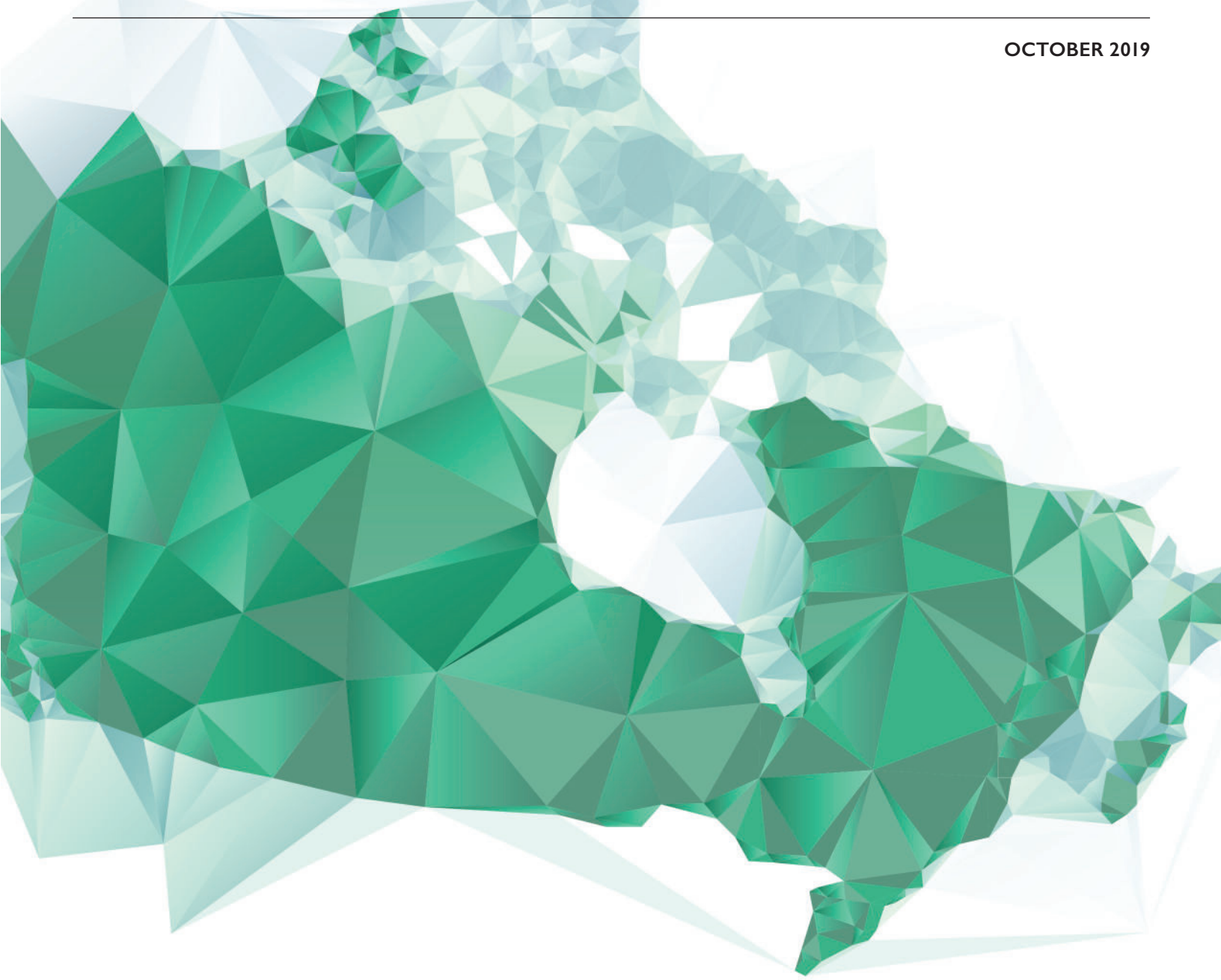
CANADIAN CARDIOVASCULAR SOCIETY

NATIONAL QUALITY REPORT: TRANSCATHETER AORTIC VALVE IMPLANTATION

OCTOBER 2019



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LETTER FROM THE CHAIRS

As Chairs of the Canadian Cardiovascular Society (CCS) Quality Project and TAVI Quality Working Group, it is our privilege to introduce the second CCS National Quality Report: TAVI. This updated national snapshot of TAVI care represents a continuation of a national dialogue on the quality and value of cardiovascular care across Canada.

Since the 2016 report, the TAVI Quality Working Group has:

- Published a best-practice toolkit to support quality implementation of TAVI care;
- Added two new evidence-based TAVI quality indicators to the existing set;
- Continued working to align data definitions, establish data linkages, and address barriers to pan-Canadian comparisons with support from key partners including the Canadian Institute for Health Information (CIHI) and provincial registries.

Unique to the 2019 National Quality Report: TAVI is the inclusion of data over four fiscal years (2013/14-2016/17), as well as data on hospital length of stay and rates of new permanent pacemakers. Consistent with the 2016 report, the development of the 2019 National Quality Report: TAVI was a stakeholder-driven process to ensure that these pan-Canadian comparable results gives care providers the tools they need to make evidence-based improvements in care and achieve better patient outcomes.

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 TAVI Quality Report Team (Anita Asgar, Sandra Lauck, Laurie Lambert, Harindra Wijeysundera, Dennis Ko, Malek Kass) who developed the report, with support from the TAVI Quality Working Group;
- Members of the TAVI Quality Report Team who managed the data collection and analysis, and supported the development of the report;
- Representatives from the TAVI hospitals and cardiovascular registries, for being open to this process and providing the data used to inform the report;
- 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, TAVI Quality Working Group
Canadian Cardiovascular Society

Paul Dorian
Chair, Quality Project Steering Committee
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PREFACE

As representatives of the Canadian Cardiovascular Society (CCS) Transcatheter Aortic Valve Implantation (TAVI) Quality Working Group and authors of this report, we are proud to share an updated national snapshot of care quality in an effort to give care providers the information they need to make targeted improvements. Despite this, we feel it is important and necessary to acknowledge the challenges we faced through the development of this report and share what is required for this work to continue.

Similar to our experience with the 2016 report, lack of clarity on the data request application process, inconsistent requirements for research ethics approval, and delayed data transfers affected the development and timely release of this report. Despite our intentions and support from the clinical community, we were unable to share site-level data, given not all provinces provided site-specific data.

Importantly, the development of this report has been primarily achieved by significant voluntary efforts of a highly engaged community of cardiovascular specialists. Yet this model of relying on practitioners for ongoing and regular national quality reporting is not their responsibility nor is it sustainable.

For efforts like this to continue, national leadership is required. Clinicians across the country have bought into and have been instrumental in building this national reporting system that the federal government called for in the *2009 Canadian Heart Health Strategy and Action Plan*. Yet governments have yet to put the necessary resources behind it.

Teams of care providers and administrators remain eager to examine their health care centre's performance in order to provide better care, achieve better patient outcomes, and offer better value. We are calling on the federal and provincial governments to do their part by positioning us to be successful.

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EXECUTIVE SUMMARY

BACKGROUND

In 2010, the Canadian Cardiovascular Society (CCS) undertook an initiative to develop a national quality reporting system better known as the Quality Project. To operationalize this, the CCS convened committees of experts (working groups) organized by sub-disciplines of cardiology and cardiac surgery to establish consensus over a set of indicators that are reflective of the quality of cardiac care in Canada. Working groups in cardiac surgery, heart failure, atrial fibrillation, percutaneous coronary interventions, cardiac rehabilitation and transcatheter aortic valve implantation (TAVI) were formed. 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 the quality of TAVI.

QUALITY INDICATORS

As of 2019, the CCS TAVI Quality Working Group has established the following 11 quality indicators (QIs) for TAVI:

Structural indicators

- Heart Team treatment recommendation
- Wait time

Process indicators

- Evaluation of procedural risk
- Evaluation of quality of life
- Length of stay*

Outcome indicators

- Mortality (30-day and 1-year)
- In-hospital stroke
- All cause hospital readmission (30-day and 1-year)
- New permanent pacemaker rate*

OVERALL GOALS

The overarching goal of the second National Quality Report: TAVI is to continue to provide evidence-based findings to:

1. stimulate local, regional, and national quality improvement;
2. support patients' access to appropriate, high quality care; and
3. foster a national strategy to optimize patient outcomes, health service utilization, and access to treatment.

This second iteration also provides feedback on improvements made since the first report and remaining challenges. The report is complementary to the recently published CCS TAVI Toolkit that contains a suite of best practice resources.

METHODS

Between fiscal years 2013/14 and 2016/17, there were 27 hospitals across eight provinces that were performing TAVI. Each of these hospitals maintains a local database or contributes to a provincial registry. Each jurisdiction provided individual de-identified patient-level data, which was transferred via a virtual private network (VPN) to a secure server at ICES under contract with the CCS. All data was collated and analyzed at ICES. This report provides results at the national and pre-specified regional levels, such that each has a similar number of sites and volume 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.

* Added since the 2016 CCS National Quality Report: TAVI

RESULTS

Data for a total of 4,906 patients who underwent TAVI in Canada between April 1st 2014 and March 31st 2017 were provided for QI analyses. There was substantial variation in access to TAVI across the country. Specifically, the procedural volume ranged from 87 per million in BC at the high end to 42 per million in Newfoundland at the low end in 2016/17. In Canada, as in the previous report, the mean age of TAVI patients remained over 81 years, and women accounted for approximately half of all patients. The predominant approach for the TAVI procedure continued to be transfemoral (81.8% in 2013/14 and 85.6% in 2016/17).

Structural Indicators

The Heart Team decision was documented in 98.8% of TAVI cases in Canada; this is a substantial improvement since the first report (87.4% of TAVI cases in Canada). In the most recent year (2016/17), median total wait time from referral to TAVI procedure in Canada was 135 days (interquartile range [IQR] 75-198). In the same year, wait times for TAVI evaluation (from referral to Heart Team decision) and TAVI procedure (from Heart Team decision to procedure) were 57 (IQR 25-101) and 56 (IQR 21-106) days, respectively. There was substantial wait time variation between hospitals. This report illustrates that despite improvements in other QIs, wait times have increased since 2013/14 reflecting an imbalance between the clinical need for TAVI and the ability to deliver care. Significant challenges in monitoring wait times across programs remains.

Process Indicators

Documentation of procedural risk by the Society of Thoracic Surgeons (STS) score increased from 55.8% in 2013/14 to 88.5% in 2016/17. Quality of life assessment using a standard instrument (either the Kansas City Cardiomyopathy Questionnaire [KCCQ] or EQ5D) continued to be challenging in spite of the consensus agreement that patient-reported outcomes are important components of the evaluation of quality of care. In 2016/17, this assessment was documented in less than 20% of cases both prior to TAVI and at 1-year post procedure. Length of stay, a new QI in this report, decreased in Canada from 2014/15 to 2016/17. Specifically, there was less time from admission to discharge (6 days in 2014/15 to 4 days in 2016/17) and less time from procedure to discharge (5 days in 2014/15 to 3 days in 2016/17). However, there was significant variation across regions.

Outcome Indicators

In 2016/17, TAVI mortality in Canada was 2.7% (range 0-5.6%) at 30-days and 8.2% (range 7.7-12.0%) at 1-year post procedure. Like the 2013/14 results, the incidence of in-hospital stroke remained low (2.6% in 2016/17). All cause hospital readmission at 30-days and 1-year were 9.4% (range 4.5-17.3%) and 23.1% (range 10.5-50.0%), respectively, in the most recent year; this is an important improvement from the 2013/14 results (16.9% (range 4.5-39.5%) 30-day hospital readmission rate, and 45.7% (range 12.2-68.0%) 1-year hospital readmission rate). New permanent pacemaker rate, the second new QI, varied across regions; pacemakers were implanted in approximately 12% of patients post-TAVI in 2016/17.

CONCLUSIONS

The second National Quality Report: TAVI has achieved the goal of measuring and reporting the quality of TAVI care delivered to Canadians. The current report demonstrates improvement in the collection of TAVI QIs. There has been encouraging progress since the first report, including a clear increase in the number of TAVI procedures performed nationally, from a mean of 34 TAVI/per million population in 2013/14 to 51 TAVI/million population in the most recent reporting year (2016/17). Still, the results indicate persistent variability across Canada for access to TAVI procedures and wait times.

The measurement and public reporting of TAVI quality of care has strengthened clinicians' and policy-makers' commitment to transparency and accountability, and has provided an important starting point for benchmarking and standardizing quality of care. It has catalyzed a national community of practice that has leveraged local clinical expertise to support quality improvement.

Moving forward, the success of these quality improvement efforts depends on ongoing refinement of the TAVI QIs to ensure they continue to reflect current quality improvement priorities as indications evolve and areas of importance change. Of equal importance is for clinicians, administrators, and health policy leaders to commit to regional and national collaboration through ongoing measurement and reporting of the TAVI QIs, and targeted improvement efforts. We believe the impact of these efforts will be amplified by the involvement and support of all stakeholders and will ultimately optimize the quality of TAVI care delivered to Canadians.

INTRODUCTION

BACKGROUND

Transcatheter aortic valve implantation (TAVI/TAVR) is a disruptive technology that has rapidly become a treatment option for patients with severe symptomatic aortic stenosis in high, intermediate, and selected low surgical risk patients.[1-5] TAVI is an accepted standard of care that utilizes transformative and rapidly evolving technology, procedural approaches and processes of care, and is driven by a growing body of evidence.[6] This therapy plays an important and growing role in the treatment of certain patients with aortic valve disease at all risk levels.

In 2016, the Canadian Cardiovascular Society (CCS) published the first National Quality Report: TAVI as part of a comprehensive strategy to measure and report on the quality of cardiovascular care at a national level. This quality report was the culmination of work to develop clinically relevant quality indicators (QIs) for TAVI, measure these QIs on a national level, and report the findings to provide a snapshot of the quality of care delivered to patients in Canada.

The inaugural report demonstrated that collection of pan-Canadian data was feasible and thus, that the measurement of the QIs was possible.[7] However, a number of challenges were identified. Canada lacks a national registry and systematic reporting mechanism for TAVI and other cardiac procedures. There are significant policy barriers to the seamless sharing of data across health jurisdictions, and inconsistent practices and policies across provinces. For most centres, evaluation was confined to self-reported results contained in local databases and was limited by the absence of standardized definitions for data elements, QIs, and other essential data quality requirements. To this end, the selected QIs targeted the variables with the highest likelihood of data quality. Further, the challenges identified in the 2016 report have persisted, as the process for data collating, analyzing, and reporting on quality of care for TAVI proved equally challenging in the development of this 2019 report.

In addition to reporting on select outcomes, the inaugural 2016 report highlighted novel information about health policy. We reported the first evidence of considerable inter-provincial variation in procedural volumes and wait times, reflecting inequity in access to care and varying funding models across the country. There was significant disparity in utilization rates between provinces and two provinces had no local program (Saskatchewan and Newfoundland) at the time. In comparison to other developed countries in 2013, the rates of TAVI in Canada fell between that of Germany (>90 procedures per million) and Poland (10 procedures per million).[8] Similar differences were found in wait times and processes of care. What constitutes an appropriate utilization rate per population and an acceptable wait time have not been defined nationally, but these data may help inform policy.

The 2016 TAVI quality framework was based on the Donabedian concepts of structure, process and outcomes (Figure 1).[9] We reported on the following:

1. The **structure** domains included documentation of a Heart Team treatment recommendation for patients treated with TAVI as recommended by the CCS TAVI Position Statement, and wait time for TAVI. In 2013/14, a Heart Team treatment recommendation was used in the majority of centers (87.4%), illustrating appropriate collaboration between cardiology and cardiac surgery for optimal treatment decisions. In contrast, the documentation of TAVI wait times was more challenging. There was no data on wait times available in up to a third of patients treated (33%). In those for whom data was available, there were highly variable wait times between regions of the country in the first time interval from referral to Heart Team decision. The second time interval from decision to procedure was better documented; however, the median number of days varied significantly (37 days, IQR 16-70). These inconsistent findings are concerning. They reflect important differences for patients waiting for therapy and highlight inequity in timely access to care in the setting of a disease with significant mortality if left untreated.

2. The **process** domains of quality centered on the assessment of individual procedural risk and quality of life. Documentation of the STS score was available in slightly more than 50% of patients, again reflecting regional differences in practice. Quality of life was measured in even fewer patients, 32% prior to TAVI and 12% a year later. This was perhaps not surprising given that although the measurement of quality of life is emerging as an important patient-centred outcome, it is rarely measured in cardiology or cardiac surgery in response to treatment.

3. Evaluation of the **outcome** domains highlighted low rates of mortality and stroke that were comparable to results seen in other countries during a similar timeframe.[10] In comparison, all cause 30-day and 1-year readmission rates were high (16.9% and 45.7%, respectively) reflecting baseline comorbidity and age.

Overall, this initial report demonstrated that the collection of the TAVI QIs was feasible and highlighted potential areas of improvement, namely improving access to care across the country, measuring wait times for TAVI, and delivering care in a timely fashion, as well as monitoring and developing strategies to reduce hospital readmissions following TAVI interventions.

The intent of the TAVI Quality Report is to be a flexible framework that responds to the rapidly evolving clinical context of care and evidence. We sought feedback from the clinical community through knowledge mobilization activities at the Canadian Cardiovascular Congress, published findings and lessons learned in the *Canadian Journal of Cardiology*, and made the report widely available through the leadership of the CCS. The Working Group remains committed to national and multidisciplinary consensus, and the on-going evaluation of each QI in an effort to provide the most accurate snapshot of contemporary practice and help guide policy and clinical care. Our strong and on-going commitment to stakeholder engagement through the working group and the wider cardiac clinical and administrative community is essential to promote the value of this project.

Following the release of the initial report, members of the working group, and the clinical and policy community argued for the inclusion of additional QIs to strengthen the impact of the findings, highlight emerging clinical concerns, and reflect temporal changes. These new QIs include:

1. **New permanent pacemaker rate:** The need for a new pacemaker is a known complication of TAVI procedures. Recent data have linked this complication to increased risk of heart failure and re-hospitalization as well as potentially mortality.[11] Given the potential long-term implications for patients, this has been added as a new **outcome** QI.

2. **Length of stay:** Index hospital length of stay after TAVI is often multifactorial. This QI is related to the patient comorbidities and complications post-intervention. It is a marker of efficiency in processes of care and discharge planning, and is an important consideration for health care planning and program capacity. Length of stay is included as a **process** QI. It is subdivided into the duration from admission to discharge and the duration from the TAVI procedure to discharge.

Based on the iterative nature of quality improvement, we anticipate that we will continue to scrutinize the QIs to ensure that all data collected provides meaningful information to guide patient care and health service delivery.

Figure 1. Structural, process, and outcome quality indicators for TAVI in Canada

GOALS OF THE REPORT

The overarching goals of this report are to:

1. provide data-based findings to catalyze local, regional, and national quality improvement;
2. support patients' access to appropriate, high quality care; and
3. foster a national strategy to optimize patient outcomes, health service utilization, and access to treatment.

The report is meant for clinicians, administrators, health agencies, and policy-makers at the local, provincial, and national levels. It is intended to motivate and support continuous quality improvement of TAVI patient care and outcomes in Canada. It also demonstrates a commitment to accountability, transparency, and delivery of high-quality care by reporting temporal trends, areas of significant improvement, and opportunities for continued progress.

REPORTING

CURRENT PROVINCIAL AND LOCAL TAVI DATA COLLECTION

As of March 2017, there were 27 TAVI hospitals in 9 provinces in Canada. Only Prince Edward Island does not have a TAVI program and eligible patients are referred out of province. At the time of data capture, TAVI was available in **87%** of hospitals that perform cardiac surgery (N=31).

All Canadian TAVI hospitals collect data prospectively for patients treated with TAVI, although data is not available to monitor the denominator of potentially eligible patients referred for assessment. Mandatory reporting to a provincial registry is uneven across Canada. In Ontario (ON) and British Columbia (BC), data submission is a requirement for provincial procedural funding. In Ontario, data collection is centrally coordinated by CorHealth Ontario while BC hospitals submit their data to Cardiac Services BC (CSBC). Similarly, Québec (QC) hospitals are required to participate in a province-wide audit and feedback process in collaboration with the province's health technology evaluation agency, Institut national d'excellence en santé et en services sociaux (INESSS). These three agencies maintain registries of many advanced cardiac procedures performed in their provincial centres. In Alberta (AB), Calgary's Foothills Medical Centre submits their data directly to the TAVI module of the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) database, which is maintained by Alberta Health Services. Conversely, the University of Alberta Hospital in Edmonton maintains a separate database. The Manitoba (MB), Nova Scotia (NS), New Brunswick (NB), and Newfoundland (NL) programs are each located in a single TAVI hospital and contribute their data to a local database. At the time of data capture, the Saskatchewan (SK) TAVI program was still in development; hence, data from this site was not collected for the current report. In addition, the opening of the programs at the Jewish General Hospital in Montreal QC, the Kelowna General Hospital in Kelowna BC, and the St. Mary's General Hospital in Kitchener ON, occurred following the observation period. Thus, data from 26 hospitals is presented in this report. Their geographical locations are presented in Figure 2 and a full list of their names are provided in Appendix 1.

Figure 2. Geographical locations of TAVI hospitals in Canada

Canada lacks an inter-provincial agreement on the collection of a minimal data set and the adoption of standardized definitions to monitor the quality of TAVI. Only data that was available across most of the 26 TAVI programs and comparable in terms of variable definitions and reporting methods were included in the analyses. The goal was to create a scientifically robust final data set that could provide a focused and strengthened second iteration of the 2016 National Quality Report: TAVI. The present cohort includes patients who underwent a TAVI procedure from April 1st 2014 to March 31st 2017 (Figure 3) although not all hospitals were able to provide data for the entire observation period.

The original intent of this report was to foster a culture of transparency and accountability to promote quality of care by reporting hospital-level findings. De-identified individual patient-level data were available for all provinces at a hospital level, with the exception of BC where the centre names were anonymized as per provincial privacy regulations. All other available data were transferred via a VPN to a secure server at ICES (see Appendix 2). Once the data were transferred, it was collated and analyzed by an ICES research team contracted by the CCS. The data structure and transmission process were consistent with privacy regulations in all provinces.

PRESENTATION OF RESULTS

Although the Working Group remains committed to discussing the opportunities and barriers to a rigorous analysis of site-specific and risk-adjusted findings in the future, the present report is limited to analyses of the four groupings adopted in 2016. This report provides results for all QI at a national and regional level, with reporting of both the central tendency (mean or median) and the variation observed across individual sites.

The regional results are presented across four groups, in order to ensure a similar number of sites and volume of patients:

a) Alberta, Manitoba, Nova Scotia, New Brunswick, and Newfoundland (for available data)
b) British Columbia
c) Ontario
d) Québec

Given that the national dataset was a combination of collated patient-level data as well as provincial summary data, only weighted averages are reported for some of the QIs. Moreover, due to the absence of a validated risk adjustment model, inferential statistical tests and modelling were not applied to the data and the results for clinical outcomes are **unadjusted for potential differences in patient profiles** across sites and regions. Therefore, as in the previous national report, it must be emphasized that the primary goal of these analyses is to provide a portrait of TAVI care in Canada. It is necessary to use caution when attempting to make any comparative inferences.

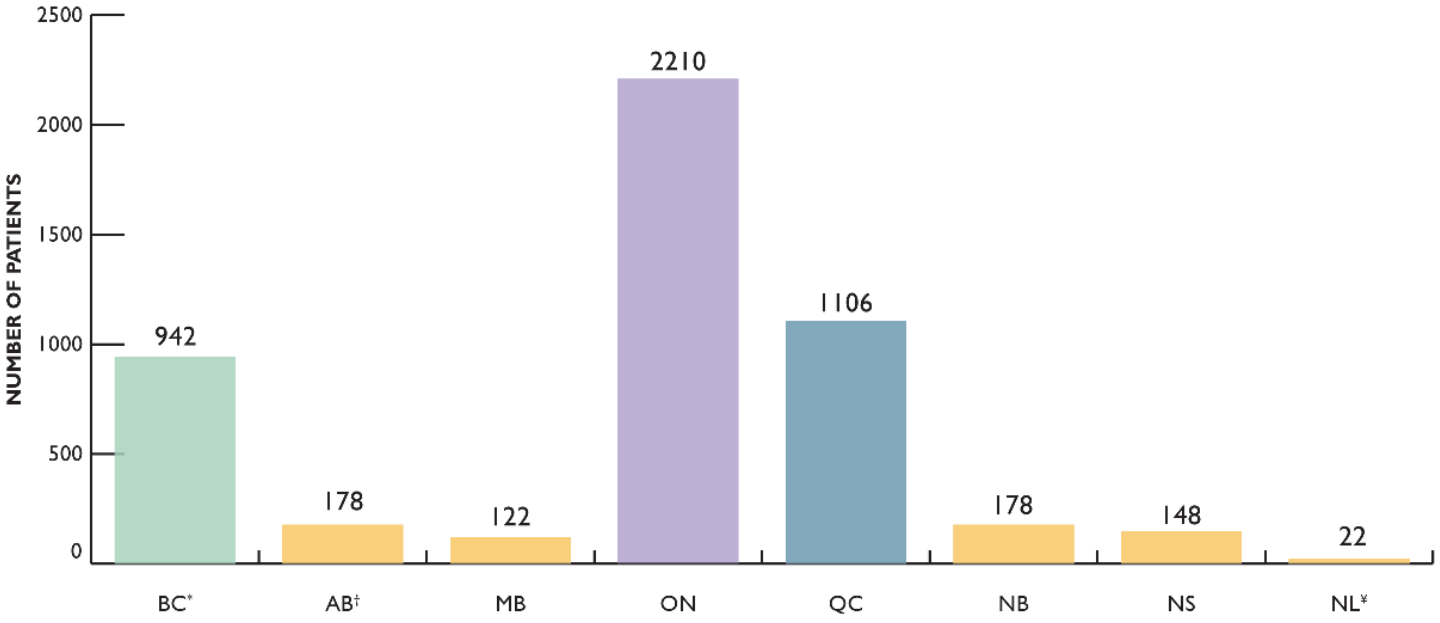

Figure 3. Volume of new patient cohort

*British Columbia Apr 2014 to Dec 2016
†Calgary, Alberta Aug 2014 to Mar 2016; Edmonton, Alberta Apr 2014 to Mar 2016
¥Newfoundland and Labrador Jan 2016 to Mar 2017

FINDINGS

ACCESS TO TREATMENT

Across Canada, a total of 4,906 patients were treated with TAVI between April 1st 2014 and March 31st 2017 and were included in this report.

The annual rate of TAVI per million population in Canada increased from 34 in 2013/14 to 51 in 2016/17. While access has improved in each province since the first quality report, rates of TAVI uses remain unequal across different regions in Canada (Figure 4).

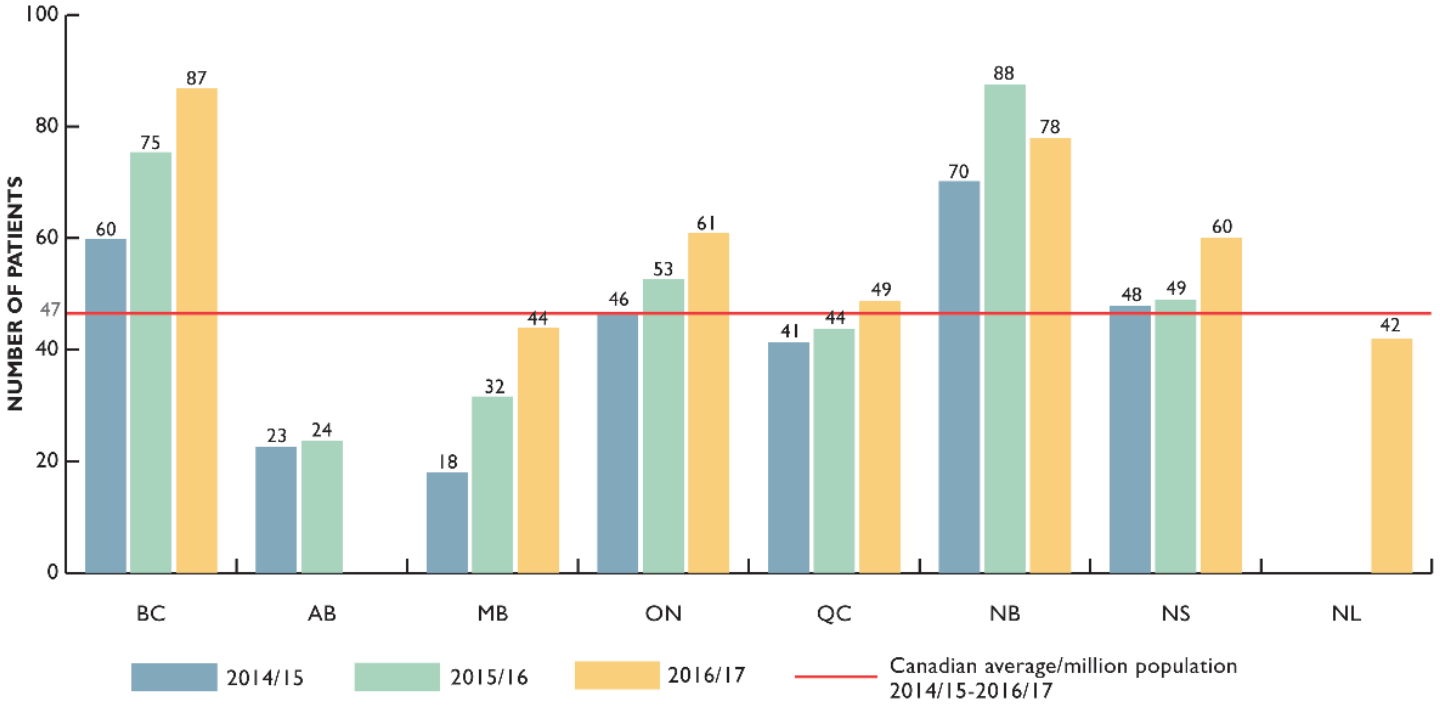

Figure 4. Rate per million population (April 1st 2014 - March 31st 2017)

PATIENT CHARACTERISTICS

At the national level, the mean age of TAVI patients has remained over 81 (81.9 years in 2013/14 and 81.6 years between 2014/15 and 2016/17), and women have accounted for approximately half of all patients (44.3% in 2013/14 and 45.3% 2014/15). Detailed patient characteristics are available in Appendix 3 and indicate that patient characteristics were relatively similar across the country.

Table 1. Age and sex of patients

	Canada	BC*	AB†	MB	ON	QC	NB	NS	NL¥
Number of patients	4906	942	178	122	2210	1106	178	148	22
Mean age (years) (± SD)	81.6 ± 7.6	81.4 ± 7.7	81.3 ± 7.5	83.6 ± 5.5	82.1 ± 7.5	81.3 ± 7.7	80.1 ± 7.9	81.3 ± 8.5	76.0 ± 9.0
Female (%)	45.3	43.4	43.3	50.8	45.6	46.8	40.4	45.3	31.8

*British Columbia Apr 2014 to Dec 2016
†Calgary, Alberta Aug 2014 to Mar 2016; Edmonton, Alberta Apr 2014 to Mar 2016
¥Newfoundland and Labrador Jan 2016 to Mar 2017

Procedural characteristics

Similar to 2013/14, most TAVI procedures were performed via the femoral artery (85.6% in 2016/17). However, there was substantial variation in the use of femoral versus non-femoral access across regions (Table 2). Frequently, patients treated via a non-femoral access have more co-morbidities and are at higher risk of mortality. However, the degree of variation in access is not in keeping with differences in patients' characteristics across regions, suggesting that this may be discretionary. This finding merits further research.

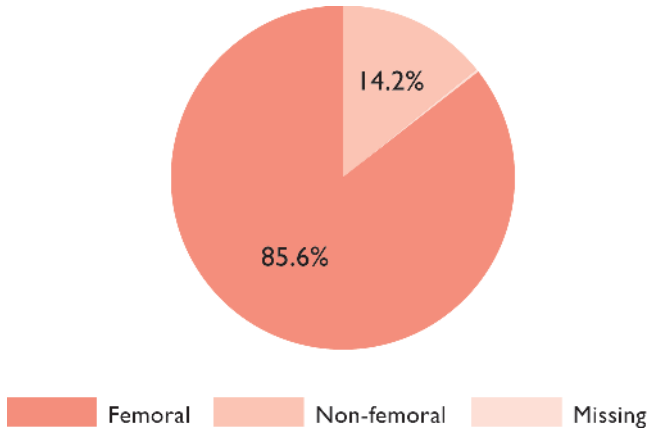

Figure 5. Vascular access for TAVI procedures in Canada (2014/15-2016/17, combined)

Table 2. Vascular access for TAVI procedures by region (2014/15-2016/17, combined)

Access	Canada (N=4906)	BC (N=942)	ON (N=2210)	QC (N=1106)	AB, MB, NB, NS, NL (N=648)
	Number of patients (%)				
Femoral	4200 (85.6%)	836 (88.7%)	1,906 (86.2%)	857 (77.5%)	601 (92.7%)
Non-femoral	699 (14.2%)	106 (11.3%)	304 (13.8%)	242 (21.9%)	47 (7.3%)
Missing data	7 (0.1%)	0 (0.0%)	0 (0.0%)	7 (0.6%)	0 (0.0%)

Patient status (urgent vs. elective) at the time of the procedure is also associated with risk of mortality and was available for all provinces except New Brunswick. The proportion of urgent in-patients ranged from 17.6% in BC to 21.2% in Québec (Table 3). This information was not collected for the 2016 report.

Table 3. Proportion of urgent out-patients vs. elective out-patients by region (2014/15-2016/17, combined)

Baseline Characteristics	Canada (N=4906)	BC (N=942)	ON (N=2210)	QC (N=1106)	AB, MB, NB, NS, NL (N=648)
	Number of patients (%)				
Urgent	870 (17.7%)	166 (17.6%)	407 (18.4%)	234 (21.2%)	63 (9.7%)
Elective	3545 (72.3%)	563 (59.8%)	1,803 (81.6%)	872 (78.8%)	307 (47.4%)
Missing data	491 (10.0%)	213 (22.6%)	0 (0.0%)	0 (0.0%)	278 (42.9%)

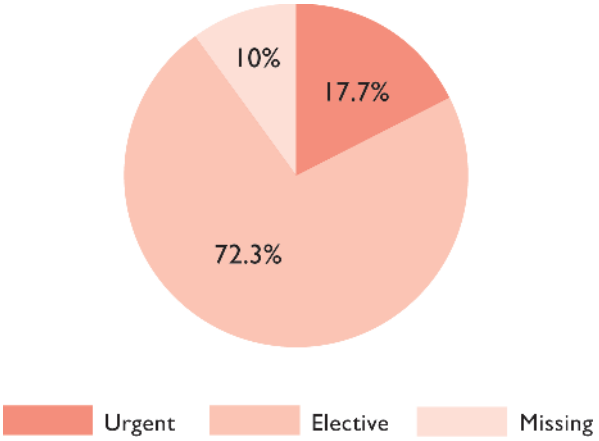

Figure 6. Proportion of urgent out-patients vs. elective out-patients in Canada (2014/15-2016/17, combined)

STRUCTURAL INDICATORS

Heart Team treatment recommendation

Canadian and other international guidelines continue to recommend that a multidisciplinary Heart Team is best suited to establish consensus treatment recommendations for patients with complex valvular heart disease. At a minimum, this team should include an interventional cardiologist and cardiac surgeon. Ideally, it is augmented by the expertise of cardiac imaging specialists, nursing specialists, the patient's treating physician, geriatrician or internist. Increasingly, there is interest in integrating a shared decision-making process to strengthen the partnership between providers and patients. This multidisciplinary team should convene regularly as a group and document how the review and interpretation of clinical data was used to arrive at a consensus on the optimal treatment strategy for each patient.

Sites self-reported the documented Heart Team treatment recommendation as reflected in Figure 7 and Table 4.

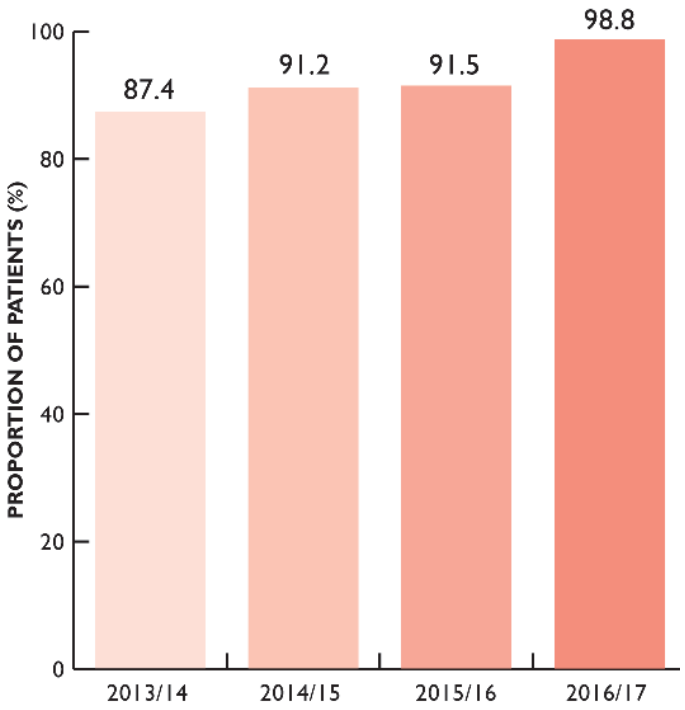

Figure 7. Documentation of Heart Team treatment recommendation in Canada

Table 4. Documentation of Heart Team treatment recommendation by region

Fiscal Year	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
	Proportion of patients (%) (range across centres (%))				
2013/14	87.4 (14.2-100)	100 (100-100)	81.6 (14.2-100)	80 (48-100)	99.4¥ (97.6-100)
2014/15	91.2 (5.1-100)	100 (100-100)	100 (100-100)	84.4 (6.7-100)	62.5 (5.1-100)
2015/16	91.5 (20.6-100)	100 (100-100)	100 (100-100)	80.6 (20.6-100)	71.1 (26.3-100)
2016/17	98.9 (78.4-100)	100 (100-100)	100 (100-100)	94.8 (78.4-100)	100 (100-100)

*Aggregated across all sites
¥2013/14 excludes data from NL

Wait time

Wait time is an important indicator of delivery of care. It is a multifactorial metric that reflects program capacity, access to diagnostic services, peri-procedure and post-procedure care, funding models, efficiency of assessment pathways and triage processes.[12]

Wait time is captured during two distinct intervals (Figure 8):
- Time 1 from Referral to Acceptance; and
- Time 2 from Acceptance to Procedure.

Total wait time represents the sum of both intervals.

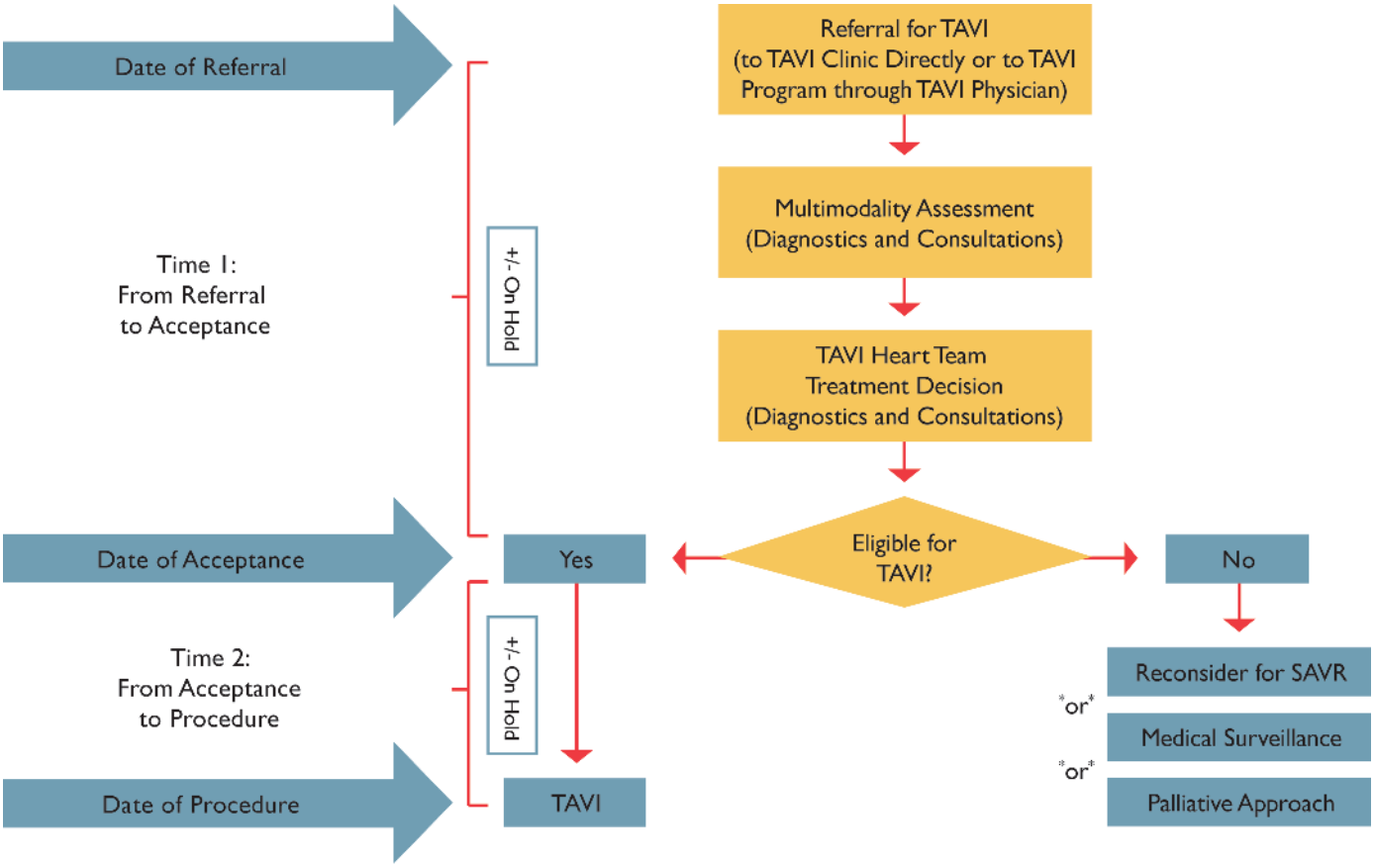

Figure 8. Standardized time points of TAVI patients' journey from referral to procedure *(Adapted from CorHealth Ontario)*

From 2013 to 2017, there was significant heterogeneity in wait times across Canadian sites (Table 5) and an increase in both evaluation and procedural wait times on a national scale. In fact, procedural wait time increased from 37 days in 2013/14 to 56 days in 2016/17.

This suggests that despite efforts made to increase access to TAVI, there is a growing gap between patient demand and TAVI capacity. In turn, this has compromised timely access to care across the country.

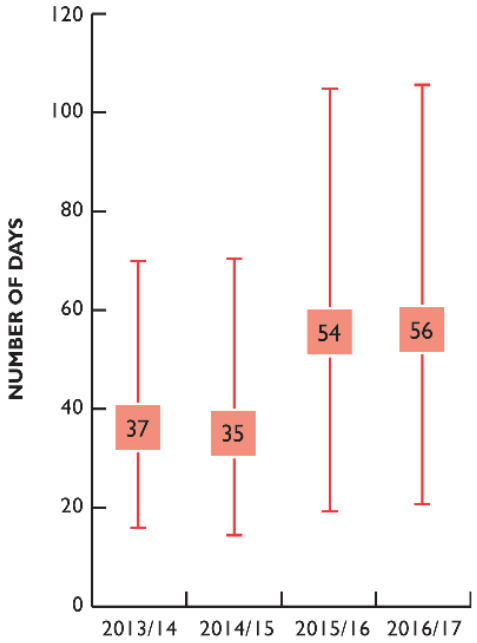

Figure 9. Procedural wait time (Heart Team treatment recommendation to procedure) in Canada

Table 5. Wait time by region

Fiscal Year	Canada	BC	ON	QC	AB, MB, NB, NS, NL
Total Wait Time			**Median days (IQR)**		
2013/14	106 (59-172)	91 (57-139)	105 (58-183)	n/a	145† (79-219)
2014/15	107 (54-170)	113 (64-151)	102 (53-165)	97 (43-188)	131 (57-216)
2015/16	128 (68-192)	157 (105-204)	123 (66-184)	110 (62-178)	116 (55-208)
2016/17	135 (75-198)	163 (112-217)	134 (75-196)	118 (62-190)	113 (66-171)
Evaluation Wait Time¥			**Median days (IQR)**		
2013/14	58 (26-110)	46 (24-76)	63 (28-136)	n/a	84§ (30-142)
2014/15	54 (18-100)	53 (22-83)	50 (15-105)	62 (21-150)	47 (18-94)
2015/16	52 (21-94)	56 (35-90)	51 (16-96)	60 (18-111)	36 (18-76)
2016/17	57 (25-101)	62 (37-91)	59 (27-107)	56 (17-112)	49 (20-81)
Procedural Wait Time§			**Median days (IQR)**		
2013/14	37 (16-70)	38 (20-65)	31 (10-72)	n/a	42† (23-76)
2014/15	35 (14-71)	44 (17-78)	36 (14-70)	21 (7-69)	31 (14-71)
2015/16	54 (19-105)	92 (43-134)	49 (18-95)	40 (12-82)	43 (15-94)
2016/17	56 (21-106)	86 (45-135)	56 (21-102)	37 (13-78)	43 (17-77)

†2013/14 excludes data from NL ¥Wait time referral to acceptance date §Wait time acceptance date to procedure

PROCESS INDICATORS

Evaluation of procedural risk

The evaluation of eligibility and risk for TAVI combines multiple assessments, including clinical consultations, imaging reports, and the expert opinion of the Heart Team. In addition, procedural risk scores remain a consideration in most clinical trials and regional registries to capture each patient's surgical risk.

In the absence of a TAVI-specific risk score, the STS predicted risk of mortality for surgical aortic valve replacement remains one of the standard indicators. Although it fails to account for some important comorbidities (e.g., porcelain aorta, frailty), the STS score provides an indication of patients' complexity that is helpful to describe patient characteristics. The documentation of STS continues to increase nationally (Figure 10), with BC and Ontario consistently reporting this indicator at the present time. More variation in reporting is seen in Québec and other regions (Table 6).

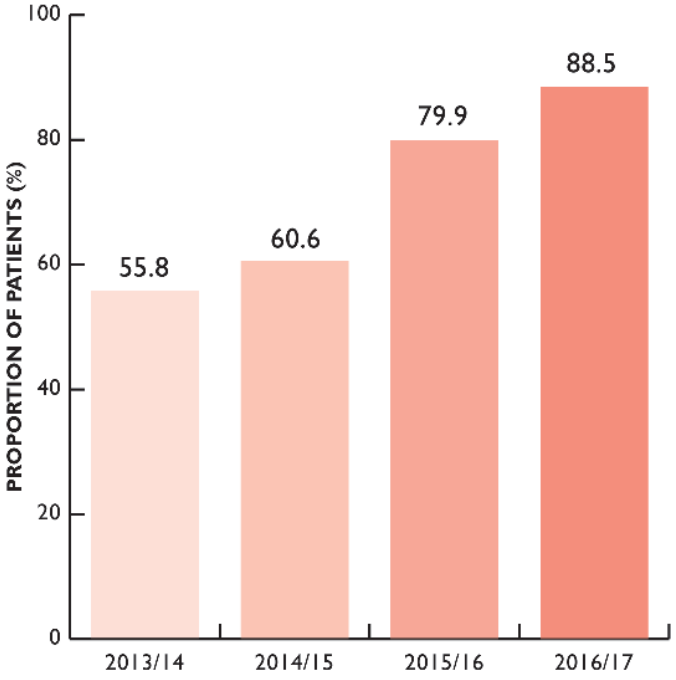

Figure 10. Evaluation of procedural risk in Canada

Table 6. Evaluation of procedural risk (documentation of STS score) by region

Fiscal Year	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
	Proportion of patients (%) (range across centres (%))				
2013/14	55.8 (0-100)	93.0 (61.3-100)	26.8 (0-75.0)	49.7 (3.3-95.7)	75.3† (0-100)
2014/15	60.6 (0-100)	90.3	58.0 (0-100)	61.9 (2.8-99.0)	25.0 (0-100)
2015/16	79.9 (0-100)	98.0	93.3 (40.2-100)	69.3 (16.2-98.4)	31.3 (0-100)
2016/17	88.5 (0-100)	98.4	99.9 (98.9-100)	69.0 (20.9-98.4)	63.8 (0-100)

*Aggregated across all sites
†2013/14 excludes data from NL

Evaluation of quality of life

In the era of patient-centred care, there is increasing scrutiny and priority placed in reporting patient-reported outcomes measurements (PROMs). The measurement of quality of life is an essential component of a patient-centred quality report. This indicator aims to improve patient selection and augment outcome evaluation by measuring and reporting on each patient's perceived health status and benefit from TAVI.

The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a validated PROM that captures cardiac-specific domains of quality of life, while the EQ-5D provides additional information of overall quality of life that can be compared with population-level benchmarks.[9] Quality of life should be assessed at baseline and at 12 months after TAVI. As a starting point, the TAVI Working Group set **the completion benchmark at 20%** of patients, with the goal of improving data quality over time.

The variation in findings reflects the differences in approach across jurisdictions (Table 7), with BC leading the integration of PROMs in the provincial evaluation framework. PROMs are not routinely collected in Ontario or Québec and variability exists in other provinces. The documentation of this QI in Canada is illustrated in Figure 11.

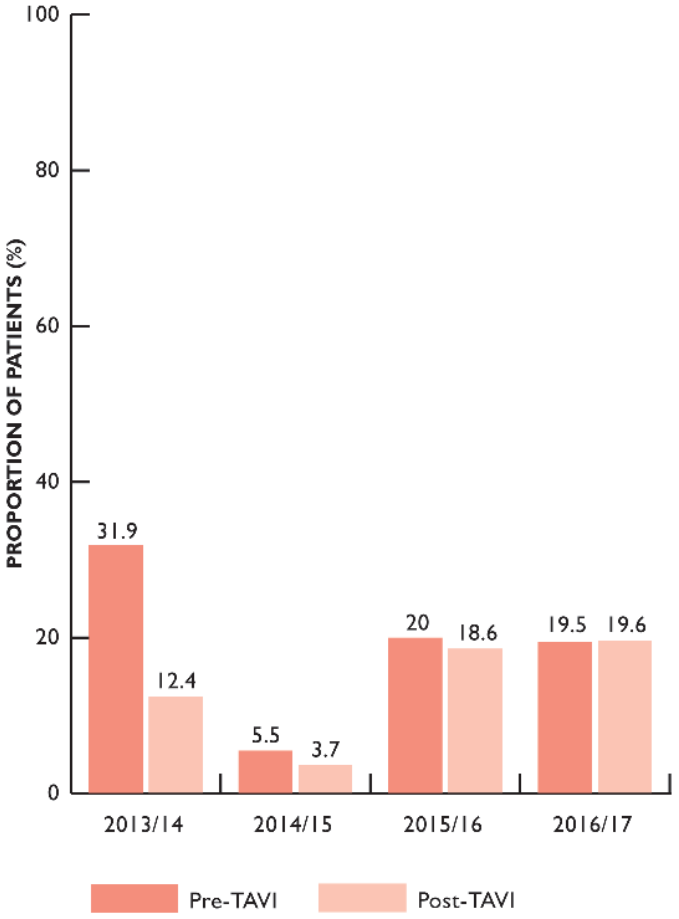

Figure 11. Evaluation of quality of life in Canada

Table 7. Evaluation of quality of life by region

Fiscal Year	Time Point	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
		Proportion of patients (%)				
2013/14	Pre-TAVI	31.9	97.8	0	0	60.1†
	Post-TAVI	12.4	21.5	0	0	55.8†
2014/15	Pre-TAVI	5.5	10.4	0	0	25.5
	Post-TAVI	3.7	10.8	0	0	12.0
2015/16	Pre-TAVI	20.0	77.1	0	0	26.2
	Post-TAVI	18.6	74.0	0	0	21.0
2016/17	Pre-TAVI	19.5	86.1	0	0	39.3
	Post-TAVI	19.6	82.9	0	0	44.9

*Aggregated across all sites
†2013/14 excludes data from NL

OUTCOME INDICATORS

Mortality (30-day and 1-year)

Advances in case selection, technology, procedural approaches and clinical pathways continue to contribute to the lowering of mortality after TAVI.[3, 13] It is important to note that data is not currently available to conduct rigorous risk adjustment to fully capture the complexity of procedures completed. Nevertheless, it is likely that the observation period includes a relatively homogenous group of elderly patients with significant comorbid burden that places them at intermediate or higher surgical risk for aortic valve replacement.

At the national level, a higher rate of 30-day mortality was noted in 2014/15 (Figure 12). However, this rate decreased in each of the following two years. In the most recent reporting year (2016/17), the national unadjusted mortality rate for all access procedures is 2.7%, ranging from 0% to 5.6% across regions (Figure 13, Table 8). For the transfemoral approach, 30-day mortality decreased nationally from 3.5% in 2013/14 to 2.4% in 2016/17 and remained lower amongst patients who had TAVI via transfemoral access at all time points.

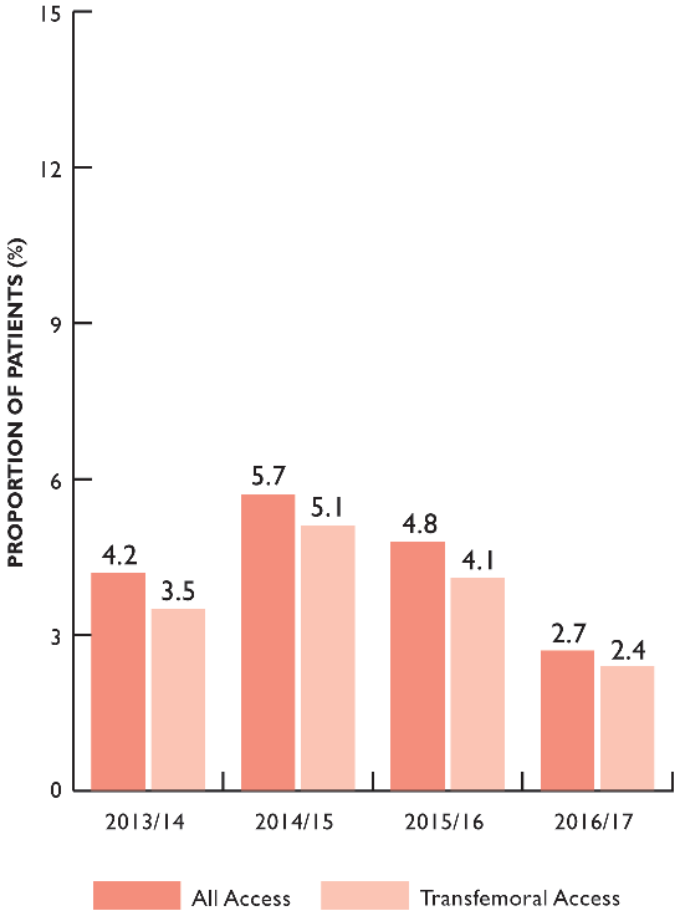

Figure 12. 30-day mortality in Canada (all access vs. transfemoral access)

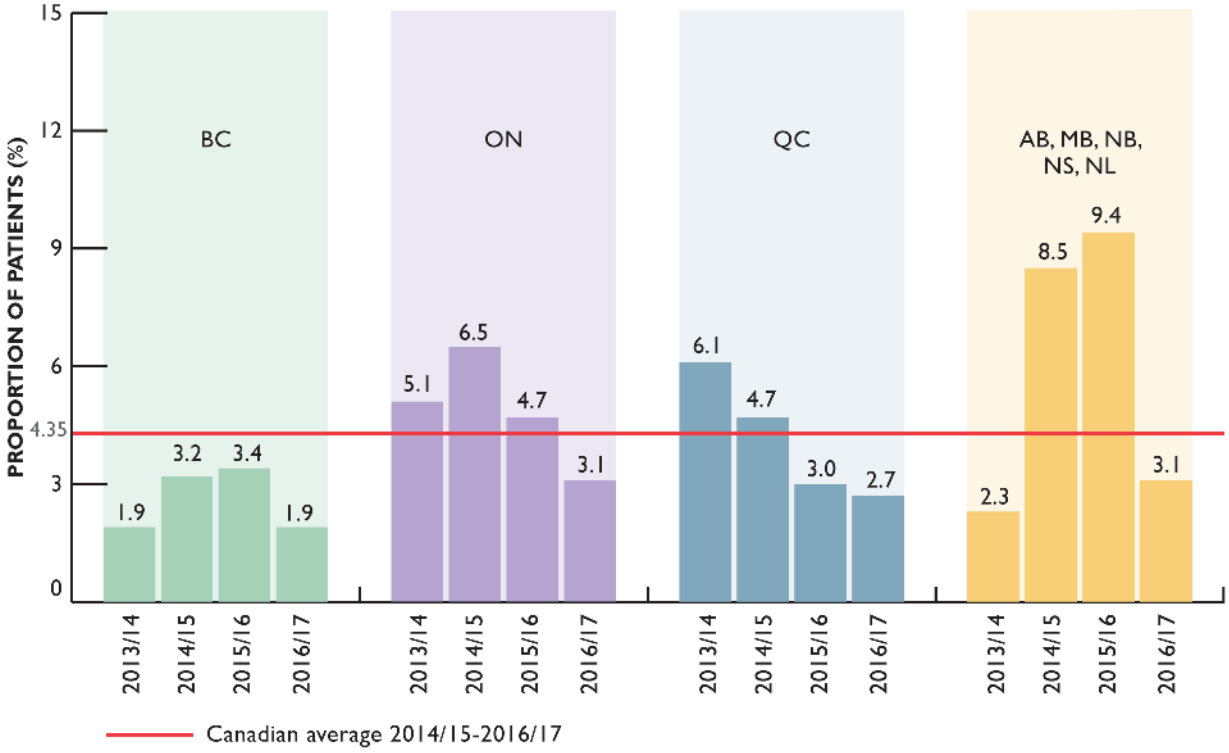

Figure 13. 30-day mortality (all access) by region

Table 8. 30-day mortality by region

Fiscal Year	Procedure Type	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
		Proportion of patients (%) (range across centres (%))				
2013/14	All Access	4.2 (0-11.9)	1.9 (0-3.2)	5.1 (0-7.5)	6.1 (0-11.9)	2.3† (0-2.8)
	Transfemoral	3.5 (0-13.7)	1.3 (0-3.2)	3.4 (0-9.1)	6.8 (0-13.7)	1.5† (0-3.1)
2014/15	All Access	5.7 (0-19.2)	3.2	6.5 (3.9-16.0)	4.7 (0-7.6)	8.5 (0-19.2)
	Transfemoral	5.1 (0-19.1)	2.8	5.9 (2.0-14.3)	3.8 (0-6.7)	7.9 (0-19.1)
2015/16	All Access	4.8 (0-34.8)	3.4	4.7 (0-8.0)	3.0 (0-5.4)	9.4 (0-34.8)
	Transfemoral	4.1 (0-36.6)	2.8	3.6 (0-5.9)	2.9 (0-5.6)	8.6 (0-36.6)
2016/17	All Access	2.7 (0-5.6)	1.9	3.1 (0-5.3)	2.7 (0-5.1)	3.1 (1.7-5.6)
	Transfemoral	2.4 (0-5.6)	2.2	2.6 (0-4.6)	2.2 (0-5.3)	3.1 (1.7-5.6)

*Aggregated across all sites
†2013/14 excludes data from NL

At 1-year, the rate of mortality for all access procedures decreased from 13.8% in 2013/14 to 10.6% in 2016/17 (Figure 14, Table 9). Similarly, the transfemoral approach 1-year mortality decreased from 11.9% in 2013/14 to 9.9% in 2016/17.

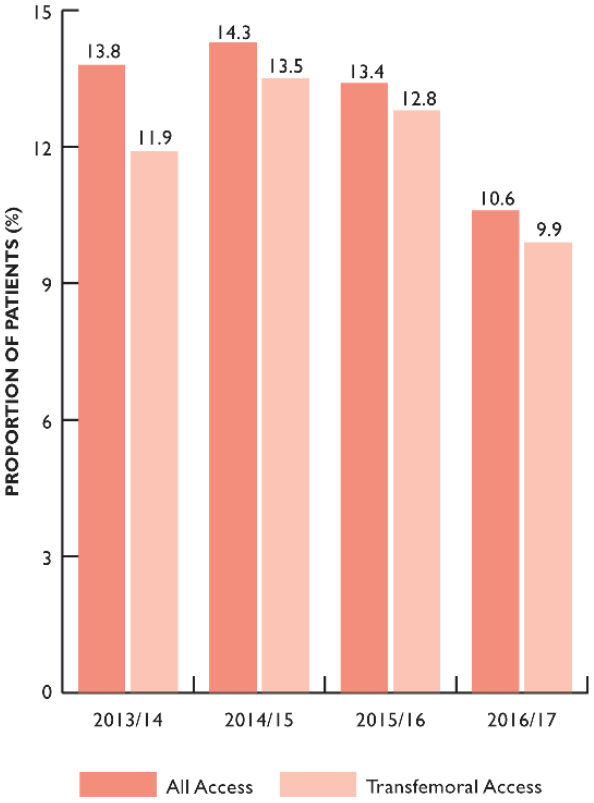

Figure 14. 1-year mortality in Canada (all access vs. transfemoral access)

Table 9. 1-year mortality by region

Fiscal Year	Procedure Type	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
		Proportion of patients (%) (range across centres (%))				
2013/14	All Access	13.8 (0-28.4)	13.0 (4.5-25.8)	14.1 (0-28.4)	14.6 (8.3-23.3)	12.4† (0-19.5)
	Transfemoral	11.9 (0-25.8)	11.3 (4.5-25.8)	12.0 (0-20.9)	14.6 (8.3-21.7)	8.0† (0-12.9)
2014/15	All Access	14.3 (2.8-27.1)	12.9	16.7 (11.1-27.1)	11.2 (2.8-16.7)	13.5 (6.7-22.2)
	Transfemoral	13.5 (3.7-27.8)	13.0	15.4 (9.0-27.8)	11.0 (3.7-16.7)	13.0 (6.5-21.7)
2015/16	All Access	13.4 (7.4-34.8)	12.1	14.7 (7.4-26.0)	10.8 (8.1-14.7)	15.1 (8.7-34.8)
	Transfemoral	12.8 (7.0-36.6)	11.4	14.0 (7.1-26.3)	10.7 (7.5-13.9)	14.2 (7.0-36.6)
2016/17	All Access	10.6 (3.3-22.2)	9.0	12.0 (3.3-14.3)	10.1	7.7 (5.3-22.2)
	Transfemoral	9.9 (3.3-22.2)	9.1	11.1 (3.3-13.6)	9.0	7.8 (5.3-22.2)

*Aggregated across all sites
†2013/14 excludes data from NL

In-hospital stroke

Although we reported an overall low incidence of stroke (2.1%) in 2013/14 (Figure 15), there was variation across institutions ranging from 0% to 9.7% (Table 10). We highlighted the challenges related to the adoption of a standardized definition, the lack of adjudication, poor data quality, and variability in procedural volume. We proposed to focus on the reporting of stroke to reflect the potentially devastating impact of this complication on patients' quality of life, morbidity, and mortality. In the most recent reporting year (2016/17), stroke rates varied across institutions from 0% to 5.6% with a national rate of 2.6%. Issues related to data quality remain important in the interpretation of these findings.

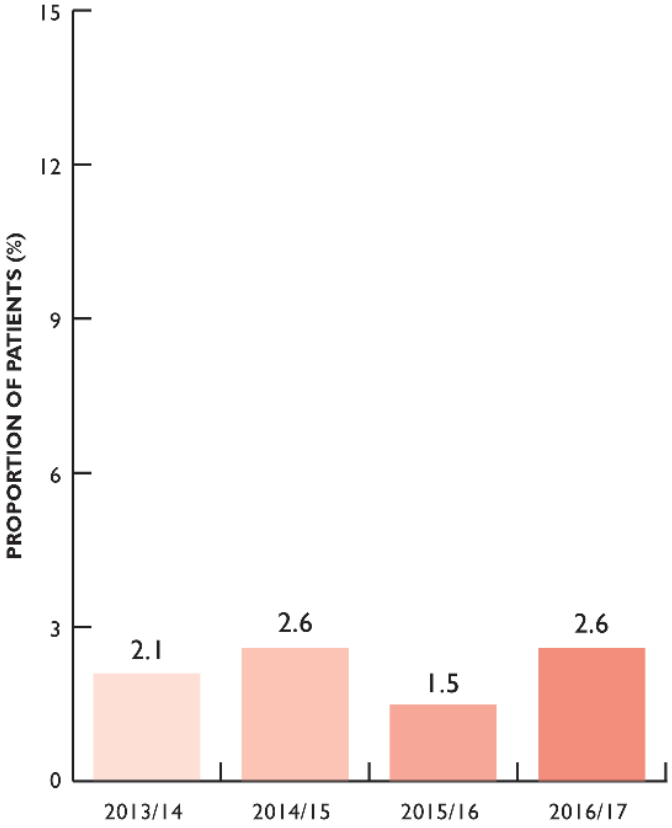

Figure 15. In-hospital stroke in Canada

Table 10. In-hospital stroke by region

Fiscal Year	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
	Proportion of patients (%) (range across centres (%))				
2013/14	2.1 (0-9.7)	3.7 (0-9.7)	1.5 (0-7.1)	2.0 (0-7.0)	1.2† (0-9.7)
2014/15	2.6 (0-12.7)	<2.2	1.9 (0-3.5)	4.4 (0-12.7)	3.0 (0-9.4)
2015/16	1.5 (0-5.9)	<1.7	1.8 (0-3.7)	2.5 (0-5.9)	<2.4 (0-3.8)
2016/17	2.6 (0-5.1)	<1.9	2.5 (0-4.3)	3.4 (0-4.8)	4.2 (3.4-5.6)

*Aggregated across all sites
†2013/14 excludes data from NL

All cause hospital readmission (30-day and 1-year)

The selection of all-cause readmission after TAVI as a CCS QI is in keeping with the concerns raised by other health policy organizations, including the US Centers of Medicare and Medicaid (CMS), Joint Commission (JCAHO) and the Institute of Medicine (IOM).[14, 15] These organizations have linked the risk of readmission to the failure of ensuring appropriate transition of care (i.e., the movement of patients between health care practitioners, settings and home as their condition and care needs change).

The wide range of readmission rates seen across Canada (Table 11) should be interpreted with significant caution. Our environmental scan revealed that some centres are able to obtain this indicator through linkages to administrative databases (Canadian Institute for Health Information (CIHI) Discharge Abstract Database), while others are limited to self-report and patient recall. Thus, it is particularly difficult to draw conclusions from this QI, and we limit our recommendations to adopting standardized linkage to robust administrative data. Changes in readmission rates in Canada over time are shown in Figure 16.

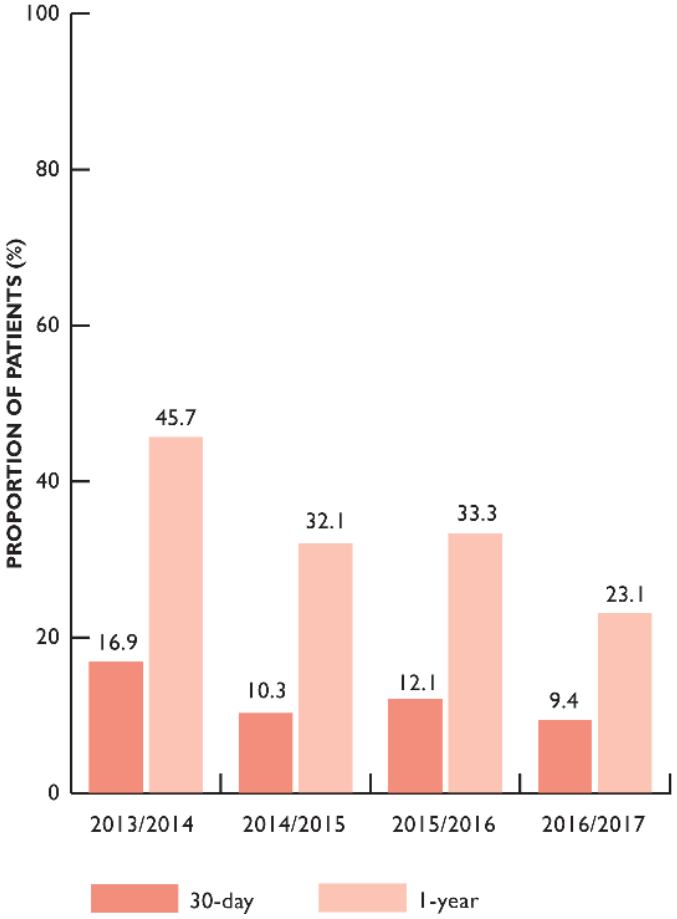

Figure 16. All cause hospital readmission in Canada

Table 11. All cause hospital readmission by region

Fiscal Year	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
30-day	**Proportion of patients (%) (range across centres (%))**				
2013/14	16.9 (4.5-39.5)	26.1 (18.2-39.5)	11.9 (7.7-22.2)	n/a	12.8† (4.5-19.4)
2014/15	10.3 (0-25.4)	18.0	14.8 (0-25.4)	n/a	5.6 (0-9.4)
2015/16	12.1 (4.0-27.0)	17.8	17.2 (10.7-27.0)	n/a	6.7 (4.0-13.6)
2016/17	9.4 (4.5-17.3)	12.9	13.3 (6.9-17.3)	n/a	6.6 (4.5-13.6)
1-year	**Proportion of patients (%) (range across centres (%))**				
2013/14	45.7 (12.2-68.0)	57.6 (54.4-58.6)	42.2 (28.6-68.0)	n/a	34.4† (12.2-60.0)
2014/15	32.1 (2.2-58.3)	58.3	44.4 (37.4-53.7)	n/a	11.0 (2.2-30.4)
2015/16	33.3 (9.4-66.7)	56.8	44.6 (31.7-66.7)	n/a	15.5 (2.2-41.5)
2016/17	23.1 (10.5-50.0)	n/a	43.2 (30.4-50.0)	n/a	19.9 (10.5-27.3)

*Aggregated across all sites
†2013/14 excludes data from NL

NEW INDICATORS

New permanent pacemaker rate

This new QI encompasses the proportion of new permanent pacemaker devices after TAVI but during the index hospitalization. The implications of a new permanent pacemaker after TAVI are substantial. This includes on-going commitment to device monitoring, long-term management and replacement, as well as the potential for left ventricular dysfunction. At the time of the index TAVI procedure, the need for a new pacemaker is associated with longer time in critical care and overall length of stay, pacemaker-related complications, and cost.[16, 17] Rates of pacemaker insertion may vary with institutional practice as well as by TAVI valve design. These variations are shown over time in Canada (Figure 17) and by region (Table 12).

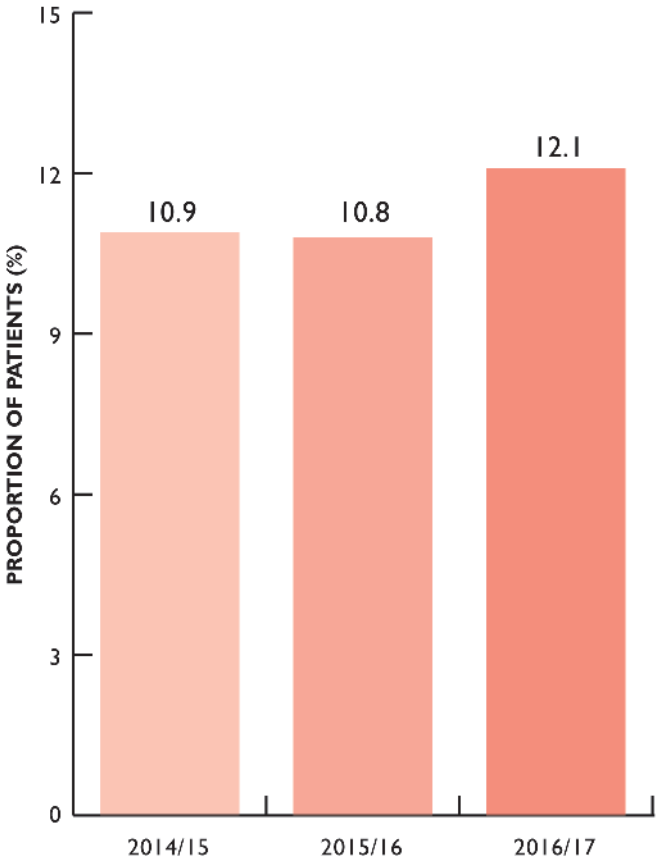

Figure 17. New permanent pacemaker rate in Canada

Table 12. New permanent pacemaker rate by region

Fiscal Year	Canada	BC*	ON	QC	AB, MB, NB, NS, NL
	Proportion of patients (%) (range across centres (%))				
2014/15	10.9 (0-20.9)	9.7	13.7 (4.2-20.9)	11.2 (5.7-15.3)	3.0 (0-11.3)
2015/16	10.8 (2.0-22.0)	10.5	11.7 (3.7-22.0)	12.5 (2.7-17.6)	6.3 (2.0-12.1)
2016/17	12.1 (1.7-29.3)	11.6	13.4 (6.7-29.3)	11.8 (5.1-20.0)	7.7 (1.7-10.5)

*Aggregated across all sites

Length of stay

The care of TAVI patients is evolving. Risk-stratified case selection, the increasing uptake of a minimalist peri-procedure approach with percutaneous vascular access and closure, local anaesthesia or light procedural sedation, the avoidance of invasive lines, and a rapid reconditioning post-procedure protocol with rapid mobilization, are contributing to shorter length of stay across programs.[18] Length of stay is a multifactorial indicator that is additionally impacted by social determinants of health (e.g., social support, geographical location) and site-specific processes.

Consistent with other regions and clinical trials,[3] median length of stay has decreased in Canada in the past three years (Figure 18). Specifically, there was less time from admission to discharge (6 days in 2014/15 to 4 days in 2016/17) and less time from procedure to discharge (5 days in 2014/15 to 3 days in 2016/17), with notable differences across regions (Table 13).

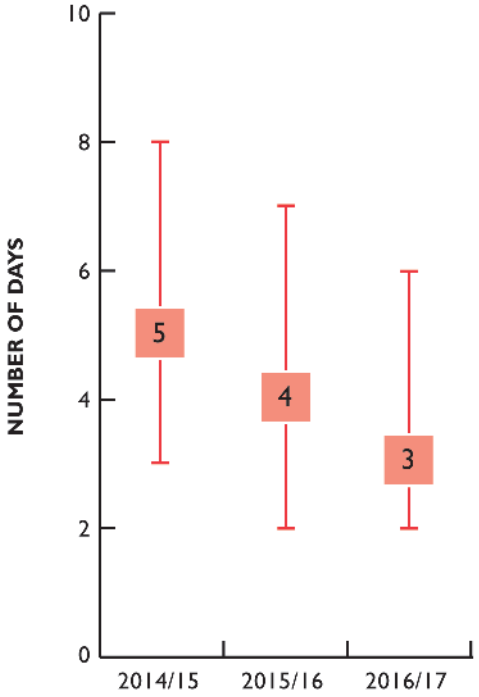

Figure 18. Length of stay (procedure to discharge) in Canada

Table 13. Length of stay (procedure to discharge) by region

Fiscal Year	Canada	BC	ON	QC	AB, MB, NB, NS, NL
Admission to Discharge	Median days (IQR)				
2014/15	6 (3-12)	4 (2-8)	7 (4-13)	7 (4-12)	6 (3-12)
Missing (%)	5.6	0	0	0	40.5
2015/16	5 (3-11)	4 (2-18)	5 (3-11)	5 (3-10)	6 (2-14)
Missing (%)	6.8	2.3	0	0	42.5
2016/17	4 (2-9)	2 (1-6)	4 (2-9)	5 (3-10)	4 (3-8)
Missing (%)	18.2	65.8	0	0	59.7
Procedure to Discharge	Median days (IQR)				
2014/15	5 (3-8)	3 (2-5)	6 (3-9)	5 (3-8)	5 (3-9)
Missing (%)	0.1	0	0	0	0.5
2015/16	4 (2-7)	2 (1-4)	4 (2-7)	4 (2-7)	5 (3-8)
Missing (%)	0.1	0.3	0	0	0
2016/17	3 (2-6)	1 (1-3)	3 (2-7)	4 (2-6)	5 (4-7)
Missing (%)	1.3	0	0	0	11.2

DISCUSSION

The second National Quality Report: TAVI offers new insights on the quality of care and outcomes of this innovative and now established procedure in Canada. The results shine a light on areas for targeted improvement, present an opportunity for national collaboration, and prove that data sharing across provinces is possible. Despite this, there were significant barriers to establishing efficient and seamless data sharing agreements across jurisdictions. These challenges varied across provinces and included a lack of clarity about application process, inconsistent requirements for research ethics approval for the purposes of de-identified aggregate data and quality improvement, and operational difficulties to transfer data.

Unlike the first report, our goal was to make site-specific data publicly available. The idea of public reporting at a more granular level had been supported by the clinical community in spite of our current inability to conduct robust and meaningful risk adjustment. Unfortunately, this data was not secured from all provinces, notably BC for which no site-specific data was provided. This highlights the challenges of transparency in public reporting and the inter-provincial variability in willingness to provide site-level data.

We are encouraged by the pioneering efforts of the US ACC/STS Transcatheter Valve Therapy (TVT) mandatory registry and other agencies that have adopted this policy. They are making strides to leverage this information to support quality of care. Unlike this, Canada lacks a national registry of TAVI procedures and outcomes, which is crucial to understanding results, maintaining the delivery of high-quality care, and facilitating evidence-based improvement efforts. Without this, the completion of the TAVI Report was made possible by a highly engaged community of clinical and administrative stakeholders who are committed to quality and accountability. We anticipate that the measurement and reporting of this treatment will becoming increasingly important as indications for TAVI increase for patients with aortic stenosis.

Some encouraging progress has been made since the 2016 report. There has been a clear increase in the number of TAVI procedures performed nationally, from a mean of 34 TAVI/million population in 2013/14 to 51 TAVI/million population in the most recent reporting year (2016/17). The report continues to demonstrate an important variation in the volume of TAVI procedures. In 2016/17, the volume ranged from 87 procedures per million in BC at the high end to 42 procedures per million in Newfoundland at the low end. From 2014 to 2017, this variation increased further across Canada. This inequity in access contrasts with the spirit of the Canada Health Act. Although the optimal volume per capita of TAVI procedures for Canada is unclear, this substantial variation leads to concerns that patients in some provinces may not have adequate access to this life-saving intervention. Future efforts should aim to understand and explain such variation. This information is critical for developing improvement strategies for better access to care, including innovative funding models on a national level. In particular, we hope that a national dialogue on provincial models of funding focused on the needs of patients with aortic stenosis can help address these disparities across provinces and centres.

Given the discrepancy in procedure volume across Canada, it is not surprising to find variations in wait time for TAVI across the country. In 2013/14, there was considerable variability in wait times that were explained by probable differences in the definition of wait time. The definition of TAVI wait times were published on the CCS website in 2015. Multiple knowledge mobilization activities were undertaken by our Working Group to disseminate this information and encourage the adoption of these standardized definitions. Since that time, the data from all regions shows an almost universal increase in total wait time for TAVI. Specifically, the national total wait time for TAVI increased from 106 days in 2013/14 to 135 days in 2016/17. This may reflect an increased demand in the setting of somewhat fixed capacity as a result of capped funding models that are not modified according to patient demand or infrastructure issues. These conditions limit our ability to ensure timely evaluation and scheduling of procedures, as well as access to procedural time and space, and adequate post-procedure recovery capacity. Studies have shown that longer wait times are associated with adverse outcomes of TAVI procedures.[12] This is particularly

true when patients' clinical status requires medical attention while waiting for TAVI, although no data to correlate longer wait time with worse outcome was available for this cohort. Accordingly, efforts to continue monitoring wait time for TAVI procedures and ensuring timely access to care are of paramount importance. There is also a need to determine predictive models of risks for waiting, appropriate benchmarks for waiting, criteria for urgency and queuing, and appropriate risk-stratified benchmarks for wait times.

The report highlights continued challenges in national data collection as pertaining to data definitions and priorities for data collection. In particular, significant variation in the characteristics of patients undergoing TAVI across the country were noted. However, the assessment was limited by the incomplete reporting of data in some provinces. We observed large variation in some comorbidities, likely due to differences in the reporting methods. For example, rates of COPD ranged from 1.4% to 47.2% across Canada. Such large variation probably reflects a lack of standardized definitions rather than a true difference in patient characteristics. The report highlights the need for standardization of data definitions and collection to enable comparisons of patients' risk and adjusted outcomes in the future.

Another gap observed in data collection was the evaluation of quality of life prior to and following TAVI. Although quality of life is increasingly accepted as an essential outcome in registry-based evaluation across international regions and disease states or procedures, the uptake of this indicator is inconsistent locally and regionally. BC has invested significant resources to integrate this indicator in the provincial registry and report findings to augment the provincial quality report. In contrast, this indicator is absent in Ontario and Québec, and inconsistently reported in other provinces. This limits our capacity to understand how patients report their outcomes after TAVI across Canada. It also presents an opportunity for national collaboration in order to improve methods of data collection for the quality of life QI. Doing so demonstrates recognition of its importance for TAVI and serves as a model for other cardiac procedures.

In addition to the structural and process QIs, outcomes are an important measure of clinical care quality. The outcome QIs include mortality (30-day and 1-year), in-hospital stroke, all-cause rehospitalization and new permanent pacemaker rate. Thirty-day mortality outcomes following TAVI were similar across Canadian provinces. However, larger variation between provinces was seen at 1-year. In addition, we observed an overall decrease in 30-day and 1-year mortality across Canada from 2013/14 to 2016/17. This likely reflects the cumulative effect of improved patient selection, maturity of procedural skills, advances in technology and/or imaging, and changes in post-procedure care. The accurate reporting of in-hospital stroke may suffer from the lack of standardized definitions. However, rates continue to be low albeit with a numerical increase from 2013/14 to 2016/17. This indicator warrants on-going scrutiny and improved data quality as the spectrum of patients treated with TAVI shifts to lower risk populations.

All cause readmission after TAVI is costly and is associated with increased risk of adverse complications.[14] The rate of all cause 30-day readmission has decreased from 16.9% in 2013/14 to 9.4% in 2016/17. For all cause 1-year readmission, the rate decreased from 45.7% in 2013/14 to 23.1% in 2016/17. There was large variation in this QI across Canada. In 2016/17, the all cause 30-day readmission rate ranged from 6.6% (range 4.5-13.6%) in the combined region of AB/MB/NB/NS/NL to 13.3% (range 6.9-17.3%) in Ontario. Similarly, 1-year rates ranged from 19.9% (range 10.5-27.3%) to 43.2% (range 30.4-50.0) in the same regions. This indicator should be interpreted cautiously because of the inconsistent linkage to more robust administrative data (e.g., CIHI DAD). Ideally all provincial programs should have a mechanism to track patients and measure hospitalization using provincial or national administrative health utilization databases. Future efforts are required to identify the causes of rehospitalization and inform targeted improvement efforts designed to reduce readmission rates in this vulnerable population.

The impact of the QIs and their measurement on changing clinical practice is further evidenced by the improvement of the structure and process indicators, Heart Team treatment recommendation and evaluation of procedural risk. Heart Teams have shaped and defined the way patients with aortic stenosis have been and will continue to be treated in the future. This multidisciplinary collaboration of cardiologists, cardiac surgeons, imaging experts and nurses, to name a few, has been essential to the evaluation and decision-making for such patients. In the most recent reporting year (2016/17), the documentation of a Heart Team treatment recommendation has increased to over 95% (from 87.4% in 2013/14). As such, it may be appropriate to remove this indicator to acknowledge this national accomplishment and continue to address more pressing issues with quality of care. The process indicator of risk assessment, which required measurement of a proxy surgical risk score (STS), showed gradual improvement over time, approaching almost 90% documentation in Canada in the most recent reporting year (88.5% in 2016/17). Such results are a tribute to the importance of establishing quality standards and encouraging clinicians to achieve them. Thus, it may be time to review the necessity of

this indicator as well, especially given rapidly emerging evidence that surgical risk stratification is increasingly irrelevant to the quality of TAVI.[19]

Since the first report, two new QIs have been introduced to evaluate the evolving field of TAVI: new permanent pacemaker rate and length of stay following TAVI intervention. New permanent pacemaker is not a benign result of a TAVI procedure. Although it is not related to increased mortality, a new permanent pacemaker is associated with higher rates of heart failure hospitalization and increased costs. There is evidence that the incidence of new pacemaker varies according to the valve technology. However, variation in Canada was seen between the higher volume provinces and the grouping of lower volume provinces. This should be interpreted with caution, given the exact significance of new pacemaker will not be known until site-level data and longer-term follow-up data is available. This new indicator warrants on-going monitoring to augment the rapidly evolving scientific evidence available to guide practice and patient care.

Length of stay is a multifactorial indicator of quality of care and health services. Longer length of stay in the elderly is associated with significant deconditioning, morbidity and mortality.[20] In addition, requirements for critical care and cardiac beds have implications for hospital resources, competing demands from other patient groups, and costs. To this end, our observation is that many hospitals and teams across Canada have focused on addressing the multiple components associated with length of stay – during the pre-, peri-, and post-procedure phases of patients' journey – to improve outcomes and reduce the burden of TAVI on health care service delivery. From 2014 to 2017, we have found a remarkable reduction in length of stay, including an overall decrease in time from TAVI admission to discharge and TAVI procedure to discharge. Length of stay decreased by a day each year over the three years captured in this report (2014/15-2016/17) in Canada. In 2016/17, the median length of stay from TAVI procedure to hospital discharge was only three days in Canada and ranged from one to five days for all procedures (transfemoral and non-transfemoral). There may be opportunities to collaborate nationally and share resources, insights, and evidence to achieve shorter length of stay across all regions, while improving outcomes and patient safety.

CONCLUSIONS

The second National Quality Report: TAVI has achieved its goal of measuring and reporting the quality of care delivered to Canadians. Picking up where the first report left off, the current report demonstrates improvement in the collection of TAVI QIs and remaining variability across regions in access to TAVI procedures and wait times.

The measurement and public reporting of TAVI quality of care has strengthened clinicians' and policy-makers' commitment to transparency and accountability, and has provided an important starting point for benchmarking and standardizing quality of care. It has catalyzed a national community of practice that has leveraged local clinical expertise to support quality improvement.

Moving forward, the success of these quality improvement efforts depends on ongoing refinement of the TAVI QIs to ensure they continue to reflect current quality improvement priorities as indications evolve and areas of importance change. Of equal importance is for clinicians, administrators, and health policy leaders to commit to inter-provincial, regional, and national collaboration through ongoing measurement and reporting of the TAVI QIs and targeted improvement efforts. We believe the impact of these efforts will be amplified by the involvement and support of all stakeholders and will ultimately optimize the quality of TAVI care delivered to Canadians.

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APPENDIX 1. TAVI HOSPITALS IN CANADA (2013/14-2016/17)

Region	City	TAVI Hospital
Alberta	Calgary	Foothills Medical Centre
	Edmonton	University of Alberta Hospital
British Columbia	New Westminster	Royal Columbian Hospital
	Vancouver	St. Paul's Hospital
	Vancouver	Vancouver General Hospital
	Victoria	Royal Jubilee Hospital
Manitoba	Winnipeg	St. Boniface General Hospital
New Brunswick	Saint John	New Brunswick Heart Centre
Newfoundland	St. John's	Health Science Centre
Nova Scotia	Halifax	Queen Elizabeth II Health Sciences Centre
Ontario	Hamilton	Hamilton Health Sciences Centre
	Kingston	Kingston General Hospital
	London	London Health Sciences Centre
	Mississauga	Trillium Health Partners
	Newmarket	Southlake Regional Health Centre
	Ottawa	University of Ottawa Heart Institute
	Sudbury	Health Sciences North
	Toronto	St. Michael's Hospital
	Toronto	Sunnybrook Health Sciences Centre
	Toronto	University Health Network
Québec	Montréal	Centre Hospitalier de l'Université de Montréal (CHUM)
	Montréal	Hôpital du Sacré-Coeur de Montréal
	Montréal	Montreal Heart Institute/Institut de Cardiologie de Montréal
	Montréal	McGill University Health Centre/Centre Universitaire de santé McGill
	Québec City	Quebec Heart and Lung Institute/Institut universitaire de cardiologie et de pneumologie de Québec
	Sherbrooke	Centre Hospitalier Universitaire de Sherbrooke (CHUS)
Saskatchewan*	Regina	Regina General Hospital

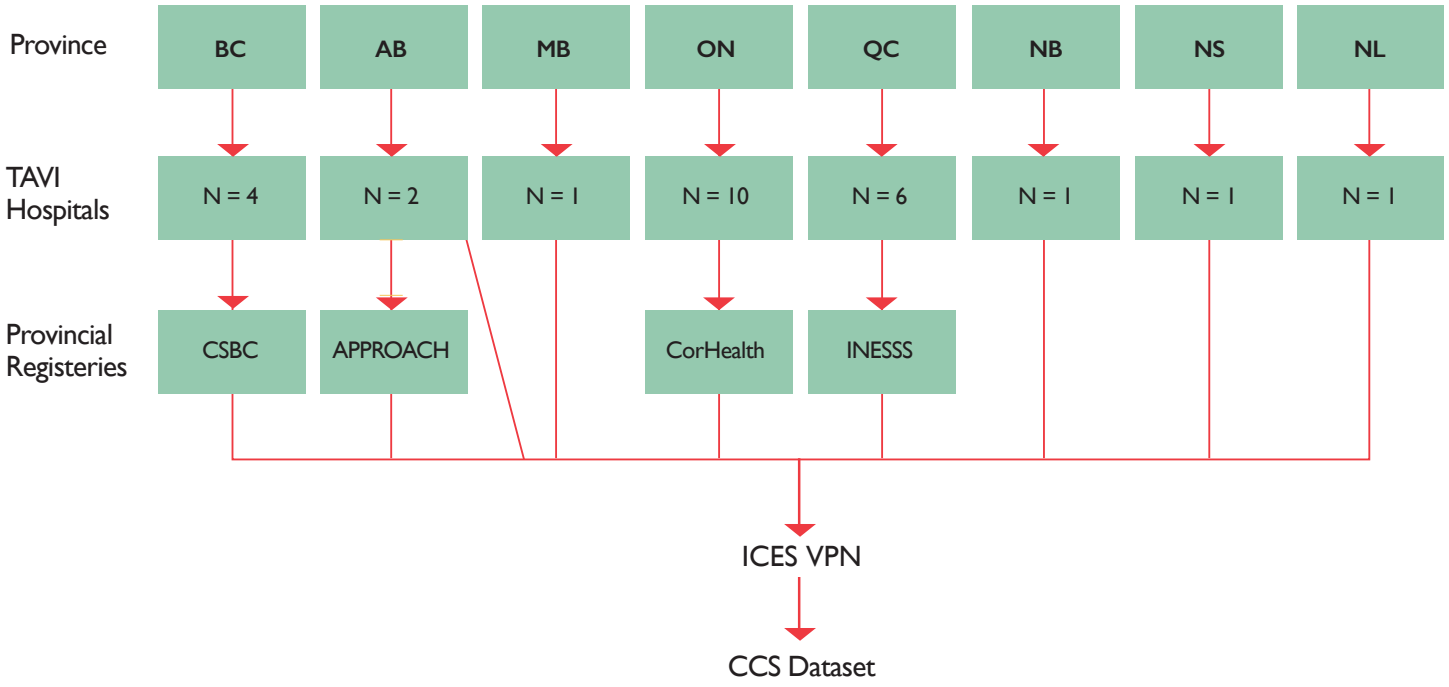
* Site not included in this report

Toronto

Montréal

Vancouver

APPENDIX 2. 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 and Evaluative Sciences; VPN = virtual private network

APPENDIX 3. PATIENT CHARACTERISTICS BY REGION

	Canada	BC	AB	MB	ON	QC	NB	NS	NL
# patients/# sites	4906/26	942/4	178/2	122/1	2210/10	1106/6	178/1	148/1	22/1
Demographic Characteristics									
Age (Mean + SD)	81.64 ± 7.64	81.42 ± 7.67	81.26 ± 7.50	83.61 ± 5.48	82.05 ± 7.54	81.25 ± 7.73	80.10 ± 7.90	81.31 ± 8.49	75.95 ± 8.95
Gender (%)									
Male	2686 (54.7%)	533 (56.6%)	101 (56.7%)	60 (49.2%)	1,202 (54.4%)	588 (53.2%)	106 (59.6%)	81 (54.7%)	15 (68.2%)
Female	2220 (45.3%)	409 (43.4%)	77 (43.3%)	62 (50.8%)	1,008 (45.6%)	518 (46.8%)	72 (40.4%)	67 (45.3%)	7 (31.8%)
Comorbidities and Risks (N, %)									
History of Congestive Heart Failure	1905 (38.8%)	n/a	32-37	46 (37.7%)	1,611 (72.9%)	n/a	130 (73.0%)	67 (45.3%)	17-22
Cardiac Arrhythmia	740 (15.1%)	n/a	27-32	38 (31.1%)	556 (25.2%)	n/a	65 (36.5%)	48 (32.4%)	<6
Peripheral Vascular Disease	562 (11.5%)	n/a	15 (8.4%)	6-11	116 (5.2%)	321 (29.0%)	72 (40.4%)	27 (18.2%)	<6
Cerebrovascular Disease	288 (5.9%)	n/a	13 (7.3%)	24 (19.7%)	111 (5.0%)	114 (10.3%)	<6	18 (12.2%)	<6
COPD	461 (9.4%)	n/a	29 (16.3%)	16-21	31 (1.4%)	262 (23.7%)	84 (47.2%)	34 (23.0%)	<6
Cancer	291 (5.9%)	n/a	7 (3.9%)	21 (17.2%)	142 (6.4%)	n/a	68 (38.2%)	47 (31.8%)	6 (27.3%)
Dialysis	122 (2.5%)	n/a	0	0	77 (3.5%)	29 (2.6%)	<6	10-14	<6
Diabetes	1612 (32.9%)	n/a	51 (28.7%)	35 (28.7%)	1,003 (45.4%)	398 (36.0%)	65 (36.5%)	50 (33.8%)	10 (45.5%)
Hypertension	2535 (51.7%)	n/a	64-69	101 (82.8%)	2,092 (94.7%)	n/a	142 (79.8%)	114 (77.0%)	17-22
Dyslipidemia	1978 (40.3%)	n/a	58-63	92 (75.4%)	1,483 (67.1%)	104 (9.4%)	128 (71.9%)	91 (61.5%)	17-22
Previous Cardiac Procedures (N, %)									
CABG	1150 (23.4%)	184 (19.5%)	54 (30.3%)	37 (30.3%)	462 (20.9%)	313 (28.3%)	55 (30.9%)	34 (23.0%)	11 (50.0%)
PCI	1289 (26.3%)	n/a	8 (4.5%)	40 (32.8%)	766 (34.7%)	396 (35.8%)	59 (33.1%)	20 (13.5%)	n/a
Valve Surgery	323 (6.6%)	n/a	13 (7.3%)	9 (7.4%)	288 (13.0%)	n/a	0	13 (8.8%)	n/a
TAVI Intra-Procedural Details (N, %)									
Status of Procedure									
Urgent	870 (17.7%)	166 (17.6%)	19 (10.7%)	<6	407 (18.4%)	234 (21.2%)	n/a	38 (25.7%)	<6
Elective	3545 (72.3%)	563 (59.8%)	61 (34.3%)	117-122	1,803 (81.6%)	872 (78.8%)	n/a	108 (73.0%)	17-22
Missing	491 (10.0%)	213 (22.6%)	98 (55.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	178 (100.0%)	<6	0 (0.0%)
Aortic valve-in-valve	308 (6.3%)	79 (8.4%)	<6	8 (6.6%)	216 (9.8%)	n/a	n/a	n/a	<6
Vascular Access									
Femoral	4200 (85.6%)	836 (88.7%)	161 (90.4%)	117-122	1,906 (86.2%)	857 (77.5%)	160 (89.9%)	141 (95.3%)	17-22
Non-Femoral	699 (14.2%)	106 (11.3%)	17 (9.6%)	<6	304 (13.8%)	242 (21.9%)	18 (10.1%)	7 (4.7%)	<6
Device Type									
Edwards Lifesciences	2730 (55.6%)	624 (66.2%)	73 (41.0%)	99 (81.1%)	1,076 (48.7%)	614 (55.5%)	123 (69.1%)	99 (66.9%)	22 (100.0%)
Medtronic	1387 (28.3%)	215 (22.8%)	0	22 (18.0%)	725 (32.8%)	386 (34.9%)	<6	34-38	0
St. Jude Portico	116 (2.4%)	21 (2.2%)	<6	0	11 (0.5%)	27 (2.4%)	50 (28.1%)	<6	0
Other	347 (7.1%)	82 (8.7%)	<6	0	189 (8.6%)	70 (6.3%)	<6	0	0

Note: Missing values are included in the denominator for the proportion.