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Specialized Multidisciplinary Community-Based Care

This document is a compilation of 3 reports related to Specialized Multidisciplinary Community-Based Care which will be published individually in October 2009. Each report retains its original pagination, table of contents, and reference list. The compilation contains the following titles:

1. Specialized Multidisciplinary Community-Based Care Series: Summary of Evidence-Based Analyses
2. Community-Based Care for the Specialized Management of Heart Failure
3. Community-Based Care for Chronic Wound Management

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Specialized Multidisciplinary Community-Based Care Series

A Summary of Evidence-Based Analyses

November 2009

Ontario

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About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series*.

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practising medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

If you are aware of any current additional evidence to inform an existing evidence-based analysis, please contact the Medical Advisory Secretariat: MASinfo.moh@ontario.ca. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html.

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List of Abbreviations

AUC	Area under the curve
CDA	Canadian Diabetes Association
CI	Confidence interval(s)
CINAHL	Cumulative Index to Nursing & Allied Health Literature
EMBASE	Excerpta Medica Database
HbA1c	Glycosylated hemoglobin
HF	Heart Failure
INAHTA	International Agency for Health Technology Assessment
MAS	Medical Advisory Secretariat
ODEM	Ontario Diabetes Economic Model
OR	Odds ratio
OHTAC	Ontario Health Technology Advisory Committee
PATH	Programs for Assessment of Technology and Health
QALY	Quality-Adjusted Life Year
RCT	Randomized controlled trial
RR	Relative risk
SBP	Systolic blood pressure
SD	Standard deviation
SROC	Summary receiver operating characteristic

Background

In August 2008, the Medical Advisory Secretariat (MAS) presented a vignette to the Ontario Health Technology Advisory Committee (OHTAC) on a proposed targeted health care delivery model for chronic care. The proposed model was defined as multidisciplinary, ambulatory, community-based care that bridged the gap between primary and tertiary care, and was intended for individuals with a chronic disease who were at risk of a hospital admission or emergency department visit. The goals of this care model were thought to include: the prevention of emergency department visits, a reduction in hospital admissions and re-admissions, facilitation of earlier hospital discharge, a reduction or delay in long-term care admissions, and an improvement in mortality and other disease-specific patient outcomes.

OHTAC approved the development of an evidence-based assessment to determine the effectiveness of specialized community based care for the management of heart failure, Type 2 diabetes and chronic wounds.

Please visit the Medical Advisory Secretariat Web site at: www.health.gov.on.ca/ohtas to review the following reports associated with the Specialized Multidisciplinary Community-Based care series.

1. *Specialized multidisciplinary community-based care series: a summary of evidence-based analyses*
2. *Community-based care for the specialized management of heart failure: an evidence-based analysis*
3. *Community-based care for chronic wound management: an evidence-based analysis*

Please note that the evidence-based analysis of specialized community-based care for the management of diabetes titled: "Community-based care for the management of type 2 diabetes: an evidence-based analysis" has been published as part of the Diabetes Strategy Evidence Platform at this URL: http://www.health.gov.on.ca/english/providers/program/mas/tech/ohtas/tech_diabetes_20091020.html

Please visit the Toronto Health Economics and Technology Assessment Collaborative Web site at: http://theta.utoronto.ca/papers/MAS_CHF_Clinics_Report.pdf to review the following economic project associated with this series:

Community-based Care for the specialized management of heart failure: a cost-effectiveness and budget impact analysis.

Objective

The objective of this report is to determine the effectiveness and cost-effectiveness of intermediate care (also called community-based multidisciplinary care) for heart failure, diabetes type 2, and chronic wound management.

Clinical Need: Target Population and Condition

Intermediate care is a community-based specialized multidisciplinary care model that manages chronic illness through formalized links between primary and specialized care. In so doing, it provides a resource to primary care for the treatment of persons with higher acuity of disease, as well as a community-based 'after hospital discharge' resource to manage patients with chronic illness.

Project Scope

Chronic disease conditions considered for analysis were determined after examining the following criteria: burden of illness, impact on health systems, previous and on-going MAS evidence based analyses, existence of a disease-specific Ontario economic model, and alignment with provincial policy directions. From this, three chronic diseases, heart failure, diabetes type 2, and chronic wounds, were put forth to form the focus of the analysis. The following report is a summary of the evidence-based analyses of the three disease conditions noted above. Where possible, economic analyses were performed using an Ontario-specific economic model.

Assessment of Quality of Evidence

In all analyses, the quality of the evidence was assessed as high, moderate, low or very low according to the GRADE methodology and GRADE Working Group (see Appendix 1).

As per GRADE the following definitions apply:

- High: Further research is very unlikely to change confidence in the estimate of effect
- Moderate: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
- Low: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate
- Very low: Any estimate of effect is very uncertain

Community-Based Care for the Management of Type 2 Diabetes

Objective

The objective of this evidence-based review is to determine the effectiveness of specialized multidisciplinary community care for the management of type 2 diabetes compared to usual care.

Clinical Need: Target Population and Condition

Diabetes (i.e. diabetes mellitus) is a highly prevalent chronic metabolic disorder that interferes with the body's ability to produce or effectively use insulin. The majority (90%) of diabetes patients have type 2 diabetes. Based on the United Kingdom Prospective Diabetes Study (UKPDS), intensive blood glucose and blood pressure control significantly reduce the risk of microvascular and macrovascular complications in type 2 diabetics. While many studies have documented that patients often do not meet the glycemic control targets specified by national and international guidelines, others factors associated with glycemic control are less well studied, one of which is the provider(s) of care.

Multidisciplinary approaches to care may be particularly important for diabetes management. According to the Canadian Diabetes Association (CDA) Guidelines, the diabetes health care team should be multi- and interdisciplinary. Presently in Ontario, the core diabetes health care team consists of at least a family physician and/or diabetes specialist and diabetes educators (a registered nurse or registered dietitian). Increasing the role played by allied health care professionals in diabetes care and their collaboration with physicians may present a more cost-effective option for diabetes management.

Several systematic reviews and meta-analyses have examined multidisciplinary care programs, but these have either been limited to a specific component of multidisciplinary care (e.g. intensified education programs), or were conducted as part of a broader disease management program, of which not all were multidisciplinary in nature. Most reviews also do not clearly define the intervention(s) of interest, making the evaluation of such multidisciplinary community programs challenging.

Evidence-Based Analysis of Effectiveness

Research Questions

1. What is the evidence of efficacy of specialized multidisciplinary community care provided by at least a registered nurse, registered dietitian, and physician (primary care and/or specialist) for the management of type 2 diabetes compared to usual care? [Herein referred to as Model 1]
2. What is the evidence of efficacy of specialized multidisciplinary community care provided by at least a pharmacist and a primary care physician for the management of type 2 diabetes compared to usual care? [Herein referred to as Model 2]

Inclusion Criteria

- English language full-reports
- Published between January 1, 2000 and September 28, 2008
- RCTs, systematic reviews, and meta-analyses
- Type 2 diabetic adult population (≥18 years of age)
- Total sample size ≥30

- Describe specialized multidisciplinary community care defined as ambulatory-based care provided by at least two health care disciplines (of which at least one must be a specialist in diabetes) with integrated communication between the care providers.
- Compared to usual care defined as health care provision by non-specialist(s) in diabetes, such as primary care providers; may include usual referral to other health care professionals or services as necessary
- ≥6 months follow-up

Exclusion Criteria

- Studies where discrete results on diabetes cannot be abstracted
- Predominantly home-based interventions
- Inpatient-based interventions

Outcomes of Interest

The primary outcomes for this review were glycated hemoglobin (HbA1c) levels and systolic blood pressure (SBP).

Search Strategy

A literature search was performed on September 28, 2008 using OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, CINAHL, the Cochrane Library, and the INAHTA database for studies published from January 1, 2000 to September 28, 2008. 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. Articles with unknown eligibility were reviewed with a second clinical epidemiologist, then a group of epidemiologists, until consensus was established. The quality of evidence was assessed as being high, moderate, low or very low according to GRADE methodology.

Given the high clinical heterogeneity of the articles that met the inclusion criteria, specific models of specialized multidisciplinary community care were examined based on models of care that are currently supported in Ontario, models of care that were commonly reported in the literature, as well as suggestions from an Expert Advisory Panel Meeting held on January 21, 2009. The inclusion criteria were revised to examine specific models of care, as described in the research questions.

Summary of Findings

The initial search yielded 2,116 unique citations. From these, a total of 22 randomized controlled trials and nine systematic reviews published between January 2000 and October 2008 were identified as meeting the eligibility criteria, assessing specialized multidisciplinary care defined by the inclusion of at least two health care professional disciplines. Of these, five studies focused on care provided by at least a nurse, dietitian, and physician (primary care and/or specialist) model of care (Model 1), while three studies focused on care provided by at least a pharmacist and primary care physician (Model 2).

A summary of the results of the meta-analyses examining the effects of both models of specialized multidisciplinary community care is presented in Tables 1 and 2. Based on moderate quality evidence, specialized multidisciplinary community care Model 1 has demonstrated a statistically and clinically significant reduction in HbA1c of 1.0% compared with usual care. Compared with usual care, the effects of this model on SBP, however, are uncertain based on very-low quality evidence. Model 2 demonstrated a statistically and clinically significant reduction in both HbA1c (-1.05%, based on high quality evidence)

and SBP (-7.13 mmHg, based on moderate quality evidence) compared to usual care. For both models, the evidence does not suggest a preferred setting of care delivery (i.e. primary care vs. hospital outpatient clinic vs. community clinic).

Table 1: Summary of Results of Meta-Analyses of the Effects of Multidisciplinary Care Model 1

Outcome	Estimate of effect* (95% CI)	Heterogeneity I^2	GRADE
Glycosylated Hemoglobin (% HbA1c %)	-1.00 (-1.27, -0.73)	4%	Moderate-quality
Subgroup: Moderate-to-High Quality	-0.91 (-1.19, -0.62)	0%	
Systolic Blood Pressure (mmHg)	-2.04 (-13.80, 9.72)	89%	Very-low quality

* Mean change from baseline to follow-up between intervention and control groups

Table 2: Summary of Results of Meta-Analyses of the Effects of Multidisciplinary Care Model 2

Outcome	Estimate of effect* (95% CI)	Heterogeneity I^2	GRADE
Glycosylated Hemoglobin (% HbA1c %)	-1.05 (-1.57, -0.52)	0%	High-quality
Systolic Blood Pressure (mmHg)	-7.13 (-11.78, -2.48)	46%	Moderate quality

*Mean change from baseline to follow-up between intervention and control groups

Conclusions

1. Model 1: Specialized multidisciplinary community care provided by at least a registered nurse, registered dietitian and physician (primary care and/or specialist) for the management of type 2 diabetes:
   - Demonstrated a statistically and clinically significant reduction in HbA1c compared to usual care based on moderate quality evidence.
   - Demonstrated an uncertain estimate of effect on SBP compared to usual care based on very-low quality evidence.
2. Model 2: Specialized multidisciplinary community care provided by at least a pharmacist and primary care for the management of type 2 diabetes:
   - Demonstrated a statistically and clinically significant reduction in HbA1c compared to usual care based on high quality evidence.
   - Demonstrated a statistically and clinically significant reduction in SBP compared to usual care based on moderate quality evidence.
3. For both models, the evidence does not suggest a preferred setting of care delivery (i.e. primary care vs. hospital outpatient clinic vs. community clinic).
4. Based on examination of an Ontario-specific multidisciplinary care program, specialized multidisciplinary community care for the management of type 2 diabetes is a cost-effective strategy.

Economic Analysis

DISCLAIMER: The Medical Advisory Secretariat uses a standardized costing method for its economic analyses of interventions. The main cost categories and the associated methods from the province's perspective are as follows:

Hospital: Ontario Case Costing Initiative cost data are used for in-hospital stay, emergency visit and day procedure costs for the designated International Classification of Diseases (ICD) diagnosis codes and Canadian Classification of Health Interventions procedure codes. Adjustments may be required to reflect accuracy in estimated costs of the diagnoses and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis or procedure, the secretariat normally defaults to considering direct treatment costs only.

Nonhospital: These include physician services costs obtained from the Ontario Schedule of Benefits, laboratory fees from the Ontario Schedule of Laboratory Fees, drug costs from the Ontario Drug Benefit Formulary, and device costs from the perspective of local health care institutions whenever possible or its manufacturer.

Discounting: For cost-effectiveness analyses, a discount rate of 5% is applied as recommended by economic guidelines.

Downstream costs: All numbers reported are based on assumptions on population trends (i.e. incidence, prevalence and mortality rates), time horizon, resource utilization, patient compliance, healthcare patterns, market trends (i.e. rates of intervention uptake or trends in current programs in place in the Province), and estimates on funding and prices. These may or may not be realized by the system or individual institutions and are often based on evidence from the medical literature, standard listing references and educated hypotheses from expert panels. In cases where a deviation from this standard is used, an explanation is offered as to the reasons, the assumptions, and the revised approach. The economic analysis represents ***an estimate only***, based on the assumptions and costing methods that have been explicitly stated above. These estimates will change if different assumptions and costing methods are applied to the analysis.

All figures are reported in Canadian Dollars, except where noted.

Objective

The objective of this economic analysis was to compare the lifetime costs, effects, and cost-effectiveness of a specialized multidisciplinary community-based care program versus no program in adults with type 2 diabetes using the Ontario Diabetes Economic Model (ODEM)

The Programs for Assessment of Technology and Health (PATH) was commissioned by MAS to predict the long-term costs and effects of strategies for successful management and treatment of type 2 diabetes, as well as their cost-effectiveness. The MAS conducts full evidence-based analyses of health technologies being considered for use in Ontario. These analyses are then presented to OHTAC, whose mandate is to provide evidence-based examination of proposed health technologies in the context of existing clinical practice and to provide advice and recommendations to Ontario practitioners, the broader health care system, and the Ministry. This report summarizes the economic analyses of the multi-disciplinary diabetes programs strategy.

An assessment of type 2 diabetes interventions requires an evaluation of both short- and long-term cost and effectiveness. Early management of diabetes can help delay and even prevent complications that can have a large impact on patients' quality of life and healthcare costs. Reductions in future complications may also offset 'up-front' medical resources invested in intensive disease management.

Evidence-Based Analysis of Cost-Effectiveness

Research Questions

1. Is a multi-disciplinary diabetes program cost-effective in improving glycemic control in adults with type 2 diabetes?
2. What are the lifetime costs, effects, health events, and the cost-effectiveness of a multi-disciplinary diabetes program in adults with type 2 diabetes?

Ontario Diabetes Economic Model

The recently developed UKPDS Outcomes Model, uses a system of equations in a computer simulation to predict the occurrence and timing of seven diabetes-related complications (fatal or non-fatal myocardial infarction, other ischaemic heart disease, stroke, heart failure, amputation, renal failure, and blindness) and death to calculate life expectancy and quality-adjusted life expectancy for Type 2 diabetes patients. To account for event-related dependencies, the model makes use of time-varying risk factors (e.g. blood pressure and HbA1c), which also facilitates its application to patient groups at different stages of the disease. The Model is based on data from over 5,000 patients with over 53,000 years of patient follow-up. If it's to be applied to other geographic areas (such as Ontario), however, the Model requires adapting. Specifically, cross-country differences may exist in: the incidence and prevalence of diabetes, baseline demographics, diabetes risk factors, overall mortality or mortality from diabetes-related complications, costs (e.g. treatment and management of complications), and the cost and effects of treatment programs. Accordingly, the Model was populated with Ontario-specific data for use in the province.

In brief, more than 734,000 patients with diabetes were identified in the Ontario Diabetes Database (ODD) and followed for up to 10 years. Various administrative databases were linked to this population in order to measure the prevalence and incidence of complications, healthcare resource utilization (i.e. inpatient and outpatient hospitalizations, outpatient visits, prescription drugs, emergency room visits, and home care), and death. Unit costs were collected and assigned to each of the different health care sectors. Complication-specific costs were divided into two time periods:

1) immediate costs that accrue within the year in which a complication first occurs; and
2) long-term costs that reflect ongoing costs in subsequent years associated with the management of the complication (including subsequent events of the same type).

Hospital inpatient and non-inpatient event and state costs were estimated for each complication. The perspective taken for estimating costs was that of the Ontario Ministry of Health and Long-term Care. All healthcare costs used in the model were based on direct costs; it was not possible to measure productivity costs or other patient costs from the data available. The ODEM was then used to conduct the cost-effectiveness analyses.

Summary of Findings

Table 3 summarizes the multi-disciplinary diabetes program based on the ODEM analysis over a 40 year time horizon. Table 4 describes the population and health system impact based on the ODEM analysis in a 40 year time horizon and the assumptions used to calculate the eligible population for a multi-disciplinary diabetes program.

Conclusions

Based on an analysis of an Ontario-specific model of diabetes care (ODEM) using data on clinical efficacy obtained from the above MAS systematic reviews, a multi-disciplinary diabetes programs would be considered cost-effective for the treatment and management of adults with type 2 diabetes.

Table 3: Summary of diabetes programs based on ODEM.

Incremental Costs, QALYS, CE and Events per 1,000	Multi-disciplinary Diabetes Program
Δ HbA1c	-1.02%
Δ Costs	$7,551
Δ QALYs	0.390
$/QALY gained	$19,869/QALY
Δ IHD	20.5
Δ MI	54.9
Δ Heart Failure	11.5
Δ Stroke	18.9
Δ Amputation	17.7
Δ Blindness	8.3
Δ Renal Failure	1.1

Table 4: Summary of health system impact based on ODEM.

Incremental Costs, QALYs, CE and Events per 1,000	Multi-disciplinary Diabetes Program*
Δ HbA1c	-1.02%
Δ Costs	$5.623
Δ QALYs	290,424
$/QALY gained	$19,869/QALY
Δ IHD	15,265
Δ MI	40,882
Δ Heart Failure	8,563
Δ Stroke	14,074
Δ Amputation	13,180
Δ Blindness	6,180
Δ Renal Failure	819

*All type 2 diabetes = 745,00

Community-Based Care for the Management of Heart Failure

Objective

The objective of this evidence-based review is to determine the effectiveness of specialized multidisciplinary care in the management of heart failure (HF).

Clinical Need: Target Population and Condition

HF is a progressive, chronic condition in which the heart becomes unable to sufficiently pump blood throughout the body. There are several risk factors for developing the condition including hypertension, diabetes, obesity, previous myocardial infarction, and valvular heart disease. Based on data from a 2005 study of the Canadian Community Health Survey (CCHS), the prevalence of congestive heart failure in Canada is approximately 1% of the population over the age of 12. This figure rises sharply after the age of 45, with prevalence reports ranging from 2.2% to 12%. Extrapolating this to the Ontario population, an estimated 98,000 residents in Ontario are believed to have HF.

Disease management programs are multidisciplinary approaches to care for chronic disease that co-ordinate comprehensive care strategies along the disease continuum and across healthcare delivery systems. Evidence for the effectiveness of disease management programs for HF has been provided by seven systematic reviews completed between 2004 and 2007 with consistency of effect demonstrated across four main outcomes measures: all cause mortality and hospitalization, and heart-failure specific mortality and hospitalization. While disease management programs are multidisciplinary by definition, however, the published evidence lacks consistency and clarity as to the exact nature of each program and usual care comparators are generally ill defined. Consequently, the effectiveness of multidisciplinary care for the management of persons with HF is still uncertain. Therefore, MAS has completed a systematic review of specialized, multidisciplinary, community-based disease management programs compared to a well-defined usual care group for persons with HF.

Evidence-Based Analysis of Effectiveness

Research Questions

What is the effectiveness of specialized, multidisciplinary, community-based care (SMCC) compared with usual care for persons with HF?

Inclusion Criteria

1. Randomized controlled trials
2. Systematic review with meta analysis
3. Population includes persons with New York Heart Association (NYHA) classification 1-IV HF
4. Intervention includes a team consisting of a nurse and physician, one of which is a specialist in HF management.
5. The control group receives care by a single practitioner (e.g. primary care physician (PCP) or cardiologist)
6. The intervention begins after discharge from the hospital
7. The studies reporting 1-year outcomes

Exclusion Criteria

1. The intervention is delivered predominately through home-visits
2. Studies with mixed populations where discrete data for HF is not reported

Outcomes of Interest

1. All cause mortality
2. All cause hospitalization
3. HF specific mortality
4. HF specific hospitalization
5. All cause duration of hospital stay
6. HF specific duration of hospital stay
7. Emergency room visits
8. Quality of Life

Search Strategy

A comprehensive literature search was completed of electronic databases including MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library and Cumulative Index to Nursing & Allied Health Literature. Bibliographic references of selected studies were also searched. After a review of the title and abstracts, relevant studies were obtained and the full reports evaluated. All studies meeting explicit inclusion and exclusion criteria were retained. Where appropriate, a meta-analysis was undertaken to determine the pooled estimate of effect of specialized multidisciplinary community-based care for explicit outcomes. The quality of the body of evidence, defined as one or more relevant studies was determined using GRADE Working Group criteria (see Appendix)

Summary of Findings

One large and seven small randomized controlled trials were obtained from the literature search. A meta-analysis was completed for four of the seven outcomes including:

1. All cause mortality
2. HF-specific mortality
3. All cause hospitalization
4. HF-specific hospitalization

Where the pooled analysis was associated with significant heterogeneity, subgroup analyses were completed using two primary categories:

- direct and indirect model of care; and
- type of control group (PCP or cardiologist).

The direct model of care was a clinic-based multidisciplinary HF program and the indirect model of care was a physician supervised, nurse-led telephonic HF program.

All studies, except one, were completed in jurisdictions outside North America. Similarly, all but one study had a sample size of less than 250. The mean age in the studies ranged from 65 to 77 years. Six of the studies included populations with a NYHA classification of II-III. In two studies, the control treatment was a cardiologist and two studies reported the inclusion of a dietitian, physiotherapist and psychologist as members of the multidisciplinary team.

All Cause Mortality

Eight studies reported all cause mortality (number of persons) at 1 year follow-up. When the results of all eight studies were pooled, there was a statistically significant RRR of 29% with moderate heterogeneity (I^2 of 38%). The results of the subgroup analyses indicated a significant RRR of 40% in all cause mortality when SMCC is delivered through a direct team model (clinic) and a 35% RRR when SMCC was compared with a primary care practitioner.

HF -Specific Mortality

Three studies reported HF-specific mortality (number of persons) at 1 year follow-up. When the results of these were pooled, there was an insignificant RRR of 42% with high statistical heterogeneity (I^2 of 60%). The GRADE quality of evidence is moderate for the pooled analysis of all studies.

All Cause Hospitalization

Seven studies reported all cause hospitalization at 1-year follow-up. When pooled, their results showed a statistically insignificant 12% increase in hospitalizations in the SMCC group with high statistical heterogeneity (I^2 of 81%). A significant RRR of 12% in all cause hospitalization in favour of the SMCC care group was achieved when SMCC was delivered using an indirect model (telephonic) with an associated (I^2 of 0%). The Grade quality of evidence was found to be low for the pooled analysis of all studies and moderate for the subgroup analysis of the indirect team care model.

HF-Specific Hospitalization

Six studies reported HF-specific hospitalization at 1-year follow-up. When pooled, the results of these studies showed an insignificant RRR of 14% with high statistical heterogeneity (I^2 of 60%); however, the quality of evidence for the pooled analysis of was low.

Duration of Hospital Stay

Seven studies reported duration of hospital stay, four in terms of mean duration of stay in days and three in terms of total hospital bed days. Most studies reported all cause duration of hospital stay while two also reported HF-specific duration of hospital stay. These data were not amenable to meta-analyses as standard deviations were not provided in the reports. In general, however, it appears that persons receiving SMCC had shorter hospital stays, whether measured as mean days in hospital or total hospital bed days.

Emergency Room Visits

Only one study reported emergency room visits. This was presented as a composite of readmissions and ER visits, where the authors reported that 77% (59/76) of the SMCC group and 84% (63/75) of the usual care group were either readmitted or had an ER visit within the 1 year of follow-up (P=0.029).

Quality of Life

Quality of life was reported in five studies using the Minnesota Living with HF Questionnaire (MLHFQ) and in one study using the Nottingham Health Profile Questionnaire (results reported in the full MAS analysis). Two studies reported the mean score at 1 year follow-up, although did not provide the standard deviation of the mean in their report. One study reported the median and range scores at 1 year follow-up in each group. Two studies reported the change scores of the physical and emotional subscales of the MLHFQ, of which only one reported a statistically significant change from baseline to 1 year follow-up between treatment groups in favour of the SMCC group in the physical sub-scale. A significant change in the emotional subscale scores in the treatment groups was not reported in either study.

Economic Analysis

Note: The disclaimer information provided on page 12 applies to the following economic section. All figures are reported in Canadian Dollars averaged over 2009.

Table 5 reports the estimated costs for fiscal year (FY) 2008 of HF hospitalizations and HF hospital transfers to either a long-term care facility or home with support service care. Emergency room visits to manage heart failure patients cost approximately $15 million. Heart failure hospitalizations totalled approximately $214 million and long-term care transfers cost approximately $85 million. The approximate cost of managing persons with heart failure who are discharged home with support services is not estimable.

Table 6 reports the estimated costs with an estimated 25% decrease in HF hospitalizations and a 1 day reduction in hospital length of stay (LOS) with an intermediate care program. The anticipated cost savings per year is $67 million. Program costs have not been included in these estimates. These savings are not constant and numbers may change based on population trends, rate of intervention uptake, trends in current programs in place in the Province, and assumptions on costs. Further economic analysis is required to estimate the current situation in Ontario and downstream costs associated uptake.

Table 5: Cost Estimates for Fiscal Year (FY) 2008

Variable	Number of Visits	Total Costs ($M)
HF ER Visits	25,852	15
HF Hospitalizations	17,578	214
Hospital Transfers		
Long Term Care Facility	2,365	85
Home with support service (e.g., home care)	3,825	Not estimable

*****Assumptions:

- ER Visits: Average total cost/case $579 (OCCI data, accessed June 11-2009)
- Hospitalization: Average total costs/case $12,405 and based on an average LOS 10 days (OCCI data, accessed June 11, 2009); costs only for hospitalization and ER visits and does not include physician costs.
- LTC provincial funding/bed $98.51 as of August 1, 2009
- Intermediate Care program costs are not included in the analysis

Table 6: Adjusted costs/yr as per 25% reduction in HF hospitalization from systematic review

Variable	Number of Visits	Costs/YR ($M, CAD.)	Adjusted no. of Visits and LOS	Adjusted costs/YR (Millions, CAD.)	Savings/YR (millions, CAD.)
HF Hospitalizations	17, 575	214	13,182	147	67

*****Assumptions:

- Hospitalization: Average total costs/case $12,405 and based on an average LOS of 10 days (OCCI data, accessed June 11-2009); Cost/day $1240, costs only for hospitalization and does not include physician costs.
- Adjusted number of visits and LOS estimated with a 25% reduction in number of visits and a 1 day reduction in LOS.
- Intermediate care program costs are not included in these cost estimates

Conclusion

There is moderate quality evidence that SMCC:

1) Reduces all cause mortality by 29-40%
2) Reduces all cause hospitalization by 12 %
3) Reduction HF-specific hospitalization by 25-27%

There is low quality evidence that SMCC:

1) Reduces HF-specific mortality by 58%
2) Contributes to a shorter duration of hospital stay
3) Improves QoL compared to usual care

The evidence supports that SMCC is effective when compared to usual care provided by either a primary care practitioner or cardiologist. It does not, however, suggest an optimal model of care or discern what the effective program components are. A field evaluation could address this uncertainty.

Community-Based Care for Chronic Wound Management

Objective

The objective of this evidence-based review is to determine the effectiveness of a multidisciplinary wound care team for the management of chronic wounds.

Clinical Need: Target Population and Condition

Chronic wounds develop from various aetiologies including pressure ulcers, diabetes, venous pathology and surgery. A pressure ulcer is defined as a localized injury to the skin/and or underlying tissue occurring most often over a bony prominence and caused by pressure, shear, or friction, alone or in combination. Approximately 1.5 million Ontarians will sustain a pressure ulcer, 111,000 will develop a diabetic foot ulcer, and between 80,000 and 130,000 will develop a venous leg ulcer. Chronic leg ulcers are associated with decreased quality of life, restricted mobility, anxiety, depression, and severe or continuous pain.

Multidisciplinary Wound Care Team

Multidisciplinary wound care teams involve the coordinated effort of specialists from multiple disciplines operating in a collaborative manner. There is general consensus that a group of multidisciplinary professionals is necessary for optimum specialist management of chronic wounds stemming from all aetiologies. There is little evidence, however, to guide the decision of which professionals might be needed to optimize a wound care team.

Evidence-Based Analysis of Effectiveness

Research Questions

What are the effectiveness and cost-effectiveness of a community based, multidisciplinary care model for the treatment and management of chronic wounds.

Inclusion Criteria

- Randomized controlled trials and Controlled clinical Trials (CCT)
- Systematic reviews with meta analysis
- Population includes persons with pressure ulcers (anywhere) and/or leg and foot ulcers
- The intervention includes a multidisciplinary (2 or more disciplines) wound care team.
- The control group does not receive care by a wound care team
- Studies published in the English language between 2004 and 2009

Exclusion Criteria

- Single centre retrospective observational studies

Outcomes of Interest

- Proportion of persons and/or wounds completely healed
- Time to complete healing
- Quality of Life
- Pain assessment

Search Strategy

A literature search was performed on July 7, 2009 using OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment, and on July 13, 2009 using the Cumulative Index to Nursing & Allied Health Literature (CINAHL), and the International Agency for Health Technology Assessment (INAHTA) for studies pertaining to leg and foot ulcers. A similar literature search was conducted on July 29, 2009 for studies pertaining to pressure ulcers. 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. Articles with an unknown eligibility were reviewed with a second clinical epidemiologist and then a group of epidemiologists until consensus was established.

Summary of Findings

Two studies met the inclusion and exclusion criteria, one randomized controlled trial (RCT) and a CCT using a before and after study design. Between the two studies, there was variation in setting, composition of the wound care team, outcome measure and follow-up period, but in both the wound care team members received training in wound care management and followed a wound care management protocol.

In the RCT by Vu et al., the authors reported a non-significant difference between the proportion of wounds healed in 6 months using a univariate analysis (61.7% vs. 52.5%, treatment vs. control, P=0.074, RR=1.19). There was also a non-significant difference in the mean time to healing (82 days vs. 101 days, treatment vs. control, p=0.095). More persons in the intervention group had a Brief Pain Inventory (BPI) score equal to zero (better pain control) at 6 months when compared with the control group (38.6% vs. 24.4%, intervention vs. control p=0.017, RR=1.58). By multivariate analysis a statistically significant hazard ratio was reported in the intervention group (1.73, 95% CI 1.20-1.50, P=0.003).

In the CCT by Harrison et al., the authors reported a statistically significant difference in healing rate between the pre (control) and post (intervention) phases of the study. Of patients in the pre phase, 23% had healed ulcers 3 months after study enrolment, whereas 56% were healed in the post phase (P<0.001, OR=4.17). As well, 27% of patients were treated daily or more often in the pre phase, while only 6% were treated at this frequency in the post phase (P<0.001), which is equal to a 34% relative risk reduction in frequency of daily treatments. The authors did not report the results of pain relief assessment.

The body of evidence was assessed using the GRADE methodology for 4 outcomes: proportion of wounds healed, proportion of persons with healed wounds, wound associated pain relief, and proportion of persons needing daily wound treatments. In general, the evidence is low to very low quality.

Conclusions

The evidence supports that managing chronic wounds with a multidisciplinary wound care team significantly increases wound healing and reduces the severity of wound-associated pain and the required daily wound treatments compared to persons not managed by a wound care team. The quality of evidence supporting these outcomes is low to very low meaning that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Overall Conclusions

Clinical Efficacy

1. Community Programs for Diabetes Type 2

There is moderate quality evidence that specialized multidisciplinary community care provided by at least a registered nurse, registered dietitian and physician (primary care and/or specialist) is an effective model of care for the improvement of glycemic control. However, the effects of this model of care on SBP control are uncertain, based on very-low quality evidence. Specialized multidisciplinary community care provided by at least a pharmacist and primary care physician is also an effective model of care for the improvement of both glycemic control (based on high quality evidence) and SBP (based on moderate quality evidence).

Cost-effectiveness: Type 2 Diabetic Population – ODEM Analyses

Based on an analysis of an Ontario-specific model of diabetes care (ODEM), using data on clinical efficacy obtained from the above MAS systematic reviews, multi-disciplinary programs would be considered cost-effective for the treatment and management of adults with type 2 diabetes.

2. Community-Based Specialized Management for Heart Failure

There is moderate quality evidence that SMCC reduces all cause mortality by 29%. There is low quality evidence that SMCC contributes to a shorter duration of hospital stay and improves quality of life compared to usual care. The evidence supports that SMCC is effective when compared to usual care provided by either a primary care practitioner or a cardiologist. It does not, however, suggest an optimal model of care or discern what the effective program components are. A field evaluation could address this uncertainty.

3. Community-Based Care for Chronic Wound Management

The evidence supports that managing chronic wounds with a multidisciplinary wound care team significantly increases wound healing and reduces the severity of wound-associated pain and the required daily wound treatments compared to persons not managed by a wound care team. The quality of evidence supporting these outcomes is low to very low meaning that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

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Appendix: GRADE Tool

Table A1: GRADE tool for grading the quality of evidence and strength of recommendations

Number of Studies	Study Design	Quality of Studies	Consistency	Directness	Other Modifying Factors
N	RCT = High Observational = Low Any other evidence = Very Low	Serious limitation to study quality (-1) Very Serious Limitation to study quality (-2)	Important inconsistency (-1)	Some uncertainty about directness (-1) Major uncertainty about directness (-2)	Association Strong (+1) Association Very Strong (+2) Dose Response Gradient (+1) All plausible confounders would have reduced the effect (+1) Imprecise or sparse data (-1) High probability of reporting bias (-1)

Source: Atkins D et al. Grading quality of evidence and strength of recommendations. BMJ 2004; 328(7454): 1490.

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Community-Based Care for the Specialized Management of Heart Failure

An Evidence-Based Analysis

Presented to the Ontario Health Technology Advisory Committee in March 2009

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Ontario

Medical Advisory Secretariat
Ministry of Health and Long-Term Care

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All analyses in the Ontario Health Technology Assessment Series are impartial and subject to a systematic evidence-based assessment process. There are no competing interests or conflicts of interest to declare.

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All Medical Advisory Secretariat analyses are subject to external expert peer review. Additionally, the public consultation process is also available to individuals wishing to comment on an analysis prior to finalization. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html.

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About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series*.

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practising medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

If you are aware of any current additional evidence to inform an existing evidence-based analysis, please contact the Medical Advisory Secretariat: MASinfo.moh@ontario.ca. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html.

Table of Contents

In August 2008, the Medical Advisory Secretariat (MAS) presented a vignette to the Ontario Health Technology Advisory Committee (OHTAC) on a proposed targeted health care delivery model for chronic care. The proposed model was defined as multidisciplinary, ambulatory, community-based care that bridged the gap between primary and tertiary care, and was intended for individuals with a chronic disease who were at risk of a hospital admission or emergency department visit. The goals of this care model were thought to include: the prevention of emergency department visits, a reduction in hospital admissions and re-admissions, facilitation of earlier hospital discharge, a reduction or delay in long-term care admissions, and an improvement in mortality and other disease-specific patient outcomes.

OHTAC approved the development of an evidence-based assessment to determine the effectiveness of specialized community based care for the management of heart failure, Type 2 diabetes and chronic wounds.

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Please visit the Toronto Health Economics and Technology Assessment Collaborative Web site at: http://theta.utoronto.ca/papers/MAS_CHF_Clinics_Report.pdf to review the following economic project associated with this series:

Community-based Care for the specialized management of heart failure: a cost-effectiveness and budget impact analysis.

Objective

The objective of this evidence-based analysis was to determine the effectiveness of specialized multidisciplinary care in the management of heart failure (HF).

Clinical Need: Target Population and Condition

HF is a progressive, chronic condition in which the heart becomes unable to sufficiently pump blood throughout the body. There are several risk factors for developing the condition including hypertension, diabetes, obesity, previous myocardial infarction, and valvular heart disease.(1) Based on data from a 2005 study of the Canadian Community Health Survey (CCHS), the prevalence of congestive heart failure in Canada is approximately 1% of the population over the age of 12.(2) This figure rises sharply after the age of 45, with prevalence reports ranging from 2.2% to 12%.(3) Extrapolating this to the Ontario population, an estimated 98,000 residents in Ontario are believed to have HF.

Disease management programs are multidisciplinary approaches to care for chronic disease that co-ordinate comprehensive care strategies along the disease continuum and across healthcare delivery

systems.(4) Evidence for the effectiveness of disease management programs for HF has been provided by seven systematic reviews completed between 2004 and 2007 (Table 1) with consistency of effect demonstrated across four main outcomes measures: all cause mortality and hospitalization, and heart-failure specific mortality and hospitalization. (4-10)

However, while disease management programs are multidisciplinary by definition, the published evidence lacks consistency and clarity as to the exact nature of each program and usual care comparators are generally ill defined. Consequently, the effectiveness of multidisciplinary care for the management of persons with HF is still uncertain. Therefore, MAS has completed a systematic review of specialized, multidisciplinary, community-based care disease management programs compared to a well-defined usual care group for persons with HF.

Evidence-Based Analysis Methods

Research Questions

What is the effectiveness of specialized, multidisciplinary, community-based care (SMCCC) compared with usual care for persons with HF?

Literature Search Strategy

A comprehensive literature search was completed of electronic databases including MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library and Cumulative Index to Nursing & Allied Health Literature. Bibliographic references of selected studies were also searched. After a review of the title and abstracts, relevant studies were obtained and the full reports evaluated. All studies meeting explicit inclusion and exclusion criteria were retained. Where appropriate, a meta-analysis was undertaken to determine the pooled estimate of effect of specialized multidisciplinary community-based care for explicit outcomes. The quality of the body of evidence, defined as one or more relevant studies was determined using GRADE Working Group criteria. (11)

Inclusion Criteria

1. Randomized controlled trial
2. Systematic review with meta analysis
3. Population includes persons with New York Heart Association (NYHA) classification 1-IV HF
4. The intervention includes a team consisting of a nurse and physician one of which is a specialist in HF management.
5. The control group receives care by a single practitioner (e.g. primary care physician (PCP) or cardiologist)
6. The intervention begins after discharge from the hospital
7. The study reports 1-year outcomes

Exclusion Criteria

1. The intervention is delivered predominately through home-visits
2. Studies with mixed populations where discrete data for HF is not reported

Outcomes of Interest

1. All cause mortality
2. All cause hospitalization
3. HF specific mortality

4. HF specific hospitalization
5. All cause duration of hospital stay
6. HF specific duration of hospital stay
7. Emergency room visits
8. Quality of Life

Summary of Findings

One large and seven small randomized controlled trials were obtained from the literature search.

A meta-analysis was completed for four of the seven outcomes including:

1. All cause mortality
2. HF-specific mortality
3. All cause hospitalization
4. HF-specific hospitalization.

Where the pooled analysis was associated with significant heterogeneity, subgroup analyses were completed using two primary categories:

- direct and indirect model of care; and
- type of control group (PCP or cardiologist).

The direct model of care was a clinic-based multidisciplinary HF program and the indirect model of care was a physician supervised, nurse-led telephonic HF program.

All studies, except one, were completed in jurisdictions outside North America. (12-19) Similarly, all but one study had a sample size of less than 250. The mean age in the studies ranged from 65 to 77 years. Six of the studies(12;14-18) included populations with a NYHA classification of II-III. In two studies, the control treatment was a cardiologist (12;15) and two studies reported the inclusion of a dietitian, physiotherapist and psychologist as members of the multidisciplinary team (12;19).

All Cause Mortality

Eight studies reported all cause mortality (number of persons) at 1 year follow-up. (12-19) When the results of all eight studies were pooled, there was a statistically significant RRR of 29% with moderate heterogeneity (I^2 of 38%). The results of the subgroup analyses indicated a significant RRR of 40% in all cause mortality when SMCCC is delivered through a direct team model (clinic) and a 35% RRR when SMCCC was compared with a primary care practitioner.

HF -Specific Mortality

Three studies reported HF-specific mortality (number of persons) at 1 year follow-up. (15;18;19) When the results of these were pooled, there was an insignificant RRR of 42% with high statistical heterogeneity (I^2 of 60%). The GRADE quality of evidence is moderate for the pooled analysis of all studies.

All Cause Hospitalization

Seven studies reported all cause hospitalization at 1-year follow-up (13-15;17-19). When pooled, their results showed a statistically insignificant 12% increase in hospitalizations in the SMCCC group with high statistical heterogeneity (I^2 of 81%). A significant RRR of 12% in all cause hospitalization in favour of the SMCCC care group was achieved when SMCCC was delivered using an indirect model

(telephonic) with an associated (I^2 of 0%). The Grade quality of evidence was found to be low for the pooled analysis of all studies and moderate for the subgroup analysis of the indirect team care model.

HF-Specific Hospitalization

Six studies reported HF-specific hospitalization at 1-year follow-up. (13-15;17;19) When pooled, the results of these studies showed an insignificant RRR of 14% with high statistical heterogeneity (I^2 of 60%); however, the quality of evidence for the pooled analysis of was low.

Duration of Hospital Stay

Seven studies reported duration of hospital stay, four in terms of mean duration of stay in days (14;16;17;19) and three in terms of total hospital bed days (12;13;18). Most studies reported all cause duration of hospital stay while two also reported HF-specific duration of hospital stay. These data were not amenable to meta-analyses as standard deviations were not provided in the reports. However, in general (and in all but one study) it appears that persons receiving SMCCC had shorter hospital stays, whether measured as mean days in hospital or total hospital bed days.

Emergency Room Visits

Only one study reported emergency room visits. (14) This was presented as a composite of readmissions and ER visits, where the authors reported that 77% (59/76) of the SMCCC group and 84% (63/75) of the usual care group were either readmitted or had an ER visit within the 1 year of follow-up (P=0.029).

Quality of Life

Quality of life was reported in five studies using the Minnesota Living with HF Questionnaire (MLHFQ) (12-15;19) and in one study using the Nottingham Health Profile Questionnaire(16). The MLHFQ results are reported in our analysis. Two studies reported the mean score at 1 year follow-up, although did not provide the standard deviation of the mean in their report. One study reported the median and range scores at 1 year follow-up in each group. Two studies reported the change scores of the physical and emotional subscales of the MLHFQ of which only one study reported a statistically significant change from baseline to 1 year follow-up between treatment groups in favour of the SMCCC group in the physical sub-scale. A significant change in the emotional subscale scores from baseline to 1 year follow-up in the treatment groups was not reported in either study.

Conclusion

There is moderate quality evidence that SMCCC reduces all cause mortality by 29%. There is low quality evidence that SMCCC contributes to a shorter duration of hospital stay and improves quality of life compared to usual care. The evidence supports that SMCCC is effective when compared to usual care provided by either a primary care practitioner or a cardiologist. It does not, however, suggest an optimal model of care or discern what the effective program components are. A field evaluation could address this uncertainty.

Background

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Heart failure (HF) is a progressive, chronic condition in which the heart is unable to sufficiently pump blood throughout the body. There are several risk factors for developing the condition including hypertension, diabetes, obesity, previous myocardial infarction and valvular heart disease.(1) Based on data from a 2005 study of the Canadian Community Health Survey (CCHS), the prevalence of congestive heart failure in Canada is approximately 1% of the population over the age of 12.(2) . This figure rises sharply after the age of 45, with prevalence reports ranging from 2.2% to 12% in this age category.(3)

Extrapolating this to the Ontario population, an estimated 98,000 residents in Ontario have HF.

Symptomatic HF is associated with high morbidity and mortality. The associated 5-year mortality rate for HF is estimated to be as high as 45%-60%.(20) In the Framingham study, the median survival of symptomatic HF patients was 1.7 years for men and 3.2 years for women. (21) The major mode of death among patients with HF is sudden death (43%), followed by worsening HF (32%), other cardiovascular causes (14%), and non-cardiovascular causes of death (11%). (22)

Disease Management Programs for HF

Disease management programs are multidisciplinary approaches to care for chronic disease that co-ordinate comprehensive care strategies along the disease continuum and across healthcare delivery systems.(4) Evidence for the effectiveness of disease management programs for HF has been provided by seven systematic reviews completed between 2004-2007 (Table 1) with consistency of effect demonstrated across four main outcomes measures: all cause mortality and hospitalization, and heart-failure specific mortality and hospitalization (Tables 2 and 3). (4-10) Limitations of this evidence include studies with a wide range of follow-up periods (3 months to 18 months), variation in the delivery model (e.g. telephonic, clinic, home visits), poor definitions of usual and multidisciplinary care, and variation in the initiation of the programs (i.e. some were initiated pre-discharge and some post-discharge).

Table 1: Systematic Reviews of Disease Management Programs

Study, Year	*Search Date	# RCTs
Gohler, 2006	1966 - 2005	36
Roccaforte, 2005	1980 - 2004	33
Holland, 2005	1966 - 2004	30
Taylor, 2005	1966 - 2003	21
McAlister, 2004	1966 - 2003	29
Gonseth, 2004	1966 - 2003	27
Gwadry-Sridhar, 2004	1966 - 2000	8

* Medline search dates

Table 2: All Cause Mortality and Hospitalization Results of Systematic Reviews of Disease Management

Study, Year	All Cause Mortality No. RCTs	All Cause Mortality [RR]	I^2 % [p-value]*	All Cause Hospitalization No. RCTs	All Cause Hospitalization [RR]	I^2 % [p-value]*
Gohler, 2006	30	0.81 [0.70, 0.93]	22.0	32	0.84 [0.77, 0.91]	57.0
Roccaforte, 2005	28	0.85 [0.73, 0.99]	31.0	25	0.84 [0.70, 1.02]	40.0
Holland, 2004	27	0.79 [0.69, 0.92]	35.5	21	0.87 [0.79, 0.95]	54.3
McAlister, 2004	22	0.83 [0.70, 0.99]	[0.15]	23	0.84 [0.75, 0.93]	[0.01]
Gonseth, 2004				16	0.88 [0.79, 0.97]	[0.25]
Gwadry-Sridhar, 2004	6	0.98 [0.72, 1.34]	[0.90]	8	0.79 [0.68, 0.91]	[0.20]

* P-value for heterogeneity

Table 3: HF-Specific Mortality and hospitalization results of systematic reviews of disease management programs.

Study, Year	HF-Specific Mortality No. RCT	HF-Specific Mortality RR	I^2 % [p-value]*	HF-Specific Hospitalization No. RCT	HF-Specific Hospitalization RR	I^2 % [p-value]*
Roccaforte, 2005	4	0.41 [0.19, 0.90]	54	20	0.69 [0.63, 0.77]	None
Holland, 2004				16	0.70 [0.61, 0.81]	[0.04]
Taylor, 2005	1	0.17 [0.06, 0.66]	NA	9		
McAlister, 2004				19	0.73 [0.66, 0.82]	[0.36]
Gonseth, 2004				11	0.70 [0.62, 0.79]	27.1

* P-value for heterogeneity

In 2007, MAS completed a systematic review of disease management programs compared to usual care for HF with a fixed follow-up period of 1 year (unpublished work). Other inclusion criteria were:

1. RCTs comparing disease management programs to usual care
2. Persons hospitalized for HF
3. Reporting at least on of the following outcomes: all cause mortality, all cause hospitalization, or hospitalization due to cardiovascular symptoms
4. Including at least one scheduled appointment after discharge (whether clinic, phone, or home visit)
5. Recruiting HF patients on admission or discharge from hospital
6. Sample size ≥50 patients
7. English language studies.

The pooled results of 12 RCTS (13;14;16;18;23-30) indicated a statistically significant, 15% relative risk reduction (RRR) in all cause hospitalization, while the results of four studies (13;14;24;28) showed a 33% RRR in HF-specific hospitalization at 1-year follow-up (Figure 1). There was a 20% RRR in all cause mortality at 1-year with the upper confidence interval (CI) at 1.00 (13;14;16;18;23;24;26-28;30). It was noted that each RCT had a unique program design in terms of the number of follow-up visits scheduled, type of visit (clinic, home, and phone), type of practitioners involved in the program, education materials provided, program duration. Inter-study differences were also noted in the age and severity of disease in the patient populations examined. These program and patient characteristics may be responsible for the heterogeneity seen in the effect estimate for all cause mortality and all cause hospitalization at 1 year.

While the heterogeneity in the disease management programs creates uncertainty as to the optimal program design and execution, the results of this analysis nonetheless support the development of a disease management program. This could perhaps be employed as an "intermediate" care stage between primary and tertiary care for persons with HF to reduce the burden on hospital services, particularly emergency department visits and unplanned hospitalizations. However, while disease management programs are by definition as multidisciplinary, the published evidence lacks consistency and clarity as to the exact nature of each program, and the usual care comparator is generally ill defined. Consequently, the effectiveness of multidisciplinary care for the management of persons with HF is still somewhat uncertain. MAS, therefore, completed a systematic review of multidisciplinary care disease management programs compared to a well-defined usual care group for persons with HF.

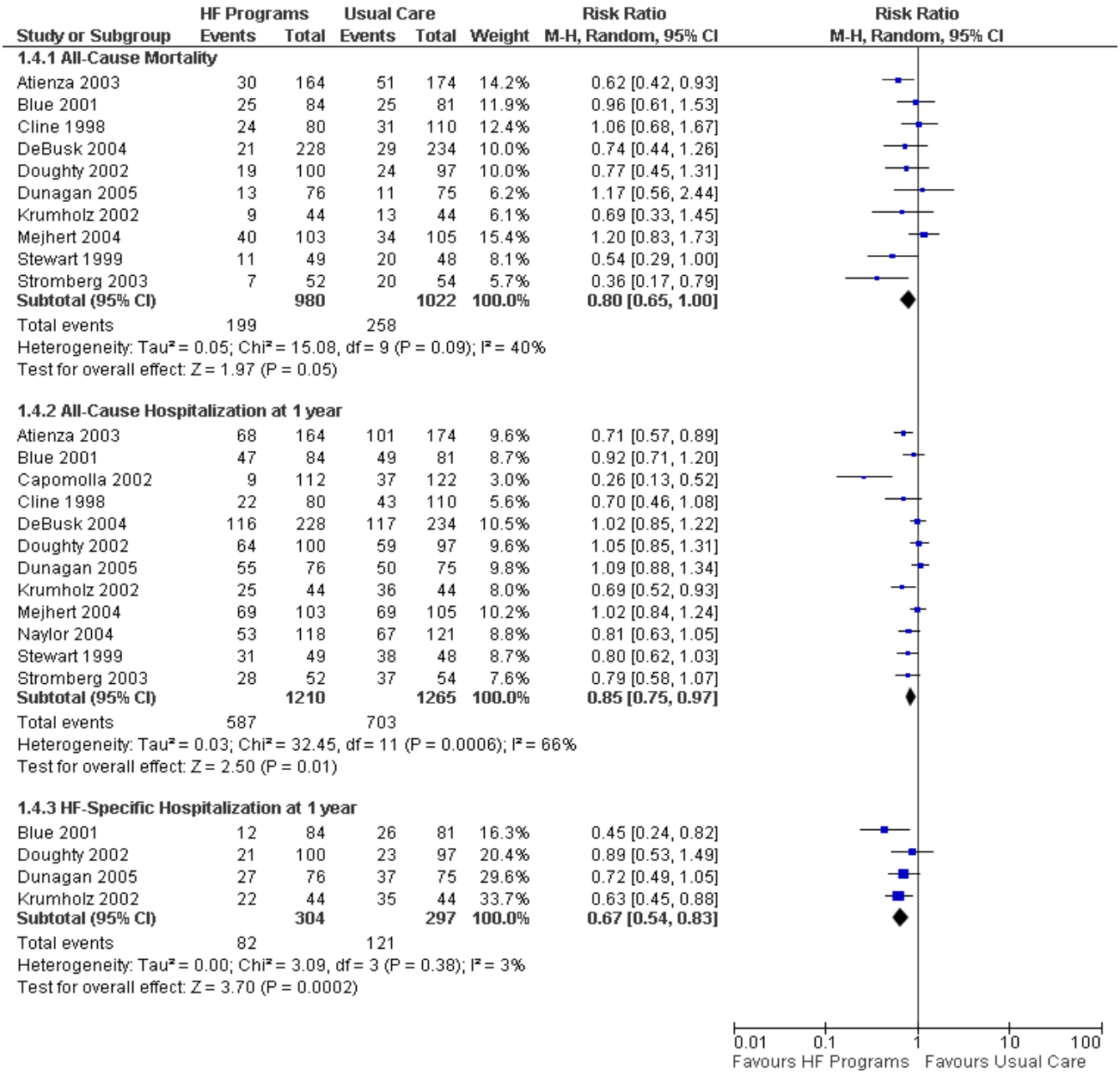

Figure 1: Meta-analysis of HF Disease Management Programs Compared with Usual Care

Evidence-Based Analysis of Effectiveness

Research Question

What is the effectiveness of SMCCC compared with usual care for persons with HF?

Methods

A comprehensive literature search was completed of electronic databases including MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library and Cumulative Index to Nursing & Allied Health Literature. Bibliographic references of selected studies were also searched. The search strategy is presented in full in Appendix 1. After a review of the title and abstracts, relevant studies were obtained and the full reports evaluated. All studies meeting explicit inclusion and exclusion criteria were retained. Where appropriate, a meta-analysis was undertaken to determine the pooled estimate of effect of specialized multidisciplinary community-based care for explicit outcomes. The quality of the body of evidence, defined as one or more relevant studies was determined using GRADE Working Group criteria.(11)

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4. The intervention includes a team consisting of a nurse and physician one of which is a specialist in HF management.
5. The control group receives care by a single practitioner (e.g. primary care physician (PCP) or cardiologist)
6. The intervention begins after discharge from the hospital
7. The study reports 1-year outcomes

Exclusion Criteria

1. The intervention is delivered predominately through home-visits
2. Studies with mixed populations where discrete data for HF is not reported

Outcomes

1. All cause mortality
2. All cause hospitalization
3. HF-specific mortality
4. HF-specific hospitalization
5. All cause duration of hospital stay
6. HF-specific duration of hospital stay
7. Emergency room visits
8. Quality of Life

Assessment of Quality of Evidence

The quality of the body of evidence was examined according to the GRADE Working Group criteria.(11) Quality refers to criteria such as the adequacy of allocation concealment, blinding, losses to follow-up, and completion of an intention to treat analysis. Consistency refers to the similarity of effect estimates across studies. If there is important unexplained inconsistency in the results, confidence in the estimate of effect for that outcome decreases. Differences in the direction of effect, the size of the effect, and the significance of the differences guide the decision about whether an important inconsistency exists. Directness refers to the extent to which the interventions, population, and outcome measures are similar to those of interest. The GRADE Working Group uses the following definitions in grading the quality of the evidence:

High: Further research is very unlikely to change confidence in the estimate of effect.

Moderate: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate

Very Low: Any estimate of effect is very uncertain

Results of Evidence-Based Analysis

Literature Search

One large and seven small randomized controlled trials were obtained from the literature search (see Figure 2, and Table 4)

Characteristics of Included Studies

All studies were completed in jurisdictions outside North America (12-19), other than that done by Dunagan et al. (14) Similarly, other than the GESICA study (15), all had a sample size less than 250 persons. The mean age in the studies ranged from 65 to 77 years. Six of the studies(12;14-18) included populations with a NYHA classification of II-III, while the studies completed by Wierzchowiecki et al. (19) and Doughty et al. (13) included a proportion of NYHA classification IV study participants. In two studies, the control treatment was a cardiologist (12;15) and two studies reported the inclusion of a dietitian, physiotherapist and psychologist as members of the multidisciplinary team (12;19).
Table 5 presents an overview of the characteristics of the studies included for review and Table 6 reports the methodology characteristics of each.(12-19). Complete study details are reported in Appendix 3.

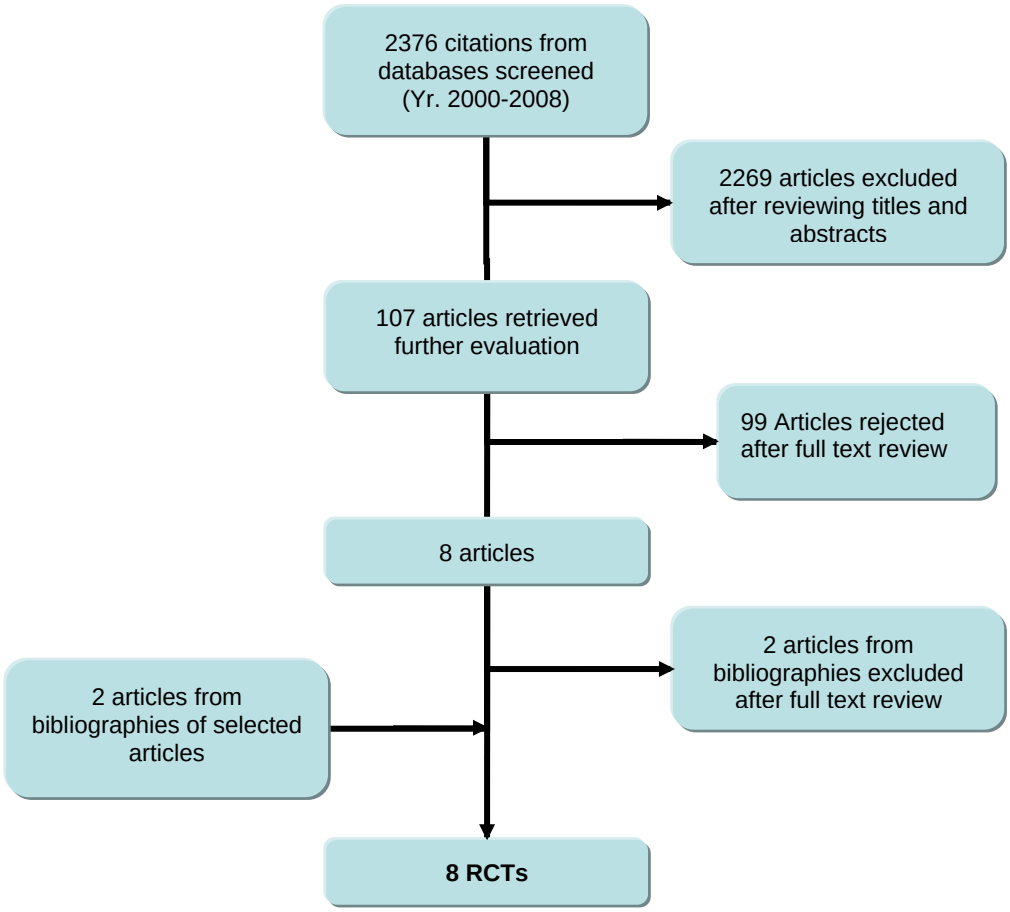

Figure 2: Systematic Literature Review Process and Results

Table 4: Quality of Evidence of Included Studies*(31)

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic review of RCTs	1	0
Large RCT unpublished but reported to an international scientific meeting	1(g)	1
Small RCT	2	7
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	0
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	0
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

* g refers to grey literature; RCT, randomized controlled trial.

Table 5: Characteristics of Studies Included for Analysis

Study	Country	N	Age (mean, yr)	NYHA class II and *III (%)	Treatment	Control	Other Disciplines
Rao 2007	UK	112	72	90	HF RN, Cardiologist	PCP	n/a
Bruggink 2007	Netherlands	240	71	*96	CV RN, HF Physician	Cardiologist	Dietitian
Wierzchowiecki 2006	Poland	160	68	60 IV-40	HF RN, Cardiologist	PCP	Physiotherapist psychologist
Mejhert 2004	Sweden	208	76	99	Nurse, Cardiologist	PCP	n/a
Stromberg 2003	Sweden	106	77	89	CV RN, Cardiologist	PCP	n/a
Doughty 2002	New Zealand	197	73	*24 IV-76	Nurse Practitioner Cardiologist	PCP	PCP
Dunagan 2005	USA	151	70	91	RN, Cardiologist	PCP	n/a
GESICA 2005	Argentina	1518	65	I-19 III to IV- 49 ;	HF RN, Cardiologist	Cardiologist	n/a

Table 6: Individual study methodology characteristics

Study	N	Adequate randomization methods	Baseline comparable	Adequate Allocation Concealment	Blinding of outcome assessors	Sample Size Calculation	Losses to †FU (%)	#ITT
Rao 2007	112	✓	✓	✓	✓	✓	0	✓
Bruggink 2007	240	✓	*† Except for gender	✓	✓	✓	0	✓
Wierzchowiecki 2006	160	✓	✓	Unclear	Not reported	Not reported	Not reported	Not reported
Mejhert 2004	208	✓	✓	$✓	¶No	✓	0	✓
Stromberg 2003	106	✓	*Except for the number of persons with hypertension and ‡†diabetes	✓	✓	✓	0	✓
Doughty 2002	197	✓	✓	Unclear	✓	✓	0.9	✓
Dunagan 2005	151	✓	*†Except for mean ACE inhibitor dose	Unclear	✓	✓	0	✓
GESICA 2005	1518	✓	✓	✓	✓	✓	0	✓

*Significantly higher proportion or dose in treatment group

† Adjusted analysis for baseline differences did not change results

‡Significantly higher proportion in the control group

¶ Primary end-point was patient self administered Quality of life questionnaire

ITT is intention to treat analysis

$ Adequate allocation concealment methods confirmed by author

The description of the multidisciplinary treatment group in each of the eight studies was reviewed and a qualitative analysis was undertaken to determine the components of the HF program. Table 7 reports the components that were developed from the study specific descriptions.

Table 7: HF Program Components

Components	Description
Disease specific education	The program provided education about the sings and symptoms and aetiology of HF
Medication Education	The program provided education about the side effects of HF medication, the relationship of medication to HF management and the importance of medication compliance
Medication Titration	The program titrated the dose of at least the diuretics and possible other HF specific medication (ACEI, Beta-blockers)
Diet Counselling	The program provided counselling on sodium and fluid restricted diets
Physical Activity Counselling	The program provided counselling on physical activity such as walking, and working and leisure activities.
Lifestyle Counselling	The program provided counselling on smoking cessation and alcohol intake
Self care support behaviours	The program encouraged the patient to monitor his/her daily weights, HF symptoms and or self manage the diuretic titration
Self-care tools	The program offered patient dairies for daily weight, diet and or symptom recording
Evidence-based guidelines	The program followed evidence based guidelines for medication management or other HF specific education and/or counselling
Regular follow-up (F/U)	The program offered regular follow-up visits between the beginning and end of the treatment phase

The study components were further categorized using the Wagener's model of Chronic Care (Table 8). (32) All studies included a decision support component in their program and seven of the eight studies also included a self management component. Only two studies (13;18) reported using evidence-based guidelines and five studies included scheduled follow-up visits (12-14;16;19). Disease specific education and diet counselling the program components most often carried out by the multidisciplinary treatment team.

Table 8: Components of Specialized Multidisciplinary Disease Management Program, Wagner's Chronic Care Model

	Wagner's Chronic Care Model									
	*Decision Support			*Self-Management					*Delivery System Design	
Study	Disease specific education	Education about medication	Titration of medication	Diet counselling	Physical activity counselling	Lifestyle counselling	Self-care support behaviour	Self-care tools	Evidence-based guidelines used	Regular F/U
Rao 2007	✓	✓	✓					Diary		
Bruggink 2007	✓	✓		✓	✓			Diary		✓
Wierzchowiecki 2006	✓	✓	✓	✓		✓	✓	Diary		✓
Mejhert 2004	✓		✓	✓		✓	✓			✓
Stromberg 2003	✓		✓	✓	✓	✓	✓		✓	
Doughty 2002	✓	✓		✓	✓		✓	Diary	✓	✓
Dunagan 2005	✓			✓			✓			✓
GESICA 2005	✓	✓	✓	✓	✓	✓	✓			

* Components of Wagner's Chronic Care Model

Summary of Existing Evidence

A meta-analysis was completed for 4 of the 7 outcomes including:

1. All cause mortality
2. HF-specific mortality
3. All cause hospitalization
4. HF-specific hospitalization.

Where the pooled analysis was associated with significant heterogeneity, subgroup analyses were completed using two primary categories:

- direct and indirect model of care; and
- type of control group (PCP or cardiologist).

The direct model of care was a clinic-based multidisciplinary HF program and the indirect model of care was a physician supervised, nurse-led telephonic HF program. Appendix 4 reports the GRADE evidence profiles for each of these four outcomes.

All Cause Mortality

Eight studies reported all cause mortality (number of persons) at 1 year follow-up (Figure 3). (12-19) When the results of all eight studies are pooled, there is a statistically significant RRR of 29% with moderate heterogeneity (I^2 of 38%). The results of the subgroup analyses indicate a significant RRR of 40% in all cause mortality when SMCCC is delivered through a direct team model (clinic) and a 35% RRR when SMCCC is compared with a primary care practitioner.

The GRADE quality of evidence is moderate for the pooled analysis of all studies and for the subgroup analysis of the direct team model.

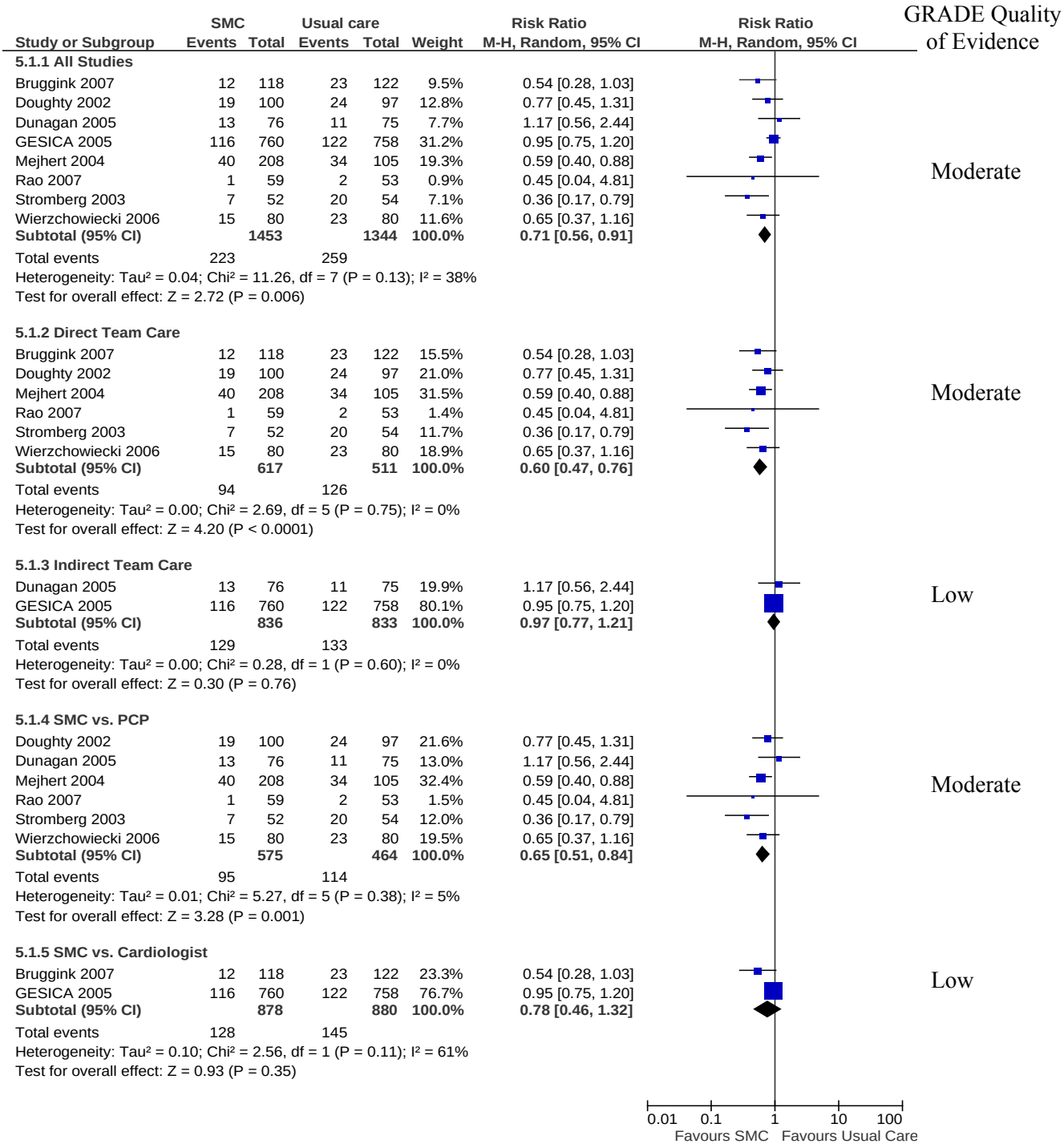

Figure 3: Meta-analysis for Outcome of All-Cause Mortality

HF-Specific Mortality

Three studies reported HF-specific mortality (number of persons) at 1 year follow-up (Figure 4). (15;18;19) When the results of these studies are pooled, there is an insignificant RRR of 42% with high statistical heterogeneity (I^2 of 60%). The results of subgroup analyses, however, indicate a significant 58% RRR in HF-specific mortality when SMCCC is delivered through a direct team model (clinic) but only a 20% RRR when delivered through an indirect model (telephonic model). A similar RRR occurred with the direct team model when SMCCC is compared to a primary care physician, as well with the indirect model when SMCCC was compared to a cardiologist. This is because the same studies are used in both subgroup analyses. It cannot, therefore, be determined from the subgroup analyses whether the effect is due to the type of model (direct or indirect) or the type comparator (PCP or cardiologist). The GRADE quality of evidence is moderate for the pooled analysis of all studies.

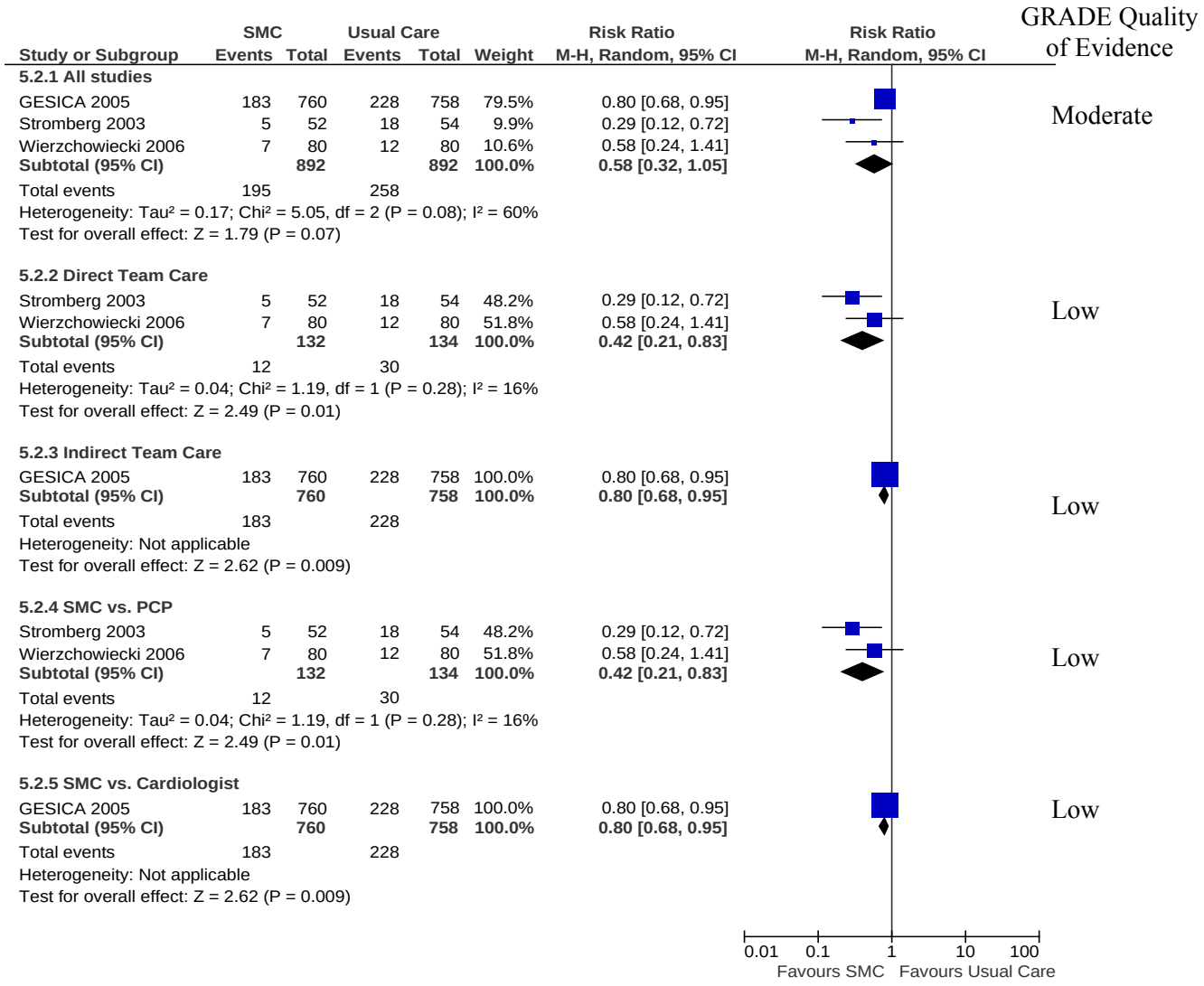

Figure 4: Meta-analysis for Outcome of HF-Specific Mortality

All Cause Hospitalization

Seven studies reported all cause hospitalization (number of persons) at 1-year follow-up (13-15;17-19). As displayed in Figure 5, a significant RRR of 12% in all cause hospitalization was only achieved when SMCCC was delivered using an indirect model (telephonic). All other analyses resulted in an insignificant risk reduction. The Grade quality of evidence was found to be low for the pooled analysis of all studies and moderate for the subgroup analysis of the indirect team care model.

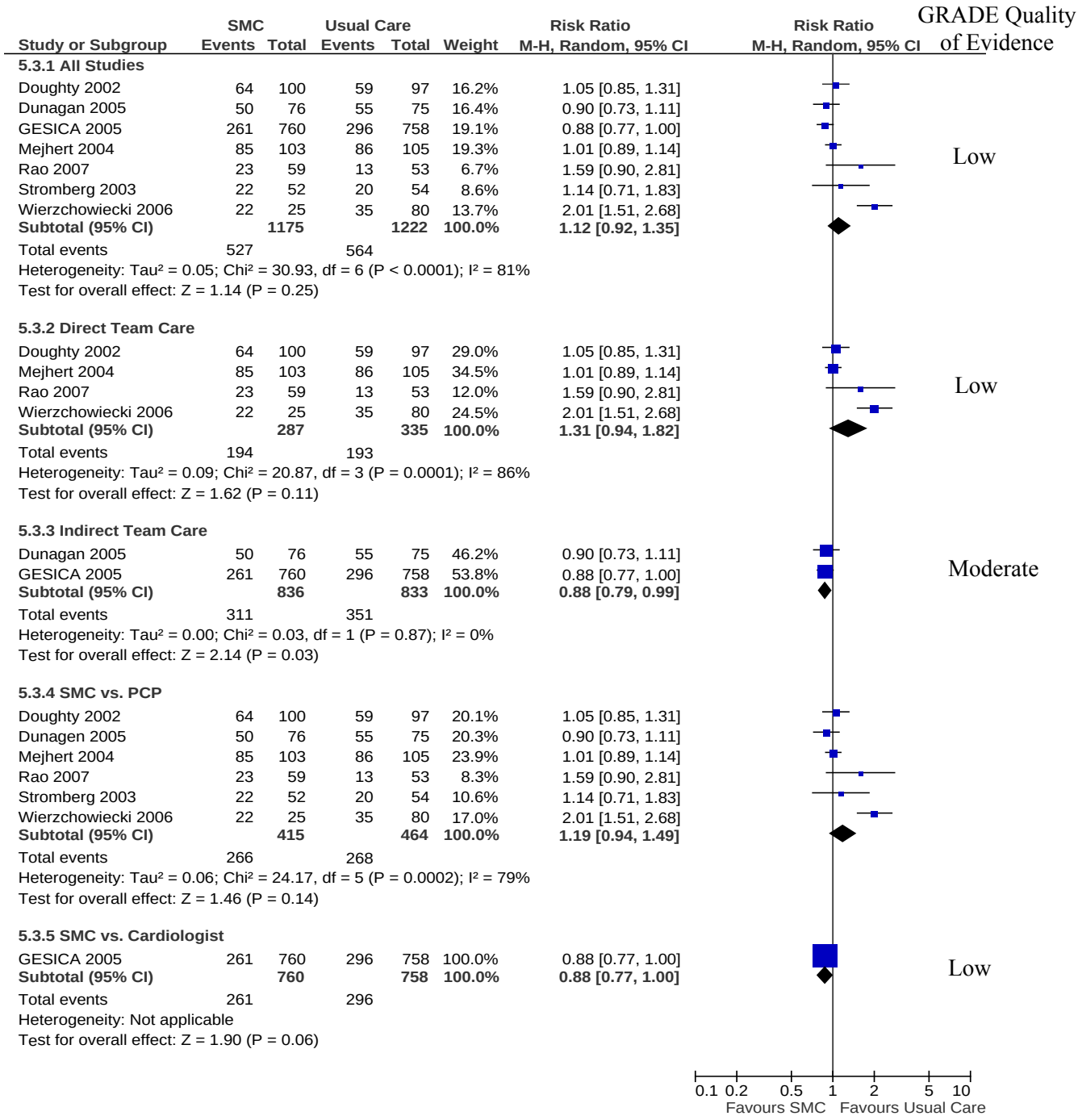

Figure 5: Meta-analysis for Outcome of All-Cause Hospitalization

HF-Specific Hospitalization

Six studies reported HF-specific hospitalization (number of persons) at 1 year follow-up (Figure 6) (13-15;17;19). When the results of these studies were pooled, there was an insignificant RRR of 14% with high statistical heterogeneity (I^2 of 60%). The results of subgroup analyses indicate a significant 25% RRR when SMCCC is delivered through an indirect team model (telephonic) and a 27% RRR when SMCCC is compared with a primary care practitioner. The quality of the evidence for the pooled analysis of all studies is low and moderate for the subgroup analyses of an indirect team care model and SMCCC compared with a primary care practitioner.

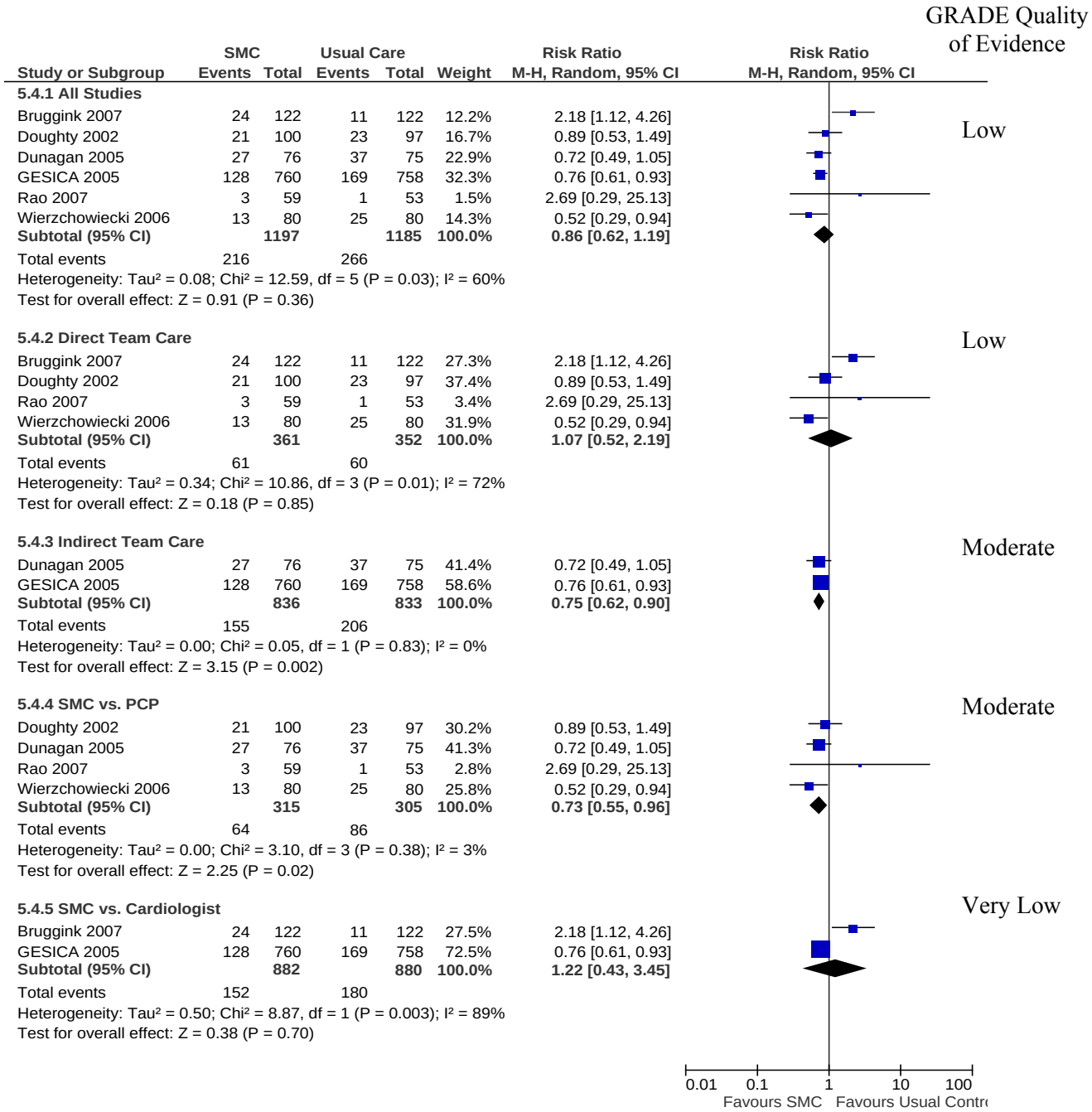

Figure 6: Meta-analysis for Outcome of HF-Specific Hospitalization

Duration of Hospital Stay (All cause and HF-specific)

Seven studies reported duration of hospital stay, four in terms of mean duration of stay in days (14;16;17;19) and three in terms of total hospital bed days (12;13;18). Most studies reported all cause duration of hospital stay except for Wierzchowiecki et al., and Doughty et al., who also reported HF-specific duration of hospital stay. These data were not amenable to meta-analyses as standard deviations were not provided in the reports.

In general, and except for the study by Rao et al.(17), it appears that persons receiving SMCCC had shorter hospital stays, whether measured as mean days in hospital or total hospital bed days.

Table 9: Duration of All Cause and †HF-Specific Hospital Stay

Study	Duration of Stay (mean days ± SD)		Total Hospital Bed Days (mean)	
	SMCCC	Usual Care	SMCCC	Usual Care
Rao 2007	12± 16	11.7±14		
Wierzchowiecki 2006	*9.3 †*9.5	12.5 13.9		
Mejhert 2004	3.7	4.1		
Dunagan 2005	13.3	14.5		
Bruggink 2007			¶359	644
Stromberg 2003			688	976
Doughty 2002			1074 †353	1170 561

*P<0.05

¶ RR 0.56, 95% CI 0.49-0.64

Emergency Room Visits

Only one study, Dunagan et al., reported emergency room visits. (14) This was presented as a composite of readmissions and ER visits and the authors reported that 77% (59/76) of the SMCCC group and 84% (63/75) in the usual care group were either readmitted or had an ER visit within the 1 year follow-up period (P=0.029).

Quality of Life

Quality of life was reported in five studies using the Minnesota Living with HF Questionnaire (MLHFQ) (12-15;19) and in one study using the Nottingham Health Profile Questionnaire. (16) The MLHFQ results are reported in our analysis (Table 10). The questionnaire is positively scored such that a higher score indicates a worsening quality of life and a negative change value indicates an improvement in quality of life from baseline to 1 year follow-up. Two studies reported the mean score at 1 year follow-up, although did not provide the standard deviation of the mean in their report. One study reported the median and range scores at 1 year follow-up in each group. Two studies reported the change scores of the physical and emotional subscales of the MLHFQ. Doughty et al. (13), but not Dunagan et al. (14), reported a statistically significant change from baseline to 1 year follow-up between treatment groups in favour of the SMCC group in the physical sub-scale. However, neither Doughty et al. (13) nor Dunagan et al. (14) reported a significant change in the emotional subscale scores from baseline to 1 year follow-up in the treatment groups.

Table 10: Minnesota Living with Heart Failure Questionnaire Scores

Study	Score at 1 year (mean ± standard deviation)		Significant improvement in SMCC group?
	SMCC	Usual Care	
Bruggink 2007	30.2	34.5	Yes
Gesica 2005	30.6	35.0	Yes
Wierzchowiecki 2006	*14 (4.5, 2.6)	*30 (20, 45)	Yes
Doughty 2002			
†Physical Scale	-11.1	-5.8	Yes
†Emotional Scale	-3.3	-3.3	No
Dunagan 2005			
†Physical Scale	8.6 ± 11.4	7.2 ± 12.0	No
†Emotional Scale	1.5 ± 6.6	2.9 ± 7.1	No

* Median (25th, 75th percentile)

† Change scores

Conclusion

There is moderate quality evidence that SMCC:

i) Reduces all cause mortality by 29-40%

ii) Reduces all cause hospitalization by 12 %

iii) Reduction HF-specific hospitalization by 25-27%

There is low quality evidence that SMCC:

i) Reduces HF-specific mortality by 58%

ii) Contributes to a shorter duration of hospital stay

iii) Improves QoL compared to usual care

The evidence supports that SMCC is effective when compared to usual care provided by either a primary care practitioner or cardiologist. It does not, however, suggest an optimal model of care or discern what the effective program components are. A field evaluation could address this uncertainty.

Appendices

Appendix 1: Literature Search Strategies

Search date: October 3, 2008
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library, CINAHL, INAHTA/CRD

Database: Ovid MEDLINE(R) <1996 to September Week 4 2008>
Search Strategy:

1 exp Intermediate Care Facilities/ (224)
2 (intermedia* adj2 care).ti,ab. (515)
3 exp ambulatory care/ (15708)
4 exp Ambulatory Care Facilities/ (14913)
5 exp Outpatients/ (3640)
6 ((outpatient* or ambulatory) adj2 (care* or service* or clinic* or facility or facilities)).ti,ab. (15903)
7 exp Patient Care Team/ (22174)
8 exp Nursing, Team/ (624)
9 exp Cooperative Behaviour/ (12391)
10 exp Interprofessional Relations/ (20840)
11 exp "Delivery of Health Care, Integrated"/ (5255)
12 team*.ti,ab. (33700)
13 (multidisciplin$ or multi-disciplin$ or interdisciplin$ or inter-disciplin$ or collaborat$ or cooperat$ or co-operat$ or multi?special$).ti,ab. (92766)
14 (integrat$ or share or shared or sharing).ti,ab. (168525)
15 exp Community Health Services/ (181506)
16 exp Program Evaluation/ (30090)
17 exp "episode of care"/ (912)
18 exp Professional Role/ (36081)
19 exp Primary Health Care/ (34220)
20 exp "Continuity of Patient Care"/ (6209)
21 exp Disease Management/ (6030)
22 disease management program*.ti,ab. (796)
23 (patient care adj2 manage$).ti,ab. (245)
24 exp Case Management/ or exp Subacute Care/ (6518)
25 (care adj2 model*).ti,ab. (2972)
26 exp Program Development/ (11557)
27 or/1-26 (565973)
28 limit 27 to yr="2000 - 2008" (425540)
29 limit 28 to (english language and humans) (319291)
30 limit 29 to (controlled clinical trial or meta analysis or randomized controlled trial) (14488)
31 exp Technology Assessment, Biomedical/ or exp Evidence-based Medicine/ (34149)
32 (health technology adj2 assess$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (617)
33 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (64522)
34 exp Random Allocation/ or random$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (368010)
35 exp Double-Blind Method/ (52776)
36 exp Control Groups/ (702)
37 exp Placebos/ (9187)
38 (RCT or placebo? or sham?).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (93365)
39 or/30-38 (474587)
40 29 and 39 (38798)
41 ((heart failure or cardiac failure or coronary failure or ventricular failure or myocardial failure) adj2 (program* or clinic* or center* or centre*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (981)
42 limit 41 to (english language and humans and yr="2000 - 2008") (689)
43 39 and 42 (168)
44 exp Heart Failure/ (30045)
45 40 and 44 (443)
46 45 or 43 (553)

Database: EMBASE <1980 to 2008 Week 39>

Search Strategy:

1 (intermedia* adj2 care).ti,ab. (631)
2 exp ambulatory care/ (12187)
3 exp Outpatient Department/ (9466)
4 exp outpatient care/ (12499)
5 ((outpatient* or ambulatory) adj2 (care* or service* or clinic* or facility or facilities)).ti,ab. (20467)
6 exp TEAM NURSING/ (6)
7 exp Cooperation/ (13299)
8 exp TEAMWORK/ or team*.ti,ab. (41041)
9 exp Integrated Health Care System/ (231)
10 (multidisciplin$ or multi-disciplin$ or interdisciplin$ or inter-disciplin$ or collaborat$ or cooperat$ or co-operat$ or multi?special$).ti,ab. (116921)
11 (integrat$ or share or shared or sharing).ti,ab. (208598)
12 exp Case Management/ (454)
13 exp Rehabilitation Care/ (2739)
14 exp community care/ (23465)
15 exp Social Care/ (34975)
16 exp ambulatory care nursing/ (5)
17 exp primary health care/ (41469)
18 *Disease Management/ (254)
19 disease management program*.ti,ab. (869)
20 (patient care adj2 manage$).ti,ab. (196)
21 exp Program Development/ (753)
22 (care adj2 model*).ti,ab. (2336)
23 exp Health Program/ (53182)
24 or/1-23 (511612)
25 limit 24 to (human and english language and yr="2000 - 2009") (194121)
26 Randomized Controlled Trial/ (162835)
27 exp Randomization/ (26273)
28 exp RANDOM SAMPLE/ (1261)
29 exp Biomedical Technology Assessment/ or exp Evidence Based Medicine/ (292930)
30 (health technology adj2 assess$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (645)
31 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab. (61896)
32 Double Blind Procedure/ (70620)
33 exp Triple Blind Procedure/ (12)
34 exp Control Group/ (2245)
35 exp PLACEBO/ or placebo$.mp. or sham$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (207387)
36 (random$ or RCT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (420855)
37 (control$ adj2 clinical trial$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (279987)
38 or/26-37 (778561)
39 38 and 25 (36604)
40 ((heart failure or cardiac failure or coronary failure or ventricular failure or myocardial failure) adj2 (program* or clinic* or center* or centre*)).ti,ab. (1310)
41 limit 40 to (human and english language and yr="2000 - 2009") (651)
42 38 and 41 (231)
43 exp Heart Failure/ (115679)
44 39 and 43 (1181)
45 42 or 44 (1336)

CINAHL

Query Limiters/Expanders Last Run Via Results
S43 (S42 and S39)
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 272
S42 (S41 or S40)
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 12707
S41 heart failure or cardiac failure or coronary failure or ventricular failure or myocardial failure
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 12700
S40 (MH "Heart Failure, Congestive+")
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 9671
S39 S37 OR S38 Limiters - Published Date from: 200001-200912; Language: English; Year of Publication from: 2000-2009

Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 10781
S38 (MH "Cardiovascular Care")
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 487
S37 (S36 and S23)
Search Screen - Advanced Search

S36 (S35 or S34)
Search Screen - Advanced Search

S35 (S33 or S32 or S31 or S30 or S29)
Search Screen - Advanced Search

S34 S28 or S27 or S26 or S25 or S24
Search Screen - Advanced Search

S33 control* N2 clinical trial*
Search Screen - Advanced Search

S32 (MH "Control (Research)+")
Search Screen - Advanced Search

S31 (MH "Placebos")
Search Screen - Advanced Search

S30 (MH "Double-Blind Studies") or (MH "Single-Blind Studies") or (MH "Triple-Blind Studies")
Search Screen - Advanced Search

S29 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 Search modes -Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search

S28 (MH "Cochrane Library") or (MH "Systematic Review")
Search Screen - Advanced Search

S27 (MH "Meta Analysis")
Search Screen - Advanced Search

S26 health technology N2 assess*
Search Screen - Advanced Search

S25 random* or sham* or RCT*
Search Screen - Advanced Search

S24 (MH "Random Assignment") or (MH "Random Sample+")
Search Screen - Advanced Search

S23 (S22 or S21 or S20 or S19 or S18 or S17 or S16 or S15 or S14 or S13 or S12 or S11 or S10 or S9 or S8 or S7 or S6 or S5 or S4 or S3 or S2 or S1) Limiters - Published Date from: 200001-200912; Language: English

Search Screen - Advanced Search

S22 multidisciplin* or multi-disciplin* or interdisciplin* or inter-disciplin* or collaborat* or cooperat* or co-operat* or multi-special* or multispecial*
Search Screen - Advanced Search

S21 (MH "Nurse-Managed Centers")
Search Screen - Advanced Search

S20 team*
Search Screen - Advanced Search

S19 care N2 model*
Search Screen - Advanced Search

S18 (MH "Professional Role+")
Search Screen - Advanced Search

S17 (MH "Subacute Care")
Search Screen - Advanced Search

S16 (MH "Case Management")
Search Screen - Advanced Search

S15 disease management program*
Search Screen - Advanced Search

S14 (MH "Disease Management")
Search Screen - Advanced Search

S13 (MH "Continuity of Patient Care")
Search Screen - Advanced Search

S12 (MH "Primary Health Care")
Search Screen - Advanced Search

S11 (MH "Community Health Services")
Search Screen - Advanced Search

S10 (MH "Health Care Delivery, Integrated")
Search Screen - Advanced Search

S9 (MH "Teamwork")
Search Screen - Advanced Search

S8 (MH "Interprofessional Relations+") or (MH "Collaboration")
Search Screen - Advanced Search

S7 (MH "Cooperative Behaviour")
Search Screen - Advanced Search

S6 (MH "Multidisciplinary Care Team+") or (MH "Team Nursing")
Search Screen - Advanced Search

S5 outpatient* care* or outpatient* service* or outpatient* clinic* or outpatient* facility or outpatient* facilities

Search Screen - Advanced Search

S4 ambulatory care* or ambulatory service* or ambulatory clinic* or ambulatory facility or ambulatory facilities
Search Screen - Advanced Search

S3 (MH "Outpatients") or (MH "Outpatient Service")
Search Screen - Advanced Search

S2 (MH "Ambulatory Care") or (MH "Ambulatory Care Facilities+") or (MH "Ambulatory Care Nursing")
Search Screen - Advanced Search

S1 intermedia* N2 care
Search Screen - Advanced Search

Appendix 2: Included Studies

BRUGGINK 2007	
Methods	A parallel group RCT.
Participants	Hospitalized persons or persons visiting a cardiology outpatient clinic with a NYHA class of II or IV HF were enrolled in the study.
Interventions	Randomized by computer generated allocation to either intensive follow-up at a HF outpatient clinic (in addition to usual care) led by a HF physician and a cardiovascular nurse. Intervention started within a week after hospital discharge or referral from the outpatient clinic, Weeks 1 and 3 visit to HF clinic: verbal and written comprehensive education was given about the disease, medication, compliance and possible adverse events. Advice was also given on diet, salt and fluid restriction, weight control, early recognition of worsening HF, physical exercise and rest, and when to seek help. A patient diary was given and appointments with a dietician were made Follow-up visits were at weeks 5 and 7, as well as at 3, 6, 9, and 12 months after study enrolment. At follow-up, a cardiovascular nurse provided counselling, check up, and reinforcement of education and a short physical examination. At the 6 and 9 months visit, the physician assessed the condition of the patient, optimized treatment, and performed an overall assessment with the nurse. Components of Program: disease specific education, education regarding medication, advice on diet, physical exercise. A patient diary was also used Usual care group was managed by a cardiologist according to the guidelines of the European Society of Cardiology (version 2001). All patients seen at an outpatient clinic.
Outcomes	An external clinical end-point committee of three experienced cardiologists blinded to the allocation status of the patient adjudicated all causes of hospitalization and health. Primary end-point was the composite of incidence of hospitalization for worsening HF and/or all cause mortality. Additional end-points were: Left ventricular ejection fraction`, NYHA class, quality of life, NT-proBNP, and self-care behaviour. Time to death, use of HF medication and costs of care were determined.
Notes	Other disciplines included dietician No losses to follow-up Baseline characteristics comparable between groups except for gender. The treatment group was 66% male and the control group was 79% male. Adjustment for baseline difference in gender did not alter the results of the study.
Allocation Concealment	Randomized computer generated allocation was used
DOUGHTY 2002	
Methods	Randomized controlled single-centre study Cluster randomization using the general practitioner as the unit of randomization was carried out. Patients assigned to groups based on the randomization of their GP.

Participants	Patients admitted to general medical wards at Auckland Hospital with a primary diagnosis of HF.
Interventions	Treatment group: patients were scheduled for an outpatient clinical review with the study team within 2 weeks of discharge from hospital, as well as six weekly visits alternating between the GP and the HF clinic. Patients were free to see their GP as they wished. Program components: disease specific education (signs and symptoms of HF), advice for dietary and exercise, patient diary for daily weights, medication record, clinical notes and appointments, as well as an education booklet were provided. Control group: care was provided by the general practitioner
Outcomes	Primary end-points were a combination of death, hospital readmission (time to first event), and quality of life questionnaire. Secondary end-points included all cause hospital readmissions, all cause hospital bed days and readmissions for worsening HF.
Notes	Computer- randomization was used to allot GPs to treatment or control groups. The decision to request admission rested with the GP The authors stated that contamination of the control group management may have occurred if a general practitioner had patients in both groups, but this is unlikely as the unit of randomization was the general practitioner. Sample size was predicated on a 30% reduction in the combined end-point of death or hospital readmission [alpha 0.05 (2-tailed), and 80% power]. The influence of clustering was determined to be insignificant so the data was analyzed using the unit of randomization assumed to be the individual. The data was also analyzed by the clustering unit (GP).
Allocation Concealment	Not reported.
DUNAGAN 2005	
Methods	An RCT with a randomly permuted bloc design with a 1:1 randomization of patients allocated to randomly selected blocks of 2, 4, or 6 patients.
Participants	Patients greater than or equal to 21 years of age with one sign or symptom of HF exacerbation and that have evidence of left ventricular systolic or diastolic dysfunction by echocardiogram, cardiac catheterization, or radionuclide imaging. Patients were NYHS class II, III, or IV at time of enrolment. Enrolment occurred during patient index hospitalization or just after discharge.
Interventions	Treatment: usual care plus enrolment in the disease management program. Study nurses provided additional education by telephone. Twenty patients received one or more home visits. Patients were called within 3 days after hospital discharge or study enrolment and then at least once a week for 2 weeks. Thereafter, the program nurses adjusted call frequency based on clinical status and self-management abilities. Patients were also given regularly scheduled telephonic monitoring by specially-trained nurses. Program components: self-management skills, diet counselling, and adherence to prescribed therapy. Usual care provided by their primary physician. Patients received education packages describing the causes of HF, principles of treatment, patient role in care and monitoring, and strategies for managing HF exacerbations.
Outcomes	Primary: Time to hospital readmission or emergency department visit (any cause). Other outcomes included time to all cause hospital readmission and time to HF-specific readmission, mortality, change in NYHA class, changes in quality of life and functional status outcomes as measures, total number of hospital encounters, hospital readmissions and hospital days and the cost of inpatient care during the follow-up period.
Notes	Sample size: study was designed to detect a 10% difference in readmission rates with an alpha of 0.05, and power of 80% and assuming a baseline

	readmission rate of 25%
Allocation Concealment	Not described
GESICA 2005	
Methods	Multi-centre RCT comparing centralized telephone intervention with usual care.
Participants	Persons with HF who are in ambulatory care defined as no admissions in the previous 2 months, not needing more than 1 clinic visit per month, and on optimal HF treatment not modified for at least 2 months before enrolment.
Interventions	Treatment group received an education booklet. Nurses trained in the management of HF made frequent telephone follow-up calls to educate and monitor patients. Components of the program: adherence to diet and drug treatment, monitoring of symptoms, control of signs of hydrosaline retention, and daily physical activity. Nurses could adjust the dose of diuretic or recommend non-schedules medical or emergency visits. Usual care: provided by cardiologist.
Outcomes	Primary end-point was all cause mortality or admission to hospital for worsening HF. Secondary end-points included total mortality, all cause hospital admission, admission for worsening HF, cardiovascular admission, quality of life, all cause mortality or overall admissions and combined end-point of all cause mortality or cardiovascular admission.
Notes	Clinical events committee was blinded to the patient groups and adjudicated all outcomes.
Allocation Concealment	Concealed randomization lists used
MEJHERT 2004	
Methods	Randomized prospective study of patients hospitalized with HF.
Participants	Persons 60 years of age and older with a NYHA class II-IV and left ventricular systolic dysfunction by echocardiology. Persons with an acute myocardial infarction or unstable angina pectoris within the previous three months, valvular stenosis, dementia, or a severe concomitant disease were excluded.
Interventions	Intervention: nurse monitored management programmed supervised by a senior cardiologist in an outpatient clinic. Regular visits were made to the clinic to meet with the nurse and at 6, 12, and 18 months to meet with the cardiologist for clinical examinations. Program components: Medication titration, disease-specific education (signs and symptoms of early deterioration), advice on diet (sodium, fluid, and alcohol intake). Education booklets and computerized education programs were also used. Usual Care group: persons in this group were managed by primary care physician.
Outcomes	Primary end-point was quality of life. Secondary end-points included function, medication, hospitalization and mortality.
Notes	None

Allocation Concealment	Allocation concealment methods not reported
RAO 2007	
Methods	A prospective randomized trial.
Participants	Patients with suspected HF from either a primary care of secondary care setting. Newly Diagnosed HF patients
Interventions	Patients were randomized by age and sex to either specialist care or care provided by their general practitioner using a random number schedule. Persons randomized to specialist care were managed in a dedicated HF clinic by a cardiology registrar and a HF nurse either in the community or in a hospital. HF nurses in the specialist care group titrated medication to maximum tolerated dosage and provided HF disease-specific education. An information booklet was also provided. Program components: titration of medication and disease-specific education. Patients were encouraged to keep a symptom diary. Usual care was by patients' general practitioners in primary care.
Outcomes	The primary outcome was prescription of optimum medication for HF. Definitions for optimal medication were provided by the authors. Secondary end-points were a composite of death and/or hospital admission for any reason. Also reported were hospital admission for worsening HF and number of days in hospital.
Notes	Treatment group (cardiologist and HF nurse in HF clinic): n=59 Control group (general practitioner) n=53 Sample size: Alpha of 0.05, power of 80% for a 25% reduction in death/readmission from 50% to 25%. Analysis was by intention to treat. No losses to follow-up Nineteen patients crossed-over between the groups. Ten patients randomized to usual care were referred to the cardiologist and nine patients randomized to specialist care requested follow-up by their general practitioner.
Allocation Concealment	Adequate
STROMBERG 2003	
Methods	Prospective randomized study with a 12 month follow-up
Participants	Persons hospitalized due to HF having a NYHA class II-IV. Inclusion criteria were diagnosed HF either by echocardiography, radiographic evidence

	of pulmonary congestion, or typical symptoms and signs of HF.
Interventions	Treatment group: nurse led HF clinic staffed by experienced cardiac nurses. Nurses had delegated responsibility for making protocol led changes in medications. Program was initiated 2-3 weeks after discharge. Patients remained in the care of the HF clinic until they were stable. Thereafter, care responsibility returned to the primary health care practitioner. Program components: Disease education (signs and symptoms), medication titration, diet counselling, lifestyle changes (smoking), exercise advice. Usual Care group: conventional follow-up in primary health care. No specialized HF nurses, no standardized education or structured follow-up for patients with HF was provided.
Outcomes	Outcomes were assessed by a nurse blinded to the intervention and not involved in the care of the patient. The primary end-point was all cause mortality or all cause hospital admission after 12 months. Secondary end-points were mortality, number of readmissions for any reason, number of days in the hospital, and self-care behaviour.
Notes	Sample size was predicated on a 50% difference in the total rate of readmission or death between the groups with a 25% event-free survival in the control group [alpha of 0.05 (2-sided) and power of 80%].
Allocation Concealment	Randomization was blinded and used a computer-generated list of random numbers and sealed envelopes.
WIERZCHOWIECKI 2006	
Methods	RCT to determine the influence of a 1-year SMCC program for persons with CHF.
Participants	Hospitalized persons diagnosed with congestive heart failure (CHF) and on optimal medical treatment.
Interventions	Participation between a cardiologist, HF nurse, physiotherapist and a psychologist in a HF clinic. The intervention was initiated 14 days after discharge from hospital and continued at 1,3,6, and 12 months post discharge. Follow-up visits included consultation with the cardiologist, HF nurse, physiotherapist and the psychologist. For patients with advanced HF who were unable to come to the HF clinic, the HF nurse arranged a home visit. Components of the program included: medication titration, disease specific education, dietary advice, and lifestyle advice. Patient diaries were also used for data collection and a patient brochure on HF was provided. Telephone counselling by nurse was also available to HF patients. The primary care physician cared for the patient between visits to the clinic. Usual care: by primary care physician only
Outcomes	Mortality, frequency of readmissions, length of hospital stays during readmission, quality of life, and level of self care.
Notes	A physiotherapist set up exercise rehabilitation programs, teaching and monitoring exercise. A psychologist presented advice on how to cope with the disease and performed psychotherapy on persons with a high level of trait anxiety.
Allocation Concealment	Unclear

Appendix 3: GRADE Evidence Profiles

Quality assessment							Summary of findings					
							No of patients		Effect			
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other	Specialized Multidiscip. Care	Usual Care	Relative (95% CI)	Absolute	Quality	Importance
All Cause Mortality												
8	RCTs	no serious limitations	no serious inconsistency	serious	no serious imprecision	none	223/1453 (15.3%)	259/1344 (19.3%)	RR 0.71 (0.56 to 0.91)	56 fewer per 1000 (from 17 fewer to 85 fewer)	⊕⊕⊕O MODERATE	CRITICAL
All Cause Mortality Direct Team Care												
6	RCTs	no serious limitations	no serious inconsistency	serious[1]	no serious imprecision	none	94/617 (15.2%)	126/511 (24.7%)	RR 0.60 (0.47 to 0.76)	99 fewer per 1000 (from 59 fewer to 131 fewer)	⊕⊕⊕O MODERATE	CRITICAL
All Cause Mortality Indirect Team Care												
2	RCTs	no serious limitations	no serious inconsistency	serious[2]	serious[3]	none	129/836 (15.4%)	133/833 (16%)	RR 0.97 (0.77 to 1.21)	5 fewer per 1000 (from 37 fewer to 34 more)	⊕⊕OO LOW	CRITICAL
All Cause Mortality SMCC vs. PCP												
6	RCTs	no serious limitations	no serious inconsistency	serious[4]	no serious imprecision	none	95/575 (16.5%)	114/464 (24.6%)	RR 0.65 (0.51 to 0.84)	86 fewer per 1000 (from 39 fewer to 120 fewer)	⊕⊕⊕O MODERATE	CRITICAL
All Cause mortality SMCC vs. Cardiologist												
2	RCTs	no serious limitations	no serious inconsistency	serious[5]	serious[6]	none	128/878 (14.6%)	145/880 (16.5%)	RR 0.78 (0.46 to 1.32)	36 fewer per 1000 (from 89 fewer to 53 more)	⊕⊕OO LOW	CRITICAL
HF-Specific Mortality												
3	RCTs	no serious limitations	no serious inconsistency	serious[7]	no serious imprecision	none	195/892 (21.9%)	258/892 (28.9%)	RR 0.58 (0.32 to 1.05)	121 fewer per 1000 (from 197 fewer to 14 more)	⊕⊕⊕O MODERATE	IMPORTANT
HF-Specific Mortality Direct Team Care												
2	RCTs	no serious limitations	no serious inconsistency	serious[8]	serious[9]	none	12/132 (9.1%)	30/134 (22.4%)	RR 0.42 (0.21 to 0.83)	130 fewer per 1000 (from 38 fewer to 177 fewer)	⊕⊕OO LOW	IMPORTANT

HF-Specific Mortality Indirect Team Care												
1	RCTs	no serious limitations	no serious inconsistency	serious[10]	serious[11]	none	183/760 (24.1%)	228/758 (30.1%)	RR 0.80 (0.68 to 0.95)	60 fewer per 1000 (from 15 fewer to 96 fewer)	⊕⊕OO LOW	IMPORTANT
HF-Specific Mortality SMCC vs. PCP												
2	RCTs	no serious limitations	no serious inconsistency	serious[8]	serious[9]	none	12/132 (9.1%)	30/134 (22.4%)	RR 0.42 (0.21 to 0.83)	130 fewer per 1000 (from 38 fewer to 177 fewer)	⊕⊕OO LOW	IMPORTANT
HF-Specific Mortality SMCC vs. Cardiologist												
1	RCTs	no serious limitations	no serious inconsistency	serious[10]	serious[11]	none	183/760 (24.1%)	228/758 (30.1%)	RR 0.80 (0.68 to 0.95)	60 fewer per 1000 (from 15 fewer to 96 fewer)	⊕⊕OO LOW	IMPORTANT
All Cause Hospitalization												
7	RCTS	no serious limitations	serious[12]	serious[13]	no serious imprecision	none	527/1175 (44.9%)	564/1222 (46.2%)	RR 1.12 (0.92 to 1.35)	55 more per 1000 (from 37 fewer to 162 more)	⊕⊕OO LOW	IMPORTANT
All Cause Hospitalization Direct Team Care												
5	RCTs	no serious limitations	serious[14]	serious[15]	no serious imprecision	none	194/287 (67.6%)	193/335 (57.6%)	RR 1.31 (0.94 to 1.82)	179 more per 1000 (from 35 fewer to 472 more)	⊕⊕OO LOW	IMPORTANT
All Cause Hospitalization Indirect Team Care												
2	RCTs	no serious limitations	no serious inconsistency	serious[16]	no serious imprecision	none	311/836 (37.2%)	351/833 (42.1%)	RR 0.88 (0.79 to 0.99)	51 fewer per 1000 (from 4 fewer to 88 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
All Cause Hospitalization SMCC vs. PCP												
6	RCTs	no serious limitations	serious[17]	serious[18]	no serious imprecision	none	266/415 (64.1%)	268/464 (57.8%)	RR 1.19 (0.94 to 1.49)	110 more per 1000 (from 35 fewer to 283 more)	⊕⊕OO LOW	IMPORTANT
All Cause Hospitalization SMCC vs. Cardiologist												
1	RCTs	no serious limitations	no serious inconsistency	serious[10]	serious[11]	none	261/760 (34.3%)	296/758 (39.1%)	RR 0.88 (0.77 to 1)	47 fewer per 1000 (from 90 fewer to 0 more)	⊕⊕OO LOW	IMPORTANT
HF-Specific Hospitalization												
6	RCTs	no serious limitations	serious[19]	serious[20]	no serious imprecision	none	216/1197 (18%)	266/1185 (22.4%)	RR 0.86 (0.62 to 1.19)	31 fewer per 1000 (from 85 fewer to 43 more)	⊕⊕OO LOW	IMPORTANT

HF-Specific Hospitalization Direct Team care												
4	RCTs	no serious limitations	serious[21]	serious[20]	no serious imprecision	none	61/361 (16.9%)	60/352 (17%)	RR 1.07 (0.52 to 2.19)	12 more per 1000 (from 82 fewer to 203 more)	⊕⊕OO LOW	IMPORTANT
HF-Specific Hospitalization Indirect Team Care												
2	RCTs	no serious limitations	no serious inconsistency	serious[16]	no serious imprecision	none	156/836 (18.7%)	206/833 (24.7%)	RR 0.75 (0.62 to 0.9)	62 fewer per 1000 (from 25 fewer to 94 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
HF-Specific Hospitalization SMCC vs. PCP												
4	RCTs	no serious limitations	no serious inconsistency[22]	serious[23]	no serious imprecision	none	64/315 (20.3%)	86/305 (28.2%)	RR 0.73 (0.55 to 0.96)	76 fewer per 1000 (from 11 fewer to 127 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
HF-Specific Hospitalization SMCC vs. Cardiologist												
2	RCTs	no serious limitations	serious[24]	serious[25]	serious[26]	none	152/882 (17.2%)	180/880 (20.5%)	RR 1.22 (0.43 to 3.45)	45 more per 1000 (from 117 fewer to 501 more)	⊕OOO VERY LOW	IMPORTANT

[1] 1 study completed in New Zealand, 1 in Netherlands, 2 in Sweden, 1 in the United Kingdom and 1 study in Poland

[2] 1 study completed in Argentina and 1 study completed in the USA

[3] Predominately one large study contributing to the estimate of effect

[4] 2 studies completed in Sweden, 1 in New Zealand, 1 in the United Kingdom, 1 in Poland and 1 in the USA

[5] 1 study completed in The Netherlands and 1 in Argentina

[6] 1 large study contributing 77% to the estimate of the effect

[7] 1 study from Argentina, 1 from Sweden, and one from Poland

[8] 1 study from Poland and one from Sweden

[9] Sample size of both studies small

[10] Study completed in Argentina

[11] Only 1 study contributing to estimate of effect

[12] Inconsistency in direction of effect, confidence intervals do not over lap, magnitude of effect ranges from RR of 0.90 to 2.01

[13] Studies completed in New Zealand, USA, Argentina, 2 in Sweden, UK, and Poland

[14] Studies vary in direction of effect and magnitude of effect ranges from a RR of 1.01 to 2.01, confidence intervals do not overlap

[15] Studies completed in New Zealand, Sweden, UK and Poland

[16] Studies completed in Argentina and USA

[17] Estimates of effect vary in direction, size and confidence intervals do not overlap

[18] Studies from New Zealand, USA, Sweden (2), UK and Poland

[19] Studies vary in size and direction of effect. RR ranges from 0.52 to 2.18

[20] Studies from The Netherlands, New Zealand, USA, Argentina, UK and Poland

[21] Inconsistency in magnitude and direction of effect. RR ranges from 0.52 to 2.67

[22] This evidence was not downgraded for inconsistency because there was only one small study contributing to 2.8% of effect size with a RR of 2.69, which is opposite in direction and magnitude of effect to the other 3 studies in the evidence profile.

[23] Studies from Poland, UK, US and New Zealand

[24] Magnitude and direction of studies differ, confidence intervals do not overlap

[25] Studies completed in The Netherlands and Argentina

[26] One large study contributing approximately 73% to the effect size

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An Evidence-Based Analysis

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About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practising medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

If you are aware of any current additional evidence to inform an existing evidence-based analysis, please contact the Medical Advisory Secretariat: MASinfo.moh@ontario.ca. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html.

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List of Abbreviations

CCT	Confidence interval(s)
MAS	Medical Advisory Secretariat
OR	Odds ratio
OHTAC	Ontario Health Technology Advisory Committee
RCT	Randomized controlled trial
RR	Relative risk
SD	Standard deviation
CI	Confidence Interval

Executive Summary

In August 2008, the Medical Advisory Secretariat (MAS) presented a vignette to the Ontario Health Technology Advisory Committee (OHTAC) on a proposed targeted health care delivery model for chronic care. The proposed model was defined as multidisciplinary, ambulatory, community-based care that bridged the gap between primary and tertiary care, and was intended for individuals with a chronic disease who were at risk of a hospital admission or emergency department visit. The goals of this care model were thought to include: the prevention of emergency department visits, a reduction in hospital admissions and re-admissions, facilitation of earlier hospital discharge, a reduction or delay in long-term care admissions, and an improvement in mortality and other disease-specific patient outcomes.

OHTAC approved the development of an evidence-based assessment to determine the effectiveness of specialized community based care for the management of heart failure, Type 2 diabetes and chronic wounds.

Please visit the Medical Advisory Secretariat Web site at: www.health.gov.on.ca/ohtas to review the following reports associated with the Specialized Multidisciplinary Community-Based care series.

1. *Specialized multidisciplinary community-based care series: a summary of evidence-based analyses*
2. *Community-based care for the specialized management of heart failure: an evidence-based analysis*
3. *Community-based care for chronic wound management: an evidence-based analysis*

Please note that the evidence-based analysis of specialized community-based care for the management of diabetes titled: "Community-based care for the management of type 2 diabetes: an evidence-based analysis" has been published as part of the Diabetes Strategy Evidence Platform at this URL: http://www.health.gov.on.ca/english/providers/program/mas/tech/ohtas/tech_diabetes_20091020.html

Please visit the Toronto Health Economics and Technology Assessment Collaborative Web site at: http://theta.utoronto.ca/papers/MAS_CHF_Clinics_Report.pdf to review the following economic project associated with this series:

Community-based Care for the specialized management of heart failure: a cost-effectiveness and budget impact analysis.

Objective

The objective of this evidence-based review is to determine the effectiveness of a multidisciplinary wound care team for the management of chronic wounds.

Clinical Need: Condition and Target Population

Chronic wounds develop from various aetiologies including pressure, diabetes, venous pathology, and surgery. A pressure ulcer is defined as a localized injury to the skin/and or underlying tissue occurring most often over a bony prominence and caused, alone or in combination, by pressure, shear, or friction. Up to three fifths of venous leg ulcers are due to venous aetiology.

Approximately 1.5 million Ontarians will sustain a pressure ulcer, 111,000 will develop a diabetic foot ulcer, and between 80,000 and 130,000 will develop a venous leg ulcer. Up to 65% of those afflicted by

chronic leg ulcers report experiencing decreased quality of life, restricted mobility, anxiety, depression, and/or severe or continuous pain.

Multidisciplinary Wound Care Teams

The term 'multidisciplinary' refers to multiple disciplines on a team and 'interdisciplinary' to such a team functioning in a coordinated and collaborative manner. There is general consensus that a group of multidisciplinary professionals is necessary for optimum specialist management of chronic wounds stemming from all aetiologies. However, there is little evidence to guide the decision of which professionals might be needed form an optimal wound care team.

Evidence-Based Analysis Methods

Literature Search

A literature search was performed on July 7, 2009 using OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment, and on July 13, 2009 using the Cumulative Index to Nursing & Allied Health Literature (CINAHL), and the International Agency for Health Technology Assessment (INAHTA) for studies pertaining to leg and foot ulcers. A similar literature search was conducted on July 29, 2009 for studies pertaining to pressure ulcers. 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. Articles with an unknown eligibility were reviewed with a second clinical epidemiologist and then a group of epidemiologists until consensus was established.

Inclusion Criteria

- Randomized controlled trials and Controlled clinical Trials (CCT)
- Systematic review with meta analysis
- Population includes persons with pressure ulcers (anywhere) and/or leg and foot ulcers
- The intervention includes a multidisciplinary (two or more disciplines) wound care team.
- The control group does not receive care by a wound care team
- Studies published in the English language between 2004 and 2009

Exclusion Criteria

- Single centre retrospective observational studies

Outcomes of Interest

- Proportion of persons and/or wounds completely healed
- Time to complete healing
- Quality of Life
- Pain assessment

Summary of Findings

Two studies met the inclusion and exclusion criteria, one a randomized controlled trial (RCT), the other a CCT using a before and after study design. There was variation in the setting, composition of the wound care team, outcome measures, and follow up periods between the studies. In both studies, however, the wound care team members received training in wound care management and followed a wound care management protocol.

In the RCT, Vu et al. reported a non-significant difference between the proportion of wounds healed in 6 months using a univariate analysis (61.7% for treatment vs. 52.5% for control; p=0.074, RR=1.19) There was also a non-significant difference in the mean time to healing in days (82 for treatment vs. 101 for control; p=0.095). More persons in the intervention group had a Brief Pain Inventory (BPI) score equal to zero (better pain control) at 6 months when compared with the control group (38.6% for intervention vs. 24.4% for control; p=0.017, RR=1.58). By multivariate analysis a statistically significant hazard ratio was reported in the intervention group (1.73, 95% CI 1.20-1.50; p=0.003).

In the CCT, Harrison et al. reported a statistically significant difference in healing rates between the pre (control) and post (intervention) phases of the study. Of patients in the pre phase, 23% had healed ulcers 3 months after study enrolment, whereas 56% were healed in the post phase (P<0.001, OR=4.17) (Figure 3). Furthermore, 27% of patients were treated daily or more often in the pre phase whereas only 6% were treated at this frequency in the post phase (P<0.001), equal to a 34% relative risk reduction in frequency of daily treatments. The authors did not report the results of pain relief assessment.

The body of evidence was assessed using the GRADE methodology for 4 outcomes: proportion of wounds healed, proportion of persons with healed wounds, wound associated pain relief, and proportion of persons needing daily wound treatments. In general, the evidence was found to be low to very low quality.

Conclusion

The evidence supports that managing chronic wounds with a multidisciplinary wound care team significantly increases wound healing and reduces the severity of wound-associated pain and the required daily wound treatments compared to persons not managed by a wound care team. The quality of evidence supporting these outcomes is low to very low meaning that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Background

In August 2008, the Medical Advisory Secretariat (MAS) presented a vignette to the Ontario Health Technology Advisory Committee (OHTAC) on a proposed targeted health care delivery model for chronic care. The proposed model was defined as multidisciplinary, ambulatory, community-based care that bridged the gap between primary and tertiary care, and was intended for individuals with a chronic disease who were at risk of a hospital admission or emergency department visit. The goals of this care model were thought to include: the prevention of emergency department visits, a reduction in hospital admissions and re-admissions, facilitation of earlier hospital discharge, a reduction or delay in long-term care admissions, and an improvement in mortality and other disease-specific patient outcomes.

OHTAC approved the development of an evidence-based assessment to determine the effectiveness of specialized community based care for the management of heart failure, Type 2 diabetes and chronic wounds.

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Community-based Care for the specialized management of heart failure: a cost-effectiveness and budget impact analysis.

Objective of Analysis

The objective of this evidence-based review is to determine the effectiveness of multidisciplinary care for the management of chronic wounds.

Clinical Need and Target Population

Chronic wounds develop from various aetiologies including pressure, diabetes, venous pathology and surgery. Without adequate management, they pose a significant risk to patient safety and may result in infection, limb loss, sepsis, and possibly death. Community-care nursing services are often required to care for pressure ulcers, diabetic foot ulcers, venous leg ulcers, and non-healing surgical wounds. (1)

A pressure ulcer is defined as a localized injury to the skin/and or underlying tissue occurring most often

over a bony prominence and caused, alone or in combination, by pressure, shear, or friction. Up to 65% of those afflicted by chronic leg ulcers report experiencing decreased quality of life, restricted mobility, anxiety, depression, and/or severe or continuous pain. (2) Those most at risk for developing pressure ulcers include the elderly and critically ill, as well as persons with neurological impairments and others who suffer from conditions associated with immobility.

Prevalence and Incidence

The prevalence of pressure ulcers in Canadian health care facilities is estimated to be 25% in acute care, 29.9% in non-acute care, 22.1% in mixed healthcare settings, and 15.1% in community care. (3) The estimated cost to care for a pressure ulcer in the community is $27,000 Cdn. Moreover, approximately 15% of diabetics will develop a foot ulcer in their lifetime and 14% to 24% of these people will require amputation. (1) The average total cost per amputation in Ontario ranges from $40,000 to &74,000. (1) The prevalence of venous leg ulcers ranges from 0.8% to 1.3% in the general population, and 2% in those over 65 years of age. If effective prevention strategies are not put in place post healing, the recurrence rate is approximately 70%. (1)

Ontario Prevalence and Incidence

Given the prevalence rates cited above, it can be expected that approximately 1.5 million Ontarians will sustain a pressure ulcer, 111,000 will develop a diabetic foot ulcer [based on an estimated 744,000 prevalent cases of diabetes type 2 in 2005 (4)] and between 80,000 and 130,000 will sustain a venous leg ulcer.

Multidisciplinary Wound Care Team

The term ‘multidisciplinary’ refers to multiple disciplines on a team, while ‘interdisciplinary’ refers to such a team functioning in a coordinated and collaborative manner. (5) There is general consensus that a group of multidisciplinary professionals is necessary for optimum specialist management of chronic wounds stemming from all aetiologies.(6) However, there is little evidence to guide the decision of which professionals might be needed to form an optimal wound care team.

Evidence-Based Analysis

Research Question(s)

The purpose of this systematic review is to determine the effectiveness and cost-effectiveness of a community based multidisciplinary wound care team for the management of chronic wounds.

Methods

Literature Search

A literature search was performed on July 7, 2009 using OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment, and on July 13, 2009 using the Cumulative Index to Nursing & Allied Health Literature (CINAHL), and the International Agency for Health Technology Assessment (INAHTA) for studies pertaining to leg and foot ulcers. A similar literature search was conducted on July 29, 2009 for studies pertaining to pressure ulcers. Details of the search strategies are reported in Appendix 1.

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. Articles with an unknown eligibility were reviewed with a second clinical epidemiologist and then a group of epidemiologists until consensus was established.

Inclusion Criteria

- Randomized controlled trials and Controlled clinical Trials (CCT)
- Systematic review with meta analysis
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- The intervention includes a multidisciplinary (two or more disciplines) wound care team.
- The control group does not receive care by a wound care team
- Studies published in the English language between 2004 and 2009

Exclusion Criteria

- Single centre retrospective observational studies

Outcomes of Interest

- Proportion of persons and/or wounds completely healed
- Time to complete healing
- Quality of Life
- Pain assessment

Statistical Analysis

Where appropriate, a meta-analysis was undertaken to determine the pooled estimate of effect of specialized multidisciplinary community-based care for explicit outcomes.

Quality of Evidence

The quality of the body of evidence was assessed as high, moderate, low, or very low according to the GRADE Working Group criteria as presented below. (7)

- Quality refers to the criteria such as the adequacy of allocation concealment, blinding and follow-up.
- Consistency refers to the similarity of estimates of effect across studies. If there are important and unexplained inconsistencies in the results, our confidence in the estimate of effect for that outcome decreases. Differences in the direction of effect, the magnitude of the difference in effect, and the significance of the differences guide the decision about whether important inconsistency exists.
- Directness refers to the extent to which the interventions and outcome measures are similar to those of interest.

As stated by the GRADE Working Group, the following definitions of quality were used in grading the quality of the evidence:

High	Further research is very unlikely to change the confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain

Results of Evidence-Based Analysis

Included studies

The literature search yielded 1,367 citations of which 37 full-text articles were obtained. Of these, two met the inclusion and exclusion criteria, one randomized controlled trial (RCT) and a CCT using a 'before and after' study design. Table 1 reports the quality of evidence by study design included in this report (8). Tables 2 and 3 report the characteristics and design models of the included studies.

There was variation in the setting, composition of the wound care team, outcome measure, and follow up period between the studies. Specifically:

- Vu et al. (9) evaluated a wound care team comprised of a community pharmacist and a nurse to manage leg and pressure ulcers in a nursing home setting.
- Harrison et al. (10) evaluated the effectiveness of a wound care team comprised primarily of nurses to manage leg ulcers in a community setting.

While the outcome measures were similar between studies, insofar as they included healing rates and pain management, the assessment methods differed for each of these outcomes between studies. Vu et al. (9) reported the proportion of wounds healed at 6 months while Harrison et al. (10) reported the proportion of persons with a healed wound at 3 months. Different methods were also used to assess wound associated pain with Vu et al.(9) using the Brief Pain Inventory (BPI) and Harrison et al. using the Short Form McGill Pain Questionnaire. In both studies the wound care team members received training in wound care management and followed a wound care management protocol.

Table 1: Quality of Evidence of Included Studies (Table Title)

Study Design	Level of Evidence†	Number of Eligible Studies
Large RCT, systematic review of RCTs	1	
Large RCT unpublished but reported to an international scientific meeting	1(g)	
Small RCT	2	1
Small RCT unpublished but reported to an international scientific meeting	2(g)	
Non-RCT with contemporaneous controls	3a	1
Non-RCT with historical controls	3b	
Non-RCT presented at international conference	3(g)	
Surveillance (database or register)	4a	
Case series (multisite)	4b	
Case series (single site)	4c	
Retrospective review, modelling	4d	
Case series presented at international conference	4(g)	
	Total	**2**

* RCT refers to randomized controlled trial;

Table 2: Characteristics of Included Studies

Author, Year	Country	Study Design	Sample Size (n)	Mean Age (years)	Type of Wound
Harrison et al, 2005 (10)	Canada	Before/After	Before: 78 After: 180	73	Leg ulcers below the knee, without arterial involvement
Vu et al, 2007 (9)	Australia	RCT	44 nursing homes, 176 residents (342 wounds) <u>Intervention</u> 21 nursing homes, 94 residents (180 wounds) <u>Control</u> 23 nursing homes, 82 residents (162 wounds)	83	25% leg ulcer 75% pressure ulcer

Table 3: Design Details of Included Studies

Author, Year	Population	Intervention and Time to Follow Up	Outcome Measure
Harrison et al, 2005 (10)	▪ Persons newly referred to homecare for leg ulcer(s) management	▪ Primary nursing delivery model with regional service for leg ulcers centralized to 1 agency. ▪ Team members received training in leg ulcer management and followed an evidence-based management protocol. ▪ Follow up: 3months	Primary: ▪ Proportion of patients whose leg ulcers healed within 3 months of admission to study. Secondary: ▪ Pain ▪ Quality of Life ▪ Resource use
Vu et al, 2007 (9)	▪ Persons with leg or pressure wounds. ▪ Excluded those with infected wounds or diabetes, long-term corticosteroid therapy, chemotherapy or treatment with immunosuppressants. ▪ Residents were withdrawn after enrolment if they were admitted to hospital or required wound related medical referral (grafts, infection)	▪ Standardized treatment from a wound care team comprised of trained community pharmacists and nurses. ▪ A standardized treatment protocol was used and training provided on wound care and the protocol to the team members. ▪ Control received usual care. No wound treatment protocol was used. ▪ Follow up: 6 months or until wounds healed.	Primary: ▪ Percentage of wounds healed in each arm, time to wound healing and treatment costs Secondary: ▪ Pain relief defined as a pain score of 0 during the trial period on the Brief Pain Inventory, an 11-point (0-10) numeric scale to assess wound associated ▪ Pain at each visit.

Individual Study Quality Assessment

The individual study quality assessment for each of the included studies is reported in Appendix 2. Vu et al. (9) designed an RCT but failed to use appropriate methods of randomization. Randomization was done at the nursing home level with nursing homes allocated alternately to either treatment or control groups and because of this, there was inadequate allocation concealment. There was also an imbalance in baseline characteristics between groups with wounds in the intervention group more likely to be severe based on mean width and the proportion with moderate or profuse exudate, to be present for less than 1 week at the time of enrolment (age of wound), more painful. Persons in the intervention group were also significantly underweight compared to the control group. Blinding of the outcome assessors was also not followed. Harrison et al. (10) completed a before and after study. Methodological limitations of this study include that the outcome measure was not done independently of the exposure status and an imbalance in the baseline characteristics between the pre and the post phase with more venous leg ulcers in the post phase group than were in the pre phase group. There was also an imbalance in the sample size between treatment phases with 78 persons enrolled in the pre phase and more than twice that (180) in the post phase of the study.

Outcomes

As mentioned previously, the outcome measures between studies included wound healing rate and adequacy of wound-associated pain management. Vu et al. (9) reported the proportion of wounds healed and assessed pain relief using the Brief Pain Inventory (BPI), an 11-point (0-10) numeric scale. Whereas Harrison et al. (10) reported the proportion of persons with a healed ulcer and used the Short Form McGill Pain Questionnaire.

Vu et al. (9) reported a non-significant difference between the proportion of wounds healed in 6 months using a univariate analysis (61.7% for treatment vs. 52.5% for control; p=0.074, RR=1.19) (Figure 1). There was also a non-significant difference in the mean time to healing in days (82 for treatment vs. 101 for control; p=0.095). There was, however, a statistically significant difference in total pain relief between groups. More persons in the intervention group had a BPI score equal to zero at 6 months when compared with the control group (38.6% for intervention vs. 24.4% for control; p=0.017, RR=1.58) (Figure 2). When a multivariate analysis was undertaken, Vu et al. (9) reported significant differences in the relative risk between treatment and control groups (RR 1.73, 95% CI 1.2-2.5; p=.003) indicating a 73% chance of wounds healing in the intervention (team care) group compared to the control (non team care) group

Harrison et al. (10) reported a statistically significant difference in healing rates between the pre (control) and post (intervention) phases of the study. Twenty three (23%) percent of patients in the pre phase had healed ulcers 3 months after study enrolment, whereas 56% were healed in the post phase (P<0.001, OR=4.17) (Figure 3). Both venous and mixed disease ulcers showed significant healing rates in the post phase compared to the pre phase. There was also a reduction in the treatment frequency in the post phase compared to the pre phase. Twenty-seven (27%) percent of patients were treated daily or more often in the pre phase whereas only 6% were treated at this frequency in the post phase (P<0.001) equal to a 34% relative risk reduction in frequency of daily treatments (Figure 4). The authors did not report the results of pain relief assessment.

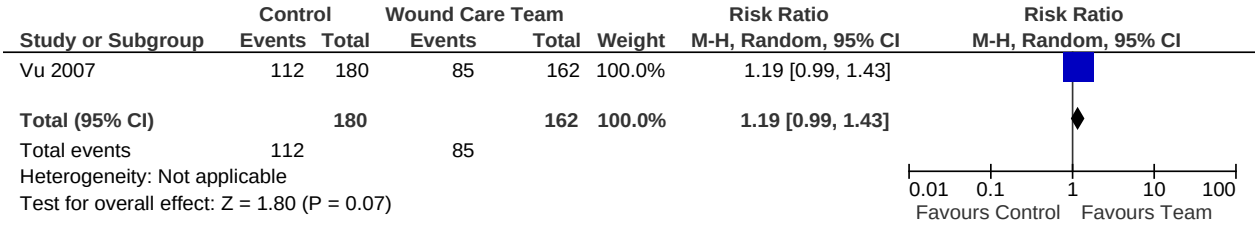

Figure 1: Proportion of Healed Wounds

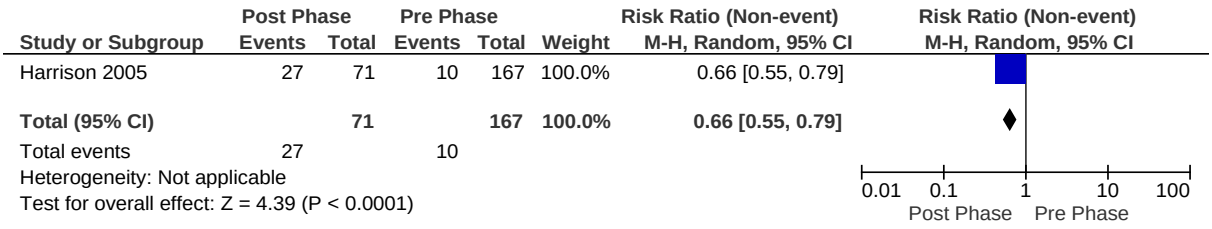

Figure 2: Proportion of Persons with a BPI score = 0

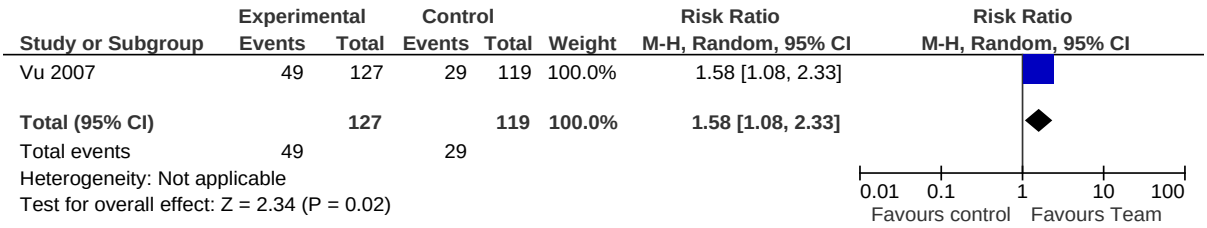

Figure 3: Proportion of Persons with Healed Wounds

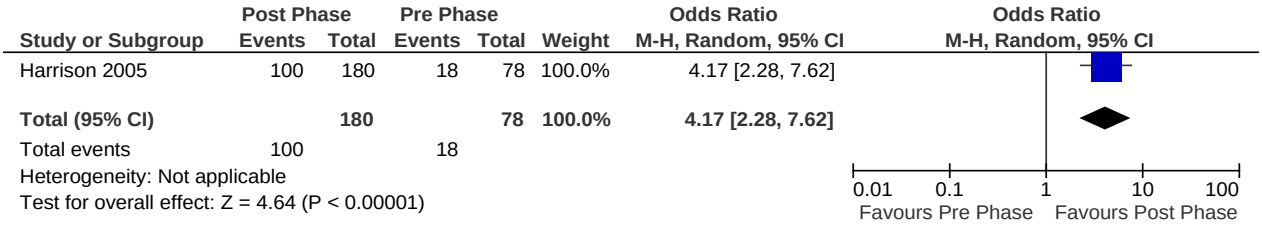

Figure 4: Proportion of Persons needing daily wound treatments

GRADE Quality Evidence

The body of evidence was assessed using the GRADE methodology for four outcomes:

1. proportion of wounds healed,
2. proportion of persons with healed wounds,
3. wound associated pain relief, and
4. proportion of persons needing daily wound treatments.

The Grade evidence profile for each of these outcomes is presented in Table 4. In general, the evidence was found to be low to very low quality.

Economic Analysis

An Ontario-based economic analysis ad budget impact could not be completed because of the low quality of evidence supporting the effectiveness of a wound care team.

Conclusion

The evidence supports that managing chronic wounds with a multidisciplinary wound care team significantly increases wound healing. The evidence also supports that the management of wounds by a multidisciplinary wound care teams reduce the severity of wound-associated pain and required daily wound treatments. The quality of evidence supporting these outcomes is low to very low, meaning that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Table 4: Grade Evidence Profiles

Quality Assessment							Summary of Findings				
							No of Patients		Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Wound Care Team	Usual Care	Relative (95% CI)	Absolute	Quality
Proportion of Wounds Healed (follow-up 6 months; Proportion of wounds healed)											
1[1]	randomised trials	serious[2]	no serious inconsistency	serious[3]	serious[4]	none	112/180 (62.2%)	85/162 (52.5%)	RR 1.19 (0.99 to 1.43)	100 fewer per 1000 (from 5 fewer to 226 more)	⊕OOO VERY LOW
Proportion of Persons with wounds healed (follow-up mean 3 months)											
1	observational studies[5]	serious[6]	no serious inconsistency	no serious indirectness	serious[7]	strong association[8]	100/180 (55.6%)	18/78 (23.1%)	OR 4.17 (2.28 to 7.62)	325 more per 1000 (from 175 more to 465 more)	⊕OOO VERY LOW
Persons with BPI score=0 (follow-up mean 6 months; Brief Pain Inventory9)											
1	randomised trials[1]	serious[2]	no serious inconsistency	serious[3]	serious[4]	none	49/127 (38.6%)	29/119 (24.4%)	RR 1.58 (1.08 to 2.33)	141 more per 1000 (from 19 more to 324 more)	⊕OOO VERY LOW
Proportion of Persons needing daily treatments (follow-up mean 3 months)											
1	randomised trials[1]	serious[2]	no serious inconsistency	serious[3]	serious[4]	none	49/127 (38.6%)	29/119 (24.4%)	RR 1.58 (1.08 to 2.33)	141 more per 1000 (from 19 more to 324 more)	⊕OOO VERY LOW

[1] One Study by Vu et al. 2007
[2] Alternating randomization, lack of allocation concealment
[3] Nursing Home setting not a community-based study
[4] Sparse data, one small study
[5] One study by Harrison et al. 2005
[6] Outcome measure not assessed independent of the exposure status
[7] One study contributing to body of evidence therefore considered sparse data
[8] Relative odds reduction of 76%
[9] 11-point scale (0-10) to assess wound-associated pain

Appendices

Appendix 1: Literature Search Strategies

Final Leg and Foot Ulcer Search – Multidisciplinary Care
Search date: July 7, 2009
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment

Database: Ovid MEDLINE(R) <1996 to June Week 4 2009>
Search Strategy:
1 exp Patient Care Team/ (23639)
2 exp Nursing, Team/ (658)
3 exp Cooperative Behavior/ (13868)
4 exp Interprofessional Relations/ (22628)
5 team*.ti,ab. (37084)
6 (integrat$ or share or shared or sharing).ti,ab. (186507)
7 (multidisciplin$ or multi-disciplin$ or interdisciplin$ or inter-disciplin$ or collaborat$ or cooperat$ or co-operat$ or multi?special$ or interprofessional* or intra-professonal* or interprofessional* or intraprofessional*).ti,ab. (102255)
8 or/1-7 (334716)
9 exp Leg Ulcer/ or exp Diabetic Foot/ (7493)
10 exp Lymphedema/ (2842)
11 ((leg* or foot* or feet or stasis or venous or varicose or arterial or diabet* or ischemic) adj2 (ulcer* or wound* or sore*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (7066)
12 lymphedema.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (2417)
13 ((leg* or foot or feet) adj2 (edema or oedema)).ti,ab. (447)
14 or/9-12 (12289)
15 8 and 14 (774)
16 limit 15 to (english language and humans and yr="2005 - 2009") (241)

Database: EMBASE <1980 to 2009 Week 27>
Search Strategy:
1 exp TEAM NURSING/ (44)
2 exp Cooperation/ (28829)
3 exp TEAMWORK/ or team*.ti,ab. (49616)
4 (integrat$ or share or shared or sharing).ti,ab. (221410)
5 (multidisciplin$ or multi-disciplin$ or interdisciplin$ or inter-disciplin$ or collaborat$ or cooperat$ or co-operat$ or multi?special$ or interprofessional* or intra-professonal* or interprofessional* or intraprofessional*).ti,ab. (124270)
6 or/1-5 (381895)
7 exp Leg Ulcer/ (11145)
8 exp foot ulcer/ or exp leg ulcer/ or exp plantar ulcer/ or exp leg varicosis/ or *diabetic foot/ or exp *leg edema/ (30203)
9 ((leg* or foot* or feet or stasis or venous or varicose or ischemic or arterial or diabet*) adj2 (ulcer* or wound* or sore*)).ti,ab. (7203)
10 ((leg* or foot or feet) adj2 (edema or oedema)).ti,ab. (716)
11 or/7-10 (32794)
12 exp venous stasis/ or exp lymphedema/ (8322)
13 exp Leg/ or exp Foot/ (52228)
14 12 and 13 (454)
15 11 or 14 (33147)
16 6 and 15 (886)
17 limit 16 to (human and english language and yr="2005 - 2009") (269)

Multidisciplinary Care – Leg and Foot Ulcers – CINAHL Search Strategy

Monday, July 13, 2009

#	Query	Results
S14	s13	231
S13	S6 and S12	542
S12	S7 or S8 or S9 or S10 or S11	7033
S11	leg edema or foot edema or lymphedema or leg oedema or foot oedema	1,043
S10	leg* ulcer* or foot* ulcer* or feet ulcer* or stasis ulcer* or venous ulcer* or varicose ulcer* or arterial ulcer* or diabet* ulcer* or ischemic ulcer*	4,141
S9	(MH "Lymphedema+")	971
S8	(MH "Diabetic Foot")	2,970
S7	(MH "Leg Ulcer+")	5,650
S6	S1 or S2 or S3 or S4 or S5	124,190
S5	integrat* or team* or share or shared or sharing or multidisciplin* or multi-disciplin* or interdisciplin* or inter-disciplin* or collaborat* or cooperat* or co-operat* or multi-special* or multispecial* or interprofessional* or inter-professional or intra-professonal* or interprofessional* or intraprofessional*	122,154
S4	(MH "Interprofessional Relations+")	11,048
S3	(MH "Cooperative Behavior")	1,719
S2	(MH "Team Nursing")	299
S1	(MH "Multidisciplinary Care Team+")	13,992

Final Search – Pressure Ulcers – Multidisciplinary Care

Search date: July 20, 2009
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, CINAHL, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment

Database: Ovid MEDLINE(R) <1950 to July Week 2 2009>
Search Strategy:
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1 exp Patient Care Team/ (43358)
2 exp Nursing, Team/ (1798)
3 exp Cooperative Behavior/ (15940)
4 exp Interprofessional Relations/ (41288)
5 team*.ti,ab. (58145)
6 (integrat$ or share or shared or sharing).ti,ab. (278305)
7 (multidisciplin$ or multi-disciplin$ or interdisciplin$ or inter-disciplin$ or collaborat$ or cooperat$ or co-operat$ or multi?special$ or interprofessional* or intra-professonal* or interprofessional* or intraprofessional*).ti,ab. (161442)
8 or/1-7 (526197)
9 exp Pressure Ulcer/ (7915)
10 ((bed or pressure or decubit*) adj2 (sore* or ulcer* or wound*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (10488)
11 bedsore*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (298)
12 or/9-11 (10565)
13 8 and 12 (659)
14 limit 13 to (english language and humans and yr="2004 -Current") (203)

Database: EMBASE <1980 to 2009 Week 29>
Search Strategy:
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1 exp TEAM NURSING/ (11)
2 exp Cooperation/ (13977)
3 exp TEAMWORK/ or team*.ti,ab. (43431)
4 (integrat$ or share or shared or sharing).ti,ab. (221977)
5 (multidisciplin$ or multi-disciplin$ or interdisciplin$ or inter-disciplin$ or collaborat$ or cooperat$ or co-operat$ or multi?special$ or interprofessional* or intra-professonal* or interprofessional* or intraprofessional*).ti,ab. (124516)
6 or/1-5 (369073)
7 exp Decubitus/ (4335)
8 ((bed or pressure or decubit*) adj2 (sore* or ulcer* or wound*)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (4870)
9 bedsore*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (168)
10 or/7-9 (6243)
11 6 and 10 (371)
12 limit 11 to (human and english language and yr="2004 -Current") (148)

CINAHL

#	Query	Limiters/Expanders	Results
S11	S10	Limiters - Published Date from: 01/2004-12/2009	275
S10	S6 and S9		2
S9	S7 or S8		71
S8	bedsore* or bed sore* or pressure ulcer* or decubit* or pressure wound*		6,886
S7	(MH "Pressure Ulcer")		5,904
S6	S1 or S2 or S3 or S4 or S5		1,498
S5	integrat* or team* or share or shared or sharing or multidisciplin* or multi-disciplin* or interdisciplin* or inter-disciplin* or collaborat* or cooperat* or co-operat* or multi-special* or multispecial* or interprofessional* or inter-professional or intra-professonal* or interprofessional* or intraprofessional*		122,601
S4	(MH "Interprofessional Relations+")		11,086
S3	(MH "Cooperative Behavior")		1,722
S2	(MH "Team Nursing")		300
S1	(MH "Multidisciplinary Care Team+")		14,053

Appendix 2: Individual Study Assessment

Table: Quality assessment for Vu et al. 2007 (9)

Study	Design	N	Adequate randomization methods	Baseline characteristics comparable	Adequate Allocation Concealment	Blinding of outcome assessors	Sample Size Calculation	Losses to Follow up (%)	#ITT
Vu et al, 2007 (11)	RCT	83	x	✓ Except for severity, age of wound and level of pain and weight.	x	x	✓	3.2%	✓

Table: Quality assessment for Harrison et al. 2005 (10)

Study	Design	Inclusion/ Exclusion Criteria Stated	Consecutive Sampling Used	Similar Baseline Characteristics in Groups?	Treatment Valid and Reliable?	Reliable and Valid Outcome Measure Used?	Outcome Measure Done Independently of Exposure Status?	Duration of Follow-Up Adequate?	Loss to Follow-Up, %
Harrison et al. 2005 (10)	Observational Before/After	✓	✓	✓ Except for cause of leg ulcers. Great number of venous disease leg ulcers in new model than in old mode.	✓	✓	x	✓	**8%** **10 % in before phase** **7% in after phase**

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