Rapid EVIDENCE Reports

Ambulatory Care Services for Patients with Chronic Heart Failure

in Newfoundland and Labrador

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Contents

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About This Report

About NLCAHR

The Newfoundland and Labrador Centre for Applied Health Research, established in 1999, contributes to the effectiveness of health and community services in Newfoundland and Labrador and to the physical, social, and psychological wellbeing of its population. NLCAHR accomplishes this mandate by building capacity in applied health research, supporting high-quality research, and fostering the effective use of research evidence by decision makers and policy makers in the provincial healthcare system.

Rapid Evidence Reports

NLCAHR designed *Rapid Evidence Reports* to provide support for evidence-based decision making in the Newfoundland and Labrador healthcare system on an expedited basis as compared to the lengthier *'Evidence in Context'* reports issued through the Contextualized Health Research Synthesis Program. Through these expedited reports, NLCAHR provides a succinct review of recent research evidence on a high-priority research topic selected by decision makers in the province.

Rapid Evidence Reports include:

- a clear statement of the issue and the background to the issue/problem;
- a description of the scope and nature of the pertinent English-language scientific literature from the past five years;
- a summary of the principal features of the available evidence – points of consensus, points of disagreement, areas of uncertainty or silence on some or all of the following issues: effectiveness of interventions, potential benefits and harms, risks, costs, and cost-effectiveness; and
- a brief analysis of the types of issues that might affect the applicability of the evidence to the local context.

It is important to note that, unlike an *'Evidence in Context'* report, a *Rapid Evidence Report* is **not** a comprehensive and systematic synthesis of the literature on the topic. The rapid report provides neither critical appraisal of included articles nor a full analysis of the contextual issues involved in applying evidence to the Newfoundland and Labrador healthcare setting. Rather, a *Rapid Evidence Report* provides decision makers with a summary of the scope and nature of the recent scientific literature on the topic in question, an initial assessment of the strengths and gaps in this literature, and a review of the key points of agreement and disagreement among researchers.

Researchers and Consultants

For this report, researchers from the Newfoundland and Labrador Centre for Applied Health Research included: Robert Kean, Research Officer, Contextualized Health Research Synthesis Program (CHRSP), Dr. Stephen Bornstein, Director of NLCAHR, and Stephanie O'Brien, Research Assistant. Our team benefitted from the advice and expertise of Dr. Robert Reid, Deputy Chief of the Division of Prevention and Rehabilitation at the University of Ottawa Heart Institute and Full Professor in the Faculty of Medicine at the University of Ottawa. Dr. Reid's credentials are included in the Appendix to this report on page 17.

Background

Heart failure is a condition in which the heart is unable to pump out enough blood to meet the metabolic needs of the body. It can be caused by structural defects, functional abnormalities, or a sudden overload beyond its capacity. Chronic heart failure (CHF) is more common than acute heart failure, which results from sudden insult to cardiac function. CHF is diagnosed in 1–2% of the general population in industrialized countries, and spending on the disease represents 1–2% of their total health-care expenditures. Mortality and hospitalization rates associated with CHF are among the highest of any medical condition (1).

On the suggestion of the Central Regional Health Authority,[1] our stakeholder partners have asked us to identify any and all ambulatory care programs and interventions that have been shown to reduce hospital admissions and mortality among patients with CHF. In requesting this review, our partners have noted that:

> There is a significant demand for acute care beds… At times, surgeries have to be cancelled and patients are on stretchers in the ER for significant periods of time. Patients with chronic conditions are sometimes admitted to hospital as the required outpatient programs/services have not been developed to provide the required level of care for these patients.

This review defines "ambulatory care" as any sort of service or program provided outside an acute hospital inpatient unit. This includes professional services delivered in outpatient clinics, in patients' homes, or via some form of telehealth technology. At the stakeholders' request, we have not included research articles that focus exclusively on models of patient self-management; however, some of the articles reviewed here evaluate packages of interventions that include a self-management component. We have also excluded from the analysis articles that focus exclusively on either prescription medications or surgical

[1] Between April 2012 and March 2013, the Central Health Region reported 432 cases of heart failure.

interventions. Our review is further limited to research articles that measure the effect of programs on *both* hospitalization *and* mortality rates.

Our research question is as follows:

"What ambulatory care services and/or programs have proved effective in reducing hospitalization and mortality among patients with chronic heart failure?"

Scope and Nature of the Scientific Literature

For this review, we sought systematic reviews and primary studies published in English since October 2008.[2] We excluded from consideration any primary study that had already been included in one of the systematic reviews we identified. We also excluded unpublished or grey literature. In total, our review includes twelve systematic reviews and 29 primary studies. Of the 29 primary studies:

- 20 were randomized controlled trials (RCTs),
- 3 used non-randomized comparative designs, and
- 6 studied a single group or cohort with no control or comparison group.

We have categorized this literature under three main headings: clinic-based CHF management, home-based CHF management, and telemedicine. We define and describe each of these below, but we would note here that there is some overlap between these categories. For instance, a number of the interventions discussed in the section on telemedicine involve both remote monitoring and forms of telephone support that may arguably qualify as home-based interventions according to our definition.

One final note about the articles under review concerns their geographical setting. The available research literature comprises studies conducted in many parts of the world, including Canada, the United States, South America, Western Europe, Australia/New Zealand, Israel, and Japan. This mix of countries and regions represents a diverse array of healthcare systems many of which are very different in various ways from this province and,

[2] We assume that evidence from earlier studies will have been captured by the systematic review literature included in this report.

for that reason, the findings generated by these papers may not always be directly generalizable to the local context.

Clinic-Based CHF Management

We define clinic-based CHF management as any package of services delivered by healthcare professionals in an outpatient clinic that specializes in CHF care. There is no consensus in the literature we retrieved concerning the benefits of clinic-based services. We identified three RCTs (2-4) on clinic-based services and two systematic reviews of RCTs, including one Cochrane review (5). The intervention groups in these articles were compared with patients receiving general practitioner (GP)-led CHF management, cardiologist-led CHF management, or some combination of both. Only one of these five articles – a systematic review of studies of supervised exercise therapy (6) – found that clinic-based care had a significantly greater effect on hospitalizations than did the care received by control groups (Risk ratio = 0.90, 95% CI 0.831—0.973),[3] and none found an effect on mortality. This finding of no effect was consistent at study follow-up periods ranging from six months to several years and in patient populations with varying levels of CHF severity.[4] Furthermore, the no-effect finding was consistent no matter what form of 'usual care' was chosen as a control – GP-led management, cardiologist-led management, or some combination of the two. According to the 2012 Cochrane review by Takeda et al., "There is little currently available evidence to support interventions whose major component is follow-up in a heart failure clinic" (5, p. 17).

Schou et al. speculate that the neutral effect observed in their study might be attributable to the high quality of the "usual" care received by their control group (3). As it happens, all three of the aforementioned RCTs – including the one by Schou et al. – were conducted in Denmark, which boasts a publicly-funded primary care system that provides >90% of all Danes with access to a personal family physician. Furthermore, elderly Danes are eligible to receive home visits by a geriatric nurse as part of their routine care, and all Danes can avail themselves of a national prescription drug plan in which annual medication-related expenses incurred by outpatients are capped at 500 Euros (3). Takeda et al. do not discuss the quality of care received by control groups in the RCTs included in their meta-analysis,

[3] It should be noted that in each case there is a range of values – called a confidence interval (CI) – within which the true value of the estimated reduction in hospitalization is expected to lie. So, while the point estimate given for the reduction in hospitalizations is 10%, it is also noted that 95 times out of 100 this number will actually fall anywhere between 3 and 17%

[4] Articles included in this review assessed CHF severity using the New York Heart Association (NYHA) performance scale. The NYHA scale classifies heart failure as mild (stage I–II), moderate (stage III) or severe (stage IV) based on symptomatic markers (9).

but it may be worth noting that these studies were conducted in Sweden, the Netherlands, New Zealand, and the U.K.

However, this finding of no effect for clinic-based care was not unanimous in all the studies in our review. We identified a number of studies on this subject that used either a non-randomized comparative design or a single-group before-and-after design, and these tended to support the effectiveness of specialized CHF clinics. Jain et al. retrospectively evaluated the effectiveness of a hospital-based multidisciplinary clinic in Baltimore and found that patients treated at the clinic had lower readmission rates than those treated by a general practitioner or cardiologist (7). There was no difference in mortality between the two groups. Likewise, Feldman et al. studied a single cohort of CHF outpatients in Québec and observed a significant decrease in hospitalizations among those treated at participating CHF clinics (8).

Telemedicine

We discovered an extensive literature on telemedical interventions for the management of CHF, comprising nine systematic reviews and ten primary studies published in the past five years . The most recent of these articles is a 2013 health technology assessment prepared by Pandor et al. under the auspices of the National Institute for Health Research (NIHR) in the U.K. Because this was the most comprehensive and up-to-date source we could find on telemedical interventions – and because the NIHR is widely recognized for the quality of the health research information it produces – we rely heavily on it in the analysis that follows.

We also make use of these authors' definitions of telemedical interventions. Pandor et al. group the various telemedical approaches to CHF management into two main categories:

- telemonitoring, in which physiological data are electronically transmitted to a health care team; and
- structured telephone support (STS), in which telephone calls are used to deliver self-care support and/or management.

Pandor et al. break STS down further into human-to-human and machine-to-human forms of telephone support. In the human-to-human variants of STS, calls are typically made by specialist nurses and include advice on self-care and medication. In the machine-to-human variants, patients respond to automated questions about their symptoms by responding on their telephone keypads. Telemonitoring interventions generally require patients to take measurements of vital parameters such as weight, blood pressure, and heart rate; these data are then transmitted to health care providers by telephone or broadband technology. In some systems, readings outside of prespecified limits generate automated warnings. Just

as with STS interventions, Pandor et al. divide telemonitoring interventions into two main categories:

- those in which medical staff review transmitted data and, if necessary, provide support only during office hours; and
- those which require the constant – i.e., 24 hours a day, 7 days a week – presence of medical personnel (9).

After performing a sensitivity analysis that excluded a study whose control group was treated differently than the control groups from the others, Pandor et al. found that, for CHF patients recently discharged from hospital, both telemonitoring with medical support during office hours and human-to-human STS were associated with significant reductions in all-cause mortality as compared to controls (Hazard ratio = 0.62, 95% CI 0.42—0.89 and 0.75, 95% CI 0.59 to 0.96, respectively).[5] Furthermore, telemonitoring with support during office hours was associated with a signficant reduction in all-cause hospitalization (Hazard ratio = 0.67, 95% CI 0.42—0.97), and human-to-human STS was associated with a significant reduction in CHF-related hospitalizations (Hazard ratio = 0.77, 95% CI 0.62—0.96) (9), p. xiv).[6] By contrast, these researchers did not observe any beneficial effects associated with machine-to-human forms of STS. These findings are broadly consistent with the other systematic reviews we found, including Cochrane reviews by Takeda et al. and Inglis et al. and a health technology assessment published by the Canadian Agency for Drugs and Technology in Health (1,5,10).

We also identified five RCTs that were published after Pandor et al. concluded their literature search; two of these (11,12) corroborated the findings of the reviews and three did not. However, two of these studies lacked the statistical power to detect differences in mortality/hospitalizations (13,14), and the third was focused exclusively on electronic weight monitoring (15).

Home-Based CHF Management

We define home-based CHF management as any package of interventions delivered by health care professionals in patients' homes. While differences exist among the various models of home-based management, three elements are common to most. First, home visits are conducted by one or more health professionals, most often a nurse with

[5] Because they found only one study on 24-7 telemonitoring, and because they judged this study to be of poor quality, Pandor et al. declined to draw any definitive conclusions about this intervention.

[6] Pandor et al. also conducted a meta-analysis of studies involving patients with stable heart failure, but the results were inconclusive (9), pp. 31-4).

specialized training in CHF or a physician. Second, home visits typically include some form of assessment, education and counselling, and monitoring of vital signs. Third, results from home visits are often reported to a specialist physician or cardiologist for possible follow-up and subsequent adjustment of the patient's care plan. The frequency of home visits can vary from daily to once a month and is often dependent on the nature and severity of the patient's condition. Oftentimes, home visits are supplemented by STS.

We identified ten primary studies on home-based CHF services: nine RCTs and one time-series comparison study. Three of the RCTs compared very specific home-based interventions – echocardiography (16), pharmacist-directed medication reviews (17), and monitoring of N-terminal pro-brain natriuretic peptide (NT-proBNP) levels (18) – with 'usual' home-based care. Only NT-proBNP-guided care was associated with a significant reduction in mortality and re-hospitalization rates (18). Almost all of the patients selected for this study had NYHA grade III or IV heart failure. Three RCTs compared more general home-based CHF management programs with routine outpatient management by a family physician or cardiologist. Two of these found that home-based interventions for patients with mild CHF (NYHA grade I – II) effectively reduced CHF-related hospitalizations without increasing the risk of mortality (Hazard ratio = 0.52, 95% CI 0.27—0.96 and 0.70, 95% CI 0.55—0.99) (19,20). The third study was unable to draw strong conclusions on the effectiveness of home-based interventions because of the small number of patients recruited to the study (21).

Three other RCTs compared home-based management programs with either hospital inpatient care or specialized, outpatient, clinic-based care. None of these studies observed significant differences between intervention and control groups in terms of the rate of hospitalization or mortality, indicating that home-based interventions are at least as safe and effective as the institutionally-based alternatives. Both Mendoza et al. and Tibaldi et al. compared "Hospital at home" (HaH) interventions for elderly CHF patients with inpatient hospital care; the former concluded that HaH "avoids traditional hospital admission for patients with decompensated chronic HF with no significant differences in clinical and functional outcomes at 1 year of follow-up" (22, p. 1212), while the latter observed a longer time to first admission in the intervention group (23).[7] Moreover, Stewart et al. found that home-based interventions for patients with NYHA II and III grade symptoms were "associated with a significant reduction in the duration of recurrent hospitalization and more prolonged survival free from hospitalization" (24, p. 1247).

The studies that found evidence in support of home-based CHF management identified a couple of factors that may help to account for the success of these interventions. Visits to

[7] It should be noted that the patients in the study by Tibaldi et al. had considerably more severe CHF symptoms than the patients in the study by Mendoza et al. The study population in the former study were 65% NYHA grade III and 35% grade IV; by contrast, the study population in the former were 59% grade II and 41% grade III.

patients and their significant others in their home environments may facilitate more comprehensive assessments of patients' overall clinical and psychosocial status and, therefore, more individually-tailored care. This more intensive, tailored support may in turn enhance patient engagement and compliance with recommended treatments.

In summary, the articles we reviewed appear to suggest that ambulatory CHF care services delivered closer to home – whether in form of actual visits to patients' homes or of telemedical intervention – appear to be effective in reducing hospitalizations without increasing the risk of mortality. By contrast, there is no consensus in the literature we reviewed concerning the benefits of care delivered in specialized outpatient clinics. We would further remind the reader that our report focuses solely on the effects of CHF interventions on hospital admissions and morality rates; these interventions may well have important effects on other patient-related outcomes (e.g., functional capacity, activities of daily living, and quality of life).

Potentially Relevant Contextual Issues

Throughout the course of this project, we have tried to identify contextual factors unique to Newfoundland and Labrador – and the Central Regional Health Authority in particular – that may influence the relevance and applicability of the research-based evidence. This section of the report addresses those factors in brief.

Geography and Service Landscape

Perhaps the most salient contextual issue confronting Newfoundland and Labrador is the dispersal of its healthcare facilities over a vast terrain. The Central Health Region, for instance, extends from Charlottetown in the east to the Baie Verte Peninsula in the west, and from Fogo Island in the north to Harbour Breton in the south. Urban areas such as Gander, Grand Falls-Windsor, and Lewisporte are readily accessible, but a number of the more remote communities within the Central Region are an hour's drive away from the nearest of the health authority's approximately 30 continuing care nurses. Poor weather – not infrequent in Central Newfoundland – can lengthen these driving times even further. Moreover, a handful of communities can be reached only by ferry. The geography of the Central Health Region would likely pose significant challenges to implementation of a home visitation program for CHF patients and the same is true for much of the rest of the province as well. However, it may be worth noting that Central Health's continuing care nurses already make home visits on a case-by-case basis to a select number of high-risk patients. Should the health authority wish to experiment with home visits for CHF patients, it would have some in-house experience to draw upon.

Financial, Administrative, and Human Resources

The telemedical and home-based interventions in the studies under review were delivered by nurses or other healthcare professionals with specialized training in CHF. To our knowledge, at present, continuing-care nurses in the Central Region have not acquired this specialized training. Before proceeding with any new programming, a health authority would be well-advised to take stock of the training needs of existing personnel to make sure they have the skills to deliver these interventions effectively.

Organizational Strengths

Newfoundland and Labrador has developed a comprehensive telehealth infrastructure that includes communication channels, technical support services, and an established network of remote telehealth sites. In 2006, the province launched HealthLine, a toll-free telephone service that provides callers with health advice and information. Callers to HealthLine speak to a registered nurse who follows computerized standardized guidelines in order to recommend the most appropriate action. Therefore, there is already some existing capacity on which Central Health can draw should it wish to deliver targeted STS services for CHF patients in the region. There may also be some potential for using the province's telehealth infrastructure to provide innovating training opportunities for health care providers interested in upgrading their skills.

Summary of Key Points

- There is a lack of consensus in the literature concerning the benefits of services delivered in specialized clinics.
- Both (a) telemonitoring with medical support during office hours and (b) human-to-human STS appear to be effective in reducing hospitalizations without increasing the risk of mortality.
- Home-based CHF management interventions (23) appear to be at least as safe and effective as similar services delivered in hospitals or specialist clinics, and may have important advantages over routine outpatient management by a cardiologist and/or general practitioner.
- The province's geography – and the geography of the Central Health Region in particular – would likely pose significant challenges to implementation of an extensive home visitation program for CHF patients.

- Health authorities would be well advised to take stock of the training needs of existing personnel to make sure they have the capacity to deliver evidence-based CHF management interventions effectively.

- There is already existing capacity for health authorities to draw upon should they wish to deliver targeted STS services for CHF patients living in the community.

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Appendix

About our consultant:

Dr. Robert Reid
Deputy Chief, Division of Prevention and Rehabilitation
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Dr. Reid is one of Canada's leading health behavior change experts, particularly concerning smoking cessation, physical activity promotion, dietary change and cardiovascular rehabilitation. His research is funded by the Heart and Stroke Foundation of Ontario, the National Cancer Institute of Canada, the Canadian Tobacco Control Research Initiative, the Ontario Ministry of Health Promotion, the Change Foundation, and Health Canada. He is a past recipient of the Heart and Stroke Foundation of Canada's New Investigator Award. In 2006, he was awarded the James Hogg Award from the Canadian Institutes of Health Research Institute for Circulatory and Respiratory Health for his contributions to clinical and population health research.

In 2011, he was named the University of Ottawa Heart Institute's Researcher of the Year. He is President of the Canadian Association of Cardiac Rehabilitation.