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THE CANADIAN CARDIOVASCULAR SOCIETY QUALITY INDICATORS E-CATALOGUE

QUALITY INDICATORS FOR PERCUTANEOUS CORONARY INTERVENTION

A CCS CONSENSUS DOCUMENT

DRAFT V2

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BACKGROUND

The quality indicators outlined in this document have been selected through a national consensus process as the key quality indicators specific to **Percutaneous Coronary Intervention (PCI)**

In addition, there is a complementary set of PCI related data elements and definitions within the data dictionary for the CCS Quality Project. Visit www.ccs.ca for the latest data dictionary.

Several of the quality indicators provide the following types of analysis options:

Cross-sectional Analysis – definition of indicator estimation using existing registries or databases.

Follow-up Analysis – definition of indicator calculation for more precise and detailed analysis using prospective databases including those designed specifically for this purpose.

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ANNUAL PCI VOLUME BY PROVIDER	
Description	Annual Percutaneous Coronary Intervention (PCI) volume by provider (interventional cardiologist).
Numerator	Number of PCI performed by a single interventional cardiologist in a year.
Denominator	N/A
Method of Calculation	Number of PCI performed by a single interventional cardiologist in a year.
Sources of Data	Hospital records (patient charts) Institutional clinical data Canadian Institute for Health Information (CIHI) -Discharge Abstract Database (DAD) Provincial medical services billing data

Rationale

Observational studies have suggested that low operator volume is associated with higher adverse events including mortality among patients undergoing PCI, especially in a complex and emergency setting.

Clinical Recommendation(s)

Procedure volume is directly related to maintenance of technical skills. There is some evidence that the individuals performing a minimum of 75 PCI cases per year may actually have better outcomes than those performing a lower volume of cases, although the evidence is weak but as a group we agree that it is an adequate number for maintaining skills. We agree that most interventional cardiologists are probably performing significantly more than 75 cases per year but currently it is an assumption unless appropriately measured and reported on a regular basis.

Method of Reporting

Annual reporting by provider with sequential trend analysis by year.

PCI volume can also be reported as a median for a selected population of providers at a hospital, regional, provincial or national level.

Challenges to Implementation/Interpretation

- In the province of Quebec, it is not obligatory to enter all PCIs into the Hospital Morbidity Database (HMDB).
- Measurement of this indicator may be challenging if a provider (interventional cardiologist) performs PCIs in multiple hospitals

ANNUAL PCI VOLUME BY CENTER	
Description	Annual Percutaneous Coronary Intervention (PCI) volume by center.
Numerator	Number of PCIs performed at a center in a year.
Denominator	N/A
Method of Calculation	Number of PCIs performed at a center in a year.
Sources of Data	Hospital records (patient charts) Canadian Institute for Health Information (CIHI) - Discharge Abstract Database (DAD) Provincial medical services billing data Institutional clinical data

Rationale

Based on the current limited evidence, the outcome of PCI procedures are related the total hospital volume and experience. Literature suggests that the incidence of death, emergency bypass surgery, and other adverse events is higher among centers performing less than 200 PCI per year. Other studies suggest a higher incidence of adverse events in centers with a yearly PCI volume of less than 400 compared with those with a volume of greater than 400 PCIs per year. Based on this we proposed that a PCI center should perform a minimum of 400 PCI cases per year. We agree that most centers are probably performing significantly more than 400 PCI cases per year but currently it is an assumption unless appropriately measured and reported on a regular basis.

Clinical Recommendation(s)

Although the current ACCF/AHA/SCAI guidelines suggest a minimum annual institutional volume of 200 PCI, the committee suggests that in the Canadian setting the minimum annual institutional volume of PCI should be 400.

Method of Reporting

Annual reporting by center with sequential trend analysis by year.

Annual PCI center volume can also be reported as a median at a regional, provincial or national level.

Challenges to Implementation/Interpretation

- In the province of Quebec, it is not obligatory to enter all PCIs into the provincial hospital discharge database.

FIRST MEDICAL CONTACT TO FIRST DEVICE TIME FOR PRIMARY PCI	
Description	The median delay in minutes between first medical contact (FMC) to first device time for adult patients undergoing a Primary Percutaneous Coronary Intervention (PPCI).
Numerator	Median delay in minutes from FMC-to-first device time for patients included in the denominator. FMC is the time of triage at the hospital or arrival of a paramedic at the side of the patient for emergency medical services (EMS) users. For patients presenting at non-PCI centers the FMC is the time of triage at the first hospital. In circumstances where the first ECG is non-diagnostic for ST elevation myocardial infarction (STEMI), then the first diagnostic ECG becomes the FMC. The time that the first device with intention to reperfuse is used after insertion of the guide wire in the infarct related artery is the first device time.
Denominator	All patients 18 years and older undergoing PPCI during the selected observation period.
Method of Calculation	Median delay in minutes, and the 25^{th} and 75^{th} percentile.
Sources of Data	Hospital records (patient charts) EMS data Institutional clinical data

Rationale

For a long time the door to balloon time has been used as a quality indicator for centers performing primary PCI, but the door to balloon time does not account for the pre-hospital system delays that occur in patients presenting with STEMI. First medical contact (FMC)-to-first device time is a more comprehensive quality indicator for patients undergoing primary PCI (PPCI) than the traditional measure of door to balloon time. It measures the efficiency of the entire system including the EMS, the referring centers without the facilities for PPCI and the center performing the PPCI. First device time was chosen because a balloon is not always the first device used in PPCI. Instead many operators currently use a thrombectomy catheter or stent as the first device following the wire insertion.

Clinical Recommendation(s)

Reporting by region, and institution, with sequential trend analysis.

The current European guidelines recommend that the FMC to first device time for direct EMS transfer and transfer from community hospitals should be less than 120 minutes. On the other hand the American guidelines recommend that FMC to first device time for direct EMS transfer should be less than 90 minutes. Both guidelines agree that delay in transfer of patients presenting to sites without PCI capability to the PCI centers should be less than 120 minutes and the delay should be less than 90 minutes for patients presenting themselves to a PCI center.

At present none of the centers in Canada report their FMC to first device time. Some centers are planning to report it in the near future and their plan is to aim for a delay of less than 90 minutes for direct EMS transfers and follow the recommendations from the American guidelines. The only disadvantage of following this recommendation is that it will reduce the catchment area for lot of Canadian centers with only one or two cardiac catheterization laboratories in the province. The reason being if one includes the time of 20 or 30 minutes that EMS has to spend in assessing and loading the patient to an ambulance then the driving time to the PCI center should be less than 30 or 40 minutes to achieve a FMC to first device time of less than 90 minutes, as it takes nearly 30 minutes at the PCI center to prepare the patient and perform PCI. The outcome in the literature is not very different among patients with a door to balloon time of 90 minutes or 120 minutes especially among the late presenters (Cannon et al. JAMA 2000).

There was significant discussion about this issue at the committee meetings and following recommendations were agreed upon.

- FMC to first device time should be less than 90 minutes for patients presenting to PCI centers and less than 120 minutes for those being transferred from the non-PCI centers.
- FMC to device time to be less than 90 minutes for direct EMS transfers to PCI centers especially for provinces with easy access to cathlab and up to 120 minutes is acceptable for provinces with fewer cathlabs. Both times should be reported by all the centers.
- The goal should be to meet the target in at least 75% of cases.

Results will be reported as a median or the 25th and 75th percentiles for the selected population and observation period.

Challenges to Implementation/Interpretation

Documentation of FMC-to-first device time for PPCI is not available in the Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB).

The time of FMC for EMS users is not always documented in the patient's medical records.

30-DAY MORTALITY AFTER PCI	
Description	The 30-day all-cause mortality for adult patients undergoing Percutaneous Coronary Intervention (PCI).
Numerator	Number of patients in the denominator who died during the 30 days after the procedure, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, up to and including 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.
Denominator	All patients 18 years and older undergoing PCI.
Method of Calculation	Crude rate: (numerator / denominator) * 100% The CIHI risk-adjusted model will be used for the population using standard univariate and multivariate modeling techniques. Predicted or expected mortality will be calculated for the specified population subset, and observed (O) divided by expected (E) ratio calculated. Risk-adjusted mortality is calculated by multiplying O/E ratio for the specified subset by the average mortality for the population. This indicator is adjusted for sex, age (younger than 70, 70 to 79, 80 and older), diabetes with complications, heart failure/pulmonary edema, renal failure, shock, cardiac dysrhythmias, PCI and cardiac surgery (CABG or valve surgery) in the same episode of care, previous AMI, previous cardiac intervention, STEMI, unstable angina and stable CAD.
Sources of Data	Canadian Institute for Health Information (CIHI)-Discharge Abstract Database (DAD) Hospital Morbidity Database (HMDB) Hospital records (patient charts) Institutional clinical data Provincial death registries

Rationale

Mortality is probably the most important outcome measure for PCI. 30-day risk-adjusted mortality was chosen because Canadian Institute for Health Information (CIHI) already reports in-hospital 30-day mortality on a regular basis for most facilities in Canada and uses an acceptable risk adjustment model.

Clinical Recommendation(s)

Annual reporting by region, institution, and provider, with sequential trend analysis by year.

Method of Reporting

Results will be reported as crude rate (%), O/E ratio, and risk-adjusted rate (%). All reporting must include 95% confidence intervals.
Reporting by region, and institution, with sequential trend analysis.
If 30-day mortality is not available, an alternative method of reporting would be to use the CIHI Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB) to report on in-hospital 30-day mortality.

Challenges to Implementation/Interpretation
Although many high quality clinical databases exist, there is no Canada-wide database with uniform outcome. Risk adjustment will be statistically challenging because of the low incidence of mortality. The risk of classifying a center as an outlier may be high (although one can use multiple year data for modeling and use the coefficients for individual year data calculation). Risk-adjusted 30-day mortality might be best used as the basis for confidential continuous QI activities. The main goal might not be public accountability but provider initiated determination of best practice, benchmarking and regional or system-wide improvement.

RENAL FUNCTION ASSESSMENT PRIOR TO NON-EMERGENT PCI	
Description	Documentation of a renal function assessment (serum creatinine and/or e-GFR measurement) within three months of the Percutaneous Coronary Intervention (PCI) for clinically stable adult patients undergoing non-emergency PCI.
Numerator	Number of patients in the denominator with a documented assessment of renal function (serum creatinine and/or e-GFR measurement) within the last 3 months.
Denominator	All patients 18 years and older who underwent non-emergency PCI during the selected observation period.
Method of Calculation	Crude rate: (numerator / denominator) * 100%
Sources of Data	Hospital records (patient charts) Institutional clinical data

Rationale

Baseline renal function assessment (serum creatinine and/or e-GFR measurement) should be a standard pre-requisite for patients undergoing cardiac catheterization and PCI, in order to calculate/define the risk of contrast-induced nephropathy (CIN) especially for individuals who are at high risk of developing CIN. The knowledge of baseline renal functions helps in reducing the overall risks to the patient by adjusting the dose of anticoagulants and other medicines used during the procedure by using appropriate hydration and by reducing the contrast volume during the procedure one can reduce the risk of CIN among these patients.

Clinical Recommendation(s)

All patients undergoing PCI in a non-emergent setting should have documented renal function assessment at least once within 3 months prior to the procedure provided the clinical condition of the patient remain unchanged. For patients who develop an clinical deterioration or require hospitalization then the renal function assessment should be repeated within 48 hours of the procedure. Centers should develop/follow a standardized protocol to protect against contrast induced nephropathy

Method of Reporting

Reporting by region, and institution with sequential trend analysis.

Challenges to Implementation/Interpretation

Documentation of renal function assessment is not available in Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB).

Although many high quality clinical databases exist, there is no Canada-wide database with uniform variables and definitions.

30-DAY READMISSION RATE AFTER PCI	
Description	The risk-adjusted rate of readmission to hospital for any cause on or before the 30th day following the date of discharge from the index Percutaneous Coronary Intervention (PCI) procedure for adult patients.
Numerator	Number of patients in the denominator who experience an urgent readmission to any hospital on or before the 30th day following the date of discharge from the index PCI procedure.
Denominator	All patients 18 years and older undergoing PCI and who were discharged alive after the index PCI.
Method of Calculation	Crude rate: (numerator / denominator) * 100% For patients transferred to another hospital, 30-day follow-up will commence on the day of discharge from the last hospital. A logistic risk-adjusted model will be developed for the population using standard univariate and multivariate modeling techniques. Predicted or expected rate of readmission will be calculated for the specified population subset, and observed (O) divided by expected (E) ratio calculated. Risk-adjusted rate of readmission is calculated by multiplying O/E ratio for the specified subset by the average rate of readmission for the population.
Sources of Data	Canadian Institute for Health Information (CIHI)-Discharge Abstract Database (DAD) Hospital Morbidity Database (HMDB) Institutional clinical data

Rationale

30-day readmission following PCI for the reasons of acute myocardial infarction, target vessel revascularization, unplanned CABG or other adverse events, is an important outcome measure for PCI. In most circumstances 30-day readmission is suggestive of procedure related adverse outcome and this has to be differentiated from a planned admission for PCI or CABG. Appropriate risk adjustment will be necessary to take care of the above mentioned and other confounders.

Clinical Recommendation(s)

Annual reporting by region and institution with sequential trend analysis by year.

Method of Reporting

Results will be reported as crude rate (%), O/E ratio, and risk-adjusted rate (%). All reporting must include 95% confidence intervals.

Challenges to Implementation/Interpretation

Appropriate risk adjustment will be necessary to take account for differences in patient populations across PCI centers and other confounders. This will be statistically challenging if the incidence of hospital readmission is low and highly variable. The risk of classifying a center as an outlier may be high (although one can use multiple year data for modeling and use the coefficients for individual year data calculation).

Although many high quality clinical databases exist, there is no Canada-wide database with uniform variables and definitions

PERI-PCI BLOOD TRANSFUSION	
Description	The risk-adjusted rate of blood transfusion during initial episode of care for adult patients after undergoing Percutaneous Coronary Intervention (PCI).
Numerator	Number of patients in the denominator who received a non-coronary artery bypass graft surgery (CABG) related blood transfusion after PCI during the index admission.
Denominator	All patients 18 years and older undergoing PCI during the selected observation period.
Method of Calculation	Crude rate: (numerator / denominator) * 100% A logistic risk-adjusted model will be developed for the population using standard univariate and multivariate modeling techniques. Predicted or expected rate will be calculated for the specified population subset, and observed (O) divided by expected (E) ratio calculated. Risk-adjusted rate is calculated by multiplying O/E ratio for the specified subset by the average for the population.
Sources of Data	Institutional clinical data Hospital records /patient medical charts

Rationale

Blood transfusion is surrogate marker of major bleeding during or following a PCI procedure. Several studies suggest that major bleeding is associated with higher mortality and increased risk of adverse events following PCI. The committee was of the opinion that it would be challenging to report on the incidence of major access site or non-access site bleeding following PCI. Therefore blood transfusion was chosen as the quality indicator to measure the post PCI major bleeding complications. It was noted that CABG related blood transfusion should be excluded from the analysis. The incidence of blood transfusion post PCI is dependent on multiple factors and for this reason risk adjustment modeling is necessary for appropriate reporting of this quality indicator (QI). It will be a challenging QI to report because of the complexity in collecting the data therefore the committee has recommended to use the index hospital admission as the most appropriate time for collecting and reporting this QI.

Clinical Recommendation(s)

Annual reporting by region, and institution with sequential trend analysis.

Method of Reporting

Results will be reported as crude rate (%), O/E ratio, and risk-adjusted rate (%). All reporting must include 95% confidence intervals.

Challenges to Implementation/Interpretation
Documentation of blood transfusion during index hospital admission after PCI was not available in Canadian Institute for Health Information (CIHI)-Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB). Fortunately as per the 2014-15 DAD Manual, the data element “Blood Transfusion Indicator” indicates whether or not the patient received a blood transfusion using blood products or components distributed by the reporting facility’s blood bank during the episode of care except for one province where it is optional.
Not all provinces submit cath lab data to DAD therefore National Ambulatory Care Reporting System data needs to be included.
It will be a challenging QI to report because of the complexity in collecting the data.
Although many high quality clinical databases exist, there is no Canada-wide database with uniform variables and definitions.
Risk adjustment will be statistically challenging if incidence is low as well as highly variable. The risk of classifying a PCI center as an outlier may be high.

PERI-PCI STROKE	
Description	The risk-adjusted rate of stroke for adult patients undergoing Percutaneous Coronary Intervention (PCI) within the same episode of care.
Numerator	Number of patients in the denominator who had a stroke during or after PCI.
Denominator	All patients 18 years and older undergoing PCI during the selected observation period.
Method of Calculation	Crude rate: (numerator / denominator) * 100% The CIHI logistic risk-adjusted model will be used for the population using standard univariate and multivariate modeling techniques. Predicted or expected rate of stroke will be calculated for the specified population subset, and observed (O) divided by expected (E) ratio calculated. Risk-adjusted rate of stroke is calculated by multiplying O/E ratio for the specified subset by the average stroke rate for the population. This indicator is adjusted for sex, age (younger than 70, 70 to 79, 80 and older), diabetes with complications, heart failure/pulmonary edema, cardiac dysrhythmia, shock, PCI and cardiac surgery (CABG and/or valve surgery) in same episode of care, previous cerebral vascular disease, previous AMI, STEMI and unstable angina.
Sources of Data	Canadian Institute for Health Information (CIHI)-Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) Hospital Morbidity Database (HMDB) Institutional clinical data Hospital records/Patient medical charts

Rationale

Stroke in this document is used as an all-inclusive term and includes any intra-cerebral/brain stem hemorrhage or infarction and sub-arachnoid hemorrhage. The initial diagnosis is mostly clinical as the radiological evidence lags behind especially in the case of a non-hemorrhagic stroke. Although the incidence of stroke is low among patients undergoing cardiac catheterization and PCI, it is a clinically important and at times a debilitating outcome of these procedures. The highest occurrence of stroke is within first 24-48 hours of the procedure. The incidence of stroke should be reported after appropriate risk adjustment.

Clinical Recommendation(s)

Annual reporting by region, institution, and provider with sequential trend analysis.

Method of Reporting

Results will be reported as crude rate (%), O/E ratio, and risk-adjusted rate (%). All reporting must include 95% confidence intervals.

Challenges to Implementation/Interpretation
Some strokes might not be related to the PCI. Also the timing of stroke (before or after PCI) may not be determined in administrative data as there is no timing on type 2 diagnoses (post-admission diagnosis). Though a DAD/NACRS data element (diagnosis prefix) can tell whether stroke happened before or after PCI, the quality of this data element is still not that reliable at this time. Although many high quality clinical databases exist, there is no Canada-wide database with uniform variables and definitions. Risk adjustment will be statistically challenging if incidence is low as well as highly variable. The risk of classifying a provider or PCI center as an outlier may be high.

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