CANADIAN CARDIOVASCULAR SOCIETY
NATIONAL QUALITY REPORT: TRANSCATHETER AORTIC VALVE IMPLANTATION
OCTOBER 2016
LETTER FROM
THE CHAIRS

As Chairs of the Canadian Cardiovascular Society (CCS) Quality Project and CCS TAVI Quality Working Group, it is our privilege to introduce the CCS National Quality Report: TAVI. As the first-ever national snapshot of TAVI care, this report marks an important contribution to the national dialogue on the quality and value of cardiovascular care in Canada.

Despite the burden of cardiovascular disease on Canadians and healthcare budgets, Canada lacks a coherent strategy to provide ongoing measurement and management of the quality and value of this care. The CCS Quality Project, driven by the tremendous support and dedication of its members, is working to address this gap.

Over the past 5 years, the CCS Quality Project has developed a standardized quality indicator development methodology, established partnerships with the Canadian Institute for Health Information and provincial registries to align data definitions, establish data linkage, and address barriers to enable pan-Canadian comparisons, and developed 37 evidence-based quality indicators across the continuum of cardiovascular care.

The CCS National Quality Report: TAVI was developed as a stakeholder-driven process. This work would not have been possible without the efforts and support of many individuals and organizations from across the country. We wish to express our sincere appreciation to everyone who has contributed to the development of the report, including:

- Members of the CCS TAVI Quality Working Group, who developed the pan-Canadian TAVI quality indicators and directed the development of the report;

- Members of the TAVI Quality Report Team who managed the data collection, analysis and report development in association with the Institute for Clinical Evaluative Sciences and Canadian Association of Interventional Cardiology;

- Representatives from the TAVI hospitals and cardiovascular registries, for being open to this process and enthusiastically providing the data used to inform the report;

- The Public Health Agency of Canada, which funded the development of the report, and the Agency staff who have acted as a resource during the development of the CCS Quality Project;

- Members of the CCS who have supported this initiative since its inception and contribute to the growing body of knowledge in cardiovascular quality measurement.

Sincerely,

Anita Asgar  
Chair, CCS TAVI Quality Working Group  
Canadian Cardiovascular Society

Paul Dorian  
Chair, Quality Project  
Canadian Cardiovascular Society
EXECUTIVE SUMMARY

BACKGROUND
In 2010, the Canadian Cardiovascular Society (CCS) undertook an initiative to establish a comprehensive set of quality indicators across the spectrum of cardiovascular disease and develop the infrastructure to monitor these indicators across Canada. Working groups in cardiac surgery, heart failure, atrial fibrillation, percutaneous coronary interventions, cardiac rehabilitation and transcatheter aortic valve implantation (TAVI) were formed and developed quality indicators for each of these cardiovascular conditions or procedures. Recognizing the historical difficulties in pooling patient-level data across jurisdictions in Canada, a pilot project was initiated to explore methods for pan-Canadian data collation and reporting. The content area for the pilot project was TAVI.

QUALITY INDICATORS
The CCS TAVI Quality Working Group developed a set of 9 quality indicators for TAVI:

Structural Indicators
• Heart Team treatment recommendation
• TAVI wait time

Process Indicators
• Evaluation of procedural risk
• Evaluation of quality of life

Outcome Indicators
• Mortality for TAVI (30-day and 1-year)
• In-hospital stroke post-TAVI
• All cause hospital readmission (30-day and 1-year)

OVERALL GOALS
The overarching goal of the CCS National Quality Report: TAVI is to provide evidence-based findings to catalyze local, regional, and national quality improvement; to support patients’ access to appropriate, high quality care; and to foster a national strategy to optimize patient outcomes, health service utilization, and access to treatment. This is the first effort of the CCS Quality Project to document cardiovascular care across the country, and will serve as a model for future pan-Canadian cardiovascular quality reports.

METHODS
In fiscal year 2013-2014, there were 25 hospitals across 7 provinces that were performing TAVI. Each of these hospitals maintain a local database. An environmental scan was performed to determine available data variables and to establish common data definitions. Individual de-identified patient-level data was transferred via a virtual private network (VPN) to a secure server at the Institute for Clinical Evaluate Sciences (ICES) in Toronto under contract with the CCS. For the 6 TAVI hospitals in Québec, summary hospital level data was transferred. At ICES, the data was collated and analyzed. This report provides results at the national and regional level, with 4 regions pre-specified, such that each has a similar number of sites and volumes of cases. Inferential statistical tests and modelling were not applied to the data for the purposes of this report, given the overall low procedural volumes and absence of a validated case-mix adjustment model.

RESULTS
A total of 1,122 patients underwent TAVI in Canada between April 1st 2013 and March 31st 2014. Annual procedural volumes by hospital ranged from 9 to 170. In Canada, the annual rate of TAVI per million population was 34. There was substantial variation in access across the country, with provincial rates per million population ranging from 16 to 61.
The mean age of TAVI patients was 81.9 years, with 44.3% being female and 30% having had previous coronary artery bypass grafting. Within the cohort, 6.4% had a degenerating previous surgical aortic valve, necessitating a valve-in-valve procedure. The majority of cases were completed via a trans-femoral approach (81.3%).

Structural Indicators
The Heart Team decision was documented in 87.4% of TAVI cases in Canada, with a range of 14.2% to 100% across hospitals. Median TAVI total wait time from referral to procedure was 106 days (interquartile range [IQR] 59-172) across Canada. Wait times for TAVI evaluation (from referral to Heart Team decision) and TAVI procedure (from Heart Team decision to procedure) were 58 (IQR 26-110) and 37 (IQR 16-70) days, respectively. There was substantial wait time variation between hospitals, and data was missing for almost one third of cases.

Process Indicators
Explicit documentation of procedural risk by the Society of Thoracic Surgery (STS) score was found in only 55.8% of cases, with a range across hospitals from 0% to 100%. Quality of life using a standard instrument (either the Kansas City Cardiomyopathy Questionnaire [KCCQ] or EQ5D) was documented in 31.9% of cases prior to TAVI and 12.4% of cases at 1-year post procedure.

Outcome Indicators
For the entire TAVI cohort, mortality in Canada was 4.2% (range 0-11.9%) at 30-day and 13.8% (range 0-28.4%) at 1-year post procedure. The incidence of in-hospital stroke was low (2.1%); however, there was a wide range across institutions from 0% to 9.7%. At the national level, all cause 30-day and 1-year readmission rates were 16.9% (range 4.5-39.7%) and 45.7% (12.2-68%) respectively.

CONCLUSIONS
This pan-Canadian TAVI quality indicator project is the first national effort of the CCS Quality Project to measure and report on the quality of cardiovascular care. Despite the substantial challenges for cross-provincial data sharing, we were able to produce a pan-Canadian dataset that provided meaningful information.

A number of data quality issues were identified, specifically that many sites did not collect key quality indicators, inconsistent definitions were utilized for several variables, and there was substantial missing data for some of the structural and process variables. For the outcome variables, a potential reason for variation may be differences in ascertainment by administrative linkage compared to clinical follow-up, raising the possibility of misclassification error. Specifically, in some jurisdictions, there may be under-reporting of some outcomes. This collaborative national effort to examine data quality and compare results across the country provides a unique opportunity for TAVI hospitals to reach a consensus on precise definitions that are consistent with international standards, and to share best practices that ensure efficient and accurate data collection for both the pre-procedural and post-procedural periods.

Our report is limited to crude, unadjusted outcomes given the absence of appropriate case-mix adjustment. This highlights the need for development of risk adjustment models that allow for valid comparisons of outcomes across Canada. Nonetheless, the findings of the CCS National Quality Report: TAVI suggest that high quality care is being provided to TAVI patients across the country, with clinical outcomes that are comparable or superior to other national registries.

This report is the first to describe the quality of TAVI care at the national level. This accomplishment attests to the feasibility and value of a collaborative and transparent effort to improve patient care across Canada. The hope is that this report will catalyze a network for peer-to-peer shared learning, and ongoing quality improvement. Most critically, we believe it will serve as a model for future pan-Canadian quality improvement initiatives in other areas of cardiovascular medicine.
1. INTRODUCTION

BACKGROUND

The Canadian Heart Health Strategy and Action Plan (CHHS-AP) was commissioned by the federal government of Canada in 2006 with the ambitious goal of developing a roadmap to reduce the burden of cardiovascular disease in Canada and targeting a reduction in cardiovascular mortality of 25% by the year 2020. In order to meet this target, the CHHS-AP roadmap identified several strategies to address a number of fundamental gaps, one of which was the inability to measure and report on the quality of cardiovascular care at a national level. A key priority highlighted by the CHHS-AP was the need to develop the capacity to translate guideline recommendations into practice, by establishing a comprehensive set of quality indicators across the spectrum of cardiovascular disease and developing the necessary infrastructure to monitor them.

In 2010, the responsibility of addressing the gaps identified by the CHHS-AP was delegated to the Canadian Cardiovascular Society (CCS). The CCS initiated two parallel and complementary approaches. The first approach focused on the development of quality indicators, while the second addressed the information infrastructure barriers that currently exist in Canada for monitoring cardiovascular disease. The quality indicator initiative included a comprehensive review of the available international cardiovascular quality indicators, a critical appraisal of the currently available quality indicators and setting standards for future quality indicator development. Working groups were then formed for specific cardiovascular conditions and procedures, including cardiac surgery, heart failure, atrial fibrillation, percutaneous coronary intervention and TAVI, as well as cardiac rehabilitation, in order to apply these standards to develop Canadian quality indicators that could be operationalized.

Despite the availability of numerous robust databases across Canada, there are substantial barriers that have historically precluded pooling data across jurisdictions. This coalescence of information is an essential prerequisite for developing a comprehensive picture of care in the country, and thereby facilitating quality improvement. The first step to address information infrastructure barriers was the standardization of data definitions across different Canadian databases. The second was to conduct a pilot project to explore methods for pan-Canadian data collation and reporting. The content area chosen for this pilot project was TAVI.

QUALITY INDICATORS

Quality indicators are intended to quantify the delivery of care by measuring adherence to specific optimal practices, in order to reduce the gap between evidence-based and actual clinical practice. As such, quality indicators can serve as measures of quality of care. Quality indicators have sufficient strength of evidence such that failure to achieve benchmarks for these indicators will result in sub-optimal patient outcomes. Moreover, quality indicators provide a measurable target for focusing quality improvement efforts and thus, can be used to evaluate the performance of health regions, hospitals and clinicians. Quality indicators are generally classified as structural indicators, processes of care indicators or outcome measures. ‘Structural’ characteristics are those that affect the health care system’s ability to meet patient needs; structural indicators measure the type and quantity of resources used for programs and services. ‘Process’ characteristics refer to the inter-related activities that produce outcomes; process indicators measure the activities undertaken in episodes of patient care. ‘Outcomes’ are states of health or health events; outcome indicators measure the effects of care on patient health.
AORTIC STENOSIS AND TAVI

Aortic stenosis (AS) is a degenerative heart valve disease, and is the most commonly acquired valvular abnormality referred for treatment with a prevalence of almost 10% in the elderly. After a potentially prolonged latent period, patients may develop symptoms, after which, AS has a grave prognosis. Left untreated, the 1-year mortality rate approaches 50%.

Traditionally, AS has been treated by surgical aortic valve replacement (SAVR). However, many patients are not candidates for SAVR due to advanced age and the presence of co-morbidities. TAVI is a transformational technology, whereby a fully collapsible valve is delivered percutaneously and implanted within the existing, diseased valve. Landmark trials have shown that TAVI is an effective treatment in terms of both mortality, and improvement of quality of life. This innovative procedure has led to a paradigm shift in treatment options for AS patients. Current practice guidelines recommend TAVI as the primary option in severe AS patients who are inoperable and as the preferred alternative to SAVR in those at high surgical risk; this has fueled the worldwide growth in this procedure, with >100,000 implantations performed in >40 countries.

Emerging research is exploring the potential expansion of TAVI to patients at intermediate surgical risk. Given the complexity of case selection and procedural approach, compounded by the advanced age and multiple co-morbidities of a high risk patient population, adverse events are not uncommon. Moreover, TAVI is extremely resource intensive. With the exponential growth in the demand for TAVI, there is a need to ensure both equitable access and a consistently high quality of care for TAVI patients across Canada. Funding policy and provincial requirements for outcome measurement and reporting vary across regions and jurisdictions. Therefore, a pan-Canadian effort to evaluate quality of TAVI care is timely, fulfills the mandate of the CCS Quality Project, and can serve to illustrate the pivotal importance and feasibility of a collaborative commitment to quality of cardiac care.

TAVI QUALITY WORKING GROUP AND QUALITY INDICATORS

The CCS TAVI Quality Working Group was established in April 2014 and is comprised of Canadian TAVI clinician experts, administrators and representatives of provincial health authorities. Its primary objective was to develop a set of quality indicators for TAVI using the standards established by the CCS. Multiple candidate indicators were considered with final selection determined by a consensus agreement on relevance and scientific merit, as well as pragmatic considerations of measurability.

The Donabedian continuous quality improvement framework was adopted to capture the multidimensional components of quality of care. As seen in Figure 1, two structural indicators were identified (Heart Team treatment recommendation and TAVI wait time) as were two process indicators (evaluation of procedural risk and evaluation of quality of life). The chosen outcome indicators were 30-day and 1-year mortality, in-hospital stroke, and 30-day and 1-year all cause readmission. Each indicator is explained in detail in section 3 of this report.

The overarching goal of the report is to provide evidence-based findings to catalyze local, regional, and national quality improvement, to support patients’ access to appropriate, high quality care, and to foster a national strategy to optimize patient outcomes, health service utilization, and access to treatment. The target audience for the report encompasses the spectrum of clinicians, administrators, health agencies and policy makers at the local hospital, provincial and national levels. Importantly, as this is the first pan-Canadian effort to document cardiovascular care across the country, it demonstrates the feasibility of this collaborative effort, and will serve as a model for future CCS National Quality Reports.

The production of the CCS National Quality Report: TAVI marks the launch of a national quality improvement strategy that will create an opportunity for peer-to-peer learning where programs can share successes, challenges, and lessons learned. By maximizing stakeholder engagement and building on the principle of transparency, this report is intended to initiate continuous improvement of TAVI patient care and outcomes in Canada.
2. REPORTING

CURRENT PROVINCIAL AND LOCAL TAVI DATA COLLECTION

In 2016, there are 27 TAVI hospitals across 9 provinces in Canada. Each hospital maintains their own database for patients undergoing TAVI assessment. Ontario and British Columbia have provincial-level registries that collate the data from each provincial site, with data reporting a mandatory requirement for provincial procedural funding. The 10 Ontario and 4 British Columbia TAVI hospitals are required to contribute their data to the Cardiac Care Network of Ontario (CCN) and the Cardiac Services British Columbia (CSBC) respectively. These agencies maintain registries of all advanced cardiac procedures performed in their provincial hospitals. Alberta’s 2 TAVI hospitals currently maintain local databases; however, these will transition to the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) database in the near future, through a newly created TAVI module.

The 6 TAVI hospitals in Québec each maintain a local, prospective database and are required to participate in a province-wide audit and feedback process in collaboration with the Institut National d’Excellence en Santé et en Services Sociaux (INESSS). Data is abstracted by INESSS from various data sources in each TAVI hospital on an ongoing basis in collaboration with the clinical teams. Manitoba, Nova Scotia and New Brunswick each have a single TAVI hospital supported by a local database. The Newfoundland and Saskatchewan programs were still in development during the time frame of this project (i.e. fiscal year 2013-2014); hence, data from these sites were not collected for this report. At present, Prince Edward Island does not have a TAVI program and eligible patients are referred out of province. Data from 25 hospitals is presented in this report. See Appendix 1 for a full list of TAVI hospitals in Canada and Figure 2 for their geographical locations.

Figure 2. Geographical locations of TAVI hospitals in Canada.
We defined a limited dataset of 30 variables to enable a focused first iteration of the CCS National Quality Report: TAVI. This decision was driven by an environmental scan of available comparable data (see Appendix 2), the establishment of common variable definitions, and the goal of creating a robust, albeit limited final data set. The patient cohort encompasses procedures performed in the 2013-2014 fiscal year, thus allowing for a complete 1-year follow-up of clinical outcome. For all provinces, with the exception of Québec, individual patient-level data from each local registry were de-identified at source and transferred via a VPN to a secure server at the ICES in Toronto, Ontario (Figure 3). For the 6 TAVI hospitals in Québec, the same data elements were collected, but provided only in summary form at the hospital level. Once data was transferred, data was collated and analyzed. This information data structure was consistent with privacy regulations in all provinces.

**LEVELS OF REPORTING**

The primary report will provide results for all quality indicators at a national and regional level, with reporting of both the central tendency (mean/median) and variation across individual sites.

The regional results are divided into 4 groups, such that each has a similar number of sites and volume of patients:

a) Alberta, Manitoba, Nova Scotia and New Brunswick *(these provinces were pooled for the purpose of reporting)*
b) British Columbia
c) Ontario
d) Québec

Given that the national dataset was a combination of collated patient-level data as well as site-specific summary data, there were limitations on the manner in which summary data could be reported. For example, only weighted averages were available for the quality indicators.

Inferential statistical tests and modelling were not applied to the data given the overall low procedural volumes and absence of a validated case-mix adjustment model. Therefore, it must be emphasized that the reporting of clinical outcomes are unadjusted and that the primary goal of the report is to provide a descriptive overview of TAVI care in Canada and advise caution with any comparative inferences.

**Figure 3. Data Sources.**

APPROACH = Alberta Provincial Project for Outcomes Assessment in Coronary Heart Disease; CSBC = Cardiac Services British Columbia; INESSS = Institut National d’Excellence en Santé et en Services sociaux, ICES = Institute for Clinical Evaluative Sciences; VPN = virtual private network
3. FINDINGS

ENVIRONMENTAL SCAN

An environmental scan was conducted prior to data collection to determine the availability of data based on the explicit definitions of the quality indicators as developed by the CCS TAVI Quality Working Group. It was recognized that there was the potential for differences in variable definitions across sites. Thus, a standardized definition of each data element was established. Representatives from each region and/or hospital were contacted, and the availability, definition, and quality of each data element were ascertained. Appendix 2 lists each site by province, with colour coding to indicate the availability of each quality indicator as per the working group definition. Data were collected at all sites for the April 1st 2013 to March 31st 2014 fiscal year.

The following challenges were noted:

Structural Indicators
Documentation of a Heart Team decision was absent for Ontario, and only partially documented in Québec. At the time of this report, comprehensive wait time data was not consistently available. While the date of the TAVI procedure was well documented, wait time from referral to Heart Team decision and from Heart Team decision to TAVI procedure was not reliably documented.

Process Indicators
Although a data element for the STS predicted risk of mortality score was available in all local registries, it was not consistently completed. Most hospitals did not collect quality of life data. Although one of the Alberta hospitals collected the generic measure Medical Outcomes Study Short Form 36 (SF-36), it was not one of the instruments specified by the CCS TAVI Quality Working Group. Moreover, this was only collected pre-procedure. The Manitoba site only began collecting quality of life measures in 2015, which was outside the study date range.

Outcome Indicators
Data was available for the majority of outcome indicators at all TAVI hospitals, although the mechanism of outcome ascertainment varied. In British Columbia and Ontario, outcome data were available through linkage with provincial administrative databases, such as vital statistics, or the Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD). At the remaining hospitals, outcomes were ascertained by the local TAVI groups through follow-up telephone calls to patients or by clinic follow-ups. Readmission data was not available for Québec during the 2013-2014 fiscal year. Only 1-year readmission data was available from the University of Alberta site in Edmonton.

PATIENT CHARACTERISTICS

Across Canada, a total of 1,122 patients were treated with TAVI between April 1st 2013 and March 31st 2014. Annual procedural volumes by hospital ranged from 9 to 170, reflecting the different maturity of TAVI programs across the country. There was wide variation in access to TAVI across different regions (Figure 4). The annual rate of TAVI per million population in Canada was 34, while rate per 100,000 population above the age of 75 years was 49. To provide context, in Europe for 2011, the mean TAVI rate per million was 33, ranging from 90 million in Germany to less than 10 in Ireland and Portugal.
The baseline characteristics of TAVI patients across Canada are shown on Table 1. Patients were relatively similar across the country with a mean age of 81 years old. Approximately one third of TAVI patients had had previous coronary artery bypass grafting surgery. In contrast, relatively few patients (6.4%) had had previous SAVR and were undergoing TAVI within a failed surgical bioprosthesis (known as “valve-in-valve” TAVI).

In all regions, the vascular access site for the majority of TAVIs was transfemoral. However, the proportion of non-transfemoral cases (e.g., transapical, direct aortic) varied across regions, from 24.8% in Québec to 14.8% in British Columbia.

Data Quality
Some data quality issues were noted in Ontario. In particular, documentation of previous coronary artery bypass grafting surgery was absent in approximately 27% as well as the specific TAVI device type in 5.6% of cases.
### Table 1. TAVI patient characteristics by region

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>81.9 ± 7.4</td>
<td>80.9 ± 8.7</td>
<td>82.4 ± 7.3</td>
<td>83.2 ± 7.9</td>
<td>81.9</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>53.8</td>
<td>53.0</td>
<td>58.9</td>
<td>59.9</td>
<td>55.7</td>
</tr>
<tr>
<td>Female</td>
<td>46.2</td>
<td>47.0</td>
<td>40.7</td>
<td>40.1</td>
<td>44.3</td>
</tr>
<tr>
<td>Aortic valve-in-valve procedure (%)</td>
<td>8.1</td>
<td>6.0</td>
<td>5.6</td>
<td>4.3</td>
<td>6.4</td>
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<tr>
<td>Previous CABG (%)</td>
<td>36.9</td>
<td>30.0</td>
<td>22.2</td>
<td>25.9</td>
<td>30.0</td>
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<tr>
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<td>0.0</td>
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<tr>
<td>Vascular Access (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoral</td>
<td>81.8</td>
<td>75.2</td>
<td>85.2</td>
<td>84.6</td>
<td>81.3</td>
</tr>
<tr>
<td>Non-femoral</td>
<td>17.9</td>
<td>24.8</td>
<td>14.8</td>
<td>15.4</td>
<td>18.6</td>
</tr>
<tr>
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<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Device Type (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medtronic*</td>
<td>46.0</td>
<td>30.0</td>
<td>30.0</td>
<td>0.0</td>
<td>31.2</td>
</tr>
<tr>
<td>Edwards Lifsciences†</td>
<td>46.7</td>
<td>66.0</td>
<td>66.3</td>
<td>100</td>
<td>64.2</td>
</tr>
<tr>
<td>Other</td>
<td>1.8</td>
<td>4.0</td>
<td>3.7</td>
<td>0.0</td>
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<td>Missing data</td>
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<td>0.0</td>
<td>0.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>

SD = standard deviation, CABG = coronary artery bypass graft. *includes CoreValve and EvolutR; † includes Sapien XT and S3
STRUCTURAL INDICATORS

Quality Indicator 1: Heart Team treatment recommendation

Given the complexity of both the patient population and the procedure, joint statements from professional societies have strongly recommended TAVI be restricted to centres of excellence, where a Heart Team-based, multi-disciplinary approach can be taken to guide treatment decision, appropriate patient selection, and procedural planning. The role of the Heart Team is to provide an objective decision-making process, and apply evidence/guideline–based therapy. Ideally, the TAVI Heart Team works in concert with the patient and their family, as well as the primary care or other treating physician(s).

The contributions of the multidisciplinary Heart Team throughout the continuum of TAVI care are widely acknowledged. For feasibility of measurement, the CCS TAVI Quality Working Group defined the Heart Team’s membership as including an interventional cardiologist and a cardiac surgeon as a minimum standard. As described in Table 2, the quality indicator is based on the written documentation of the in-person discussion held and the treatment recommendation made jointly by an interventional cardiologist and a cardiac surgeon.

At the national level, the Heart Team recommendation was documented for 87.4% of cases but there was a wide range across hospitals from 14.2% to 100%.

Data Quality

During the environmental scan (see Appendix 2), we found that an important gap in the local databases for several regions was the availability of an explicitly defined data variable for the documentation of the Heart Team recommendation. For the purpose of this report, we used a number of proxy measures when such a data variable was not available. Where a proxy was used, there was a substantially greater range as seen in Table 2.

In Ontario, a field evaluation conducted by the CCN of Ontario reported that all 10 TAVI hospitals have Heart Teams in place for determination of patient eligibility. Therefore, if a patient’s eligibility date was documented in the CCN registry, we accepted this as a proxy for a Heart Team discussion and decision. In Québec, we used the documentation of a cardiac surgery consultation as a proxy for a heart team recommendation over the time period of the report. Based on feedback from provincial stakeholders, the performance of this quality indicator in several hospitals likely reflects the absence of explicit documentation rather than the absence of a Heart Team process per se. As such, one immediate area for improvement is the introduction of an explicit data field for a documented Heart Team recommendation in all TAVI databases across the country. Indeed, it should be noted that the strict CCS definition is now being applied by INESSS in Québec for current cases.

Table 2. Quality Indicator: Heart Team treatment recommendation

<table>
<thead>
<tr>
<th>HEART TEAM TREATMENT RECOMMENDATION</th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented Heart Team recommendation* (mean and range, %)</td>
<td>81.6 (14.2-100)</td>
<td>80 (48-100)</td>
<td>100</td>
<td>99.4 (97.6-100)</td>
<td>87.4 (14.2-100)</td>
</tr>
</tbody>
</table>

*Documented consensus treatment recommendation made by Heart Team at multidisciplinary meeting to review patients. The Heart Team should meet the minimum requirements of an interventional cardiologist and cardiac surgeon, but should ideally be composed of the patient’s treating physician, geriatrician or internist, cardiac imaging specialist and TAVI nursing coordinator. This multi-disciplinary team should convene as a group on a regular basis to review and interpret clinical data to arrive at a consensus on the optimal treatment strategy for each patient.
Quality Indicator 2: TAVI wait time

As highlighted in section 2, there are a limited number of TAVI hospitals in Canada and funding for TAVI programs is closely managed by funding agencies. Restricted capacity coupled with a growing demand, may translate into prolonged wait times for TAVI. Given the high mortality of untreated severe AS, delays to treatment are associated with adverse clinical consequences, with wait time deaths being reported in excess of 10%. Moreover, patients’ pre-procedural functional status may deteriorate due to a prolonged wait time, which can lead to an extended post-operative hospital stay, with both clinical and economic implications.

There are currently no published guidelines on an appropriate wait time for TAVI. However, national benchmarks, developed through expert consensus are available for SAVR through the Canadian Wait Time Alliance (www.waittimealliance.ca). The upper limit for an elective SAVR as an outpatient is 42 days (6 weeks) while that for an urgent inpatient is 14 days.

A previous study from Ontario, using discrete event simulation models to determine the potential impact of prolonged wait times on TAVI effectiveness, found that even modest TAVI wait times of >60 days were associated with marked reductions in TAVI effectiveness, in terms of morbidity and mortality compared to SAVR.

Table 3 describes the TAVI wait time quality indicator as defined by the CCS TAVI Quality Working Group. Total wait time for TAVI encompasses the time trajectory from the date of referral to the date of procedure (see Figure 5). The total wait time is comprised of two components: TAVI evaluation time (Time 1), which is the period from referral for TAVI to the Heart Team decision, and TAVI procedural wait time (Time 2), which is the period from the Heart Team decision to the TAVI procedure. The purpose of dividing the total wait time into these two time periods is to objectively evaluate specific delays associated with the TAVI evaluation process, and the time spent waiting for the intervention.

Figure 5. TAVI evaluation process
Median TAVI total wait time was 106 days for Canada while wait times for the TAVI evaluation time and TAVI procedure time were 58 and 37 days respectively. There was a substantial variation in wait time across regions and hospitals (Table 3).

Data Quality
On review of TAVI wait times across the country, a number of key observations were noted. First, there were a number of data quality issues in both Ontario and Québec in respect to missing values, reinforcing the need for referral and eligibility time stamps to become mandatory data fields. Second, it was apparent that wait times are highly skewed due to a limited number of outlier cases with very long wait times, in particular from initial referral to eligibility. This resulted in an inflated total wait time and TAVI evaluation wait times, as seen in Table 3. Indeed, there are numerous cases in which the time from referral to eligibility was well beyond one year, which is considerably longer than one would anticipate for diagnostic test delays. These were likely patients who had completed their work-up and were being followed until their symptoms warranted intervention or other issues were addressed. These observations highlight the need for greater consistency in documentation of when a patient is officially waiting for TAVI, as opposed to being closely followed by the TAVI team and “on hold” prior to being explicitly listed for the procedure. As illustrated in Figure 5, the time a patient is considered “on hold” should be identified but excluded from the measured wait time, to ensure that these intentional or unavoidable delays are not reflected in the wait time metrics. As active wait time management is closely linked to capacity planning, the need for uniform wait list definitions is critical for efficient use of resources.

Finally, given these issues, the TAVI procedural wait time, when available, appeared to be a more accurate metric to reflect capacity restraints and access to care (Figure 6). There was less variation in TAVI procedural wait times, with the majority of cases in Canada waiting less than 60 days from the time of treatment decision to procedure.

Table 3. Quality Indicator: TAVI wait time

<table>
<thead>
<tr>
<th>TAVI WAIT TIME</th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Wait Time (median and IQR, days)</td>
<td>105 (58-183)</td>
<td>n/a</td>
<td>91 (57-139)</td>
<td>145 (79-219)</td>
<td>106 (59-172)</td>
</tr>
<tr>
<td>Missing data (%)</td>
<td>0.2</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>26.3</td>
</tr>
<tr>
<td>Evaluation Wait Time* (median and IQR, days)</td>
<td>63 (28-136)</td>
<td>n/a</td>
<td>46 (24-76)</td>
<td>84 (30-142)</td>
<td>58 (26-110)</td>
</tr>
<tr>
<td>Missing data (%)</td>
<td>18.4</td>
<td>100</td>
<td>0</td>
<td>1.8</td>
<td>33.0</td>
</tr>
<tr>
<td>Procedural Wait Time** (median and IQR, days)</td>
<td>31 (10-72)</td>
<td>n/a</td>
<td>38 (20-65)</td>
<td>42 (23-76)</td>
<td>37 (16-70)</td>
</tr>
<tr>
<td>Missing data (%)</td>
<td>17.4</td>
<td>100</td>
<td>0</td>
<td>5.1</td>
<td>32.9</td>
</tr>
</tbody>
</table>

*TAVI Evaluation time is defined as the time from referral to TAVI team to Heart Team decision.

**TAVI Procedural Wait time, defined as time from “Date of Heart Team decision” (i.e., consensus treatment recommendation for TAVI, and patient is ready, willing and able) to “Date of procedure.” IQR = interquartile range
Figure 6. TAVI procedural wait time (from Heart Team decision to procedure), by region and for Canada. Median and interquartile range is displayed.
PROCESS INDICATORS

Quality Indicator 3: Evaluation of procedural risk

The pre-procedural work-up for severe AS involves a comprehensive assessment of patients’ anatomy, symptoms, cardiovascular and non-cardiovascular co-morbidities, frailty, functional status and cognition, in order to recommend the most appropriate treatment among the options of SAVR, TAVI, medical management and palliative care. The currently approved indications for TAVI are for severe AS patients who are either inoperable or at high risk for SAVR.

Appropriate risk assessment requires the individualized weighting of patient factors by a Heart Team. The CCS TAVI Quality Working Group recognizes that both the complexity and subtlety of risk stratification cannot be captured by a simple score, and that a TAVI-specific risk score is currently lacking; however, an explicit metric of this process was still deemed necessary. Therefore, the CCS TAVI Quality Working Group recommended documenting procedural risk with the use of the STS risk score in all patients, in addition to Heart Team documentation and recommendations. The STS risk score is a well validated predictor of short term SAVR mortality and morbidity, and is an accurate reflection of surgical risk. However, it is important to note that the surgical score does not appropriately capture some risks associated with comorbidities that are particularly pertinent to the TAVI population, including frailty, the presence of porcelain aorta or a hostile chest wall.

Table 4 and Figure 7 provide a description of the evaluation of procedural risk quality indicator as defined by the CCS TAVI Quality Working Group. There was explicit documentation of procedural risk by the STS score in only 55.8% of cases. This was despite the universal availability of a data field for the STS score in all local registries. Moreover, there was a wide range in the documentation of the STS scores across regions and hospitals. The numerical value of the STS score is not a quality indicator per se and as such, has not been provided in this report.

Table 4. Quality Indicator: Evaluation of procedural risk

<table>
<thead>
<tr>
<th>EVALUATION OF PROCEDURAL RISK</th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented STS score* (mean and range, %)</td>
<td>26.8 (0-75.0)</td>
<td>49.7 (3.3-95.7)</td>
<td>93.0 (61.3-100)</td>
<td>75.3 (0-100)</td>
<td>55.8 (0-100)</td>
</tr>
</tbody>
</table>

*In the absence of a specific risk score for TAVI, documentation of risk is recommended using the Society of Thoracic Surgery (STS) score in addition to documentation of a heart team discussion for those patients not deemed to be high risk by risk score calculation.
Figure 7. Documented procedural risk score (STS score), by region and all of Canada, with bar representing the mean proportion of cases, and the bars the range across hospitals.
Quality Indicator 4: Evaluation of quality of life

The treatment of AS aims to improve both quantity and quality of life. Demonstrating improved quality of life as measured by the patient’s direct perspective is a pivotal component of the evaluation of appropriate case selection, procedural success and long term benefit of TAVI.

The selection and timing of the quality of life indicators were guided by a number of principles. First, at baseline, it represents a patient-reported assessment of symptoms and health status to help identify patients in whom aortic valve intervention is warranted and potentially helps to mitigate against the possibility of a futile intervention. Indeed, patient-reported outcomes measurements (PROMs) are increasingly being recognized as an important evaluation of health interventions. PROMs provide objective measures of self-reported physical, mental and social health status, and serve to quantify change in these measures over time. Finally, the Valve Academic Research Consortium-2 (VARC-2) recommends a comprehensive assessment of quality of life for TAVI patients, using a heart failure specific instrument such as the KCCQ, in addition to a generic tool such as the EQ5D. The disease specific instrument is sensitive and responsive to changes in health status for a TAVI population, while the generic instrument captures additional quality of life information in non-cardiac health domains.

The CCS TAVI Quality Working Group recognized the challenges associated with the collection of PROMs, but stressed the importance of integrating a patient-centered perspective in the CCS National Quality Report: TAVI. Recognizing that the measurement of quality of life may not be a standard component of TAVI evaluation, the indicator metric was limited to reporting the documentation of a quality of life assessment at the two time points as a first step towards the end goal of reporting change between pre-procedure (baseline) and 1-year quality of life. The CCS TAVI Quality Working Group’s pre-specified benchmark was a 20% documentation rate for the 2013-2014 fiscal year. The CCS TAVI Quality Working Group is committed to the future reporting of PROMs to augment reporting of mortality, stroke and hospital readmission outcomes.

In Canada, the measurement of quality of life was captured in 31.9% of patients pre-TAVI, above the benchmark established by the CCS TAVI Quality Working Group. However, only 12.4% of patients had a post-TAVI quality of life measurement.

Data Quality
The majority of hospitals and regions did not include quality of life as part of their standard pre or post procedural documentation, highlighting a key area for improvement in patient assessment and data availability.

Table 5. Quality Indicator: Evaluation of quality of life

<table>
<thead>
<tr>
<th>EVALUATION OF QUALITY OF LIFE</th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>KCCQ and EQ5D* (mean and range, %)</td>
<td>Pre-TAVI 0.0 0.0 97.8 (80.6-100) 60.1 (0-100) 31.9 (0-100)</td>
<td>Post-TAVI 0.0 0.0 21.5 (6.5-25.9) 55.8 (0-100) 12.4 (0-100)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*The proportion of patients with a comprehensive assessment of health related quality of life incorporating a heart failure-specific measure, KCCQ, and a generic measure, EQ5D to enhance compatibility and compare patients with population-level benchmarks. Quality of life should be assessed prior to the procedure (PRE) and at 12 months post-intervention (POST). KCCQ= Kansas City Cardiomyopathy Questionnaire
OUTCOME INDICATORS

Quality Indicators 5 & 6:
Mortality for TAVI (30-day and 1-year)

Examination of “hard” outcomes after cardiac invasive procedures is a foundation of quality of care assessment. Unadjusted crude 30-day and 1-year mortality without risk adjustment were selected as outcome quality indicators, as appropriate case-mix adjustment models have not been developed for TAVI.

For the entire TAVI cohort, mortality across Canada was 4.2% at 30-day and 13.8% at 1-year post procedure (Figure 8). These results compare favourably with those observed in the United States over a similar time period. The 30-day and 1-year mortality in the STS/American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) registry (2011-2013) were 7.0% (95% confidence interval [CI] 6.5-7.4%) and 23.7% (95% CI 22.8-24.5%) respectively.57,58

When restricted to transfemoral cases alone, the 30-day and 1-year mortality rate were 3.5% and 11.9% respectively in Canada. Table 6 indicates that mortality at 30-day and at 1-year varied by region as well as by hospital. Meaningful comparisons are not possible given that hospital volumes were small and there was no case-mix adjustment. As such, the findings must be interpreted with caution.

Data Quality

The pooled results for Canada represent a mix of outcomes ascertained via linkage with administrative databases (i.e. vital statistics) and manually ascertained by TAVI clinic staff. It is likely that the inability to link to administrative data may result in a greater degree of misclassification error, with an under-estimation of mortality.

Table 6. Quality Indicators: Mortality for TAVI (30-day and 1-year)

<table>
<thead>
<tr>
<th></th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>30-day mortality for TAVI (mean and range, %)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall 30-day crude mortality</td>
<td>5.1 (0-7.5)</td>
<td>6.1 (0-11.9)</td>
<td>1.9 (0-3.2)</td>
<td>2.3 (0-2.8)</td>
<td>4.2 (0-11.9)</td>
</tr>
<tr>
<td>Transfemoral 30-day crude mortality</td>
<td>3.4 (0-9.1)</td>
<td>6.8 (0-13.7)</td>
<td>1.3 (0-3.2)</td>
<td>1.5 (0-3.1)</td>
<td>3.5 (0-13.7)</td>
</tr>
<tr>
<td><strong>1-year mortality for TAVI (mean and range, %)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall 1-year crude mortality</td>
<td>14.1 (0-28.4)</td>
<td>14.6 (8.3-23.3)</td>
<td>13.0 (4.5-25.8)</td>
<td>12.4 (0-19.5)</td>
<td>13.8 (0-28.4)</td>
</tr>
<tr>
<td>Transfemoral 1-year crude mortality</td>
<td>12.0 (0-20.9)</td>
<td>14.6 (8.3-21.7)</td>
<td>11.3 (4.5-25.8)</td>
<td>8.0 (0-12.9)</td>
<td>11.9 (0-25.8)</td>
</tr>
</tbody>
</table>
Figure 8. Crude mortality at 30-day and 1-year, by region and all of Canada. Error bars represent the range across hospitals.
Quality Indicator 7: In-hospital stroke post-TAVI

The CCS TAVI Quality Working Group included stroke as a quality indicator given that it was identified as a potential complication of TAVI in early randomized trials comparing TAVI to SAVR. A stroke can have a significant impact on patients’ quality of life, morbidity and mortality. In-hospital stroke was chosen for the purposes of feasibility and reliability of measurement.

Table 7 outlines the definition used for in-hospital strokes. Events were captured from the clinical record in all cases, with supplementation from administrative databases where available (e.g. Ontario).

Across Canada, in-hospital stroke incidence was 2.1%. There was a wide range across institutions; however this may be a reflection of variability due to low procedural volumes. In the STS/ACC TVT registry in the United States, the in-hospital stroke rate was 2.0%.

Table 7. Quality Indicator: In-hospital stroke post-TAVI

<table>
<thead>
<tr>
<th></th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital stroke post-TAVI* (mean and range, %)</td>
<td>1.5 (0-7.1)</td>
<td>2.0 (0-7.0)</td>
<td>3.7 (0 – 9.7)</td>
<td>1.2 (0-4.2)</td>
<td>2.1 (0-9.7)</td>
</tr>
</tbody>
</table>

*Stroke, defined as an acute episode of focal or global neurological dysfunction caused by the brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction, occurring after TAVI and during the index admission for TAVI procedure as confirmed by either brain imaging or documentation of a neurologist.

Data Quality

Strokes were not adjudicated events and as such there is the potential for under-capture of neurological findings. The CCS TAVI Quality Working Group recognizes that reporting disabling stroke would be a more meaningful indicator and should be considered in the future using a standardized definition.
Quality Indicators 8 & 9: All cause hospital readmission (30-day and 1-year)

All cause hospital readmission at 30-days and 1-year were also included as outcome indicators. Readmissions are recognized as events associated with significant morbidity in patients and substantial economic burden on the health care system. Understanding the nature of readmissions and determining if they are avoidable is an important metric by which to evaluate quality of care.

In Canada, all cause 30-day and 1-year readmission rates were 16.9% and 45.7% respectively (Figure 9). The 1-year readmission rate in the ACC/STS TVT registry was 24.4%, substantially lower than that observed in Canada.

Data Quality: For the period of interest from 2013-2014, there was no data available in Québec; however, this issue is being addressed and data should be available for subsequent time periods.

There was a wide range in the rates of all cause hospital readmission across regions and hospitals as seen in Table 8. We hypothesize that there are two explanations for this finding. First, the very low procedural volumes at some of the TAVI hospitals will translate to unreliable estimates. Second, there were different methods of outcome ascertainment, with administrative data linkage used in Ontario and British Columbia with the CIHI DAD, while self-reported outcome determination by the TAVI group was used in the other provinces. Readmission in the CIHI DAD has been validated and is accurate for all cause hospitalization, while there is the potential for under-capture of outcomes by self-reported ascertainment. There are opportunities to improve the reporting of this indicator by studying the causes of readmission and standardizing the data quality.

Table 8. Quality indicators: All cause hospital readmission (30-day and 1-year)

<table>
<thead>
<tr>
<th></th>
<th>Ontario (N=396)</th>
<th>Québec (N=294)</th>
<th>British Columbia (N=270)</th>
<th>Alberta, Manitoba, New Brunswick, Nova Scotia (N=162)</th>
<th>Canada (N=1,122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day readmission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mean and range, %)</td>
<td>11.9 (7.7-22.2)</td>
<td>n/a</td>
<td>26.1 (18.2-39.5)</td>
<td>12.8 (4.5-19.4)</td>
<td>16.9 (4.5-39.5)</td>
</tr>
<tr>
<td>1-year readmission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mean and range, %)</td>
<td>42.2 (28.6-68.0)</td>
<td>n/a</td>
<td>57.6 (54.4-58.6)</td>
<td>34.4 (12.2-60.0)</td>
<td>45.7 (12.2-68.0)</td>
</tr>
</tbody>
</table>
Figure 9. All-cause 30-day and 1-year hospital readmission by region and all of Canada. Error bars represent the range across hospitals.
4. DISCUSSION AND NEXT STEPS

CHALLENGES AND OPPORTUNITIES

This is the first national effort of the CCS Quality Project to measure and report on the quality of cardiovascular care. The development of the quality indicators was initiated and led by clinicians with the goal of improving care for TAVI, a new disruptive technology that is rapidly disseminating across the country. This accomplishment attests to the feasibility and value of a collaborative and transparent effort to improve patient care across Canada.

As was identified by the CHHS-AP, we encountered substantial challenges in sharing data across provinces. Nonetheless, we were able to overcome these challenges and produce a pan-Canadian dataset that provides meaningful information. This report is the first portrait of the quality of TAVI care in Canada. In addition, this collaboration was successful in gaining support from all Canadian TAVI stakeholders, including clinicians, administrators, health agencies and policy makers. It is hoped that this report will initiate a network for peer-to-peer shared learning, and ongoing quality improvement. Most critically, we believe it will be a model for future pan-Canadian quality improvement initiatives in other areas of cardiovascular medicine.

Data Quality

This report leveraged existing data collection processes coordinated provincially or developed organically at individual TAVI hospitals. Both the environmental scan and the data analyses suggest that many sites did not collect key quality indicators, that inconsistent definitions were utilized for several variables, and that the amount of missing data for some of the variables were substantial. Specific examples include STS documentation, documentation of Heart Team recommendation, wait time data and quality of life.

For STS, despite the existence of this data element in all registries, it was not consistently entered. Moreover, it generally had a lower rate of completion as compared to the documentation of Heart Team recommendation, suggesting that risk stratification was occurring, albeit with an alternative method than the STS. Given the limitations of the STS to inform TAVI-specific risk stratification, our findings may require that the definition of this quality indicator be revisited. We anticipate that future validated TAVI risk scores will be adopted in Canada and replace the use of STS.

For the documentation of Heart Team recommendation, we found that the hospitals which had an explicit field for this metric had a higher rate of completion than in those using a proxy measure. This suggests that a uniform data field across all registries would likely improve performance.

An examination of the range of data for wait time showed that some patients have unusually long wait times (particularly for evaluation wait time) that is inconsistent with what one would anticipate while awaiting diagnostic tests. We hypothesize that extreme delays, may be due to patients being kept on the wait list for surveillance in order to identify symptoms, as opposed to being booked for a procedure. If this is the case, it suggests the need to distinguish such patients such that wait times accurately reflect access to care.

This effort of examining data quality and comparing across the country provides a unique opportunity for TAVI hospitals to agree on standard definitions across the country, that are consistent with international standards, and to share best practice on how to ensure efficient and accurate data collection for both the pre-procedural and post-procedural periods.
Cross Jurisdictional Data Transfer
Data sharing across provincial boundaries presented challenges, in particular because this was the first attempt to do so for patient-level data. However, this project has demonstrated that it can successfully be achieved when there is strong support from the clinical community and other stakeholders. Moreover, it demonstrated that data linkage can be completed within strict timelines. Future collaborations should focus on efforts to streamline the processes in place to share data across provincial borders, such that data transfers can occur at more frequent intervals. The leadership of the CCS provides a model for joint collaboration that can transcend the limitations of the availability of data across jurisdictions for the purpose of improving cardiac care in Canada.

Case Mix Adjustment
Our report was limited to crude, unadjusted outcomes given the absence of appropriate case-mix adjustment models. This is a clear limitation. However, it is an area of active research and as TAVI case volumes increase, the application of such models will allow for more opportunities for comparative analyses of outcomes across regions and hospitals.

INSIGHTS INTO CANADIAN TAVI CARE
This CCS National Quality Report: TAVI provides several novel insights into the care of TAVI patients in Canada. First, there is substantial inequality in access across the country, as evidenced by the differential rates of TAVI per population in the country. There was an almost 4-fold difference in TAVI rates between provinces, from 16 TAVI/million population in Manitoba to 61 TAVI/million in British Columbia. Our evaluation did not investigate the potential drivers of this variation, but we hypothesize that this may be due to historical developments during the early pioneering period, different provincial funding strategies as well as varied maturity of the available infrastructure for both patient evaluation and procedural capacity.

The inequality in access is further evidenced by the prolonged wait times for TAVI, with a median delay across the country of over 3 months from referral to procedure. Although the upper limit of an appropriate TAVI wait time is not known, modelling work has suggested that a delay of greater than 60 days is associated with worse outcomes. This report reinforces the need for a national wait time strategy that provides tools for TAVI hospitals for appropriately triaging TAVI candidates in those at high versus low risk of pre-procedural adverse events. Moreover, there is a need for explicit benchmarks as to an appropriate wait time. In addition, such a strategy will inform policy makers as to the appropriate capacity and funding required within a specific jurisdiction in order to meet the established wait time benchmarks.

Our findings suggest that, in Canada, high quality care is being provided to patients who undergo TAVI, with outcomes that are comparable to other national registries, in particular for mortality, and stroke. However, readmission rates were considerably higher than that observed in the STS/ACC TVT registry. Readmissions were highly variable across regions. Hospital readmissions are a substantial burden to patients, providers and the health care system. As such, it is critical to understand the reasons for the seemingly higher rate of readmission in Canada and the variability across jurisdictions. We hypothesize that inter-provincial and inter-institutional variation may be related to incomplete follow-up in some hospitals, resulting in underestimation of outcome rates during follow-up. However, given that TAVI patients are elderly and often have multiple co-morbidities, it raises the possibility that greater attention is required to ensure appropriate supports are in place to allow for a safe transition home after the acute care hospitalization. This is especially important in the context of the growing interest to decrease the length of stay for TAVI patients, through early mobilization and directed care pathways, as a means to reduce hospitalization costs and make more efficient use of the limited TAVI capacity. Further evaluation of the drivers of readmission and interventions to mitigate the risk should be a focus of future quality improvement.

FUTURE DIRECTION
TAVI is a rapidly evolving field, with technology advancements as well as expansion of indications and use in lower risk patients. This will be accompanied by ongoing strain on provincial healthcare budgets, thus reinforcing the need for both efficient and high quality care. Therefore, it is paramount to continue collection of high quality data and measurement of quality indicators, such that care can be evaluated and improved.
## APPENDIX I. TAVI HOSPITALS IN CANADA

<table>
<thead>
<tr>
<th>Region</th>
<th>City</th>
<th>TAVI Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>Calgary</td>
<td>Foothills Medical Centre</td>
</tr>
<tr>
<td></td>
<td>Edmonton</td>
<td>University of Alberta Hospital</td>
</tr>
<tr>
<td>British Columbia</td>
<td>New Westminster</td>
<td>Royal Columbian Hospital</td>
</tr>
<tr>
<td></td>
<td>Vancouver</td>
<td>St. Paul's Hospital</td>
</tr>
<tr>
<td></td>
<td>Vancouver</td>
<td>Vancouver General Hospital</td>
</tr>
<tr>
<td></td>
<td>Victoria</td>
<td>Royal Jubilee Hospital</td>
</tr>
<tr>
<td>Manitoba</td>
<td>Winnipeg</td>
<td>St. Boniface General Hospital</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>Saint John</td>
<td>New Brunswick Heart Centre</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Halifax</td>
<td>Queen Elizabeth II Health Sciences Centre</td>
</tr>
<tr>
<td>Ontario</td>
<td>Hamilton</td>
<td>Hamilton Health Sciences Centre</td>
</tr>
<tr>
<td></td>
<td>Kingston</td>
<td>Kingston General Hospital</td>
</tr>
<tr>
<td></td>
<td>London</td>
<td>London Health Sciences Centre</td>
</tr>
<tr>
<td></td>
<td>Mississauga</td>
<td>Trillium Health Sciences Centre</td>
</tr>
<tr>
<td></td>
<td>Newmarket</td>
<td>Southlake Regional Health Centre</td>
</tr>
<tr>
<td></td>
<td>Ottawa</td>
<td>University of Ottawa Heart Institute</td>
</tr>
<tr>
<td></td>
<td>Sudbury</td>
<td>Health Sciences North</td>
</tr>
<tr>
<td></td>
<td>Toronto</td>
<td>St. Michael’s Hospital</td>
</tr>
<tr>
<td></td>
<td>Toronto</td>
<td>Sunnybrook Health Sciences Centre</td>
</tr>
<tr>
<td></td>
<td></td>
<td>University Health Network</td>
</tr>
<tr>
<td>Québec</td>
<td>Montréal</td>
<td>Centre Hospitalier de l’Université de Montréal (CHUM)</td>
</tr>
<tr>
<td></td>
<td>Montréal</td>
<td>Hôpital du Sacré-Cœur de Montréal</td>
</tr>
<tr>
<td></td>
<td>Montréal</td>
<td>Montreal Heart Institute</td>
</tr>
<tr>
<td></td>
<td>Montréal</td>
<td>McGill University Health Centre</td>
</tr>
<tr>
<td></td>
<td>Québec City</td>
<td>Quebec Heart and Lung Institute</td>
</tr>
<tr>
<td></td>
<td>Sherbrooke</td>
<td>Centre Hospitalier Universitaire de Sherbrooke (CHUS)</td>
</tr>
</tbody>
</table>

* Site not included in this report, as TAVI hospital still in development during time frame of study
## APPENDIX 2. ENVIRONMENTAL SCAN OF TAVI STRUCTURAL, PROCESS, AND OUTCOME DATA

<table>
<thead>
<tr>
<th></th>
<th>Ontario</th>
<th>Québec</th>
<th>British Columbia</th>
<th>Alberta - Calgary Site</th>
<th>Alberta - Edmonton Site</th>
<th>Manitoba</th>
<th>New Brunswick</th>
<th>Nova Scotia</th>
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</thead>
<tbody>
<tr>
<td>Heart Team Recommendation</td>
<td>●</td>
<td>■</td>
<td>●</td>
<td>■</td>
<td>●</td>
<td>●</td>
<td>■</td>
<td>●</td>
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<tr>
<td>Wait time 1</td>
<td>●</td>
<td>●</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>●</td>
<td>■</td>
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<tr>
<td>Wait time 2</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>■</td>
<td>■</td>
<td>●</td>
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<td>■</td>
</tr>
<tr>
<td>Total wait time</td>
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<td>●</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
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<tr>
<td>STS score</td>
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<td>●</td>
<td>■</td>
<td>■</td>
<td>●</td>
<td>●</td>
<td>■</td>
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<tr>
<td>Quality of life pre and 1-year post</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>30-day mortality</td>
<td>●</td>
<td>●</td>
<td>■</td>
<td>■</td>
<td>●</td>
<td>●</td>
<td>■</td>
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<tr>
<td>I-year mortality</td>
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<td>●</td>
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<td>■</td>
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<tr>
<td>In-hospital stroke</td>
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<td>●</td>
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<td>■</td>
<td>●</td>
<td>●</td>
<td>●</td>
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</tr>
<tr>
<td>30-day readmission</td>
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<td>●</td>
<td>●</td>
<td>●</td>
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<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>1-year readmission</td>
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<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

*A “Green” status indicates that the data are consistent with the QI definition and complete. A “Yellow” status indicates that the data are consistent with regards to definitions but has missing data. A “Red” status indicates the data are either not available or not consistent with the indicator definition.*
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Catherine Kells
Andrew Krahn
Mario Talajic
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Lindsay Jacobi
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