Performance and Evaluation of Quality Indicators in the Management of Patients with Heart Failure

QI- HEART

By

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A thesis submitted in conformity with the requirements for the degree of Masters of Science

Institute of Medical Science

University of Toronto

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Masters of Science
Institute of Medical Science
University of Toronto
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Abstract

The systematic evaluation of evidence-based quality indicators (QIs) in patients with heart failure (HF) is important to assess the quality of care provided to these patients. Guideline-recommended therapies have proven to reduce clinical event rates, however quality of life (QoL) is frequently missed as an endpoint in the measurement of treatment efficacy. We hypothesized that there was high adherence to the Canadian Cardiovascular Society (CCS) outpatient QIs, and the adherence was positively associated with QoL. We evaluated the performance of the outpatient QIs extracted from the CCS recommendations and examined their relationship with patient-reported QoL, measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the Kansas City Cardiomyopathy Questionnaire (KCCQ). We found that there was high adherence (89%) to evidence-based QIs and patients reported a clinically significant improvement in QoL (>5 points), however, there appears to be no association between the performance of these indicators and patient-reported QoL.
ACKNOWLEDGEMENTS

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To our research students - Vianca Evangelista and Marienell Talla – you ladies were a key piece in this study and I would not have made it without your help and hard work. I thank you for every minute that you dedicated to this project.

Lastly, I want to express my profound gratitude to my family for providing me with unfailing support and continuous encouragement throughout my entire life and through this thesis process. This accomplishment would not have been possible without you and your continuous texts messages, phone calls and long nights conversations. Thank you for showing me again that distance is just a number.
CONTRIBUTIONS

The extensive data collection was completed with the contribution of Vianca Evangelista, who meticulously reviewed patients’ charts and EMRs. Marienell Talla contributed with the data entry and questionnaires scoring.
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Appendix B. Kansas City Cardiomyopathy Questionnaire (KCCQ)
## LIST OF ABBREVIATIONS

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACC</td>
<td>American College of Cardiology</td>
</tr>
<tr>
<td>ACEI</td>
<td>Angiotensin Converting Enzyme Inhibitor</td>
</tr>
<tr>
<td>ADHERE</td>
<td>Acute Decompensated Heart Failure National Registry</td>
</tr>
<tr>
<td>ADHF</td>
<td>Acute Decompensated Heart Failure</td>
</tr>
<tr>
<td>AHA</td>
<td>American Heart Association</td>
</tr>
<tr>
<td>ARB</td>
<td>Angiotensin Receptor Blocker</td>
</tr>
<tr>
<td>ARNI</td>
<td>Angiotensin Receptor Neprilysin Inhibitor</td>
</tr>
<tr>
<td>BNP</td>
<td>B-type natriuretic peptide</td>
</tr>
<tr>
<td>BP</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>BUN</td>
<td>Blood Urea Nitrogen</td>
</tr>
<tr>
<td>BW</td>
<td>Body Weight</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary Artery Disease</td>
</tr>
<tr>
<td>CCS</td>
<td>Canadian Cardiovascular Society</td>
</tr>
<tr>
<td>CRUSADE</td>
<td>Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines</td>
</tr>
<tr>
<td>CTA</td>
<td>Computed tomographic angiography</td>
</tr>
<tr>
<td>CXR</td>
<td>Chest X-Ray</td>
</tr>
<tr>
<td>ECHO</td>
<td>Echocardiogram</td>
</tr>
<tr>
<td>ED</td>
<td>Emergency Department</td>
</tr>
<tr>
<td>EKG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>EMRs</td>
<td>Electronic Medical Records</td>
</tr>
<tr>
<td>HF</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>HFrEF</td>
<td>Heart Failure with Reduced Ejection Fraction</td>
</tr>
<tr>
<td>HFpEF</td>
<td>Heart Failure with Preserved Ejection Fraction</td>
</tr>
<tr>
<td>K</td>
<td>Potassium</td>
</tr>
<tr>
<td>KCCQ</td>
<td>Kansas City Cardiomyopathy Questionnaire</td>
</tr>
<tr>
<td>LV</td>
<td>Left Ventricular</td>
</tr>
<tr>
<td>LVEF</td>
<td>Left Ventricular Ejection Fraction</td>
</tr>
<tr>
<td>MLHFQ</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
</tr>
</tbody>
</table>
MPI                     Radionuclide Myocardial Perfusion Imaging
MRA                   Mineralocorticoid Receptor Antagonist
Na                    Sodium
NP                     Natriuretic peptide
NSTEMI                Non-ST Elevation Myocardial Infarction
NT-proBNP             Amino-terminal pro-b-type natriuretic peptide
NYHA                New York Heart Association
OPTIMIZE –HF  Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure
QIs                   Quality Indicators
QoL                   Quality of Life
RCTs                  Randomized Control Clinical Trials
1. Background and Rationale

1.1 Heart Failure

The Canadian Cardiovascular Society (CCS) defines Heart Failure (HF) as “a complex syndrome in which abnormal heart function results in, or increases the subsequent risk of, clinical symptoms and signs of low cardiac output and/or pulmonary or systemic congestion”. (1) The guidelines highlight that “it is largely a clinical diagnosis that is based on a careful history and physical examination.” As HF is a syndrome and not a disease, its diagnosis relies on a clinical examination and can be challenging. (2)

Heart Failure is a major public health issue with a high worldwide prevalence that carries substantial morbidity and mortality. (3) It is estimated that there are 600,000 Canadians living with HF (4) and 50,000 new patients are diagnosed each year. (5) It is the leading cause of hospitalization in Canada, in patients over 65 years old (6)(7)(2,8), and it is associated with a high mortality rate of up to 50% annually. (1) Once a patient has been diagnosed with HF, the survival estimate is 50% at 5 years and 10% at 10 years. (2) The Framingham Heart Study(8)(9) showed significant mortality in these patients, with 10% within 30 days, 20-30% within 1 year and 45-60% mortality within 5 years after initial diagnosis of HF. And after hospitalization the prognosis worsens, with an increase of up to 75% mortality within 5 years.

HF is an emerging epidemic due to the rise of hospitalizations and poor prognosis for these patients, despite the development of effective therapies. (10) Furthermore, there are substantial economic costs associated with HF as a consequence of long and frequent hospitalizations, and emergency room visits. The result is direct costs of more than 2.8 billion dollars per year in Canada. (4) HF admissions are one of the strongest prognostic predictors for increased mortality. Half of the patients that are admitted for HF have a preserved ejection fraction (EF) and their prognosis after discharge is similar to those with reduced EF. (11) HF admissions are frequently used as a quality metric and an outcome measure in clinical trials.
The Canadian Institute for Health Information reported in 2012 that HF patients had the highest readmission rate with 21% being readmitted to acute inpatient care within 30 days. The most frequent condition for readmission was the same condition as the index case. Similarly, HF is the second medical condition with the highest Emergency Department (ED) return volume and a return rate of 11.4%. The median length of stay (LoS) for patients with HF in Canada is 8 days, \( (12) \) compared to the US median LoS of 4 days,\( (11) \) which is attributable to the complexity and multiple comorbidities of these patients that are difficult to manage during admission.

A study on the trends in the incidence of HF in Ontario \( (13) \) showed that the incidence started to decline since the late 1990s, which reflects the fact that the burden of HF hospitalizations are related to persisting difficulties in managing the existing condition, rather than an increasing number of new cases of HF.\( (2) \) This study also demonstrated that although survival after HF diagnosis remains quite poor, improvements have been detected, \( (13) \) which coincides with major changes in the treatment of HF. On the other hand, latest reports show an increase of the proportion of patients with HFpEF,\( (2,3)(14) \) for which there is no specific treatment, \( (15)(16) \) hence its prevalence will likely increase in the next few years, urging the need for new therapeutic approaches.

The causes of death in HF can be challenging to identify. Cardiovascular deaths are less frequent among subjects with preserved EF, with previous studies showing an approximate 49% due to non-cardiovascular death versus coronary disease with 43% for subjects with reduced EF.\( (2) \) This distribution towards non-cardiovascular causes corresponds with the major burden of comorbid conditions in HF and is important for the management of these patients and the interpretation of clinical outcomes, which suggest that indeed HF is an epidemic of hospitalizations among patients who now live longer with the disease.\( (2,10) \)

### 1.1.1 Pathophysiology, Clinical Presentation, Diagnosis and Treatment of HF

HF can result from abnormalities of systolic and diastolic function. The diastolic left ventricular (LV) dysfunction is the inability of the left ventricle to dilate appropriately and allow for the normal ventricular filling.\( (17) \) On the other hand, in the systolic dysfunction there is reduced cardiac contractility, mostly due to coronary artery disease, dilated cardiomyopathy, valvular heart disease, hypertensive heart disease, toxin-induced cardiomyopathy such as alcohol, and congenital heart disease. Ischemic heart disease continues to be the most important risk factor for
HF. In the years that follow a myocardial infarction, more than one-third of patients will develop HF, and ischemia has been documented as the primary cause of hospitalization in 15% of the patients.(3,18)

Pathophysiologically, in HFrEF the early dysfunction begins after the myocardium has been injured and the neurohormonal mechanisms are activated to compensate for the failing heart. To restore the circulating volume and contractility after the myocardial insult, there is activation of the renin-angiotensin system, the sympathetic nervous system and secretion of vasopressin. These hormones will begin a progressive LV remodeling process that causes myocyte necrosis and fibrosis. The circulatory effects of the LV hypertrophy due to poor contractility are evidenced in the low stroke volume and depressed cardiac output that these patients have, (19) which correlates with the symptoms of exercise intolerance such as dyspnea, fatigue with effort and lightheadedness. (17) These patients are especially vulnerable to the development of pulmonary edema(17). Congestive symptoms such as peripheral edema, orthopnea and distended neck veins indicate an elevated LV filling pressure as a result of increased resistance to the LV inflow. (20)Although these neurohormonal pathways initially are compensatory and beneficial, eventually they are deleterious, and neurohormonal modulation is the basis for modern medical treatment of HF. (21)

The left ventricular ejection fraction (LVEF) enables the classification of HF with preserved (HFpEF) or reduced EF (HFrEF). Different arbitrary thresholds have been recommended, mostly determined by imaging studies with intrinsic variability. (22) The threshold of 55% was recommended in the American Society of Echocardiography guidelines, then the American Heart Association (AHA) and American College of Cardiology (ACC) guidelines (23) recommended 50% as a cutoff, which was used in the Framingham Heart Study (8) and Olmsted County Study. (2) The Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) registry used 40% as the cut point, (2) as did the Acute Decompensated Heart Failure National Registry (ADHERE) database, (24) and the current recommendations by the CCS. (25)

There is a wide spectrum of potential clinical manifestations of HF. Most patients have signs and symptoms of fluid overload and pulmonary congestion, including dyspnea, orthopnea, and paroxysmal nocturnal dyspnea. Patients with right ventricular failure have jugular venous
distention, peripheral edema, hepato-splenomegaly, and ascites. Others, however, do not have congestive symptoms but signs and symptoms of low cardiac output, including fatigue, exercise intolerance, cachexia, and renal hypoperfusion. (26,27) (28)(29)

The New York Heart Association (NYHA) classification is a symptoms-based system created in 1928 and subsequently revised, that provides a standardized functional capacity classification for patients with HF. (30)(31) In this clinician-assigned scheme, the patients are classified based on their limitations to perform daily activities due to their HF symptoms. The system consists of four categories, with higher class indicating more severe symptoms and increased functional limitation. Clinicians assign a NYHA class based on the interpretation of patient-reported symptoms, clinical evaluation and results from cardiac function assessments. (26) It correlates fairly well with prognosis, so it remains as a good routine clinical prognostic marker since functional capacity is a powerful determinant of outcome in these patients. The following table shows a summary of this classification:

**Table 1. New York Association (NYHA) Heart Failure Symptom Classification System**

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Level of Impairment</th>
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<tbody>
<tr>
<td>I</td>
<td>No symptom limitation with ordinary physical activity</td>
</tr>
<tr>
<td>II</td>
<td>Ordinary physical activity somewhat limited by dyspnea (e.g., long-distance walking, climbing two flights of stairs)</td>
</tr>
<tr>
<td>III</td>
<td>Exercise limited by dyspnea with moderate workload (e.g., short-distance walking, climbing one flight of stairs)</td>
</tr>
<tr>
<td>IV</td>
<td>Dyspnea at rest or with very little exertion</td>
</tr>
</tbody>
</table>

Clinical diagnosis of HF is often unreliable and additional investigations are needed to confirm the diagnosis, including an electrocardiogram (EKG), chest X-Ray (CXR) and brain natriuretic peptide (BNP)/amino-terminal pro-B-type natriuretic peptide (NT-proBNP).

BNP/NT-proBNP demonstrated 90% sensitivity and specificity for HF, (32) their levels are increased and correlate well with ventricular wall stress and severity of the condition, and decrease as the patient reaches a compensated state. (27) These biomarkers are used to exclude or confirm the diagnosis of HF, especially when is unclear during the initial assessment. (32–34)
The addition of testing for BNP/NT-proBNP to standard clinical assessment has been shown to be valuable for an accurate and efficient diagnosis and prognosis of HF, and its use may be associated with improved clinical outcomes.\(^{(34,35)}\)\(^{(36)}\) When added to a comprehensive clinical assessment, BNP and NT-proBNP are both incrementally useful for the diagnosis of ADHF, and both are endorsed in current medical guidelines for HF evaluation.\(^{(23,37)}\)

Echocardiography-Doppler (ECHO) examination is indicated for the evaluation of HF and categorized as a Class I recommendation in the HF guidelines.\(^{(23,38)}\) ECHO can assess systolic and diastolic function, provide meaningful prognostic information, severity of hypertrophy, and more importantly, distinguish between HFpEF and HFrEF, that is used in the clinical decision-making. \(^{(27)}\)

Acute decompensated HF (ADHF) is the “gradual or rapid change in heart failure signs and symptoms resulting in a need for urgent therapy”.\(^{(2)}\) This definition comprises 3 clinical situations: worsening chronic HF, new onset HF, and advanced HF. ADHF constitutes one cause among several causes of hospitalization in patients with HF. If the patient develops ADHF, the pharmacologic management is guided by the patient's hemodynamic status, treating fluid overload, hypoperfusion or both. Intravenous (IV) loop diuretics are the mainstay of ADHF treatment despite conflicting data regarding mortality and morbidity benefit. \(^{(39)}\) The unmanaged effects of rapid diuresis, such as electrolyte imbalances and renal dysfunction, may lead to prolonged hospitalization, so electrolytes and serum creatinine should be monitored frequently.\(^{(23)}\)

Evidence has demonstrated the importance of proper discharge planning, including treating exacerbation factors, achieving optimal volume status, optimizing pharmacologic therapy and transitioning to outpatient therapy. \(^{(21)}\)\(^{(23)}\) Written instructions and educational material for patients and caregivers are recommended at discharge, with details on the activity level, diet, medications, follow up instructions, weight monitoring and what to do if the symptoms worsen.\(^{(23)}\) Moreover, there is documented benefit of initiating mortality-lowering oral therapy during hospital admission, and discharge support that includes a multidisciplinary, team-based approach that deals with medications, patient education, follow up planning, and coordination of information and resources.\(^{(40)}\)
The treatment of HF includes non-pharmacological and pharmacological therapies. Non-pharmacological management is as important as prescribing appropriate medications. Dietary sodium and fluid restrictions should be implemented in all patients with HF in order to lessen congestion and decrease the need for diuretics. There have been previous studies suggesting that moderate fish consumption (1–2 servings per week) is associated with a lower incidence of HF (both systolic and diastolic); however, this has not been consistently reported. Although omega-3 supplementation seems to improve cardiovascular death, there have not been significant differences in lipid profiles and in the incidence of sudden cardiac death. Patient education plays a critical role in understanding the importance of complying with recommended medications, interventions, and lifestyle changes (activity, diet, sodium restriction), and bridging the transition from hospital to home for the patients that have been admitted. Self-management strategies should be encouraged to closely monitor general health status and to detect early signs of worsening HF. Seeking appropriate early medical attention in the outpatient setting may avoid unnecessary readmissions. The patient should be aware that partial or total recovery of LV function is possible and that HF is not always a progressive and fatal condition when properly treated. Smoking cessation and regular physical activity is recommended using a program tailored to suit the individual, and cardiac rehabilitation can improve exercise tolerance and symptoms, as well as the reduction and prevention of skeletal muscle atrophy.

The blockade of the renin-angiotensin-aldosterone system (RAAS) is the cornerstone of the medical treatment for HF, which consists in a judicious management of preload, while minimizing afterload, and involves some degree of reversal of maladaptive cardiac remodeling and prevention of life-threatening arrhythmias. Current pharmacological therapies significantly reduce morbidity and mortality in patients with reduced EF of less than 40%, as demonstrated in randomized control clinical trials. All patients with LV systolic dysfunction or patients with a history of myocardial infarction should be treated with an Angiotensin Converting Enzyme Inhibitor (ACEI) unless they have a contraindication or intolerance and the dose should be titrated to the maximum tolerated dose or the target dose. One of the challenges of HF therapy is achieving that 'target dose' of a medication. For ACEIs, pushing to these target doses often means risking hypotension, worsening renal function, and hyperkalemia. Previous evidence has shown that, despite the decrease in hospitalization rates for patients with
high dose of ACEIs, the decrease in mortality rate is not significant.(53)(54)(55) Thus, it is recommended to titrate afterload reduction as much as possible to at least the target dose; however, if patients develop symptomatic hypotension or worsening kidney function, the medication should be kept at the dose not associated with such adverse reactions, hence having a patient on even a very low-dose of ACEI is better than no ACEI at all. ACEIs are often discontinued due to 'intolerance.' A mild (<30%) increase in serum creatinine is expected, so renal dysfunction should not immediately prohibit the use of an ACEI.(56) The most common side effect prompting discontinuation is the ACEI-induced cough, which occurs in up to 35% of patients,(57) and that warrants a switch of medication to an Angiotensin Receptor Blocker (ARB). However, the clinician must be discerning in diagnosing an ACEI-associated cough that is not wheeze or cough from pulmonary congestion from HF.

ARBs have not been shown to be superior to ACEIs, (58)(59)(60) however they are the best option for the treatment of patients with contraindications to ACEIs. Both, ACEIs and ARBs can be titrated quickly to achieve target BP and target doses, making them an ideal medication to initiate treatment in patients with newly diagnosed HF. With both medications, serum potassium (K) concentration levels should be checked ideally on day 3 and day 7 as well as monthly for the first 3 months.(1,23)(25) With respect to ACEI plus ARB combination therapy, the evidence for the use of an ACEI versus an ARB, shows that ACEIs and ARBs are equivalent in terms of outcomes, and that the combination may actually lead to worse outcomes. (61)

ACEI should be used in combination with beta blockers in most patients and either agent may be started first. Carvedilol, metoprolol, and bisoprolol, have been shown to improve survival,(62,63) and they should be initiated before hospital discharge or on an outpatient basis at a low dose and titrated slowly (every 1-2 weeks) to target levels or maximally tolerated doses, to prevent decompensation of cardiac function. All stable patients with reduced LVEF should receive a beta blocker unless it is contraindicated, as occurs in patients with severe bronchospasm and hypotension. As discussed with ACEIs and ARBs, guidelines recommend titrating beta blockers to 'target dosages’, however, a 2009 meta-analysis found that there was no significant difference in effect on mortality between low and high dose trials - with 'high dose' defined as >50% of patients achieving target dose. (64)
Mineralocorticoid Receptor Antagonist (MRA) therapy in the form of spironolactone and eplerenone have also shown a reduction in mortality and admissions, (65)(66)(67) preventing sodium (Na) and water retention, endothelial dysfunction, and myocardial fibrosis. Diligent monitoring of serum K levels is mandatory since these patients can develop hyperkalemia, they should be avoided in patients with a creatinine level higher than 2.5 mg/dL.(21,37) The CCS recommends the addition of MRA therapy as part of the triple therapy for HF patients with EF<40%, typically in patients with continuing HF symptoms and once the ACEI titration is finished.(25) Lastly, current medical guidelines specifically recommend against therapy consisting of an ACEI plus an ARB and a MRA.(21)

The newer combination of valsartan/sacubitril (LCZ696), which is an Angiotensin Receptor Neprilysin Inhibitor (ARNI), have proven to be superior to ACEI in reducing the risk of death and admissions for HF, (68) and has recently been added to the CCS recommendations.(25) It is recommended as a replacement for ACEI for patients with HFrEF who remain symptomatic despite optimal treatment with ACEI, beta blocker and MRA.(69)

There are other medications for the management of symptoms in HF, such as diuretics and digoxin, however these have not shown to improve mortality. (37) On the other hand, approximately 50% of patients with HF die suddenly, so implantation of an implantable cardioverter defibrillator (ICD) can improve survival in certain subsets of patients and has been shown to be superior to antiarrhythmic drug therapy in preventing sudden death.(70)

Unfortunately, there is no therapy for HF with preserved EF that has been shown to improve survival.(15,16) Hence, current treatments should focus on managing predisposing and exacerbating conditions, such as hypertension and atrial fibrillation, and volume status.
The table below shows the guideline-recommended HF medications and doses for patients with an EF<40%. (25,37)

**Table 2. Evidence-based HF medications and doses for patients with LVEF<40%**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Start Dose</th>
<th>Target Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACEIs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enalapril</td>
<td>1.25 – 2.5 mg BID</td>
<td>10 mg BID</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>2.5 – 5 mg OD</td>
<td>20-35 mg OD</td>
</tr>
<tr>
<td>Perindopril</td>
<td>2 – 4 mg OD</td>
<td>4 – 8 mg OD</td>
</tr>
<tr>
<td>Ramipril</td>
<td>1.25 – 2.5 mg BID</td>
<td>5 mg BID</td>
</tr>
<tr>
<td><strong>Beta blockers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bisoprolol</td>
<td>1.25 mg OD</td>
<td>10 mg OD</td>
</tr>
<tr>
<td>Carvedilol</td>
<td>3.125 mg BID</td>
<td>25 mg BID</td>
</tr>
<tr>
<td><strong>ARBs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valsartan</td>
<td>40 mg BID</td>
<td>160 mg BID</td>
</tr>
<tr>
<td>Candesartan</td>
<td>4 mg OD</td>
<td>32 mg OD</td>
</tr>
<tr>
<td><strong>MRAs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spironolactone</td>
<td>12.5 mg OD</td>
<td>50 mg OD</td>
</tr>
<tr>
<td>Eplerenone</td>
<td>25 mg OD</td>
<td>50 mg OD</td>
</tr>
<tr>
<td><strong>ARNIs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacubitril/Valsartan</td>
<td>24/26 mg BID</td>
<td>97/103 mg BID</td>
</tr>
</tbody>
</table>

So, not only are these patients at increased risk of death, but their quality of life (QoL) is also significantly impacted. The prevalence of depression among HF patients ranges from 20% to 34%, and it has been reported in almost half of NYHA class IV patients (71) with consequent worse outcomes, including increase in risk of death, heart transplantation, or other cardiac events. (71,72) Sexual dysfunction, on the other hand, may be significantly under-reported in HF patients; with fear of exertion during intercourse being more common than erectile dysfunction, and patients being much less likely to participate in sexual intercourse after the diagnosis of HF; (73) however, the physical demands of intercourse are usually well tolerated by NYHA class I-III patients. (74) In order to improve QoL in these patients, screening for and treating depression and sexual dysfunction can be quick and non-invasive and can also improve morbidity.
The multidisciplinary approach to the treatment of HF with a focus on patient education and medication adherence is of the utmost importance. Early referral to an advanced HF clinic for an optimal medication regimen, in particular, use of an ACEI/ARB, a beta blocker, and a MRA, can significantly reduce mortality in patients with systolic HF; (75) (76) combined with a sensible use of diuretics and digoxin, morbidity can also be substantially reduced. The strong evidence supporting the benefits of the above medical therapies has been translated into actions and referred to in medical guidelines.

1.1.2 Medical Guidelines

Medical guidelines are systematically developed recommendations to assist healthcare practitioners with clinical decisions for specific patients' circumstances. They are considered to be the best representation of evidence-based medicine. (77) Nonetheless, these recommendations always imply not only an evaluation of the evidence but also a personal judgment that takes into account organizational preferences, risks and benefits of specific medical interventions. Thus, evidence-based medicine is an integration of individual clinical expertise and the best available external clinical evidence.

Guidelines and recommendations must indicate whether the evidence is high quality and the desirable effects clearly outweigh the undesirable effects. Desirable effects include reduction in morbidity and mortality, improvement in QoL, reduction in the burden of treatment, and reduced resource utilization. Undesirable consequences include adverse effects that have a deleterious impact on morbidity, mortality, or QoL or increase use of resources. (78,79)

The American College of Cardiology (ACC) and the American Heart Association (AHA) use a grading system based on the level of evidence and class of recommendation. (77) Depending on the types of research studies and expert consensus that support the recommendation, the level of evidence is classified as follows in table 3.
Table 3. Classification of Levels of Evidence by ACC/AHA

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Recommendation based on evidence from multiple randomized clinical trials or meta-analyses.</td>
</tr>
<tr>
<td>B</td>
<td>Recommendation based on evidence from a single randomized trial or nonrandomized studies.</td>
</tr>
<tr>
<td>C</td>
<td>Recommendation based on expert opinion, case studies, or standards of care.</td>
</tr>
</tbody>
</table>

The class of recommendation indicates the strength of a specific recommendation, taking into account the risks and benefits identified by the evidence, and the presence of conflicting findings among multiple studies. The classes of recommendations are:

Table 4. Classes of Recommendations by ACC/AHA

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>There is evidence and/or agreement that a given procedure or treatment is useful and effective.</td>
</tr>
<tr>
<td>Class II</td>
<td>There is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.</td>
</tr>
<tr>
<td>Class IIa</td>
<td>The weight of evidence/opinion is in favor of usefulness/efficacy.</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Usefulness/efficacy is less well established by evidence/opinion.</td>
</tr>
<tr>
<td>Class III</td>
<td>There is evidence and/or agreement that the procedure or treatment is not useful/effective and in some cases may be harmful.</td>
</tr>
</tbody>
</table>

The CCS adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) scale in 2010, for rating the strength of recommendations and the quality of evidence. The GRADE system classifies the quality of evidence in high, moderate, low and very low. (79)
Table 5. Quality of Evidence by the GRADE System Adopted by CCS

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High quality</td>
<td>Further research is very unlikely to change confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Moderate quality</td>
<td>Further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>Low quality</td>
<td>Further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate.</td>
</tr>
<tr>
<td>Very low quality</td>
<td>Any estimate of effect is very uncertain.</td>
</tr>
</tbody>
</table>

The strength of the recommendations by the GRADE system can be:

Table 6. Strength of Recommendations by the GRADE System

<table>
<thead>
<tr>
<th>Strength</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>When the desirable effects of an intervention clearly outweigh the undesirable effects, or clearly do not.</td>
</tr>
<tr>
<td>Weak</td>
<td>When the benefits-risks are less certain because of low quality evidence or the evidence suggests that desirable and undesirable effects are closely balanced.</td>
</tr>
</tbody>
</table>

Adherence to guidelines and treatments at optimal doses improve survival in patients with cardiovascular disease, and is associated with lower mortality rates, in patients with CAD(80)(81) and acutely decompensated HF(82)(83). However, the therapies proven to be effective in clinical trials are not widely used in practice over all. (5). Patients in the clinical trials are usually over a decade younger, the enrollment criteria generally exclude patients with major comorbidities or contraindications, (84)(85) yet these are the majority of patients encountered in clinical practice. There are also limitations in the administrative datasets such as inaccurate coding of HF, and challenges in assessing treatment since hospital-based registries only report in-hospital metrics.(86)(87)

A systematic review conducted by Grimshaw(88) showed that medical guidelines improve clinical practice but the size of the improvement varies depending on the clinical context and the evaluation of the implementation. Similarly, a study from the CRUSADE database demonstrated that there was limited association between the prescription of appropriate evidence-based
treatments and patient safety across different institutions in patients with acute coronary syndrome (ACS). (81)

An important point to take into account with the medical guidelines is that some patients may have their own preferences when deciding on their management, particularly if they are faced with many new medications or suggestions to change lifestyle. Thus, when it comes to prioritizing recommendations, clinicians and health care providers must also consider factors beyond the strength of a medical guideline recommendation, such as patients’ values and choices, costs and the potential for improvement in quality of care.

Medical guidelines are therefore written to suggest diagnostic and therapeutic interventions for most patients in most circumstances but their use is ultimately the decision of the clinician,(89) reason why, the strongest evidence in the medical guidelines is now used to develop performance measures which are “explicit standards of care against which actual clinical care is judged”.(77)(89)

The development and application of performance measures is required to assess and improve quality of health care, which is an important goal in current medical practice. However, quantifying health care quality is a complex and challenging process. This is the main reason why there has been increasing interest in developing performance measures, also described as Quality Indicators (QIs), to identify the gaps in the delivery of care.(6)

The Institute of Medicine defined quality of health care as the degree to which health services meant for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Further revisions added safety, patient-centered, timely, efficient and equitable as part of the “quality health care” definition, and this became the foundation upon which all QIs was built. (90)(91) The proposed framework for the evaluation of quality of care(92) defines 3 main components: structure, process, and outcomes. Structure refers to the components of the health care system, which in this case, includes the medical guidelines and the organizational culture. Process refers to the measurement of the process-of-care through the use of appropriate diagnostic and therapeutic interventions for individual patients. Outcomes refer to the consequences of the therapies and represent markers of disease progression such as mortality, hospital admissions, quality of life, and cost. This three-part approach to quality assessment aims to establish a relationship between these factors so that high-quality structure
can lead to high-quality processes of care, which in turn should lead to favorable outcomes.(93)(92)

It is important to note that medical guidelines are not performance measures. Performance measures “imply that physicians are in error if they do not care for patients according to these standards”, whereas medical guidelines’ use is left to the discretion of the physician depending on each individual patient. (89)

Thus, performance measures or QIs are a powerful addition to the medical guideline development process and an instrument for more rapid translation of strong new evidence into clinical practice. QIs have been identified as knowledge translation tools to evaluate quality of care, improve outcomes, and quantify adherence to standards of care. They should be meaningful, useful, and feasible to measure using regular data collection and overall assessment, have potential for improvement in clinical practice and impact on patient outcomes. (89)(94) These indicators can be used to assess performance of individual practitioners or health care organizations with the intention of reducing the gap between evidence-based optimal and actual patterns of clinical care. (95)

Stafford and colleges showed that the implementation of medical guidelines into routine clinical practice was often suboptimal and as a result, many patients had frequently received substandard care,(96) and the CRUSADE study that evaluated the performance of multiple hospitals with respect to NSTEMI guidelines, adds to this finding by demonstrating that institutions and practice sites accounts for some variability in the adherence to the evidence-based prescriptions. Thus, patients with multiple comorbidities, clinical instability and cared for by non-cardiologists were more likely to have a low adherence to quality and safety metrics. (81) Consequently, QIs have been developed to evaluate and report quality of care at the level of the hospital and individual practitioners, and to design and test methodologies for improving quality.(97)

Quality improvement strategies are underway in multiple organizations and a variety of indicators have been developed. Abrahayman performed an international environmental scan and established over 20 initiatives to measure and improve quality of cardiac care through the development of QI.(98) However, most of these indicators are collected from administrative databases and are difficult to measure. In some cases, there is still controversy about the quality
of the evidence that suggests that specific indicators should be included and is necessary to collect the data from clinical databases to obtain the most accurate information. (6)

Public reporting and differential payment based on the quality of practice (77) generated a trend of rankings and assessments of hospitals and individual health care providers that was initially overestimated,(89) considering that the “Effectiveness of public report cards for improving the quality of cardiac care” (EFFECT) study found that there was no significant improvement in patient morbidity and mortality when health care organizations were provided with a public report card on the performance of established QIs in patients with HF, which suggested that further studies needed be done to demonstrate that strict adherence to evidence-based guidelines can contribute to significant improvement in patient’s care. (99)

In addition, these strategies should measure and improve both quality and patient safety since these two aspects have been associated with better chances of improving patient outcomes by Mehta et al., which includes the appropriateness of evidence-based treatments but also the use of appropriate treatments in the right dose. (81)

The Canadian Heart Health Strategy and Action Plan (CHHS-AP) worked on an ambitious project commissioned by the government of Canada with the goal of reducing the burden of cardiovascular disease in Canada. (100) In 2009, Building a Heart Healthy Canada (101) was presented and one specific recommendation was focused around the lack of systematic clinical QIs to measure and report on quality of care. This gap was identified as a fundamental barrier to improving care; and the responsibility to address this concern was delegated to the CCS.

HF was of special interest because it represents a significant burden to the patients and the health care system, and there is a variation in the clinical management and/or the clinical outcomes of these patients.
In 2010, the CCS developed a standard method of cardiac indicator development (95) that consisted in 3 phases:

**Figure 1. Process Flow for the Development of QIs proposed by the CCS**

<table>
<thead>
<tr>
<th>Phase I</th>
<th>• Plan and organize the QI development initiative - refers to the selection of the content area, definitions, and establishing a working group including the involvement of stakeholders.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td>• Develop and select the QIs – includes the performance of a thorough systematic review of the literature to formulate a preliminary list of QIs, rate and review to select the final QIs.</td>
</tr>
<tr>
<td>Phase III</td>
<td>• Operationalize the QIs – refers to the finalization of the technical specifications, piloting of the QIs and developing a knowledge translation strategy.</td>
</tr>
</tbody>
</table>

After this process, “the resulting QIs will be used to measure adherence to national practice guidelines and to report on health system performance at local, provincial and national levels”. (95)

The CCS working group identified and rated a list of 49 QIs for HF (102) that were carefully defined and categorized in a consensus document that was intended to be publicly available as an e-catalogue. The indicators were divided by the phases in which they were performed during patient care and instructions on how to measure and report them were clearly explained.

These phase II indicators were divided into indicators measured during acute /inpatient phase, discharge/transition phase, outpatient phase and palliative care phase. Subsequent ranking and discussion led to the selection of 6 inpatient QIs that the CCS recently published and that were considered feasible to measure nationally. (102)
Inpatient QIs are generally easier to be captured since the information is recorded during the patient’s hospital stay,(1,63) however, it is not feasible to systematically collect this information across Canada due to multiple barriers, the most important being the processes for collection of the information and the knowledge infrastructure. Obtaining the kind of data needed for this purpose can be difficult and expensive, and errors can occur at multiple levels. For example: studies that rely on hospital discharge codes may overestimate the true burden of ADHF by “counting” all cases ever diagnosed as HF.(2) At an organizational level, the first step would be to identify the patients with HF, evaluate the severity of the condition to determine whether they are appropriate candidates for the measurement of QIs, and if the outcomes are assessed, there must be accurate collection to ensure that any difference to the standards of care are attributable to quality of care and not to underlying patient characteristics. (89) Evidently, this process can be challenging and complicated.

Currently in Canada, there is no system in place to collect data on HF patients that are being managed in primary care settings, which means that it is difficult to know specific information on the processes of care such as prescription of evidence-based medications and clinical status assessment. Electronic Medical Records (EMRs) are the best resource to capture comprehensive data required for the measurement of the QIs, especially in the outpatient setting. (25)(102)

The recent indicators proposed by the CCS are a good start to measure quality of care. Few studies have addressed the performance of QIs in HF, (103) and most of the measurements have been directed at the inpatient performance. (104) Since the majority of HF patients are treated as outpatients, there is an important need to measure the quality of care among these patients. The chronicity of this condition, the variation in the delivery of health care services, management and medication adherence,(63) create a good opportunity to identify potential gaps and develop quality improvement strategies,(103) that can potentially be evaluated and reiterated in order to provide a better care for patients with HF.(105)(106) Moreover, patient care does not end with the discharge from the hospital, so a smooth transition with the outpatient primary care clinician is an essential part of high-quality of care.

Therefore, we decided to use the 2013 CCS e-catalogue for the selection of the QIs to be measured and evaluated in this study. Twelve phase II QIs have been selected to include the not-yet studied outpatient phase and to perform a comprehensive evaluation of quality.
1.2 Quality Indicators

The QIs that were studied are supported by the CCS medical guidelines through multiple evidence in clinical trials and positive outcomes in previous studies. We created an individualized set of descriptions for each indicator as presented in Tables 8 to 19, based on the information provided by the CCS e-catalogue and the AHA/ACC indicators, (102,107,108) with summarizing information that includes name and definition, numerator and denominator, exclusion criteria, rationale and clinical recommendations with CCS guidelines citations where possible, and method of reporting.

Meaningful, valid and reliable, adjusted to patient variability, modifiable and feasible to measure are the 5 principles recommended by the CCS and AHA/ACC for the selection of the QIs.(89) Meaningfulness means that the outcome is important to patients and the population. Validity and reliability refers to the measurement of the structure, process or outcome of interest. Adjustment to patient variability is necessary to explain the observed outcomes as a result of the performance of health care processes and not because of patient characteristics. To be a useful measure of quality, there must be an opportunity to improve the performance of the QI and there should be evidence showing that modifications in the process of care can favorably influence this QI.(63,89,93) Lastly, the feasibility principle has been a topic of discussion over the last few years for most of the indicators, since the quantification of quality in healthcare is complex and costly. The expenses of collecting baseline and follow up data for patients with HF may be too much to perform on a routine basis. (89,93)

Therefore, QIs have been developed for both the inpatient management of ADHF and for outpatient care. As seen in table 7, the process indicators are indicators that directly measure the performance of key processes in the management of patients with HF and specific actions can be taken to improve the performance of these indicators.(63)(109) Whereas, safety indicators are indicators that provide information on potential complications and adverse events and that are actionable and preventable. And access indicators are indicators that reflect the ability to use services when they are needed.
The following table shows the classification of the QIs that were evaluated:

**Table 7. Classification of the QIs**

<table>
<thead>
<tr>
<th>PHASE</th>
<th>INDICATOR</th>
<th>CLASSIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. INPATIENT PHASE</strong></td>
<td>1. Daily Assessment of Blood Chemistry: Electrolytes - sodium (Na), potassium (K), Blood Urea Nitrogen (BUN), creatinine</td>
<td>Safety Indicator See table 8</td>
</tr>
<tr>
<td></td>
<td>2. Chest X-Ray</td>
<td>Safety Indicator See table 9</td>
</tr>
<tr>
<td></td>
<td>3. Assessment of LV Function</td>
<td>Process Indicator See table 10</td>
</tr>
<tr>
<td></td>
<td>4. Early Outpatient Assessment for HF patients discharged from hospital</td>
<td>Access Indicator See table 11</td>
</tr>
<tr>
<td><strong>II. OUTPATIENT PHASE</strong></td>
<td>5. Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARB) use</td>
<td>Process Indicator See table 12</td>
</tr>
<tr>
<td></td>
<td>6. Mineralcorticoid receptor antagonists (MRA) use – also known as Aldosterone antagonists</td>
<td>Process Indicator See table 13</td>
</tr>
<tr>
<td></td>
<td>7. Beta Blocker use</td>
<td>Process Indicator See table 14</td>
</tr>
<tr>
<td></td>
<td>8. Documentation of HF etiology</td>
<td>Process Indicator See table 15</td>
</tr>
<tr>
<td></td>
<td>9. Documentation of Left Ventricular (LV) Systolic Function</td>
<td>Process Indicator See table 16</td>
</tr>
<tr>
<td></td>
<td>10. Blood Pressure Measurements</td>
<td>Safety Indicator See table 17</td>
</tr>
<tr>
<td></td>
<td>11. Body Weight Assessment</td>
<td>Safety Indicator See table 18</td>
</tr>
<tr>
<td></td>
<td>12. Patient Education</td>
<td>Access Indicator See table 19</td>
</tr>
</tbody>
</table>
In the inpatient indicators, the daily assessment of blood chemistry is a key component in the evaluation of ADHF and can influence the treatment. Renal failure -measured by the electrolytes (Na and K), creatinine and BUN- is common in HF and is a known marker of prognosis, which makes its daily measurement essential to adjust doses of Intravenous (IV) diuretics and K supplements if needed. (1) Moreover, two of these key laboratory parameters indicate an increased risk of inpatient mortality according to the Acute Decompensated Heart Failure National Registry (ADHERE) trial: a BUN of $\geq 43$ g/dL and/or serum creatinine $>2.75$ mg/dL. (110) Thus, these chemical parameters need to be monitored closely, as significant abnormalities can occur quickly during the hospital admission.(102)

The performance of CXR within the first 8 hours after the first medical contact is another inpatient QI based on the CCS HF Guidelines 2006 (Class IIb, Level of Evidence C) and the 2012 Practical Tip that states that response to therapy should be reassessed < 2 hours after therapy initiation, and thus ideally, the CXR should be performed before this reassessment. The CXR is a key component in the evaluation of acute HF and for the differential diagnosis of acute dyspnea.(102) Furthermore, some findings on the CXR may lead to modification of diagnosis and/or therapy, such as pericardial effusion, parenchymal infiltrates, cardiomegaly.

The CCS recommends that patients with a documented history or diagnosis of HF admitted to hospital should have at least one assessment of LV function within 18 months of admission date or planned within 30 days from discharge from ED. (Class I, Level of Evidence C). (1) The evaluation of LV function is fundamental for decisions on diagnosis, prognosis, therapy and referral and its assessment is widely available, of low-risk and usually re-assessed over time to evaluate the response to therapy or changes in clinical status.(102)(108)

Patients with HF discharged from hospital should see a health care professional within 2 weeks of hospital discharge since they will experience lower 30-day readmission if they are seen within that period of time. (Class I, Level of evidence C). (1)(25) Outpatient assessment can include telephone, videoconference/ telehealth visit, or in-person visits. (1) There is evidence comparing different disease management interventions, in which the multidisciplinary approach and the case management follow up by a HF specialist nurse have shown reduction in the HF-related and all cause-related admissions after 12 months follow up. (111)(112)(113)
Regarding the outpatient indicators, all patients with symptomatic HF and LVEF <40% or no symptoms and a LVEF<35% should be assessed as to whether they are taking an ACEI or an ARB at each clinic visit, (1) since ACEI/ARB prescription is a guideline-recommended therapy based on the previously discussed evidence. (CCS CHF Guidelines 2006, Class I, Level of evidence A). (1)(102) And the similar principle applies to the MRA therapy, where all patients with HF and LVEF <30% should be assessed as to whether they are taking a MRA - spironolactone or eplerenone- at each clinic visit, and for patients not receiving either, the reasons should be clearly documented. (CCS CHF Guidelines 2006, Class I, Level of evidence A) (1)

Another indicator that assesses the prescription of guideline-recommended therapy is the beta blocker use, which recommends that all patients with HF and LVEF <40% should be assessed as to whether they are taking a guideline endorsed beta blocker at each clinic visit. (CCS CHF Guidelines 2006, Class I Recommendation, Level of evidence A). (1) Therapy should be initiated at low dose and titrated to the target dose used in clinical trials or the maximum tolerated dose (CCS CHF Guidelines 2006, Class I Recommendation, Level of evidence B).(1)

For the above indicators, previous studies have defined the “ideal candidate” as the patients without contraindications for each cardiac medication,(89) thus these patients will be counted towards the denominator and those who received the appropriate treatment will be reported as the numerator. Ultimately, the goal of measuring therapy as a QI, is to understand why recommended treatments are not received, and move from quality measurement to quality improvement with this information.

The documentation of HF etiology is an important outpatient indicator due to the fact that it is necessary for optimal management, (1) and it must be recorded to ensure appropriate treatment, education and ongoing monitoring. The same applies to the documentation of LV function, since evidence based treatments result in improved outcomes and this parameter is necessary to assess clinical response and medication titration.(102) Monitoring of BP allows reasonable judgment about the rate of medication titration, whether recommended doses can be achieved; and monitoring of BW is a key clinical measure of fluid retention. (1)
There is one particular indicator that is directly related to patient self-management. This indicator is patient education and its importance lies in the promotion of healthy lifestyles and behaviors that can control symptoms and prevent HF decompensation. The interventions generally aim to equip patients with skills to actively participate in the management of their chronic condition, through symptom monitoring and enhancing problem-solving and decision-making skills. (114)

For example, all patients should measure their own body weight at home to monitor fluid retention. (1) These self-management interventions have received increased attention since they have shown to affect admissions; (115)(116) so individual behavior measures are extremely useful in designing quality improvement processes. Patient and family members should receive at least one session of education regarding HF management, which may have been conducted either in-hospital, in the clinic or via telehealth. (1)

As mentioned above in the development of the QIs, previous findings have played an important role in categorizing and selecting the most relevant measurements. For example: systolic blood pressure has been documented as a predictor of mortality and increase in body weight as a predictor of re-admissions, (117,118) reasons why both measurements have been recommended as outpatient QIs. Furthermore, patient-related factors such as medication non-adherence and dietary indiscretion, and system-related factors including inadequate access to follow up care and poor transitions of care, have been described as important precipitants of re-admissions, which make them targets for quality improvement.

1.3 Quality of Life (QoL)

In clinical practice, the efficacy of medical therapies is often assessed by parameters such as clinical status, EF indices and biomarkers. However, from the patient’s perspective, QoL parameters such as functional capacity, exercise performance, psychological status and social engagement are more significant. (119) Despite the growing importance of QoL, patient-reported outcomes are not frequently measured in most cardiovascular trials, let alone in routine clinical practice, and the reasons may be associated with the lack of familiarity with the measurement tools and their interpretation. (120)
Nieminin et al. suggest that HF re-admissions may be a comprehensive measure of disease burden and progression; hence its evaluation could be used as a measure of QoL. They are easy to identify and quantify and include the patient’s point of view on the amount of days out of the hospital. (119) Early re-readmissions are associated with worse outcomes, prognosis and increase health costs. (121)(122) However, these are not necessarily a sign of system failure since patients that die during the index admission can never be re-admitted, and there may be elective readmissions for enhancement of medical therapy that represents successful care. Therefore, HF admissions rates vary among institutions and are used as a parameter of quality of care but do not entirely evaluate the perspective of the patient.

QoL measures can be used to prioritize problems, facilitate communication, screen for potential complications, identify preferences and monitor changes or response to treatment. (123) Its use in clinical practice ensures that treatment and evaluations are focused on the patient rather than the disease. (124) Nonetheless, QoL measures are not a substitute of clinical outcomes measures but an adjunct to them; so they need to be valid, reliable, appropriate and responsive to clinical change. On the other hand, if these measures are to be implemented in routine practice, they must also be simple, quick to complete, easy to score and provide useful clinical data (125).

Introducing QoL measures in a clinic environment often means that the staff needs to change their practice and their organizations’ culture, training will have to take place for the use and the interpretation of the measure and it must be incorporated into the medical records for further discussion in a case by case format. Hence, the use of QoL measures on a daily basis may be challenging.

The main challenge lies in its uniqueness to each patient and so its existence is relative to individual and cultural expectations. (124) Several studies have shown that there is disparity between what patients, physicians and caregivers think of the patient’s QoL,(126)(127) or that physicians are not accurate in identifying aspects of disease and treatment that are important to patients, which confirms the fact that there are factors that are weighed differently depending on the individuals, there may be aspects that are not included in the standardized measures and QoL is a dynamic concept that changes in response to illness. This brings up another challenge when using these measurements: the interpretation and analysis of this data, due to its individualized nature it can be a complex process, with difficulties when comparing among groups or even within the same individual over time.
There is an overall lack of evidence for the benefits to patients using QoL measures since they are rarely used in clinical practice and if they are being used, they may not influence clinical decision-making. Moreover, little is known about these measurements and their impact in practice and the quality of care provided. There have been no studies demonstrating improvements in care with the use of patient-reported outcomes, however there is evidence that worse patient-reported outcomes is associated with hospital re-admissions and death due to HF. Clinicians are not entirely comfortable with the interpretation of the scales and even though some of the measurement instruments can detect changes that are clinically significant, they do not provide clear actionable information about the specific cause.

HF affects QoL more profoundly than many other chronic diseases, yet there is little research focused on this aspect of patient’s care. The management of HF requires close monitoring so that changes in condition can be promptly recognized and treated, however the daily variation in HF makes QoL an outcome that is challenging to quantify. Furthermore, in many cases, this variability is related to other medical conditions of the patient. For example, depression is one of the most important determining factors in the QoL of HF patients. Its prevalence varies from 11% to 25% in patients followed in the outpatient setting, and is a predictor of LoS and mortality in patients during hospitalization.

HF patients’ own assessment of symptoms has shown to be a good predictor of future outcomes, compared to NYHA class, and a more sensitive method to detect deterioration and significant clinical changes. The available HF QoL scoring instruments focus on three dimensions: physical, emotional and social. There are two standard assessment instruments frequently used to measure QoL in patients with HF: the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the Kansas City Cardiomyopathy Questionnaire (KCCQ). Both offer good prognostic information in HF, although the KCCQ has recently shown to be superior to MLHFQ overall and in patients with reduced EF when comparing predictive accuracy of clinical events, and in better reflecting magnitude and direction of clinical changes over the use of NYHA classification and the 6-minute walk test.
The MLHFQ is a 21 items self-administered questionnaire that evaluates physical, emotional and social aspects related to HF in a time frame of past 4 weeks. Each question is measured using a 6 point Likert scale, with a total range from 0 to 105, in which the higher the score, the worse the QoL. Usually, scores between 0-35 are related to good QoL, from 35-70 moderate QoL and >70 are related to poor QoL. It does not measure separate QoL domains and is summarized with a single score. An improvement of 5-points has been considered as a clinically meaningful change. (135) This questionnaire asks the patients whether HF has prevented them from living as they wanted within the last 4 weeks due to effects on physical, emotional, social and mental aspects of QoL.

The KCCQ is a 23 items self-administered questionnaire divided into functional score that includes physical activity and symptoms, and summary score that includes the functional score plus QoL in a time frame of past 2 weeks. The QoL aspect is evaluated using 2 specific dimensions: self-efficacy and social limitation. Each question is measured using a 5-7 point Likert scale, with a total range from 0 to 100, where the higher score, the better. Previous studies have reported that scores between 0-30 are related to poor Qol, between 30-70 moderate QoL and >70 are good QoL. (133,134) The specific distribution of the questions is as follows: question 1 refers to physical limitations; question 3, 5, 7 and 9 to frequency of symptoms; questions 4, 6 and 8 to the severity of symptoms and question 2 to change of symptoms over time. Self-efficacy and knowledge is assessed with questions 11 and 12, social interference with question 16 and QoL with questions 13, 14 and 15. (136) A change of ≥ 5-points is considered to be a small, clinically important change, ≥ 10-points is a moderately clinical change, and ≥ 20-points is a large clinical change. (134)

QoL takes an important role in advanced HF patients in which end-of life care needs to be addressed, since there have been conflicting findings around preferences between QoL and longevity. (137)(138) Patient- perspective has frequently been missed as an endpoint in all the clinical trials, let alone in clinical practice, despite being a valuable measure of treatment efficacy. Hence, none of the medical guidelines addresses QoL as an outcome. (119) It is therefore necessary to evaluate the impact of HF care and current evidence-based therapies on patient’s QoL.
1.4 Clinical Outcomes

As mentioned before, the mortality rate of HF patients remains high, with rates that vary between 5-15% at 60 and 90 days post discharge, (139,140) and patients with preserved EF have similar rates of mortality compared to those with reduced EF. (3,140) HF admissions are also an important clinical outcome with rates of up to 30% at 60 days post discharge.(3,11)

It is presumed that the application of performance measures in clinical practice is associated with improved clinical outcomes, however the effectiveness of these QIs is unclear and in some cases the appropriate link has not yet been established. (141)(109) On the other hand, the collection of outcome data is a complex and expensive task. Deaths can be tracked through administrative resources, although in some cases, this is only for in-hospital events and there can be a substantial lag time. Most of the other outcomes require the tracking of individual patients over time and due to the clinical nature of HF, some patients may be lost to follow up.

Despite these challenges, clinical outcomes are an important measure of the success of patient care and, although the absence of adequate risk-stratification models represents the most important limitation when interpreting this data, there is an opportunity to improve care if clinicians collect these measurements and use them for internal quality-improvement activities.(89)

Mortality as a clinical outcome should be evaluated carefully in patients with HF, since is not always an indication of poor-quality care and may be the inevitable consequence of this condition for which the patient may have received excellent care. On the contrary, poor QoL and suffering associated with HF may be substantial, and health status measures may be as important as survival rates.(109,141)

There are a few studies addressing the potential relationship between performance of evidence-based QIs and patient outcomes in the inpatient setting.(142)(141)(143)(144)(145) These studies suggested that there was a positive association between an increase in adherence to the inpatient HF performance measures and clinical outcomes, especially with the prescription of ACEI or ARB at the time of discharge from the hospital and the assessment of LV function during admission. (109) The association was still positive but weaker when it comes to adherence to discharge instructions. The prescription of ACEI or ARB at the time of discharge has been
associated with a lower risk of mortality and readmissions, and is well documented in the literature. (CCS CHF Guidelines 2006, Class I, Level of evidence A) More recent studies demonstrated that the performance of QIs across multiple organizations was not a significant predictor of mortality and could not identify any relationship with care that led to better or worse outcomes.(107,108,146,147)

The clinical trials have also elucidated on the most appropriate doses of the evidence–based therapy that have proven to reduce morbidity and mortality, (23) and the medical guidelines recommend that these medications be initiated at low starting doses and doubled every 2-4 weeks until meeting the target or maximum tolerated dose.(148) Despite the evidence that supports these guidelines, many patients continue to receive suboptimal treatment and at suboptimal doses that has been documented primarily for ACEI/ARB and beta-blockers.

A systematic review performed by Maeda in 2010, demonstrated that the clinical outcomes after discharge did not show significant improvement and the performance of QIs was variable across institutions. (149) It is not clear yet if the adherence to all of the performance measures creates a combined effect in patient outcomes, or if it is the performance of specific indicators by themselves that made the difference in the clinical outcomes studied. Hence, the ideal evaluation of QIs should give equal consideration to all the performance measures for which patients are eligible. This review also found that there was an inverse relationship between an increase in adherence to treatment guidelines and mortality rates.(109)

In addition to these clinical outcomes, initiatives or interventions related to HF may increase or decrease costs, and impact the allocation of resources.(78) Since the medical guidelines are now used to develop performance measures, and in turn, these performance measures are used to evaluate the quality of practice; the context of public reporting and differential payment have been weighing up in the establishment of standards of care and in the development of benchmarks that define quality of care. (77) Thus, resource utilization should be considered when deciding on the quality of evidence regarding other clinical outcomes, and on the selection and implementation of QIs.(79)
1.5 Rationale

Clinical decision-making is complex and medical guidelines have the potential to help clinicians and patients with complex choices, to improve the quality of care, and to help ensure the best use of health care resources. (78) It is imperative to define, develop and evaluate valid, reliable, cost effective, and responsive measures for tracking HF specific components of QoL, self-management behaviors and patient satisfaction, particularly in the outpatient settings or with the perspective of the continuum of care. (93) The measurement of QIs could identify the barriers and limitations in HF care to further develop initiatives that will help in achieving the standard guideline recommendations. Previous studies suggest that research should be carried out in high-performing organizations with effective HF teams to help identify the specific processes that may lead to superior patient outcomes.

Efforts are underway to implement Canadian key performance indicators for HF care, and data on some of the inpatient indicators have been previously obtained, (63) however, outpatient performance measures have not been thoroughly studied, nor documented. These data showed variable use of evidence-based recommendations across different organizations with disperse identification of the factors that improve patient outcomes. Given that the majority of HF patients are treated as outpatients, there is need to systematically measure the quality of care in these patients.

Furthermore, patient-reported outcomes are seldom studied in the context of performance indicators, and since this is a chronic condition that implies a significant burden on patients and caregivers, it is necessary to examine the impact and potential association of the application of standards of care in patients’ QoL.

In this study, we will therefore determine the adherence to the QIs in a HF clinic and correlate with patients’ quality of life and clinical outcomes.
1.6 Hypothesis

Our hypothesis was that the adherence with quality indicators in the management of patients with heart failure is positively associated with quality of life and patient outcomes.

1.7 Objectives

The objectives of this study were to determine the average level of adherence to the QIs in the management of patients with Heart Failure, and to determine how this level of adherence is associated with quality of life and hospital admission and mortality at 30 days.

1.8 Outcomes

The primary outcome is the change on patient-reported QoL scores between the baseline and 3-months.

The secondary outcomes are the proportion of patients admitted to hospital and died at 30 days from the time of enrolment.
CHAPTER 2

2. METHODS

2.1 Study setting

We conducted a prospective cohort study in a specialized Heart Failure clinic at St. Michael's Hospital from September 2015 until June 2016. The combined total of HF patients followed in this clinic is ~ 500 annually. Institutional research ethics board approval was obtained. The clinical team in the Heart Failure clinic was aware that a quality of care study was being conducted, however they did not have knowledge on the performance measures that were being evaluated nor the method of assessment and reporting.

During the study period, consecutive HF patients presenting to the clinic were identified using their clinic chart. We included all HF patients, 18 years old and older, who presented to the HF clinic. Patients with serious comorbidities such as terminal cancer, severe chronic obstructive pulmonary disease, expected life expectancy < 1 year, acute renal failure, on cardiac transplant list, end stage cirrhosis, severe dementia and congenital heart disease were excluded. To avoid selection bias, we were consistent and strict with our inclusion and exclusion criteria, and if there were doubts regarding the eligibility of a patient, we would ask for clinical clarification, especially with regards to multiple comorbidities.

Patients were approached directly during their clinic visit. All the management and disposition were left to the discretion of the HF clinical team. The nature of the study was clearly explained to the patients and when consent was given, the patients were asked to complete both the MLHFQ and the KCCQ baseline QoL questionnaires. For patients that did not speak English, we offer them the licensed KCCQ version in other languages (Cantonese, Mandarin, Portuguese and Spanish). Patients were expected to complete the questionnaires on their own (if possible) and the investigator addressed doubts (if any) during the completion of the questionnaires. If the patient was not able to complete the questionnaires on his/her own, the investigator asked for permission to administer the questionnaires to the subject. If this was the case, the questions were
read out exactly as they were printed, no non-verbal clues were given; participant’s right to confidentiality was kept by conducting the questionnaires in a comfortable, private setting.

Patients that consented were followed up at 3-months during their clinic appointment, by mail or by telephone by the research team. QoL questionnaires were completed again during the 3-month follow up. If the patient was not able to complete the questionnaires on his/her own during the follow up, the investigator administered the questionnaires again, to avoid variability in the data collection.

2.2 Data Collection

2.2.1 Baseline demographics/patient characteristics, HF admission and clinical presentation

We followed chart review protocols as outlined by Gilbert.(150) Two data abstractors, trained by the investigator, independently abstracted data during the study period. Data were abstracted from the electronic database at St. Michael's Hospital, including the ED visit chart, nursing notes, laboratory tests, echocardiograms, imaging results, clinic notes, consult and discharge notes. The data were abstracted onto case report forms (CRFs) and entered into a centralized database. Random checks were conducted throughout the study period, and any unclear data were reviewed and resolved with the primary investigator.

The following data were collected during the clinic visit for all patients: demographics (age, gender), HF admission - if the patient was previously admitted at any time due to HF and referred to the HF clinic after discharge (blood chemistry assessment, CXR and LV function), HF clinic referral information (inpatient vs. outpatient, date of the initial referral and date of initial clinic visit), clinical presentation at the time of enrolment (NYHA classification), documentation of the QIs during the clinic visit (etiology, LVEF, blood pressure, weight and patient education).

Age was abstracted directly from the demographic section of the patient chart. All other data were abstracted from the ED triage note, clinic notes, consult notes and prior investigations such as laboratory tests, echocardiograms and radiography.
The HF admission data were abstracted from the hospital discharge notes, ED triage note and laboratory investigations during hospital admission. We reviewed admission data for each patient dating back to the first admission after which they were referred to the HF clinic. The clinical presentation was recorded from the clinic note.

The following tables were created with the information provided by the CCS and the ACC/AHA performance measures guidelines (102,107,108) and show the comprehensive description of the inpatient indicators examined.
Table 8. Indicator Description: Inpatient Indicator #1

**Daily Assessment of Blood Chemistry: Electrolytes - sodium (Na), potassium (K), Blood Urea Nitrogen (BUN), creatinine**

The CCS recommends that patients presenting with a working diagnosis of HF admitted to hospital should have electrolytes and renal function assessment as part of their daily assessment. (1)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The number of patients who were assessed for sodium, potassium, BUN and creatinine daily.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The number of patients with acute HF admitted to the hospital receiving IV therapy for HF.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale is that the evaluation of electrolytes and renal function are key components in the evaluation of acute HF and can influence its treatment. Renal failure is common in HF and is a known marker of prognosis. Low levels of sodium identify patients at higher risk. (1) Furthermore, daily assessment of renal function and electrolytes are essential to adjust doses of Intravenous (IV) diuretics and potassium supplements if needed. (1)

**Method of Reporting**

Per population - the reported statistic is the proportion (numerator/denominator) or percent of qualifying HF patients receiving all four blood tests (Na, K, BUN and creatinine), on a daily basis, while receiving IV therapy.

Per patient – the reported statistic is whether or not all four blood tests were performed on a daily basis.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
**Table 9. Indicator Description: Inpatient Indicator #2**

*Chest X-Ray*

The CCS recommends that patients seen in the ED and/or admitted to hospital with acute HF should receive a chest X-Ray (CXR) on the same day of admission. (1)

The CCS HF Guidelines 2006 (Class IIb, Level of Evidence C) and 2012 Practical Tip states that response to therapy should be reassessed < 2 hours after therapy initiation, and thus ideally, the CXR should be performed before this reassessment. According to these Guidelines, patient disposition should be decided <8 hours after first medical contact.

<table>
<thead>
<tr>
<th><strong>Numerator</strong></th>
<th>The numerator is the number of patients with CXR performed within eight (8) hours from presentation to the first medical contact, usually in the ED.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Denominator</strong></td>
<td>The denominator is the number of patients admitted to hospital with acute HF.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale is that the CXR is a key component in the evaluation of acute HF and for the differential diagnosis of acute dyspnea. Some findings on the CXR may lead to modification of diagnosis and/or therapy (e.g. pericardial effusion, parenchymal infiltrates). Known markers of prognosis in HF can also be identified on the CXR (e.g. cardiomegaly).

**Method of Reporting**

Per population - the reported statistic is a proportion (numerator/denominator).

Per patient – the reports statistic is whether or not CXR was performed.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
Table 10. Indicator Description: Inpatient Indicator #3

**Assessment of LV Function**

The CCS recommends that patients with a documented history or working diagnosis of HF admitted to hospital should have at least one assessment of left ventricular (LV) function within 18 months of admission date or planned within 30 days from discharge from ED. This constitutes a Class I, Level of Evidence C. (1)

<table>
<thead>
<tr>
<th><strong>Numerator</strong></th>
<th>The numerator is the number of patients who receive an assessment of LV function by quantitative imaging modality (echocardiogram, cardiac MRI or MUGA scan) within 18 months from admission date or within 30 days from the ED visit.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Denominator</strong></td>
<td>The denominator is the number of patients with a documented history or a diagnosis of HF admitted to the hospital.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale is that the evaluation of LV function is fundamental for decisions on diagnosis, prognosis, therapy and referral. Assessment is widely available, low-risk and usually re-assessed over time for response to therapy, with a change in clinical status or before other modality of treatment.

**Method of Reporting**

Per population – the reported statistic is a proportion (numerator/denominator).

Per patient – the reported statistic is whether or not LV function was assessed.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
Table 11. Indicator Description: Inpatient Indicator #4

**Early Outpatient Assessment for HF patients discharged from hospital**

The CCS recommends that patients with HF discharged from hospital should see a health care professional within 2 weeks of hospital discharge. Outpatient assessment can include telephone, videoconference/telemedicine visit, or in-person visits. (1)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The numerator is the number of patients with a diagnosis of HF who are discharged alive from hospital and with an outpatient assessment by a health care professional within 2 weeks of separation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The denominator is the number of patients with a diagnosis of HF who are discharged alive from hospital.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale and clinical recommendations is that patients with HF discharged from hospital will experience lower 30-day readmission if they are seen by a health care professional within two weeks. This is a HF Guidelines, Class I, Level of evidence C. (1)

**Method of Reporting**

Per population - the reported statistic is a proportion (numerator/denominator).

Per patient – the reported statistic is whether or not the patient was seen within 2 weeks after discharge.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)

The following tables were created with the information provided by the CCS and the ACC/AHA performance measures guidelines, (102,107,108) and show the comprehensive description of the outpatient indicators examined.
Table 12. Indicator Description: Outpatient Indicator #5

**Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARB) use**

All patients with symptomatic HF and left ventricular ejection fraction (LVEF) <40% or no symptoms and a LVEF<35% should be assessed as to whether they are taking an ACE-I or an ARB at each clinic visit. (1)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The numerator is the number of patients with HF with a documented LVEF&lt; 40% who are prescribed ACE-I or ARB.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The denominator is the number of patients with a documented history of HF and LVEF &lt;40%. Patients with elevated serum creatinine, hyperkalemia, hypotension, allergy or intolerance to ACE-I or ARB were excluded from the denominator.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale and clinical recommendations is that ACE-I should be prescribed to all patients with symptomatic HF and LVEF <40% (CCS CHF Guidelines 2006, Class I, Level of evidence A). And to all patients without symptoms and a LVEF <35% (CCS CHF Guidelines 2006, Class I, Level of evidence A). (1)

**Method of Reporting**

Per population - the reported statistic is a proportion (numerator/denominator), with all denominator exclusions applied.

Per patient – the reported statistic is whether or not the patient was prescribed ACEI or ARB.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
### Table 13. Indicator Description: Outpatient Indicator #6

**Mineralcorticoid receptor antagonists (MRA) use – also known as Aldosterone antagonists**

All patients with HF and left ventricular ejection fraction (LVEF) <30% should be assessed as to whether they are taking a mineralocorticoid antagonist (MRA) - spironolactone or eplerenone, at each clinic visit; for patients not receiving either, the reasons should be clearly documented. (1)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The numerator is the number of patients with LVEF &lt;40% that are taking an MRA (spironolactone or eplerenone).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The denominator is the total number of patients with a documented history of HF and LVEF &lt;40%. Patients with elevated serum creatinine, persistent hyperkalemia, hypotension, allergy or intolerance were excluded from the denominator.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale and clinical recommendations are the following: (1)

a) Aldosterone antagonists should be considered in all patients with severe symptomatic HF and LVEF < 30% with creatinine <200 umol/L and potassium <5.2 mmol/L despite optimization of other therapies (CCS CHF Guidelines 2006, Class I, Level of evidence A).

b) Aldosterone antagonists should be considered in patients with acute HF with LVEF<30% following myocardial infarction with creatinine<200umol/L and potassium <5.2mmol/L (CCS CHF Guidelines 2006, Class IIa, Level of evidence B). (1)

c) Aldosterone antagonists should be considered in patients >55 years old with LVEF<30% and recent hospitalization for cardiovascular reason with eGFR> 30ml/min and serum potassium <5.2 mmol/L (CCS CHF Guidelines 2011) (Strong Recommendation, High Quality Evidence).

**Method of Reporting**

Per population - the reported statistic is a proportion (numerator/denominator), with all denominator exclusions applied.

Per patient – the reported statistic is whether or not the patient was prescribed MRA therapy.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
### Table 14. Indicator Description: Outpatient Indicator #7

<table>
<thead>
<tr>
<th><strong>Beta Blocker use</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients with HF and left ventricular ejection fraction (LVEF) &lt;40% should be assessed as to whether they are taking a guideline endorsed beta blocker at each clinic visit; for patients not receiving a beta blocker, the reasons should be clearly documented.</td>
<td></td>
</tr>
</tbody>
</table>

| **Numerator** | The numerator is the number of patients with LVEF <40% that are prescribed with a beta blocker. |
| **Denominator** | The denominator is the total number of patients with a documented LVEF <40%. Patients with allergy, severe asthma, bradycardia and hypotension were excluded from the denominator. |

### Rationale

The rationale and clinical recommendations are the following: (1)

a) Beta blockers should be considered in all patients with symptomatic HF and LVEF <40% (CCS CHF Guidelines 2006, Class I Recommendation, Level of evidence A).

b) Patients with New York Heart Association (NYHA) Class IV symptoms should be stabilized before initiation of a beta blocker (CCS CHF Guidelines 2006, Class I Recommendation, Level of evidence C).

c) Therapy should be initiated at low dose and titrated to the target dose used in clinical trials or the maximum tolerated dose (CCS CHF Guidelines 2006, Class I Recommendation, Level of evidence B). (1)

### Method of Reporting

Per population - the reported statistic is a proportion (numerator/denominator), with all denominator exclusions applied.

Per patient – the reported statistic is whether or not the patient was prescribed beta-blocker.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
Table 15. Indicator Description: Outpatient Indicator #8

### Documentation of HF etiology

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The numerator is the number of HF patients who have recorded etiology of HF.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The denominator is the total number of HF patients.</td>
</tr>
</tbody>
</table>

#### Rationale

The rationale and clinical recommendations are the following:

a) Etiology of HF is important to document for optimal management. (1)

b) It must be recorded to ensure appropriate treatment, education and ongoing monitoring.

#### Method of Reporting

Per population - the reported statistic is a proportion (numerator/denominator).

Per patient – the reported statistic is whether or not there is documentation of HF etiology.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
**Table 16. Indicator Description: Outpatient Indicator #9**

<table>
<thead>
<tr>
<th>Documentation of Left Ventricular (LV) Systolic Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left ventricular (LV) systolic function must be assessed by echocardiography or other means within the last 3 years.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The numerator is the number of patients seen in the practice/clinic who have had LV systolic function assessed within the last 3 years.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The denominator is the total number of patients seen in the clinic.</td>
</tr>
</tbody>
</table>

**Rationale**

Recommendations for evidence-based treatment are predominantly for HF with reduced LVEF. If the LVEF has not been assessed, patients may be denied recommended therapies. (1)

**Method of Reporting**

Per population - the reported statistic is a proportion (numerator/denominator).

Per patient – the reported statistic is whether or not there is documentation of LV function.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
Table 17. Indicator Description: Outpatient Indicator #10

<table>
<thead>
<tr>
<th>Blood Pressure Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients should have a recorded blood pressure on the patient medical chart.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Numerator</strong></th>
<th>The numerator is the number of patients with blood pressure recorded in the clinic note.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Denominator</strong></td>
<td>The denominator is the total number of patients seen in the HF clinic.</td>
</tr>
</tbody>
</table>

**Rationale**

The rationale and clinical recommendations are the following:

a) Evidence based treatments result in improved outcomes.

b) Medication titration rate depends on clinical response.

c) Monitoring of blood pressure allows reasonable judgment about the rate of medication titration, whether recommended doses can be achieved. (1)

**Method of Reporting**

Per population - the reported statistic is a proportion (numerator/denominator).

Per patient – the reported statistic is whether or not BP was measured during the clinic visit.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
**Table 18. Indicator Description: Outpatient Indicator #11**

<table>
<thead>
<tr>
<th><strong>Body Weight Assessment</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients should have a recorded body weight on the patient medical chart.</td>
<td></td>
</tr>
</tbody>
</table>

| **Numerator** | The numerator is the number of patients with body weight recorded in the clinic note. |
| **Denominator** | The denominator is the total number of patients seen in the HF clinic. |

<table>
<thead>
<tr>
<th><strong>Rationale</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The rationale and clinical recommendations are the following:</td>
<td></td>
</tr>
<tr>
<td>a) Evidence based treatments result in improved outcomes.</td>
<td></td>
</tr>
<tr>
<td>b) Medication titration rate depends on clinical response.</td>
<td></td>
</tr>
<tr>
<td>c) Monitoring of body weight is a key clinical measure of fluid retention. (1)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Method of Reporting</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Per population - the reported statistic is a proportion (numerator/denominator).</td>
<td></td>
</tr>
<tr>
<td>Per patient – the reported statistic is whether or not BW was measured during clinic visit.</td>
<td></td>
</tr>
</tbody>
</table>

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)
### Table 19. Indicator Description: Outpatient Indicator #12

**Patient Education**

Patient and family members should receive at least one session of education regarding HF management. Education may have been conducted either in-hospital, in the clinic or via telehealth. (1)

Patient education should be a key component of the activities of a HF disease management program.

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The numerator is the number of patients who have had at least one education session (in-hospital, in clinic or telehealth) on HF management during the clinic appointment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The denominator is the number of HF patients.</td>
</tr>
</tbody>
</table>

**Rationale**

Patient education and close supervision is recommended for patients with HF to reduce the likelihood of non-compliance and lead to the detection of changes in body weight or clinical status early enough for effective treatment to be instituted.

**Method of Reporting**

Per population - the reported statistic will be per patient as proportion (numerator/denominator).

Per patient – the reported statistic is whether or not patient education was provided.

Created from the CCS e-catalogue and the AHA/ACC performance measures guidelines. (102,107,108)

The data to assess the performance of the indicators was obtained for each patient using the resources presented in Table 20.
Table 20. Data Collection Sources for the QIs

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>SOURCES OF DATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Daily Assessment of Blood Chemistry: Electrolytes - sodium (Na), potassium (K), Blood Urea Nitrogen (BUN), creatinine</td>
<td>EMR laboratory investigations during the respective HF admission.</td>
</tr>
<tr>
<td>2. Chest X-Ray</td>
<td>EMR radiography records during the HF admission</td>
</tr>
<tr>
<td>3. Assessment of LV Function</td>
<td>EMR cardiac investigation records during the HF admission.</td>
</tr>
<tr>
<td>4. Early Outpatient Assessment for HF patients discharged from hospital</td>
<td>EMR discharge notes, clinic notes and paper charts.</td>
</tr>
<tr>
<td>5. Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARB) use</td>
<td>Clinic notes were abstracted to identify ACE-I s or ARBs, MRA and beta-blocker at the time of enrolment. Doses and contraindications were determined using the information recorded in the clinical notes.</td>
</tr>
<tr>
<td>6. Mineralcorticoid receptor antagonists (MRA) use – also known as Aldosterone antagonists</td>
<td></td>
</tr>
<tr>
<td>7. Beta Blocker use</td>
<td></td>
</tr>
<tr>
<td>8. Documentation of HF etiology</td>
<td>EMR clinic notes.</td>
</tr>
<tr>
<td>9. Documentation of Left Ventricular (LV) Systolic Function</td>
<td>EMR cardiac investigations and clinic notes.</td>
</tr>
<tr>
<td>10. Blood Pressure Measurements</td>
<td>Clinic notes at the time of enrolment</td>
</tr>
<tr>
<td>11. Body Weight Assessment</td>
<td></td>
</tr>
<tr>
<td>12. Patient Education</td>
<td>Clinic notes throughout all the patient's visits.</td>
</tr>
</tbody>
</table>
2.2.2 Quality of Life (QoL):

QoL data were assessed using two standardized validated tools: the MLHFQ and the KCCQ. Both questionnaires were performed during the patients' clinic visit at the time of enrolment (baseline), when possible and they were asked to be completed by the patients. In cases where the patients could not complete them on their own, the investigator asked for permission to administer the questionnaires. If the patients' preference was to take the questionnaires home, they were given an envelope to return to the research personnel once finished.

For the 3-month follow up, similarly, the QoL questionnaires were done in the clinic whenever the patients had a 3-month follow up, in other cases they were mailed to the patients that preferred that option, and for some patients a phone call was the preferred method of contact. Questionnaires scores were recorded for both times.

2.2.3 Clinical outcomes:

30-day and 60-day admissions, ED visits and mortality were evaluated using the time of enrolment as the start date for the collection of prospective data. This data were obtained directly from the Decisions Support and Outcomes Department at St. Michael’s Hospital, and it only accounted for in-hospital events. We obtained raw data with all-cause admissions and ED visits, and we further classified this health care utilization into cardiac-related and non-cardiac related events.

2.3 Data analysis:

2.3.1 Sample Size

Our sample size calculation was based on estimating a correlation between the proportion of eligible QIs performed and the change in the mean score of QoL, where a minimum of 5-points change is considered to be clinically important. (134,135) The proportion of eligible QIs performed was defined as the percentage of QIs performed over the number of eligible QIs per patient. A sample size of 120 patients will be sufficient to show a correlation coefficient that differs from zero of at least 0.25, with a power of 80% and a significance level of 5%.
2.3.2 Baseline demographics, patient characteristics and QoL scores

Descriptive statistics were used for baseline patient data, performance measures, admission data, and quality of life results. Discrete data were presented as proportions, whereas continuous data were presented as a mean +/- 1 standard deviation. We used version 21 of the SPSS software for all the statistical analysis.

LVEF at 40% was the cut-off point for classification of the study group, since it is the main determinant in the prescription of medical therapy, hence for the performance of the three indicators related to cardiac medications. Baseline characteristics were compared between the group with LVEF<40% and the group with LVEF>40 % by using a student t-test for age, chi-square for gender and NYHA class, and Kruskal-Wallis test for LoS.

Each QI was assessed using the recommended method of reporting by the CCS e-catalogue and the AHA/ACC. If the QI was performed according to these descriptions (See Tables 8 to 19), then it was considered ‘appropriately performed’. We estimated the proportion of QIs performed per patient, and the adherence proportion to the QIs within the study group. The adherence proportion was defined as the number of patients that had each QI performed divided by the number of eligible patients for that QI.

Quality of Life was assessed using the MLFHQ and the KCCQ scores at the initial visit and at 3-month follow up visit; and to determine the change in the QoL mean scores between baseline and 3-months, we conducted a paired t-test.

2.3.3 Estimation of the performance of the QIs

We conducted separate analyses to estimate the performance of the indicators and test association with QoL. Our first analysis was the adherence proportion of each QI. This ‘per population’ analysis was a calculation of the proportion of eligible patients for which each QI was performed, using the previously defined numerators and denominators (Tables 8 to 19). For example: the proportion of eligible patients for whom assessment of LVEF was performed. We used interquartile ranges to report on low (<25%), moderate (26%-75%) and high (>75%) adherence proportions. The following scheme shows the definition and reporting method for this analysis.
2.3.4 Testing of association between QIs and outcomes

**QIs and QoL Δ**

For all our association analyses, the change in the QoL mean score was the variable that we used to examine the association with the performance of the QIs and to answer our primary question. In order to assess the relationship between these two variables – QIs and QoL Δ, we used two different approaches that are presented in detail in the following scheme:

**Scheme Analysis 2. Examination of Association**

- **QIs and QoL Patient analysis 1**
  - Definition: QI performed? - Yes/No
  - See table 21 for performance sheet
  - 3 analyses:
    - All patients (100) - 5 indicators
    - Medications only for patients with LVEF <40% - 3 indicators
    - All indicators plus medications in patients with LVEF <40% - 8 indicators
  - Report: Proportion (%)
  - Results on page 66-68 - tables 28, 29, 30.

- **QIs and QoL Patient analysis 2**
  - Definition: QIs performed/QIs eligible
  - All 100 patients regardless on LVEF
  - Report: Composite proportion
  - Results on page 69-70 - Figure 6 and 7
For ‘per patient’ analysis 1,(102,107) we determined whether or not each QI was performed for each patient, so that we obtained a proportion of appropriately performed QIs in each individual patient. For example: whether or not assessment of LVEF was performed in a patient. Since not all the patients were eligible to be on cardiac medications (only patients with LVEF<40%), then this analysis was also divided into 3 analyses: one where all the 100 patients were eligible for the performance of the outpatient QIs -5 indicators, the second where only the patients that had EF<40% were eligible for the QIs related to medications, so a total of 3 indicators were expected to be performed in this group of patients; and the third one where we added all the indicators (outpatient +medications) for the patients that had an EF<40%. We then tested the association between the performance of these indicators and the change in QoL mean score from baseline to 3-months, using a multiple regression analysis.

The appropriateness of HF medications and dosing was examined using the 2012 and 2014 CCS guidelines and the 2015 special HF companion that recommended the use of triple therapy for patients with a LVEF < 40%. Appropriate HF treatment was defined as: triple therapy prescription in those with an EF less than 40% as documented in the latest echocardiogram.

We developed flow diagrams based on the CCS guidelines to assess the appropriateness of the medications for each patient with an EF <40% at the time of enrolment. These diagrams are shown as follows in Figures 2 to 4.

The ‘per patient’ analysis 2,(102,107) was the calculation of the proportion of all eligible QIs performed, so that our resulted measurement was a composite percentage of the QIs performed over the number of eligible QIs for each patient. We obtained a proportion that represents the overall performance of the QIs within the study group. For example: one patient was eligible to have 5 indicators performed but only had 4, so the performance proportion was 80% for this patient. Then, we estimated the Pearson correlation coefficient between the mean proportion of performance in the study group and the change in QoL mean score from baseline to 3-months.

For both analyses, we adjusted for the following confounding variables: age, LVEF and clinical status at the time of enrolment using the NYHA classification. We did not add other comorbidities in our regression model, since we only had one study group and HF is considered as the most significant burden affecting these patients’ QoL.
# Table 21. Quality Indicators Performance Sheet

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Inpatient (if applicable)</th>
<th>Outpatient (all patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Assessment of LV Function</td>
<td>4. Early Outpatient Assessment for HF patients discharged from hospital</td>
<td>6. Mineralocorticoid receptor antagonists (MRA) use – also known as Aldosterone antagonists</td>
</tr>
<tr>
<td>NUMBER OF ELIGIBLE QIS</td>
<td>NUMBER OF PERFORMED QIS</td>
<td></td>
</tr>
</tbody>
</table>
Figure 2. Therapeutic Approach for the Appropriateness of ACEI/ARB created using the 2012 and 2014 CCS guidelines and the 2015 special HF companion. *If the patient is on the same (not on target) dose for more than two visits, with no documented reason, consider neglect. ** If there is no documented reason for not being on the guideline-recommended therapy or dose, consider neglect.
**Figure 3.** Therapeutic Approach for the Appropriateness of Beta blocker created using the 2012 and 2014 CCS guidelines and the 2015 special HF companion. *If the patient is on the same (not on target) dose for more than two visits, with no documented reason, consider neglect. **If there is no documented reason for not being on the guideline-recommended therapy or dose, consider neglect.
Figure 4. Therapeutic Approach for the Appropriateness of MRA created using the 2012 and 2014 CCS guidelines and the 2015 special HF companion. *If the patient is on the same (not on target) dose for more than two visits, with no documented reason, consider neglect. ** If there is no documented reason for not being on the guideline-recommended therapy or dose, consider neglect.
**QIs and clinical outcomes**

To assess relationship between QIs and clinical outcomes, we used the resulted proportion of QIs performed in ‘per patient analysis 2’ and examine clinical outcomes in the form of 30-day ED/admission rate, 60-day ED/admission rate and 30 and 60 days mortality using a logistic regression analysis. Statistical significance was defined by a 2-tailed p value of <0.05.

**Scheme Analysis 3. Estimation of association with clinical outcomes**

- Definition: Association of overall proportion of QIs performed and rate of clinical outcome events
- Results on page 71
CHAPTER 3

3. RESULTS AND ANALYSES

3.1 RESULTS

3.1.1 Baseline demographics/ patient characteristics and clinical presentation

From September 2015 to July 2016, a total of 188 eligible patients with HF who presented to the HF clinic were identified. Due to slower than expected enrolment and frequent lost to follow up;(151) we could only report on the results of the first 100 patients that consented to participate in the study. Figure 5 shows the flow of our patients during the study period.

Half of the patients enrolled in the study (50 patients) were initially referred to the HF clinic from the inpatient settings, whereas the other 50 patients were referred from other primary care physicians, specialists or clinics. For the patients that were admitted for HF prior to referral, the date of the admission in some cases goes back to the year 2000, and in other cases within 2 weeks of enrolment. Hence, the admission period covers from 2000 until 2016.

For these 50 patients that were admitted, we assessed the performance of the inpatient indicators: daily assessment of blood tests, CXR, assessment of LV function and early assessment after discharge (within 2 weeks after being discharged from the hospital).

Then, we assessed the performance of the outpatient indicators in all the 100 patients that consented – documented etiology, documented LVEF, BP assessment, BW assessment, patient education – and divided the cohort into patients that had an EF $\geq 40\%$ and patients that had EF $< 40\%$ to determine adherence to cardiac medications as previously explained. The patients that had EF $\geq 40\%$ were 54 and the patients that had EF $< 40\%$ were 46. For these 46 patients we assessed performance of the indicators related to medications: ACEI/ARB use, beta-blocker use, MRA use.
For all the 100 patients seen in the clinic, we assessed QoL through both questionnaires: at baseline there were 93 respondents of the MLHFQ and 86 completed the KCCQ. For the 3-month follow up questionnaires: 69 patients completed both the MLHFQ and the KCCQ.

During the 3-month period, 3 patients died before completing the study, 2 patients became palliative and were unable to answer the questionnaires and 26 patients were lost to follow up - either they refused to answer the questionnaires, they were unable to be contacted or they were no-show to their clinic appointment.

As stated above, there was an equal distribution of patients referred from the inpatient and outpatient clinics, 50 from each. For the 50 patients that had a previous HF admission before they were referred to the clinic, the median Length of Stay (LoS) was 7 days (IQR from 5 to 10 days), the median LoS for the patients with EF < 40% was 8 days (IQR from 7 to 14 days) and for the patients with EF ≥ 40% the median LoS was 6 days (IQR from 5 to 9 days). A Kruskal-Wallis non-parametric test to compare both groups resulted in a p value of 0.47, which means that the distribution of LoS is the same regardless of patients’ LVEF during admission.
**Figure 5.** Patient flow for the evaluation of the inpatient and outpatient QIs in a HF clinic with sample sizes distribution for each section of the study.
The baseline characteristics of these 100 patients at the time of enrolment are presented in the following table:

Table 22. Baseline Characteristics of the Study Sample (n=100)

<table>
<thead>
<tr>
<th></th>
<th>LVEF &lt; 40% (n=46)</th>
<th>LVEF ≥ 40% (n=54)</th>
<th>Overall (n=100)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68 ± 13</td>
<td>73 ± 14</td>
<td>71 ± 13</td>
<td>0.07</td>
</tr>
<tr>
<td>Gender - Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>32 (70%)</td>
<td>28 (52%)</td>
<td>60 (60%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Female</td>
<td>14 (30%)</td>
<td>26 (48%)</td>
<td>40 (40%)</td>
<td></td>
</tr>
<tr>
<td>NYHA class - I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>1 (2%)</td>
<td>7 (13%)</td>
<td>8 (8%)</td>
<td>0.07</td>
</tr>
<tr>
<td>II</td>
<td>34 (74%)</td>
<td>40 (74%)</td>
<td>74 (74%)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>11 (24%)</td>
<td>7 (13%)</td>
<td>18 (18%)</td>
<td></td>
</tr>
</tbody>
</table>

The mean age for the overall study group was 71 years ± 13. There was a similar distribution between female and male in the group with HFpEF, and men were more than the double of women in the group with HFrEF. The majority of the patients were classified as having a NYHA Class II (74%) and there were no patients classified with NYHA class IV at the time of enrolment. When we compared the group with EF< 40% and the group with EF ≥ 40%, we found that there was no statistically significant difference in the age, gender and NYHA class of the patients in both groups, p value of 0.07.
3.1.2 Quality Indicators (QIs):

**Inpatient Quality Indicators:**

For the inpatient QIs, the denominator was the number of patients that had a previous HF admission (n=50).

The adherence proportion to the daily assessment of blood chemistry was high for Na with 78%, K 78% and creatinine 76%. However, the same did not apply to the assessment of BUN, which resulted in a moderate adherence proportion of 36%. The performance of CXR within the first 8 hours of ED contact resulted in a high adherence proportion of 80%, as well as the assessment of LVEF during the HF admission with an 82% rate. Table 23 shows these specific results.

**Table 23. Adherence proportion (%) with Inpatient Quality Indicators (n=50)**

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Unit of Assessment</th>
<th>Denominator</th>
<th>Numerator</th>
<th>Adherence Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily Assessment of Blood Chemistry</td>
<td>Sodium (Na)</td>
<td>Patients</td>
<td>50</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>Potassium (K)</td>
<td>Patients</td>
<td>50</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>Patients</td>
<td>50</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>BUN</td>
<td>Patients</td>
<td>50</td>
<td>18</td>
</tr>
<tr>
<td>Chest X-Ray (within 8 hours)</td>
<td>Patients</td>
<td>50</td>
<td>40</td>
<td>80 %</td>
</tr>
<tr>
<td>Assessment of LVEF</td>
<td>Patients</td>
<td>50</td>
<td>41</td>
<td>82 %</td>
</tr>
</tbody>
</table>
**Outpatient Quality Indicators:**

The QI that measures early assessment of the patient – within 2 weeks of being discharge from the hospital - in the outpatient clinic had a moderate adherence proportion of 42%, taking into account that this indicator only applies to the 50 patients that were referred from the inpatient during their HF admission. Of these 50 patients, 21 were seen within 2 weeks after discharge and the median amount of days was 18 (IQR= 14 to 24 days). We also determined the time to be seen for the 50 patients that were referred from outpatient clinics and the median time was 31.5 days (IQR = 18 to 41 days).

For the 100 patients seen in the clinic at the time of enrolment, the documentation of both HF etiology and LVEF had high adherence proportion of 86% and 100% respectively. The most common documented HF etiology was ischemic cardiomyopathy, as a consequence of CAD that accounts for48 % of the cases; then Afib/Aflutter was the second most frequent documented etiology with 16% and the other etiologies combined for a 35% of the cases. The mean EF documented during the outpatient clinic visit was 42% ± 15. Blood pressure assessment was performed in 98% of the patients, being the mean systolic measurement 123 mmHg ±20 and the mean diastolic measurement was 68 mmHg ±11. The adherence proportion to body weight assessment was 83%; the mean weight was 176 Lbs. ± 51.

The patient education indicator was performed in 85% of the patients, and adherence to this indicator was considered positive if the HF management education was given at any visit. We further divided this indicator into patients that had education during their initial visit and patients that had education during the follow up visits. 83% of patients had education during their initial visit and 82% of patients had education in subsequent clinic visits. These results correspond to the ‘population analysis’ explained on page 36 and are presented in detail in Table 24.
Table 24. Adherence Proportion (%) with Outpatient Quality Indicators (n=100)

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Unit of Assessment</th>
<th>Denominator</th>
<th>Numerator</th>
<th>Adherence Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Outpatient Assessment</td>
<td>Patients</td>
<td>50</td>
<td>21</td>
<td>42 %</td>
</tr>
<tr>
<td>Documentation of HF etiology</td>
<td>Patients</td>
<td>100</td>
<td>86</td>
<td>86 %</td>
</tr>
<tr>
<td>Documentation of LV function</td>
<td>Patients</td>
<td>100</td>
<td>100</td>
<td>100 %</td>
</tr>
<tr>
<td>Blood Pressure Assessment</td>
<td>Patients</td>
<td>100</td>
<td>98</td>
<td>98 %</td>
</tr>
<tr>
<td>Body Weight Assessment</td>
<td>Patients</td>
<td>100</td>
<td>83</td>
<td>83 %</td>
</tr>
<tr>
<td>Patient education</td>
<td>Patients</td>
<td>100</td>
<td>85</td>
<td>85 %</td>
</tr>
</tbody>
</table>

HF medications were considered only in the patients that had an EF less than 40%, as recommended by the CCS medical guidelines and the evidence associated with HF with reduced ejection fraction. At the time of enrolment in the clinic, 46 patients had an EF less than 40%.

For the use of ACEI/ARB therapy, the denominator was 42 since patients with the following documented contraindications were excluded: 1 due to hyperkalemia and 3 due to renal dysfunction as documented in each patients’ chart. The adherence proportion was 100% with the use of ACEI/ARB. The denominator for beta-blocker therapy was 45; only 1 patient was excluded due to hypotension. The resulting adherence proportion was 100%. For the use of MRA therapy, the denominator was 32, 7 patients were excluded due to hyperkalemia, 5 due to renal dysfunction and 2 due to NYHA class <II. Only 1 patient did not have any documentation of the reason for not being on MRA therapy, therefore it was considered neglect. The adherence proportion was 97%. Table 25 presents the performance of these indicators.
Table 25. Adherence Proportion (%) with Medications in Patients with LVEF <40% (n=46)

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Unit of Assessment</th>
<th>Denominator</th>
<th>Numerator</th>
<th>Adherence Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of ACEI/ARB therapy</td>
<td>Patients</td>
<td>42</td>
<td>42</td>
<td>100 %</td>
</tr>
<tr>
<td>Use of BB therapy</td>
<td>Patients</td>
<td>45</td>
<td>45</td>
<td>100 %</td>
</tr>
<tr>
<td>Use of MRA therapy</td>
<td>Patients</td>
<td>32</td>
<td>31</td>
<td>97 %</td>
</tr>
</tbody>
</table>

We also determined the dosage of the evidence-based medications at which patients were at the time of enrolment. This analysis is presented in Table 26.

Table 26. Distribution of patients with evidence-based medication dosage in patients with LVEF <40% (n=46)

<table>
<thead>
<tr>
<th>Cardiac Medication</th>
<th>Prescribed Target Dose</th>
<th>Not Prescribed Target Dose</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Being Titrated</td>
<td>Intolerance</td>
<td>Renal Dysfunction</td>
</tr>
<tr>
<td>ACEI/ARB therapy</td>
<td>11 (26 %)</td>
<td>21 (50 %)</td>
<td>8 (19 %)</td>
<td>2 (4 %)</td>
</tr>
<tr>
<td>BB therapy</td>
<td>11 (24 %)</td>
<td>24 (53 %)</td>
<td>9 (20 %)</td>
<td>0</td>
</tr>
<tr>
<td>MRA therapy</td>
<td>1 (3 %)</td>
<td>24 (77 %)</td>
<td>1 (3 %)</td>
<td>1 (3 %)</td>
</tr>
</tbody>
</table>

Of the 42 patients on ACEI/ARB therapy, 11 were prescribed the target dose, which represents 26%, 21 patients (50%) were on appropriate medication titration, 2 (5%) had documented renal dysfunction and 8 (19%) were intolerant. For the 45 patients that were prescribed with appropriate beta-blocker therapy, 11 (24%) were prescribed target dose, and for the 34 patients that were not on the recommended medication dose, 24 (53%) were being titrated, 9 (20%) were intolerant, and 1 (2%) had no documentation of the reason for not being at target dose so it was considered as neglect.
And for the 31 patients that were on MRA therapy, only 1 patient was prescribed the recommended target dose (3 %), 24 (77%) patients were on documented medication titration, 2 (7 %) patients had EF recovery, 1 (3%) patient had renal dysfunction, 1 (3%) patient was intolerant and 2 (7 %) patients did not have any documentation of the reason for not being on the target dose, so it was considered as neglect.

3.1.3 Quality of Life (QoL):

Of the 100 patients, 3 died before completion of the 3-month period, 2 were deemed palliative and 26 were lost to follow up, leaving 69 patients with data for the 3-month follow up questionnaires.

We conducted a student- t test to compare the baseline characteristics of the patients that completed the study and the 26 patients that were lost to follow up, and we found that there was no statistically significant difference between both groups with regards to age (p=0.9) and NYHA class (p=0.1), which means that the patients that did not complete the study were not older, not sicker at the time of enrolment.

The MLHFQ was completed by 93 and 66 patients at the initial visit and 3-month follow up visit, respectively. The average quality of life score at baseline was 34 ± 25, and 28 ± 22 at 3-months, which means that in both cases patients reported a moderate QoL and moderate functional capacity. There was a 6-points change between the initial and the 3-month follow up scores.

The KCCQ was completed by 86 patients at their initial visit and by 66 patients at 3-months follow up. The average two summary scores were: functional status score 64 ± 25 at baseline and 70 ± 22 at 3-months; clinical summary score 66 ± 24 at baseline and 73 ± 23 at 3-months; which suggests that patients reported a fair QoL at both times and moderate physical limitations. There was a 7-points variation for both the functional score and the clinical summary score, and a comparable change was also observed in the 6 questionnaire domains. Table 27 summarizes the mean scores at baseline and follow-up among the patients that completed the questionnaires at both times.
Therefore, patient-reported QoL showed statistically significant improvement in most of the domains measured by the KCCQ, and not statistically significant improvement with the MLHFQ.

Table 27. Mean QoL scores and mean change at baseline and at 3-months for the patients that responded to the questionnaires at both times. (n=66)

<table>
<thead>
<tr>
<th>Questionnaire and Scale</th>
<th>Baseline Mean Score</th>
<th>3-Month Mean Score</th>
<th>Mean Difference</th>
<th>SEM</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>KCCQ</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical limitation</td>
<td>62</td>
<td>70</td>
<td>7</td>
<td>3.4</td>
<td>0.04</td>
</tr>
<tr>
<td>Symptoms</td>
<td>69</td>
<td>76</td>
<td>7</td>
<td>2.6</td>
<td>0.01</td>
</tr>
<tr>
<td>Symptom stability</td>
<td>52</td>
<td>41</td>
<td>-11</td>
<td>5.1</td>
<td>0.03</td>
</tr>
<tr>
<td>Social limitation</td>
<td>61</td>
<td>70</td>
<td>9</td>
<td>3.8</td>
<td>0.03</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>82</td>
<td>89</td>
<td>7</td>
<td>2.3</td>
<td>0.00</td>
</tr>
<tr>
<td>Quality of life</td>
<td>62</td>
<td>65</td>
<td>3</td>
<td>3.3</td>
<td>0.32</td>
</tr>
<tr>
<td>KCC functional status</td>
<td>64</td>
<td>70</td>
<td>7</td>
<td>2.8</td>
<td>0.01</td>
</tr>
<tr>
<td>KCCQ clinical summary</td>
<td>66</td>
<td>73</td>
<td>7</td>
<td>2.7</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>MLHFQ</strong></td>
<td>34</td>
<td>29</td>
<td>6</td>
<td>3.1</td>
<td>0.06</td>
</tr>
</tbody>
</table>
3.2 QIs Association Analyses

3.2.1 QIs and QoL:

As stated in our methods, we ran separate analyses to determine the association of the performance of the QIs and the change in QoL scores. Since not all patients responded to the QoL questionnaires at both times (baseline and 3-months), the analysis of QoL change can only account for the patients that had both measurements, which means that our n is 66.

The following analysis corresponds to ‘patient analysis 1’, where we operationalized the estimation of performance into 3 different analyses. In the first analysis, we evaluated the performance of all the eligible outpatient indicators in the 100 patients, which means the evaluation of the following 5 indicators: documentation of HF etiology, documentation of LVEF, BP assessment, BW assessment and patient education. And we determined if there was an association between the performance of these indicators and the QoL mean scores change, measured by MLHFQ and KCCQ, over the 3-month period.

The analysis showed that these outpatient indicators are not statistically significantly associated with the QoL change measured by the MLHFQ, $R^2 = 0.04$, F=0.66, p=0.62; nor by the KCCQ, $R^2 = 0.02$, F=0.30, p=0.87, which means that none of the variables were associated with QoL change. Table 28 shows a summary of the multiple regression analysis.
Table 28. Summary of the Multiple Regression Analysis for the Outpatient QIs on QoL Score Variation Using the MLHFQ and KCCQ (n=66)

<table>
<thead>
<tr>
<th>Variable</th>
<th>MLHFQ</th>
<th></th>
<th>KCCQ</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>B</strong></td>
<td><strong>St. Error</strong></td>
<td><strong>P value</strong></td>
<td><strong>B</strong></td>
</tr>
<tr>
<td>Documented LVEF</td>
<td>-36.30</td>
<td>29.00</td>
<td>.21</td>
<td>21.10</td>
</tr>
<tr>
<td>Documented Etiology</td>
<td>-1.80</td>
<td>9.70</td>
<td>.85</td>
<td>-1.50</td>
</tr>
<tr>
<td>BP Assessment</td>
<td>39.00</td>
<td>27.80</td>
<td>.16</td>
<td>-11.70</td>
</tr>
<tr>
<td>BW Assessment</td>
<td>-2.80</td>
<td>8.30</td>
<td>.73</td>
<td>-6.00</td>
</tr>
<tr>
<td>Patient Education</td>
<td>-4.70</td>
<td>9.40</td>
<td>.61</td>
<td>4.10</td>
</tr>
<tr>
<td>R²</td>
<td></td>
<td>0.04</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For the second analysis, we examined the relationship between performance of the indicators that were related to cardiac medications and QoL change. Since it was only applicable to the 46 patients that had an EF less than 40%, we determined the amount of patients that responded to the QoL questionnaires at both times for this group, and our n resulted in 28 patients. This analysis then comprised the following: the use of ACEI/ARB, BB and MRA therapy; and its association with the QoL mean scores change over the 3-month period.

We found similar results for both the MLHFQ and the KCCQ, with $R^2=0.01$, $F=0.12$, $p=0.88$ and $R^2=0.07$, $F=1.0$, $p=0.38$ respectively; which suggests that no statistically significant association resulted from the prescription of the triple therapy on patients with an EF<40% and the QoL scores change seen after 3-months. Table 29 summarizes these results.
Table 29. Summary of the Regression Analysis of the Cardiac Medications on QoL Score Variation Using the MLHFQ and KCCQ (n=28)

<table>
<thead>
<tr>
<th>Variable</th>
<th>MLHFQ</th>
<th></th>
<th></th>
<th>KCCQ</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>St. Error</td>
<td>P value</td>
<td>B</td>
<td>St. Error</td>
<td>P value</td>
</tr>
<tr>
<td>Beta blocker use</td>
<td>0.50</td>
<td>19.90</td>
<td>0.98</td>
<td>8.17</td>
<td>13.10</td>
<td>0.54</td>
</tr>
<tr>
<td>ACEI/ARB use</td>
<td>-11.10</td>
<td>23.60</td>
<td>0.64</td>
<td>9.70</td>
<td>16.13</td>
<td>0.55</td>
</tr>
<tr>
<td>MRA use</td>
<td>1.05</td>
<td>13.90</td>
<td>0.94</td>
<td>-14.20</td>
<td>10.10</td>
<td>0.17</td>
</tr>
<tr>
<td>R²</td>
<td></td>
<td>0.01</td>
<td></td>
<td></td>
<td>0.07</td>
<td></td>
</tr>
</tbody>
</table>

For the third analysis, we added the 5 outpatient QIs to the 3 indicators related to medications in the patients that had an EF<40%, which accounts for 8 indicators in this group of 28 patients. These indicators are the following: documentation of HF etiology, documentation of LVEF, BP assessment, BW assessment, patient education, ACEI/ARB therapy, BB therapy and MRA therapy.

The results of this analysis showed that no statistically significant association was present between the QoL change and the performance of these 8 indicators: R²=0.09, F=0.38, p=0.88 for the MLHFQ and R²=0.16, F=0.66, p=0.67 for the KCCQ. Table 30 summarizes this analysis.
Table 30. Summary of the Regression Analysis of the Outpatient QIs and Cardiac Medications for Patients with an EF<40% on QoL Score Variation using MLHFQ and KCCQ (n=28)

<table>
<thead>
<tr>
<th>Variables</th>
<th>MLHFQ</th>
<th>KCCQ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>St. Error</td>
</tr>
<tr>
<td>(Constant)*</td>
<td>-29.13</td>
<td>47.80</td>
</tr>
<tr>
<td>Documented Etiology</td>
<td>17.80</td>
<td>30.20</td>
</tr>
<tr>
<td>BP Assessment</td>
<td>19.00</td>
<td>41.50</td>
</tr>
<tr>
<td>BW Assessment</td>
<td>2.50</td>
<td>18.40</td>
</tr>
<tr>
<td>Patient Education</td>
<td>-9.70</td>
<td>20.00</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>-14.90</td>
<td>25.80</td>
</tr>
<tr>
<td>MRA</td>
<td>7.30</td>
<td>16.40</td>
</tr>
<tr>
<td>R²</td>
<td></td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Documentation of LVEF and BB therapy are (Constant) variables, hence they were taken out from the regression model.

For the ‘patient analysis 2’, we first determined the proportion of QIs performed in the patients that had EF<40% and that were eligible for 8 indicators, so the calculation was: number of indicators performed /8 indicators. Then we did the same for the 100 patients that were eligible for 5 indicators regardless of LVEF, so this calculation was: number of indicators performed/5 indicators. The results are shown in the following graphs.

For the 46 patients that had an EF<40%, 8 indicators were expected to be performed - documentation of HF etiology, documentation of LVEF, BP assessment, BW assessment, patient education, ACEI/ARB therapy, BB therapy and MRA therapy. The distribution was as follows:
22 patients (48%) had 8 indicators performed, 15 patients (33%) had 7, 7 patients (15%) had 6, and 2 patients (2%) had 4 and 5 indicators performed respectively. This is shown in Figure 6.

![Per patient analysis: Proportion of QIs performed](image)

**Figure 6** ‘Per patient analysis 2’ for the performance of QIs in patients with LVEF <40%. The bars indicate the proportion of patients that had eligible QIs performed out of the 8 expected indicators for this group with EF<40%. N=46, the numbers inside the bars indicate the distribution of patients in each set of indicators.

On the other hand, for the 54 patients that had an EF > 40%, 5 indicators were expected to be performed: documentation of HF etiology, documentation of LVEF, BP assessment, BW assessment and patient education. This distribution is shown in Figure 7: 30 patients (56%) had 5 indicators performed, 19 patients (35%) had 4, 2 patients (4%) had 3 and 3 patients (6%) had 2 indicators performed.
Figure 7. ‘Per patient analysis 2’ for the performance of QIs in patients with LVEF ≥40%. The bars indicate the proportion of patients that had eligible QIs performed out of the 5 expected indicators for this group with EF<40%. N=54, the numbers inside the bars indicate the distribution of patients in each set of indicators.

The composite proportion was then calculated as the total proportion of QIs performed within the study group, which is the number of QIs performed over the number of eligible QIs. This composite measurement resulted in a mean proportion of 89%, which means that the QIs were performed on average in 89% of the cases in which they were expected to be performed.

A Pearson correlation analysis was conducted to determine the relationship between this high proportion of QI performance and the change in the QoL scores, and the result was no statistically significant, R= -0.06, p=0.60 for MLHFQ, and R= -0.09, p=0.44 for KCCQ, which suggests that the variation in the QoL scores cannot be explained by the high-performance of QIs.
3.2.2 QIs and Clinical Outcomes:

The outcomes data collected by the hospital Decisions Support and Outcomes Department showed that out of the 100 patients in our study: 2 patients (2%) had a cardiovascular-related ED visit within 30-days after being seen in the HF clinic and 1 (1%) of these patients died during this ED visit; 2 patients (2%) had a cardiovascular admission within 30-days and 4 (4%) patients were admitted within 60-days. Of the patients that were admitted within 60-days, 1 (1%) died during admission. Further revision showed that 8 patients (8%) had a cardiovascular ED visit/admission after 60-days of being seen in the HF clinic, most of them within 6-9 months after initial clinic enrolment, and this group of patients also had multiple ED/admissions for other non-cardiac related conditions.

Thus, a total of 8 patients (8%) were seen in the ED or admitted to hospital for management of HF and other cardiac-related conditions within 60 days of being seen in the clinic, and 2 patients (2%) died during this ED visit or admission.

We conducted a logistic regression analysis to examine if the high proportion of adherence to the QIs resulted from ‘patient analysis 2’ (89%), had any effect on the likelihood of having an ED visit or admission at 30-days, and we found that there was no statistically significant relationship, $x^2=0.01$, $p=0.59$. Similarly, with ED visits and admissions at 60-days, $x^2=0.06$, $p=0.28$; and mortality at 30 and 60 days, $x^2=0.12$, $p=0.91$, suggesting that there was no statistically significant association between the high-performance of QIs and mortality within 30 and 60 days.
CHAPTER 4

4. DISCUSSION AND CONCLUSIONS

4.1 DISCUSSION

We examined adherence proportion to the CCS QIs among patients with HF that presented to a specialized HF clinic at St. Michael's Hospital; and determined the association of the performance of these indicators with QoL and clinical outcomes. We found that there is a high adherence proportion of 89% with the majority of the inpatient and outpatient indicators and, patient-reported QoL improved over the 3-month period of study with a clinically significant 7-point variation, however the performance of the QIs did not show a significant association with this QoL improvement.

The novelty of our study in measuring outpatient QIs broadens the previous knowledge on adherence to inpatient performance measures, mostly developed by the American Heart Association (AHA) and the American College of Cardiology (ACC)\(^\text{(107)}\)(18,146) and under continuous reiteration.\(^\text{(108)}\) The evaluation of outpatient performance measures has been limited by administrative challenges such as data collection and standardized processes across different organizations. Moreover, it is just recently that the CCS published a recommended set of QIs to measure quality of care for patients with HF in Canada.\(^\text{(102)}\) Hence, this is the first comprehensive study that examines and evaluates the performance of the Canadian indicators in the care of patients with HF, more importantly in the outpatient settings.

Another first in our study is the assessment of the relationship between the QIs and patient-reported QoL, including functional capacity, patient satisfaction and social limitations; since most of the previous studies have only reviewed mortality and re-admissions.\(^\text{(128)}\)(141,146) This allows us to expand our quality assessment knowledge and explore other outcomes that may be of interest.
This rather exploratory study provides an insight into the quality of care of outpatients and highlights a significant piece of the knowledge translation bridge by demonstrating the use of medical guidelines in clinical practice. We have to start by acknowledging that our sample size is smaller than expected, first of all due to slow enrolment and secondly due to multiple patients that were lost to follow up; so our final analysis is limited by this important factor.

Our demographic distribution coincides with previous studies where the majority of patients are over 65 years old, (3)(5,6) and approximately half of the patients have a preserved EF. (3) There was no statistical difference in the distribution of age, gender and NYHA class when we compared the group that had EF<40% versus the group with EF>40%, which suggests that, the demographic risk profile is similar for both preserved and reduced EF. (11)(2,8)(3)(152)

It is important to note in this regard that we did not conduct an analysis of previous medical history in these patients, so we cannot assess the presence of other risk factors involved in this distribution, such as history of hypertension and atrial fibrillation in female versus male. Ischemic cardiomyopathy was the most common documented etiology followed by atrial fibrillation/atrial flutter and hypertension, as documented in previous studies.(3)(2,8)

For the patients that were admitted, the median LoS of 7 days was comparable to the one reported by CIHI in 2012,(12) and there was no difference in the LoS with regards to EF during admission.

A persistent finding across the literature (2,3) that we also observed, was around the increasing proportion of patients with HFpEF, and the fact that even though the heart has a normal systolic function in these patients, that does not necessarily translate into better outcomes nor decrease morbidity, (16) which reinforces the need to find new therapeutic approaches for this group.

We found that all the QIs were feasible to measure using the hospital EMRs and patients' charts, which suggest that systematic evaluation of these performance measures could be achieved if the appropriate resources are put in place, such as dedicated data abstractors and complete data sources. There were challenges when collecting the data, since not all the information needed was located in one place, and we had to review multiple sources to accurately obtain specific details especially for the patients that had been followed for many years. The use of EMRs is a great aid in obtaining these data points in a standardized way, and administrative databases are an efficient source of information on specific metrics and clinical outcomes within the
institution, but there is delay in the access and transfer of these data, which makes it difficult to obtain results that can be acted upon in a timely manner to improve care at a local level.

There was an overall high adherence proportion to all the QIs, between 76% and 100%, which indicates that the gaps in the quality of outpatient care are not related to the performance of evidence-based medicine, and that clinical teams in charge of the management of these patients are well informed of the clinical guidelines and the benefits that these recommendations and therapies have shown in the clinical trials.

There were two QIs that had a moderate - low adherence proportion: the assessment of BUN during hospital admission with 36% and the early outpatient assessment after discharge with 42%.

We believe that the daily assessment of BUN during admission is not performed in 100% of cases due to the clinician's concern of multiple daily blood tests for these patients, and the fact that is believed that the same kidney function information can be obtained with the assessment of creatinine, so redundancy may be an important factor in the measurement of this laboratory test. Previous studies have found the same result and although BUN has shown to be a better predictor of re-admissions and 60-days mortality,(24)(153) the current practice continues to be towards the performance of creatinine over BUN. (154)

On the other hand, the QI developed by the CCS establishes that the reported statistic on the assessment of blood chemistry should be that of the percent of patients that received all four blood tests (Na, K, creatinine and BUN), on a daily basis, while they received IV therapy. This measurement may be unfair and biased since the performance of the daily assessment of Na, K and creatinine was high -between 76%-78%, and the performance of BUN was only 36%. Had we reported adherence to only on the daily performance of the 4 blood tests together, the rate would be 40%.

Since this is the first time that this evaluation has been done in a systematic way, we would recommend the reporting of this indicator as an independent measurement per blood test and not for the 4 blood tests altogether. Thus, the adherence will be reported as individual percentages for Na, K, creatinine and BUN. Moreover, further research needs to be performed to better
understand why clinicians prefer the use of creatinine to BUN, and if this may be a factor in the development of future guidelines and QIs.

Our observation of patient management during admission and in the outpatient setting, suggests that the biomarkers BNP/NT-proBNP are frequently used for the diagnosis of HF in patients presenting with dyspnea in the ED, and for monitoring disease progression in the clinic. Considering that these biomarkers are independent predictors of mortality, adverse cardiovascular events and health care resource utilization in HF, (33,35,36)(155) and increased levels despite treatment suggests progression of disease or resistance to treatment requiring intensification of medication management; (34–36,134) it is worth studying their use as potential inpatient and outpatient indicators of quality of care. Previous CCS recommendations have emphasized, the utility of NPs in patients in whom the diagnosis of HF is uncertain, and the significance of increased levels in the prognosis of these patients, (25,37) with recommended measurements on admission, after 24 hours of treatment and at discharge. Furthermore, recent guidelines recommend the use of these biomarkers to monitor disease progression by stratifying risk and individualizing therapy, (155) and combining commonly used clinical features with NP values to improve diagnosis and decision-making.(156) We should consider these important biomarkers as potential QIs that can be further studied and implemented as part of the management of HF patients.

The other indicator that had a moderate adherence proportion was the early outpatient assessment, and this is an indicator that measures process of care. We believe that there are a few reasons why not all the patients were seen within the two weeks period following discharge. The first reason, previously reported, is cardiovascular related admissions or ED visits within 30 days after discharge, which means that patients are not seen in the clinic because they are either back in-hospital or they had been in the ED within the days that the initial outpatient visit was scheduled. This is a common cause of no-shows that accounts for an approximate 21% of the patients being readmitted within 30 days. (12) Unfortunately, our study did not measure readmissions after initial discharge.
The second reason may be that patients were seen by their primary care provider (PCP) or another specialist before the HF clinic appointment, which extended the amount of days prior to the index HF clinic visit. In this case, the appointment with the PCP and/or specialist should be considered as the early follow up assessment and counted as compliant with this indicator. However, this measurement outside of the hospital database was not in the purpose of our study. Other reasons for the lower adherence proportion with this indicator were related to scheduling conflicts with the patients, availability of a caregiver support and transportation resources. Since the disease management interventions also vary across different organizations, it is important to take into account that some patients may have received a case management follow up led by a HF specialist nurse or a multidisciplinary intervention to guide the patient between hospital admission and discharge home.

Previous studies have shown considerable variability in the performance of quality of care indicators across different hospitals in the US that translates into high variability in outcomes such as mortality and re-admissions. However, we found minor variations in adherence proportions (from 75% to 100%) for most of the measures. This is explained by the fact that our study was in a single site with a highly specialized and consistent HF clinical team, a HF specialist and the standardization of clinical guidelines in the daily practice. We consider that this is a very important contributing factor to variability in treatment, as demonstrated by previous studies. Further work in different practice sites is needed to understand the performance of the same QIs and its impact in quality of care.

Knowledge translation studies have found that there is a gap in the delivery of care for HF patients that accounts for most of the variability across different practices, however it is not clear where the gap is. Realizing that there is a problem is not enough to indicate what exactly needs to be changed, and what we found in our study is that clearly it is possible to attain high levels of adherence to the recommended standards of care. The clinic environment and patterns of practice with guideline familiarity seem to be important factors in the management of these patients. Hence, a specialized HF clinic where patients are closely followed, in a very similar way as to how it is done in clinical trials, should have comparable levels of adherence to what we found in our study.
The documentation of LVEF and etiology had very high adherence proportions, which means that the recommended parameters for the decision on optimal therapy are taken into account in every single patient. This translates into appropriate medical therapies, and speaks to the fact that both are valid and meaningful indicators of quality of care. Similarly, the assessments of BP and BW as safety indicators to monitor patient status, detect early decompensation and titrate medication, were performed and documented appropriately in the majority of the patients. The ACC/AHA latest agreement on these 2 indicators was that they should be performed as standard practice, thus its adherence is expected to be high, which means that these measurements are not likely to have a significant impact on care or improved outcomes, and since there is no modifiable intervention possible in this regard, they should not be considered as QIs but rather as routine clinical practice.\(^{(108)}\) The CCS did not include any of these 4 indicators mentioned above as part of their latest QIs recommendations since the publication was focused on the inpatient indicators.\(^{(102)}\)

Our findings regarding the evidence-based medications for patients with reduced EF are consistent with previous studies, \(^{(157)}\) with a slightly higher rate of ACEI/ARB (100% in our study, 80% in IMPROVE HF, 79% in PINNACLE and 89% in HART) and BB (100% in our study, 86% in IMPROVE HF, 89% in PINNACLE and 76% in HART) use in the outpatient setting. \(^{(158)}(103)(159)\) Patients with contraindications were excluded from the denominator in the evaluation of each medication.

Adherence to MRA therapy has been previously documented as significantly lower than ACEI/ARB and BB,\(^{(160)(161)}\) however our findings show a comparable adherence proportion of 97%, to both ACEI/ARB and BB.

Although dosing of the evidence-based medications is not a QI, we thought it was important to assess in our study since attaining target doses has demonstrated to be associated with reduction of morbidity, mortality and hospitalization rates in randomized control clinical trials. \(^{(52)(148)}\) Our analysis shows that despite the high adherence to the guidelines-recommended triple therapy for patients with EF<40%, the majority of patients are not on the recommended target dose. A few studies have reviewed medication dosage in HF, mostly associated with beta-blockers, and our results coincide with those findings that report a variable proportion of 8-40% of patients that achieve target dose.\(^{(86)(162)(163)(62)(164)}\) One recent study found a notable
increase in the proportion of patients that achieve the recommended dose (69%), however they considered optimal therapy at least 50% of the target dose, did not report on contraindications or intolerance and their population was younger by an average of 10 years. (148)

Nonetheless, most of the patients in our study are on appropriate medication titration defined as initiation at low starting doses and doubled every 2-4 weeks depending on patients’ clinical response, until meeting the target or maximum tolerated dose. These findings confirm the complex nature of HF patients, with multiple comorbidities and contraindications that make this a challenging condition to manage;(5,86,93) and reinforce the need of identifying effective management strategies in this subgroup of patients. It is important to note here that our study only included provider adherence to the evidence-based standards of care, and this may not reflect patient individual adherence to prescription medications, diet restriction and/or self-management strategies.

Patient education has been described as an important component of HF management, requiring patients to actively participate in the monitoring and self-management of their own condition. We considered compliant with patient education, the documentation of at least one of the following: weight monitoring, diet advice (sodium restriction), symptom management, physical activity, medication instructions and follow up plans. It is also necessary to reinforce HF education in every opportunity, and this is the reason why we decided to operationalized this indicator and find out if patients were receiving education only during their initial visit or in every follow up visit. Another important piece to consider in the future when evaluating patient education as a QI, is the inclusion of the discussion of end-of-life issues. This is an increasingly relevant point that should be warranted for every patient with chronic and disabling conditions such as HF.

Similarly to previous studies, (3)(2) we found that patient-reported outcomes are comparable regardless of EF, which means that patients that have a preserved EF report the same level of functional capacity as the patients with reduced EF. (11) The analysis of the QoL questionnaires showed a significant but small improvement in the patient-reported QoL when we compared the KCCQ scores at the initial versus at 3-months visit, which has been reported to be the most sensitive and accurate HF QoL tool in the detection of clinical change. (134,136) Consideration should be given to our follow up numbers when interpreting these results, since the patients that
did not complete the 3-month follow up questionnaires may have had poorer QoL or declining cognitive function. We compared the baseline demographics between the patients that completed the QoL at both times and the patients that were lost to follow up, and we found that they were not older, neither they had worse clinical status at the time of enrolment.

The KCCQ captured significant changes in all the domains, reflecting the benefits and importance of functional status assessment and patient-reported outcomes in the daily practice. This finding coincides with previous studies in which the KCCQ was the most accurate measure in quantifying magnitude and tendency of clinical changes, followed by the NYHA class; suggesting that this instrument can be useful to monitor clinical status of patients over time.(134)

The MLHFQ also showed improvement in the patient-reported QoL; however this was not statistically significant. This may be due to 2 reasons: one is that the MLHFQ is not as sensitive to clinical changes as the KCCQ,(136) and the other one is that patients interpret and respond to their symptoms and functional status in complex ways, making it difficult sometimes to describe how they feel using standardized questions as in MLHFQ.

When we analyzed the QoL improvement captured by the KCCQ, and determined if there was an association with the performance of the QIs in the clinic, the findings were not as expected. Our population and patient analyses showed that none of the indicators were a significant predictor of QoL, neither as a single variable nor as a composite measurement. These results, however, do not contradict previous findings in which the only HF performance measures that have significantly been associated with patient outcomes were the use of ACEI/ARB, beta-blockers and LV function assessment. (109)(141)(165)(145)

Given the strong association between age more than 60 years, reduced EF <40% and higher NYHA class; (166) with HF hospitalizations and cardiovascular deaths, we adjusted our analyses for these confounding variables, previously described as important predictors of morbidity and mortality. However, we realize that the lack of control for comorbidities may underestimate or overestimate the true effect of the adherence with evidence-based QIs on the patients’ QoL. Especially, since there have been specific factors known to influence patient-reported outcomes such as depression, diabetes and previous hospitalizations.
As recommended by previous studies, we decided to give equal weight to each and all the QIs measured in our analyses, since it is not clear yet if better outcomes are expected due to the adherence to one or two indicators versus a combined effect by the performance of all the indicators in each patient. (109)

Even though, we found no association between the performance of these indicators and the QoL, the patients reported significant improvement in their functional and clinical status, which cannot be ruled out as a result of multiple factors including a synergistic effect between the adherence to all the indicators when they are combined, plus patient-specific conditions. The fact that we found no link between the performance measures and the patient-reported outcomes does not undermine the use of evidence-based QIs or the current efforts to improve quality of care, but should be used to better understand the assessment of quality in HF. On the other hand, since we did not adjust for other previously mentioned predictors of outcome, we cannot conclude that our findings are neither definitive nor generalized to other HF clinics.

Despite high performance of evidence-based indicators and standards of care, there was a roughly 8 - 10% of patients that were admitted or ended up in the ED as a consequence of HF within 60-days of enrolment date, some of them within a shorter period of time after being followed in clinic. If we took a look at these patients medical records, we would find that they were appropriately treated in every possible way, taking into account some medication contraindications and dosages, but ‘appropriately treated’ as recommended by the guidelines, which suggests that there are other patient-specific factors – namely other comorbidities, psychosocial and socioeconomic aspects - that may limit adherence with medications, self-monitoring and self-management. (122) Considering that this is a lower than average rate of admission at 60-days (4,12)(11) and that is based on a one-site hospital data that does not include out-of hospital admissions or deaths, we also have to recognize that some admissions are needed and, although hospitalizations are relevant as a countable cost and as marker for disease severity, QoL and prognosis; there are other elements that should be taken into account when evaluating successful outcomes in quality of care. Furthermore, the high-performing practices and/or organizations may also receive more complex patients, so high adherence to guidelines is not a reliable predictor of outcomes.(122,167)
For example, most of these patients have multiple comorbidities and become high-users of the health care system, which translates into frequent admissions, high health care costs and higher mortality rate, regardless of whether they have HF or not. Previous studies have recommended that a distinction should be made between outcomes in outpatients with chronic HF and patients with admissions for HF,(11) since the prognosis for the first one has significantly improved over the years with the use of the recommended therapies, however, the patients that have frequent admissions continue to have higher mortality rate. Although, we did not separate our study group into these categories, our findings show that similar trend of high-users that are frequently admitted for HF and/or other medical conditions, especially after 60-days of being seen in the clinic.

Our findings reaffirm that HF is a very complex condition in which current evidence-based recommendations may improve QoL, but we still fall short in demonstrating a positive effect that is robust and significant across the indicators developed by the CCS. Nevertheless, when we review the findings from OPTIMIZE-HF and more recent studies (141)(144)(146) with over three thousand patients in the US, where none of the current ACC/AHA performance measures were significant independent predictors of mortality, and did not show any particular pattern to identify organizations or hospitals that provide care leading to better or worse outcomes; we cannot conclude that the QIs are not useful nor reliable but rather suggest that there are opportunities to create better methodologies in the evaluation of these measurements and find a way to identify indicators that may be more tightly linked to patient outcomes.

Careful evaluation is recommended when measuring these indicators in a broader scale and larger organizations in Canada since high adherence to performance measures does not warrant better outcomes, but the opposite has not shown any benefits either. Furthermore, the evaluation of these recently established indicators in a systematic way would require the allocation of significant time and personnel resources for the collection of prospective data. Ideally, these indicators could be measured routinely using administrative databases linked to EMRs, chart review instruments and patient interview instruments.
As part of the reiterative evaluation process for these indicators, we reviewed some of the QIs that we examined and the ones recommended by the ACC/AHA in their latest report, where they made major revisions, (108) retiring some of the performance measures such as BP and BW assessments; changing the category of other measurements such as patient education, and adding new measurements such as symptom management. The rationale for these changes were that although some of them are useful, the supporting evidence may be poor and the expected performance is high, so they are not likely to significantly impact patient outcomes. On the other hand, the patient education indicator raised a concern around the fact that adherence to this measurement can be achieved without regard to the quality of the education provided. Although, there is no doubt that education about lifestyle, physical activity, diet and medications are important for the management of these patients; the documentation of the performance of this activity in the medical records does not guarantee the improvement of outcomes, thus this indicator was changed to a quality metric for internal improvement only. (108)

An interesting addition to this set of performance measures is the indicator on symptom management,(108) which includes documentation of a care plan to attempt to alleviate ongoing symptoms in patients who are poorly controlled. The goal of this indicator is to closely monitor clinical status by changing medication doses, considering device therapy, or referring patients to advanced care when needed. Since one of the most sensitive tools to assess clinical status has proven to be the KCCQ, (132–134) and our study also showed clinically meaningful improvement measured by this instrument, this quantitative assessment of patients’ level of activity and QoL can be used as an ongoing measurement of patient symptoms and serve as the main basis for monitoring and titrating therapy.

Our study adds an important piece to the current knowledge, on the performance of the outpatient indicators and QoL as a potential end-point for future studies, especially clinical trials, where more robust and strict therapeutic effect can be investigated. More studies are needed in this field, as the goals of the CCS with the development of the indicators were to evaluate, monitor, reiterate and refine these QIs according to the resources and methods available, and more importantly to the impact on patient outcomes.
4.2 LIMITATIONS

Several limitations should be considered in the interpretation of our study. First, HF clinics are regarded as having high rates of adherence to evidence-based therapies. Therefore, observed adherence proportions may be higher than in regular outpatient clinics, such as internal medicine and family practice clinics. Furthermore, this HF clinic is located in a teaching hospital, which may also limit the generalizability of our findings. Particularly, for the inpatient QIs, in some cases, the admission data went back to the year 2000, and as medical guidelines change over time, this may have been a factor in the adherence to certain performance measures at that time.

Second, this evaluation was performed by dedicated personnel that carefully reviewed all the administrative and clinical documentation for each patient, which may not be the case if this evaluation was performed using only administrative data. However, it should be in the best interest of healthcare organizations to evaluate complete data and report accurately on the performance of QIs.

Third, the number of patients enrolled in our study denotes a small percentage of all patients with HF. It is clear that, an approximate 20% of the patients seen annually in the clinic are not representative of the general population with HF and certainly does not reproduce the entire picture of HF care across different practices and organizations. Furthermore, our lower than expected follow up rates add to the lack of generalizability of our findings. Even so, considering that there is no current system in place to measure these indicators in Canada, our study provides an insight into this process and could serve as a pilot test to verify the validity, feasibility and reliability of the QIs developed by the CCS.
4.3 FUTURE DIRECTIONS

**QIs and clinical outcomes**

Our study provided an overview on QIs measurement feasibility, adherence levels and QoL association; however, adequately powered studies are needed to examine association with other outcomes such as readmissions and mortality. We are currently enrolling more patients in our study to increase our sample size and assess QoL at 6-months.

**Systematic measurement of QIs**

Being this, a novel study of the outpatient QIs, and based on our findings that there is a high-performance of these indicators in a HF clinic; we would like to implement their in-hospital systematic measurement so that we can obtain a longitudinal evaluation over longer periods of time that will allow us to re-examine association with patient outcomes. It would be interesting to know if the repeated performance of these standards of care has any relationship with the rate of ED visits and/or admissions due to HF. Likewise, this systematic measurement should be implemented in other HF clinics and health care organizations that follow HF patients.

**Practice-site dependent evaluation**

Since practice-site factors such as guideline familiarity, pattern of practice and implementation of specific systems are important contributors to the performance of quality measures; our next work would potentially be directed at the measurement of adherence proportion in a community hospital. We would be able to measure the performance of the same indicators and determine if there are any changes in practice, system organization or adherence to the guidelines. If the results show a lower level of performance of the QIs, then a good opportunity for quality improvement strategies can be developed. Furthermore, the type of disease management intervention also plays an important role in patient outcomes, thus, reporting on the type of approach, either by a HF specialist nurse, a pharmacist or a multidisciplinary team is also recommended.
Creatinine versus BUN

An unanswered aspect of our study that could be explored in more detail is the performance of the BUN lab test versus creatinine to assess kidney function. As mentioned above in our discussion, BUN is a better predictor of re-admissions and mortality, however is not routinely performed. Since both are guideline-recommended lab tests in patients admitted with HF, we should find out if there are more specific reasons as to why one is preferred over the other. More research needs to be conducted to answer this question.

Early outpatient assessment

Similarly, since the 2-weeks assessment recommendation had a moderate adherence proportion, we need to determine how many patients (if any) were seen by their PCP or another health care provider before attending their initial HF appointment after discharge. It would be important to know if there was patient education during this visit, or medication adjustment and if the patients that did not have any health care support within this time-frame were more likely to return to the ED or be re-admitted.

Guideline-recommended dosages

Another interesting finding from our study was related to guideline-recommended medication dosage. Previous studies have shown the importance of being adherent to the recommended medications and more specifically the use of ACEIs and Beta blockers to reduce morbidity and mortality, however, the effect of dosages and medication titration on these outcomes have been poorly documented. Thus, we would suggest a more in-depth study comparing different dosages of the recommended therapy with patient-reported QoL and patient outcomes.

QoL as symptom management performance measure

In our current healthcare system, where increasing relevance is being given to the model of personalized medicine, the inclusion of patient-oriented outcomes such as QoL should become part of the daily practice. Hence, we would recommend the use of QoL questionnaires as a measurement of activity level at each outpatient visit. Our study demonstrated that the KCCQ is a sensitive tool to assess functional capacity that can be used in the management of these patients.
As previously discussed, the goal of a symptom management indicator is to closely monitor clinical status, and although QoL has been used as an outcome measurement in certain studies including ours, it seems useful to add it as a performance measure in the future development of indicators, since it serves as a quantitative measurement of patient symptoms and activity level to monitor and titrate therapy.

**QIs continuous process flow**

Considering that the retirement of measures that no longer serve their initial purpose is part of the performance measure cycle, we would like to review the QIs studied and determine if there are missing pieces in their individual assessment as part of the refinement process suggested by the CCS. As we discussed before, the ACC/AHA have reiterated their indicators recommendations and made major changes because in their perspective, some of them were not found to reflect quality of care. Similarly, with our findings on the performance of certain indicators, we can re-evaluate their significance and in the cases where there is limited opportunity for further improvement, such as the BP measurement and the documentation of LVEF, then perhaps these measures can also be established as standards of care, which means that they are expected to be performed for every patient regardless of patient clinical diagnosis. This performance measure cycle could help in the development of future indicators and their standardization across different healthcare organizations.

**Novel therapies in HF**

Since the only two performance measures that have shown to be associated with patient outcomes are the use of ACEI/ARB and beta blockers, both HF specific therapies for patients with reduced EF, we would examine the newer guideline-recommended LCZ-696 - that has proven to be superior to ACEI- as a potential performance measure. The CCS guidelines have recommended the switch to this newer therapy, when indicated,(25) and although it is still early to assess long-term outcomes, it is envisioned as a cost-effective treatment in the future.
Performance measurements in Canada

With the recent publication from the CCS on the evaluation of QIs, the next step for the health care organizations across Canada would be to implement a system to start measuring these indicators, and a collaborative study would be of high importance at that point, to determine the presence of any gaps and variations that could potentially change patient care. Furthermore, with the large amount of patients that could be gathered in this type of study, we could obtain a meaningful correlation with clinical outcomes. Subsequently, formal economic modelling would be recommended to obtain results in costs, such as cost per HF admission prevented - cost effectiveness analysis, cost per quality adjusted life year gained - cost utility analysis, or both cost-benefit analysis. These will be helpful for deciding on the next steps in implementation and development of future QIs.

4.4 CONCLUSIONS

In summary, the HF clinic evaluated in this exploratory study is a high-performing practice site in which the management of HF patients follows the medical guidelines recommendations and standards of care. QIs are feasible and useful measures in the quality improvement process, and can accurately describe the quality of HF care, however regular revisions of the developed performance measures are needed since supporting evidence can change the validity or reliability of these indicators. QoL is an increasingly important outcome that has shown to be sensitive to clinical changes and in which patients’ perspective can impact the therapeutic decision-making process. There appears to be no association between the performance of the QIs that we evaluated and the patient-reported QoL. Additional studies and measurements across different practice sites are needed to identify the variables that can be more closely associated with patient outcomes; and to validate the indicators that can reflect the care given to HF patients.
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APPENDIX A
MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

<table>
<thead>
<tr>
<th>Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -</th>
<th>No</th>
<th>Very Little</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. causing swelling in your ankles or legs?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2. making you sit or lie down to rest during the day?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3. making your walking about or climbing stairs difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4. making your working around the house or yard difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5. making your going places away from home difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>6. making your sleeping well at night difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>7. making your relating to or doing things with your friends or family difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>8. making your working to earn a living difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>9. making your recreational pastimes, sports or hobbies difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>10. making your sexual activities difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>11. making you eat less of the foods you like?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>12. making you short of breath?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>13. making you tired, fatigued, or low on energy?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>14. making you stay in a hospital?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>15. costing you money for medical care?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>16. giving you side effects from treatments?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>17. making you feel you are a burden to your family or friends?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>18. making you feel a loss of self-control in your life?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>19. making you worry?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>20. making it difficult for you to concentrate or remember things?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>21. making you feel depressed?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Cardiomyopathy Questionnaire (Kansas City)

The following questions refer to your heart failure and how it may have affected your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. Heart failure affects different people in different ways. Some feel mainly shortness of breath while others feel mainly fatigue. Please indicate how limited you have been over the past 2 weeks by heart failure (for example, shortness of breath or fatigue) when doing the following activities:

Please put a \( \sqrt{ } \) in one box on each line

<table>
<thead>
<tr>
<th>Activity</th>
<th>Extremely limited</th>
<th>Quite a bit limited</th>
<th>Moderately limited</th>
<th>Slightly limited</th>
<th>Not at all limited</th>
<th>Limited for other reasons or did not do the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing yourself</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Showering/bathing</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Walking about 100 metres on level ground</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Doing yardwork, housework or carrying groceries</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Climbing a flight of stairs without stopping</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Jogging or hurrying (as if to catch a bus)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

2. Compared with 2 weeks ago, have your symptoms of heart failure (for example, shortness of breath, fatigue, or ankle swelling) changed?

My symptoms of heart failure are now...

<table>
<thead>
<tr>
<th>Much worse</th>
<th>Slightly worse</th>
<th>Not changed</th>
<th>Slightly better</th>
<th>Much better</th>
<th>I've had no symptoms over the past 2 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

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KCCQ – Canada/English
3. Over the past 2 weeks, how many times have you had swelling in your feet, ankles or legs when you woke up in the morning?

- Every morning [ ]
- 3 or more times a week, but not every day [ ]
- 1-2 times a week [ ]
- Less than once a week [ ]
- Never over the past 2 weeks [ ]

4. Over the past 2 weeks, how much has swelling in your feet, ankles or legs bothered you?

- Extremely bothersome [ ]
- Quite a bit bothersome [ ]
- Moderately bothersome [ ]
- Slightly bothersome [ ]
- Not at all bothersome [ ]
- I’ve had no swelling [ ]

5. Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you wanted?

- All of the time [ ]
- Several times a day [ ]
- At least once a day but not every day [ ]
- 3 or more times a week [ ]
- 1-2 times a week [ ]
- Less than once a week [ ]
- Never over the past 2 weeks [ ]

6. Over the past 2 weeks, how much has your fatigue bothered you?

- Extremely bothersome [ ]
- Quite a bit bothersome [ ]
- Moderately bothersome [ ]
- Slightly bothersome [ ]
- Not at all bothersome [ ]
- I’ve had no fatigue [ ]

7. Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?

- All of the time [ ]
- Several times a day [ ]
- At least once a day but not every day [ ]
- 3 or more times a week [ ]
- 1-2 times a week [ ]
- Less than once a week [ ]
- Never over the past 2 weeks [ ]
8. Over the past 2 weeks, how much has your shortness of breath bothered you?

<table>
<thead>
<tr>
<th>Extremely bothersome</th>
<th>Quite a bit bothersome</th>
<th>Moderately bothersome</th>
<th>Slightly bothersome</th>
<th>Not at all bothersome</th>
<th>I've had no shortness of breath</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

9. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up in bed because of shortness of breath?

<table>
<thead>
<tr>
<th>Every night</th>
<th>3 or more times a week, but not every night</th>
<th>1-2 times a week</th>
<th>Less than once a week</th>
<th>Never over the past 2 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

10. Heart failure symptoms can get worse for a number of reasons. How sure are you that you know what to do, or whom to call, if your heart failure gets worse?

<table>
<thead>
<tr>
<th>Not at all sure</th>
<th>Not very sure</th>
<th>Somewhat sure</th>
<th>Mostly sure</th>
<th>Completely sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

11. How well do you understand what you can do to keep your heart failure symptoms from getting worse (for example, weighing yourself regularly, eating a low-salt diet etc.)?

<table>
<thead>
<tr>
<th>Do not understand at all</th>
<th>Do not understand very well</th>
<th>Understand somewhat</th>
<th>Understand quite a bit</th>
<th>Understand completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

12. Over the past 2 weeks, how much has your heart failure limited your enjoyment of life?

<table>
<thead>
<tr>
<th>It has extremely limited my enjoyment of life</th>
<th>It has limited my enjoyment of life quite a bit</th>
<th>It has moderately limited my enjoyment of life</th>
<th>It has slightly limited my enjoyment of life</th>
<th>It has not limited my enjoyment of life at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
13. If you had to spend the rest of your life with your heart failure the way it is right now, how would you feel about this?

<table>
<thead>
<tr>
<th>Completely dissatisfied</th>
<th>Mostly dissatisfied</th>
<th>Somewhat satisfied</th>
<th>Mostly satisfied</th>
<th>Completely satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

14. Over the past 2 weeks, how often have you felt discouraged or depressed because of your heart failure?

<table>
<thead>
<tr>
<th>I have felt that way</th>
<th>I have felt that way</th>
<th>I have occasionally felt that way</th>
<th>I have rarely felt that way</th>
<th>I have never felt that way</th>
</tr>
</thead>
<tbody>
<tr>
<td>all of the time</td>
<td>most of the time</td>
<td>felt that way</td>
<td>that way</td>
<td></td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

15. How much does your heart failure affect your lifestyle? Please indicate how limited you have been over the past 2 weeks by heart failure in doing the following activities:

Please put a √ in one box on each line

<table>
<thead>
<tr>
<th>Activity</th>
<th>Extremely limited</th>
<th>Quite a bit limited</th>
<th>Moderately limited</th>
<th>Slightly limited</th>
<th>Not at all limited</th>
<th>Limited for other reasons or did not do the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hobbies, recreational activities</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Working or doing household chores</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Visiting family or friends</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Intimate or sexual relationships</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
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