conduct duplicate full-text screening of publications for which it is difficult to determine eligibility based on title and abstract alone. Differing judgments about publication inclusion will be resolved through discussion. Study selection will be documented and reported using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA) flow diagram.[34]

At this stage, the qualitative reviewers will assess the set of included studies and discuss whether the final set of included studies contains appropriate and sufficient data for analysis, or if there is need to modify the literature search and selection criteria. As qualitative evidence syntheses aim to provide a rich understanding of the experience, perspectives, and expectations of people around remote monitoring, the review team will assess the overall volume of included studies and the relevance of these included studies. To provide appropriately rich data for description, at least 20 studies are needed and ideally these should be highly relevant to the review's research questions.

Given the potential for qualitative literature to include a focus on remote monitoring technologies as opposed to programs, a decision may be needed on the inclusion of studies of single remote monitoring technologies. Device-specific studies (e.g., user experience studies on specific technologies) may be included if they address features of users' experiences that relate to remote monitoring programs more broadly (e.g., learning curve, incentives or disincentives for adoption) and are not solely focused on specific technological design features or users' preferences relating to the specific technology. However, as these types of studies are unlikely to provide needed information on how remote monitoring programs, as a model of health care delivery, shape people's experiences with health care, their self-monitoring, and those of their caregivers and they may otherwise be considered for exclusion. In the event that a set of potentially eligible but not relevant studies on user experiences with specific technologies appears in our search results, the qualitative reviewers will refine the inclusion and exclusion criteria to articulate the features of user experience studies that are being excluded so as to ensure their consistent application.

A second decision may be needed around the types of chronic conditions included in this review. An environmental scan of the Canadian landscape identified that the majority of remote monitoring programs in Canada are targeted to people with COPD.[3] A decision may need to be made that expands the inclusion criteria to other chronic conditions, particularly those that have the potential for acute exacerbations such as COPD and cancer, to capture an appropriate breadth of empirical evidence on remote monitoring programs.

In the event of a high number of potentially eligible studies at the full-text stage, the research team may modify either the inclusion criteria to reduce the number of included studies or use a sampling strategy. If the latter, a purposive sampling strategy will be used. This will begin with the qualitative reviewers independently mapping out key characteristics of the potentially eligible studies including participant type (e.g., a person living with a chronic condition, a family member, a care provider), type of cardiac condition (i.e., atrial fibrillation,

heart failure, hypertension) or post-cardiac event (e.g., heart attack, valve replacement surgery), type of remote monitoring program (i.e., duration, type of technology, setting of care (rural, remote, urban), country, and data richness (assessed as how trustworthy and related to the research question the study is). Based on these attributes, publications will be sampled to ensure diversity in study and participant characteristics, starting with those studies judged to be rich in data. Sampling and analysis will stop when additional included studies do not add further concepts, categories or dimensions to the descriptive and analytic themes.

Data Extraction

One reviewer will extract data describing study and participant characteristics for each included publication, using electronic data extraction forms. Data extraction forms, built a priori, will capture key study features (i.e., first author and country, setting, research objective, methods [study design, data collection], and inclusion criteria), and participant characteristics (i.e., number of participants, type of chronic cardiac conditions, age and gender of participants), and description of remote monitoring (i.e., objective of remote monitoring, duration of monitoring, what was monitored and by whom). Fields may be modified or added during data extraction to aid with the data analysis and assessment of transferability. Study and participant characteristics will be reported in tables and summarized narratively.

Critical Appraisal

The process of critical appraisal is intended to support the qualitative reviewers' understandings of the rigour of the included publications and relevance to this review. The primary reviewer will assess the quality of included publications and will follow Krefting's[35] interpretation of Lincoln and Guba's[36] approach to assessing trustworthiness in quality research. The appraisal will be guided by three primary questions intended to assess if and how a study demonstrated that it collected rich data, conducted a rigorous analysis, and incorporated reflexive practices leading to robust results that were useful for the objectives of this review: Is it credible? Is it trustworthy? Are the results transferable?[35] The 10 items of the Critical Appraisal Skills Programme qualitative checklist[37] will be used as prompts to engage with questions of credibility, trustworthiness, and transferability.

The primary reviewer will conduct the appraisal. The second reviewer will play the role of devil's advocate and will probe the primary reviewer's assessment of the literature on key issues around credibility, trustworthiness and dependability, and transferability through conversation and a review of a table of quality appraisal. Disagreements on the appraisal will be resolved through conversation. Results of the critical appraisal will not be used to exclude studies from this review, but instead to understand the methodological and conceptual limitations of the included publications in specific relation to this review. In particular, the process of critical appraisal will inform the analysis in terms of the limits of what the available empirical research can tell us about peoples' engagement with remote monitoring and the transferability of the results to the research questions and Canadian contexts.

The results of the critical appraisal will be reported as a narrative summary and in a table of quality appraisal, which will document key issues around the credibility, trustworthiness, and transferability of each of the included studies.

Data Analysis and Synthesis

NVivo 11[38] will be used to support the analysis through coding and the management of qualitative data from the included publications.

The primary qualitative reviewer will conduct the analysis, with the second reviewer playing a supporting role to ensure that the concepts, findings, and their connections make sense; to probe and explore other configurations and relationships in the analysis and the data; and to ensure the review and its findings remain relevant to the decision problem this HTA seeks to address.

The analysis will follow the principles of thematic synthesis, which draws on meta-ethnography and grounded theory.[29,39] It involves three stages of formal coding procedures: open coding, descriptive coding, and developing analytic findings.[29] These inductive coding practices draw heavily from grounded theory and use the constant comparison method in which codes and data are compared across codes and within and across publications. From meta-ethnography, thematic synthesis borrows the concept of "reciprocal translation" whereby, in the first and second stage of coding, the process of coding and sorting "like with like" works to translates findings across studies.

The primary qualitative reviewer will begin by open coding the set of included studies, which will enable the identification and description of categories, concepts, issues, and ideas that emerge. Coding at this stage is largely descriptive of the content of the included studies, with the aim of describing the breadth and variation of information therein. Open coding will be guided by the primary research question and short, descriptive codes will be used. Memos will document the primary qualitative reviewer's initial thoughts, impressions, and insights. The primary qualitative reviewer will share written memos and discuss with the second qualitative reviewer periodically during open coding so that interpretations and observations are open to questioning and alternative lines of inquiry and connections can be explored.

Using the secondary research questions as guides, the primary qualitative reviewer will begin to develop and refine a set of descriptive codes, accompanied by memoing and diagramming. This descriptive coding will remain close to the data, describing "second order interpretations" that are consistent with reciprocal translation.[29] Coding is an iterative process, and as new codes emerge inductively, the primary reviewer will recode already coded studies to identify all instances of the concept. As the descriptive codes become hierarchical (i.e., whereby the qualitative reviewers are able to identify higher-order constructs or categories for which descriptive codes are dimensions or facets) and the relationship between codes becomes the subject of the analysis, the coding will move from descriptive coding to analytic synthesis. The second reviewer will be engaged during descriptive coding by reading written memos and diagrams, and will contribute to concept mapping sessions where diagrams of findings and their dimensions and their connections are made; and will encourage reflection on the relationship between descriptive findings and the review questions. Using the constant comparison method, the analysis will explore how differences in types of cardiac conditions and severity, characteristics of patients (e.g., age, gender) and providers (e.g., type of provider), setting (e.g., urban, rural, remote), and program characteristics explain or account for differences in people's perceptions and experiences.

Analytic synthesis is the development of constructs and categories that are interpretations of the data and descriptive findings. To develop analytic themes, memoing and diagramming will be used to assemble and sort the previously established descriptive findings, going back to the data to further develop the relationship between themes and codes. In keeping with the iterative nature of qualitative analysis, the reviewer may revert to descriptive coding to additionally describe dimensions or facets of particular codes or themes in order to develop findings that are conceptually rich (i.e., described in rich detail and clearly supported by data). The purpose of this third stage of coding is interpretation — a new synthesis or interpretation of the existing published data in relation to the decision problem. Analytical synthesis will stop once findings and their relationships have been richly described and no additional descriptive or interpretive insights arise from further analysis.

Triangulating the resultant descriptive and analytic findings with other syntheses and exploring reasons for differences and similarities will strengthen descriptive and analytic findings analysis by enabling the exploration of divergent cases.

Integrating the Qualitative Review Within the HTA

This review aims to complement the other components of this HTA. The primary qualitative reviewer will participate in meetings with people engaged as part of CADTH's patient engagement for this assessment. Listening to these conversations is a way to orient the qualitative analysis to people's experiences with the technology in Canadian jurisdictions and may sensitize the qualitive reviewer to topics or issues arising from their engagement with remote monitoring.

A written draft of preliminary descriptive findings will be shared with the other review authors, and a follow-up conversation to identify areas of convergence and divergence regarding our understanding of the key issues around the uptake, use, and expansion of remote monitoring programs will take place. The descriptive findings of this qualitative review may provide empirical data for the ethics review. Additionally, the findings of this qualitative review will be used to inform the development of the logic models that will be developed as part of the realist review.

Situations or issues of ethics concerns identified in the preliminary findings of the ethics review will be incorporated into the qualitative review during the analysis phase and will be used as sensitizing concepts to explore codes and data. Similarly, with the realist review, particular experiences or concerns of users of remote monitoring may be explored further in the qualitative literature and developed as part of the analysis.

Reflexivity

Reflexivity is an epistemological principle and methodological approach in qualitative research that recognizes the role of the researcher as instrument. Reflexive practices and techniques are those that allow for and facilitate making researcher's observations and interpretations transparent and explicit versus implicit and unacknowledged. This study employs the reflexive practices of memoing and frequent dialogue between the two qualitative reviewers to probe and position reviewers in relation to the analysis. Further, the qualitative reviewers will proactively search for possible alternative interpretations of the analytic findings and triangulate them with additional empirical sources (e.g., published qualitative reviews) and patient engagement activities to identify possible observations and alternative interpretations ignored.

Ethics Analysis

The purpose of this analysis is to identify and reflect upon key ethical concerns that should be taken into account when considering remote monitoring programs. Although other sections of this HTA touch upon broadly ethical concerns, the aim of this analysis is to make such issues explicit and to identify others that may be relevant to any decisions in this regard.

The issues raised in this section can go beyond narrowly defined ethical concerns to encompass broader legal, social, and cultural considerations as well. Nevertheless, the primary emphasis here will be on ethical considerations rather than on legal and social issues.

There are two questions to consider when analyzing remote monitoring programs for managing chronic heart failure, atrial fibrillation, hypertension, and cardiac rehabilitation for acute and chronic conditions:

1. What are the ethical issues related to remote monitoring programs?
2. How might these issues be addressed in rural, remote, and urban settings?

The scope of remote monitoring is quite broad. The ethics analysis will be directed toward decision-makers considering questions at the level of implementing remote monitoring programs rather than toward individual clinicians facing the question of whether to prescribe a given remote monitoring technology at an individual patient level. The scope will not include hypertension associated with pregnancy.

Inquiry

Bioethical analysis requires a two-step approach to identifying potential issues. The first is a review of the ethics, clinical, and public health literatures to identify existing ethical analyses of the technology. The second is a novel ethical analysis based on gaps identified in the ethics literature and the results of concurrent reviews. This may require selective searches to provide the basis in theoretical ethics, in applied ethical analyses of similar technologies, and in evidence for the ethical analysis of emerging issues specific to remote monitoring programs. By this approach, we identify and assess the relative importance and strength of the identified concerns and proposed solutions, identify and assess issues that have not yet come to the attention of the ethics researchers, and delineate ethical desiderata for possible solutions to the issues where such solutions have not yet been proposed.

Insofar as this process involves ethical concerns in applied ethics, typically the analysis will reflect on the specific details of community and patient perspectives, clinical utility, economic analysis, environmental impacts, and implementation considerations. As such, the ethical review involves an iterative process whereby the analysis is responsive to results emerging from the perspectives and experiences, and realist reviews.

Based on early discussions within the project team, it is anticipated that the ethics inquiry will at least consider the extent to which the technology may:

- pose risks to, or incursions on a patient's privacy and confidentiality, specifically to do with how health data gathered by the technology will be owned, stored, transmitted, and accessed
- limit or affect a patient's capacity to exercise their autonomy, particularly if the technology includes ongoing monitoring and surveillance

- raise concerns regarding justice in the health care system, particularly regarding the funding and accessibility of remote monitoring programs (e.g., would funding of remote monitoring result in disinvestment in other aspects of cardiology programs, including technologies or access to in-person clinical services) and possibly related to people with comorbidities or who are less able to self-manage care, and so forth.
- elicit tensions or inconsistencies between the interests of industry and those of the health system, particularly if the technology is being heavily marketed directly to patients and physicians
- produce signals that patients require medical intervention or appointments when such access is not available (e.g., in remote settings).

Perspectives

The relevant perspectives that need to be considered in identifying and addressing the ethical issues associated with the various treatments for remote monitoring programs include patients, family members or informal caregivers, patient organizations, health care providers, and health care system-level decision-makers.

Review of the Bioethics Literature

A review of the empirical and normative bioethics literature will be conducted to identify literature relevant to the identification and analysis of the potential ethical issues related to the use of remote monitoring programs.

We will search primarily for articles, studies, and reports that explicitly and specifically raise ethical issues related to the use of remote monitoring technologies for management (not diagnosis) of chronic heart failure, atrial fibrillation, hypertension, and cardiac rehabilitation for acute and chronic conditions across rural, remote, and urban settings.

If this initial search fails to yield sufficiently detailed or comprehensive resources, literature which implicitly points to ethical issues may also be included.

Literature Search Methods

The search for literature identifying explicit ethical considerations will be performed by an information specialist using a peer-reviewed search strategy according to the PRESS checklist (https://www.cadth.ca/resources/finding-evidence/press).[30] The search strategy will be available on request.

Published literature will be identified by searching the following bibliographic databases: MEDLINE All (1946–) via Ovid and the CINAHL via EBSCO. The search strategy will comprise both controlled vocabulary, such as the National Library of Medicine's MeSH, and keywords. The main search concepts will be chronic cardiac conditions, cardiac rehabilitation, and remote monitoring.

Search filters will be applied to limit retrieval to citations related to empirical and normative ethical considerations. Retrieval will not be limited by publication date but will be limited to the English or French language. The initial search was be completed in the summer 2020. Regular alerts will update the search until the publication of the final report.

Grey literature (literature that is not commercially published) will be identified by searching sources listed in relevant sections of the *Grey Matters: A Practical Tool For Searching Health-Related Grey Literature* checklist (https://www.cadth.ca/grey-matters),[31] which

includes the websites of regulatory agencies, HTA agencies, clinical guideline repositories, systematic review repositories, patient-related groups, and professional associations. Google will be used to search for additional internet-based materials. These searches will be supplemented by reviewing bibliographies of key papers and through contacts with experts and industry, as appropriate. See Appendix 1 for more information on the grey literature search strategy.

Literature Screening and Selection

The selection of relevant literature will proceed in two stages. In the first stage, the title and abstracts of citations will be screened for relevance independently by a single reviewer. Articles will be categorized as "retrieve" or "do not retrieve," according to the following criteria:

- explicitly provides normative analysis of an ethical issue arising in the use of remote monitoring, whether for the treatment of the conditions of interest or more generally
- presents empirical research directly addressing an ethical issue arising in the use of remote monitoring.

The goal in a review of bioethics literature is to canvass what arises as an ethical issue from a broad range of relevant perspectives. As such, the quality of normative analysis does not figure in the article selection criteria: any identification of an issue by the public, patients, health care providers, researchers, or policy-makers is of interest whether presented through rigorous ethical argumentation or not. For example, academic ethicists may focus on certain issues because these relate to theoretical trends in their discipline, while an opinion piece by a clinical or policy leader, or a patient experience, may point to ethical questions that are neglected by academic ethicists but highly pertinent to the assessment of the technology in the relevant context. Despite the different standards of normative argumentation for each kind of report, the importance of the issues raised cannot be assessed solely by these standards and so literature cannot be excluded based on methodological standards.

In the second stage, the full-text reports will be reviewed by a single reviewer with ethics expertise. Reports meeting the aforementioned criteria will be included in the analysis, while reports that do not meet these criteria will be excluded from analysis.

Data Extraction and/or Abstraction Strategy

The bibliographic details for each report (e.g., author, publication date, journal), the potential ethical issues raised, and the report's conclusions (issues identified, values at stake identified through normative analysis, and solutions proposed, and their normative justification if presented) may be summarized in a table if this is deemed relevant and useful.

Analysis

The ethical issues identified, values described, and solutions proposed in the literature will at this stage be evaluated using the methods of ethical (applied philosophical) analysis. This includes applying standards of logical consistency and rigour in argumentation, particularly where specific implications are identified and specific solutions advocated; responsiveness to important values of health care and health care policy in the field in which the technology is proposed for implementation; adequacy to the context for which the technology is being considered; and the representation of perspectives from diverse relevant communities,

particularly attending to the possibility of the neglect of marginalized and vulnerable populations.

The proposed analysis will draw most directly on two classic perspectives that are well-established in the health ethics literature, namely the utilitarian/consequentialist approach and the deontological/duty-based approach. The former focuses more directly on the overall consequences of a particular course of action and deals with questions of individual rights and duties, and considerations of social justice, only indirectly. Conversely, the deontological approach gives priority to considerations of individual rights and concomitant duties, while treating overall utility (i.e., the greatest good for the greatest number) as of only secondary importance. While these two theoretical approaches are often treated as opposed, there is a well-established tradition within contemporary health care ethics that treats them as complementary. Depending on the nature of the issue and the context in which it arises, it is possible that other normative ethical perspectives may be invoked in the analysis.

Summarizing and Presenting Results

The reporting of ethical issues will follow the key values identified or issues being explored and will be determined by the values and issues that are identified. For example, the results may be summarized according to a principlist framework (issues concerned with autonomy, beneficence, non-maleficence, and justice) or by categorizing moral concerns as micro-, meso-, and macro-level issues. Regardless of the framework selected, the implications of the choice of framework on how the findings are presented and interpreted will be described. In addition, where the report undertakes analysis that is not derived from the peer-reviewed literature, this will be noted. It may also be appropriate to summarize the bibliographic details for each report (e.g., author, publication date, journal), the potential ethical issues raised, and the report's conclusions, as well as other information. The relevance and appropriateness of providing this summary will be determined after the analysis is complete.

Ethical analysis assists in social and policy decision-making but is not itself the site of legitimate social decision-making, which requires the consultation and deliberation on the part of relevant stakeholders in a given context. Decisions will also be sensitive to emerging empirical evidence. Furthermore, the ethical implications of a health technology are often determined by the nature of the local context. The implications of values of fair access and consistency of service within the population, for example, are determined by facts about how health care services are arranged and provided.

Given these features of ethical decision-making, results of the ethics review will be presented in a way that helps decision-makers better understand the ethical implications of the decisions and recommendations they come to. For example, a number of contextualizing questions may be developed based on the identified issues so that decision-makers can assess localized impact; and proposed solutions will be analyzed to indicate the relevant ethical trade-offs at stake and mitigation strategies that could be employed to manage these trade-offs.

Stakeholder Consultation

To help inform decision-making about the design, delivery, and spread of remote monitoring programs, stakeholder consultations will be used to explore and identify the human and system factors that influence the successful adoption, implementation, and expansion of remote monitoring programs for chronic cardiac conditions and for cardiac rehabilitation in Canada.

CADTH staff will identify potential stakeholders through existing CADTH networks and other relevant national or provincial stakeholder groups. Stakeholders will include, but will not be limited to, policy-makers (e.g., at the ministry level), clinicians (e.g., cardiologists, primary care providers, nurse educators), technical staff (e.g., information technology staff), and health system managers. Potential participants will be sampled using a purposive sampling strategy to focus on exploring emergent findings relating to the question of how to increase the spread of remote monitoring programs and/or to scale up existing programs. Additionally, consideration will be given to the breadth across types of stakeholders, geography (e.g., rural, remote, and urban), and of remote monitoring program (e.g., cardiac rehabilitation, chronic heart failure). The aim is to continue with stakeholder consultations until no new information is emerging (data saturation); however, sample size may also be limited because of time and resource constraints. Stakeholders will be asked to provide informed consent on the purpose and process of the consultations, as well as permission to anonymously use any relevant information they may provide as part of the final HTA report results. The consultation sessions will be recorded, with consent.

The consultations will be facilitated by CADTH staff members with expertise in stakeholder engagement, policy analysis, and in interview techniques. A semi-structured consultation guide will be used and will include domains of human (e.g., ease of use, perceptions of value) and system factors (e.g., resource needs, workforce training needs) that may shape the implementation of remote monitoring programs. The guide will be tailored to the type of stakeholder being consulted (e.g., policy-maker, clinician, program support staff, health system manager) and will be refined and modified throughout the consultation process as new domains or issues of interest arise.

Memos and diagraming will be used to organize the initial findings arising from stakeholder consultations.

The results of the stakeholder consultations will be reported narratively and key policy issues and considerations raised by stakeholders will be described. Additionally, the stakeholder consultations will inform other sections of this review and initial findings will be presented orally to the ethics, qualitative, and clinical reviewers, as well as being reflected on during the writing of the discussion and consultation section of this HTA.

Knowledge Mobilization

Knowledge mobilization activities will include relevant educational outreach and related activities to increase the demand and use of the HTA. This includes supporting the implementation of any resulting decisions or changes to the health care system or health service delivery. Efforts will also be made to ensure CADTH activities and products meet the needs of key stakeholders, such as jurisdictional bodies, health care providers, remote monitoring program users, and other users of health evidence. Implementation issues identified in the report will help guide some of the knowledge mobilization activities.

Patient Engagement

CADTH involves patients, families, and patient groups to improve the quality and relevance of our assessments, ensuring that those affected by the assessments have an opportunity to contribute to them. CADTH has adopted a Framework for Patient Engagement in HTA. The Framework includes standards for patient involvement in individual HTAs and is used to support and guide our activities involving patients. For this HTA, the value of relevance and

the belief that patients have knowledge, perspectives, and experiences that are unique and contribute to essential evidence for HTA will guide our patient engagement activities. CADTH will engage between 1 and 5 adults with the experience of being in a remote monitoring program for their cardiac condition.

Invitation to Participate and Consent

People will be identified through CADTH's connections to heath care staff operating remote monitoring programs in Ontario, New Brunswick, and Newfoundland. A CADTH Patient Engagement Officer will contact potential participants by phone to explore their interest in becoming involved. The preliminary request will include the purpose and scope of this HTA, the purpose of engagement, and the nature of engagement activities. The Patient Engagement Officer will obtain the person's informed consent to share their information and comments with CADTH staff.

Engagement will occur prior to protocol finalization, during drafting of the initial reviews, and upon completion of final report.

Perspectives gained through engagement processes will be used in several ways, including ensuring the relevance of outcomes of interest for the realist review, commenting on themes emerging from the experiences and perspectives and ethics reviews, and stakeholder consultations, and commenting on other key concepts that were initially identified through prior scoping activities. Patient engagement enables the research team to consider the evidence alongside an understanding of the wider experiences of patients and caregivers. Patients may provide valuable feedback on the clarity of writing and comment on the relevance of the findings to Canadian patients and families.

Once preliminary findings are available, the same people will be invited to a discussion with the researchers. The conversation will explore the person's perceptions of key findings, including if the findings are understandable, and if they reflect personal experiences or understandings. This conversation will be used to consider the possible need to explore avenues of analysis that have been missed or underdeveloped, add additional concepts or experiences that relate to identified categories, or inform the processes underlying the remote monitoring program and the context of analysis.

Final conversations will be had upon completion of the final clinical report. Through conversation, CADTH will share the key results of the full assessment and describe how engagement activities were used.

Reporting

The reporting of this section will follow the GRIPP2 short form reporting checklist[40] and include the outcomes, discussion, and reflection items as suggested by that guidance to outline in a final report the process of engagement and where and how participants' contributions were used in the assessment. The Patient Engagement Officer will keep track of patient engagement activities and interactions in detailed notes and communications. CADTH will provide reflections and critical perspectives on the experience of the involvement for the patient, the family caregiver, and the research team in the final report.

Opportunities for Stakeholder Feedback

All stakeholders will be given the opportunity to provide feedback on the draft report, the draft included studies list, and the recommendations, if applicable. Unpublished data identified as part of the feedback process may only be included if the source of data is in the public domain.

Protocol Amendments

If amendments are required at any time during the HTA, reasons for changes will be recorded in a study file and subsequently reported within the final HTA report. If necessary, a rescreening of any previous literature search or an updated literature search will be performed to capture additional data, according to the amendments.

References

1. Connecting Patients with Providers: A Pan-Canadian Study on Remote Patient Monitoring. Toronto (ON): Canada Health Infoway; 2014: https://www.infoway-inforoute.ca/en/component/edocman/1918-rpm-benefits-evaluation-study-full-report-final/view-document?Itemid=0. Accessed 2019 Jun 22.
2. Care Innovations. What Is Telehealth? What Is Remote Patient Monitoring? How Are They Different? https://news.careinnovations.com/blog/what-is-telehealth-what-is-remote-patient-monitoring-how-are-they-different. Accessed 2020 Sep 22.
3. Mackey S, Bornstein S. Remote patient monitoring: a jurisdictional scan. St. John's (NL): Newfoundland & Labrador Centre for Applied Health Research (NLCAHR); 2018: https://www.nlcahr.mun.ca/CHRSP/Remote_Patient_Monitoring_SEPT_2018.pdf. Accessed 2019 Jun 22.
4. The Burden of Heart Failure. Ottawa (ON): Heart and Stroke Foundation; 2016: https://www.heartandstroke.ca/-/media/pdf-files/canada/2017-heart-month/heartandstroke-reportonhealth-2016.ashx?la=en&hash=0478377DB7CF08A281E0D94B22BED6CD093C76DB. Accessed 2020 Sep 22.
5. Heart disease in Canada: Highlights from the Canadian Chronic Disease Surveillance System. Ottawa (ON): Public Health Agency of Canada; 2017: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/heart-disease-canada-fact-sheet.html. Accessed 2020 Sep 22.
6. Heart and Stroke Foundation. What is Atrial Fibrillation? http://www.heartandstroke.ca/heart/conditions/atrial-fibrillation. Accessed 2018 Oct 5.
7. Statistics Canada. Table 13-10-0096-09 High blood pressure, by age group. 2018; https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310009609. Accessed 2020 Sep 22.
8. Grace SL, Bennett S, Ardern CI, Clark AM. Cardiac rehabilitation series: Canada. *Prog Cardiovasc Dis.* 2014;56(5):530-535.
9. Lear SA, Banner-Lukaris D. The use of the internet to deliver cardiac rehabilitation remotely to patients with cardiovascular disease: report of the "Virtual" Cardiac Rehabilitation Program. Burnaby (BC): Simon Fraser University; 2014: https://www.infoway-inforoute.ca/en/component/edocman/2111-the-use-of-the-internet-to-deliver-cardiac-rehabilitation-remotely-to-patients-with-cardiovascular-disease/view-document?Itemid=0. Accessed 2020 Jun 22.
10. Medical Advisory Secretariat, Ministry of Health and Long Term Care. Remote monitoring of implantable cardioverter-defibrillators, cardiac resynchronization therapy, and permanent pacemakers: a health technology assessment. *Ont Health Technol Assess Ser.* 2018;18(7):1-199. https://www.hqontario.ca/Portals/0/documents/evidence/reports/hta-remote-monitoring-of-implantable-cardioverter-en.pdf. Accessed 2020 Sep 23.
11. Yee R, Verma A, Beardsall M, Fraser J, Philippon F, Exner DV. Canadian Cardiovascular Society/Canadian Heart Rhythm Society joint position statement on the use of remote monitoring for cardiovascular implantable electronic device follow-up. *Can J Cardiol.* 2013;29(6):644-651.
12. Ontario Telemedicine Network Telehomecare Deployment Project: Phase 2 - Remote Patient Monitoring RPM-05B - Benefits Evaluation Report. Toronto (ON): Canada Health Infoway; 2016: https://www.infoway-inforoute.ca/en/component/edocman/3176-ontario-telemedicine-network-telehomecare-deployment-project-phase-2-remote-patient-monitoring/view-document?Itemid=0. Accessed 2020 Sep 22.
13. Buhler H. Interior Health Cardiac Home Monitoring Project – Phase II: 2016- 2018. Benefits Evaluation Report. Kelowna (BC): Interior Health; 2018: https://www.infoway-inforoute.ca/en/component/edocman/3550-interior-health-cardiac-home-monitoring-project-phase-ii-2016-2018/view-document?Itemid=0. Accessed 2020 Sep 22.
14. Hypertension Canada. Blood Pressure Devices: Blood Pressure Devices Recommended by Hypertension Canada. 2018; https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/. Accessed 2020 Sep 22.
15. AliveCor. Kardiamobile. 20202; https://www.alivecor.com/kardiamobile. Accessed 2020 Sep 23.
16. FibriCheck. Home Page. 2018; https://fibricheck.com/. Accessed 2020 Sep 22.
17. Apple. Apple Watch Series 4: Health. 2018; https://www.apple.com/ca/apple-watch-series-4/health/. Accessed 2018 Oct 30, 2018.
18. Cloud Dx. Pulsewave Health Monitor. 2018; https://www.clouddx.com/#/pulsewavedevice. Accessed 2020 Sep 22.
19. TELUS Health. Home Health Monitoring (HHM). 2018; https://www.telushealth.co/health-solutions/patient-and-consumer-health-platforms/products/home-health-monitoring/. Accessed 2020 Sep 22.
20. Second Opinion Telemedicine Solutions Inc. Horizon Health Network New Brunswick. 2017; https://www.sotelemed.com/portfolio/horizon.html. Accessed 2020 Sep 22.
21. Ezekowitz JA, O'Meara E, McDonald MA, et al. 2017 Comprehensive Update of the Canadian Cardiovascular Society Guidelines for the Management of Heart Failure. *Can J Cardiol.* 2017;33(11):1342-1433.
22. Remote Patient Monitoring Project: Canada Health Infoway - Benefits Evaluation Report. Charlottetown (PE): Health PEI; 2017: https://www.infoway-inforoute.ca/en/component/edocman/3476-remote-patient-monitoring-project-prince-edward-island/view-document?Itemid=0. Accessed 2020 Sep 23.

23. Zeidenberg J. 'Tricorder' enables patients to diagnose 15 illnesses. Thornhill (ON): Canadian Healthcare Technology; 2015: https://www.canhealth.com/2015/02/27/tricorder-enables-patients-to-diagnose-15-illnesses/. Accessed 2020 Sep 22.
24. Remote Monitoring Programs for Cardiac Conditions in Canada. *(CADTH Environmental Scan)*. Ottawa (ON): CADTH; [forthcoming]: https://cadth.ca/remote-monitoring-programs-cardiac-conditions-canada. Accessed 2020 Sep 23.
25. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. London (UK): Medical Research Council; 2019: https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/. Accessed 2020 Sep 22.
26. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review--a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy.* 2005;10(Suppl 1):21-34.
27. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC Med.* 2013;11(21):21.
28. Tong A, Flemming K, McInnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. *BMC Med Res Methodol.* 2012;12:181.
29. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol.* 2008;8:45.
30. McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS Peer Review of Electronic Search Strategies: 2015 guideline statement. *J Clin Epidemiol.* 2016;75:40-46. https://www.sciencedirect.com/science/article/pii/S0895435616000585?via%3Dihub. Accessed 2019 Apr 10.
31. Grey matters: a practical tool for searching health-related grey literature. Ottawa (ON): CADTH; 2018: https://www.cadth.ca/resources/finding-evidence. Accessed 2019 Apr 10.
32. Cooke A, Smith D, Booth A. Beyond PICO: the SPIDER tool for qualitative evidence synthesis. *Qual Health Res.* 2012;22(10):1435-1443.
33. *Distiller SR* [computer program]. Ottawa (ON): Evidence Partners; 2017.
34. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol.* 2009;62(10):e1-e34.
35. Krefting L. Rigor in qualitative research: the assessment of trustworthiness. *Am J Occup Ther.* 1991;45(3):214-222.
36. Lincoln Y, Guba E. *Naturalistic inquiry.* Thousand Oaks (CA): SAGE Publishing; 1985.
37. CASP qualitative checklist. Oxford (UK): Critical Appraisal Skills Programme; 2018: https://casp-uk.net/wp-content/uploads/2018/01/CASP-Qualitative-Checklist-2018.pdf. Accessed 2019 Aug 21.
38. *NVivo qualitative data analysis.* Version 11 ed. Doncaster (AU): QSR International Pty Ltd; 2015.
39. Booth A, Noyes J, Flemming K, et al. Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex interventions. Bremen (DE): Integrated Health Technology Assessment for Evaluating Complex Technologies (INTEGRATE-HTA); 2016: https://www.integrate-hta.eu/wp-content/uploads/2016/02/Guidance-on-choosing-qualitative-evidence-synthesis-methods-for-use-in-HTA-of-complex-interventions.pdf. Accessed 2020 Sep 22.
40. Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ.* 2017;358:j3453.

Appendix 1: Literature Search Strategy

Perspectives and Experiences

OVERVIEW	
Interface:	Ovid
Databases:	MEDLINE All (1946 to present) **Note:** Subject headings have been customized for each database. Duplicates between databases were removed in Ovid.
Date of Search:	Summer 2020
Alerts:	Monthly search updates until project completion
Study Types:	Qualitative studies
Limits:	Language limit: English- and French-language

SYNTAX GUIDE	
/	At the end of a phrase, searches the phrase as a subject heading
MeSH	Medical Subject Heading
exp	Explode a subject heading
*	Before a word, indicates that the marked subject heading is a primary topic; or, after a word, a truncation symbol (wildcard) to retrieve plurals or varying endings
#	Truncation symbol for one character
adj#	Requires terms to be adjacent to each other within # number of words (in any order)
.ti	Title
.ab	Abstract
.kf	Author keyword heading word (MEDLINE)
.pt	Publication type
.jw	Journal word title

OVID MEDLINE STRATEGY

Line #	Search Strategy
1	exp heart failure/
2	((heart or cardiac* or cardio* or myocardi* or diastolic* or systolic* or paroxysmal*) adj5 (failure* or edema* or oedema* or decompensation* or dyspnea* or asthma* or chronic*)).ti,ab,kf.
3	((preserved ejection* or reduced ejection*) adj5 fraction*).ti,ab,kf.
4	(congestive heart* adj5 disease*).ti,ab,kf.
5	((cardio renal* or cardiorenal* or reno cardiac* or renocardiac*) adj5 syndrome*).ti,ab,kf.
6	exp Hypertension/

OVID MEDLINE STRATEGY	
Line #	**Search Strategy**
7	(hypertension* or ((high* or elevat*) adj5 (blood pressure* or bloodpressure* or diastolic pressure* or systolic pressure*))).ti,ab,kf.
8	exp Arrhythmias, Cardiac/
9	(arrhythmia* or dysrhythmia* or bradycardia* or bradyarrhythmia* or tachycardia* or tachyarrhythmia*).ti,ab,kf.
10	((irregular* or slow* or rapid* or fast or junctional*) adj3 (heartbeat* or heart beat* or rhythm*)).ti,ab,kf.
11	((atrial or auricular or ventricular) adj5 (fibrillation* or flutter*)).ti,ab,kf.
12	((heart rhythm* or cardiac rhythm*) adj5 disorder*).ti,ab,kf.
13	(premature adj3 (atrial or ventricular or junctional or cardiac) adj3 (contraction* or complex*)).ti,ab,kf.
14	((accelerat* or junctional*) adj5 rhythm*).ti,ab,kf.
15	(extra beats or heart block or heart blocks or AV block or AV blocks).ti,ab,kf.
16	Coronary Artery Disease/
17	(atherosclerosis or atherosclerоses or arteriosclerosis or arteriosclerоses or (coronary adj5 disease*)).ti,ab,kf.
18	(hard* adj3 arter*).ti,ab,kf.
19	(plaque adj4 build*).ti,ab,kf.
20	Cardiac Rehabilitation/
21	((cardiac* or cardio* or heart*) adj5 (rehab* or conditioning*)).ti,ab,kf.
22	or/1-21
23	exp telemedicine/ or exp Videoconferencing/ or exp computer communication networks/
24	(teleconsult* or telemonitor* or RPC or RPM or telemetry or telemetric* or telepatholog* or teleradialog* or videoconference* or video conference* or asynchron* or ((remote or tele or virtual or rural or urban) adj5 (consult* or monitor* or checkin or check in or pathol* or radialog*))).ti,ab,kf.
25	(telehealth* or telemed* or telecommunicat* or tele communicat* or e health* or ehealth* or m health* or mhealth* or e consult* or econsult* or telecar* or HBPMTM or ((tele or mobile or virtual) adj5 (health* or med* or care or caring or visit or visits or appointment*))).ti,ab,kf.
26	(telerehab* or ((remote* or tele* or virtual*) adj5 rehab*)).ti,ab,kf.
27	(telemed* or tele med* or telehealth* or tele health* or telerehab* or tele rehab* or telecar* or tele car* or e health* or ehealth or m Health* or mHealth* or e consult* or econsult*).jw.
28	or/23-27
29	exp Empirical Research/ or Interviews as Topic/ or Personal Narratives as Topic/ or Focus Groups/ or exp Narration/ or Nursing Methodology Research/ or Narrative Medicine/
30	(Interview or Personal Narrative).pt.
31	interview*.ti,ab,kf.
32	qualitative.ti,ab,kf,jw.
33	(theme* or thematic).ti,ab,kf.
34	ethnological research.ti,ab,kf.
35	ethnograph*.ti,ab,kf.
36	ethnomedicine.ti,ab,kf.

OVID MEDLINE STRATEGY	
Line #	**Search Strategy**
37	ethnonursing.ti,ab,kf.
38	phenomenol*.ti,ab,kf.
39	(grounded adj (theor* or study or studies or research or analys?s)).ti,ab,kf.
40	life stor*.ti,ab,kf.
41	(emic or etic or hermeneutic* or heuristic* or semiotic*).ti,ab,kf.
42	(data adj1 saturat$).ti,ab,kf.
43	participant observ*.ti,ab,kf.
44	(social construct* or postmodern* or post-structural* or post structural* or poststructural* or post modern* or post-modern*).ti,ab,kf.
45	(action research or cooperative inquir* or co operative inquir* or co-operative inquir*).ti,ab,kf.
46	(humanistic or existential or experiential or paradigm*).ti,ab,kf.
47	(field adj (study or studies or research or work)).ti,ab,kf.
48	(human science or social science).ti,ab,kf.
49	biographical method.ti,ab,kf.
50	theoretical sampl*.ti,ab,kf.
51	((purpos* adj4 sampl*) or (focus adj group*)).ti,ab,kf.
52	(open-ended or narrative* or textual or texts or semi-structured).ti,ab,kf.
53	(life world* or life-world* or conversation analys?s or personal experience* or theoretical saturation).ti,ab,kf.
54	((lived or life) adj experience*).ti,ab,kf.
55	cluster sampl*.ti,ab,kf.
56	observational method*.ti,ab,kf.
57	content analysis.ti,ab,kf.
58	(constant adj (comparative or comparison)).ti,ab,kf.
59	((discourse* or discurs*) adj3 analys?s).ti,ab,kf.
60	(heidegger* or colaizzi* or spiegelberg* or merleau* or husserl* or foucault* or ricoeur or glaser*).ti,ab,kf.
61	(van adj manen*).ti,ab,kf.
62	(van adj kaam*).ti,ab,kf.
63	(corbin* adj2 strauss*).ti,ab,kf.
64	or/29-63
65	22 and 28 and 64
66	limit 65 to (english or french)

OTHER DATABASES		
Scopus	Searched to capture records not found in MEDLINE. Same MeSH, keywords, limits, and study types used as per MEDLINE search, with appropriate syntax used.	
CINAHL	Same MeSH, keywords, and limits used as per MEDLINE search, excluding study types and human restrictions. Syntax adjusted for EBSCO platform, including the addition of CINAHL headings.	

Grey Literature

Search dates:	Summer 2020
Keywords:	[(remote monitoring OR remote consultation OR remote check-in) AND (heart failure OR atrial fibrillation OR hypertension OR cardiac rehabilitation)]
Limits:	No date limits
Updated:	Search updated prior to the completion of stakeholder feedback period

Relevant websites from the following sections of the CADTH grey literature checklist *Grey Matters: A Practical Tool For Searching Health-Related Grey Literature* (https://www.cadth.ca/grey-matters) were searched:

- Health Technology Assessment Agencies
- Health Economics
- Clinical Practice Guidelines
- Drug and Device Regulatory Approvals
- Advisories and Warnings
- Drug Class Reviews
- Clinical Trial Registries
- Databases (free)
- Health Statistics
- Internet Search
- Open Access Journals