Quality-Based Procedures: Clinical Handbook for **Heart Failure (Acute and Postacute)**

Health Quality Ontario &
Ministry of Health and Long-Term Care

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(This handbook includes, in its acute phase, an update of the Clinical Handbook for Congestive Heart Failure, published in April 2013.)

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. Health Quality Ontario works with clinical experts, scientific collaborators, and field evaluation partners to develop and publish research that evaluates the effectiveness and cost-effectiveness of health technologies and services in Ontario.

Based on the research conducted by Health Quality Ontario and its partners, the Ontario Health Technology Advisory Committee (OHTAC)—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy makers.

Rapid reviews, evidence-based analyses and their corresponding OHTAC recommendations, and other associated reports are published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About the Quality-Based Procedures Clinical Handbooks

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Funding initiative, Health Quality Ontario works with multidisciplinary expert advisory panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Funding initiative, visit www.hqontario.ca.

Disclaimer

The content in this document has been developed through collaborative efforts between the Ministry of Health and Long-Term Care, the Evidence Development and Standards branch at Health Quality Ontario, and the Acute and Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel. The template for the Quality-Based Procedures Clinical Handbook and all content in the "Purpose" and "Introduction to Quality-Based Procedures" sections were provided in standard form by the Ministry. All other content was developed by Health Quality Ontario with input from the expert advisory panel. As it is based in part on rapid reviews and expert opinion, this handbook may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its reports. In addition, it is possible that other relevant scientific findings may have been reported since completion of the handbook and/or rapid reviews. This report is current to the date of the literature search specified in the Research Methods section of each rapid review. This handbook may be superseded by an updated publication on the same topic. A list of all Health Quality Ontario's Quality-Based Procedures Clinical Handbooks is available at: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/clinical-handbooks.

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List of Abbreviations

AGREE	Appraisal of Guidelines for Research & Evaluation
CCI	Canadian Classification of Health Interventions
CCS	Canadian Cardiovascular Society
DAD	Discharge Abstract Database
DNR	Do not resuscitate
ED	Emergency department
EHMRG	Emergency Heart Failure Mortality Risk Grade
Expert advisory panel	Acute Heart Failure Episode-of-Care Advisory Panel or Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel
GRADE	Grades of Recommendation, Assessment, Development, and Evaluation
HARP	Hospital Admission Risk Prediction
HBAM	Health-Based Allocation Model
HF	Heart failure
HIG	HBAM Inpatient Grouper
ICD-10-CA	International Classification of Diseases
ICES	Institute for Clinical Evaluative Sciences
LHIN	Local Health Integration Network
LOS	Length of stay
LVAD	Left ventricular assistive device
MCC	Major clinical category
NACRS	National Ambulatory Care Reporting System
OHTAC	Ontario Health Technology Advisory Committee
QBP	Quality-Based Procedure
RCT	Randomized controlled trial

Preface

This document has been developed through collaborative efforts between the Ministry of Health and Long-Term Care, Health Quality Ontario, and its Acute Heart Failure Episode-of-Care Advisory Panel and Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel (the "expert advisory panel").

The content in the following "Purpose" and "Introduction" sections were provided in standard form by the Ministry. Health Quality Ontario developed all other content with input from the expert advisory panels.

The content of this Clinical Handbook was developed to conform with specific deliverables agreed upon by the Ministry and Health Quality Ontario.

In the area of quality-based procedures, Health Quality Ontario will:

- Take a provincial leadership role in knowledge translation related to quality-based procedures (QBP) work.
- Include in their analyses consultations with clinicians and scientists who have knowledge and expertise in identified priority areas, either by convening a reference group or engaging an existing resource of clinicians and scientists.
- Work with the reference group to:
  - Define the population or patient cohorts for analysis and refine inclusion and exclusion criteria for the QBP, using data to review use and length of stay (LOS) trends.
  - Develop clinical best practices for defined QBP including transition to the community.
  - Seek consensus on a set of evidence-based clinical pathways and standards of care for each episode of care.
- Submit to the Ministry, within the deadlines set by the Agreement, a draft report and clinical handbook, including:
  - A summary of Health Quality Ontario's clinical engagement process.
  - Guidance on the real-world implementation of recommended practices contained in the Clinical Handbook, with a focus on implications for multidisciplinary teams, service capacity planning considerations, and new data collection requirements.

The Ministry also asked Health Quality Ontario to recommend performance indicators aligned with the chosen episodes of care, in order to inform the Ministry's Integrated Scorecard and to provide guidance on real-world implementation of the recommended practices contained in the Clinical Handbook. The Ministry asked that recommendations focus on implications for multidisciplinary teams, service capacity planning considerations, and new data collection requirements.

Key Principles

Discussions between Health Quality Ontario, expert advisory panels, and the Ministry established a set of key principles or "ground rules" to guide this evolving work:

- **Handbook analysis does not involve costing or pricing.** The Ministry will complete all costing and pricing related to the QBP funding methodology by using a standardized approach, informed by the content produced by Health Quality Ontario. This principle also extends to the deliberations of the expert advisory panels, where discussions are steered away from considering the dollar cost of particular interventions or models of care and instead toward focusing on quality considerations and noncost measures of use, such as LOS.
- **The scope of this work includes both hospital care and postacute, community care.** Recognizing the importance of this issue, the Ministry has communicated that conditions analyzed will span all parts of the continuum of care.
- **Recommended practices, supporting evidence, and policy applications will be reviewed to determine if an updated is required, at least every 2 years**. The limited time frame provided for completion of this work meant that many of the recommended practices in this document could not be assessed with the full rigour and depth of Health Quality Ontario's established evidence-based analysis process. Recognizing this limitation, Health Quality Ontario reserves the right to revisit the recommended practices and supporting evidence later by conducting a full evidence-based analysis or to update this document with relevant newly published research. In cases where episode-of-care models are updated, any policy applications informed by the models should also be similarly updated.
  Consistent with this principle, the Ministry has stated that QBP models will be reviewed at least every 2 years.
- **Recommended practices should reflect the best patient care possible, regardless of cost or barriers to access.** Health Quality Ontario and its expert advisory panels are instructed to focus on defining best practice for an *ideal* episode of care, regardless of cost implications or potential barriers to access. Hence, the resulting cost implications of the recommended episodes of care are unknown. However, all of the expert advisory panels have discussed various barriers that will challenge implementation of their recommendations across the province. These include gaps in measurement capabilities for tracking many of the recommended practices, shortages in health human resources, and limitations in community-based care capacity in many parts of the province.
  Some of these barriers and challenges are briefly addressed in the section "Implementation of Best Practices." However, with the limited time available to address these issues, the considerations outlined here should be viewed as only an initial starting point toward a comprehensive analysis of these challenges.

Finally, Health Quality Ontario and the expert advisory panels recognize that, given the limitations of their mandate, the ultimate effect of the analysis and advice in this document will depend on how the Ministry incorporates it into the QBP policy and funding methodology. This work will be complex, and it will be imperative to ensure that any new funding mechanisms are aligned with the recommendations of the expert advisory panels.

In addition to aiding decisions regarding funding methodology, recommended practices can also provide the basis for broader provincial standards of care for patients with heart failure. These standards could be linked not only to funding mechanisms, but to other health system change levers, such as guidelines and care pathways, performance measurement and reporting, program planning, and quality improvement.

Purpose

Provided by the Ministry of Health and Long-Term Care

This Clinical handbook has been created to serve as a compendium of the evidence-based rationale and clinical consensus driving the development of the policy framework and implementation approach for the management of acute and postacute heart failure.

This document has been prepared for informational purposes only. It does not mandate health care providers to provide services in accordance with the recommendations included herein. The recommendations included in this document are not intended to take the place of the professional skill and judgment of health care providers.

Introduction to Quality-Based Procedures

Provided by the Ministry of Health and Long-Term Care

The Ministry of Health and Long-Term Care (ministry) established Health System Funding Reform (HSFR) in Ontario in 2012 with a goal to develop and implement a strategic funding system that promotes the delivery of quality health care services across the continuum of care and is driven by evidence and efficiency. HSFR is based on the key principles of quality, sustainability, access, and integration, and aligns with the four core principles of the *Excellent Care for All Act* (ECFAA):

- Care is organized around the person to support their health;
- Quality and its continuous improvement is a critical goal across the health system;
- Quality of care is supported by the best evidence and standards of care; and
- Payment, policy, and planning support quality and efficient use of resources.

Since its inception in April 2012, the ministry has shifted much of Ontario's health care system funding away from the its current global funding allocation (currently representing a large proportion of funding) toward a funding model that is founded on payments for health care based on best clinical evidence-informed practices. HSFR comprises two key components:

- Organizational-level funding, which will be allocated as base funding using the Health-Based Allocation Model (HBAM); and
- Quality-Based Procedure (QBP) funding, which will be allocated for targeted activities based on a "(price x volume) + quality" approach premised on evidence-based practices and clinical and administrative data.

"Money Follows the Patient"

Prior to the introduction of HSFR, a significant proportion of hospital funding was allocated using a global funding approach, with specific funding for select provincial programs, wait times services, and other targeted activities. However, a global funding approach may not account for complexity in patients, service levels, and costs, and it may reduce incentives to adopt clinical best practices that result in improved patient outcomes in a cost-effective manner. These variations in patient care evident in the global funding approach warranted a move toward a system in which "the money follows the patient."

Under HSFR, provider funding is based on the types and quantities of patients providers treated, the services they delivered, the quality of care delivered, and patient experiences/outcomes. Specifically, QBPs incent give health care providers an incentive to become more efficient and effective in their patient management by accepting and adopting clinical best practices that ensure Ontarians get the right care, at the right time and in the right place.

QBPs were initially implemented in the acute care sector, but as implementation evolves, they are being expanded across the continuum of care, including the community home care sector, to address the varying needs of different patient populations.

Internationally, similar models have been implemented since 1983. Ontario is one of the last leading jurisdictions to move down this path, but this positions the province uniquely to learn from international best practices and pitfalls to create a sustainable, efficient, and effective funding model that is best suited for the province and the people of Ontario.

What Are Quality-Based Procedures?

QBPs are clusters of patients with clinically related diagnoses or treatments who have been identified using an evidence-based framework as providing an opportunity for process improvements, clinical redesign, improved patient outcomes, enhanced patient experience, and potential health system cost savings.

Initially developed in the acute (hospital) sector, QBPs were defined as "procedures." However, implementation has evolved since the introduction of QBPs in 2012, and the approach has as well. Currently, the expanded focus is on care provided in other parts of the health care sector, and on a more functional/programmatic/population-based approach. As a result, the definition of QBPs is expanding to include quality-based procedures, programs, and populations.

QBPs have been selected using an evidence-based framework. The framework uses data from various sources such as, but not limited to: the Discharge Abstract Database (DAD) and the National Ambulatory Care Reporting System (NACRS), adapted by the ministry for its HBAM repository. The HBAM Inpatient Grouper (HIG) groups inpatients based on the diagnosis or treatment responsible for the majority of their patient stay. Additional data have been used from the Ontario Case Costing Initiative (OCCI) and the Ontario Cost Distribution Methodology (OCDM). Evidence published in literature from Canada and international jurisdictions, as well as in World Health Organization reports, has also assisted with the definition of patient clusters and the assessment of potential opportunities (e.g., reducing variation, improving patient outcomes, sustainability).

The evidence-based framework assesses patients using five perspectives, as presented in Figure 1. This evidence-based framework has identified QBPs with the potential to improve quality of care, standardize care delivery across the province, and show increased cost-efficiency.

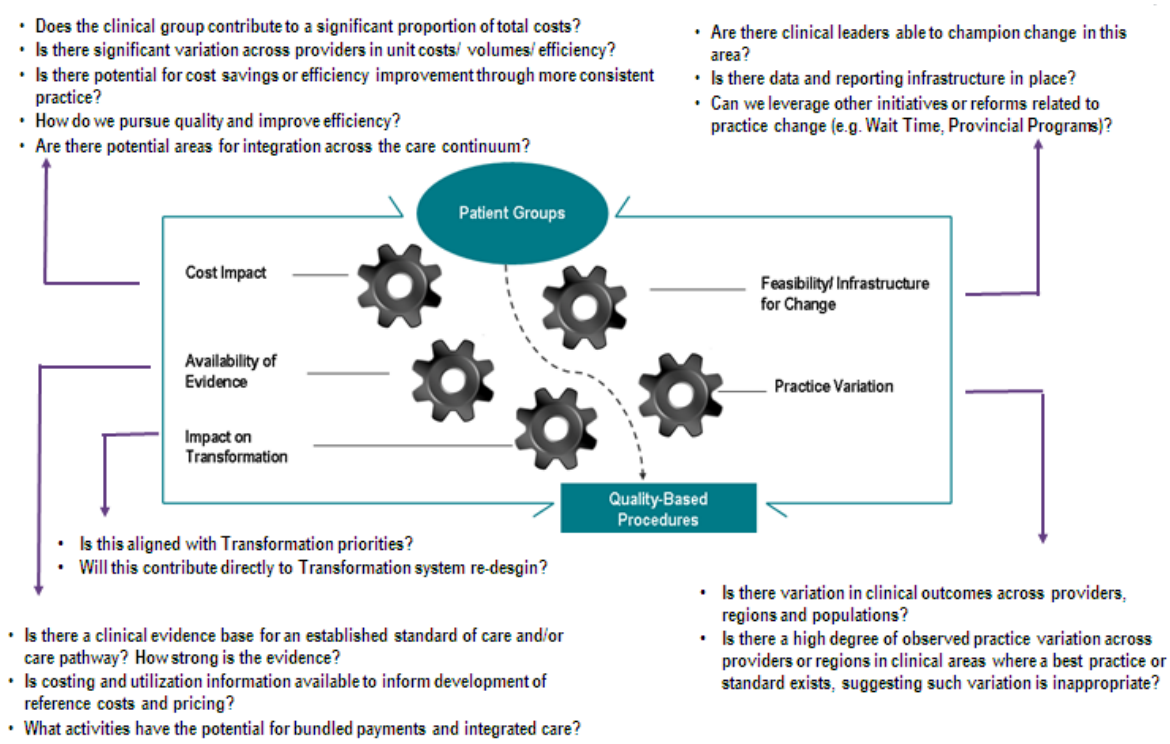

Figure 1: Evidence-Based Framework

Practice Variation

Practice variation is the cornerstone of the QBP evidence-based framework. A demonstrated large practice or outcome variance across providers or regions in clinical areas, where a best practice or standard exists, represents a significant opportunity to improve patient outcomes by focusing on the delivery of standardized, evidence-informed practices. A large number of "beyond expected length of stay" and a large standard deviation for length of stay and costs have been flags to such variation.

Availability of Evidence

A significant amount of research has been conducted and collected, both nationally and internationally, to help develop and guide clinical practice. Working with clinical experts, best practice guidelines and clinical pathways can be developed for QBPs and establish appropriate evidence-informed indicators. These indicators can be used to measure the quality of care and help identify areas for improvement at the provider level, and to monitor and evaluate the impact of QBP implementation.

Feasibility/Infrastructure for Change

Clinical leaders play an integral role in this process. Their knowledge of the identified patient populations and the care currently provided and/or required for these patients represents an invaluable element in the assessment of much needed clinical delivery and clinical process improvements. Many groups of clinicians have already developed care pathways to create evidence-informed practice. There is now an opportunity for this knowledge to be transferred provincially.

Cost Impact

The provincial footprint from a financial perspective also impacts the selection of the QBP. This may include QBPs that are high-volume and low-cost, as well as those that are low-volume and high-cost (i.e., specialized procedures that demonstrate an opportunity for improvement).

A selected QBP should have, as a guide, no fewer than 1,000 cases per year in Ontario and represent at least 1% of the provincial direct cost budget. For patient cohorts that fall below these thresholds, the resource requirements to implement a QBP can be restrictive. Even where the patient cohorts represent an opportunity for improvement, it may not be feasible to create a QBP, even if there are some cost efficiencies.

Impact on Transformation

The *Action Plan for Health Care* was launched in January 2012 and is already making a difference to Ontarians and the Ontario health care system:

- We have bent the cost curve since 2011/2012;
- We are improving the health of Ontarians;
- We are enhancing the experience of Ontarians when they use the health care system; and
- We are working with our health sector partners to improve the quality of health care.

The next phase of transformation will build on and deepen implementation of the action plan. HSFR is a key element of the health system transformation agenda because it ensures sustainability and quality.

Selected QBPs should, where possible, align with the government's transformational priorities. In addition, the impact on the transformation of certain patient populations not previously prioritized by the framework can be included as QBPs. This will ensure that QBPs are wide ranging in their scope (e.g., paediatric patient populations or patients requiring community care). QBPs with a lower cost impact but a higher impact on the provincial health care system may still be a high priority for creation and implementation.

How Will QBPs Encourage the Delivery of High-Quality, Evidence-Based Care and Innovation in Health Care Delivery?

The QBP methodology is driven by clinical evidence and best practice recommendations from expert advisory panels. Expert advisory panels comprise a cross-sectoral, multi-geographic, and multidisciplinary membership, including representation from patients. Members leverage their clinical experience and knowledge to define patient populations and recommend best practices.

Once defined, best practice recommendations are used to understand the required resource utilization for QBPs and will further assist in the development of evidence-informed prices. The development of evidence-informed pricing for the QBPs is intended to give health care providers an incentive to adopt best practices in their care delivery models, maximize their efficiency and effectiveness, and engage in process improvements and/or clinical redesign to improve patient outcomes.

Best practice development for QBPs is intended to promote the standardization of care by reducing inappropriate or unexplained variation and ensuring that patients get the right care at the right place and at the right time. Best practice standards will encourage health service providers to ensure that appropriate resources are focused on the most clinically effective and cost-effective approaches.

QBPs create opportunities for health system transformation where evidence-informed prices can be used as a financial lever to incent providers to:

- adopt best practice standards
- re-engineer their clinical processes to improve patient outcomes
- improve coding and costing practices
- develop innovative care delivery models to enhance the experience of patients

An integral part of the enhanced focus on quality patient care is the development of indicators to allow for the evaluation and monitoring of actual practice and support ongoing quality improvement.

In addition, the introduction of additional QBPs—such as outpatient and community-based QBPs—will further help integrate care across sectors and encourage evidence-based care across the health care continuum.

Methods

Overview of Episode-of-Care Analysis Approach

To produce this work, Health Quality Ontario has developed a novel method known as an *episode-of-care analysis* that draws conceptually and methodologically from several of Health Quality Ontario's core areas of expertise:

- **Evidence Based Analyses**: Recommended practices incorporate components of Health Quality Ontario's evidence-based analysis method and draw from the recommendations of the Ontario Health Technology Advisory Committee (OHTAC).
- **Case-mix grouping and funding methodology:** Cohort and patient group definitions use clinical input to adapt and refine case-mix methods from the Canadian Institute for Health Information (CIHI) and the Ontario Health-Based Allocation Model (HBAM).
- **Clinical practice guidelines and pathways:** Recommended practices synthesize guidance from credible national and international bodies, with attention to the strength of evidence supporting each guideline.
- **Analysis of empirical data:** Expert advisory panel recommendations were supposed by descriptive and multivariable analysis of Ontario administrative data (e.g., Discharge Abstract Database and National Ambulatory Care Reporting System) and data from disease-based clinical data sets (e.g., the Ontario Stroke Audit and Enhanced Feedback for Effective Cardiac Treatment databases). Health Quality Ontario works with researchers and Ministry analysts to develop analyses for the expert advisory panel's review.
- **Clinical engagement**: All aspects of this work were guided and informed by leading clinicians, scientists, and administrators with a wealth of knowledge and expertise in the clinical area of focus.
- **Performance indicators**: Health Quality Ontario has been asked to leverage its expertise in performance indicators and public reporting to support the development of measurement frameworks to manage and track actual performance against recommended practices in the episodes of care.

Phases of Development

This full continuum of the episode of care was developed in 3 phases:

Phase 1: developed the acute episode of care
Phase 2: developed the postacute (or "community") episode of care
Phase 3: updated the acute episode of care and integrated with the postacute episode of care for one coherent continuum of care

Each phase had its own unique leadership, expert advisory panel membership, and stakeholders engaged. All individuals involved in all phases were aware of the previous work done and built on prior efforts to ensure consistency and flow between the phases. In 2012 the first expert advisory panel was created to develop the acute episode of care. Stemming from the work of this acute episode of care, another expert advisory panel was convened in fall 2013 to develop a postacute episode of care. Finally, in summer 2014 the acute episode of care was updated and at the same time integrated with the postacute episode of care to create one coherent continuum of care.

The development of the episode-of-care analysis involves the following key steps:

1. **Defining the cohort and patient stratification approach**
2. **Defining the scope of the episode of care**
3. **Developing the episode-of-care model**
4. **Identifying recommended practices, including the Rapid Review process**
5. **Supporting the development of performance indicators to measure the episode of care**

The following sections describe each of these steps in further detail.

Defining the Cohort and Patient Stratification Approach

At the outset of this project, the Ministry of Health and Long-Term Care provided Health Quality Ontario with a broad description of each assigned clinical population (e.g., "heart failure"), and asked Health Quality Ontario to work with the Acute Heart Failure Episode-of-Care Advisory Panel and Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel to define inclusion and exclusion criteria for the cohort they would examine using data from routinely reported provincial administrative databases. Each of these populations might encompass multiple distinct subpopulations (referred to as "patient groups") with varying clinical characteristics. For example, the heart failure population includes subpopulations with HF, myocarditis, and cardiomyopathies. These patient groups have very different levels of severity, different treatments, and different distributions of expected resource use. Consequently, these groups could need different funding policies.

Conceptually, the process employed here for defining cohorts and patient groups shares many similarities with methods used around the world for the development of case-mix methodologies, such as Diagnosis-Related Groups or CIHI's Case Mix Groups. Case-mix methodologies have been used since the late 1970s to classify patients by similarities in clinical characteristics and in resource use for the purposes of payment, budgeting, and performance measurement (1). Typically, these groups are developed using statistical methods such as classification and regression tree analysis to cluster patients with similar diagnoses, procedures, age, and other variables. After the initial statistical criteria have been established, clinicians are often engaged to ensure that the groups are clinically meaningful. Patient groups are merged, split, and otherwise reconfigured until the grouping algorithm reaches a satisfactory compromise between cost prediction, clinical relevance, and usability. Most modern case-mix methodologies and payment systems also include a final layer of patient complexity factors that modify the resource weight (or price) assigned to each group upward or downward. These can include comorbidity, use of selected interventions, long- or short-stay status, and social factors.

In contrast with these established methods for developing case-mix systems, the approach the Ministry asked Health Quality Ontario and the expert advisory panels to undertake is unusual in that patient classification *begins* with the input of clinicians rather than with statistical analysis of resource use. The expert advisory panels were explicitly instructed not to focus on cost considerations, but instead to rely on their clinical knowledge of patient characteristics that are commonly associated with differences in indicated treatments and expected resource use. Expert advisory panel discussions were also informed by summaries of relevant literature and descriptive tables containing Ontario administrative data.

On the basis of this information, the expert advisory panels recommended a set of inclusion and exclusion criteria to define each disease cohort. Starting with identifying the *International Classification of Diseases*, 10th Revision (Canadian Edition) (ICD-10-CA) diagnosis codes included for the population, the expert advisory panels then excluded diagnoses with treatment protocols that

would differ substantially from those of the general population, including pediatric cases and patients with very rare disorders. Next, the expert advisory panels recommended definitions for major patient groups within the cohort. Finally, the expert advisory panels identified patient characteristics that they believe would contribute to additional resource use for patients within each group. This process generated a list of factors ranging from commonly occurring comorbidities to social characteristics, such as housing status.

In completing the process described above, the expert advisory panel encountered some noteworthy challenges:

- **Absence of clinical data elements capturing important patient complexity factors:** the expert advisory panels quickly discovered that several important patient-based factors related to the severity of patients' conditions or to expected resource use are not routinely collected in Ontario hospital administrative data. These include both key clinical measures (such as ratio of forced expiratory volume in 1 second to forced vital capacity for chronic obstructive pulmonary disease [COPD] patients and AlphaFIM®[*] scores for stroke patients) and important social characteristics (such as caregiver status).[†] For stroke and heart disease, some of these key clinical variables have been collected in the past through the Ontario Stroke Audit and Enhanced Feedback for Effective Cardiac Treatment data sets, respectively. However, these data sets were limited to a group of participating hospitals and at this time are not funded for future data collection.
- **Limited focus on a single disease or procedure grouping within a broader case-mix system:** while the expert advisory panels were asked to recommend inclusion and exclusion criteria for only specified populations, the patient populations assigned to Health Quality Ontario are a small subset of the many patient groups under consideration for Quality-Based Procedures (QBPs). Defining population cohorts introduced some additional complications; after the expert advisory panels had recommended their initial definitions (based largely on diagnosis), the Ministry informed the expert advisory panels that several other patient groups that were planned for future QBP funding efforts overlapped with the cohort definitions.

  For example, while nearly all patients discharged from hospital with a "most responsible diagnosis" (MRDx) of COPD receive largely ward-based medical care, a few patients diagnosed with COPD receive much more costly interventions, such as lung transplants or resections. On the basis of this substantially different use of resources, the Ministry's HBAM algorithm assigns these patients to a group different from the general COPD population. Given this methodologic challenge, the Ministry requested that the initial cohorts defined by the expert advisory panels be modified to exclude patients that receive selected major interventions. These patients are likely to be assigned to other QBP patient groups in the future. This document presents both the initial cohort definition defined by the expert advisory panel and the modified definition recommended by the Ministry.

In short, the final cohorts and patient groups described here should be viewed as a compromise based on currently available data and the parameters of the Ministry's HBAM grouping.

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[*]The Functional Independence Measure (FIM) is a composite measure consisting of 18 items assessing 6 areas of function. These fall into 2 basic domains; physical (13 items) and cognitive (5 items). Each item is scored on a 7-point Likert scale indicative of the amount of assistance required to perform each item (1 = total assistance, 7 = total independence). A simple summed score of 18–126 is obtained where 18 represents complete dependence / total assistance and 126 represents complete independence.

[†]For a comprehensive discussion of important data elements for capturing various patient risk factors, see Iezzoni. (3)

Defining the Scope of the Episode of Care

Health Quality Ontario's episode-of-care analysis draws on a conceptual theory from the emerging worldwide use of episode-based approaches for performance measurement and payment. Averill et al(1), Hussey et al (2), and Rosen and Borzecki (3) describe the key parameters required for defining an appropriate episode of care:

- **Index event:** The event or time point triggering the start of the episode. Examples of index events include admission for a particular intervention, presentation at the emergency department (ED), or diagnosis of a particular condition.
- **Endpoint:** The event or time point triggering the end of the episode. Examples of endpoints include death, 30 days after hospital discharge, or a "clean period" with no relevant acute health care service use for a defined window of time.
- **Scope of services included:** Although an "ideal" episode of care might capture all health and social care interventions received by the patient from index event to endpoint, in reality not all these services may be relevant to the objectives of the analysis. Hence, the episode could exclude some types of services such as prescription drugs or services tied to other unrelated conditions.

Ideally, the parameters of an episode of care are defined on the basis of the nature of the disease or health problem studied and the intended applications of the episode (e.g., performance measurement, planning, or payment). For Health Quality Ontario's initial work here, many key parameters were set in advance by the Ministry in the government's QBP policy parameters. For example, in fiscal year 2013/2014 the QBPs will focus on reimbursing acute care and will not include payments for physicians or other non-hospital providers. These policy parameters limited flexibility to examine non-hospital elements, such as community-based care or readmissions.

Largely restricted to a focus on community care, the Chairs of the expert advisory panels recommended that the episode of care for HF begin with a patient's discharge from the hospital in order to allow discharge planning to be incorporated. The expert advisory panels included all elements of postacute care during the 60-day postdischarge period.

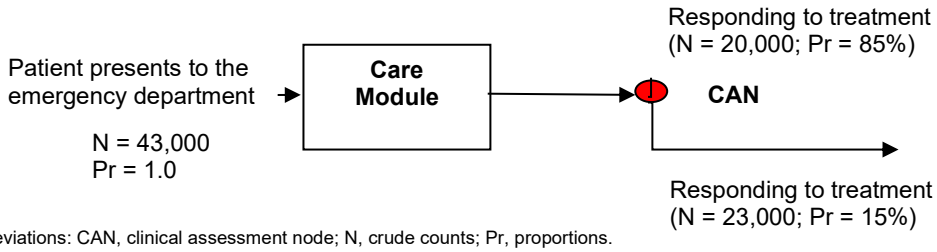
Developing the Episode-of-Care Pathway Model

Health Quality Ontario has developed a model that brings together key components of the episode-of-care analysis through an integrated schematic. The model is structured around the parameters defined for the episode of care, including boundaries set by the index event and endpoints, segmentation (or stratification) of patients into the defined patient groups, and relevant services included in the episode. The model describes the pathway of each patient case included in the defined cohort, from initial presentation through segmentation into one of the defined patient groups on the basis of their characteristics, and finally through the subsequent components of care that patients receive before reaching discharge or endpoints otherwise defined.

Although the model bears some resemblance to a clinical pathway, it is not intended to be used as a traditional operational pathway for implementation in a particular setting. Rather, the model presents the critical decision points (clinical assessment nodes [CANs]) and phases of treatment (care modules) within the episode of care. Clinical assessment nodes provide patient-specific criteria for whether a particular case proceeds down one branch of the pathway or another. Once a particular branch is determined, a set of recommended practices are clustered together as a care module. Care

modules represent the major phases of care that patients receive during a hospital episode, such as treatment in the ED, care on the ward, and discharge planning. The process for identifying the recommended practices within each CAN and care module is described in the next section.

Drawing from the concepts of decision analytic modelling, the episode-of-care model includes crude counts and proportions of cases proceeding down each branch of the pathway model. For this Clinical Handbook, these counts were determined on the basis of utilization data from administrative databases including the Discharge Abstract Database and NACRS. These counts are based on current Ontario practice and are not intended to represent normative or ideal practice. For some clinical populations, evidence-informed targets have been set at certain CANs for the proportions of cases that should ideally proceed down each branch. For example, a provincial target has been set for 90% of pneumonia patients to be discharged home (versus discharged to an inpatient rehabilitation setting) from acute care, on the basis of a 2005 OHTAC recommendation. Where relevant, these targets have been included in the episode model. Figure 2 provides an example of a care module and CAN:



Abbreviations: CAN, clinical assessment node; N, crude counts; Pr, proportions.

Figure 2: Episode-of-Care Model

Identifying Recommended Practices

Consideration of Evidence Sources

Several evidence sources were considered and presented to the expert advisory panels to develop the episode-of-care model and populate individual modules with best practice recommendations. Preference was given to OHTAC recommendations. Where OHTAC recommendations did not exist, additional evidence sources were sought including guidelines from other evidence-based organizations, Health Quality Ontario's rapid reviews, empirical analysis of Ontario data, and, where necessary and appropriate, expert consensus.

OHTAC Recommendations

The OHTAC recommendations are considered the criterion standard of evidence for several reasons:

- **Consistency:** While many guidance bodies issue disease-specific recommendations, OHTAC provides a common evidence framework across all the clinical areas analyzed in all disease areas.
- **Economic modelling:** The OHTAC recommendations are often supported by economic modelling to determine the cost-effectiveness of an intervention, whereas many guidance bodies assess only effectiveness.
- **Decision-Making Framework:** The OHTAC recommendations are guided by a decision determinants framework that considers the clinical benefit offered by a health intervention, in

addition to value for money; societal and ethical considerations; and economic and organizational feasibility.

- **Context:** In contrast with recommendations and analyses from international bodies, OHTAC recommendations are developed specifically for Ontario. This ensures that the evidence is relevant to the Ontario health system.

Notwithstanding these strengths, it is also crucial to mention several important limitations in the mandate and capacity of OHTAC to provide a comprehensive range of evidence to support Health Quality Ontario's episode-of-care analyses:

- **Focus on non-drug technologies:** While evidence shows that various in-hospital drugs are effective in treating all 3 of the patient populations analyzed, OHTAC traditionally does not consider pharmaceuticals under its mandate. Recently, OHTAC has reviewed some drug technologies in comparison with non-drug technologies for a given population as part of mega-analyses.
- **Capacity constraints:** There are a considerable number of candidate practices and interventions that require consideration for each episode of care. As OHTAC makes recommendations largely based on evidence-based analyses supplied by Health Quality Ontario, it may be limited in its capacity to undertake new reviews in all required areas.
- **Focus on high-quality evidence:** The OHTAC uses the GRADE criteria to assess the strength of evidence for an intervention, with randomized controlled trials considered the gold standard of evidence here. Not every practice within an episode of care may be appropriate or feasible to study through a randomized controlled trial. For example, some interventions may be regarded as accepted clinical practice, while others may be unethical to evaluate as part of a clinical trial.

Thus, in situations where OHTAC recommendations do not exist, Health Quality Ontario's episode-of-care analysis makes use of other sources of evidence:

Clinical Guidelines

Published Canadian and international guidelines that encompass the entirety of the heart failure pathway were searched with guidance from Health Quality Ontario's medical librarians. Additionally, the expert advisory panels were further consulted to ensure all relevant guidelines were identified.

The methodological rigour and transparency of clinical practice guidelines were evaluated by use of the Appraisal of Guidelines for Research & Evaluation (AGREE) II instrument. (4) The AGREE II instrument comprises 23 items organized into 6 quality domains—scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence. (4) The AGREE II domain scores provide information about the relative quality of the guideline. A score of 1 indicates an absence of information or poor reporting; a score of 7 indicates exceptional reporting that meets all criteria. Guidelines were selected for inclusion on the basis of individual AGREE scores, with an emphasis on the rigour of development score, which reflects the methods used to assess the quality of evidence supporting the recommendations. The final selection of guidelines included a minimum of 1 contextually relevant guideline (i.e., a Canadian guideline) and 3 to 4 highest quality guidelines, when available.

The contextually relevant, or Canadian, guideline served as the baseline and was directly compared with the other included guidelines. The quality of the evidence supporting each recommendation, as

assessed and reported by the published guidelines, was identified, and inconsistencies and gaps between recommendations were noted for further evaluation.

Rapid Reviews

Where there was inconsistency between guidelines, disagreement among expert advisory panel members, or uncertainty about evidence, a Health Quality Ontario evidence review was considered. Recognizing that a full evidence-based analysis would be impractical for all topics, a rapid review of evidence was used to identify the best evidence within the compressed timeframe of developing the entire episode-of-care pathway. Where a rapid review was deemed insufficient or inappropriate to answer the research question, a full evidence-based analysis was considered.

Articles were reviewed if they were:

- English language full-text reports
- published within 5–10 years
- health technology assessments, randomized controlled studies, observational studies, systematic reviews, and meta-analyses

The methodological quality of systematic reviews was assessed using the Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool. (5) The quality of the body of evidence for each outcome was examined according to the GRADE Working Group criteria. (6) The overall quality was determined to be very low, low, moderate, or high using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations or serious limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 factors that could raise the quality of evidence were considered: large magnitude of effect, dose response gradient, and accounting for residual confounding. (6) For more detailed information, please refer to the latest series of GRADE articles. (6) As stated by the GRADE Working Group, (6) the final quality score can be interpreted using the following definitions (6):

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Analysis of Administrative and Clinical Data

In addition to evidence reviews of the published literature, the expert advisory panels also examined the results of descriptive and multivariable regression analysis using Ontario administrative and clinical data sets. Analyses modeling such patient characteristics as age, diagnoses, and procedures

were developed for their association with such outcomes of interest as LOS, resource use, and mortality. Dependent (outcome) and independent variables for analysis were identified by expert advisory panel members on the basis of their clinical experience and their review of summaries of the literature evaluating the association between patient characteristics and a range of outcomes. The expert advisory panels also provided advice on the analytical methods used, including data sets included and the most functional forms of the variables.

Other analyses reviewed included studies of current utilization patterns, such as average hospital LOS and regional variation across Ontario in admission practices and hospital discharge settings.

Expert Consensus

The expert advisory panels assessed the best evidence for the Ontario health care system to arrive at the best practice recommendations (see "Recommended Practices"). Where the available evidence was limited or nonexistent, recommendations were made on the basis of consensus agreement by the expert advisory panel members.

Description of Heart Failure

Heart failure (HF) is a complex syndrome in which abnormal heart function is responsible for the failure of the heart to pump blood at a rate that is necessary for metabolizing tissues. (7-10) Common symptoms of HF include shortness of breath; cough; sudden weight gain; bloating; loss of energy; loss or change in appetite; increased swelling of the ankles, feet, legs, sacrum (base of spine), or abdomen; and increased urination at night. (11) However, it is difficult to diagnose HF because the symptoms are nondiscriminating and, therefore, have limited diagnostic value. (12-16) Some leading causes for HF are coronary artery disease, hypertension, diabetes, heart valve disease, obesity, and excessive use of alcohol or drugs. (17-20)

The number of people with HF in North America is estimated to exceed 5 million. (21) Between 1997 and 2008, there were 419,551 incident cases of heart failure in Ontario. (22) Heart failure is characterized by high mortality and hospitalization as well as physical, emotional, and functional impairment; reduced quality of life; and increased caregiver burden. (23, 24) Heart failure is the most common cause of hospitalization for adults older than the age of 65 years. (21)

Recommended Heart Failure Cohort Definition and Patient Grouping

Cohort Inclusion and Exclusion Criteria

The expert advisory panel recommended that heart failure (HF) cohorts be defined by an index event of initial presentation to hospital (including both emergency department [ED] visits and direct inpatient admissions) with a recorded diagnosis of HF, as defined in Table 1 below. Hence, this cohort definition should include activity in the ED, acute inpatient care, and postacute care (including community-based services, such as home care and heart failure clinics). It is important that the funding definition for the quality-based procedure (QBP) should include patients that can be treated and discharged from the ED without requiring inpatient admission. As of the time of writing this document, the QBP definition did not include these cases and applied only to admitted HF cases. This could create perverse financial disincentives against hospitals that are able to implement strategies to reduce the need for inpatient hospitalization.

The parameters for the cohort definition are as follows:

- The HF pathway has been developed for adult patients presenting to Ontario's EDs with a major diagnosis of HF. These patients are admitted to an inpatient bed, transferred to another hospital, or discharged from the ED. Patients with a primary diagnosis of HF received from another hospital or who develop HF during their stay in hospital are not included in this pathway.
- For QBP funding purposes, cases are included only if HF-related diagnoses are assigned as the most responsible diagnosis for an acute inpatient (Discharge Abstract Database [DAD] data) or as the main problem for an ED patient (National Ambulatory Care Reporting System [NACRS] data) and have not had a "major qualifying procedure" performed.

The following age ranges, diagnosis codes (*International Classification of Diseases, 10th Revision [Canadian Edition]* [ICD-10-CA]), and diagnosis types were used to define the HF population for this episode-of-care analysis.

Age: 20 years and older

Heart failure is predominantly a disease of older people; the largest cohort of patients is those 75 years of age or older. Patients younger than age 20 with HF are quite rare, and their disease tends to result from congenital factors; the care pathway and treatment protocols for such patients are likely to be substantially different. The expert advisory panel developed the HF care pathway for adult patients using the 20-year age threshold used in many Institute for Clinical Evaluative Sciences studies.

Note that, although the original expert advisory panel defined an age threshold of 20 years and older for inclusion, it was recommended that the ministry should strive for consistency across QBPs in terms of the age ranges included. Thus, the ministry could consider standardizing QBPs to an age cut-off of 18 years, for example, unless the QBP was intended to include pediatric populations.

Diagnosis codes

The ICD-10-CA codes used to define the cohort of patients with HF are listed below.

- I50.x heart failure, left ventricular dysfunction, etc.
- I25.5 ischemic cardiomyopathy
- I40.x, I41.x myocarditis
- I42.x, I43.x cardiomyopathies
- I11.x plus I50.x (secondary diagnosis) hypertensive heart disease plus heart failure, left ventricular dysfunction
- I13.x plus I50.x (secondary diagnosis) hypertensive heart disease and renal disease plus heart failure, left ventricular dysfunction)

Appendix 1 shows ICD-10-CA details for the HF patient groups.

Diagnosis types

The following diagnosis types are included in the HF patient definition, depending on the hospital care–type setting where the encounter occurs:

- *Acute inpatient cases* include most responsible diagnosis codes—the diagnosis determined as the diagnosis or condition held most responsible for the greatest portion of the length of stay or greatest use of resources.
- *Emergency department* cases include main problem codes—the diagnosis or condition determined to be most responsible for the greatest proportion of the length of stay or greatest use of resources.

As noted above, using the DAD and the NACRS databases, the following codes defined the HF population:

- Most responsible diagnosis of "I50.X" "I25.5" "I40.X" "I41.X" "I42.X" "I43.X"
  OR
- Most responsible diagnosis of "I11.X" and comorbidity "I50.X" code
  OR
- Most responsible diagnosis of "I13.X" and comorbidity "I50.X" code

It should be noted that comorbidity diagnoses are only with diagnosis type "1" preadmission comorbidity, "2" postadmission comorbidity, or "W," "X," "Y" service transfer diagnosis.

Typical HF patients

In the DAD, typical patients include those coded as both "typical" and "short stay" using the Health Based Allocation Model Inpatient Grouper (HIG). Deaths, transfers, sign-outs, and long-stay outliers are considered atypical cases. Table 1 shows the breakdown of HF patients by type and distribution of the resource intensity weights for 2010/2011.

Table 1: Patients With Congestive Heart Failure in 2010/2011

Case Type	Number of Cases	Weight (Mean)	Weight (Minimum)	Weight (50th Percentile)	Weight (Median)	Weight (75th Percentile)	Weight (Maximum)
All	22,342	1.89	0.24	0.98	1.06	1.84	134.77
Atypical	3,298	4.76	0.24	1.04	2.85	5.38	134.77
Typical	19,044	1.39	0.26	0.98	1.06	1.29	40.66

Source: Discharge Abstract Database 2010/2011.

The expert advisory panel considered both typical and atypical patients in the development of the HF care pathway. The expert advisory panel believed smaller hospitals would need to transfer patients to other acute care hospitals with more appropriate resources, such as catheterization laboratories.

Exclusions

The Acute Heart Failure Episode-of-Care Advisory Panel recommended the following exclusion criteria be applied in addition to the original acute care definition:

- **Intervention:** Cases are excluded if they are assigned to an intervention-based HIG cell, given the current methodology. (i.e., major clinical category [MCC] partition variable is not "I")
- **Palliative cases:** Cases are excluded if they have a record of palliative hospice care in the 6 months preceding the index hospitalization. *Definitions for other excluded community-based palliative cases to be determined.*
  Post-transplants: Cases are excluded if they have received a heart transplant in the 6 months preceding the index hospitalization.
- **Postimplantation of LVADs:** Cases are excluded if they have received a left ventricular assist device (LVAD) in the 6 months preceding the index hospitalization.

Recommended HF Patient Stratification Approach: Acute Care

Patients Presenting to the Emergency Department

The expert advisory panel recommends that patients presenting to hospital with acute HF be classified into the following 3 broad groups for the purposes of establishing care pathways and defining major groups for QBP funding:

- **Low-intensity:** These patients can be treated in the ED or as outpatients and discharged home without requiring inpatient admission.
- **Average-intensity:** These patients require admission to inpatient care with normal nurse-to-patient staffing.
- **High-intensity:** These patients require ventilation (either noninvasive or invasive ventilation) or admission to an intensive care unit with higher nurse-to-patient staffing.

These 3 patient groups are largely recognized to be based on level of care. The expert advisory panel has identified several high-risk markers:

- respiratory distress
- hypoxemia
- severity of pulmonary edema
- poor response to furosemide administered in the ED
- hemodynamic compromise
- significant arrhythmias
- positive troponin
- concomitant acute life-threatening directives

The expert advisory panel suggests that an acute heart failure risk score—for example, the Emergency Heart Failure Mortality Risk Grade (EHMRG)—be calculated to assist with clinical decision-making and predicting the 7-day mortality risk of HF patients (predicted mortality risk increases incrementally with higher EHMRG risk score). As a general guide, patients who are low-risk (e.g., EHMRG quintiles 1 and 2) can be considered for discharge home if they have responded to initial treatment in the ED, provided that there are no other considerations (e.g., advanced-directives, severe dementia, estimated impact of admission on life-expectancy, bed-availability). Patients who are high-risk (e.g., EHMRG quintile 5) can be considered for admission to a higher-intensity unit.

Ultimately, the decision to admit is based on clinical judgment and the availability of hospital resources.

Note: a full review of the evidence is required to determine the essential markers and defined thresholds for the 3 HF patient groups (high-intensity, average-intensity, and low-intensity).

Admitted Patients

The expert advisory panel identified 2 pathways for admitted patients based on severity:

- High-intensity case-mix–adjusted patient
- Average-intensity case-mix–adjusted patient

The high-intensity case-mix–adjusted patient implies that a patient is high-risk enough to necessitate a 1:1 nurse-to-patient ratio. Similarly, the lower-intensity case-mix–adjusted patient implies that a patient is of sufficiently low risk to be managed with the usual hospital-ward 1:5 nurse-to-patient ratio.

The case-mix adjustment implies that the high-intensity as well as average-intensity care pathway corresponds to an individual of average comorbidity for HF patients in the province of Ontario. Patients with higher-than-average or lower-than-average comorbidity would not necessarily alter the patient intensity level or the care pathway, but rather the cost bundle associated with the care pathway. The rationale for cost adjustments for case-mix variation is based on the understanding that care intensity and length of stay correlate with the management of other (not related to heart failure) chronic conditions. Such management of other comorbidities is not taken into account in this care pathway. Case-mix cost attribution could use several methodologies, including resource intensity weights.

The mean total length of hospital stay for the high-intensity and low-intensity patients using the 2005 EFFECT database and the 2010/2011 DAD are:

- High-intensity (2005 EFFECT): 8.8 days (SD = 8) with mean length of ward stay of 5.0 days (SD = 8.2)
- High-intensity (2010/2011): 12.2 days (SD = 21.3)
- Low-intensity (2005 EFFECT): 8.5 days (SD = 10.7)
- Low-intensity (2010/2011): 8.8 days (SD = 15.1)

Factors Contributing to Patient Complexity

Using 2010/2011 DAD data, the expert advisory panel reviewed preadmission and postadmission comorbidities. Preadmission comorbidities are conditions that exist before admission and have been assigned an ICD-10-CA code that satisfies the requirements for determining comorbidity (Table 2). Similarly, postadmission comorbidities are conditions that arise after admission (Table 3).

Table 2: Top 30 Preadmission Comorbidities in Heart Failure

ICD-10 Description	Number	Percent
I48.0 Atrial fibrillation	3,977	9.61
J18.9 Pneumonia, unspecified	2,076	5.02
N17.9 Acute renal failure, unspecified	1,898	4.59
I10.0 Benign hypertension	1,224	2.96
N39.0 Urinary tract infection, site not specified	1,162	2.81
D64.9 Anaemia, unspecified	1,042	2.52
E11.52 Type 2 diabetes mellitus with certain circulatory complications	969	2.34
J90 Pleural effusion, not elsewhere classified	959	2.32
Z51.5 Palliative care	951	2.30
I25.10 Atherosclerotic heart disease of native coronary artery	802	1.94
J44.1 Chronic obstructive pulmonary disease with acute exacerbation, unspecified	796	1.92
E11.23 Type 2 diabetes mellitus with established or advanced kidney disease (N08.3-)	740	1.79
J44.0 Chronic obstructive pulmonary disease with acute lower respiratory infection	718	1.74
I21.4 Acute subendocardial myocardial infarction	693	1.67
J44.9 Chronic obstructive pulmonary disease, unspecified	559	1.35
E11.64 Type 2 diabetes mellitus with poor control, so described	556	1.34
E87.1 Hypo-osmolality and hyponatraemia	523	1.26
N18.9 Chronic kidney disease, unspecified	517	1.25
E87.6 Hypokalaemia	478	1.16
I35.0 Aortic (valve) stenosis	430	1.04
L03.11 Cellulitis of lower limb	415	1.00
E87.5 Hyperkalaemia	385	0.93
I25.5 Ischaemic cardiomyopathy	352	0.85
I27.2 Other secondary pulmonary hypertension	349	0.84
I50.0 Congestive heart failure	349	0.84
I42.0 Dilated cardiomyopathy	298	0.72
I95.9 Hypotension, unspecified	282	0.68
I48.1 Atrial flutter	238	0.58
D50.9 Iron deficiency anaemia, unspecified	234	0.57
E86.0 Dehydration	232	0.56

Abbreviation: ICD-10, International Classification of Diseases, 10th Revision.
Data source: Discharge Abstract Database 2010/2011.

Table 3: Top 20 Postadmission Comorbidities for Heart Failure

ICD-10 Description	Number	Percent
N39.0 Urinary tract infection, site not specified	530	8.03
N17.9 Acute renal failure, unspecified	341	5.16
E87.6 Hypokalaemia	261	3.95
I95.9 Hypotension, unspecified	205	3.10
J18.9 Pneumonia, unspecified	203	3.07
I48.0 Atrial fibrillation	168	2.54
I46.9 Cardiac arrest, unspecified	139	2.10
R33 Retention of urine	110	1.67
E11.63 Type 2 diabetes mellitus with hypoglycaemia	109	1.65
E87.5 Hyperkalaemia	105	1.59
A04.7 Enterocolitis due to *Clostridium difficile*	104	1.57
J96.0 Acute respiratory failure	102	1.54
E87.1 Hypo-osmolality and hyponatraemia	100	1.51
F05.9 Delirium, unspecified	99	1.50
I46.0 Cardiac arrest with successful resuscitation	93	1.41
A09.9 Gastroenteritis and colitis of unspecified origin	90	1.36
I21.4 Acute subendocardial myocardial infarction	85	1.29
J96.9 Respiratory failure, unspecified	77	1.17
R57.0 Cardiogenic shock	77	1.17
I47.2 Ventricular tachycardia	75	1.14

Abbreviations: ICD-10, International Classification of Diseases, 10th Revision.
Source: Discharge Abstract Database 2010/2011.

Preadmission and postadmission comorbidities are not included in the current episode-of-care pathway for the "typical" HF case. Following completion of the current pathway, the expert advisory panel may consider the implications of commonly occurring comorbidities, such as pneumonia, acute renal failure, and diabetes. While it is expected that the foundational pathway will remain the same, inclusion of comorbidities could lead to recommendation of additional interventions in each care module.

Inclusion and Exclusion Criteria for QBP Funding

During the development of the episode-of-care pathway, ministry representatives explained the challenges of incorporating HF cohort definitions into the QBP funding methodology. To align the HF cohort to the present HIGs, the following ICD-10-CA diagnosis codes, diagnosis types, and ICD-10 Canadian Classification of Health Interventions (CCI) intervention exclusion criteria are recommended for the purposes of funding HF through the QBP funding mechanism:

- **Age:** Age greater than or equal to 20 years at time of admission.
- **Diagnosis codes:** The ICD-10-CA most responsible diagnosis codes are listed below.
  - I50.x Heart failure, left ventricular dysfunction, etc.
  - I40.x, I41.x Myocarditis
  - I25.5 Ischemic cardiomyopathy
  - I42.x, I43.x Cardiomyopathies
  - I11.x plus I50.x (secondary diagnosis) Hypertensive heart disease plus heart failure, left ventricular dysfunction

I13.x plus I50.x (secondary diagnosis) Hypertensive heart disease and renal disease plus heart failure, left ventricular dysfunction)

- **Intervention:** Patients are not assigned to an intervention-based HIG cell, given the current methodology (i.e., major clinical category [MCC] partition variable is not "I"). Case management group algorithms used by the Ministry for QBP funding typically assign cases to groups based on either principal intervention (typically a major qualifying procedure, such as a surgery) or in cases where there is no major qualifying procedure, by most responsible diagnosis. Case management groups should be mutually exclusive: that is, the logic of the grouping algorithm should assign a case to 1 group or another—not both.

When the MCC partition variable "I" is included, HF patients fall into many HIGs. Using the existing case management group funding methodology and 2011/2012 inpatient data, most of the 22,435 admitted HF patients as defined by the expert advisory panel fall into 3 HIGs: HIG 195 "Heart Failure With Coronary Angiogram," HIG 196 "Heart Failure Without Coronary Angiogram," and HIG 209 "Other/Miscellaneous Cardiac Disorder."

Cases assigned to an intervention-based HIG cell are likely to be more advanced and funded using a different episode-of-care pathway (to be developed in the future). As a result, for funding purposes, the MCC partition "I" has been excluded from the current pathway.

Table 4 shows the distribution of HF patients in the ED using the Comprehensive Ambulatory Care Classification System.

Table 4: Distribution of HF Patients in ED Across CACS Cells

CACS	CACS Description	Patients with HF Diagnosis Codes, n	All Patients in These CACS Cells, n
A001	Dead on arrival	8	696
A002	Left without being seen or triaged and not seen	2	193,799
B001	Cardiovascular condition with acute admission/transfer	18,506	97,974
B051	Emergency visit interventions	233	73,648
B053	Interventions generally performed by non-emergency department service: other	19	1,559
B121	Congestive heart failure	8,645	8,645
B122	Other disease or disorder cardiac system	203	278,635
C154	Pleurocentesis	3	41
E201	Cardiovascular disorders	4	115
E202	Congestive heart failure	27	27

Abbreviations: CACS, Comprehensive Ambulatory Care Classification System; ED, emergency department.
Source: National Ambulatory Care Reporting System 2011/2012.

For funding purposes, the Ministry will be considering methods of dealing with low-volume Comprehensive Ambulatory Care Classification System cells.

Recommended Patient Stratification Approach: Postacute Care

The expert advisory panel noted that the patient groups defined for the acute care phase of the HF QBP were based largely on disposition—mild if discharged from the ED, moderate if admitted to a ward, and severe if admitted to the ICU—but did not necessarily reflect patients' complexity or risk of adverse outcomes in the postacute setting. A new risk stratification model is required to assign these patients to the appropriate level of risk for the postdischarge period analyzed in this project. Such a risk stratification model can inform the development of patient groups on the basis of differing levels of risk.

The expert advisory panel discussed the heart failure–specific utility of existing risk stratification methods currently applied in Ontario, including the LACE index (length of stay "L"; acuity of admission "A"; comorbidity, as measured with the Charlson comorbidity index score, "C"; emergency department use, as measured by the number of visits in the 6 months before admission, "E") and Health Quality Ontario's Hospital Admission Risk Prediction (HARP) tool. Members of the expert advisory panel expressed skepticism about the predictive power of the LACE index in a HF population. This discussion concluded with the recommendation that an analysis be conducted to evaluate methods for stratifying the posthospital HF cohort by risk of adverse outcomes.

Risk Stratification Analysis

The following analysis has been conducted by Dr. Douglas Lee and team at the Institute for Clinical Evaluative Sciences.

The expert advisory panel identified the following patient characteristics as factors that they believed, on the basis of their clinical experience, were likely to be associated with differences in patient complexity and risk of adverse outcomes:

- age
- sex
- new (incident) HF
- known HF within past year:
  - no HF hospitalization
  - 1 HF hospitalization
  - 2+ HF hospitalization
- discharged from ED
- long-term care resident
- receiving Community Care Access Centre nursing care

They also cited the LACE index, because of its common use as a variable that might be worth including in a heart failure–specific model, even if LACE in itself does not perform well for the HF population.

The preliminary analysis compared the LACE index, HARP "simple" model, HARP "complex" model, and an "HF-specific" model that uses the variables identified by the expert advisory panel, together with the LACE index. The analysis used 30-day unplanned readmissions as the outcome of interest (further analysis will include mortality as well), was conducted on 3 years (2009–2011) of

heart failure discharges of both ED patients and inpatients, and used the previously established HF QBP definition.

The results presented in Table 5 indicate that all covariates identified by the expert advisory panel—including the number of prior HF hospitalizations, long-term care residency status, and receipt of Community Care Access Centre nursing services—were all significant predictors of increased risk of readmission. Notably, patients discharged from the ED have a 1.425 times greater risk (95% CI 1.341–1.514, $P < 0.001$) of readmission, suggesting the need to pay particular focus to this oft-neglected population.

Table 5: Heart Failure–Specific + LACE Model

Variable[a]	OR (95% CI)	*P* Value
Age	1.009 (1.007–1.011)	<0.001
Sex	1.113 (1.065–1.162)	<0.001
New HF	0.887 (0.843–0.932)	<0.001
Known HF in past year		
▪ No HF hospitalization		
▪ 1 HF hospitalization	1.121 (1.049–1.198)	0.007
▪ 2+ HF hospitalization	1.326 (1.199–1.466)	<0.001
Discharged from ED	1.425 (1.341–1.514)	<0.001
LTC resident	1.444 (1.254–1.662)	<0.001
Receiving CCAC nursing	1.249 (1.176–1.326)	<0.001
LACE index	1.097 (1.088–1.107)	<0.001

Abbreviations: CCAC, Community Care Access Centre; CI, confidence interval; ED, emergency department; HF, heart failure; LACE, length of stay "L"; acuity of admission "A"; comorbidity, as measured with the Charlson comorbidity index score, "C"; emergency department use, as measured by the number of visits in the 6 months before admission, "E"; LTC, long-term care; OR, odds ratio.
[a]C statistic 0.610, lowest decile rate 12.5%

Tables 6 and 7 compare the results of the 4 models for patients discharged from inpatient care and the ED, respectively. The results demonstrate that the HARP complex model and the HF-specific model perform similarly well ($P = 0.744$) for admitted cases, but the HF-specific model performs significantly better ($P = 0.006$) for the ED patient subgroup.

Notwithstanding the comparative performance of the models, the results in Tables 6 and 7 also demonstrate that the predictive power of all these models as measured by the C statistic is relatively low, with the HF-specific model returning C statistics of 0.610 and 0.622 for inpatient and ED discharges, respectively. This C statistic will likely be improved with the addition of mortality as an outcome to these models, as previous studies have shown risk prediction models to predict mortality more accurately than readmissions.

Table 6: Comparison of Risk Models for Heart Failure Discharges From Hospital

Risk Model	C Statistic	Change in C Statistic	P Value
HF-specific with LACE index	0.610	0	n/a
LACE alone	0.604	−0.00601	<0.001
HARP Simple	0.599	−0.0108	<0.001
HARP Complex	0.611	0.000688	0.744

Abbreviations: HARP, Hospital Admission Risk Prediction; HF, heart failure; LACE, length of stay "L"; acuity of admission "A"; comorbidity, as measured with the Charlson comorbidity index score, "C"; emergency department use, as measured by the number of visits in the 6 months before admission, "E"; n/a, not applicable.

Table 7: Comparison of Risk Models for Heart Failure Discharges From the Emergency Department

Risk Model	C Statistic	Δ C	P Value
HF-specific with LACE index	0.622	0	n/a
LACE alone	0.613	−0.00917	<0.001
HARP simple	0.607	−0.0148	<0.001
HARP complex	0.616	−0.00637	0.006

Abbreviations: HARP, Hospital Admission Risk Prediction; HF, heart failure; LACE, ; n/a, not applicable.

Conclusions and Recommendations

The results of the preliminary analysis described above suggest that an HF cohort–specific postacute risk prediction model is feasible to develop and can outperform other generic risk prediction models. The relatively low predictive power demonstrated for the outcome of unplanned 30-day readmissions should be noted; further analysis will incorporate mortality outcomes and likely result in improved predictive power for the combined outcome of 30-day mortality or 30-day readmission.

Upon the completion of this analysis, the risk score generated by the HF-specific model can be used to stratify the HF patient cohort into QBP subgroups through establishing threshold values to segment the population by levels of risk.

In-Hospital Utilization Analysis

At the initial expert advisory panel meetings, the HF patient journey was mapped out. Patient presentation at the ED with suspected HF was established as the index event, and administrative data were used to inform and guide the HF patient journey in hospital. Using Canadian Institute for Health Information administrative databases, the disposition of ED patients and admitted patients was reviewed. In 2010/2011, 62.5% of patients presenting to the ED with the main problem reported as HF were admitted (Table 8).

Table 8: Patient Visit Dispositions from Emergency Departments in Ontario, 2010/2011

Visit Disposition	Frequency	%
01 – Discharged home (private dwelling, not an institution; no support services)	8,819	30.54
02 – Client register, left without being seen or treated by a service provider	—	—
03 – Client triaged and then left ED; not seen by physician or primary care provider	2	0.01
04 – Client triaged, registered, and assessed by a service provider and left without treatment	7	0.02
05 – Client triaged, registered, and assessed by a service provider and treatment initiated; left against medical advice before treatment completed	101	0.35
06 – Admitted into reporting facility as an inpatient to critical care unit or operating room directly from an ambulatory care visit functional centre	2,151	7.45
07 – Admitted into reporting facility as an inpatient to another unit of the reporting facility directly from the ambulatory care visit functional centre	15,895	55.05
08 – Transferred to another acute care facility directly from the ambulatory care visit functional centre	818	2.83
09 – Transferred to another non–acute care facility directly from an ambulatory care visit functional centre	28	0.10
10 –DAApatient expired after initiation of ambulatory care visit; resuscitative measures (e.g., CPR) could occur during the visit but were not successful	78	0.27
11 –DOA—patient was dead on arrival to the ambulatory care service; generally there is no intent to resuscitate (e.g., perform CPR); includes cases where patient is brought in for pronouncement of death	8	0.03
12 – Intra-facility transfer to day surgery	2	0.01
13 – Intra-facility transfer to ED	—	—
14 – Intra-facility transfer to clinic	42	0.15

Abbreviations: CPR, cardiopulmonary resuscitation; DAA, death after arrival; DOA, death on arrival; ED, emergency department.
Source: National Ambulatory Care Reporting System 2010/2011.

The expert advisory panel also investigated HF patients transferred from other facilities, and the types of facilities transferring patients. For 2010/2011, 13% of transferred HF patients were from acute care facilities. Table 9 shows the number of HF patients transferred to Ontario's acute care hospitals in 2010/2011, as reported in the DAD. After careful consideration, the expert advisory panel chose to treat HF patients transferred from other institutions as a special cohort; these patients were excluded from the episode-of-care pathway model developed for this report.

Table 9: Patients Transferred From Other Institutions, 2010/2011

From Institution by Type	Frequency	Percent
0 – Organized outpatient department of reporting facility	1	0.02
1 – Acute care	722	13.06
2 – General rehabilitation facility	111	2.01
3 – Chronic care facility	108	1.95
4 – Nursing home	1,189	21.5
5 – Psychiatric facility	16	0.29
6 – Unclassified or other type of facility	71	1.28
7 – Special rehabilitation facility	11	0.20
8 – Home care	577	10.43
9 – Home for the aged	1,563	28.26
N – Ambulatory care	1,161	20.99

Data source: DAD 2010/2011.

Finally, the expert advisory panel reviewed discharge disposition data for HF patients admitted from the ED (Table 10). Most patients admitted for HF are discharged home; 21% require further supportive services.

Table 10: Discharge Disposition for Patients With Heart Failure, 2010/2011

Discharge Disposition	Total	Percent
01 – Transferred to another facility providing inpatient hospital care (includes other acute, subacute, psychiatric, rehabilitation, cancer centre/agency, pediatric hospital, etc.)	863	3.84
02 – Transferred to a long-term care facility (personal care home, auxiliary care, nursing home, extended care, home for the aged, senior's home, etc.)	2,858	12.73
03 – Transferred to other (palliative care/hospice, addiction treatment centre, etc.)	103	0.46
04 – Discharged to a home setting with support services (senior's lodge, attendant care, home care, Meals on Wheels, homemaking, supportive housing, etc.)	4,716	21.01
05 – Discharged home	11,719	52.20
06 – Signed out (against medical advice)	169	0.75
07 – Died	2,022	9.01
Total	**22,450**	100.00

Data source: DAD 2010/2011.

On the basis of these data, the expert advisory panel established the ED visit disposition to include patients returning home or to their place of residence, patients transferred to another acute care facility, admission to the hospital, or death.

Utilization Analysis of Postacute Care

In collaboration with Dr. Jason Sutherland and a team from the Centre for Health Services and Policy Research, University of British Columbia, costs and service utilization for postacute episodes of care were analyzed for HF patients. These analyses compared costs and utilization for episodes of 30, 60,

and 90 days' duration, as well as variation in these outcomes across the 14 Local Health Integration Networks (LHINs), by patient residence.

Figure 3 describes average Ontario costs for postacute HF episodes, illustrating the increase in postacute costs from just under $3000 for a 30-day postacute episode to just under $7000 for a 90-day episode. Whatever the duration, the 2 largest spending components were physician services, ranging from $705 for 30 days to $1,543 over 90 days, and readmissions to acute inpatient care, ranging from $605 over 30 days to $1,558 over 90 days. Other substantial spending components include complex continuing care and long-term care and also emergency department and outpatient costs. Home care and inpatient rehabilitation make up smaller proportions of total expenditure.

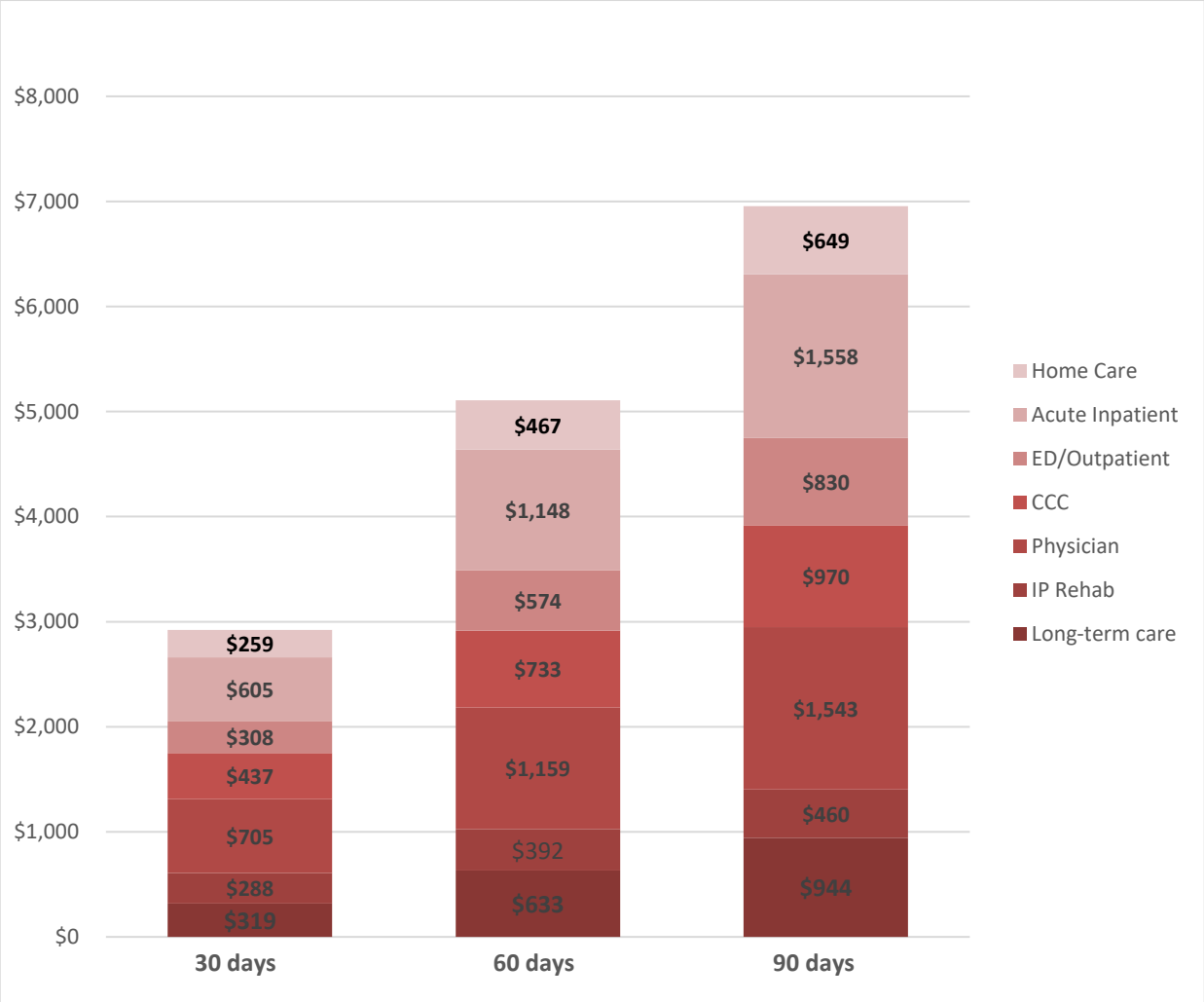


Figure 3: Ontario's Costs for Treatment of Heart Failure by Health Service for 30-, 60- and 90-day Postacute Episodes (2009/2010–2010/2011 Discharges)
Abbreviations: CCC, complex continuing care; ED, emergency department; IP, inpatient.

While Figure 3 presents average HF patient postacute cost and utilization across Ontario, there is considerable regional variation in these utilization patterns. Figure 4 presents 90-day postacute episode costs both for patients' LHIN of residence and for Ontario overall. As the graph illustrates, the largest areas of inter-LHIN variation from a cost perspective are in the use of inpatient rehabilitation and complex continuing care during the postacute period. This variation in discharge patterns tends to also drive variation in total episode costs between LHINs.

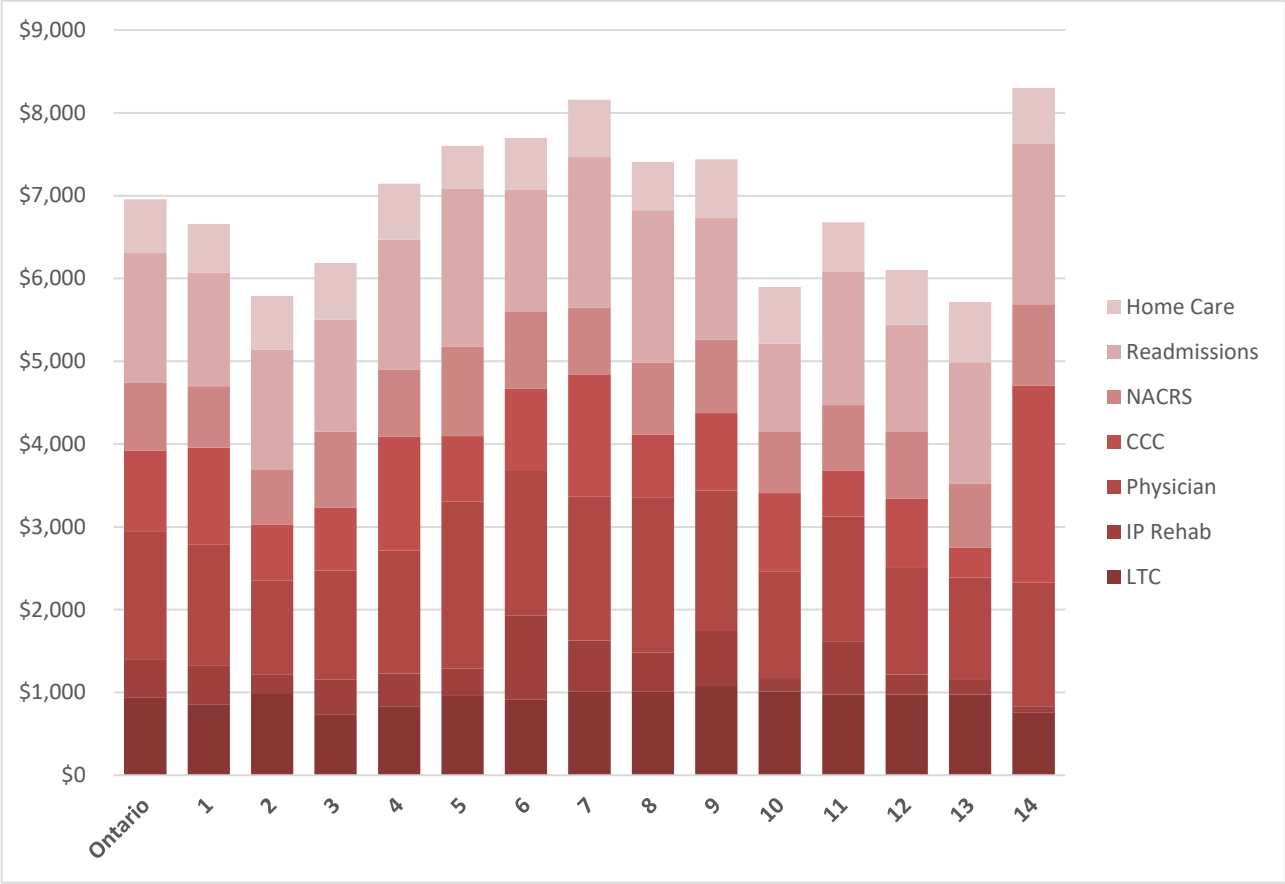


Figure 4: 90-Day Costs of Postacute Care by Health Service in Ontario Local Health Integration Networks Where Patients Reside (2009/2010–2010/2011 Discharges)

Abbreviations: CCC, community care canter; IP, inpatient; LTC, long-term care; NACRS, National Ambulatory Care Reporting System.

Continuum-of-Care Model

As mentioned previously, this clinical handbook integrates the acute heart failure handbook and the postacute (community) heart failure handbook. The integration of the 2 handbooks is represented in Figure 5. The model has served as a working model as the components of this clinical handbook were developed. Beginning as a simplified sketch of key phases in the heart failure episode of care, the model has been modified to reflect the elements of the pathway.

The following sections lay out the recommended practices for the modules in Figure 5 and divide the continuum into 2 episodes of care: acute care (Figure 6) and postacute community care (Figure 7).

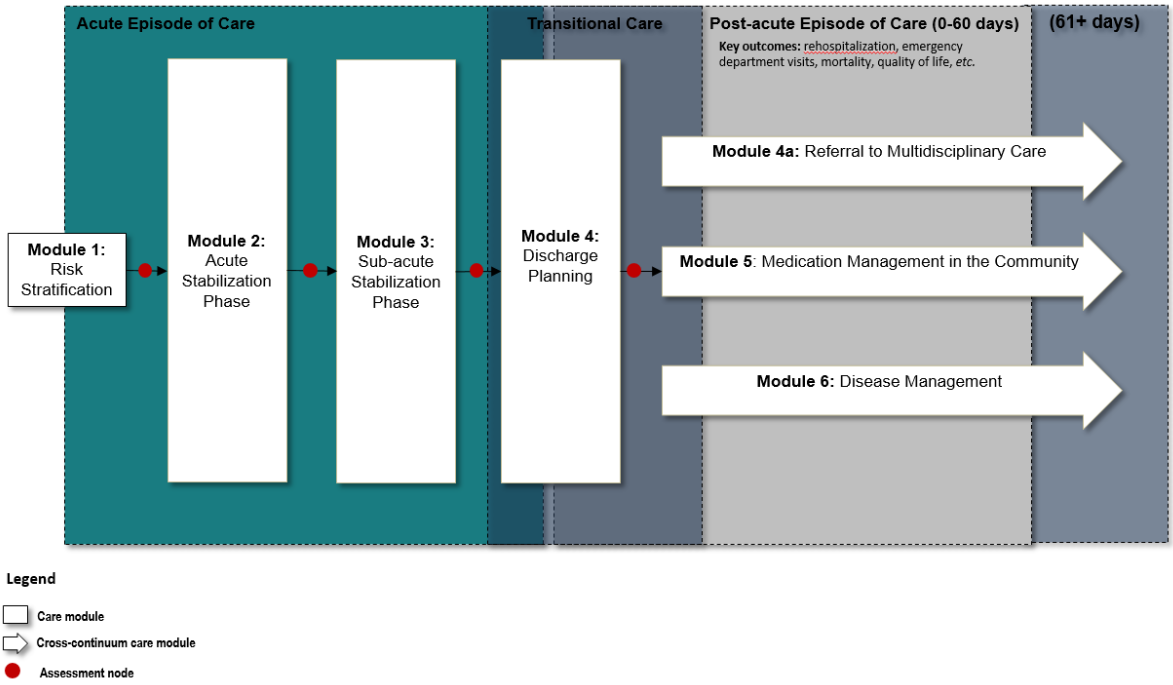


Figure 5: Integrated Continuum-of-Care Model for Heart Failure, Including Both Acute and Postacute (Community) Phases of Care

Recommended Practices for Heart Failure

Evidence Used to Develop Recommended Practices

OHTAC Recommendations

Four evidence-based analyses from Health Quality Ontario and corresponding OHTAC recommendations were identified that directly relate to the heart failure episode of care:

- Specialized Community-Based Care: An Evidence-Based Analysis (25)
- Experiences of Living and Dying With COPD: A Systematic Review and Synthesis of the Qualitative Empirical Literature (26)
- Health Care for People Approaching the End of Life: An Evidentiary Framework (27)
- OHTAC Recommendation: Implantable Cardioverter Defibrillators for Primary Prevention of Sudden Cardiac Death (28)

Clinical Handbooks

Four clinical handbooks from Health Quality Ontario containing recommendations relevant to the heart failure episode of care were incorporated as sources of evidence:

- Quality-Based Procedures: Clinical Handbook for Congestive Heart Failure (29)
- Quality-Based Procedures: Clinical Handbook for Chronic Obstructive Pulmonary Disease (30)
- Quality-Based Procedures: Clinical Handbook for Community-Acquired Pneumonia (31)
- Quality-Based Procedures: Clinical Handbook for Postacute Medical Discharge Short-Stay Populations (32)

Health Quality Ontario's Rapid Reviews

Rapid reviews were conducted on specific topics requested by the expert advisory panels or where gaps or inconsistencies in the evidence were identified:

Rapid Reviews completed for the Acute Heart Failure Clinical Handbook

- Coronary revascularization in ischemic heart failure patients
- Early mobilization and ambulation in hospitalized heart failure patients
- Vasodilators for in hospital heart failure management
- Chest x-rays for diagnosing pulmonary infection as a precipitant of acute heart failure
- B-type natriuretic peptide testing
- In hospital performance indicators for in hospital heart failure management
- Implantable cardioverter defibrillators or cardiac resynchronization therapy for in hospital heart failure
- Intra-aortic balloon pumps for heart failure management
- Electrocardiograms for diagnosing ischemia as a precipitant to acute heart failure
- Inotropic and vasoactive agents for in hospital heart failure
- In hospital electrocardiographic (ECG) telemetry monitoring for acute heart failure

- Invasive monitoring with pulmonary artery catheters in heart failure

Rapid Reviews completed for the Update of the Acute Heart Failure Clinical Handbook

- Ultrafiltration in heart failure: a rapid review
- Vasodilators for inhospital heart failure management: a rapid review (update)

Rapid Reviews completed for the Postacute Heart Failure Clinical Handbook

- Communication of discharge instructions for heart failure patients: a rapid review
- Medication reconciliation at discharge: a rapid review
- Criteria for referral to home care: a rapid review
- Criteria for referral to heart failure clinics: a rapid review
- Home-based exercise programs in heart failure: a rapid review
- Aerobic exercise training in patients with heart failure: a rapid review
- Physical activity counselling for heart failure patients: a rapid review
- Sodium restriction in heart failure: a rapid review

Clinical Guidelines

The guideline review process identified 1 series of Canadian guidelines that was used as the reference standard owing to its relevance and local context: Canadian Cardiovascular Society, 2006 (33); 2008 (34); 2010 (35); 2011 (36); 2012 (37); 2013. (38)

Three additional international clinical guidelines encompassing the continuum of care for heart failure were identified:

- American College of Cardiology Foundation/American Heart Association 2009 (39) and 2013 (40)
- National Institute for Health and Care Excellence, 2010 (41)
- Scottish Intercollegiate Guidelines Network, 2007 (42)

Quality assessment using the AGREE domain scores for each of the guidelines are presented in Table 13. Given the limited number of guidelines identified for each cohort, all guideline recommendations were included for consideration by the expert advisory panel.

Table 13. AGREE II Domain Scores for Heart Failure Guidelines

Guideline, Year	AGREE II Domain (*maximum possible score*)					
	Scope and Purpose	Stakeholder Involvement	Rigour of Development	Clarity of Presentation	Applicability	Editorial Independence
CCS, 2006	28%	33%	40%	78%	32%	83%
CCS, 2008	42%	50%	45%	81%	52%	83%
CCS, 2010	56%	50%	55%	78%	44%	92%
CCS, 2012	33%	39%	58%	89%	44%	92%
CCS, 2013	33%	50%	66%	94%	52%	92%
ACCF/AHA, 2009	11%	11%	58%	94%	40%	92%
ACCF/AHA, 2013	11%	22%	57%	89%	36%	92%
NICE, 2010	83%	89%	79%	89%	88%	83%
SIGN, 2007	8%	33%	84%	92%	60%	92%

Abbreviations: ACCF, American College of Cardiology Foundation; AGREE, Appraisal of Guidelines for Research & Evaluation; AHA, American Heart Association; ATS, American Thoracic Society; BOA, British Orthopaedic Association; BTS, British Thoracic Society; CCS, Canadian Cardiovascular Society; CIDS, Canadian Infectious Disease Society ; CTS, Canadian Thoracic Society; IDSA, Infectious Diseases Society of America; NICE, National Institute for Clinical Excellence; NSW, New South Wales; NVALT, Dutch Association of Chest Physicians; SIGN, Scottish Intercollegiate Guidelines Network; SWAB, Dutch Working Party on Antibiotic Policy.

The guidelines supporting expert advisory panel recommendations, in addition to the quality of evidence supporting individual guideline recommendations, were summarized. The quality-assessment tools used by each guideline are summarized in Table 14.

Table 14. Summary of Evidence Assessments Used by Guidelines

Organization	Grade of Recommendation/Level of Evidence
CCS (CA)[a]	Body of evidence is composed of: **A**: Multiple RCTs or meta-analyses **B**: Single RCT or nonrandomized studies **C:** Consensus of opinion of experts or small studies **Class of recommendations:** **Class I:** Evidence that a treatment is beneficial, useful, and effective **Class II:** Conflicting evidence about the usefulness of the treatment **Class IIa:** Weight of evidence indicates usefulness **Class IIb:** Usefulness is less well established by evidence or opinion **Class III:** Weight of evidence indicates treatment is not useful, and in some cases can be harmful
NICE (UK)	No explicit level of evidence applied to the recommendations
ACCF/AHA (US)	Body of evidence is composed of: **A**: Multiple populations evaluated. Multiple RCTs or meta-analyses **B**: Limited populations evaluated. Single RCT or nonrandomized studies **C**: Very limited populations evaluated. Consensus opinion of experts, case studies, or standard of care **Level of uncertainty:** **Class I:** Procedure should be performed or administered **Class IIa:** Procedure is reasonable to perform or administer **Class IIb:** Procedure may be considered **Class III:** Procedure has no benefit or could risk harm
SIGN (SCT)	Body of evidence is composed of: **A**: At least one MA, SR of RCTs, or high-quality RCTs directly applicable to the target population **B**: High-quality SRs of case control or cohort studies directly applicable to the target population **C**: Well-conducted case-control or cohort studies with high risk of confounding or bias **D**: Expert opinion, nonanalytic studies, or extrapolated evidence from case-control or cohort studies **Good Practice Points:** Based on clinical experience of guideline development group

Abbreviations: ACCF, American College of Cardiology Foundation; AHA, American Heart Association; CA, Canada; CCS, Canadian Cardiovascular Society; GRADE, ; MA, meta-analysis; NICE, National Institute for Health and Clinical Excellence; RCT, randomized controlled trial; SCT, Scotland; SIGN, Scottish Intercollegiate Guideline Network; SR, systemic review; UK, United Kingdom; US, United States
[a]CCS adopted GRADE methods after 2006 to assess quality of studies (explained on pg 24).

The expert advisory panels reviewed guideline recommendations to inform their recommendations and identify gaps or inconsistencies in the evidence that would be good candidates for rapid reviews. Some discrepancies in details were identified in several areas; for example, while all of the guidelines emphasized the importance of sodium restriction, daily intake of sodium varied across the recommendations.

Other Sources Contributing to Recommendations

In addition to the evidence provided through OHTAC recommendations, Health Quality Ontario's clinical handbooks, rapid evidence reviews, and international guidelines, the following sources of evidence were used to devise and further inform recommendations and to ensure consistent care is provided throughout the province:

- Health Quality Ontario Initiative: Adopting a Common Approach to Transitional Care Planning: Helping Health Links Improve Transitions and Coordination of Care (43)
- CCS Consensus Conference, 2003: Assessment of the cardiac patient for fitness to drive and fly (44)

- Expert advisory panel evidence: Any scientific report presented by members of the expert advisory panel was incorporated into drafting corresponding recommendations, particularly if the evidence placed the recommendation for Ontario into context. Specifically, we used the Cardiac Care Network Heart Failure Strategy 2014. (45)
- Expert advisory panel consensus: Where other forms of evidence were lacking, expert advisory panel members' opinions and consensus were incorporated.

Language Used to Reference Contributing Sources of Evidence

For clarity and transparency, the following terms were consistently applied to describe how the expert advisory panel used various evidence sources to develop episode-of-care best practice recommendations.

Taken from	• Recommendation was taken directly from another source
Modified	• Minor modifications were made to the recommendation from the source materials
Consistent with	• Recommendation was developed by the expert advisory panel and was consistent with other sources
Based on	• Recommendation was largely derived from a source but was not taken verbatim, or it was developed by expert panel consensus.

What's New?
During Phase 3, recommended practices could have been added, amended (e.g., owing to reorganization of modules, new evidence has changed an original recommendation), or deleted. Below is a summary of these changes; recommendations follow in the modules.

Additions

- 1.1 Risk Assessment/Stratification
- 2.4 Investigation of Ischemia
- Recommendations in Modules 4–7 (from the Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel)

Amendments

- 2.7 Advanced Care Discussions and Planning
- 2a.1 Ventilation Support
- 2a.2 High-Intensity Heart Failure Treatment Considerations

Deletions

Counselling (in Module 4 on discharge planning—it was expanded into multiple recommendations by the Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel)

Episode of Care for Acute Heart Failure

The Acute Heart Failure Episode-of-Care Advisory Panel developed the episode-of-care model for acute heart failure (Figure 6). Modules 1 through 3 represent the acute heart failure episode of care. The following recommendations include the recommendations from the clinical handbook on acute heart failure published in 2013 (29) and updates to the recommendations (as noted in the What's New box above).

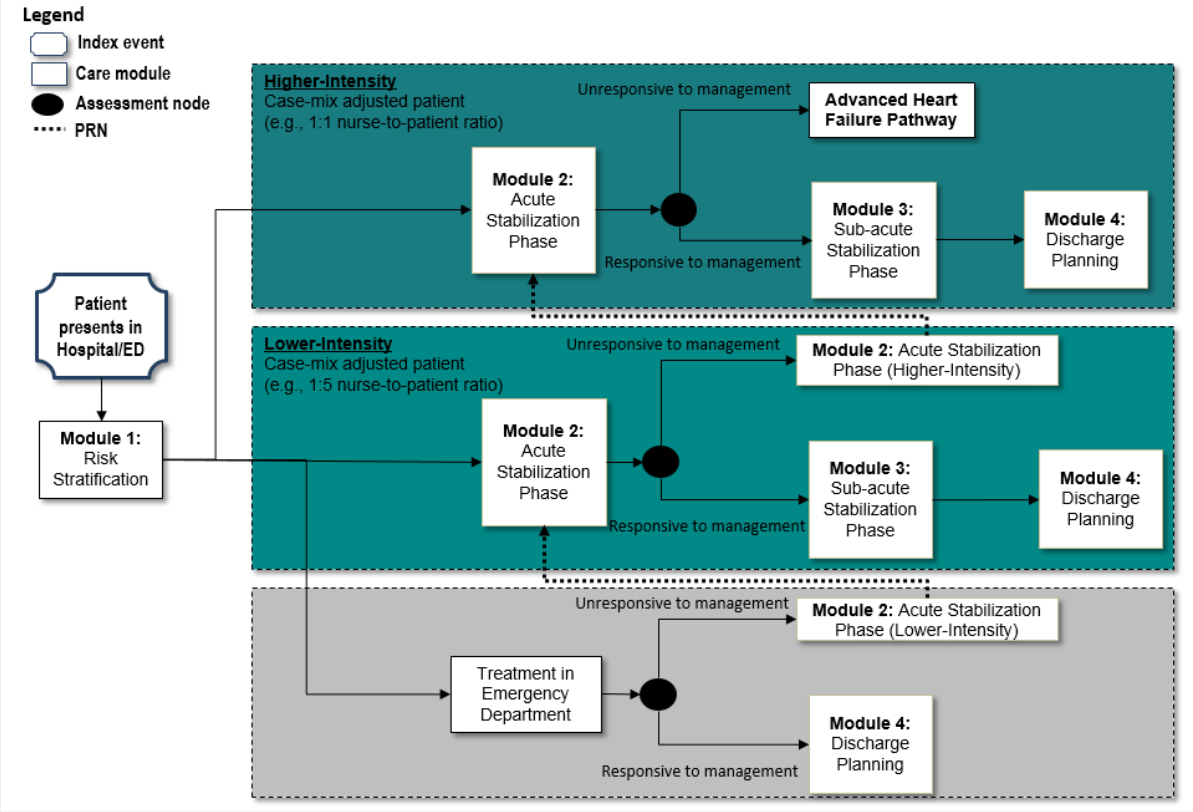


Figure 6. Episode-of-Care Model for Acute Heart Failure

Module 1: Risk Stratification

Recommended Practices	Contributing Sources of Evidence
1.1 Risk Assessment/Stratification	
Risk-stratification tools that can be used for multiple conditions (including HF) should be developed and consistently applied across all Ontario hospitals	Based on expert advisory panel consensus
1.2 Responsiveness to Diuresis	
Initial investigations should include: serum creatinine and electrolyte levels troponin measurements complete blood count electrocardiogram chest x-ray examination and an echocardiogram if no recent echocardiogram is available frequent measurement of heart rate, blood pressure, and oxygen saturation until patient is stabilized	Consistent with: CCS, 2006 (Class I, level C evidence) NICE, 2010 AHA/ACCF, 2013 (Class I, level C evidence)

Recommended Practices	Contributing Sources of Evidence
1.3 Risk Stratification Patient Groups	
Low intensity: Patients can be treated in the ED or in outpatient settings and discharged home without requiring inpatient admission. However, these patients require a follow-up visit with their primary care provider within days of discharge from the ED **Average intensity:** Patients require admission to inpatient care with normal nurse-to-patient staffing **High intensity:** Patients require ventilation (either noninvasive or invasive ventilation) and/or admission to an intensive care unit with higher nurse-to-patient staffing High-risk markers include: respiratory distress hypoxemia severity of pulmonary edema poor response to furosemide administered in ED hemodynamic compromise significant arrhythmias positive troponin	Based on expert advisory panel consensus
1.4 Heart Failure Risk Score	
An acute heart failure risk score—for example, the EHMRG—be calculated to assist with clinical decision-making and predicting the 7-day mortality risk of HF patients (predicted mortality risk increases incrementally with higher EHMRG risk score). As a general guide, patients who are low-risk (e.g., EHMRG quintiles 1 and 2) can be considered for discharge home if they have responded to initial treatment in the ED, provided that there are no other considerations (e.g., advanced-directives, severe dementia, estimated impact of admission on life-expectancy, etc.). Patients who are at higher-risk (e.g., EHMRG quintiles 3-5) should be admitted to hospital.	Consistent with AHA/ACCF, 2013 (Class IIa, level B evidence)

Abbreviations: ACCF, American College of Cardiology Foundation; AHA, American Heart Association; CCS, Canadian Cardiovascular Society; ED, emergency department; EHMRG, Emergency Heart Failure Mortality Risk Grade; HF, heart failure; NICE, National Institute for Clinical Excellence.

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations:

General Considerations for Risk Stratification

- Hospitals should use a common standardized risk stratification assessment tool or process to determine where and how to assist with clinical decision making when patients present to the emergency department.
- All hospitals should have a pathway or mechanism to transfer patients to a higher level provider

Module 2: Acute Stabilization Phase

Recommended Practices	Contributing Sources of Evidence
2.1 Diuretic monitoring and management (acute phase)	
Diuretic management approaches should take an "early and frequently" approach where initially a higher dose of diuretics could be considered for many patients Those at higher intensity should receive IV bolus of furosemide every 6 to 12 hours (twice daily) or continuous IV infusion Those at lower intensity should receive IV bolus of furosemide daily or BID Recording of: ▪ Daily weights ▪ Input and output every 6 hours ▪ Sodium intake ▪ Possible fluid restriction ▪ Electrolytes (at least daily for first 2–3 days) ▪ Renal function (creatinine, at least daily for first 2–3 days) ▪ Chest x-ray results: frequency of chest x-ray examinations depends on extent of pulmonary edema at baseline, a patient's clinical status, and his/her responsiveness to diuretics	Consistent with: ▪ CCS, 2012 (strong recommendation, moderate-quality evidence) ▪ NICE, 2010 ▪ ACCF/AHA, 2013 (Class I, level C evidence)
2.2 Identifying and treating precipitating factors	
Efforts to identify precipitating factors should include exploration of all the usual known factors, including medication and dietary noncompliance. However, precipitating factors should focus on identification of 2 particular prognostic indicators that have been shown to correlate with poorer 30-day outcomes of death or recurrent hospitalization, either of which would be severe enough to warrant surgical or interventional procedures: ▪ presence of myocardial ischemia ▪ worsening of valvular heart disease Evaluation for precipitating factors must also include application of a risk-stratification process, to help clinicians decide whether a patient should or should not undergo cardiac catheterization	Based on expert advisory panel consensus Consistent with: ▪ NICE, 2010 ▪ ACCF/AHA, 2009 (Class I, level C evidence)
2.3 Echocardiography	
Most patients should be considered for 2D echocardiography for assessment of left ventricular systolic and diastolic function and underlying valvular disease	Consistent with: ▪ CCS, 2006 (Class I, level C evidence) ▪ NICE, 2010 ▪ AHA/ACCF, 2009 (Class I, level C evidence) ▪ SIGN, 2007 (level B evidence)
2.4 Investigation of Ischemia	
Inclusion of a process that requires health care providers to document that they have considered patient for cardiac catheterization or noninvasive cardiac imaging for evaluation of coronary ischemia or valvular abnormality, and that patient was deemed either appropriate or inappropriate candidate, along with the reason If severe valvular heart disease is found, and patient is a potential candidate for valve surgery or repair, patient should be considered for cardiac catheterization	Based on expert advisory panel consensus

Recommended Practices	Contributing Sources of Evidence
We recommend coronary angiography be performed in patients with angina pectoris who are deemed suitable candidates for coronary revascularization	Taken from CCS, 2012 (strong recommendation, low-quality evidence)
2.5 Evidence-based pharmacotherapy management	
Patients with left ventricular systolic dysfunction who have not been prescribed evidence-based medications before admission should have these medications initiated in hospital. ACE inhibitors and ARBs should be initiated early after the acute event (e.g., > 24 hours) if the patient is hemodynamically stable. However, initiation of β-blockers should begin only once patient has had diuresis and pulmonary congestion is stable For patients who have been introduced recently to β-blockers and have acute decompensated heart failure associated with the increase, consideration should be given to halving the dose if they have severe pulmonary edema. However, health care providers should be discouraged from discontinuing ACE inhibitors or ARBs unless there is acute renal insufficiency or discontinuing ACE inhibitors or ARBs and β-blockers unless patient is hemodynamically unstable ACE inhibitors, ARBs, and β-blockers should be continued, particularly if patient is already receiving long-term treatment with these agents (provided that no new contraindications to therapy are present) Initial doses of ACE inhibitors, ARBs, and β-blockers should be low, and increased slowly In patients with severe left ventricular systolic dysfunction and NYHA Class II to IV heart failure, use of other evidence-based pharmacotherapy (e.g., aldosterone receptor antagonists) should be considered if ACE inhibitors, ARBs, or β-blockers have already been prescribed. Patients should be closely monitored for hyperkalemia and worsening renal function	Consistent with: ▪ CCS, 2006 (Class I, level A evidence) ▪ CCS, 2012 (strong recommendation, moderate-quality evidence) ▪ ACCF/AHA, 2009 (Class I, level A evidence) ▪ ACCF/AHA, 2013 (Class I, level A evidence)
2.6 Telemetry	
Telemetry may be considered, but due to lack of evidence, this intervention needs to be reassessed. Furthermore, hospitals using telemetry should develop policies identifying patients' eligibility and timing for reassessment.	Based on expert advisory panel consensus
2.7 Advanced Care Discussions and Planning (same recommendation as 6.16)	
In making palliative care services available, fluctuating physical, psychosocial, spiritual, and information needs should be considered without necessarily forgoing acute care. Caregivers should not give up hope for improvement during and after severe exacerbations	OHTAC for HQO COPD Mega-Analysis Systematic Review and Synthesis of the Qualitative Empirical Literature on Palliative Care
Device therapy, if applicable, should be discussed with patients. For instance, health care providers might discuss discontinuing antitachycardia therapy in patients with ICDs	Based on expert advisory panel consensus
End-of-life care for patients with HF should be based on total assessment of needs, symptoms, and estimated life expectancy	Taken from CCS, 2011 (strong recommendation, low-quality evidence)
Plans for end-of-life care should be communicated to ALL health care providers on the team	Based on expert advisory panel consensus

Recommended Practices	Contributing Sources of Evidence
Advanced care planning with patients and their caregivers should not be limited to DNR requests, but include discussions about specific life-supporting treatments, such as intubation, ventilation, defibrillation, and inotropic support	Based on expert advisory panel consensus
2.8 Reassessment and Re-evaluation	
Re-evaluate underlying and precipitating cause ▪ Echocardiography ▪ Cardiac catheterization ▪ Noninvasive cardiac imaging Screen for complications (e.g., arrhythmia, urosepsis, COPD, renal failure, pneumonia) Continue management and monitoring as per care pathway Discuss advanced directives	Based on expert advisory panel consensus

Abbreviations: 2D, 2-dimensional; ACE, angiotensin-converting enzyme ACCF, American College of Cardiology Foundation; AHA, American Heart Association; ARB, angiotensin receptor blockers; COPD, chronic obstructive pulmonary disease; CCS, Canadian Cardiovascular Society; DNR, do not resuscitate; ED, emergency department; HQO, Health Quality Ontario; ICD, Implantable cardioverter defibrillator; OHTAC, Ontario Health Technology Advisory Committee; SIGN, Scottish Intercollegiate Guidelines Network.

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations.

General Considerations for Acute Stabilization Phase

- Predischarge planning should commence shortly after admission to hospital.
- Where required, discussion with the family and patient regarding end-of-life care, advance care directives, and DNR orders should take place shortly after admission to hospital.
- At a system level, OHTAC end-of-life recommendations should be fully implemented.
- DNR forms should include discussions on components of DNR (i.e., defibrillation, ventilator support).
- Advance care planning should occur at each transition point in patient care.
- DNR orders should include management of patients in a nonacute setting.
- A province-wide standardized DNR form and process should be developed and implemented.
- Collect DNR as a data element in DAD and National Ambulatory Care Reporting System.

Module 2a: Acute Stabilization Phase—High-Intensity Heart Failure Inpatients

Recommended Practices	Contributing Sources of Evidence
2a.1 Ventilation Support	
Endotracheal intubation with mechanical ventilation may be used if less invasive modes of respiratory support fail or if the patient is in cardiogenic shock	Taken from: CCS, 2012 (Expert consensus)
2a.2 High-Intensity Heart Failure Treatment Considerations (Advanced Care Pathway)	
Patients requiring treatment of advanced heart failure should be managed in a higher intensity unit (e.g., ICU) by health care providers with expertise in management of heart failure. The following interventions may be considered for these patients: • IV inotropes and/or IV vasodilators	Based on expert advisory panel consensus Vasodilators for Inhospital Heart Failure Management: • Based on moderate quality of evidence, there was no statistically significant difference in renal function

Recommended Practices	Contributing Sources of Evidence
• Pulmonary arterial catheterization • IABP and other assistive devices • Ultrafiltration Note: Access to these interventions could require transferring patients to hospitals with these facilities	biomarkers (at baseline, 24 h, 48 h, and discharge) among patients who received nesiritide versus nitroglycerin • Based on low quality of evidence, there was no statistically significant difference in mortality (at 3 or 6 months postdischarge) among patients who received nesiritide versus nitroglycerin **Ultrafiltration in Heart Failure:** Despite several systematic reviews on ultrafiltration, effectiveness of ultrafiltration remains unclear: ▪ Based on low quality of evidence, there is a significant improvement in fluid removal and weight loss in patients with heart failure receiving ultrafiltration compared with diuretic therapy after 48 hours of treatment. However, the duration of the effect is unclear. ▪ Based on very low quality of evidence, there do not appear to be any significant differences in the rates of adverse events among patients with heart failure receiving ultrafiltration compared with diuretic therapy

Abbreviations: CCS, Canadian Cardiovascular Society; HQO, Health Quality Ontario; IABP, Intra-aortic balloon pump; ICU, intensive care unit; IV, intravenous.

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations:

General Considerations for High-Intensity Heart Failure

Use of IV inotropes and IV vasodilators should be restricted to CCU or ICU settings if patients in the acute stabilization phase have high-intensity heart failure.

Module 3: Subacute Stabilization Phase

Recommended Practices	Contributing Sources of Evidence
3.1 Diuretic Monitoring and Management (Subacute Phase)	
Diuretic monitoring and management in the subacute phase is similar to that of the acute phase, recognizing that the patient is now more stable, has less pulmonary congestion, and has been responsive to more intensive diuretics Weight and input/output should still be recorded daily. Electrolytes and renal function can be monitored daily, every second day, or every third day, depending on the patient's clinical status, dose of furosemide, responsiveness to therapy, and prior electrolyte or renal laboratory abnormalities	Consistent with: • CCS, 2012 (strong recommendation, moderate-quality evidence) • NICE, 2010 • ACCF/AHA, 2013 (Class I, level C evidence)

Recommended Practices	Contributing Sources of Evidence
3.2 Early mobilization	
The mobilization/activity care map should follow early-mobilization maps for other care pathways (e.g., COPD) Mobilization depends upon responsiveness to diuresis, and activities such as walking should not be encouraged for patients with severe residual pulmonary congestion or refractory heart failure. Nevertheless, for most patients, activities should be scaled from sitting up in bed to sitting in a chair with bathroom privileges, to walking (in the room and on the ward) Patients should be encouraged to mobilize (with walking) at least once every 6 hours during daytime waking hours	Based on expert advisory panel consensus
3.3 Evidence-based pharmacotherapy (subacute phase)	
Similar to the acute phase, patients in the subacute phase should be treated with β-blockers (assuming there is no absolute contraindication), and ACE inhibitors/ARBs. Nitrates and hydralazine should be used in patients intolerant of or with contraindications to ACE inhibitors/ARBs. Again, the focus (in treatment-naïve patients) should be on initiating therapy at low doses and titrating slowly The use of mineralocorticoid receptor antagonists should be considered (as described in section 2.5)	Consistent with: • CCS, 2006 (Class I, level A evidence) • CCS, 2012 (strong recommendation, moderate-quality evidence) • ACCF/AHA, 2009 (Class I, level A evidence) • ACCF/AHA, 2013 (Class I, level A evidence)
3.4 Other Heart Failure Management Considerations	
Other heart failure management considerations include: ▪ CPAP for patients with confirmed sleep apnea and as recommended by a sleep specialist ▪ Nitrates can be considered for preload reduction ▪ Digoxin can be considered if heart failure symptoms persist despite otherwise optimal therapy ▪ If patient is older and has atrial fibrillation, digoxin should be used with caution ▪ Patients can be considered for an ICD or CRT at the discretion of the treating physician The decision to insert ICD or CRT devices should be made after optimization of heart failure therapy and reassessment of ejection fraction, unless the patient who requires the ICD presents after cardiac arrest or with sustained ventricular tachyarrhythmia	Consistent with SIGN, 2007 (level B evidence) Based on expert advisory panel consensus Consistent with: ▪ CCS, 2006 (Class I, level A evidence) ▪ CCS, 2012 (strong recommendation, moderate-quality evidence) ▪ ACCF/AHA, 2013 (Class IIa, level B evidence) Consistent with OHTAC recommendation: ICDs for Primary Prevention of Sudden Cardiac Death

Abbreviations: ACCF, American College of Cardiology Foundation; AHA, American Heart Association; CCS, Canadian Cardiovascular Society; CPAP, continuous positive airway pressure; CRT, cardiac resynchronization therapy; ICD; implantable cardioverter defibrillator; NICE, National Institute for Health and Care Excellence; OHTAC, Ontario Health Technology Advisory Committee; SIGN, Scottish Intercollegiate Guidelines Network.

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations:

General Considerations for Subacute Stabilization Phase

- Early referral to physiotherapy to mobilize patient once condition is stable
- Assess patient's and caregiver's level of health literacy
- Ensure patient is informed, in language of choice, of treatment options

Postacute (Community) Heart Failure Episode of Care

Modules 4 through 7 represent the postacute (community) heart failure episode of care. Figure 7 is the postacute heart failure episode-of-care model developed by the Postacute (Community) Care for Heart Failure Episode-of-Care Advisory Panel. The following recommendations were developed through a separate, but not independent, process of the earlier modules. The evidence sources and expert advisory panel members used for these modules differ from those used for the acute episode of care and were targeted to postacute episode of care for patients with heart failure. With that said, some aspects of the following recommendations refer to care processes that could, or should, occur in hospital. Consequently, the following modules are not intended to be considered in isolation from the earlier modules, and the entire episode of care should be considered as a whole for providing good quality of care across the continuum.

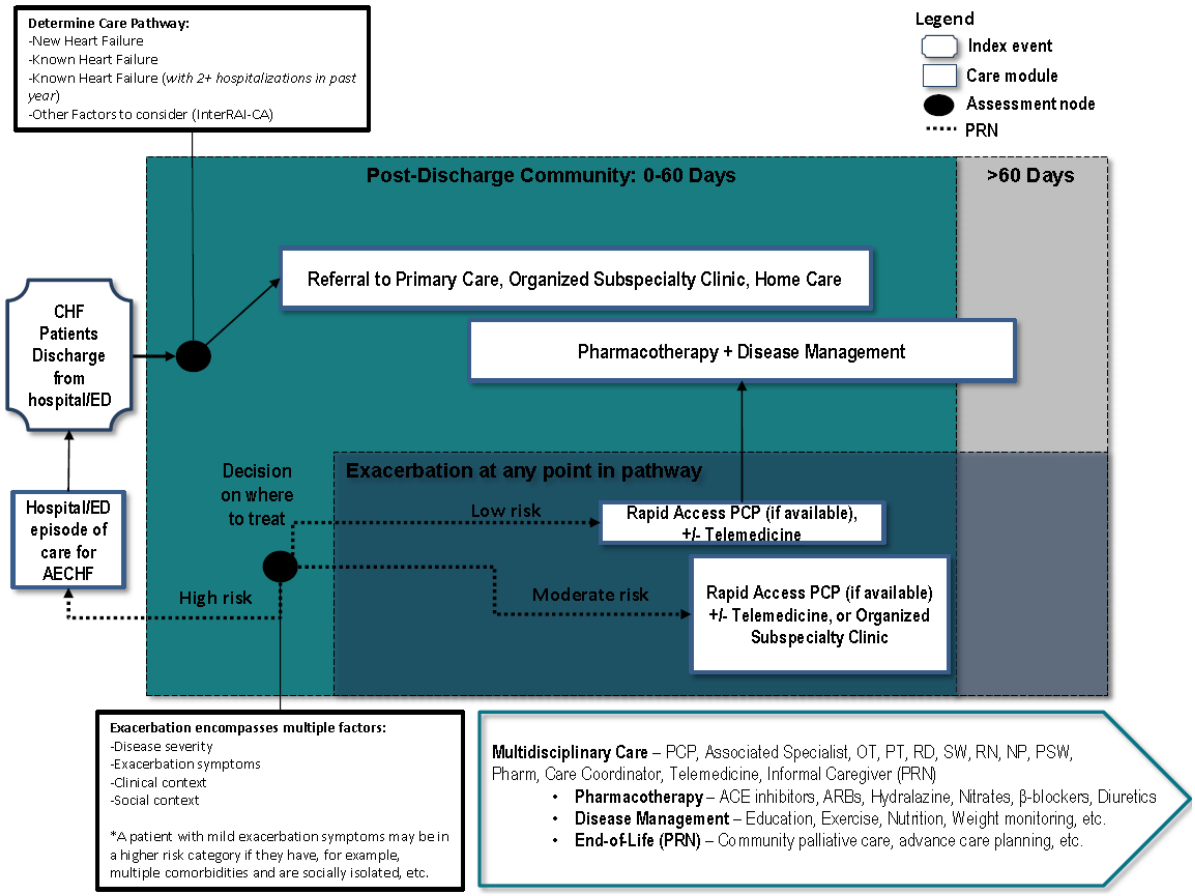


Figure 7. Episode-of-Care Model for Postacute (Community) Heart Failure

Module 4: Discharge Planning

Recommended Practices	Contributing Sources of Evidence
4.1 Medication Reconciliation	
Protocol should be established (consider Accreditation Canada) to ensure medication reconciliation occurs at all transition points. Medication therapy should be communicated to ALL health care providers on the team	Consistent with: • HQO Acute CHF QBP Handbook, 2012 • HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014 • Adopting a Common Approach to Transitional Care Planning, 2013 • ACCF/AHA, 2009 (Class I, level of evidence C) • SIGN, 2007 (good practice point) • **Medication Reconciliation at Discharge**: It is impossible to determine effect of medication reconciliation on patient outcomes, as there is limited evidence on medication reconciliation in isolation of other care-coordination interventions
4.2 Predischarge Planning	
Predischarge planning encompasses the following standards: ▪ Predischarge planning is incorporated as a standard of care for patients admitted to hospital ▪ Patients and caregivers are involved in the discharge planning process ▪ Individualized comprehensive assessments and care plans are developed for patients on admission ▪ Individualized discharge plans[a] are developed on admission for patients ▪ Families and caregivers are provided with information and resources to support transition ▪ Standardized risk-assessment tools should be used to assess and stratify patients at discharge	Taken from Adopting a Common Approach to Transitional Care Planning, 2013
4.3 Predischarge Assessments	
Assessment before discharge should include: • Functional capacity assessment (e.g., 6MWT or able to walk around ED or hospital ward) • Social support assessment (e.g., does patient have a caregiver, access to community resources, suitable living situation, financial stability?) • For clinically overt cognitive impairment, refer patient to geriatrician or appropriate clinic • Consider cognitive assessment for heart failure patients after discharge If any of these assessments warrant further investigation, patient should be referred to appropriate provider (or arrangements made to support access to postdischarge appointments)	Consistent with SIGN, 2007 (good practice point)
4.4 Timing of Initial Follow-Up After Discharge	
Patients who are discharged after hospital admission should be evaluated by their family physician within 3 d Patients who are discharged from the ED should be evaluated by their family physician within 3 d	Modified Adopting a Common Approach to Transitional Care Planning, 2013

Recommended Practices	Contributing Sources of Evidence
Patients requiring specialized HF care should have rapid access to follow-up regardless of outpatient care setting (home care, HF clinic, specialists, primary care, cardiac rehabilitation, etc.) Patients should ideally receive a follow-up phone call from a designated health care provider within 48 h of discharge from hospital. To ensure continuity, the designated health care provider should be from the same institution where the initial hospitalization occurred ***Note:*** *Expert advisory panel members agreed that communication shortly after discharge is critical for continuity of care; however, logistics of making connection between hospital and primary care might be challenging*	Consistent with CCN Heart Failure Strategy, 2014
4.5 Timely Documentation	
Discharge notes should be dictated and sent to primary care (and relevant other) provider(s) within 1 wk of patient discharge, but preferably within 48 h	Consistent with: • ACCF/AHA, 2009 • CCS, 2008
4.6 Type of Communication as Discharge	
Written and verbal discharge plans[a] (accounting for health literacy, numeracy, and language barriers) should be given to patients and caregivers At minimum patients and their caregivers should know signs and symptoms of worsening HF and know which health care providers they should contact As an example provided by the community HF expert advisory panel, patients could be provided the "Stop Light" document for information on what do to when they have worsening HF (Appendix: Stop Light Document)	Consistent with: • ACCF/AHA, 2009 (Class I, level of evidence C) • CCS, 2008 (Class IIa, level of evidence B) • **Communication of Discharge Instructions for Heart Failure Patients**: Communication of discharge plans is important; however, there is limited evidence on the best method of communicating the discharge plan
4.7 Discharge Plan[a]	
Individualized discharge plans[a] (medications, referrals, investigations [including lab tests] that need to be done postdischarge, etc.) should be dictated and sent to the family physician and other relevant provider(s) before discharge including home care follow-up within 1 wk of patient discharge, but preferably within 48 h Patients and their caregivers should have their follow-up appointment(s) booked by a designated health care provider with a family physician or specialist before discharge. In addition, patients and caregivers should be given a copy of the discharge plan Barriers to accessing early postdischarge appointments should be identified and addressed **Consider Referral to Multidisciplinary Community Care (Module 4a)**	Consistent with: ▪ HQO Acute CHF QBP Handbook, 2012 ▪ CCS, 2008 (Class IIa, level of evidence B) ▪ CCN Heart Failure Strategy, 2014 Modified Adopting a Common Approach to Transitional Care Planning, 2013

Abbreviations: 6MWT, 6-minute walk test; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; CCN, Cardiac Care Network; CCS, Canadian Cardiovascular Society; CHF, congestive heart failure; ED, emergency department; HF, heart failure; HQO, Health Quality Ontario; QBP, Quality-Based Procedure; SIGN, Scottish Intercollegiate Guideline Network.
[a]*Discharge plan* refers to the official hospital documentation including the dictated details of the hospital episode and full care plan.

Implementation considerations expressed by members of the expert advisory panel concerning the module recommendations are listed in Table 15.

Table 15: Implementation Considerations for Modules

Predischarge planning should commence shortly after admission to hospital
Advanced planning discussion should take place at each health care transition point
Where required, hospital-based CCAC Care Coordinator should be engaged shortly after patient's admission to hospital
Readiness for discharge should be based on patient's being clinically, socially, physically, and mentally ready for discharge
Cognitive ability triage should be undertaken as a component of predischarge planning and, where required, referral made for assessment while in hospital or as part of postdischarge follow-up plan
Follow-up care should be with a family physician. If possible, the family physician should have direct access to a health care provider with expertise in HF
Patients who require highly specialized care providers, advanced diagnostics, and interventions should be assessed by a HF clinic within a tertiary care centre
Until accepted community-based risk assessment and stratification tools are available, best clinical practices should be adopted to reduce the risk of avoidable readmission to hospital or presentation to the ED
Service providers should do the following when undertaking discharge planning: • Confirm the preferred maintenance therapy and gauge patient's daily care practices • Arrange follow-up and home care • Provide clear instructions about appropriate medication use and potential adverse effects • Formally assess daily living activities if concerns remain about how patient will cope at home • Ensure that hospitals identify or establish services to review people admitted to hospital with a primary diagnosis of HF within 2 wk after discharge • Follow-up contact should be made by hospital-based staff within 48 h of discharge • Medication reconciliation should be completed before discharge
Ensure that discharge plan identified the cause for admission and treatment provided so that family physician can assist in providing appropriate community-based service
Ensure that HQO/Health Transformation Secretariat Transitions standards for discharged are fully implemented

Abbreviations: CCAC, Community Care Access Centre; ED, emergency department; HF, heart failure; HQO, Health Quality Ontario.

Recommended practices in Module 4a address appropriate referrals to health care professionals.

Module 4a: Referral to Multidisciplinary Care

Recommended Practices	Contributing Sources of Evidence
4a.1 Referral to Home Care	
Patients with an *apparent* need for home care service (nursing monitoring of HF, functional issues, mobility limitations, limited access to transportation, caregiver burden, etc.) or patients who have frequent admissions or ED visits should be referred for a home care assessment. Home care referral should be considered for patients where home assessments might be beneficial	Consistent with **Criteria for Referral to Home Care**: Patients without an obvious need for home care services can be overlooked and experience poor outcomes as a result. Patients with major mobility limitations, longer hospital stays, more comorbidities, and older age are more likely to be identified for home care services than those without an obvious need
4a.1.1. Care coordination is recommended in accordance with the HQO Community Home Care Handbook	Taken from HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014
4a.1.2. Nursing assessment and monitoring, wound care, intravenous therapy, continence, and pain management should accord with the HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations	Taken from HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014
4a.1.3. Occupational therapy services should accord with the HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations	Taken from HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014
4a.2 Referral to Cardiologist/Specialist	

Recommended Practices	Contributing Sources of Evidence
4a.2.1. Patients with HF without a completed diagnostic workup have persistent symptoms, new unexplained symptoms or clinical instability requiring investigation or treatment, need for cardiovascular interventions, need for frequent follow-up, difficulty with initiation or optimization of medical therapy, or patients for whom a family physician is unable to provide necessary care should be referred to an internist specializing in cardiac care, cardiologist, or HF clinic	Consistent with: ▪ CCS, 2006 (Class I, level of evidence C) ▪ CCN Heart Failure Strategy, 2014
4a.2.2. Referral for advanced HF therapy, high-risk CV surgery program, mechanical circulatory support, or transplantation	Consistent with: • CCS, 2006 (Class I, level of evidence C) • CCN Heart Failure Strategy, 2014
4a.2.3. Referral to regional congenital program for patients with HF and congenital heart disease	Consistent with: CCS, 2006 (Class I, level of evidence C)
4a.3 Referral to Geriatrician	
Refer for geriatrician assessment when an older patient has multiple comorbidities, difficulty with medication management, cognitive impairment, or functional limitations	Based on expert advisory panel consensus (Modified wording from BC Guidelines & Protocols Advisory Committee) Consistent with CCN Heart Failure Strategy, 2014
4a.4 Referral to Outpatient Subspecialty Clinic	
We recommend that patients with HF who have the following characteristics should be considered for referral to an outpatient subspecialty clinic: ▪ Patients with high-risk HF ▪ Recurrent hospitalizations ▪ New-onset HF that requires diagnostic or therapeutic intervention ▪ Concomitant ischemia ▪ NYHA Class III–IV ▪ Asymptomatic or symptomatic patients with LVEF <35% ▪ Renal dysfunction (not requiring dialysis) ▪ Multiple comorbidities ▪ Concomitant RV dysfunction	Consistent with: • OHTAC Recommendation on Community-Based Care for the Specialized Management of Heart Failure, 2009 • HQO Acute CHF QBP Handbook, 2012 • ACCF/AHA, 2013 (Class I, level of evidence B) • CCS, 2006 (Class I, level of evidence C) • CCN Heart Failure Strategy, 2014 • **Criteria for Referral to Heart Failure Clinics**: Optimal eligibility criteria for HF clinics are unclear
4a.5 Referral to Cardiac Rehabilitation Program	
Patients should be referred to cardiac rehabilitation, where available	Consistent with: • ACCF/AHA, 2013 (Class IIa, level of evidence B) • CCS, 2008 (Class I, level of evidence C) • CCN Heart Failure Strategy, 2014
4a.6 Services Provided in Outpatient Subspecialty Clinic	
Health care professionals should provide education, self-management training, and counselling (as outlined in recommendations 4.1 to 4.16) to patients and their caregivers. Special efforts should be made to encourage caregivers to participate in patient management to ensure knowledge translation has been successful whenever possible	Taken from OHTAC Recommendation on Community-Based Care for the Specialized Management of Heart Failure, 2009 Consistent with: CCS, 2006 (Class I, level of evidence A)

Abbreviations: ACCF, American College of Cardiology Foundation; AHA, American Heart Association; BC, British Columbia; ED, emergency department; CCN, Cardiac Care Network; CCS, Canadian Cardiovascular Society; CV, cardiovascular; CHF, congestive heart failure; HF, heart failure; HQO, Health Quality Ontario; LVEF, left ventricle ejection fraction; NYHA, New York Heart Association; OHTAC, Ontario Health Technology Advisory Committee; RV, right ventricular.

General Considerations for Discharge and Referral Planning

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations:

- A predischarge functional assessment should be completed and care plan followed up or re-assessed in patients' homes.
- A provincial database accessible to all patients outlining where in their community they can receive treatment, advice, and education should be developed.
- Direction on where to go if symptoms worsen should be provided to patients and their caregivers on discharge.
- Referral to a geriatrician should be considered.
- Barriers that restrict access to a HF clinic and cardiac rehabilitation program should be removed at a system level, provider level, and patient level.

Module 5: Medication Management in the Community

This module identifies recommended practices for prescribing pharmacotherapy for patients with heart failure.

Recommended Practices	Contributing Sources of Evidence
5.1 Evidence-Based Pharmacotherapy	
For heart failure with reduced ejection fraction: • All patients without contraindications should receive ACE inhibitors or ARBs. If patients cannot tolerate ACE inhibitors or ARBs or have contraindications, they should receive hydralazine and nitrates • All patients without contraindications should receive β-blockers • The use of aldosterone-receptor antagonists should be considered for patients with symptomatic heart failure (NYHA Class II–IV) despite optimal medical therapy with ACE inhibitors or ARBs, β-blockers, and diuretics (if necessary)	Consistent with: • HQO Acute CHF QBP Handbook, 2012 • CCS, 2006 (Class I, level of evidence A) • CCS, 2012 (Class I, level of evidence A) • CCN Heart Failure Strategy, 2014
5.2 Other Relevant Medical Therapies	
Additional therapies include diuretics, cardiac glycosides (digoxin) for symptom management, statins and antiplatelets for patients with ischemic heart disease, or anticoagulation for patients with atrial fibrillation	Modified HQO Acute CHF QBP Handbook, 2012 Consistent with: • CCS, 2006 (Class I, level of evidence A) • CCS, 2012 (Class I, level of evidence A) • CCN Heart Failure Strategy, 2014

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin-receptor blockers; CHF, congestive heart failure; CCN, Cardiac Care Network; CCS, Canadian Cardiovascular Society; HQO, Health Quality Ontario; NYHA, New York Heart Association.

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations:

General Considerations for Medical Management in the Community

- Financial barriers to accessing drugs should be identified early and action taken to eliminate or minimize cost to patients who cannot afford to pay for medications.
- All patients and their caregivers should be educated on proper use of prescribed medications, including who can answer any questions.

- All patients should have a complete list of all of their medications (including nonprescription and complementary medications).
- Practitioners should know the contraindication(s) and known side effects of each medication and advise patients accordingly.
- Patient medication allergies should be entered in the electronic health record.
- Medication reconciliation should be undertaken as a component of postdischarge follow-up and, where possible, in patients' homes.
- All changes to medications, which can be frequent, should be communicated to the entire health care team.

Module 5 identifies recommended practices for patients with HF being discharged to the community. The recommended practices in this module can be undertaken by family physicians, interdisciplinary group practices, home care, heart failure clinics, internal medicine and cardiology specialists, and other health service providers in the community.

Module 6: Disease Management

Recommended Practices	Contributing Sources of Evidence
6.1 Patient Education	
• Informal assessment of health literacy, numeracy, and cognition should be completed to adapt the education plans as necessary (including materials in various languages) • Education should start before discharge (e.g., Stop Light document, Appendix 1) and should be continued and enhanced in the community • Education should be provided frequently, consistently, and through a variety of mediums • Education should be provided to patients, caregivers, and primary care providers on medication management, smoking cessation, alcohol use, weight monitoring, symptom monitoring, nutritional assessment (e.g., sodium restriction, fluid intake), physical activity and exercise, and advanced care planning • By the end of educational programs, patients and caregivers should be able to state, at a minimum, the plan for dealing with worsening signs and symptoms (or exacerbation)	Consistent with: • HQO Acute CHF QBP Handbook, 2012 • HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014 • ACCF/AHA, 2013 (Class I, level of evidence C) • NICE, 2010 • CCN Heart Failure Strategy, 2014
6.2 Medication Management	
Patients and medications should be assessed to ensure: ▪ Optimization of evidence-based and guideline-recommended medications ▪ Use of appropriate symptom-relief medications ▪ Adherence is assessed (e.g., community HF expert advisory panel noted patients could be assessed with Morisky's 4-Item Medication Adherence Questionnaire from Appendix 1. Health care providers should address reasons for poor compliance where possible) ▪ Identification of potential medication therapy problems or discrepancies	Consistent with: • OHTAC Recommendation on Community-Based Care for the Specialized Management of Heart Failure, 2009 • CCN Heart Failure Strategy, 2014 • HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014

Recommended Practices	Contributing Sources of Evidence
6.3 Nutritional Assessment	
When initially diagnosed with HF, patients should ideally receive education on sodium and fluid restriction. This could be done individually or in a group (either inpatient or outpatient) The following patients should be referred for an individualized nutritional assessment, through an outpatient subspecialty clinic, primary care, or home care: ▪ Patients with advanced heart failure (NYHA Class III or IV) ▪ Frail elderly patients ▪ Patients with unintended weight loss of nonedematous weight of more than 6% of the previous normal weight over 6 mo associated with HF (cardiac cachexia) ▪ Patients with frequent readmissions to hospital for decompensated HF ▪ Patients with serious comorbidities affecting nutrition	Based on expert advisory panel consensus Consistent with HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014
6.4 Sodium Restriction	
Use clinical judgment and be realistic about patient factors when prescribing sodium restrictions. Patients should be advised to: ▪ Add little or no salt when cooking or at the table ▪ Start reading food labels and choose foods that contain less than 200 mg of sodium, or 8% of daily value, per serving ▪ Look for products that claim to have low sodium or no salt added ▪ Try to limit prepared, processed, and restaurant foods and to cook more at home ▪ Prepare more meals at home using fresh ingredients	Consistent with: • CCS, 2006 (Class I, level of evidence C) • ACCF/AHA, 2013 (Class IIa, level of evidence C) • **Sodium Restriction in Heart Failure:** There is conflicting evidence about effects of restricting sodium in patients with HF
6.5 Fluid Intake	
Concomitant restriction of daily fluid intake to between 1.5 L/d and 2 L/d should be considered for all patients with fluid retention or congestion not easily controlled with diuretics, or in patients with substantial renal dysfunction or hyponatremia	Consistent with: • CCS, 2006 (Class I, level of evidence C) • ACCF/AHA, 2013 (Class IIa, level of evidence C)
6.6 Weight Monitoring	
Daily weights should be recorded for all patients who receive diuretics on a standing or PRN basis. Patients or caregivers should be able to state action plan for changes in weight, and should be aware of their target weight	Consistent with: • HQO Acute CHF QBP Handbook, 2012 • CCS, 2006 (Class I, level of evidence C) • SIGN, 2007
6.7 Physical Activity Counselling	
Patients should be encouraged to be physically active consistently by all members of their health care team. Patients who find it difficult to maintain physical activity should be considered for physical activity counselling with the appropriate provider	Consistent with: ▪ HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014 ▪ SIGN, 2007 ▪ **Physical Activity Counselling for Heart Failure Patients**: The largest and longest study on physical activity counselling identified by this review found that a 50-min individualized physical activity counselling session with a physiotherapist, followed up with 4–5 telephone sessions over the next 2 y resulted in maintenance of mobility in older adults
▪ Physiotherapy services are recommended to be provided in accordance with the HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations,	Taken from HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014

Recommended Practices	Contributing Sources of Evidence
2014	
6.8 Exercise	
All stable HF patients (regardless of disease severity) should be referred to cardiac rehabilitation or an alternative exercise program where home-based rehabilitation is unavailable. Senior patients who are frail should be referred to geriatric rehabilitation. Patients should be physically active or engage in regular exercise that does not produce uncomfortable symptoms. Expert advisory panel endorses recommendations on exercise frequency and intensity by severity of HF from CCS 2013 Guidelines	Consistent with: • HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014 • CCS, 2013 (Class I, level of evidence A) • ACCF/AHA, 2013 (Class I, level of evidence A) • NICE, 2010 • SIGN, 2007 (good practice point) • **Home-Based Exercise Programs in Heart Failure**: Home-based exercise training increased 6MWT distance compared with usual care. Peak VO2 and QOL did not differ between home-based exercise training and usual care • **Aerobic Exercise Training in Patients With Heart Failure**: There is a trend toward improved QOL in patients with HF who receive exercise training. Exercise training reduces HF-related hospital admissions
6.9 Smoking Cessation	
Patients who smoke should receive smoking cessation counselling and referral to smoking cessation program. Could include providing information to patients with contact information and instructions for resources or other guidance	Consistent with: • HQO Acute COPD Handbook, 2012 • HQO Community-Acquired Pneumonia QBP Handbook, 2013
6.10 Alcohol Consumption	
If HF is alcohol-related, patients should be advised to abstain from consuming alcohol	Consistent with: • NICE, 2010 • SIGN, 2007 (level C)
6.11 Vaccinations	
Patients who do not have up-to-date influenza (annual) or pneumococcal vaccinations should be vaccinated, unless contraindications are present	Taken from: • HQO Acute COPD Handbook, 2012 • HQO Community-Acquired Pneumonia QBP Handbook, 2013
6.12 Sleep Apnea	
Referral to sleep laboratory with expertise in HF. Criteria for referral can include risk factors for sleep-disordered breathing or suspicion on basis of clinical assessment	Modified HQO Acute CHF QBP Handbook, 2012 Consistent with: • CCS, 2011 (weak recommendation, moderate-quality evidence) • ACCF/AHA, 2013 (Class IIa, level of evidence B)
6.13 Depression	
Assess psychological status once HF has stabilized and carefully consider risks and benefits of drug treatment and cognitive behavioural therapy for depression	Modified NICE, 2010
Mental health support services are recommended in accordance with HQO Community Home Care Handbook	Taken from HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014
6.14 Support for Caregivers	

Recommended Practices	Contributing Sources of Evidence
Health care providers should be aware of resources (home care, community support services, advocacy groups, community centres, etc.) available for caregivers and should provide support when needed	Consistent with: • HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014 • NICE, 2010 • SIGN, 2007 (good practice point) • CCN Heart Failure Strategy, 2014 Caregiver Support for Postdischarge Patients With Chronic Conditions:* Caregiver or family support interventions are effective at improving physical (level of dependency, activities of daily living) and mental (QOL) outcomes for community-living, adult patients who were recently discharged from hospital owing to exacerbation of HF, stroke, COPD, or pneumonia
Caregiver and family support interventions are recommended in accordance with HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014	
Personal support services are recommended in accordance with HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014	Taken from HQO Community Home Care Handbook for Postacute Medical Discharge Short-Stay Populations, 2014
6.15 Driving	
Health care providers should consider the CCS's Consensus Conference 2003: Assessment of HF patients for fitness to drive and fly to determine whether patient should maintain his or her driving licence	Based on expert advisory panel consensus
6.16 Advanced Care Discussions and Planning (same recommendation as 2.7)	
In making palliative care services available, fluctuating physical, psychosocial, spiritual, and information needs should be considered, without necessarily forgoing acute care. Caregivers should not give up hope for improvement during and after severe exacerbations	OHTAC for HQO COPD Mega-Analysis Systematic Review and Synthesis of the Qualitative Empirical Literature on Palliative Care
Device therapy, if applicable, should be discussed with patients. For instance, health care providers might discuss discontinuing antitachycardia therapy in patients with ICDs	Based on expert advisory panel consensus
End-of-life care for patients with HF should be based on total assessment of needs, symptoms, and estimated life expectancy	Taken from CCS, 2011 (strong recommendation, low-quality evidence)
Plans for end-of-life care should be communicated to ALL health care providers on the team	Based on expert advisory panel consensus
Advanced care planning with patients and their caregivers should not be limited to DNR requests, but include discussions about specific life-supporting treatments, such as intubation, ventilation, defibrillation, and inotropic support	Based on expert advisory panel consensus

Abbreviations: ACCF, American College of Cardiology Foundation; AHA, American Heart Association; CCN, Cardiac Care Network; CCS, Canadian Cardiovascular Society; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; DNR, do not resuscitate; HF, heart failure; HQO, Health Quality Ontario; ICD, implantable cardioverter-defibrillator; NICE, National Institute for Health and Clinical Excellence; NYHA, New York Heart Association; OHTAC, Ontario Health Technology Advisory Committee; PRN, as needed; QBP, Quality-Based Procedure; QOL, quality of life; SIGN, Scottish Intercollegiate Guideline Network; VO2, oxygen uptake.

The following implementation considerations were expressed by members of the expert advisory panel concerning the module recommendations.

*McMartin, K. Caregiver support for post-discharge patients with chronic conditions: a rapid review. Toronto: Health Quality Ontario. In press.

General Considerations for Disease Management

Patient and caregiver education should include information on medications, sodium intake, fluid intake, diet and weight monitoring, exercise, alcohol consumption, sleep apnea, how to deal with stress, and end of life. Materials should be provided to both patient and primary caregiver and must include contacts on where to get additional information in the community.

Smoking Cessation

Smoking cessation strategies that specifically target patients with HF and COPD should be developed and implemented. Targeted smoking cessation materials and messaging should be heavily stressed to all HF patients, as smoking cessation in this group is shown to have a substantial positive and immediate clinical outcome.

Nicotine replacement therapy should be made a free benefit to any Ontario resident with a health card issued by the Ontario Ministry of Health and Long Term Care.

Public Health departments should provide free nicotine replacement therapy under the "STOP" program; pharmacies should be permitted to do the same when following up or screening patients.

Smoking cessation drug therapies should be made available at no cost to all Ontarians with a prescription by a health care provider trained in smoking cessation.

Screening and Education/Self-Management

Standardized self-management education materials should be available and consistently used both in hospitals and in communities to ensure consistent messaging to patients and caregivers. At a minimum, patient education materials (for both the patient and primary caregiver) should include:

- how to deal with worsening HF symptoms as well as other aspects of managing the disease, including where to find medical intervention if required
- medication management
- diet and nutrition counselling
- weight monitoring
- sodium intake
- fluid intake
- alcohol consumption
- smoking cessation
- physical activity
- sleep apnea
- vaccinations

All patients should have a formal exercise program developed by a health professional.

The Centre for Addiction and Mental Health's behavior modification program "the universal 6 pack" (smoking, weight loss, sleep, exercise, stress, and alcohol) should be explored for province-wide implementation.

When goals of therapy related to medications are not being reached, a medication adherence assessment should be conducted. Actions to resolve identified issues should be taken, which typically requires better communication between family physicians and other health care providers.

Implementation of Best Practices

The Expert Advisory Panel on postacute, community-based care for HF patients believes that implementation of best practices related to community-based HF care will require significant investment. The following points highlight some of the key issues for and barriers to the successful implementation of the community-based HF QBP best practices discussed:

1. A transitional approach to funding is recommended so as to enable the building of capacity in the community and to avoid the consequences of patients receiving no specialized service.

2. It will not be possible to promote the movement of appropriate patients to community or ambulatory care and achieve the associated cost efficiencies without addressing best practices for capacity and access issues, and whether there is adequate outpatient HF clinic services and cardiac rehabilitation (CR) services post discharge.

3. Information within patient education materials should be standardized, available in multiple languages, and be accessible for people with reading challenges. Education materials for patients and their caregivers at discharge should be used and reinforced by the home care team. Patients have concerns that new educational materials distributed by home care service providers were conflicted with materials provided on discharge or were confusing.

4. Pathways recommended in this report should be adopted by all providers. Provincial guidelines and pathways should be available in electronic format for health care providers. **Provincial versus local care pathways:** It should be recognized that the practices recommended in this clinical handbook have been defined at an aspirational provincial level to guide all hospitals across the province. It is not intended to be an operational care pathway—individual providers will have to implement these best practices based on their own local circumstances and available capacities. In many cases, the implementation of these recommendations will be challenged by local arrangements or the availability of services.

5. All hospitals and health care providers should adopt the forthcoming health transformation discharge planning standards.

6. Smoking cessation counselling should be made readily available at no cost to all patients and caregivers.

7. Barriers to accessing Nicotine Replacement Therapy should be removed.

8. Barriers to accessing smoking cessation drug therapy should be removed.

9. Patient self-management programs should be developed and incorporated into care plans. Monitoring of self-management care plans is a responsibility of all health care providers. Barriers to communication that hinder multidisciplinary care provision should be removed.

10. The Health Quality Ontario/Healthlinks care coordination initiative should be adopted by all primary care providers to facilitate greater coordination and integration with community health services.

11. Once developed, the Health Quality Ontario/Healthlinks care coordination e-chart should be adopted by all primary care providers, Community Care Access Centres, and their contracted service providers to improve communication and integration in patient care

12. The impact on hospitals of implementing the 9 discharge standards identified in the Health Quality Ontario/Health Transformation Secretariat should be addressed early in the roll out.

13. All home care service providers should work to integrate care to drive performance and improve communication to ensure common care plan are followed, and to report health changes and changes related to self-management plans along with the home care coordinator.

14. The challenge of shortages in human resources on the implementation of community care for post-discharge populations in some regions of the province should be considered. In regions where human resources are in shortage, the regional LHIN and provincial government should be involved to grow capacity

15. The impact of this QBP should be analyzed on a regular basis and updated where required.

16. Physicians and other health care leaders should be engaged early in the development of funding programs and quality-based measures to promote understanding and acceptance and ensure successful uptake of the clinical handbook recommendations.

17. Health care leaders, clients, and their caregivers should be involved in the development of implementation materials.

18. Family physicians, other health care providers, and HF specialty clinics should have adequate decision support to respond to the increasing demand for data and the analytics to examine/report on trends, etc.

19. Once developed, implementation of this QBP should use evidence-based Knowledge Translation and Exchange (KTE) strategies to increase the uptake of recommendations

20. Once completed, OHTAC recommendations on end-of-life care and planning should be implemented.

21. Where a patient would benefit from an interdisciplinary heart failure clinic, barriers (e.g. too unwell to attend outpatient setting, unreasonable distance from the clinic location) to access should be removed.

22. Actions should be taken to improve communication between multi-speciality care providers and patient transitions through the continuum of care.

Implement as a Program of Care

Many of these considerations speak to the need to approach the implementation of the recommended practices not simply at the level of individual patients and clinicians, but within a program of care that requires organization-level planning, resourcing, and the involvement of administrators. Program design should also involve a measurement system for tracking performance, supporting quality improvement

Track Current Practice Against Recommended Practices

Many of the practices recommended by the expert advisory panel are not currently tracked in any consistent way at either the local or provincial level. Thus, it is difficult to know what the "gap" is between current and ideal CHF practice or how much this gap varies across different organizations and parts of the province. A key objective of developing a CHF performance measurement strategy should be to enable organizations to track, audit, and evaluate the implementation of care pathways and recommended practices at the organizational level. Through such monitoring, variances can be identified, progress can be monitored, and the pathway can be refined over time.

As a quality improvement initiative, the expert advisory panel suggests that the Ministry of Health and Long Term Care undertake a review of ambulatory care data that can be used to determine where gaps exists in service delivery and where best to optimize funding in an outpatient setting. Where data do not currently exist, the ministry should consider identifying mechanisms to collect and report data.

Expert Advisory Panel Membership

Health Quality Ontario's Expert Advisory Panel on Episodes of Care for Congestive Heart Failure

Name	Role	Organization/Affiliation
Dr. David Alter	Senior Scientist	Institute for Clinical Evaluative Sciences Research Program Director and Associate Staff, The Cardiac and Secondary Prevention Program at the Toronto Rehabilitation Institute-UHN Associate Professor of Medicine, University of Toronto
Dr. Douglas Lee	Senior Scientist, Associate Professor	Institute for Clinical Evaluative Sciences, ICES, Toronto General Hospital
Dr. Catherine Demers	Associate Professor	Division of Cardiology, Department of Medicine McMaster University
Dr. Susanna Mak	Cardiologist	University of Toronto, Department of Medicine, Division of Cardiology, Mount Sinai Hospital
Dr. Lisa Mielniczuk	Medical Director, Pulmonary Hypertension Clinic	University of Ottawa Heart Institute
Dr. Peter Liu	President, International Society of Cardiomyopathy and Heart Failure of the World Heart Federation Director, National C-CHANGE Program Scientific Director/VP Research, University of Ottawa Heart Institute Professor of Medicine	University of Ottawa Heart Institute - UHN??
Dr. Robert McKelvie	Professor of Medicine, Cardiologist	McMaster University, Hamilton Health Sciences
Dr. Malcolm Arnold	Medical Officee, Staff Cardiologist, Professor of Medicine	University of Western Ontario, London Health Sciences Centre, PROOF (Prevention of Organ Failure)
Dr. Stuart Smith	Chief of Cardiovascular Services Director, Heart Failure Program	St. Mary's General Hospital
Dr. Atilio Costa Vitali	Assistant Professor of Medicine Division of Clinical Science	Sudbury Regional Hospital
Dr. Jennifer Everson	Physician Lead	Hamilton Niagara Haldimand Brant Local Health Integration Network
Dr. Lee Donohue	Family Physician	Ottawa
Linda Belford	Nurse Practitioner, Practice Leader PMCC	University Health Network
Jane MacIver	Nurse Practitioner Heart Failure/Heart Transplant	University Health Network
Sharon Yamashita	Clinical Coordinator, Critical Care	Sunnybrook Health Sciences Centre
Claudia Bucci	Clinical Coordinator, Cardiovascular Diseases	Sunnybrook Health Sciences Centre
Andrea Rawn	Evidence Based Care Program Coordinator	Grey Bruce Health Network
Darlene Wilson	Registered Nurse	Heart Function Clinic, Trillium Health Centre
Kari Kostiw	Clinical Coordinator	Health Sciences North Ramsey Lake Health Centre
Heather Sherrard	Vice President, Clinical Services	University of Ottawa Heart Institute
Sue Wojdylo	Manager, Case Costing	Lakeridge Health
Anne Forsey	Director, Clinical Services	Cardiac Care Network of Ontario

Health Quality Ontario's Expert Advisory Panel on Postacute Community-Based Care for Congestive Heart Failure Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr. Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist

Name	Affiliation(s)	Appointment(s)
Dr. Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr. Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr. Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr. Catherine Demers	McMaster University	Associate Professor
Dr. Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr. George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr. Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr. Jess Goodman	Summerville Family Health Team,	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1

Exercise Guidelines for Your Patients With Heart Failure

Causes of Effort Intolerance

The causes of fatigue and exercise intolerance in patients with heart failure (HF) are multifactorial. Possible reasons include:

- skeletal muscle alterations and dysfunction
- exaggerated increases in ventilation disproportionate to increase in CO_2 production
- inadequate tissue perfusion due to inadequate cardiac output
- deconditioning from lack of physical activity
- aging (reduced muscle strength and power, reduced joint range of motion)
- Comorbidities (e.g., COPD, peripheral vascular disease, arthritis)
- Inspiratory muscle weakness

Clinical Benefits of Regular Physical Activity and an Exercise Program

- improve skeletal muscle function and efficiency
- improve endothelial function
- improve ventilatory function (especially with respiratory training)
- decrease risk of falls in the elderly
- improve quality of life
- decrease hospitalization
- improve HF symptoms

Exercise training in HF improves skeletal muscle function, and facilitates several physiological mechanisms that collectively improve functional capacity. Patients are then able to complete activities with reduced sensations of shortness of breath or fatigue.

The purpose of this information is to guide family physicians and primary care providers who provide exercise advice for patients with HF. Most patients with HF will benefit from referral to a cardiac rehabilitation program (or physiotherapist where programs are unavailable) for additional advice regarding exercise.
Please refer to the patient education pamphlet on exercise guidelines that can be given to your patients with HF.

Types of Exercise

Aerobic

Aerobic exercise includes any physical activity that uses large muscle groups and increases the heart rate (e.g., walking). Walking or riding a stationary bike (no resistance) is an excellent way to begin an exercise program.

When starting an exercise program, encourage patients to walk (or ride a stationary bike) for a total of 10–15 minutes each day. Gradually work up to 30 minutes a day as tolerated.

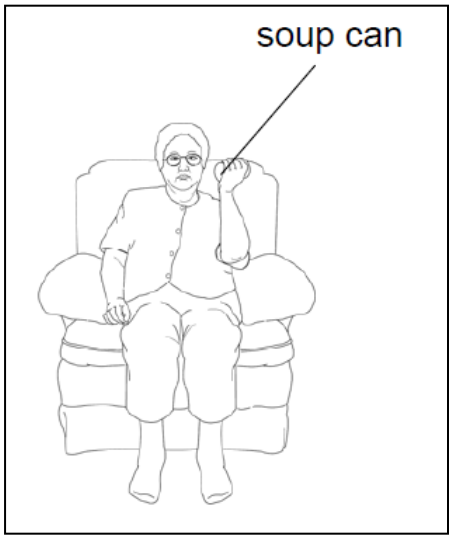
Patients should include a 5- to 10-minute warm up and cool down with light stretching before and after exercise.

Tip: Often patients with HF will need to pace themselves and might not be able to exercise for 10–15 minutes during a single session. In this case, patients can try 2–3 sessions of 5 minutes for a total of 15 minutes a day. Patients with HF tend to tolerate increasing the number of sets rather than the time for each set as they gradually increase their physical activity.

Strength Training or Resistance Training

The goal of resistance training is optimizing muscle strength and therefore is also known as "strength training." Progressive resistance training involves moving joints through range-of-motion exercises with some form of resistance.

For people recently discharged from hospital or severely deconditioned, resistance training can be initiated using gravity as resistance. This type of exercise can be completed at home, in bed, or in a seated position. Conventional weights can be added under direction of or with advice from an exercise specialist.



Tip: Resistance training is not as stressful on the cardiovascular system as traditional aerobic exercise, allowing for building of peripheral muscle strength with lower perceptions of shortness of breath. This is an attractive option for patients with advanced HF who might not be able to complete aerobic exercise training because of intolerable shortness of breath or leg fatigue.

Overexercise

Exercise should be stopped when patients experience symptoms of overexertion. Patients need to stop an activity if they feel dizzy, have palpitations, nausea or chest pain. If symptoms are severe and do not go away within 15 minutes of rest, they should call 911.

The rating of perceived exertion (RPE) scale is used to measure how easy or difficult an activity is to complete. Patients often find this scale easier to use as to guide their response to activity than monitoring their pulse.
The RPE scale ranges in perceived difficulty from 0 (nothing at all) to 10 (maximal). Patients should target an RPE score of 3–5 (moderate to hard) while exercising.

RPE Scale

Rating	Perceived Exertion
	Nothing at all, very easy
1	Very slight
2	Slight
3	Moderate
4	Somewhat difficult
5	Difficult
6	
7	Very difficult
8	
9	Very, very difficult
10	Maximal

Tip: "Walk so you can talk rule". It is normal for patients with HF to feel short of breath during activity. However, they should have enough breath to carry on a conversation. If patients cannot talk while exercising, they need to slow down or rest.

Exercise routines should be reduced (by approximately 50%) when patients are:

- Experiencing worsening symptoms of HF or requiring additional diuretics for recent weight gain
- Involved in other activities that are tiring (e.g., family gatherings, social events)
- Experiencing other health difficulties (e.g., infection)
- Unable to exercise for the previous 5–7 days

What activities should be avoided until reviewed by an exercise specialist?

- Lifting an object over 10 pounds
- If a patient has to hold his/her breath or strain to lift an object, it is too heavy.
- Shoveling snow
- Activities that require stretching with both arms above the head, as he/she may become lightheaded or dizzy
- Using a sauna or hot tub

What patients should not engage in progressive exercise training?
Any patient with stable HF can engage in a level of physical activity that does not produce uncomfortable symptoms. However, a progressive exercise program is not indicated for the following:

- NYHA Class IV symptoms
- Decompensated or uncontrolled HF
- High-risk unstable angina
- Left main or coronary stenosis or equivalent
- Acute noncardiac comorbidities (e.g., infection)
- Severe or critical aortic stenosis
- Hypertrophic cardiomyopathy or other forms of outflow tract obstruction
- Poorly or uncontrolled atrial fibrillation
- Tachydysrythmias or bradydysrhythmias

General exercise tips

- Avoid exercising in extreme temperatures or windy weather. Climate-controlled locations, such as shopping malls, are better.
- Avoid exercising for at least 90 minutes after a large meal.
- If patients feel tired during exercise, it is better to sit down and rest than to take a nap in bed, as lying down reduces exercise tolerance.
- Schedule exercise into a daily routine and at a time when patients feel most rested. Patients should be encouraged to record their exercise and symptoms on a daily log, as this practice can encourage participation and help caregivers monitor progress.
- When drinking fluids during exercise, continue to keep within fluid-restriction guidelines.

Morisky Medication-Taking Adherence Scale-MMAS (4-item)

English Version

(Please check one box on each line)

	Yes	*No*
1. Do you ever forget to take your (name of health condition) medicine?	o	o
2. Do you ever have problems remembering to take your (name of health condition) medication?	o	o
3. When you feel better, do you sometimes stop taking your (name of health condition) medicine?	o	o
4. Sometimes if you feel worse when you take your (name of health condition) medicine, do you stop taking it?	o	o

MEASUREMENT AND SCORING CRITERIA

The MMAS is a generic self-reported, medication-taking behavior scale in which the specific health issue (high blood pressure, diabetes, elevated cholesterol, HIV, contraception, etc.) is inserted for the "health concern".The MMAS consists of four items with a scoring scheme of "Yes" = 0 and "No" = 1. The items are summed to give a range of scores from 0 to 4.

Stoplight Tool

Signs of Worsening Heart Failure

Your heart failure may be getting worse if you have:

- Gained more than 2 pounds (1 kg) in one day.
- Gained more than 5 pounds (2 to 3 kg) in one week.
- An increase in swelling in your feet, ankles, or legs.
- Fullness or bloating in your stomach.
- More shortness of breath than usual.
- Difficulty breathing when lying flat.

When you have any of the symptoms listed above:

- Call your doctor or nurse practitioner right away because your medications may need to be changed.

Call 911 or have someone take you to the hospital if you are extremely short of breath, cannot sleep because of your breathing, have chest pain that is not relieved with nitrospray, feel like your heart is "racing", or you are coughing up frothy or pink sputum.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

Appendix 1: Rapid Reviews

1. Ultrafiltration in heart failure: a rapid review
2. Vasodilators for inhospital heart failure management: a rapid review (update)
3. Communication of discharge instructions for heart failure patients: a rapid review
4. Medication reconciliation at discharge: a rapid review
5. Criteria for referral to home care: a rapid review
6. Criteria for referral to heart failure clinics: a rapid review
7. Home-based exercise programs in heart failure: a rapid review
8. Aerobic exercise training in patients with heart failure: a rapid review
9. Physical activity counselling for heart failure patients: a rapid review
10. Sodium restriction in heart failure: a rapid review

Ontario
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Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews must be completed in a 2- to 4-week time frame. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, the Evidence Development and Standards branch and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
RCT	Randomized controlled trial

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this rapid review was to assess the effectiveness of ultrafiltration in patients with acute heart failure.

Clinical Need and Target Population

Heart failure is a complex syndrome, in which abnormal heart function is responsible for the failure of the heart to pump blood at the necessary rate for metabolizing tissues. (1) Common symptoms include shortness of breath; cough; sudden weight gain; bloating; loss of energy; loss or change in appetite; increased swelling of the ankles, feet, legs, sacrum (base of spine), or abdomen; and increased urination at night. (1) Leading causes of heart failure are coronary artery disease, hypertension, diabetes, heart valve disease, obesity, and excessive use of alcohol or drugs. (3)

Technology/Technique

Ultrafiltration is an alternative treatment for patients with acute heart failure who are not responding sufficiently to diuretic therapy. (4) An ultrafiltration device creates "a hydrostatic pressure gradient [that] triggers the mechanical removal of fluid across a filter membrane and isotonic plasma water is separated from blood without affecting serum electrolytes and other solutes." (4) A number of ultrafiltration devices have been licenced by Health Canada.

Both the Canadian Cardiovascular Society and the American Heart Association have made recommendations about the use of ultrafiltration in patients with heart failure:

- Canadian Cardiovascular Society (2012): Patients with persistent congestion despite diuretic therapy, with or without impaired renal function, may, under experienced supervision, receive continuous venovenous ultrafiltration. (5)
- American Heart Association (2009): Ultrafiltration is reasonable for patients with refractory congestion not responding to medical therapy. (6)

Rapid Review

Research Question

What is the effectiveness of ultrafiltration compared to usual care in patients with acute heart failure?

Research Methods

Literature Search

Search Strategy

A literature search was performed on July 22, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, and EBM Reviews, for studies published from January 1, 2009, to July 22, 2014. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2009, and July 22, 2014
- systematic reviews and meta-analyses
- patients with acute heart failure admitted to hospital
- comparison of ultrafiltration to diuretic therapy

Exclusion Criteria

- non-systematic reviews
- patients whose main diagnosis was not heart failure

Outcomes of Interest

- fluid removal/weight loss
- adverse events

Expert Panel

In July 2014, the Episode of Care Expert Advisory Panel to Inform Quality-Based Funding for Congestive Heart Failure was reconvened to update the handbook. Members of the panel included health care providers, health care administrators and personnel from the Ministry of Health and Long-Term Care.

The role of the Expert Advisory Panel was to review the recommendations and the episode-of-care pathway they had developed in 2012 on acute heart failure. They were asked to identify any gaps in the original recommendations and confirm that the existing recommendations were still current and accurate. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of Expert Advisory Panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (7)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (8) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: the large magnitude of effect, the dose response gradient, and any residual confounding factors. (8) For more detailed information, please refer to the latest series of GRADE articles. (8)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect.
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different.
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect.
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of the effect.

Results of Rapid Review

The database search yielded 21 citations published between January 1, 2009, and July 22, 2014 (duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

One systematic review met the inclusion criteria. (9) Other systematic reviews were identified in the literature search, but the Wen et al review (9) was selected because of its high AMSTAR rating, recent publication date, and reporting of both outcomes of interest outlined above.

For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman, 1996. (10)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	1
Large RCT	
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	
Studies presented at an international conference	
Expert opinion	
Total	**1**

Abbreviations: RCT, randomized controlled trial

The 2013 systematic review by Wen et al (9) included 5 RCTs; the comparator group in all 5 was diuretic therapy.

Fluid Removal/Weight Loss

Three of the RCTs in the systematic review reported on fluid removal and weight loss. After 48 hours of treatment, there was a significantly higher rate of fluid removal ($P < 0.0001$) and weight loss ($P < 0.0002$) in patients receiving ultrafiltration than in those on diuretic therapy alone. The quality of the evidence for this outcome was low.

Adverse Events

The authors of the systematic review reported the results for a number of adverse events, including infection, renal function deterioration, cardiac arrest, anemia and hemorrhage, and worsening heart failure. Two RCTs in the systematic review reported on all of the adverse events reported. The authors of

the systematic review found no significant differences between ultrafiltration therapy and diuretic therapy for any of the adverse events reported. The quality of the evidence for this outcome was very low.

Limitations

The individual primary studies evaluated in the systematic review by Wen et al (9) were not critically appraised by Health Quality Ontario. Ultrafiltration is thought to be most potentially beneficial in patients who have not responded to diuretics, but it is unclear without looking at the individual reports whether the patients included in these studies had "failed" diuretic therapy prior to enrolling in the studies.

The duration of effect of ultrafiltration is unclear; Wen et al reported that after 48 hours of treatment, ultrafiltration led to significantly higher rates of fluid and weight loss, but it is not clear how long this difference is sustained. (9)

Wen et al acknowledged that their systematic review was based on a relatively small number of studies, and that data on hemodynamic parameters and adverse electrolytes were lacking. (9)

Conclusions

- Based on low quality evidence, there was a significant improvement in fluid removal and weight loss after 48 hours of treatment in patients with heart failure who received ultrafiltration compared to those who received diuretic therapy. However, the duration of effect was unclear.
- Based on very low quality evidence, there was no significant difference in the rate of adverse events in patients with heart failure who received ultrafiltration compared to those who received diuretic therapy.

Acknowledgements

Editorial Staff
Jeanne McKane, CPE, ELS(D)

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader

Name	Affiliation(s)	Appointment(s)
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: July 22, 2014
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 2014>, EBM Reviews - ACP Journal Club <1991 to July 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <2nd Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <June 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <2nd Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <2nd Quarter 2014>, Ovid MEDLINE(R) <1946 to July Week 2 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <July 21, 2014>
Search Strategy:
---
1 exp Heart Failure/ (92568)
2 (((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab. (135768)
3 or/1-2 (162490)
4 exp Ultrafiltration/ (14721)
5 (ultrafiltrat* or ultra filtrat* or hemofiltrat*).mp. (23870)
6 or/4-5 (25135)
7 Meta Analysis.pt. (50365)
8 Meta-Analysis/ or Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (72511)
9 (((systematic* or methodologic*) adj3 (review* or overview*)) or pooled analysis or published studies or published literature or hand search* or handsearch* or medline or pubmed or embase or cochrane or cinahl or data synthes* or data extraction* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab. (184826)
10 (meta analy* or metaanaly* or health technolog* assess*).mp. (133838)
11 or/7-10 (265019)
12 3 and 6 and 11 (29)
13 limit 12 to (english language and yr="2009 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CLCMR; records were retained] (21)
14 remove duplicates from 13 (21)

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Included Systematic Reviews

Author, Year	AMSTAR Score[a]	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Wen et al, 2013 (9)	9/11					x					x	

Abbreviation: AMSTAR, Assessment of Multiple Systematic Reviews.
[a]Maximum possible score is 11. Details of AMSTAR score are described in Shea et al. (7)

Table A2: GRADE Evidence Profile for Comparison of Ultrafiltration and Diuretic Therapy

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Fluid Removal/Weight Loss							
3 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	No serious limitations	Likely (–1)[b]	None	⊕⊕ Low
Adverse Events							
2 (RCTs)	Serious limitations (–1)[a]	Serious limitations (–1)[c]	No serious limitations	No serious limitations	Likely (–1)[b]	None	⊕ Very Low

Abbreviation: RCT, randomized controlled trial.
[a]All of the studies had risk of bias limitations including allocation concealment, inconsistent blinding, and incomplete reporting of outcomes for all patients.
[b]Other systematic reviews on ultrafiltration have been published recently and have included more studies. The excluded studies are not listed.
[c]Inconsistencies in some of the adverse events reported. The studies were likely not powered to detect the differences in adverse events.

Table A3: Risk of Bias[a] Among Randomized Controlled Trials for the Comparison of Ultrafiltration and Diuretic Therapy

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Bart et al, 2005 (11)	Limitations[b]	No limitations	Limitations[c]	No limitations	No limitations
Costanzo et al, 2007 (12)	Limitations[b]	Limitations[d]	Limitations[c]	No limitations	No limitations
Rogers et al, 2008 (13)	Limitations[b]	Limitations[e]	Limitations[c]	No limitations	No limitations
Giglioli et al, 2011 (14)	Limitations[b]	Limitations[d]	Limitations[c]	No limitations	No limitations
Bart et al, 2012 (15)	Limitations[b]	Limitations[d]	Limitations[c]	No limitations	No limitations

[a]Risk of bias was taken directly from the systematic review by Wen et al (9); Health Quality Ontario did not conduct an additional critical appraisal.
[b]Unclear if allocation concealment was part of the study design.
[c]Incomplete accounting of patients.
[d]No blinding.
[e]Unclear if the study included blinding.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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Vasodilators for Inhospital Heart Failure Management: A Rapid Review (Update)

A Schaink and A Lambrinos

February 2015

This report is an update of a rapid review of the same name published in January 2013.

Evidence Development and Standards Branch at Health Quality Ontario

Suggested Citation

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, the Evidence Development and Standards branch and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
ASCEND-HF	Acute Study of Clinical Effectiveness of Nesiritide and Decompensated Heart Failure
BUN	Blood urea nitrogen
CHF	Congestive heart failure
GRADE	Grades of Recommendation, Assessment, Development, and Evaluation
HF	Heart failure
QBP	Quality-based procedure
RCT	Randomized controlled trial

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

On the advice of the Expert Panel for the Update and Integration of the Acute Congestive Heart Failure (CHF) Quality-Based Procedure (QBP), a rapid review was published in 2013 that examined the risk of adverse events associated with vasodilators used for inhospital management of heart failure; in particular, what is the effect on renal function and risk of mortality for patients administered intravenous nitroglycerin or nesiritide in hospital? (1) Researchers found that one RCT comparing nesiritide with placebo met their inclusion criteria—the Acute Study of Clinical Effectiveness of Nesiritide and Decompensated Heart Failure (ASCEND-HF) study. (2)

The objective of the *current* analysis was to address a broader comparison, nesiritide with active vasodilators (e.g., dobutamine or nitroglycerin), to reflect real practice, and to do this by evaluating RCTs published since 2011.

Clinical Need and Target Population

Symptomatic Decompensation of Heart Failure

Patients with heart failure (HF) who are hospitalized for an acute decompensation may present with symptoms such as volume overload, pulmonary congestion, and dyspnoea. (3) Vasodilators, including nitroglycerin and nesiritide, may be administered to address volume overload in HF. (4)

Technique

Intravenous vasodilators as adjunctive therapy facilitate a number of beneficial hemodynamic effects, including: a reduction in pulmonary capillary wedge pressure, reduced myocardial oxygen consumption, a decrease in both systemic vascular resistance and ventricular workload, an increase in stroke volume, and improved cardiac output overall. (5) Surrogate endpoints have been the focus of studies to date, (6) assuming or lacking power to detect clinically relevant outcomes resulting from such physiological effects. (7, 8) Pooled data from small clinical trials have raised specific concerns, such as deleterious effects on renal function and increased risk of mortality. (9, 10)

Nitroglycerin is administered to facilitate prompt relief of pulmonary congestion. (11) As with other common pharmaceuticals for HF, despite the role of nitroglycerin as a cornerstone therapy there is a shortage of evidence, especially at the level of current regulatory and clinical standards for safety and efficacy. (12, 13) Nesiritide is a newer vasodilator approved by the Federal Drug Administration in the United States in 2001 for relief of dyspnoea in acutely decompensated HF. (14) Nesiritide was subsequently granted conditional marketing authorization from Health Canada in 2008, pending verification of promising early findings with further data. (15)

Rapid Review

Research Question

What is the effect of intravenous nesiritide compared with active vasodilators (e.g., dobutamine or nitroglycerin) on renal function and risk of mortality for heart failure inpatients?

Research Methods

Literature Search

The original literature search was revisited in light of an addition to the inclusion and exclusion criteria. The expert panel believed that instead of examining nesiritide compared with placebo, the studies should examine nesiritide compared with active vasodilators (e.g., dobutamine or nitroglycerin), to be representative of real practice. There was also a modification to the search dates that limited them to 2011 onwards (search dates from January 1, 2011, to July 2013).

Literature search strategies are presented in Appendix 1.

Inclusion Criteria

- English language full-text reports
- published between January 1, 2011 and July 2013
- health technology assessments, systematic reviews, and meta-analyses, RCTs
- studies comparing adult hospital inpatients with HF administered intravenous nesiritide or active vasodilators (e.g., dobutamine or nitroglycerin)

Exclusion Criteria

- observational studies, case reports, editorials

Outcomes of Interest

- renal function
- mortality

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.
The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The quality of the body of evidence for each outcome was examined according to the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group criteria. (16) The overall quality was determined to be very low, low, moderate, or high using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: large magnitude of effect, dose response gradient, and accounting for all residual confounding factors. (16) For more detailed information, please refer to the latest series of GRADE articles. (16)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	Very confident that the true effect lies close to the estimate of the effect
Moderate	Moderately confident in the effect estimate—the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Confidence in the effect estimate is limited—the true effect may be substantially different from the estimate of the effect
Very Low	Very little confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Evidence quality assessment is presented in Appendix 2.

Results of Rapid Review

Literature Search Results

One RCT was identified and is discussed briefly in Table 1.

Table 1: Overview of Included RCT Assessing the effect of Nesiritide on the Treatment of Acute Decompensated Heart Failure (ADHF)

Author, Year	Study Design	Sample Size (Nesiritide/Nitroglycerin)	Intervention (Dose)	Outcomes
Chow et al., 2011 (17)	Randomized controlled trial	89 (45/44)	Nesiritide or nitroglycerin Nesiritide: 2 mcg/kg optional bolus + 0.01 mcg kg^{-1} min^{-1} infusion for at least 48 h Nitroglycerin: 10 mcg/min and titrated every 5–10 min until symptom relief[a]	Primary clinical outcomes: - changes in renal and neurohormonal markers Secondary clinical outcomes: - changes in serum creatinine, blood urea nitrogen (BUN), and creatinine clearance[b] at 24 and 48 h of infusion Tertiary clinical outcomes: - median length of stay, need for dialysis, and symptomatic hypotension - mortality and rehospitalization at 3 and 6 mo

[a]Symptom relief was defined as marked improvement in dyspnea, or both dyspnea and fatigue if symptoms were jointly present on admission.
[b]Estimated using the Cockcroft-Gault equation.

Outcomes of Interest

Renal Function

The markers obtained to measure renal function included serum creatinine, blood urea nitrogen (BUN), and creatinine clearance. Chow et al (17) identified no statistically significant differences (no *P* values provided) at baseline or during vasodilator therapy between the nesiritide and nitroglycerin groups. The duration of infusion of both nesiritide and nitroglycerin (24 vs 48 h) was also not associated with any changes in serum creatinine or creatinine clearances (Table 2).

Table 2: Renal Function Markers at Specified Time Points

Renal Function Marker	Baseline		24 h		48 h		Discharge	
	NTG	NES	NTG	NES	NTG	NES	NTG	NES
BUN (mg/dL)	27.5 ± 15.9	24.9 ± 8.9	28.6 ± 15.3	24.3 ± 10.6	28.4 ± 16.2	25.1 ± 9.3	29.6 ± 17.7	26.7 ± 9.7
sCr (mg/dL)	1.3 ± 0.4	1.3 ± 0.4	1.4 ± 0.4	1.3 ± 0.4	1.4 ± 0.4	1.3 ± 0.4	1.3 ± 0.4	1.3 ± 0.4
CrCl (mL/min)	52.5 ± 25.5	51.5 ± 16.7	50.9 ± 25.4	50.3 ± 17.9	49.5 ± 26.0	49.7 ± 16.0	50.8 ± 23.4	49.1 ± 16.2

Abbreviations: BUN, blood urea nitrogen; CrCl, creatinine clearance; NES, nesiritide; NTG, nitroglycerin; sCr, serum creatinine.

Mortality

Chow et al (17) found no statistically significant differences between the nitroglycerin and nesiritide groups for mortality at 3 or 6 months post-discharge (Table 3).

Table 3: Mortality at 3 and 6 Months Post-discharge

Time Point	Intervention/Control		*P* Value
	NES (%)	NTG (%)	
3 mo	4 (9)	4 (9)	0.97
6 mo	7 (16)	7 (16)	0.96

Abbreviations: NES, nesiritide; NTG, nitroglycerin.

The study by Chow et al (17) was adequately powered to detect differences in serum creatinine based on observations from a previous study. However, the study was not specifically powered to assess the outcome of mortality.

The renal function outcome is measured differently in this study than it is in the ASCEND-HF (2) study examined in the previous rapid review. (1) Renal impairment was defined as a > 25% decrease in glomerular filtration rate from study-drug initiation through day 30. Chow et al (17) measured renal function through biomarkers serum creatinine, BUN, and creatinine clearance at baseline, 24 hours, 48 hours, and time of discharge. Also, the outcome of mortality was measured at different time points in both studies. In the ASCEND-HF (2) study, mortality was measured at 30 days. Chow et al (17) examined mortality at 3 and 6 months.

Conclusions

The following conclusions were drawn from the examination of 1 RCT comparing nesiritide versus nitroglycerin as part of the addendum to the rapid review:

- Based on moderate quality of evidence, there was no statistically significant difference in renal function biomarkers (at baseline, 24 hours, 48 hours, and discharge) among patients who received nesiritide versus nitroglycerin.
- Based on low quality of evidence, there was no statistically significant difference in mortality (at 3 or 6 months post-discharge) among patients who received nesiritide versus nitroglycerin.

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Editorial Staff
Susan Harrison

Medical Information Services
Corinne Holubowich, Bed, MLIS
Kellee Kaulback, BA(H), MISt

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader

Name	Affiliation(s)	Appointment(s)
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: July 23, 2014
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, Embase, All EBM Databases (see below)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 2014>, EBM Reviews - ACP Journal Club <1991 to July 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <2nd Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <June 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <2nd Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <2nd Quarter 2014>, Embase <1980 to 2014 Week 29>, Ovid MEDLINE(R) <1946 to July Week 2 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <July 22, 2014>
Search Strategy:
---
1 exp Heart Failure/ (388287)
2 (((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab. (307097)
3 or/1-2 (491633)
4 Vasodilator Agents/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or Nitroglycerin/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed (50855)
5 Nesiritide/ use emez or Vasodilator Agent/ use emez or Coronary Vasodilating Agent/ use emez or glyceryl trinitrate/ use emez (55999)
6 (vasodilator* or (vasodilat* adj agent*)).ti,ab. (70358)
7 (nesiritide or natrecor or noratak or nitroglycerin*).mp. (31902)
8 or/4-7 (162842)
9 3 and 8 (20378)
10 (Meta Analysis or Controlled Clinical Trial).pt. (223588)
11 Meta-Analysis/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or Meta-Analysis as Topic/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or exp Technology Assessment, Biomedical/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed (72466)
12 Meta Analysis/ use emez or "Meta Analysis (Topic)"/ use emez or Biomedical Technology Assessment/ use emez (104716)
13 (((systematic* or methodologic*) adj3 (review* or overview*)) or pooled analysis or published studies or published literature or hand search* or handsearch* or medline or pubmed or embase or cochrane or cinahl or data synthes* or data extraction* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab. (373125)
14 (meta analy* or metaanaly* or health technolog* assess*).mp. (261263)
15 exp Randomized Controlled Trial/ (725061)
16 exp Random Allocation/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or exp Double-Blind Method/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or exp Control Groups/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or exp Placebos/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed (349383)
17 exp Randomization/ use emez or exp RANDOM SAMPLE/ use emez or Double Blind Procedure/ use emez or exp Triple Blind Procedure/ use emez or exp Control Group/ use emez or exp PLACEBO/ use emez (429271)
18 (random* or RCT or RCTs or placebo* or sham* or (control* adj2 clinical trial*)).ti,ab. (2318796)
19 or/10-18 (3206612)
20 9 and 19 (4685)
21 limit 20 to english language [Limit not valid in CDSR,ACP Journal Club,DARE,CLCMR; records were retained] (4203)
22 limit 21 to yr="2011 -Current" [Limit not valid in DARE; records were retained] (656)
23 remove duplicates from 22 (552)

Appendix 2: Evidence Quality Assessment

Table A1: GRADE Evidence Profile for Comparison of Nesiritide and Nitroglycerin

No. of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Mortality (death from any cause within 3 and 6 mo)							
1 (RCT)	Serious limitations (−1)[a]	No serious limitations	No serious limitations	Serious limitations (−1)[b]	Undetected[c]	None	⊕⊕ Low
Renal function (measured by serum creatinine, BUN, and creatinine clearance)							
1 (RCT)	Serious limitations (−1)[a]	No serious limitations	No serious limitations	No serious limitations	Undetected[c]	None	⊕⊕⊕ Moderate

Abbreviations: BUN, blood urea nitrogen; RCT, randomized controlled trial.
[a]With all studies that are not blinded, bias from the knowledge of the treatment could affect the outcomes of the study.
[b]This study was not powered based on this outcome.
[c]Publication bias is nearly impossible to assess with a single study.

Table A2: Risk of Bias in the Randomized Controlled Trial Comparing Nesiritide and Nitroglycerin

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Chow et al, 2011 (17)	Limitations[a]	Limitations[b]	No limitations[c]	No limitations[d]	No limitations

[a]The authors state that participants were randomized but do not explain the method (e.g., computer generated etc).
[b]Participants or those conducting group assignment were not blinded. However, the treatment group assignment was blinded to the statisticians before and during statistical analysis.
[C]No loss to follow-up.
[d]Results for all prespecified outcomes were reported.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

Ontario
Health Quality Ontario
Qualité des services de santé Ontario

Communication of Discharge Instructions for Heart Failure Patients: A Rapid Review

Health Quality Ontario

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
GRADE	Grading of Recommendations Assessment, Development, and Evaluation

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of the rapid review was to establish if providing a written discharge plan in addition to oral information improve patient outcomes in patients being discharged from hospital to home.

Clinical Need and Target Population

The target population for this rapid review is patients being discharged from hospital, either an inpatient setting or from the emergency department. Transitions from hospital to home have the potential to be challenging because of the change in primary care provider. In 2013, Health Quality Ontario (HQO) published an evidence-based analysis on "Discharge Planning in Chronic Conditions". (1) This analysis highlights the necessity for discharge planning.

Discharge instruction or the education of patients includes of 5 key steps: 1) assessment of the patient's knowledge about his or her condition; 2) learning ability of the patient; 3) learning styles; 4) cognitive level; and 5) the patient's motivation. (2)

Ontario Context

According to HQO's evidence-based analysis on discharge planning, "[t]here is a process for discharge planning in approximately 80%–90% of hospitals in Ontario. However, this practice is not standardized throughout the province. It is likely more of an organic process with varying elements tailored to suit the needs of the community." (1)

Rapid Review

Research Question

For patients being discharged from hospital to home, does providing a written discharge plan in addition to oral information improve patient outcomes?

Research Methods

Literature Search

Search Strategy

A literature search was performed on November 13, 2013, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, and EBM Reviews for studies published from January 1, 2003, to November 13, 2013. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- systematic reviews, meta-analyses, health technology assessments
- English-language full-text publications
- published between January 1, 2003, and November 13, 2013
- patients discharged from an acute hospital to home (from either inpatient setting or emergency department)

Exclusion Criteria

- patients discharged from hospital to another facility (e.g. long term care home, complex continuing care, convalescent home, etc.)

Outcomes of Interest

- 30-day readmission
- patient satisfaction
- functional measures (e.g., activities of daily living)[4] .

[4] This outcome was included to comply with the objectives of the QBP Community Home Care and Patient Functionality Committee, although none of the studies included reported functionality as an outcome.

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (3)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (4) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: the large magnitude of effect, the dose response gradient, and any residual confounding factors. (4) For more detailed information, please refer to the latest series of GRADE articles. (4)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect.
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different.
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect.
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect.

Results of Rapid Review

The database search yielded 268 citations published between January 1, 2003, and November 13, 2013, (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Two systematic reviews met the inclusion criteria. (5;6) The reference lists of the included studies and health technology assessment websites were searched to identify any other citations, but none were found that met the inclusion criteria.

For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman (1996). (7)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	1
Large RCT	
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of RCTs and observational studies	1
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	
Studies presented at an international conference	
Expert opinion	
Total	**2**

Abbreviation: RCT, randomized controlled trial.

Two systematic reviews met the inclusion criteria for this rapid review. The first was a Cochrane systematic review by Johnson and Sandford (6) that examined the literature comparing written and verbal information on discharge from hospital to just written information on discharge. This systematic review scored highly on the AMSTAR scale, with a score of 10 out of a possible 11. The one limitation of the study was that they did not search grey literature for additional studies. The other systematic review, Isaacman et al (8), examined information on discharge from the emergency department. This review scored 4 out of 11 on the AMSTAR scale. The systematic review did not have duplicate reviewers, nor did they provide details of the studies included in the systematic review (no study design, characteristics of patients included in studies, quality of study, etc.). Despite these substantial limitations, it was the only systematic review identified that looked at patients being discharged from the emergency department.

Discharge from Acute Hospitalization to Home

In their systematic review, Johnson and Sandford (6) conducted an extensive search of the literature with no limitations on the reason for hospitalization, and they found only 2 randomized control trials that met

their inclusion criteria. (8;9) The population in both studies were parents of children. The study by Isaacman et al (8) was actually a study discharging children from the emergency department, not an acute hospital stay. This study will be further described in the next section, below.

Jenkins et al (9) developed a questionnaire for the parents to complete. They found that there was higher patient knowledge in the group that received both written and verbal instructions compared to the group receiving verbal instructions alone. The GRADE quality of evidence for this outcome of knowledge score was low.

Discharge From Emergency Department to Home

With the exception of a brief description of the literature search, Jenkins et al (9) did not provide sufficient detail on the methodology used to select and analyze studies. The primary outcomes of interest are unclear and the narrative format does not comment on the type or quality of the studies used to draw conclusions. Due to the limited information provided, no GRADE quality of evidence was assigned to the outcomes reported.

The study by Isaacman et al (8) reported the number of emergency department (ED) visits within 3 days of discharge and found that the group that received both written and verbal instruction had fewer ED visits than the group that received verbal instructions alone (3.1% versus 10.1%, $P < 0.05$). The GRADE quality of evidence for this outcome of knowledge score was very low.

Limitations

There are several studies on the management of patients with heart failure that compare intensive, comprehensive heart failure management to standard care. The limitation of these studies is that they often include a variety of interventions (care coordination, more intensive education, more patient support, self-management education, etc.) in the treatment arm, so it is difficult to assess which intervention or combination of interventions is having the greatest impact on outcomes. (10-14) As noted by Hansen et al (14), "[n]o study examined the isolated effect of [patient-centered discharge instructions]."

There was only 1 study identified that compared methods of discharge communication in patients being discharged from an acute hospital stay. (9) It is very difficult to make a generalizable statement about methods of discharge communications based on the results of 1 study of parents of children with burn wounds.

Conclusions

Many studies have been published describing comprehensive discharge planning, which includes thorough discharge communication; unfortunately, there is limited evidence on the effect of methods for discharge communication in isolation of other discharge planning interventions. Therefore, it is not possible to make a conclusion regarding the optimal form of communicating the discharge instructions.

Acknowledgements

Editorial Staff
Timothy Maguire

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader

Name	Affiliation(s)	Appointment(s)
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 2013>, EBM Reviews - ACP Journal Club <1991 to October 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <4th Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <October 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <4th Quarter 2013>, Ovid MEDLINE(R) <1946 to October Week 5 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <November 12, 2013>
Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19905
2	exp Aftercare/ or exp Convalescence/	10298
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	49399
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37828
5	or/1-4	107305
6	exp Stroke/	89117
7	exp brain ischemia/ or exp intracranial hemorrhages/	132313
8	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	199794
9	or/6-8	287112
10	exp Heart Failure/	93122
11	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	135687
12	or/10-11	162171
13	exp Pulmonary Disease, Chronic Obstructive/	26665
14	exp Emphysema/	11098
15	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	59959
16	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	37701
17	or/13-16	84745
18	exp Pneumonia/	78260
19	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	147195
20	or/18-19	174702
21	or/5,9,12,17,20	778857
22	exp Patient Education as Topic/	76739
23	exp Caregivers/ed [Education]	1923
24	exp Patient Care Planning/	53283
25	Pamphlets/	3764
26	((discharge adj2 (information or advice or education or communication)) or ((patient* or carer* or caregiver*) adj2 (information or education or communication)) or ((Written or oral or spoken) adj2 information) or (pamphlet* or booklet* or leaflet*)).ti,ab.	63499
27	or/22-26	179862
28	21 and 27	14700
29	Meta Analysis.pt.	52731
30	Meta-Analysis/ use mesz or exp Technology Assessment, Biomedical/ use mesz	61456
31	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab.	210621
32	((health technolog* or biomedical technolog*) adj2 assess*).ti,ab.	2732
33	or/29-32	227128
34	28 and 33	434
35	limit 34 to (english language and yr="2003 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	332
36	remove duplicates from 35	268

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Included Systematic Reviews

Author, Year	AMSTAR Score[a]	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Samuels-Kalow et al, 2012 (5)	4	Yes (1)	No (0)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	Yes (1)[b]	No (0)	Yes (1)
Johnson and Sandford, 2005 (6)	9	Yes (1)	Yes (1)	Yes (1)	No (0)	Yes (1)	Yes (1)	Yes (1)	Yes (1)	No (0)	Yes (1)	Yes (1)

Abbreviations: AMSTAR, Assessment of Multiple Systematic Reviews; RCT, randomized controlled trial.
[a]Maximum possible score is 11. Details of AMSTAR score are described in Shea et al. (3)
[b]Although not explicitly stated, the studies included in the analysis would not have been amenable to combining in a meta-analysis.

Table A2: GRADE Evidence Profile for Comparison of Verbal and Written Discharge Instructions Versus Verbal Instructions Alone

Number of Studies (Design)	Risk of Bias[a]	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Outcome A: Knowledge score							
1 (RCT)	Serious limitations (–1)	Serious limitations (–1)[b]	No serious limitations	No serious limitations	Undetected	None	⊕⊕ Low
Outcome B: 3-Day Return to Emergency Department							
1 (RCT)	Serious limitations (–1)	Serious limitations (–1)[b]	No serious limitations	Serious limitations (–1)[c]	Undetected	None	⊕ Very Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a]See Table A3 for risk of bias details.
[b]Only 1 study—inconsistency can't be assessed.
[c]No variance or confidence intervals provided.

Table A3: Risk of Bias Among Randomized Controlled Trials for the Comparison of Verbal and Written Discharge Instructions Versus Verbal Instructions Alone

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Jenkins et al, 1996 (9)	No limitations	Limitations[a]	Limitations[b]	No limitations	Limitations[c]
Isaacman et al, 1992 (8)	Limitations[d]	Limitations[a]	Limitations[b]	No limitations	No limitations

[a]It was not possible to blind patients since the intervention studied was the effectiveness of providing written materials.
[b]No intent to treat follow-up.
[c]No validation of the questionnaire provided. In addition, it was unclear what the primary outcomes were and whether the study was powered to detect a significant difference between the groups.
[d]No allocation concealment—placement in treatment or control group was based on the day of the month the patient presented to the emergency department.

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(2) Paul S. Hospital discharge education for patients with heart failure: what really works and what is the evidence? Crit Care Nurse. 2008;28(2):66-82.

(3) Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol. 2007;7(10):1-7.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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Medication Reconciliation at Discharge: A Rapid Review

A Lambrinos

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in by the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

ADE	Adverse Drug Events
AMSTAR	Assessment of Multiple Systematic Reviews
BPMH	Best Possible Medication History
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
PADE	Possible Adverse Drug Events
RCT	Randomized controlled trial

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this analysis is to determine the effectiveness of medication reconciliation on hospital readmission rates, emergency department visits, and clinically significant unintended drug discrepancies by comparing those patients who received medication reconciliation at predetermined care transition points to those who did not.

Clinical Need and Target Population

Medication errors are frequent, costly, and potentially harmful. (1) Up to 67% of patients have unintended medication discrepancies at hospital admission (2) and these discrepancies remain common at discharge. (3;4) Transitional care is a key focus of error reduction (5) as more than 40% of medication errors take place when patients move between different stages and settings of care. (6) Specifically, for those patients transitioning from hospital to home, medications discrepancies have been linked to increased re-hospitalization rates. (3)

Technology/Technique

Medication reconciliation involves a systematic and comprehensive review of all the medications a patient is taking to ensure that medications being added, changed or discontinued are carefully assessed and documented. It is intended to ensure accurate communication and documentation consistently across transitions of care. (7)

Medication reconciliation is a three-step process that should be uniform across care transition points:

1. Create an accurate Best Possible Medication History (BPMH) of the patient's medication (prescribed and non-prescribed), which includes documenting the name, dosage, route, and frequency using one or more sources of information (e.g., general practitioner medical records, patient's own supply, pharmacy records, patient/family interview);

2. Use the BPMH to create admission orders or compare medication history against admission, transfer, or discharge medication orders, and resolve any discrepancies;
3. Document and communicate to the patient, family/caregiver, and the next provider of care any changes in medication orders. (8;9)

Regulatory Status

Over 1,100 health care organizations participate in Accreditation Canada programs every year. Medication reconciliation was introduced into the Accreditation Canada program in 2005. (9;10) This program assesses and validates compliance that contributes to improving quality and safety, and mitigates risk through Required Organizational Practices (ROPs). ROPs are evidence-based practices. Two ROPs exist for medication reconciliation, these are*:* Medication Reconciliation at Admission and Medication Reconciliation at Transfer or Discharge. (9;10) These ROPs are detailed steps (explained above) that are to be followed when performing medication reconciliation.

For those organizations that participate in Accreditation Canada programs, at the service level, compliance rates for Medication Reconciliation at Admission improved from 47% in 2010 to 60% in 2011, and Medication Reconciliation at Transfer or Discharge improved from 36% in 2010 to 50% in 2011. (10)

Rapid Review

Research Question

What is the effectiveness of medication reconciliation at discharge compared to no medication reconciliation on patient outcomes?

Research Methods

Literature Search

Search Strategy

A literature search was performed on November 14, 2013, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid Embase, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews for studies published from January 1, 2008, to November 14, 2013. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2008, and November 14, 2013
- systematic reviews, meta-analyses, health technology assessments
- patients being discharged from acute hospital to home

Exclusion Criteria

- Patients being discharged from hospital to another facility (e.g., long-term-care home)
- Studies focusing on an electronic system for medication reconciliation
- Studies that did not include a control group

Outcomes of Interest

- 30-day hospital readmission
- Emergency department visits
- Clinically significant unintended medication discrepancies
    - This includes Adverse Drug Events (ADE) and Potential Adverse Drug Events (PADE)

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (11)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (12) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: the large magnitude of effect, the dose response gradient, and any residual confounding factors. (12) For more detailed information, please refer to the latest series of GRADE articles. (12)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect.
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different.
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect.
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect.

Results of Rapid Review

The database search yielded 109 citations published between January 1, 2008, and November 14, 2013, (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

One systematic review met the inclusion criteria. The reference lists of the included studies and health technology assessment websites were hand-searched to identify other relevant studies, but none were found that met the inclusion criteria.

The systematic review by Kwan et al (13) examined medication reconciliation on discrepancies with the potential to harm ("clinically significant discrepancies") and hospital utilization after discharge, specifically emergency department visits and hospital readmission within 30 days of discharge. This systematic review scored highly on the AMSTAR scale with a score of 8 out of a possible 11. Some limitations included no assessment of publication bias, no list provided of excluded studies and not searching of grey literature. Three systematic reviews were also reviewed but not utilized for this review because they did not directly address the question for this review, added no extra articles that were not already included within the systematic review utilized and were not the most recent.

Table 1 provides the characteristics of the 5 RCTs and 2 observational studies that were extracted from Kwan et al (13) because they included medication reconciliation as an intervention and took place at discharge from acute care.

Table 1: Summary of Studies Examining Medication Reconciliation on Patient Outcomes

Author, Year	Setting (Country)	Population	Study Design (Sample Size)	Person performing Medication Reconciliation	Additional Interventions	Outcomes	Results[a]
Parry et al, 2009 (14)	Any unit (except for psychiatric) in 2 community-based hospitals (USA)	Patients 65 and older[b]	RCT (98) Intervention group (49) Control group (49)	Transitional coaches	Patient education, timely clinic follow-up, home visit, transition coach, patient-centered discharge instructions	30-day hospital readmission	Intervention patients had lower hospital readmission rates than control patients at 30 days (2.3% vs. 9.5%, *P* = 0.20)
Dedhia et al, 2009 (15)	Medical unit in academic medical centre, community teaching hospital and urban community hospital (USA)	Patients 65 and older[b]	Prospective before-and-after study (185)	Physician followed by a Pharmacist (for review)	Safe STEPS intervention, including admission assessment, communication with PCP, and multidisciplinary discharge meeting	30-day hospital readmission Emergency department visits within 30 days of discharge	The intervention period had a lower rate of hospital readmission (22% vs. 14%, OR, 0.59; 95% CI, 0.34–0.97) and fewer visits to the emergency department (21% vs. 14%, OR, 0.61; 95% CI, 0.36–1.03; *P* = 0.06) compared to the control period.
Jack et al, 2009 (16)	Medical unit in academic medical centre (USA)	Patients aged 18 and older	RCT (738) Intervention group (370) Control group (368)	Nurse discharge advocate	Post-hospitalization care plan and post-discharge telephone call	30-day hospital readmission Emergency department visits within	Intervention participants had a lower rate of readmission than usual care participants (IRR, 0.720; 95% CI, 0.445-1.164; *P* = 0.090) Intervention participants had a lower rate of emergency

Author, Year	Setting (Country)	Population	Study Design (Sample Size)	Person performing Medication Reconciliation	Additional Interventions	Outcomes	Results[a]
						30 days of discharge	department visits than did usual care participants (IRR=0.674; 95% CI, 0.476-0.955; *P* = 0.014) Intervention participants had a lower rate of hospital utilization than did usual care participants (IRR, 0.695; 95% CI, 0.515-0.937; *P* = 0.009)[c]
Koehler et al, 2009 (17)	Medical unit in academic medical centre (USA)	Patients age ≥70 years with ≥5 medications, ≥3 chronic comorbid conditions, with ≥1 requiring assistance with ADL[b]	RCT (41) Intervention group (20) Control group (21)	Pharmacist	Counselling by pharmacist, post-discharge telephone call, discharge letter to PCP	30-day hospital readmission Emergency department visits within 30 days of discharge	Intervention group readmission/ED visit rates were reduced at 30 days compared to the control group (10.0% vs. 38.1%, *P* = 0.04)
Schnipper et al, 2006 (18)	Medical unit in academic medical centre (USA)	Patients admitted to the medical unit	RCT (176) Intervention group (92) Control group (84)	Pharmacist	None	30-day hospital readmission ED visits within 30 days of discharge	The rate of preventable, medication-related ED visits or hospital readmissions was 1% in the intervention group and 8% in those assigned to usual care (*P* = 0.03)
						Clinically significant discrepancies (ADE, PADE)	PADEs had occurred in 1 patient in the intervention group and 8 in the usual-care group (1% vs. 11%; *P* = 0.01; unadjusted odds ratio, 0.10; 95% CI, 0.013-0.86) The groups did not differ significantly with respect to total ADEs (*P* > 0.99), total

Author, Year	Setting (Country)	Population	Study Design (Sample Size)	Person performing Medication Reconciliation	Additional Interventions	Outcomes	Results[a]
							health care utilization (*P* > 0.99)
Walker et al, 2009 (19)	Medical unit in academic centre (USA)	≥1 of the following: ≥5 medications, ≥1 targeted medications, medication requiring monitoring, ≥2 changes to regimen, dementia or confusion, or inability to manage medications[b]	Prospective quasi-experimental study (358)	Pharmacist or pharmacy resident	None	30-day hospital readmission ED visits within 30 days of discharge Clinically significant discrepancies (PADE)	Readmission rates did not differ significantly between groups at 30 days (22.1% vs. 18%; *P* = 0.17), nor did ED visits (2.8% vs. 2.2%; *P* = 0.60) Medication discrepancies at discharge were identified in 33.5% of intervention patients and in 59.6% of control patients (*P* < 0.001)
Kripalani et al, 2012 (20)	Medical and Cardiology units in 2 academic medical centres (USA)	Patients admitted into the medical and cardiology units	RCT (851) Intervention group (423) Control group (428)	Pharmacist	Inpatient pharmacist counselling, low-literacy adherence aids, post-discharge telephone calls	Clinically significant discrepancies (PADE)	The mean number of PADE was similar in the intervention and usual care groups (0.87 vs. 0.95 per patient). Although the treatment effect favored the intervention, this difference was not statistically significant (unadjusted IRR, 0.92; 95% CI, 0.77-1.10)

Abbreviations: ADL, activities of daily life; ED, emergency department; RCT, randomized controlled trial; STEPS, Safe and Successful Transition of Elderly Patients; ADE, adverse drug event; CI, confidence interval; IRR, incidence rate ratio; OR, odds ratio; PADE, potential adverse drug events; PCP, primary care physician.
[a]Green font, statistically significant results; blue font, a trend towards significant results; red font, no statistically significant results.
[b]Defined as high-risk patients.
[c]Defined as the sum of emergency department visits plus rehospitalizations. An emergency department visit that leads to a rehospitalization is counted only as a rehospitalization.

It is difficult to isolate factors that contribute to a successful discharge plan. However, there are some common factors that may contribute to a successful intervention. First, most (5 of 7) of the interventions studied relied heavily on pharmacists, with 4 studies finding lower readmission, emergency, or medication discrepancies rates. Second, some studies (4 of 7) included what they defined as a high-risk sample, with 3 finding lower readmission, emergency, or medication discrepancies rates.

Limitations

Some limitations arise when drawing conclusions about medication reconciliation as an intervention. Five of the 7 individual studies bundled medication reconciliation with other interventions aimed at improving care coordination at hospital discharge, but the specific effect of medication reconciliation within a multifaceted approach may not be apparent.

Conclusions

Based on low to moderate quality evidence, results of medication reconciliation on patient outcomes are mixed. Three individual studies (2 RCTs and 1 observational) found no difference in hospital readmission rates within 30 days of discharge between intervention and control groups. However, 3 studies (2 RCTs and 1 observational) found a statistically significant reduction in hospital readmission rates within 30 days in the intervention group compared to the control group. Two observational studies found no difference in emergency department visits within 30 days of discharge between the intervention and control group, and 3 RCT studies found a statistically significant reduction in emergency department visits within 30 days of discharge between the intervention and control groups. Two RCT studies found clinically significant difference in medication discrepancies (PADE or ADE) between intervention and control groups. On the other hand, 2 studies (1 RCT and 1 observational) found a statistically significant reduction in medication discrepancies (PADE or ADE) between the intervention and control groups.

It is not possible to make conclusions about the effect of medication reconciliation on patient outcomes as there is limited evidence on medication reconciliation in isolation of other care coordination interventions.

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Medical Information Services
Corinne Holubowich, BEd, MLIS
Kellee Kaulback, BA(H), MISt

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program

Name	Affiliation(s)	Appointment(s)
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: November 14, 2013
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below)

Q: What is the effectiveness of medication reconciliation at transitions of care (i.e., discharge from hospital) compared to no medication reconciliation on hospital readmission and adverse drug events?
Limits: January 1, 2008, to November 14, 2013
Filters: Meta-analyses, systematic reviews, health technology assessments

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 2013>, EBM Reviews - ACP Journal Club <1991 to November 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <4th Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <October 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <4th Quarter 2013>, Ovid MEDLINE(R) <1946 to November Week 3 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <November 27, 2013>.

Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19905
2	exp Aftercare/ or exp Convalescence/	10298
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	49399
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37828
5	or/1-4	107305
6	exp Stroke/	89117
7	exp brain ischemia/ or exp intracranial hemorrhages/	132313
8	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	199794
9	or/6-8	287112
10	exp Heart Failure/	93122
11	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	135687
12	or/10-11	162171
13	exp Pulmonary Disease, Chronic Obstructive/	26665
14	exp Emphysema/	11098
15	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	59959
16	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	37701
17	or/13-16	84745
18	exp Pneumonia/	78260

19	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	147195
20	or/18-19	174702
21	or/5,9,12,17,20	778857
22	exp Medication Reconciliation/	282
23	exp Medication Errors/	11392
24	exp "Drug Utilization Review"/	3231
25	exp Drug Monitoring/	15716
26	exp Pharmaceutical Services/	51222
27	(((medication* or medicine* or drug or drugs or pharmacist* or pharmacy or pharmacies or formulary or formularies or prescription* or prescrib*) adj3 (reconcil* or review* or discrepanc* or discontinuit* or assess* or audit*)) or (med* reconcil* or medrec* or med rec or stopp criteria* or beer's criteria)).ti,ab.	31691
28	or/22-27	103340
29	21 and 28	4660
30	Meta Analysis.pt.	52731
31	Meta-Analysis/ use mesz or exp Technology Assessment, Biomedical/ use mesz	61456
32	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab.	210621
33	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab.	210621
34	or/30-33	226141
35	29 and 34	230
36	limit 35 to (english language and yr="2008 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	129
37	remove duplicates from 36	109

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Included Systematic Reviews

Author, Year	AMSTAR Score[a]	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Kwan et al, 2013 (13)	8	✓	✓	✓[b]	✗	✗	✓	✓	✓	✓[c]	✗	✓

Abbreviation: AMSTAR, Assessment of Multiple Systematic Reviews.

[a]Maximum possible score is 11. Details of AMSTAR score are described in Shea et al. (11)

[b]This information is provided in Kwan et al. *Supplement: Medication Reconciliation During Transitions of Care as a Patient Safety Strategy*. http://annals.org/article.aspx?articleid=1656444&resultClick=3.

[c]The article explicitly states that the populations included in the review are heterogeneous populations and only meta-analysis was performed on three similar RCTs.

Table A2: GRADE Evidence Profile for Comparison of Medication Reconciliation on Patient Outcomes in Randomized Controlled Trials

Number of Studies (Design)	Risk of Bias[a]	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
30-day hospital readmission							
4 (RCTs)	No serious limitations	Serious limitations (–1)[b]	Serious limitations (–1)[c]	No serious limitations	Undetected	None	⊕⊕⊕ Moderate
30-day emergency visit							
3 (RCTs)	No serious limitations	Serious limitations (–1)[b]	Serious limitations (–1)[c]	No serious limitations	Undetected	None	⊕⊕⊕ Moderate
Clinically significant unintended discrepancies							
2 (RCTs)	No serious limitations	Serious limitations (–1)[b]	Serious limitations (–1)[c]	No serious limitations	Undetected	None	⊕⊕⊕ Moderate

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.

[a] See table A4 for risk of bias details.

[b] Heterogeneity unexplained by the differing disease severity of populations.

[c] Medication Reconciliation was tested with multiple other interventions in most studies, so it is impossible to isolate this intervention.

Table A3: GRADE Evidence Profile for Comparison of Medication Reconciliation on Patient Outcomes in Observational Studies

Number of Studies (Design)	Risk of Bias[a]	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
30-day hospital readmission							
2 (observational)	No serious limitations	No serious limitations	Serious limitations (–1)[b]	No serious limitations	Undetected	None	⊕⊕ Low
30-day emergency visit							
2 (observational)	No serious limitations	No serious limitations	Serious limitations (–1)[b]	No serious limitations	Undetected	None	⊕⊕ Low
Clinically significant unintended discrepancies							
1 (observational)	No serious limitations	No serious limitations	No serious limitations	No serious limitations	Undetected	None	⊕⊕ Low

[a] See Table A5 for risk of bias details.
[b] Medication Reconciliation was tested with multiple other interventions in most studies, so it is impossible to isolate this intervention.

Table A4: Risk of Bias Among Randomized Controlled Trials for the Comparison of Medication Reconciliation on Patient Outcomes

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Parry et al, 2009 (14)	No limitations	Limitations[a]	No limitations	No limitations	No limitations
Jack et al, 2009 (16)	No limitations	No limitations	No limitations	No limitations	No limitations
Koehler et al, 2009 (17)	No limitations	No limitations	No limitations	No limitations	No limitations
Schnipper et al, 2006 (18)	No limitations	Limitations[b]	No limitations	No limitations	No limitations
Kripalani et al, 2012 (20)	No limitations	Limitations[c]	No limitations	No limitations	No limitations

[a]The participants were not blinded to whether they were in the intervention or control group.
[b]Patients and pharmacists were not blinded to what group (intervention or control) participants were assigned to.
[c]One unblinded research coordinator from each site administered the randomization.

Table A5: Risk of Bias Among Observational Trials for the Comparison of Medication Reconciliation on Patient Outcomes

Author, Year	Appropriate Eligibility Criteria	Appropriate Measurement of Exposure	Appropriate Measurement of Outcome	Adequate Control for Confounding	Complete Follow-Up
Dedhia et al, 2009 (15)	No limitations	No limitations	No limitations	Limitations[a]	No limitations
Walker et al, 2009 (19)	No limitations	No limitations	No limitations	No limitations	No limitations

[a] No statement of the variables controlled for in the analysis.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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Criteria for Referral to Home Care: A Rapid Review

Health Quality Ontario

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2-4–week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
ED	Emergency department
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
RCT	Randomized controlled trial

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this rapid review is to identify evidence-based criteria regarding when to refer a patient for home care services.

Clinical Need and Target Population

Home care refers to a diverse number of services that can be provided in the home. It encompasses many disciplines of care including, but not limited to, nursing, physiotherapy, occupational therapy, speech language pathology, social work, and personal support services. Many people will require some degree of home care support at some time in their lives. Deciding when a patient needs home care can be a challenging determination for health care providers to make—and it is always an important one. As stated by Bowles et al (2003), "[w]hen referrals are missed and patients discharged with unmet needs, patients often experience poor post-discharge outcomes…" (1)

According to the Ontario Association of Community Care Access Centres (OACCAC), there were 532,000 home care visits in Ontario in 2012/2013. (2) As the population ages, the need for home care services will continue to increase. Thus, knowing when and whom to refer to home care is critical because it is a limited resource that needs to be managed effectively to provide the highest quality of care to the most patients.

A recent American study by Holland et al (3) surveyed post-discharge patients about their transitions from hospital to home. None of the patients surveyed had been referred to home care upon discharge. More than 30% of them were unaware of how to access nursing care at home or personal support assistance once they were home.

Referrals to home care can also be made from emergency departments (EDs) for patients being discharged home from there. In 2009, McCusker et al (4) conducted a review of seniors being discharged from EDs in Quebec and found that 21% of them returned to the ED within 30 days. The investigators reported that those who were discharged from smaller EDs had higher rates of satisfaction with home care and with the transmission of information (smaller EDs meaning those with less than 14 beds, usually based in health centres rather than hospitals, and usually in rural areas). In another study of factors related to repeat ED visits, Naughton et al (5) looked at 306 elderly patients in Ireland. They found that 48% of

them were discharged from the ED with no documented referral to community services (including to a primary care provider) and that, of this group, 38% had been admitted to hospital or had at least 1 other ED visit within the past 6 months.

Rapid Review

Research Question

What criteria should be used to determine when to refer a patient for home care services?

Research Methods

Literature Search

Search Strategy

A literature search was performed on February 19, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews, for studies published from January 1, 2000, to February 19, 2014. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2000, and February 19, 2014
- observational studies, randomized controlled trials (RCTs), systematic reviews, and meta-analyses
- referrals to home care from hospital, emergency departments, or primary care

Exclusion Criteria

- studies predominantly of children
- case studies, editorials

Outcomes of Interest

- quality of life
- health resource utilization (hospital readmissions, ED visits)
- avoidance or delay of long-term care home admission

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the

methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The methodology for a rapid review of primary studies assesses the quality of the evidence through a risk of bias assessment of the individual studies in the review including allocation concealment, blinding, accounting of patients and outcome events, selective reporting bias and other limitations. (6) A full quality of evidence assessment is not typically performed, due to the time limitations associated with rapid reviews.

Results of Rapid Review

The database search yielded 444 citations published between January 1, 2000, and February 19, 2014, (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Four observational studies were identified that met the inclusion criteria. The reference lists of the included studies and health technology assessment websites were hand-searched to identify other relevant studies.

For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman, 1996. (7)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	
Large RCT	
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	3
Retrospective review, modelling	1
Studies presented at an international conference	
Expert opinion	
Total	**4**

Of the 4 studies included in this rapid review (1, 8-10), 3 have the same lead author, Dr. Kathryn Bowles. These studies are distinct, however, with different methods and participants. The risk of bias assessment

of the 4 observational studies indicated that all of the studies had some limitations, including post-hoc study design, and providing expert opinion as the outcome, rather than actual patient experience.

The most recent study included is an observational study by Bowles et al from 2009. (8) It looked for the factors predicting home care referral, and was based on expert consultation. The experts named the following 6 predictors: limited informal support at home; major walking restrictions; less than excellent self-rated health; longer hospital stay; higher depression score; and higher number of co-morbidities. Unfortunately, no actual patient outcomes were reported in this study, so there is no way to measure the accuracy of the predictors.

Employing a similar study design, Narsavage and Naylor (10) conducted a retrospective review of patients from 3 different studies who were receiving home care, and analyzed which characteristics resulted in a referral to home care. They found 4 predictors that led to an increased likelihood of a referral: having both congestive heart failure and chronic obstructive pulmonary disease; needing personal support assistance; being unmarried; and having a length of stay longer than 6 days. Similar to the Bowles et al study from 2009 (8), the major limitation of this study was the impossibility of knowing whether the patients were appropriately referred to home care. Furthermore, there were no outcomes regarding the rate of hospital readmission or the delay of long-term care admission for patients who received home care compared with those who did not.

In 2003, Bowles et al (1) conducted a qualitative research study to analyze the home care referral patterns of various health care professionals including nurses, social workers, discharge planners, and physicians. Professionals were asked to comment on 4 cases: 2 with poor outcomes (multiple repeat ED visits, hospital readmissions, death) and 2 without poor outcomes. The patients in all 4 cases had an average of 4 chronic conditions and 4 medications, and had been hospitalized for a cardiac or pulmonary condition. The health care professionals were given detailed medical records for each case. They were asked if they would refer the patient for home care and, if so, which services they would recommend. Based on the professionals' responses, the investigators identified 3 broad themes regarding why patients with unmet needs might not receive home care referrals. They described the themes as follows (1):

- Patient characteristics
  —included patients who looked fine or refused help, patients with a short length of stay, patients who appeared functionally able ("bluffing"), and patients "beyond help" or too "difficult" to refer for home care services (i.e., either non-compliant or requiring more assistance than home care services can provide)
- Workload and staffing
  —included lack of teamwork, lack of time, concern that referral would delay discharge, weekend discharge
- Education
  —included insufficient knowledge of the discharge process or of community services, lack of documentation, lack of a systematic approach to identifying patients for referral

Then in 2008 Bowles et al (9) published a secondary analysis of an RCT comparing patients who were referred to home care after cancer surgery with those who were not. The investigators' outcomes of interest were hospital readmission, decline in functionality, and death within 12 weeks of discharge. They looked at the characteristics of patients who were not referred for home care and who went on to have poor outcomes. They found that patients in this group were more likely to have had a length of stay longer than 1 week, be under 70 years of age, have no problem with concentration, and be receiving adjuvant care. In addition, these patients were less likely to need skilled home care (e.g., nursing, physiotherapy, occupational therapy). It is logical to assume, though, that they may have benefited from a personal support worker's help with bathing, laundry, cleaning, and other activities of daily living.

These studies by Bowles et al in 2003 (1) and 2008 (9) reached interesting and similar findings through different methodologies. The qualitative study in 2003 (1) found that patients who "looked fine" or appeared functionally able were less likely to be referred to home care than patients with an obvious need for services. The 2008 study (9) found that patients who were not referred to home care after hospitalization for cancer surgery, and who went on to have poor outcomes, were more likely to be younger and have no problems with concentration and no need for skilled home care. In other words, they too "looked fine," thus echoing the findings of the earlier study.

Table 2: Summary of Included Studies on Criteria for Referral to Home Care

Author, Year	Study Design	Sample Size (Description of Population)	Description of Study	Results/Conclusions
Bowles et al, 2009 (8)	Observational study	355 (hospitalized older adults)	Need for referral defined by expert consultation.	Factors predicting referral to home care: • No/limited informal support at home • Major walking restrictions • Less than excellent self-rated health • Longer hospital stay • Higher depression score • Higher number of co-morbidities
Bowles et al, 2008 (9)	Secondary analysis of RCT	375 (127 not referred for home care) (hospitalized adults > 60 years admitted for solid tumour cancer surgery)	Multiple logistic regression related home care referral to poor discharge outcomes.	27 patients (21%) had poor outcomes at 12 weeks. Correlates of poor discharge outcome among patients who were not referred to home care: • Length of stay > 1 week • Age < 70 • Without need for skilled care • No problem with concentration • Receiving adjuvant treatment
Bowles et al, 2003 (1)	Qualitative study	6 (health care professionals)	Health care professionals reviewed 4 cases.	Identified 3 themes: Patient characteristics, workload and staffing, education.
Narsavage and Naylor, 2000 (10)	Retrospective review	159 (adults > 65 years)	Multiple logistic regression identified predictors of post-discharge referral to home care.	Predictors of receiving home care: 1. Having both CHF and COPD 2. Needing personal support assistance 3. Not married 4. Length of stay > 6 days

Abbreviations: CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease.

Conclusions

The criteria for referring patients to home care is unclear. With the exception of 1 study based on expert consultation, we found no studies that explicitly defined criteria for referral; instead, studies attempted to define predictors for the need of home care services.

Based on the results of 4 observational studies, each with its own limitations, patients without an obvious need for home care services are the ones who may be overlooked and may experience poor outcomes as a result. Older patients and those with major mobility limitations, longer hospital stays, and more co-morbidities are more likely to be referred to home care than those with less obvious need.

Acknowledgements

Editorial Staff
Sue MacLeod, BA

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
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Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: February 19, 2014
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below), CINAHL

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 2013>, EBM Reviews - ACP Journal Club <1991 to January 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <January 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <1st Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2014>, Ovid MEDLINE(R) <1946 to February Week 1 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 18, 2014>
Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19216
2	exp Aftercare/ or exp Convalescence/	10054
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	46227
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	36832
5	exp Stroke/	85027
6	exp brain ischemia/ or exp intracranial hemorrhages/	129002
7	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	195049
8	exp Heart Failure/	89257
9	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	130161
10	exp Pulmonary Disease, Chronic Obstructive/	36493
11	exp Emphysema/	10699
12	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	56219
13	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	34637
14	exp Pneumonia/	74413
15	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	137338
16	or/1-15	752690
17	exp "Referral and Consultation"/	57178
18	exp Needs Assessment/	21862
19	(referral* or (refer* adj4 home care)).ti,ab.	70337
20	or/17-19	132268
21	16 and 20	8529
22	exp Home Care Services/	41032
23	exp Home Care Agencies/ or exp Home Health Aides/ or exp House Calls/	4275
24	(((home or domicil* or communit*) adj2 (visit* or care or caring or caregiver* or healthcare or assist* or aid* or agenc* or service* or rehabilitation)) or homecare or homemaker service* or home nurs* or meals on wheels).ti,ab.	52032
25	or/22-24	79006
26	21 and 25	755
27	limit 26 to yr="2000 -Current" [Limit not valid in DARE; records were retained]	514
28	limit 27 to english language [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	473
29	remove duplicates from 28	444

CINAHL

#	Query	Results
S1	(MH "Patient Discharge+") or (MH "After Care") or (MH "Recovery") or (MH "Continuity of Patient Care+")	45,293
S2	((patient* N2 discharge*) or aftercare or after care or post medical discharge* or postdischarge* or post discharge* or convalescen*)	29,381
S3	(MH "Stroke+") or (MH "Cerebral Ischemia+") or (MH "Intracranial Hemorrhage+") or (MH "Stroke Patients")	49,543
S4	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) N1 (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or ((brain or cerebral) N2 (ischemia or ischaemia)) or ((intracranial or brain) N2 (hemorrhag* or haemorrhag*)))	61,720
S5	(MH "Heart Failure+")	22,525
S6	((cardia* or heart) N1 (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) N1 (failure or insufficiency))	29,142
S7	(MH "Pulmonary Disease, Chronic Obstructive+") or (MH "Emphysema+")	11,559
S8	((chronic obstructive N2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) N1 (disease* or disorder*)) or (copd or coad or chronic airflow obstruction* or (chronic N2 bronchitis) or emphysema))	14,705
S9	(MH "Pneumonia+")	12,497
S10	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) N1 inflammation*))	19,509
S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10	175,149
S12	(MH "Referral and Consultation+")	22,057
S13	(MH "Needs Assessment")	10,156
S14	referral* or (refer* N4 home care)	34,222
S15	S12 OR S13 OR S14	44,979
S16	S11 AND S15	3,834
S17	(MH "Home Health Care+")	32,989
S18	(MH "Home Health Aides") or (MH "Home Health Agencies") or (MH "Home Nursing")	8,189
S19	(((home or domicil* or communit*) N2 (visit* or care or caring or caregiver* or healthcare or assist* or aid* or agenc* or service* or rehabilitation)) or homecare or homemaker service* or home nurs* or meals on wheels)	94,223
S20	S17 OR S18 OR S19	99,472
S21	S16 AND S20	677
S22	S16 AND S20 Limiters - Published Date: 20000101-20141231; English Language	486

Appendix 2: Evidence Quality Assessment

Table A1: Risk of Bias Among Observational Trials for Referral to Home Care

Author, Year	Appropriate Eligibility Criteria	Appropriate Measurement of Exposure	Appropriate Measurement of Outcome	Adequate Control for Confounding	Complete Follow Up
Bowles et al, 2009 (8)	Limitations[a]	No limitations	No limitations	Limitations[b]	No limitations
Bowles et al, 2008 (9)	No limitations	No limitations	No limitations	Limitations[c]	No limitations
Bowles et al, 2003 (1)	No limitations	No limitations	No limitations	Limitations[d]	No limitations
Narsavage & Naylor, 2000 (10)	No limitations	No limitations	No limitations	Limitations[b]	No limitations

[a] Recruitment was changed after study had begun—so both retrospective and prospective cases were included.

[b] The outcomes are based entirely on expert consultation; there are no actual outcomes reported. It is therefore not clear whether patients' health outcomes were affected by their having/not having referrals to home care.

[c] Secondary analysis of a randomized controlled study, designed post hoc.

[d] This is a qualitative study.

References

(1) Bowles KH, Foust JB, Naylor MD. Hospital discharge referral decision making: a multidisciplinary perspective. Appl Nurs Res. 2003;16(3):134-43.

(2) Ontario Association of Community Care Access Centres. CCAC fast facts, CCACs by the numbers [Internet]. Toronto, Ontario: Ontario Association of Community Care Access Centres; 2013 [cited 2014 July 8, 2014]. Available from: http://oaccac.com/Quality-And-Transparency/Fast-Facts.

(3) Holland DE, Mistiaen P, Bowles KH. Problems and unmet needs of patients discharged "home to self-care". Prof Case Manag. 2011;16(5):240-50.

(4) McCusker J, Roberge D, Vadeboncoeur A, Verdon J. Safety of discharge of seniors from the emergency department to the community. Healthc Q. 2009;12:Spec-32.

(5) Naughton C, Drennan J, Treacy P, Fealy G, Kilkenny M, Johnson F, et al. The role of health and non-health-related factors in repeat emergency department visits in an elderly urban population. Emerg Med J. 2010;27(9):683-7.

(6) Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. J Clin Epidemiol. 2011;64(4):380-2.

(7) Goodman C. Literature searching and evidence interpretation for assessing health care practices. Stockholm, Sweden: Swedish Council on Technology Assessment in Health Care, 1996 SBU Report No. 119E.

(8) Bowles KH, Holmes JH, Ratcliffe SJ, Liberatore M, Nydick R, Naylor MD. Factors identified by experts to support decision making for post acute referral. Nurs Res. 2009;58(2):115-22.

(9) Bowles KH, McCorkle R, Nuamah IF. Homecare referrals and 12-week outcomes following surgery for cancer. Oncol Nurs Forum. 2008;35(3):377-83.

(10) Narsavage GL, Naylor MD. Factors associated with referral of elderly individuals with cardiac and pulmonary disorders for home care services following hospital discharge. J Gerontol Nurs. 2000;26(5):14-20.

Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

Ontario
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Criteria for Referral to Heart Failure Clinics: A Rapid Review

Health Quality Ontario

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, the Evidence Development and Standards branch and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

BNP	Brain natriuretic peptide
CHFN	Canadian Heart Failure Network
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
NYHA	New York Heart Association
RCT	Randomized controlled trial
SCBC	Specialized community-based care

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this rapid review is to identify evidence-based criteria for referring patients to heart failure clinics.

Clinical Need and Target Population

Several systematic reviews have demonstrated survival benefits for patients who are enrolled in heart failure clinics, compared with patients who are not. (1) Health Quality Ontario, in a 2012 report on specialized community-based care (SCBC), of which such clinics are part, concluded that "There appears to be an added benefit to offering SCBC to patients with heart failure" and other specified conditions. (2)

On its website, the Canadian Heart Failure Network (CHFN) states that "All patients with suspected and established heart failure (NYHA Classes I to IV) should be eligible for treatment at [heart failure] clinics." (3) However, this is not feasible because of the resources that would be required. (4) Thus, the purpose of this review is to establish whether evidence-based criteria exist for determining patients' eligibility for heart failure clinic enrolment.

Note that some heart failure clinics have clearly defined referral criteria in place. For instance, St. Mary's Regional Cardiac Care Centre in Kitchener restricts referral eligibility to patients with NYHA Classes III to IV congestive heart failure who have had at least 2 hospital visits for heart failure within the past year. (5)

Rapid Review

Research Question

What criteria should be used to determine when to refer a patient to a heart failure clinic?

Research Methods

Literature Search

Search Strategy

A literature search was performed on March 19, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, and EBM Reviews, for studies published from January 1, 2008, to March 19, 2014. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2008, and March 19, 2014
- observational studies, randomized controlled trials (RCTs), systematic reviews, and meta-analyses
- purpose of the study to determine eligibility criteria for heart failure clinics

Exclusion Criteria

- studies of any clinics designed for treating conditions other than heart failure
- case studies, editorials

Outcomes of Interest

- quality of life
- health resource usage (e.g., hospital readmissions, emergency department visits)
- patient mortality

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care

pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The methodology for a rapid review of primary studies includes a risk of bias assessment based on GRADE Working Group criteria (6) to assess quality of evidence. Risk of bias is evaluated based on consideration of appropriate eligibility criteria, appropriate measurement of exposure, appropriate measurement of outcome, adequate control for confounding, and complete follow-up (see Appendix 2, Table A1).

Results of Rapid Review

The database search yielded 2,879 citations published between January 1, 2008, and March 19, 2014 (duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Three observational studies met the inclusion criteria. The reference lists of the included studies and health technology assessment websites were hand-searched to identify other relevant studies, but none were identified. For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman, 1996. (7)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	
Large RCT	
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	1
Case series	
Retrospective review, modelling	2
Studies presented at an international conference	
Expert opinion	
Total	**3**

Of the 3 studies identified that assessed the criteria for heart failure clinic enrolment, 2 (8;9) compared the characteristics of patients who were, versus those who were not, referred to heart failure clinics. In the third study, Amir et al (4) specifically assessed the role that patients' brain natriuretic peptide (BNP) can play in their eligibility for referral.

Table 2 summarizes the 3 studies. It is important to note, however, that neither the Gravely et al study (9) nor the Gharacholou et al study (8) are able to identify which patients are best suited for referral to heart failure clinics; and that the Amir et al study (4), as well as having a more specific objective, theorizes that the most severely ill patients are the ones who should be considered for heart failure clinics. This is in contrast to the much more inclusive CHFN website statement quoted earlier.

Table 2: Summary of the Observational Studies Included in This Rapid Review

Author, Year Country	Sample Size and Population	Objective	Study Design and Methods	Results Statistically Significant Differences Between Patients Enrolled in/ Not Enrolled in HF Clinics
Gravely et al, 2012 (9) Canada	270 patients hospitalized for HF (note: patients were part of a larger prospective cohort study in Ontario)	To observe the rates of referral and use of HF clinics	Patient survey	35 (13%) of the patients were enrolled in an HF clinic Enrolled patients were more likely to have: 1. university education 2. LVEF <40% 3. other referrals to DMPs 4. referral to CR 5. referral to diabetes clinic 6. referral to OT or PT 7. referral to a dietician 8. referral to a smoking cessation program
Gharacholou et al, 2011 (8) United States	57,969 HF patients at 235 U.S. sites from 2005 to 2010	To determine the characteristics of HF patients referred to HF clinics	Examination of administrative data	11,150 (19.2%) of patients were enrolled in an HF clinic Enrolled patients were more likely to: 1. be younger (mean 67 vs. 73) 2. be male 3. have co-morbidities 4. be smokers 5. have >2 HF admissions in past 6 months 6. be referred to CR
Amir et al, 2008 (4) Israel	70 patients referred to HF clinic	To determine if BNP can be used to guide HF clinic referrals	Prospective cohort study, measured BNP	BNP was the strongest predictor of 6-month mortality compared to ejection fraction, body mass index, NYHA class, ischemic etiology, presence of atrial fibrillation Enrolled/not enrolled comparison: N/A

Abbreviations: BMI, body mass index; BNP, brain natriuretic peptide; CR, cardiac rehabilitation; DMP, disease management program; HF, heart failure; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; OT, occupational therapy; PT, physical therapy; vs., versus.

Limitations

This rapid review has several limitations. The greatest limitation is that no studies were identified that were designed to define the optimal patients for referral to heart failure clinics. Also, the studies that were identified reported only on current practice, rather than ideal practice. In addition, there are many models of heart failure clinics, with different objectives. (2) This makes it challenging to develop a single list of criteria that would meet the needs of all.

Conclusions

Heart failure clinics have been shown to be effective at reducing patient mortality, and arguments have been made that the benefits of the clinics extend to all patients with suspected or established heart failure. Given resource limitations, a dilemma is posed as to how to best determine a patient's eligibility for referral to a heart failure clinic.

This rapid review found no studies designed to define the optimal patients for referral to heart failure clinics. Thus, it is unable to identify the criteria that should be used for making such referrals. The optimal eligibility criteria for heart failure clinics are unclear.

Acknowledgements

Editorial Staff
Sue MacLeod

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario (HQO)'s Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team,	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services

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Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: March 19, 2014
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to February 2014>, EBM Reviews - ACP Journal Club <1991 to February 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <January 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <1st Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2014>, Ovid MEDLINE(R) <1946 to March Week 1 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <March 18, 2014>
Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19360
2	exp Aftercare/ or exp Convalescence/	10095
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	46813
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37077
5	exp Stroke/	86536
6	exp brain ischemia/ or exp intracranial hemorrhages/	130198
7	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	197802
8	exp Heart Failure/	90065
9	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	131398
10	exp Pulmonary Disease, Chronic Obstructive/	37018
11	exp Emphysema/	10760
12	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	56838
13	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	35191
14	exp Pneumonia/	74882
15	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	138506
16	or/1-15	760031
17	exp "Referral and Consultation"/	57552
18	exp Needs Assessment/	22038
19	(referral* or (refer* adj4 (heart failure* or CHF or heart function* or specialty outpatient clinic* or disease management program*))).ti,ab.	71493
20	or/17-19	133813
21	16 and 20	8957
22	limit 21 to (english language and yr="2008 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	3050
23	remove duplicates from 22	2879

Appendix 2: Evidence Quality Assessment

Table A1: Risk of Bias Among Observational Trials Included in This Rapid Review

Author, Year	Appropriate Eligibility Criteria	Appropriate Measurement of Exposure	Appropriate Measurement of Outcome	Adequate Control for Confounding	Complete Follow-Up
Gravely et al, 2012 (9)	No limitations	No limitations	Limitations[a]	Limitations[b]	No limitations
Gharacholou et al, 2011 (8)	No limitations[a]	No limitations	Limitations[a]	Limitations[b]	No limitations
Amir et al, 2008 (4)	No limitations	No limitations	No limitations	No limitations	No limitations

[a]These studies are seeking criteria for heart failure clinic referral using existing referral patterns, not necessarily ideal referral patterns.
[b]These are retrospective studies with little control for confounding.

References

(1) Thomas R, Huntley A, Mann M, Huws D, Paranjothy S, Elwyn G, et al. Specialist clinics for reducing emergency admissions in patients with heart failure: a systematic review and meta-analysis of randomised controlled trials. Heart. 2013;99(4):233-9.

(2) Health Quality Ontario. Specialized community-based care: an evidence-based analysis [Internet]. Toronto: Health Quality Ontario. 2012 [cited: 2014 Apr 23]. 60 p. Available from: http://www.hqontario.ca/portals/0/Documents/eds/full-report-specialized-care.pdf.

(3) Canadian Heart Failure Network. Establishing a heart failure clinic [Internet]. [updated 2014; cited 2014 May 20]. Available from: http://www.chfn.ca/clinic-resource-manual/the-hf-clinic

(4) Amir O, Paz H, Ammar R, Yaniv N, Schliamser JE, Lewis BS. Usefulness and predictive value of circulating NT-proBNP levels to stratify patients for referral and priority treatment in a specialized outpatient heart failure center. Isr Med Assoc J. 2008;10(2):109-12.

(5) St.Mary's Regional Cardiac Care Centre. Heart Function Clinic Referral Form [Internet]. [updated 2014; cited 2014 Apr 23]. Available from: http://www.smgh.ca/wp-content/uploads/2012/02/Heart-Function-Clinic-Referral-Form.pdf

(6) Guyatt GH, Oxman AD, Vist G, Kunz R, Brozek J, Alonso-Coello P, et al. Rating the quality of evidence - study limitations (risk of bias). J Clin Epidemiol. 2011;64(4):407-15.

(7) Goodman C. Literature searching and evidence interpretation for assessing health care practices. Stockholm,Sweden: Swedish Council on Technology Assessment in Health Care; 1996 -81 p. SBU Report No. 119E. p.

(8) Gharacholou SM, Hellkamp AS, Hernandez AF, Peterson ED, Bhatt DL, Yancy CW, et al. Use and predictors of heart failure disease management referral in patients hospitalized with heart failure: insights from the Get With the Guidelines program. J Card Fail. 2011;17(5):431-9.

(9) Gravely S, Ginsburg L, Stewart DE, Mak S, Grace SL. Referral and use of heart failure clinics: what factors are related to use? Can J Cardiol. 2012;28(4):483-9.

Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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Home-Based Exercise Programs in Heart Failure: A Rapid Review

A Lambrinos

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

Home-Based Exercise Programs in Heart Failure: A Rapid Review. February 2015; pp. 1–21

Suggested Citation

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
CHF	Congestive heart failure
CI	Confidence interval(s)
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
MWT	Minute walk test
RCT	Randomized controlled trial
QOL	Quality of life
VO_2	Oxygen uptake

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

To determine the effectiveness of home-based exercise programs for patients with heart failure versus the following:

- supervised centre-based (or hospital) exercise programs or
- usual care for exercise capacity and quality of life (QOL).

Clinical Need and Target Population

Description of Disease/Condition

Congestive heart failure (CHF) is a complex syndrome in which abnormal heart function is responsible for the failure of the heart to pump blood at a rate that is necessary for metabolizing tissues. (1)

Ontario Prevalence and Incidence

The number of people with CHF in North America is estimated to exceed 5 million. (2) Between 1997 and 2008, there were 419,551 incident cases of heart failure in Ontario. (3) Congestive heart failure is the most common cause of hospitalization for adults over the age of 65 years. (2)

Technology/Technique

Exercise training for patients with CHF has a positive effect on physical capacity, such as exercise duration and maximal peak oxygen consumption. (4) Studies have also shown an association between exercise programs and increased QOL in patients with heart failure. (5)

Traditionally, centre-based programs usually incorporate group exercise training in a supervised gym environment and can include an educational component. However, they are resource-intensive and have suboptimal participation. Some reasons for lack of participation in centre-based exercise programs are problems with accessibility, a dislike for groups, and work or domestic commitments. (6;7) Home-based exercise training can include aerobic training, such as the use of exercise bikes, outdoor and treadmill walking, and strength training, such as resistive bands or weights, similar to that of centre-based exercise training. Home-based exercise training is usually unsupervised but can include regular contact with research staff. Home-based exercise programs potentially increase participation and bridge the gap on accessibility issues. (8)

Rapid Review

Research Question

What is the effectiveness of home-based exercise programs for patients with heart failure versus the following:

- centre-based exercise programs or
- usual care for patient outcomes?

Research Methods

Literature Search

Search Strategy

A literature search was performed on December 10, 2013, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, and all evidence-based medicine databases for studies published from January 1, 2008, to December 10, 2013. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2008, and December 10, 2013
- randomized controlled trials (RCTs), systematic reviews, and meta-analyses

Exclusion Criteria

- patients who have undergone cardiac surgical procedures
- interventions that incorporate both centre- and home-based exercise programs

Outcomes of Interest

- exercise capacity
    - measured by the 6-minute walk test (MWT) and peak VO_2 (oxygen uptake)
- quality of life

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and

prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodologic quality of systematic reviews. (9)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (10) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that RCTs are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that can raise the quality of evidence were considered: large magnitude of effect, dose-response gradient, and accounting for all residual confounding factors. (10) For more detailed information, please refer to the latest series of GRADE articles. (10)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Rapid Review

The database search yielded 610 citations published between January 1, 2008, and December 10, 2013 (with duplicates removed). Articles were excluded on the basis of information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Two systematic reviews met the inclusion criteria. The systematic review used in this review by Chien et al (11) examined effectiveness of home-based exercise programs compared with usual activity in patients with heart failure on exercise capacity, QOL, and adverse events. This systematic review scored moderately on the AMSTAR scale with 8 of a possible 11 points. Some limitations included no search of grey literature, no assessment of publication bias, not considering the methodologic quality of the studies

in the conclusion, and no statement of conflict of interest. The systematic review by Hwang and Marwick (12) that was not included in this review examined effectiveness of home-based exercise programs compared with usual medical care on exercise capacity in patients with heart failure. This systematic review scored poorly on the AMSTAR scale with 4 of a possible 11 points. Some limitations included only one reviewer, no search of grey literature, no assessment of publication bias, no list of excluded studies, no assessment of the methodologic quality of the primary studies, not considering the methodologic quality of the studies in the conclusion, and no statement of conflict of interest.

There were consistencies across all primary studies included in the Chien et al (11) review. All the exercise programs within the studies incorporated a combination of aerobic exercise (walking or cycling) and resistance training. Also, the control groups of all studies maintained usual care with one exception (home-based electrical stimulation).

The effect of home-based exercise training on peak VO_2 was examined by pooling data from 4 studies with 248 participants using a random effects model (Figure 1). There was no difference for peak VO_2 between those participating in home-based exercise training and usual activity (0.55, 95% confidence interval [CI]: −0.03 to 1.14). The effect of home-based exercise training on 6 MWT was examined by pooling data from 4 studies with 256 participants using a random effects model (Figure 2). Home-based exercise training increased 6 MWT distance compared with usual activity (44.09, 95% CI: 4.57– 83.61). The effect of home-based exercise training on QOL was examined by pooling data from 2 studies with 78 participants (Figure 3). The third study, by Oka et al, (13) did not use the same measure for QOL and therefore was not included in the analysis. There was no difference for QOL between those participating in home-based exercise training and usual activity (13.29, 95% CI: −10.98 to 37.57).

Some limitations of this review included 3 studies examining 2 weeks of hospital-based exercise training before home-based exercise and 2 studies examining 3 months of supervised exercise training before home-based exercise. Only 5 RCTs participated solely in home-based exercise programs. Second, the exercise programs examined in the primary studies had different time and frequencies of exercise duration. Third, the studies included had very small sample sizes with no studies exceeding 100 participants. Last, those in the control groups presumed normal activity (usual care), which did not consist of an exercise program in a supervised setting, so no true comparison of home versus centre-based exercise can be done. The descriptions of the studies are presented in Table 1.

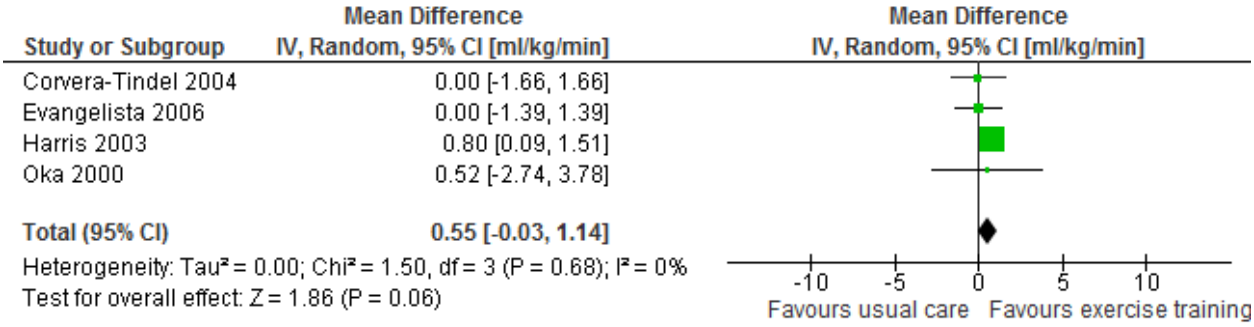

Figure 1: Effect of Home-Based Exercise Programs on Peak Oxygen Uptake

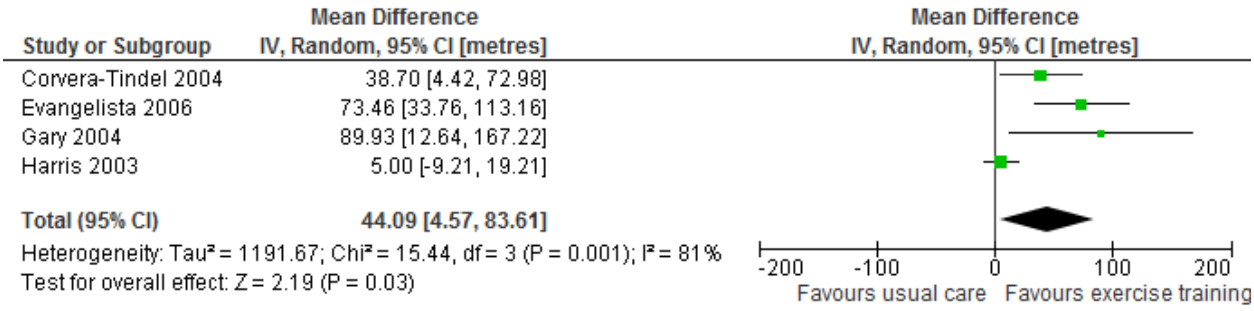

Figure 2: Effect of Home-Based Exercise Programs on the 6-Minute Walk Test

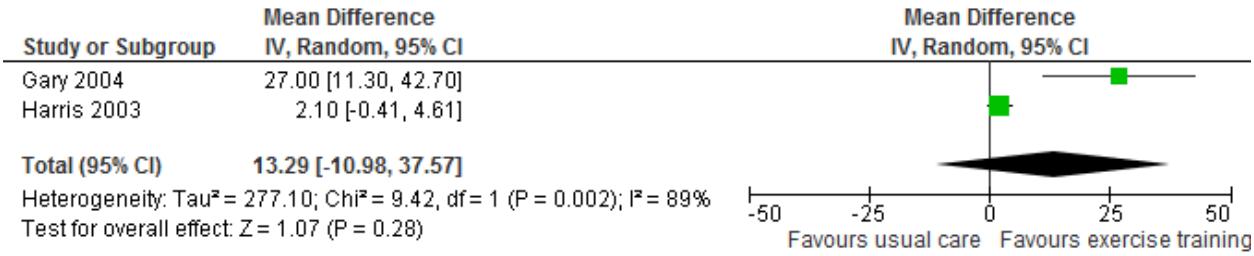

Figure 3: Effect of Home-Based Exercise Programs on Quality of Life

Table 1: Randomized Controlled Trials in Chien et al Review

Author, Year	Participants (n)	Outcome	Exercise Training		Result	
			Intervention	Control	Outcomes	Other
Corvera-Tindel et al (14)	HF secondary to IHD and non-IHD, NYHA II–IV, EF 24.7%–29.1%, Age = 61–63 yr (n = 79)	Peak VO_2 (mL/kg/min) 6 MWT (ft)	12-wk home walking exercise with intensity at 40%–65% max HR, 60 min/d, 5 d/wk	Usual care	Peak VO_2 did not differ between intervention and control groups over time (14.3 ± 3.7 to 15.3 ± 3.8 vs. 14.2 ± 3.4 to 15.2 ± 4.1, *P* = 0.70) 6 MWT was improved in the intervention group compared with the control group (1,219.0 ± 241.5 to 1,337.1 ± 272.2 vs. 1,273.2 ± 249.2 to 1,263.9 ± 254.5, *P* = 0.008)	Global rating of dyspnea and fatigue symptoms was reduced in the intervention group compared with the control group (3.2 ± 0.10 vs. 3.7 ± 0.8, *P* = 0.03)
Evangelista et al (15)	Advanced HF, BMI ≥ 27 (measured in kg/m^2), NYHA II–IV, EF ≤ 40%, Age = 53–55 yr (n = 99)	Peak VO_2 (mL/kg/min) 6 MWT (ft)	6-month home walking program with intensity at 60% max HR, 45 min, combined with resistance exercise, ≥4 times/week	Usual care	Peak VO_2 and 6 MWT did not differ between intervention and control groups (14 ± 3 to 14 ± 4 vs. 13 ± 3 to 13 ± 4, *P* = 0.72, and 1,379 ± 338 to 1,577 ± 404 vs.1,331 ± 231 to 1,288 ± 320, *P* = 0.51)	Depression and anxiety scores did not differ between intervention and control groups (14.0 ± 7.6 to 7.2 ± 3.4 vs. 16.2 ± 5.3 to 9.0 ± 3.9, *P* = 0.82, and 7.0 ± 4.1 to 7.2 ± 4.2 vs. 8.6 ± 4.0 to 8.5 ± 4.1, *P* = 0.69)
Gary et al (16)	HF secondary to IHD and non-IHD, NYHA II–III, EF 54%–57%, Age = 67–69 yr (n = 32)	6 MWT (ft) QOL (MHFQ)	12-wk home walking program with intensity at 40%–60% max HR, 40 min/d, 3 d/wk, 12 weekly home visits with education program	Usual care and 12 weekly home visits with education program only	6 MWT was improved in the intervention compared with the control group (840 ± 366 to 1,043 ± 317 vs. 824 ± 367 to 732 ± 408, *P* = 0.002) QOL improved in the intervention group compared with the control group at 12 weeks (41 ± 26 to 24 ± 18 vs. 27 ± 18 to 28 ± 22, *P* = 0.002) and 3-month follow-up (24 ± 18 to 19 ± 18 vs. 28 ± 22 to 32 ± 27, *P* = 0.01)	Depression scores improved in the intervention compared with the control group at 12 weeks (6 ± 4 to 4 ± 4 vs. 5 ± 3 to 7 ± 5, *P* = 0.012) and 3-month follow-up (4 ± 4 to 4 ± 4[a] vs. 7 ± 5 to 7 ± 5,[a] *P* = 0.009)
Harris et al (17)	HF secondary to DCM and IHD, NYHA II–III, EF 28.3%–32.0%, age = 61–63 yr (n = 46)	Peak VO_2 (mL/kg/min) 6 MWT (m) QOL (MHFQ)	6-wk home bicycle exercise with intensity at 70% max HR, 30 min/d, 5 d/wk	Functional electrical stimulator, no specific exercise	Peak VO_2 did not improve in either the intervention or control group (19.0 ± 1.14 to 19.8 ± 1.10, *P* = 0.276, vs. 18.6 ± 1.27 to 18.6 ± 1.07) 6 MWT improved in both the intervention and control group (495 ± 24 to 540 ± 23, *P* < 0.001 vs. 491 ± 26 to 531 ± 25, *P* < 0.001) QOL improved for both groups on average (32.7 ± 3.16 to 28.4 ± 2.91, *P* = 0.024), but no improvement was seen independently in the intervention or control group (36.3 ± 4.21 to 31.0 ± 3.66, *P* = 0.105, vs. 28.7 ± 4.70 to 25.5 ± 4.61, *P* = 0.094)	
Oka et al (13)	Mixed HF, NYHA II–III, EF 22.3%–24.9%, Age = unknown (n = 40)	Peak VO_2 (mL/kg/min) QOL (CHFQ)	12-wk aerobic walking with intensity at 70% max HR, 40–60 min/d, 3 d/wk Resistance training = 75% 1RM, 30–40 min/d, 2 d/wk	Usual care	Peak VO_2 did not differ between intervention and control groups over time (18.37 ± 4.0 to 18.89 ± 4.69 vs. 19.00 ± 3.75 to 19.00 ± 3.82) QOL improved on the mastery (23.0 ± 4.2 to 25.6 ± 3.1 vs. 21.1 ± 4.1 to 21.3 ± 5.1, *P* = 0.04) and emotion (38.8 ± 4.8 to 42.1 ± 4.8 vs. 35.7 ± 6.6 to 33.2 ± 8.7, *P* = 0.02) subscales in the intervention group compared with the control group	

Abbreviations: BMI = body mass index, CHFQ = Chronic Heart Failure Questionnaire, DCM = dilated cardiomyopathy, EF = ejection fraction, HF = heart failure, IHD = ischemic heart disease, MHFQ = Minnesota Heart Failure Questionnaire, 6 MWT = 6-minute walk test, NYHA II-IV = New York Heart Association (Functional Class I–IV), QOL = quality of life.

[a]Depression scores did not change from the 12-week to 3-month follow-up visit in the Gary et al article.

Conclusions

Low- to moderate-quality evidence indicates home-based exercise training increases the 6 MWT distance compared with usual activity. However, peak VO_2 and quality of life did not differ between participants who received home-based exercise training and patients who maintained their usual activity levels.

Acknowledgements

Editorial Staff
Elizabeth Jean Betsch, ELS

Medical Information Services
Corinne Holubowich, BEd, MLIS
Kellee Kaulback, BA(H), MISt

Health Quality Ontario (HQO)'s Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program

Name	Affiliation(s)	Appointment(s)
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: December 10, 2013
Databases searched: Ovid MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below)

Q: What is the effectiveness of home-based exercise programs versus centre-based exercise programs in patients with heart failure on patient outcomes?
Limits: 2008-current; English
Filters: Meta-analyses, systematic reviews, health technology assessments

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 2013>, EBM Reviews - ACP Journal Club <1991 to November 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <4th Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <November 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <4th Quarter 2013>, Ovid MEDLINE(R) <1946 to November Week 3 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <December 09, 2013>

Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19905
2	exp Aftercare/ or exp Convalescence/	10298
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	49411
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37891
5	exp Heart Failure/	93131
6	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	135925
7	exp Pulmonary Disease, Chronic Obstructive/	26667
8	exp Emphysema/	11099
9	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	60068
10	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	37815
11	exp Pneumonia/	78260
12	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	147382
13	or/1-12	513261
14	exp Exercise Tolerance/	9966
15	exp Exercise/	127308
16	exp Rehabilitation/	162816
17	exp Rehabilitation Nursing/	1136
18	exp "Physical and Rehabilitation Medicine"/	19975
19	exp Rehabilitation Centers/	12881
20	exp Physical Therapy Modalities/	136983

21	(rehabilitat* or (physical* adj (fit* or train* or therap* or activit*)) or ((exercise* or fitness) adj3 (treatment or intervent* or program*)) or (train* adj (strength* or aerobic or exercise*)) or wellness program* or ((pulmonary or lung* or respirat* or cardiac) adj2 (physiotherap* or therap* or rehabilitat*)) or angina plan* or heart manual*).ti,ab.	235554
22	or/14-21	536336
23	Meta Analysis.pt.	52738
24	Meta-Analysis/ use mesz or exp Technology Assessment, Biomedical/ use mesz	61456
25	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab.	211340
26	((health technolog* or biomedical technolog*) adj2 assess*).ti,ab.	2746
27	or/23-26	227857
28	13 and 22 and 27	1230
29	limit 28 to (english language and yr="2008 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	773
30	remove duplicates from 29	613

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Systematic Reviews

Author, Year	AMSTAR Score[a]	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Hwang et al, 2009 (12)	4	✓	✗	✓	✗	✗	✓	✗	✗	✓	✗	✗
Chien et al, 2008 (11)	8	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗	✗

Abbreviations: AMSTAR, Assessment of Multiple Systematic Reviews; RCT, randomized controlled trial.
[a]Maximum possible score is 11. Details of AMSTAR score are described in Shea et al. (9)

Table A2: GRADE Evidence Profile for Comparison of Home-Based Exercise Versus Usual Care

Number of Studies (Design)	Risk of Bias[a]	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
6-Minute Walk Test							
4 (RCTs)	No serious limitations	Serious limitations (–1)[b]	Serious limitations (–1)[c]	No serious limitations	Undetected	None	⊕⊕ Low
Peak VO_2							
4 (RCTs)	No serious limitations	No serious limitations	Serious limitations (–1)[c]	No serious limitations	Undetected	None	⊕⊕⊕ Moderate
Quality of Life							
3 (RCTs)	No serious limitations	No serious limitations	Serious limitations (–1)[c]	No serious limitations	Undetected	None	⊕⊕⊕ Moderate

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a] See Table A3 for risk of bias details.
[b] Heterogeneity in estimates not due to disease severity.
[c] Differences in duration and frequency of exercise training.

Table A3: Risk of Bias Among Randomized Controlled Trials for Comparison of Home-Based Exercise Versus Usual Care

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Corvera-Tindel et al, 2004 (14)	No limitations	Limitations[a]	No limitations	No limitations	No limitations
Evangelista et al, 2006 (15)	No limitations	Limitations [a]	Limitations [b]	No limitations	No limitations
Gary et al, 2004 (16)	Limitations [c]	No limitations	No limitations	No limitations	No limitations
Harris et al, 2003 (17)	No limitations	No limitations	Limitations [c]	No limitations	No limitations
Oka et al, 2000 (13)	Limitations	No limitations	Limitations [c]	No limitations	No limitations

[a] No blinding among research assistants, participants, or data analysts.
[b] No intention-to-treat analysis.
[c] No allocation concealment.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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Aerobic Exercise Training in Patients With Heart Failure: A Rapid Review

Health Quality Ontario

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Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

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In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
NYHA	New York Heart Association functional classification
SR	Systematic review

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective is to determine if exercise training in patients with heart failure improves survival and health-related quality of life and reduces health resource use.

Severity of heart failure is frequently reported using the New York Heart Association functional classification (NYHA), where NYHA I refers to a patient with cardiac disease but no symptoms and NYHA IV refers to a patient with severe limitations, even at rest.

The target population for this rapid review are patients discharged from hospital (or the emergency department) with heart failure. It is well established that exercise training in patients with heart failure can improve exercise capacity (1), but it is unclear if exercise training improves other outcomes such as quality of life, survival, or health resource utilization. Supervised exercise training for patients with heart failure can be offered through cardiac rehabilitation, heart failure clinic, or another structured program.

Rapid Review

Research Question

What is the effectiveness of aerobic exercise training compared to no exercise training in patients with heart failure in terms of health resource utilization, health-related quality of life, and survival?

Research Methods

Literature Search

Search Strategy

A literature search was performed on December 10, 2013, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid Embase, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews for studies published from January 1, 2008 to December 10, 2013. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2008, and December 10, 2013
- systematic reviews (SRs), meta-analyses, and health technology assessments
- aerobic exercise training compared to usual care
- ≥ 6 months of follow-up
- patients with heart failure and NYHA II-IV

Exclusion Criteria

- exercise training for patients with cardiac diseases, but not specifically heart failure
- non-English studies
- primary studies, grey literature

Outcomes of Interest

- health resource utilization
- survival
- health-related quality of life

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (2)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (3) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: large magnitude of effect, dose response gradient, and accounting for all residual confounding factors. (3) For more detailed information, please refer to the latest series of GRADE articles. (3)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Rapid Review

The database search yielded 613 citations (with duplicates removed) published between January 1, 2008, and December 10, 2013. Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

One systematic review met the inclusion criteria. The reference lists of the systematic review and health technology assessment websites were hand-searched to identify other relevant studies, but none were identified.

For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman (1994). (4)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	1
Large RCT	
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	
Studies presented at an international conference	
Expert opinion	
Total	**1**

Abbreviation: RCT, randomized controlled trial.

The Cochrane systematic review by Davies et al (5) was the only systematic review identified that included the outcomes of interest (health resource utilization, mortality, health-related quality of life) of this rapid review. This systematic review had a high AMSTAR score of 9 out of a possible 11. The greatest limitation of this review was an issue of heterogeneity and whether it was appropriate to meta-analyze studies that offer such diverse exercise programs. There were many other systematic reviews identified that investigated exercise in patients with heart failure; however, these SRs primarily reported exercise capacity outcomes.

The inclusion criteria for the Davies et al (5) systematic review were limited to:

- randomized controlled trials (parallel group or cross-over design)
- adults with a diagnosis of systolic heart failure
- exercise intervention either in isolation or as a component of a cardiac program

Davies et al (5) identified 19 primary studies to include in their review; they assessed the quality of the studies and reported that the overall quality was poor. Nonetheless, Davies et al (5) meta-analyzed the studies (a brief description of the 19 studies is provided in Table 2), and it is clear that the exercise interventions varied considerably among the studies in terms of the duration of the study and the exercise, the type and frequency of the exercise, etc.

Mortality

Thirteen of the studies in Davies et al (5) reported mortality as an outcome. They did not find a significant difference in pooled mortality between the groups receiving the exercise intervention compared to those that did not. Since most of the studies had follow-up periods of <12 months, it is difficult to know the long term effects of exercise on mortality. The duration of follow-up may not have been long enough to assess significant differences in mortality.

Hospital Admissions

There were 7 studies identified in Davies et al (5) that reported hospital admissions due to heart failure. They found that when these studies were pooled, there was a significant reduction in the number of heart failure-specific hospital admissions in the group receiving the exercise intervention compared to the group receiving usual care (risk ratio 0.72, 95% confidence interval, 0.52-0.99, $P = 0.004$). When the all-cause hospital admissions were pooled, Davies et al (5) did not find a significant difference between the treatment groups.

Health-Related Quality of Life

Ten studies reported a validated health-related quality of life measure. Davies et al (5) reported that although there were different measures used to assess quality of life, quality of life was consistently rated higher in the exercise group compared to the control group. This reached significance in the 6 studies that reported health-related quality of life using the Minnesota Living with Heart Failure questionnaire ($P < 0.001$).

Table 2: Description of Studies in Davies et al (5) systematic review[a]

Study	N (mean age in years)	NYHA	Exercise Type	Frequency	Duration of Study
Austin et al, 2005	200 (72)	NYHA II-III	Aerobic and resistance	2 x 2.5-hour sessions/week for 8 weeks, 1 hour/week group, 3 x 1 hour/week at home, for 16 weeks	24 weeks
Belardinelli et al, 1999	99 (56)	NYHA II-IV	Aerobic and resistance	2-3 sessions/week, 40 minutes/session; 8 weeks supervised, 12 months maintenance	14 months
Dracup et al, 2007	173 (54)	NYHA II-IV	Aerobic and resistance	4 sessions/week, 10-45 minutes/session	12 months
Giannuzzi et al, 2003	90 (60)	NYHA II-III	Aerobic	3-5 sessions/week, 30 minutes/session	6 months
Gielen et al, 2003	20 (55)	NYHA II-III (90% II)	Aerobic	7 sessions/week, 20 minutes/session	6 months
Gottlieb et al, 1999	33 (67)	NYHA II-III	Aerobic	3 sessions/week, (length of session not reported)	3 months
Hambrecht et al, 1995	22 (50)	NYHA II-III	Aerobic	4-6 sessions/week, 10-60 minutes/session	6 months
Hambrecht et al, 1998	20 (54)	NYHA II-III	Aerobic	2-6 sessions/day, 10-20 minutes/session	6 months
Hambrecht et al, 2000	73 (54)	NYHA I-III	Aerobic	6-7 sessions/week, 10-20 minutes/session	6 months
HF ACTION, 2009	2331 (59)	NYHA II-III	Aerobic	3-5 sessions/week, 15-35 minutes/session	3 months
Keteyian et al, 1996	40 (56)	NYHA II-III	Aerobic	3 sessions/week, 33 minutes/session	24 weeks
Klecha et al, 2007	50 (60)	NYHA II-III	Aerobic	3 sessions/week, 25 minutes/session	6 months
Klocek et al, 2005 (i)	42 (57)	NYHA II-III	Aerobic	3 sessions/week, 25 minutes/session	6 months
Klocek et al, 2005 (ii)	42 (54)	NYHA II-III	Aerobic	3 sessions/week, 20 minutes/session	6 months
Koukouvou et al, 2004	26 (52)	NYHA II-III	Aerobic and resistance	3-4 sessions/week, 60 minutes/session	6 months
McKelvie et al, 2002	181 (65)	NYHA I-III	Aerobic and resistance	2 sessions/week, 30 minutes/session	9 months
Mueller et al, 2007	50 (55)	NR	Aerobic	5 sessions/week, 30 minutes/session + 90 minutes walking/day	1 month
Passino et al, 2006	95 (60)	NYHA I-III	Aerobic	>3 sessions/week, 30 minutes/session	9 months
Pozehl et al, 2008	21 (66)	NYHA II-IV	Aerobic and resistance	3 sessions/week, 50 minutes/session	24 weeks
Willenheimer et al, 2000	54 (64)	NYHA mean 2.2	Aerobic/ interval	2-3 sessions/week, 15-45 minutes/session	4 months

Abbreviation: NYHA, New York Heart Association functional classification.
[a]These studies are the included studies in the Davies et al (5) systematic review.

Conclusions

The results of the Davies et al (5) systematic review were generally inconclusive due to the heterogeneity and poor quality of the studies included in the review. Exercise is a life-long intervention, and these studies may not have been of a long enough duration to clearly establish changes in mortality and health resource utilization, although it would seem that with these relatively short studies there is a trend towards an improvement in health-related quality of life in patients with heart failure who receive exercise training compared to those who do not.

Based on low quality of evidence:

- There is a trend towards improved health-related quality of life in patients with heart failure who receive exercise training.
- Exercise training reduces heart failure–related hospital admissions, but did not improve survival. However, these studies may not have been long enough to assess the impact on mortality.

Acknowledgements

Editorial Staff
Timothy Maguire

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader

Name	Affiliation(s)	Appointment(s)
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: December 10, 2013
Databases searched: OVID MEDLINE, MEDLINE In-Process, and Other Non-Indexed Citations, All EBM Databases (see below)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 2013>, EBM Reviews - ACP Journal Club <1991 to November 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <4th Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <November 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <4th Quarter 2013>, Ovid MEDLINE(R) <1946 to November Week 3 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <December 09, 2013>.

Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19905
2	exp Aftercare/ or exp Convalescence/	10298
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	49411
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37891
5	exp Heart Failure/	93131
6	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	135925
7	exp Pulmonary Disease, Chronic Obstructive/	26667
8	exp Emphysema/	11099
9	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	60068
10	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	37815
11	exp Pneumonia/	78260
12	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	147382
13	or/1-12	513261
14	exp Exercise Tolerance/	9966
15	exp Exercise/	127308
16	exp Rehabilitation/	162816
17	exp Rehabilitation Nursing/	1136
18	exp "Physical and Rehabilitation Medicine"/	19975
19	exp Rehabilitation Centers/	12881
20	exp Physical Therapy Modalities/	136983
21	(rehabilitat* or (physical* adj (fit* or train* or therap* or activit*)) or ((exercise* or fitness) adj3 (treatment or intervent* or program*)) or (train* adj (strength* or aerobic or exercise*)) or wellness program* or ((pulmonary or lung* or respirat* or cardiac) adj2 (physiotherap* or therap* or rehabilitat*)) or angina plan* or heart manual*).ti,ab.	235554
22	or/14-21	536336
23	Meta Analysis.pt.	52738
24	Meta-Analysis/ use mesz or exp Technology Assessment, Biomedical/ use mesz	61456
25	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab.	211340
26	((health technolog* or biomedical technolog*) adj2 assess*).ti,ab.	2746
27	or/23-26	227857
28	13 and 22 and 27	1230
29	limit 28 to (english language and yr="2008 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	773
30	remove duplicates from 29	613

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Included Systematic Reviews

Author, Year	AMSTAR Score[a]	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Davies et al, 2010	9	✓	✓	✓	✓	✓	✓	✓	✓	?	✗	✓

Abbreviations: AMSTAR, Assessment of Multiple Systematic Reviews.
[a]Maximum possible score is 11. Details of AMSTAR score are described in Shea et al. (2)

Table A2: GRADE Evidence Profile for Exercise Training Compared to No Exercise Training in Patients With Heart Failure

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Outcome Mortality							
13 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	None	⊕⊕ Low
Outcome Hospital Admission							
7 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	None	⊕⊕ Low
Outcome Health-Related Quality of Life							
10 (RCTs)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	Serious limitations (–1)[b]	Undetected	None	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a]Many of the studies had risk of bias concerns, see Table A3.
[b]The small number of events in many of the studies led to wide confidence intervals.

Table A3: Risk of Bias Among Randomized Controlled Trials for Exercise Training Compared to No Exercise Training in Patients With Heart Failure[a]

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Austin et al, 2005	No limitations	Limitations[b]	No limitations	No limitations	No limitations
Belardinelli et al, 1999	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Dracup et al, 2007	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Giannuzzi et al, 2003	Limitations[c]	Limitations[d]	No limitations	No limitations	No limitations
Gielen et al, 2003	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Gottlieb et al, 1999	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Hambrecht et al, 1995	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Hambrecht et al, 1998	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Hambrecht et al, 2000	Limitations[c]	Limitations[d]	No limitations	No limitations	No limitations
HF ACTION, 2009	No limitations	No limitations	No limitations	No limitations	No limitations
Keteyian et al, 1996	Limitations[c]	Limitations[d]	No limitations	No limitations	No limitations
Klecha et al, 2007	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Klocek et al, 2005 (i)	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Klocek et al, 2005 (ii)	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Koukouvou et al, 2004	Limitations[c]	No limitations	Limitations[e]	No limitations	No limitations
McKelvie et al, 2002	No limitations	No limitations	Limitations[e]	Limitations[f]	No limitations
Mueller et al, 2007	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Passino et al, 2006	Limitations[c]	Limitations[d]	Limitations[e]	Limitations[f]	No limitations
Pozehl et al, 2008	Limitations[c]	Limitations[d]	Limitations[e]	No limitations	No limitations
Willenheimer et al, 2000	Limitations[c]	No limitations	Limitations[e]	No limitations	No limitations

[a]Results are from the systematic review by Davies et al. (5)
[b]Blinding was not used in this study.
[c]Not clear if allocation concealment was part of the methodology of the study.
[d]Unclear if blinding was used in this study.
[e]Unclear if there was complete accounting of patients and outcome events.
[f]Unclear if selective reporting bias was assessed.

References

(1) Haykowsky MJ, Timmons MP, Kruger C, McNeely M, Taylor DA, Clark AM. Meta-analysis of aerobic interval training on exercise capacity and systolic function in patients with heart failure and reduced ejection fractions. Am J Cardiol. 2013;111(10):1466-9.

(2) Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol. 2007;7(10):1-7.

(3) Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal fo Clinical Epidemiology. J Clin Epidemiol. 2011;64(4):380-2.

(4) Report from the Swedish Council on Technology Assessment in Health Care (SBU). Literature searching and evidence interpretation for assessing health care practices. Int J Technol Assess Health Care. 1994;10(4):714-5.

(5) Davies EJ, Moxham T, Rees K, Singh S, Coats AJ, Ebrahim S, et al. Exercise based rehabilitation for heart failure. Cochrane Database of Systematic Reviews. 2010;(4):CD003331.

Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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Qualité des services de santé Ontario

Physical Activity Counselling for Heart Failure Patients: A Rapid Review

Health Quality Ontario

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

RCT	Randomized controlled trial
SCAMOB	Screening and Counseling for Physical Activity and Mobility

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this analysis is to review the literature on the effectiveness of physical activity counselling in a heart failure or elderly population living in the community. The outcomes of interest are exercise adherence and physical function.

Clinical Need and Target Population

Physical activity or exercise has been demonstrated to be very beneficial to patients with heart failure and in an elderly population in general. The Canadian Society of Exercise Physiology guidelines on physical activity state that adults over 65 years should accumulate 150 minutes of moderate to vigorous physical activity per week, with individual events lasting at least 10 minutes. They also recommend 2 days per week of muscle and bone strengthening exercises. (1) Physical activity improves physical functioning, exercise capacity, mobility, and health-related quality of life (2) and, over the long term, it reduces hospital readmissions and mortality. (2) There is evidence to suggest that advice regarding physical activity provided by health care providers is inconsistent. (3)

Several strategies have been proposed to support physical activity in older adults, including those with heart failure. Among them are developing organized exercise training programs, offering a variety of exercise options (swimming, tai chi, aerobic classes, etc.), home-based exercise programs, telephone support programs, etc.

This review focuses specifically on the concept of physical activity counselling from a health care provider. There are studies indicating that physicians can increase the likelihood of their patients becoming more physically active by speaking with them about exercise and their readiness to exercise. (4)

Rapid Review

Research Question

What is the effectiveness of exercise counselling in a heart failure population or an elderly population living in the community on exercise adherence and physical function?

Research Methods

Literature Search

Search Strategy

A literature search was performed on January 24, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews, for studies published from January 1, 2008, to January 24, 2014. (Appendix 1 provides details of the search strategy.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search. In addition, members of the Community Congestive Heart Failure Expert Panel also provided relevant citations.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2008, and January 24, 2014
- randomized controlled trials (RCTs), systematic reviews, and meta-analyses
- intervention included counselling with a health care provider regarding physical activity compared to no counselling
- any type and location of physical activity was included
- population included patients with either heart failure, stroke, COPD, post-discharge from hospital, frail elderly, and patients with multiple chronic conditions

Exclusion Criteria

- studies of exercise counselling on healthy adults or children
- studies on non-exercise related counselling (diet, medication adherence, etc.)

Outcomes of Interest

- physical function (activities of daily living, instrumental activities of daily living)
- exercise adherence
- health-related quality of life

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the Expert Advisory Panel was to provide advice on primary CHF patient groupings, review the evidence, guidance, and publications related to defined CHF patient populations, identify and prioritize interventions and areas of community-based care, and to advise on the development of a care pathway model. The role of Panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The methodology for a rapid review of primary studies assesses the quality of the evidence through a risk of bias assessment of the individual studies in the review, including allocation concealment, blinding, accounting of patients and outcome events, selective reporting bias, and other limitations. (5) A full quality of evidence assessment is not typically performed due to the time limitations associated with rapid reviews of primary studies.

Results of Rapid Review

The database search yielded 144 citations published between January 1, 2008, and January 24, 2014, (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment. In addition, members of the expert panel also provided citations to be considered. Five studies (all RCTs) met the inclusion criteria.

For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman, 1996. (6)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	
Large RCT	5
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	
Studies presented at an international conference	
Expert opinion	
Total	**5**

There was a systematic review identified by Tierney et al (7) that asked, "What strategies are effective for exercise adherence in heart failure?" Although similar to the question posed by this rapid review, it includes strategies for adherence that do not involve counselling from health care providers. The RCT included studies of internet interventions and remote monitoring. It also includes the randomized controlled trial by Brodie et al (8), which was also identified for inclusion in this review.

The Screening and Counseling for Physical Activity and Mobility (SCAMOB) study (9;10) was the largest and most recent study with the longest follow-up period identified. It was a randomized controlled trial that included a 2-year intervention and then a 1.5 year follow-up. To be eligible for inclusion into the SCAMOB study patients had to be able to walk 500 metres independently, have a Mini-Mental State Examination (MMSE) score of >21, and be moderately physically active or sedentary (no more than 4 hours of walking/week). All patients in the intervention group received a 50-minute, individualized motivational physical activity counselling session with a physiotherapist at the beginning of the study. The aim of the sessions was to help the participants recognize the difference in their current level of physical activity compared to their desired level of activity, and help the participants to use problem-solving techniques to develop a plan to increase physical activity. The same physiotherapist followed up with the participants 4 to 5 times over a 2-year period. The control group did not receive the counselling sessions, but continued to receive usual care. Both groups had equal access to the same public exercise facilities.

The results of the SCAMOB study (9;10) found that the participants in the intervention group maintained their mobility significantly better than the participants in the control group at the end of the 2-year study and at the 1.5-year follow-up in the longer "advanced" mobility assessment (2 km walked). They did not find a significant difference between the intervention and control groups for the "basic" mobility assessment (0.5 km walked). Figure 1 shows the trend of the change in mobility over time. In addition to the primary outcome of mobility limitation, the SCAMOB study also reported that participants in the intervention group were significantly more likely to remain at least moderately active or more compared to the control group (83% vs. 72%, odds ratio, 2.0; 95% CI, 1.3-3.0).

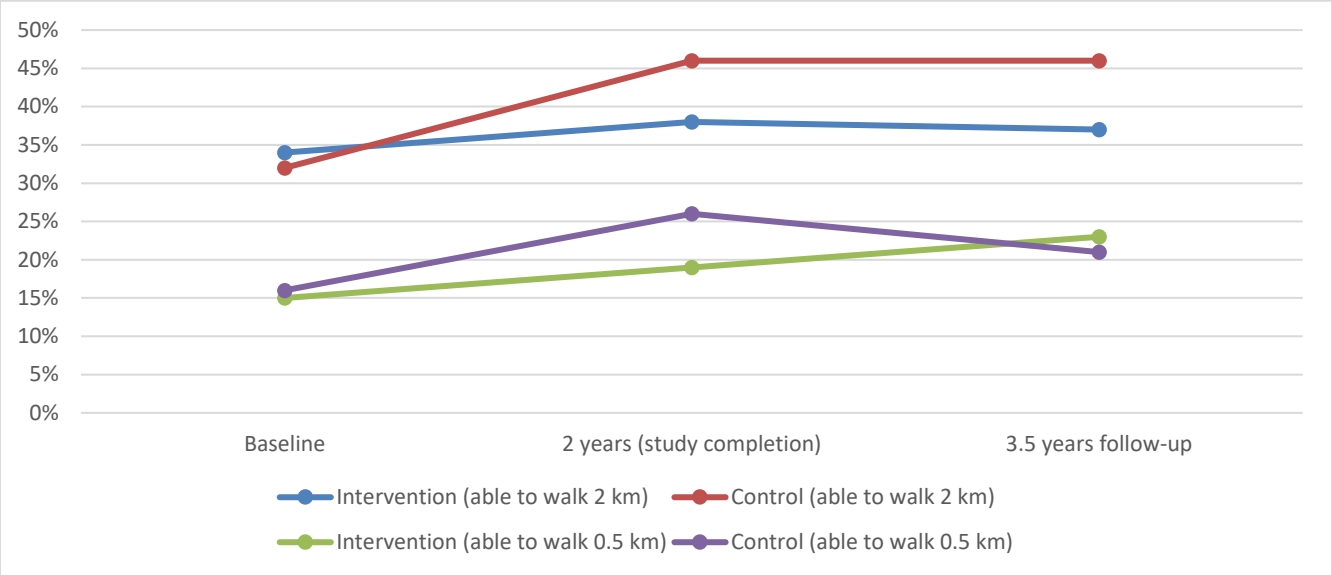

Figure 1. Percentage of participants in SCAMOB study (9;10) with mobility difficulties in the intervention and control groups

The other 4 RCTs identified are summarized with SCAMOB study in Table 2. Two of these studies focussed on a particular disease (stroke (11)], heart failure (8)), while the other 2 focussed on older populations. (12;13) The risk of bias assessment for the 5 RCTs that met the inclusion criteria varied. The studies with the least risk of bias were the SCAMOB study (9;10) and the study by Boysen et al. (11) The details of the risk of bias assessment are provided in Appendix 2.

Limitations of the Rapid Review

The type, frequency, delivery, and duration of counselling varied across the studies identified in the review. Three of the studies included the older adult population, while the other 2 studies included specific disease populations (heart failure and stroke). The largest and most recent study to date, the SCAMOB study, was not limited to the post-discharge population, but rather focussed on older adults with, on average, 3 chronic conditions. No studies were identified specifically on a COPD population that met the inclusion criteria.

Table 2. Summary of Studies

Study	Population	N	Intervention	Control	Outcomes	Results	Conclusion
Manty et al, 2009 (9); Rasinaho et al, 2012 (10) (SCAMOB)	Older adults with a mean of 3 chronic diseases (75-81 years, 77.6 SD ±1.9)	632 (75% women)	In-person counselling session, followed by 4-5 telephone sessions over 2 years	No counselling	Mobility limitation	Basic mobility (0.5 km) OR 87; 95% CI, 0.69-1.09 Advanced mobility (2 km) OR 0.84; 95% CI, 0.70-0.99	There was a significant difference between the intervention and control groups in terms of maintaining advanced mobility, but no difference was observed in basic mobility.
Boysen et al, 2009 (11)	Stroke patients	314	Instructions on an exercise program before discharge, then during 5 follow-up visits over 24 months	Same frequency of visits, but without instructions on exercise program	PASE	PASE: 69.1 intervention 64.0 control (mean difference 5.0; 95% CI -5.8 to 15.9)	There was no difference in the PASE assessment between the intervention and control groups.
Morey et al, 2009 (13)	Older men (≥70 years)	398	Multicomponent physical activity counselling, in person, telephone, and mailed reminders	No counselling	Gait speed, self-reported physical activity, function, disability	Rapid gait speed (P = 0.04) Minutes of moderate/vigorous physical activity per week (P < 0.001)	Rapid gait speed and moderate/vigorous physical activity improved in the intervention group compared to the control group. Changes in functional outcomes were not observed.
Brodie et al, 2008 (8)	Heart failure patients	60	Motivational interviewing	Standard care (advice to exercise from heart failure nurse)	Health-related quality of life, readiness-to-change assessment	SF-36 P < 0.05 on 3 dimensions Minnesota LHFQ P NS (all groups improved) Motivation Readiness scale trend for all groups to be more motivated	There were some slight improvements in quality of life in the intervention group compared to the control group, but overall both groups improved.
Dubbert et al, 2008 (12)	Older men (60-85 years)	224	Exercise counselling for home-based walking	Brochure on exercise	Duration of walking	At 5 months: Intervention: 64.5 min/week Control: 50.5 minutes/week At 10 months: Intervention: 60.6 min/week Control: 45.7 minutes/week P < 0.001	There was a significant difference in the duration of exercise per week in the intervention group compared to the control group at both 5 and 10 months.

Abbreviations: Minnesota LHFQ, Minnesota Living with Heart Failure; N, number; OR, odds ratio; PASE, Physical Activity Scale for the Elderly; SCAMOB, Screening and Counseling for Physical Activity and Mobility; SF-36, short form-36;

Conclusions

The largest and longest study on physical activity counselling identified by this review found that a 50-minute individualized physical activity counselling session with a physiotherapist, followed up with 4-5 telephone sessions over the next 2 years, resulted in increased maintenance of mobility in a population of older adults.

Acknowledgements

Editorial Staff
Timothy Maguire

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader

Name	Affiliation(s)	Appointment(s)
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategy

Search date: January 24, 2014
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below), CINAHL

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 2013>, EBM Reviews - ACP Journal Club <1991 to December 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <4th Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <December 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <4th Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <4th Quarter 2013>, Ovid MEDLINE(R) <1946 to January Week 2 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <January 15, 2014>.

Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19088
2	exp Aftercare/ or exp Convalescence/	10015
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	45893
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	36397
5	exp Stroke/	84308
6	exp brain ischemia/ or exp intracranial hemorrhages/	128360
7	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	190539
8	exp Heart Failure/	88591
9	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	128470
10	exp Pulmonary Disease, Chronic Obstructive/	36229
11	exp Emphysema/	10637
12	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	55678
13	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	34224
14	exp Pneumonia/	73947
15	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	136047
16	or/1-15	743343
17	exp Exercise/	125431
18	exp Exercise Therapy/	33932
19	exp Motor Activity/	200091
20	exp Physical Fitness/	22994
21	exp Exercise Tolerance/	9211
22	or/17-21	243077
23	exp Counseling/	34753
24	exp Health Promotion/	54755
25	or/23-24	87891
26	((exercis* or (physical adj2 (condition* or activit*)) or strength train* or aerobic* or fitness) adj5 (counsel* or advic* or advis* or referral* or promot*)).ti,ab.	8648
27	(22 and 25) or 26	14348
28	16 and 27	566
29	(Meta Analysis or Controlled Clinical Trial).pt.	214017
30	Meta-Analysis/ or exp Technology Assessment, Biomedical/	52815
31	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane or ((health technolog* or biomedical technolog*) adj2 assess*)).ti,ab.	190945
32	exp Randomized Controlled Trial/ or exp Random Allocation/ or exp Double-Blind Method/ or exp Control Groups/ or exp Placebos/	585768
33	(random* or RCT or placebo* or sham* or (control* adj2 clinical trial*)).ti,ab.	1196285
34	exp Standard of Care/ or exp Guideline/ or exp Guidelines as Topic/	134708
35	(guideline* or guidance or consensus statement* or standard or standards).ti.	112882
36	or/29-35	1787621
37	28 and 36	261

38	limit 37 to (english language and yr="2008 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	151
39	remove duplicates from 38	109

CINAHL

#	Query	Results
S1	(MH "Patient Discharge+") or (MH "After Care") or (MH "Recovery") or (MH "Continuity of Patient Care+")	44,877
S2	((patient* N2 discharge*) or aftercare or after care or post medical discharge* or postdischarge* or post discharge* or convalescen*)	29,136
S3	(MH "Stroke+") or (MH "Cerebral Ischemia+") or (MH "Intracranial Hemorrhage+") or (MH "Stroke Patients")	48,958
S4	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) N1 (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or ((brain or cerebral) N2 (ischemia or ischaemia)) or ((intracranial or brain) N2 (hemorrhag* or haemorrhag*)))	60,888
S5	(MH "Heart Failure+")	22,288
S6	((cardia* or heart) N1 (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) N1 (failure or insufficiency))	28,739
S7	(MH "Pulmonary Disease, Chronic Obstructive+") or (MH "Emphysema+")	11,369
S8	((chronic obstructive N2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) N1 (disease* or disorder*)) or (copd or coad or chronic airflow obstruction* or (chronic N2 bronchitis) or emphysema))	14,436
S9	(MH "Pneumonia+")	12,353
S10	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) N1 inflammation*))	19,254
S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10	172,967
S12	(MH "Exercise+")	62,277
S13	(MH "Physical Activity")	19,255
S14	(MH "Therapeutic Exercise+")	31,771
S15	(MH "Motor Activity+")	7,002
S16	(MH "Physical Fitness+")	9,762
S17	(MH "Exercise Tolerance+")	3,664
S18	S12 OR S13 OR S14 OR S15 OR S16 OR S17	103,053
S19	(MH "Counseling+")	21,512
S20	(MH "Health Promotion")	34,654
S21	S19 OR S20	55,357
S22	((exercis* or (physical N2 (condition* or activit*)) or strength train* or aerobic* or fitness) N5 (counsel* or advic* or advis* or referral* or promot*))	3,933
S23	(S18 AND S21) OR S22	8,672
S24	S11 AND S23	294
S25	(MH "Random Assignment") or (MH "Random Sample+") or (MH "Meta Analysis") or (MH "Systematic Review") or (MH "Double-Blind Studies") or (MH "Single-Blind Studies") or (MH "Triple-Blind Studies") or (MH "Placebos") or (MH "Control (Research)") or (MH "Practice Guidelines") or (MH "Randomized Controlled Trials")	187,376
S26	((health technology N2 assess*) or meta analy* or metaanaly* or pooled analysis or (systematic* N2 review*) or published studies or medline or embase or data synthesis or data extraction or cochrane or random* or sham*or rct* or (control* N2 clinical trial*) or guideline* or guidance or consensus statement* or standard or standards or placebo*)	471,342
S27	S25 OR S26	480,710
S28	S24 AND S27	121
S29	S24 AND S27 Limiters - Published Date: 20080101-20131231; English Language	69

Appendix 2: Evidence Quality Assessment

Table A1: Risk of Bias Among Randomized Controlled Trials for the Comparison of Physical Activity Counselling Versus No Counselling

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
SCAMOB, 2010 (9;10)	No limitations	No limitations	No limitations	No limitations	No limitations
Boysen et al, 2009 (11)	No limitations	No limitations	No limitations	No limitations	No limitations
Morey et al, 2009 (13)	Limitations[a]	Limitations[b]	No limitations	Limitations[c]	No limitations
Brodie et al, 2008 (8)	No limitations	Limitations[b]	No limitations	Limitations[c]	No limitations
Dubbert et al, 2008 (12)	Limitations[a]	No limitations	No limitations	Limitations[c]	No limitations

[a] Not reported whether allocation concealment was part of the methodology.
[b] Not reported whether participants or researchers were blinded.
[c] No intention to treat. Thirty-two patients were lost in the follow-up period (mostly through death), and these were not accounted for in the final results.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

Ontario
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Sodium Restriction in Heart Failure: A Rapid Review

Health Quality Ontario

February 2015

Evidence Development and Standards Branch at Health Quality Ontario

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Rapid reviews are completed in 2–4-week time frames. Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses. The methods prioritize systematic reviews, which, if found, are rated by AMSTAR to determine the methodological quality of the review. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to 2 outcomes. If no systematic review is found, then RCTs or observational studies are included, and their risk of bias is assessed. All rapid reviews are developed and finalized in consultation with experts.

About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series,* which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

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To conduct its rapid reviews, the Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Evidence Development and Standards branch at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current as of the date of the literature search specified in the Research Methods section. Health Quality Ontario makes no representation that the literature search captured every publication that was or could be applicable to the subject matter of the report. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

List of Abbreviations

NYHA	New York Heart Association
RCT	Randomized controlled trial

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Procedures (QBP) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Procedures initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this rapid review was to examine the effects of restricting sodium in patients with heart failure. The outcomes of interest were health resource utilization and mortality.

Clinical Need and Target Population

High consumption of sodium has been associated with an increased risk of many diseases, including hypertension, left ventricular hypertrophy, and cardiovascular disease. (1) Although many public health campaigns have attempted to persuade the general population to reduce the amount of sodium they consume, average daily consumption remains high. (2)

Technology/Technique

Several guidelines have recommended that sodium be restricted in patients with heart failure, (1,3,4) but the evidence on which these recommendations are based is limited. A randomized trial at the University of Alberta called SODIUM-HF is currently comparing a low-sodium diet to a normal-sodium diet in ambulatory patients with heart failure, (5) but results have yet to be published.

Rapid Review

Research Question

What are the effects of restricting sodium in patients with heart failure?

Research Methods

Literature Search

Search Strategy

A literature search was performed on April 1, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid Embase, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews, for studies published from January 1, 2003, to April 1, 2014. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2003, and April 1, 2014
- randomized controlled trials (RCTs), systematic reviews, meta-analyses, and prospective observational studies with historical or contemporaneous controls
- patients presumed to be returning to the community if hospitalized (i.e., not to palliative care or long-term care)
- ≥ 20 patients
- ≥ 30 days' follow-up
- reported at least 1 outcome of interest

Exclusion Criteria

- case series (studies with no comparison group)

Outcomes of Interest

- health resource utilization (emergency department visits, hospitalizations)
- mortality (all-cause or cardiac-related)

Expert Panel

In December 2013, an Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients was struck. Members of the community-based panels included family physicians, physician specialists, community health care administrators, and allied health professionals.

The role of the expert advisory panel was to provide advice on primary CHF patient groupings; to review the evidence, guidance, and publications related to defined CHF patient populations; to identify and prioritize interventions and areas of community-based care; and to advise on the development of a care pathway model. The role of panel members was to provide advice on the scope of the project, the methods used, and the findings. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of the expert panel members.

Quality of Evidence

The methodology for a rapid review of primary studies assesses the quality of the evidence using a risk of bias assessment of the individual studies, including allocation concealment, blinding, accounting of patients and outcome events, selective reporting bias, and other limitations. (6) A full quality of evidence assessment is not typically performed due to time limitations.

Results of Rapid Review

The database search yielded 954 citations published between January 1, 2003, and April 1, 2014, (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Eight studies (5 RCTs and 3 observational studies) met the inclusion criteria. The reference lists of the included studies were hand-searched to identify other relevant studies, but no additional citations were included.

For each included study, the study design was identified and is summarized below in Table 1, a modified version of a hierarchy of study design by Goodman, 1996. (7)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	
Large RCT	5
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	3
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	
Studies presented at an international conference	
Expert opinion	
Total	**8**

Abbreviation: RCT, randomized controlled trial.

DiNicolantonio et al published a systematic review in 2012 that compared low- to normal-sodium diets in patients with heart failure, (8) but it was retracted last year due to a possible duplication of data in 2 of the included studies (the duplication could not be verified because according to the authors, there was a computer failure and all data were lost). All 6 RCTs in the systematic review were by the same group of authors, but 2 of the 6 were excluded from this rapid review because they selected severely ill heart failure patients (refractory New York Heart Association [NYHA] IV heart failure) and may not be generalizable to a population with NYHA I–III heart failure. The remaining 4 RCTs were included in this rapid review, (9-12) as well as 1 other RCT by Aliti et al (13) and 3 observational studies. (14-16) The characteristics of the included studies are listed in Table 2.

Table 2: Study Characteristics—Sodium Restriction in Heart Failure

Author, Year	Recruitment Period (Location)	N	Age, y	NYHA Class	Ejection Fraction	Treatment	Control	Primary Outcomes (Secondary Outcomes)	Follow-up
Paterna et al, 2008[ab] (RCT) (12)	January 2000 to May 2005 (Palermo, Italy)	232	55–83	II at 30 days post-discharge	< 35%	Oral furosemide + 120 mmol Na/day	Oral furosemide + 80 mmol Na/day	Readmissions (mortality, BNP)	From 30 days post-discharge to 180 days
Parrinello et al, 2009[ab] (RCT) (9)	September 2005 to August 2007	173	72.5 (SD 7)	II at 30 days post-discharge	< 35%	Oral furosemide + 120 mmol Na/day	Oral furosemide + 80 mmol Na/day	Readmissions (mortality)	From 30 days post-discharge to 12 months
Paterna et al, 2009[a] (RCT) (11)	June 2005 to September 2007 (Palermo, Italy)	410 (8 groups)	53–86	II at 30 days post-discharge	< 35%	Oral furosemide + 120 mmol Na/day	Oral furosemide + 80 mmol Na/day	Readmissions (mortality, BNP, aldosterone, PRA)	Study period 30–180 days post-discharge
Arcand et al, 2011 (Obs) (14)	2003 to 2007 (Toronto, Canada)	123	60 (SD 13)	I–IV	< 35%	3-day food record; patients divided into 3 tertiles		Acute decompensated heart failure (all-cause hospitalization, death)	3 years
Lennie et al, 2011 (Obs) (15)	Unclear (Kentucky/ Georgia/ Indiana/Ohio, USA)	302	62 (SD 12)	I–IV (results stratified by I/II and III/IV)	< 40%, or preserved LVEF ≥ 40%	In-hospital 24-hour urinary Na ≥ 3 g (Group 1)	In-hospital 24-hour urinary Na < 3 g (Group 2)	Composite endpoint: first cardiac-related ED visit, cardiac-related hospitalization, cardiac-related death, all-cause death	12 months
Paterna et al, 2011[a] (RCT) (10)	September 2000 to August 2007 (Palermo and Naples, Italy)	1,771	74.7 (SD 11, range 57–84)	III	< 40%	IV furosemide + hypertonic saline solution 2 x/day + 120 mmol Na/day	IV furosemide + 80 mmol Na/day	Mortality and readmission for heart failure (cardiac-related death, change in NYHA)	Mean 57 months (SD 15 months, range 31–83 months)
Son et al, 2011 (Obs) (16)	Unclear (Seoul, South Korea)	232	65 (SD 10)	II–IV	< 40%	In-hospital 24-hour urinary Na ≥ 3 g (Group 1)	In-hospital 24-hour urinary Na < 3 g (Group 2)	Composite endpoint: first cardiac-related ED visit, cardiac-related hospitalization, cardiac-related death (symptom burden: breathlessness, swelling of legs, lethargy, etc.)	12 months
Aliti et al, 2013 (RCT) (12)	July 2009 to April 2012 (Brazil)	75	60 (SD 11)	III–IV	< 45%	800 mg Na/day + ≤ 800 mL fluid/day	3–5 g Na/day + ≥ 2.5 L fluid/day	Weight loss and clinical stability at 3 days (perceived thirst, readmissions within 30 days)	30 days

Abbreviations: BNP, brain natriuretic peptide; ED, emergency department; IV, intravenous; LVEF, left ventricular ejection fraction; Na, sodium; NYHA, New York Heart Association; Obs, observational study; PRA, plasma renin activity; RCT, randomized controlled trial; SD, standard deviation.

[a]Study included in the DiNicolantonio et al systematic review. (8)

[b]A notice of concern was issued by the *Journal of Cardiac Failure* because of the possibility of patient duplication in the Parrinello et al (9) and Paterna et al 2008 (12) studies.

The 4 RCTs from the DiNicolantonio et al systematic review (9-12) had several limitations related to the rigour of reporting:

- As mentioned previously, there was speculation about duplication of data between 2 RCTs, but this concern could not be verified due to a computer malfunction. (9,12)
- The results of the 4 RCTs were controversial; they indicated that patient outcomes were better in patients with a normal sodium intake than in those with a low sodium intake, and this finding was inconsistent with international guidelines (1-3) and observational studies in this area. (14-16) While challenging previous knowledge is acceptable and exciting, the challenge must be reinforced with high-quality study design and outcome reporting.
- The 4 RCTs reported very high compliance rates in both treatment groups (normal sodium intake and low sodium intake) based on reviews of patient diaries, but all 4 RCTs included a similar phrase: "patients showed a good compliance with assigned diet and fluid intake." Studies of sodium restriction usually report between 43% and 88% compliance in patients with heart failure. (17)
- With the exception of patients who died during the follow-up period, 3 of the 4 RCTs reported that no patients were lost to follow-up after randomization. (9,11,12) The study reported that 8% were lost to follow-up, (10) but that these patients were excluded from the final analysis (i.e., no intent-to-treat analysis was performed).

Due to this list of potential flaws in 4 of the 5 RCTs, they were not subjected to meta-analysis; separate outcomes are reported in Table 3.

Table 3: Results of RCTs Comparing Low Sodium to Normal Sodium in Patients With Heart Failure

Author, Year	N	Heart Failure Readmissions		Mortality	
		Low Sodium	Normal Sodium	Low Sodium	Normal Sodium
Paterna et al, 2008[ab] (12)	232	30/114	9/118	15/114	6/118
Parrinello et al, 2009[ab] (9)	173	44/86	12/87	20/86	4/87
Paterna et al, 2009[a] (11)	370 (8 treatment groups)	130/179	75/191	26/179	14/191
Paterna et al, 2011[a] (10)	1,771	305/890	163/881	212/890	114/881
Aliti et al, 2013 (13)	71	11/37	7/34	NR	NR

Abbreviations: NR, not reported; RCT, randomized controlled trial.
[a]Study included in the DiNicolantonio et al systematic review. (8)
[b]A notice of concern was issued by the *Journal of Cardiac Failure* because of the possibility of patient duplication in Parrinello et al (9) and Paterna et al 2008 (12) studies.

The observational study by Son et al (16) found that, after 12 months, patients whose in-hospital 24 hour urinary sodium excretion was < 3 g had fewer heart failure–related symptoms and better health outcomes than patients whose sodium excretion was > 3 g. Similarly, the observational study by Lennie et al (15) found that patients with NYHA class III and IV heart failure had better outcomes when sodium was restricted to < 3 g/day. The observational study by Arcand et al (14) found that heart failure patients with a diet high in sodium (based on a 3-day nutrition diary) had poorer outcomes than patients with a diet lower in sodium.

Conclusions

There is conflicting evidence about the effects of restricting sodium in patients with heart failure. More high-quality research is needed in this area.

Acknowledgements

Editorial Staff
Jeanne McKane, CPE, ELS(D)

Medical Information Services
Corinne Holubowich, BEd, MLIS

Health Quality Ontario's Expert Advisory Panel on Post-Acute, Community-Based Care for CHF Patients

Name	Affiliation(s)	Appointment(s)
Panel Co-Chairs		
Dr Douglas Lee	Toronto General Hospital Institute for Clinical Evaluative Sciences (ICES)	Cardiologist Senior Scientist
Dr Jennifer Everson	Hamilton Niagara Haldimand Brant LHIN	Primary care LHIN Lead
Cardiology		
Dr Robert McKelvie	McMaster University Hamilton Health Sciences Hamilton Health Sciences Heart Function Clinic	Professor of Medicine Cardiologist Medical Director
Dr Paul Oh	Toronto Rehab Cardiac Program, University Health Network	Medical Director
Dr Catherine Demers	McMaster University	Associate Professor
Dr Robert Maranda	Ottawa Cardiovascular Centre University of Ottawa	Physician Assistant Professor
Geriatric Medicine		
Dr George Heckman	University of Waterloo, University of McMaster	Associate Professor Assistant Clinical Professor
Primary Care		
Dr Agatha Szlanta	Providence Continuing Care Center, St. Mary's of the Lake Hospital	Attending Medical Staff
Dr Jess Goodman	Summerville Family Health Team	Staff Physician, Department of Family Practice
Nursing		
Karen Harkness	McMaster University, Heart Function Clinic	Registered Nurse Clinician
Heather Sherrard	University of Ottawa Heart Services	Vice President, Clinical Services
Jan Hoffman	London Health Sciences Centre	Advanced Practice Nurse Heart Failure Treatment
Jane MacIver	Toronto General Hospital	Nurse Practitioner-Heart Failure and Heart Transplant Program
Linda Belford	University Health Network	Nurse Practitioner, Practice Leader

Name	Affiliation(s)	Appointment(s)
Physiotherapy		
Diana Hopkins-Rosseel	Canadian Physiotherapy Association, Queens University	Cardiorespiratory Clinical Specialist
Clinical Pharmacy		
Heather Kertland	St. Michael's Hospital	Clinical Pharmacy Specialist, Heart and Vascular Program
Dietary Care		
Anne-Marie Leuchs	University of Ottawa Heart Institute	Registered Dietician, Cardiac Care
Administration		
Rosalind Tarrant	Hamilton/Niagara LHIN	Director, Access to Care
Sherry Grace	York University University Health Network	Associate Professor
Kory Kingsbury	Cardiac Care Network	Chief Executive Officer

Appendices

Appendix 1: Literature Search Strategies

Search date: April 1, 2014
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Databases (see below), CINAHL

Databases: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to February 2014>, EBM Reviews - ACP Journal Club <1991 to March 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <January 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <1st Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2014>, Ovid MEDLINE(R) <1946 to March Week 3 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <March 31, 2014>
Search Strategy:

#	Searches	Results
1	exp Patient Discharge/	19415
2	exp Aftercare/ or exp Convalescence/	10105
3	"Continuity of Patient Care"/ or exp "Recovery of Function"/	47006
4	((patient* adj2 discharge*) or after?care or post medical discharge* or post?discharge* or convalescen*).ti,ab.	37224
5	exp Stroke/	86862
6	exp brain ischemia/ or exp intracranial hemorrhages/	130437
7	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) adj (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or (brain adj2 isch?emia) or (cerebral adj2 isch?emia) or (intracranial adj2 h?emorrhag*) or (brain adj2 h?emorrhag*)).ti,ab.	198358
8	exp Heart Failure/	90261
9	(((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab.	131739
10	exp Pulmonary Disease, Chronic Obstructive/	37119
11	exp Emphysema/	10774
12	(copd or coad or chronic airflow obstruction* or (chronic adj2 bronchitis) or emphysema).ti,ab.	57116
13	(chronic obstructive adj2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) adj (disease* or disorder*)).ti,ab.	35373
14	exp Pneumonia/	74999
15	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) adj inflammation*)).ti,ab.	138936
16	or/1-15	762112
17	Diet, Sodium-Restricted/	5887
18	exp Sodium, Dietary/	8604
19	exp Sodium Chloride, Dietary/	4247
20	(low sodium or salt free or low salt or sodium chloride or table salt or ((salt or sodium or NaCL) adj2 diet*) or (sodium adj2 restrict*)).ti,ab.	29922
21	or/17-20	37123
22	16 and 21	1838
23	limit 22 to (english language and yr="2003 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained]	824
24	remove duplicates from 23	730

CINAHL

#	Query	Results
S1	(MH "Patient Discharge+") or (MH "After Care") or (MH "Recovery") or (MH "Continuity of Patient Care+")	45,983
S2	((patient* N2 discharge*) or aftercare or after care or post medical discharge* or postdischarge* or post discharge* or convalescen*)	29,736
S3	(MH "Stroke+") or (MH "Cerebral Ischemia+") or (MH "Intracranial Hemorrhage+") or (MH "Stroke Patients")	50,226
S4	(stroke or poststroke or tia or transient ischemic attack or ((cerebral vascular or cerebrovascular) N1 (accident* or infarct*)) or CVA or cerebrovascular apoplexy or brain infarct* or ((brain or cerebral) N2 (ischemia or ischaemia)) or ((intracranial or brain) N2 (hemorrhag* or haemorrhag*)))	62,512
S5	(MH "Heart Failure+")	22,829
S6	((cardia* or heart) N1 (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) N1 (failure or insufficiency))	29,505
S7	(MH "Pulmonary Disease, Chronic Obstructive+") or (MH "Emphysema+")	11,763
S8	((chronic obstructive N2 (lung* or pulmonary or airway* or airflow* or respiratory or bronchopulmonary) N1 (disease* or disorder*)) or (copd or coad or chronic airflow obstruction* or (chronic N2 bronchitis) or emphysema))	15,056

S9	(MH "Pneumonia+")	12,640
S10	(pneumoni* or peripneumoni* or pleuropneumoni* or lobitis or ((pulmon* or lung*) N1 inflammation*))	19,831
S11	S1 OR S2 or S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10	177,673
S12	(MH "Diet, Sodium-Restricted")	856
S13	(MH "Sodium, Dietary+")	2,303
S14	(MH "Sodium Chloride, Dietary")	1,824
S15	low sodium or salt free or low salt or sodium chloride or table salt or ((salt or sodium) N2 diet*) or (sodium N2 restrict*) or NaCL diet*	5,977
S16	S12 OR S13 OR S14 OR S15	5,977
S17	S11 AND S16	537
S18	S11 AND S16 Limiters - Published Date: 20030101-20141231; English Language	434

Appendix 2: Evidence Quality Assessment

Table A1: Risk of Bias Among Randomized Controlled Trials for the Comparison of Low Sodium Versus Normal Sodium in Patients With Heart Failure[a]

Author, Year	Allocation Concealment	Blinding	Complete Accounting of Patients and Outcome Events	Selective Reporting Bias	Other Limitations
Paterna et al, 2008 (12)	No limitations	Limitations[b]	Limitations[c]	Limitations[d]	Limitations[e]
Parrinello et al, 2009 (9)	No limitations	Limitations[b]	Limitations[c]	Limitations[d]	Limitations[e]
Paterna et al, 2009 (11)	No limitations	Limitations[b]	Limitations[c]	Limitations[d]	No limitations
Paterna et al, 2011 (10)	No limitations	Limitations[b]	Limitations[f]	Limitations[d]	No limitations
Aliti et al, 2013 (13)	No limitations	Limitations[b]	No limitations	No limitations	No limitations

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation.
[a]The GRADE assessment was not completed, because these studies were not combined in a meta-analysis due to flaws in the studies themselves.
[b]Single-blinding of physicians performing evaluations; patients were not blinded.
[c]No statement to indicate whether any patients were lost to follow-up.
[d]Indicated high compliance with sodium and fluid restrictions, but it is unclear how authors maintained this compliance when several studies indicate compliance is challenging for patients with heart failure. (17)
[e]Risk of study sample duplication.
[f]Patients lost to follow-up were excluded from the analysis.

Table A2: Risk of Bias Among Observational Trials for the Comparison of Low Sodium Versus Normal Sodium in Patients With Heart Failure

Author, Year	Appropriate Eligibility Criteria	Appropriate Measurement of Exposure	Appropriate Measurement of Outcome	Adequate Control for Confounding	Complete Follow-Up
Arcand et al, 2011 (14)	No limitations	No limitations	No limitations	Limitations[a]	No limitations
Lennie et al, 2011 (15)	No limitations	No limitations	Limitations[b]	Limitations[a]	No limitations
Son et al, 2011 (16)	No limitations	No limitations	No limitations	Limitations[a]	No limitations

Abbreviations: NYHA, New York Heart Association.
[a]Unclear what bias was associated with how sodium level was determined at baseline: was a 1-time measurement sufficient?
[b]The outcome was reported mostly by NYHA class rather than by sodium status.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca