



## **CCN Registries**

## **Data Entry Reference Manual and Data Standards**





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## I Introduction

The Cardiac Care Network of Ontario (CCN) has a solid history of advising the Ministry of Health and Long-Term Care (MOHLTC; Ministry), Local Health Integration Networks (LHINs), hospitals and care providers to improve the quality, efficiency, accessibility and equity of cardiac services for patients across Ontario. Currently, CCN's mandate has expanded to include the management of vascular and more recently stroke services for patients and providers in Ontario.

CCN has played an integral role in enhancing health system improvements in Ontario through the use of a more proactive, comprehensive and transparent approach to the planning, funding, performance management, and ongoing quality improvement of cardiac and vascular systems of care in Ontario. In partnership with the Ministry, and other stakeholders, CCN's growing mandate will include emphasis on improved system design, capacity planning, funding policy, and performance management.

Working with key stakeholders, CCN helps to plan, coordinate, implement, and evaluate cardiovascular care and is responsible for the Ontario Cardiac and Vascular Registries (the CCN Registries or "the Registry"). The data collected include specific clinical parameters required to evaluate key components of care and determine risk-adjusted outcomes. In addition, information collected in the Cardiac Registry includes wait times information required to calculate an urgency rating score (URS)<sup>1</sup> and/or determine the priority level<sup>2</sup> for select cardiac procedures (for more details see Appendix 1 for CCN Cardiac Wait Times Patient Triage). Through scientific evidence, expert panels and working groups, CCN uses evidence and consensus driven methods to identify best practices and strategies to effectively deliver cardiovascular services across the continuum of care.

Data is crucial to CCN's decision making and informing provincial best practices, standards, and recommendations. As such, it is essential that information collected and entered into the Registry is of excellent quality. In collaboration with multiple stakeholders, CCN endeavors to ensure quality data is entered and maintained in the CCN Registries. Likewise, CCN aims to create a consistent understanding and interpretation of information that will be entered into the Registry. This standardized approach to data entry will increase the uniformity of Registry data, which is especially important when making comparisons across hospitals or regions. The purpose of this document is to provide the user with a reference guide to understand Registry data entry as well as to provide guidance for documentation of select cases that vary from standard process.

<sup>&</sup>lt;sup>1</sup> Coronary angiogram (for CAD), coronary artery bypass graft (CABG) surgery, CABG + valve surgery

<sup>&</sup>lt;sup>2</sup> Coronary angiogram (cath), percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) surgery, valve surgery, implantation of implantable cardioverter-defibrillator (ICD)



## II Stakeholders of CCN Registry Data

Stakeholders of the Registry include hospital personnel, health care providers, health system administrators and research partners. Each group often has unique needs for the same information (Figure 1). Designated hospital personnel such as the cardiac and vascular coordinators as well as data clerks collect and enter data into the Registry at different time points during the course of patient's hospital encounter. Once entered, data can be extracted by different internal users such as clinicians (i.e., physicians and other health care professionals), decision support, finance, and hospital administrators for performance evaluation, research, reporting and analytics. External users of the Registry data include the MOHLTC and LHINs who may receive regular reports or request to obtain information on an *adhoc* basis. In addition, clinical and administrative researchers may use the Registry data for research purposes.



Figure 1. Stakeholders and Needs for Registry Data

#### III The CCN Registries

The Registry includes the cardiac and vascular components. The Registry is a clinical database that contains information such as cardiac wait times, comorbidities, procedural details, and complications of patients who received a cardiac and/or vascular procedure. The Registry was



initially developed and implemented in the early 1990's at the request of the MOHLTC to track cardiac surgery wait times, specifically coronary artery bypass graft surgery (CABG). Tracking referrals and wait times for cardiac surgery helps to identify and prevent barriers to timely access to these procedures.

The Registry has expanded over the years to include all cardiac surgical procedures, cardiac catheterization, percutaneous coronary intervention (PCI), electrophysiology procedures (diagnostic studies and ablations), cardiac device implantation, transcatheter aortic valve implantation (TAVI), and other transcatheter structural heart interventions e.g., mitral valve clip, left atrial appendage closure. In 2016, the Vascular Registry was launched to capture information related to procedures such as aortic aneurysm and dissection repairs (open surgical and endovascular procedures), and lower extremity revascularization procedures (open surgical and endovascular intervention). The Registry is updated as needed to reflect changes in clinical practice guidelines, to collect information on new technologies and to ensure meaningful outcome and process measures can be reported.

Further enhancement of the Registry was made to better track and monitor cardiac surgical procedures. In order to create a more robust environment to collect cardiac surgery and outcomes data, CCN provided all cardiac surgical sites the opportunity to participate in the Society for Thoracic Surgeons (STS) Database. The STS Database complements the Cardiac Registry through collection of additional cardiac surgery procedure details and outcomes up to 30 days post-surgery. In addition, the STS Database enables benchmarking to hospitals with similar volumes and case mix, and provides in-depth reports to assist in improving processes and the quality of care delivered. As part of the Registry, the Cardiac Registry-STS Database is used to retrospectively document perioperative details and 30-day follow-up information and links with the international STS Database for reporting and analytics.

The cardiac and vascular data collected in the Registry include patient demographics, clinical information, procedural details, and peri-procedural outcomes. In addition, specific clinical parameters required to evaluate key components of care and determine risk-adjusted outcomes are collected. The information is used to report procedure volumes to key stakeholders, identify gaps and opportunities for quality improvement in the delivery of cardiovascular services at the hospital and system levels in Ontario. Data are available for extraction and analysis 15 minutes after entry into the Registry (see Figure 2 for CCN data flow and processes).





Figure 2. The Cardiac and Vascular Registries Data Flow and Work Processes

## **IV** Scope of Patient Care/Patient Journey

Cardiac and vascular patients present to hospitals for procedures and are prioritized according to their clinical urgency. The urgency or priority level of procedures is determined by the referring healthcare care provider (e.g., primary care physician) as indicated at referral as well as system generated urgency rating scores and priorities which are calculated based on the unique priority drivers for cardiac surgery and coronary angiogram. In the event of a clinical status change while on the waitlist for a procedure, the clinical information is updated and the priority is reassessed. This enables more acute patients to be prioritized ahead of those deemed less urgent or elective. In some cases, the urgency of a procedure may be re-assessed by the procedural physician based on clinical data or a change in the patient's clinical status. For example, a stable aortic aneurysm patient referred for a scheduled (or elective) endovascular aortic aneurysm repair (EVAR) becomes symptomatic two days before the scheduled procedure. Due to a change in patient's clinical condition, the patient is admitted to the procedural hospital and the priority of procedure is elevated to 'urgent'. As a result, the previously scheduled elective EVAR is now done urgently, two days ahead of the original booking date.



Any unstable or symptomatic cardiac or vascular patient may present to the hospital emergency department (ED) by self–transport or ambulance. In the ED, patients are assessed and triaged within a target time of less than 15 minutes of their arrival.<sup>3</sup> For a patient with chest pain or suspected of having heart attack, a 12 lead ECG must be obtained within 10 minutes of hospital arrival.<sup>4</sup> If necessary, patients are kept briefly in ED for monitoring and observation. Patients with life-threatening conditions or symptoms requiring invasive intervention are prioritized as 'emergent' and the required procedure is performed immediately. Following an emergent procedure, the patient is usually admitted in hospital for a few days depending on the patient's condition and the procedure.

Generally, minimally invasive catheter-based procedures such as coronary angiogram, EVAR and other percutaneous intervention require a shorter hospital length of stay than their corresponding open surgical procedures. Furthermore, certain percutaneous cardiac and vascular procedures can be performed on an outpatient basis. This section describes the disease and in-hospital healthcare journey of patients with coronary artery disease (CAD), valvular heart disease (VHD), arrhythmia, aortic aneurysm/dissection (AA), and lower extremity occlusive disease (LEOD), from detection of disease to completion of procedures and discharge back to community. The flow diagrams illustrate these patients' journeys and highlight the way in which patients enter a hospital for further diagnosis and/or treatment of their disease.

#### **Cardiac Patient**

#### Coronary Artery Disease (CAD)

CAD is the result of progressive narrowing and obstruction of the lumen of the heart's arteries (coronary arteries) secondary to atherosclerosis (i.e., build-up of plaque). CAD is a spectrum of stable angina (also known as stable CAD) and acute coronary syndrome (ACS). Stable angina is defined as an established pattern of transient angina pectoris (i.e., chest pain lasting for 5 minutes or less) resulting from episodes of myocardial ischemia due to the narrowing or blockage in one or more coronary arteries.<sup>5</sup> Figure 3 illustrates the typical health care journey of a patient with CAD which begins at detection of the disease. Figure A in Appendix 2 depicts the journey through a hospital of stable CAD patient undergoing a cardiac procedure.

<sup>&</sup>lt;sup>3</sup> Access to Care. (2016). Emergency Room Information: Reference Manual. Cancer Care Ontario: Toronto, Version 25, January 2016.

<sup>&</sup>lt;sup>4</sup> Cardiac Care Network of Ontario (CCN). (2013). Recommendations for Best-Practice STEMI Management in Ontario. CCN: Toronto, June 2013.

<sup>&</sup>lt;sup>5</sup> Angina Pectoris (stable angina). (2016, September 19). Retrieved November 10, 2016, from

http://www.heart.org/HEARTORG/Conditions/HeartAttack/DiagnosingaHeartAttack/Angina-Pectoris-Stable-Angina\_UCM\_437515\_Article.jsp#.WCR6jPkrKUk.



ACS is an acute event where the plaque in the artery may become less stable and/or may rupture resulting in unstable angina (UA) or myocardial infarction (MI) i.e., ST elevation MI (STEMI) or non-ST elevation MI (NSTEMI). STEMI is a severe form of heart attack that can cause death if not treated quickly. ACS patients require immediate medical attention. Due to the severity of symptoms, ACS patients may present at a hospital emergency department rather than a physician's office (see Figure 3 below). Furthermore, the degree of severity of ACS dictates the urgency of treatment and/or intervention the patient receives. Figure B and Figure C in Appendix 2 illustrate the clinical pathways of ACS-NSTEMI/UA and ACS-STEMI, respectively, presenting at the hospital ED.



### Figure 3. Coronary Artery Disease (CAD) Patient Journey

The diagnosis of CAD is confirmed by a coronary angiogram (i.e., cardiac catheterization or cath) which is an imaging procedure utilizing x-ray and selective injection of x-ray dye into the coronary arteries. This test is required to determine the location and severity of lesion (or blockage) before revascularization treatment such as PCI and CABG surgery (Figure D in Appendix 2) can be performed. A cath procedure is usually performed on a different date from the date of CABG surgery. However, for PCI it is common practice for both the diagnostic cath



and intervention to be performed on the same date and at the same time (i.e., *ad hoc* or samesitting). Figure E in Appendix 3 shows the algorithm in which referrals for cardiac procedures are managed.

#### Valvular Heart Disease (VHD)

VHD occurs when there is damage or defect in one or more of the four heart valves: mitral, aortic, tricuspid or pulmonic, which results in the inability of the heart to efficiently pump blood. VHD manifests in two ways: obstruction to the flow of blood (stenosis) or leakage backward (regurgitation). VHD is caused by a variety of factors and conditions including aging, congenital abnormality, calcification, infection, coronary artery disease, hypertension, etc. Early diagnosis and treatment of VHD is important to prevent debilitating sequelae such as heart failure, and sometimes sudden death.

The most common valve disease in North America and Europe is aortic stenosis (AS), which is most often seen in elderly patients with comorbidities. AS is the narrowing of the aortic valve, which restricts blood flow from the left ventricle to the aorta. AS has a 12.4% prevalence among the population over the age of 75 and severe AS is present in 3.4 %.<sup>6</sup> Similarly, mitral regurgitation (MR) is common in the elderly population. MR results from valve leaflets that do not close tightly causing the blood to flow backward into the left atrium. Significant MR occurs in about 2% of the population<sup>7</sup> and affects almost 10% of individuals over 75 years of age.<sup>8</sup> Open-heart surgery is the gold standard treatment of severe AS and MR; however, a large proportion of elderly patients are deemed high risk for open surgical treatment.<sup>9 10</sup>A less invasive transcatheter aortic and mitral valve interventions i.e., TAVI and mitral valve clip procedures may be the alternative therapeutic options for the high-risk or non-surgical candidates in this valve population.

Generally, VHD patients are clinically stable and those requiring valve repair are scheduled for elective procedure (see Figure 4). Clinically unstable VHD patients require urgent treatment and in some cases hospitalization while awaiting procedure. For example, an AS patient develops

 <sup>&</sup>lt;sup>6</sup> Osnabrugge, R. L. J., Mylotte, D., Head, S. J., Van Mieghem, N. M., Nkomo, V. T., LeReun, C. M., ... Kappetein, A. P. (2013).
 Aortic Stenosis in the elderly. *Journal of the American College of Cardiology, 62*(11), 1002–1012. doi:10.1016/j.jacc.2013.05.015
 <sup>7</sup> Jones, E.C., Devereux RB, Roman MJ, et al. (2001). Prevalence and correlates of mitral regurgitation in a population-based sample (the Strong Heart study). *Am J Cardiol.*87: 298-304.

<sup>&</sup>lt;sup>8</sup> Nkomo, V.T., Gardin, J.M., Skelton, T.N., Gottdiener, J.S., Scott, C.G., Enriquez-Sarano, M. (2006). Burden of valvular heart diseases: a population-based study. *Lancet*; 368:1005–1011.

<sup>&</sup>lt;sup>9</sup> Mirabel, M., Iung, B., Baron, G., Messika-Zeitoun, D. Detaint, D., Vanoverschelde, J.L., Butchart, E.G., Ravaud, P., Vahanian, A. (2007). What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J*; 28:1358–1365.

<sup>&</sup>lt;sup>10</sup> Nishimura, R., Otto, C., Bonow, R., Carabello, B., Erwin, J. I., Guyton, R., et al. (2014). AHA/ACC guideline for the management of patients with valvular heart disease. *Circulation*, 129, 1-235.



acute heart failure and is admitted in hospital. During hospitalization, this patient receives treatment for heart failure and may undergo urgent aortic valve repair (AVR) via open surgery or transcatheter approach (TAVI). Prior to AVR, the patient is often sent for a coronary angiogram to determine the presence and extent of CAD. AS patients with CAD may also need CABG surgery performed at the same time as AVR (refer to Figures F, G, H in Appendix 2).



Figure 4. VHD Patient Journey

#### Arrhythmia

Arrhythmia is a condition where the heart beats in abnormal fashion. Arrhythmia may be a consequence of other cardiac condition such as CAD and valve disease. Cardiac diseases are not exclusive of each other and a patient may suffer from more than one type of disease (co-existing diseases). Often a cardiac patient may require multiple invasive diagnostic procedures and interventions. For example, a CAD patient who had a cath and PCI may subsequently require electrophysiology study (EPS) and ablation for investigation and treatment of abnormal heart rhythm. Figure 5 illustrates how arrhythmia may be detected and treated in hospital.

Cardiac patients may suffer from many different forms of arrhythmia such as bradycardia (slow heartbeat <60 beats/minute), supraventricular tachycardia (fast heartbeat originating in the top



chambers or atria), atrial fibrillation (different signals originating in the atria firing in an irregular pattern), ventricular tachycardia (fast heartbeat originating in the lower chambers or the ventricles), Wolfe Parkinson White syndrome (presence of extra pathway between the upper and lower chambers) and other complex arrhythmias. Arrhythmias can be diagnosed through a catheter-based EPS or through the implantation of recording devices such as an implantable loop recorder (ILR). There are a variety of treatment options related to these disorders including: medications, ablation therapy or the use of implantable devices (e.g., pacemakers, implantable cardioverter-defibrillators (ICD), and cardiac resynchronization therapy devices (CRT)). It is not uncommon for an arrhythmia patient to have both an ablation therapy and a cardiac device implanted.



#### Figure 5. Arrhythmia Patient Journey

#### **Vascular Patient**

#### Aortic Aneurysm/Dissection (AA)

An array of physiologic, environmental and genetic factors may affect the lining of the aorta resulting in an aneurysm (a localized ballooning or bulging) and/or a dissection (a localized splitting or tearing between the structural layers within the aortic wall). Figure 6 illustrates the

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typical journey of an aortic disease patient. Overtime, aneurysms and dissections grow and, if left untreated, can rupture which is life-threatening.

Aortic aneurysm and dissection are often undetected until ruptured or when the patient is severely symptomatic. Typically, aneurysms that are 5cm or smaller are not recommended for surgical treatment unless accompanied with symptoms. Some aneurysms rapidly grow in size lending itself to early surgical intervention.





Elective and/or prompt surgical repair of AA aims to prevent death from rupture. AA can be repaired through open surgery or via a less invasive technique called endovascular aneurysm repair (EVAR). Occasionally, both surgery and endovascular techniques are used to complete a repair. Refer to Figures I and J in Appendix 2 for asymptomatic and symptomatic AA repair clinical pathways. The complexity of a procedure depends on patient clinical factors and the anatomical location of the disease.

#### Lower Extremity Occlusive Disease (LEOD)

Arterial occlusive disease or peripheral artery disease (PAD) is the result of progressive narrowing and obstruction of the lumen of arteries in the lower extremities secondary to



atherosclerosis and related disorders. PAD, in the lower extremities, can be detected at a physician's office using a measure of ankle-brachial index (ABI) and by imaging tests such as duplex ultrasound, angiography, computed tomography scan (CT scan) and magnetic resonance imaging (MRI) (see Figure 7).





Lower extremity PAD patients may present to a hospital with claudication (exercise-induced leg or buttock pain that resolves with rest) or with critical limb ischemia manifested by ischemic rest pain, non-healing sores or ulcers, tissue loss, gangrene, or diabetic foot infections. PAD patients may also present with acute limb-threatening symptoms that mandate urgent or emergent therapy. These symptoms could include severe pain as well as loss of motor and sensory function. In these circumstances, immediate revascularization is required to prevent limb loss.

Revascularization by surgical (bypass or endarterectomy) and/or endovascular (balloon angioplasty and/or stenting) intervention in patients with PAD is directed towards symptom relief and/or limb salvage (refer to Figures K and L in Appendix 2). Endovascular intervention are often performed as an outpatient procedure.



## V Patient Referral/Selection Process

#### Cardiac

Patients that are ≥18 years of age who receive a cardiac procedure<sup>11</sup> in Ontario are included in the Cardiac Registry. The referral process for a cardiac procedure begins when a physician (i.e., primary care healthcare provider or cardiologist) completes a referral and sends it to an appropriate advanced cardiac centre<sup>12</sup> for consideration. Additional cardiac procedures and device implantation or insertions may also be entered in the Registry (see Section VII on Data Standards for these specific procedures). The majority of catheter-based procedures are performed in a procedure room equipped with fixed imaging system (e.g., cath lab); however, there are certain procedures also completed in these rooms that are not entered into the Registry, for example, renal angiogram or angioplasty, and fluoroscopy-only procedures. These additional procedures can be tracked by the individual centres.

The Regional Cardiac Care Coordinator (RCCC) at each advanced cardiac centre processes the cardiac referral, and creates the wait list entry (or record) in the Cardiac Registry (i.e., onlist the referral) **within 24 hours** (see Figure E in Appendix 8 for referral triage and management). If a referral is received outside of office hours, the referral is entered into the Registry on the next business day. All patient clinical information including comorbidities and cardiac diagnostic test results are entered into the Registry.

For select cardiac procedures<sup>13</sup>, an urgency rating score (URS), a priority level (from 1-4), and an associated recommended maximum wait time (RMWT) are generated based on specific patient clinical information in the Registry. The patient is triaged according to the priority level and a procedure booking is made.

#### Vascular

All patients  $\geq$  18 years of age who receive an inpatient or outpatient vascular procedure<sup>14</sup> in Ontario, and meet the following inclusion criteria are to be included in the Vascular Registry,

<sup>&</sup>lt;sup>11</sup> Cardiac procedures include: cardiac catheterization, percutaneous coronary intervention (PCI), coronary artery bypass graft surgery, valvular repair (open surgical and percutaneous/transcatheter), heart rhythm electrophysiology studies (EPS) and ablation, and cardiac device implantation.

<sup>&</sup>lt;sup>12</sup> Advanced cardiac centre refers to a hospital with a cardiac program that provides one or more advanced cardiac procedures such as cardiac catheterization, percutaneous coronary intervention (PCI), cardiac surgery, heart rhythm procedures (i.e., electrophysiology diagnostic and ablation procedures), cardiac devices implantation, and transcatheter valve/structural heart procedures.

<sup>&</sup>lt;sup>13</sup> Cardiac catheterization, PCI, CABG, valve surgery, and ICD/CRT device implantation.

<sup>&</sup>lt;sup>14</sup> Aortic aneurysm and dissection repair via open surgery and endovascular intervention, including graft removal/revision; lower extremity occlusive disease repair via open bypass and endovascular intervention



regardless of how the patient clinically presents at the hospital for procedure (i.e., stable (elective), urgent or emergent). Vascular patient inclusion criteria are:

### Aortic aneurysm/dissection repair:

- i. Aortic aneurysm involves any part of the aorta from the distal edge of the innominate artery (zone 1) to aortoiliac aneurysms extending to the external iliac artery or internal iliac artery (zone 11). See CCN Vascular Registry data dictionary for a description of aortic zones.
- ii. Aortic dissection includes any aortic dissection of the descending aorta except dissection caused by traumatic aortic injury.

#### Lower extremity revascularization:

- i. Eligible procedures include surgical bypass, endarterectomy, embolectomy/ thrombectomy, angioplasty with or without use of a stent, atherectomy and aneurysm repair.
- ii. Eligible vessels include from the aorta to the dorsalis pedis (in the foot).

Note that repair of aneurysms that involve the aorta should be entered as an aortic aneurysm repair. Only aneurysms that are <u>completely distal to</u> the aortic bifurcation should be entered as a lower extremity revascularization.

Unlike cardiac procedures, there is no centralized referral process for vascular procedures, rather, each referral is managed by either individual healthcare providers or a specialty department (e.g., surgery, medical imaging). Referrals are typically received in Vascular Surgery or Medical Imaging. It is recommended that referral forms used include patient demographic and comorbidity information that is required in the Registry.

## VI Data Entry

Data entry into the Registry is governed by processes and standards outlined in this document to ensure quality data. The data dictionaries and training manual (see Appendices 4-8) along with the Registry User Guide provide general reference and guidance on entry of data into the Registry. Since the Registry contains personal health information (PHI), access to and management of patient level data is provided only to those who have permission from the hospital administrator, have signed the confidentiality agreement and received appropriate privacy training. In addition, education and training on the Registry are required to efficiently input information into the web-based application. For cardiac procedures<sup>11</sup>, data entry into the Registry is prospective to enable accurate wait time calculation and/or case prioritization. Vascular procedures<sup>14</sup> do not require wait times data, hence data entry for these procedures is done retrospectively.

Within the CCN data source, there are three distinct Registries:

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- Cardiac Registry Peri-procedural information in this application is related to the following cardiac procedures: coronary angiogram, PCI, cardiac surgery, TAVI, device implants (implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT)), electrophysiology studies and ablations;
- 2. Cardiac Registry-STS Database Detailed cardiac surgery information including perioperative and 30-day follow-up data; and
- **3.** Vascular Registry Peri-procedural information on aortic aneurysm/dissection repairs and lower extremity revascularization.

#### **Data Entry Process and Timelines**

Cardiac Registry data entry process:



- The information on the General Referral tab in Cardiac Registry is important for case prioritization and must be entered within 24 hours of referral.
- Waitlist information including Offlisting details must be completed within 48 hours of the procedure.
- Discharge dates should be entered as soon as possible. As part of the month-end data review and confirmation process, ensure that all discharge dates are entered by the third business day (month-end cut-off).

Cardiac Registry-STS Database data entry process:



• Each form in Cardiac Registry-STS Database may be completed independently.



- Data on the operative form must be completed within 14 days of the date of surgery.
- Complete record must be entered within 37 days of the surgery date.

Vascular Registry data entry process:



- Pre-procedure information may be entered into the Vascular Registry as available.
- Complete vascular information including patient demographics, comorbidities, preprocedure and procedure details must be entered within 5 business days of the procedure.
- Post procedure information must be entered within 5 business days of patient's discharge from hospital. At this point, the patient entry should be complete.

#### **CCN Data Verification and Reconciliation Requirements**

Data review and verification is an ongoing process and reconciliation of data should be conducted on a regular basis. Pre-defined reports such as the Missing Data Report and Utilization (or volume) Report were created by CCN and are available through the CCN-Custom Reporting Service (CCN-CRS) (see Figures 7 & 8). The purpose of these reports is to address incomplete records and assist data entry staff to perform record reconciliations. This reconciliation process helps to ensure that all appropriate cases are entered into the Registry and that case entries are complete. All hospital cardiac and vascular programs are expected to complete case reconciliation activities at the end of each month. Pre-defined missing data and volume reports are available in CRS and may be accessed at any time by end-users thereby providing flexibility to complete data verification and validation activities for month end (Table 1).

Designated **month-end is the 3rd (cardiac data) or 5th (vascular data) business day of** the month unless specified otherwise by CCN.

#### Table 1. Month-End Activities for Data Preparation



| 1 <sup>st</sup> Business day of  | Enter all data from previous month by this time  |
|--|--|
| the month  | <ul> <li>Run data reconciliation and verification reports</li> </ul>   |
|  | <ul> <li>Make the required corrections/updates</li> </ul>  |
| 2 <sup>nd</sup> Business day of<br>the month   | <ul> <li>Re-run reports if any corrections were made to the database</li> <li>Make further required corrections/updates</li> </ul> |
| 3 <sup>rd</sup> (for cardiac data)<br>or 5 <sup>th</sup> (for vascular<br>data) Business day<br>of the month | <ul> <li>Complete all corrections/updates</li> <li>Finalize data for CCN reporting by end of business day</li> </ul>               |

### Figure 7. Sample Cardiac Utilization Report

|                                    | Procedure: ELECTROPHYSIOLOGY<br>Date Range: 2017-02-01 to 2017-09-28<br>Report Type: Summary | Animas Medical Center |                    |             |  |
|------------------------------------|--|-----------------------|--------------------|-------------|--|
| ICD                                |  | ONTARIO FUNDED        | NON-ONTARIO FUNDED | GRAND TOTAL |  |
| WHO                                | D  | 18                    | 0                  | 15          |  |
| D00-40                             | :0   | 10                    | 0                  | 10          |  |
| CRT-IC                             | D C  | 24                    | 0                  | 24          |  |
| CRT-PI                             | ACEMAKER   | 2                     | 0                  | 2           |  |
| Implan                             | table Loop   | 11                    | 0                  | **          |  |
| OTHER                              | t <mark>e</mark>   | 0                     | 0                  | 0           |  |
| Lead E                             | straction with laser   | 0                     | 0                  | 0           |  |
| Lead E                             | straction without laser  | ,                     | 0                  | 1           |  |
| Lead in                            | isertion   | 3                     | 0                  | 3           |  |
| Lead o                             | eplacement   | 0                     | 0                  | Ð           |  |
| Lead n                             | extalon  | 0                     | 0                  | 0           |  |
| Pocket                             | nevision   | 0                     | 0                  | 0           |  |
| Device                             | Explant with laser   | 0                     | 0                  | 0           |  |
| Device                             | Explant without laser  | 2                     | 0                  | 2           |  |
| DFT te                             | sting  | 0                     | 0                  | 0           |  |
| EPS.                               |  | ONTABIO FUNDED        | NON-ONTABLO FUNDED | GRAND TOTAL |  |
| EP Stu                             | dy   | ġ.                    | 0                  | D           |  |
| Ablatic                            | 0  | 0                     | 0                  | 0           |  |
| Standa                             | ed   | 0                     | 0                  | 0           |  |
| Compl                              |  | 0                     | Ð                  | 0           |  |
|                                    |  |                       |                    |             |  |
| Same Printerson Street as Rel Tra- | Acceptions to Personal   |                       |                    |             |  |



| Proce   | White River<br>dure Date From<br>Physician Spec | Medical Hospital<br>Jan-01-2017 To: Jan-31-2017<br>Halty: Vascular Surgery |                       |  |
|---|---|--|-----------------------|--|
| Aortic Aneurysm   | Repair  | Lower Extrem   | ity Repair            |  |
| EVAR  | 2   | Endo   | 1                     |  |
| Standard  | 1   | Asymptomatic   | 0                     |  |
| Moderate  | 1   | Other  | 0                     |  |
| Advanced  | 0   | Claudication   | 0                     |  |
|   |   | CLI  | 1                     |  |
| Open  | 3   | Bypass   | 8                     |  |
| Standard  | 3   | Asymptomatic   | 0                     |  |
| Moderate  | 0   | Other  | 0                     |  |
| Advanced  | 0   | Claudication   | 1                     |  |
|   |   | CLI  | 7                     |  |
| Procedures Total  | 5   | Procedures Total   | 9                     |  |
| Hybrids   | 0   | Concomitants   | 1                     |  |
| Conversions   | 0   |  |                       |  |
| Status, D - Awaiting Olecharga, C - Closed<br>Conce. Concombart procedure (Sypans, Entertemediany or PTA)<br>Indicatant of Procedure Arkhympomatic, D-Arkanyam or Othar, C + Internitient Cla | autorion, Cui = Ress?M                          | l<br>gts Pan, Major Taswe Loss, Wroo' Taswe L                              | ans or Acute Jastemia |  |

#### Figure 8. Sample Vascular Volume Report

#### VII Data Standards

Generally, procedure information is entered into the Registry using the data dictionaries (see Cardiac, Vascular and TAVI Data Dictionaries in Appendices 4-6) as a guide and reference. The STS Data Dictionary (see Appendix 7) and Training Manual (see Appendix 8) provide additional reference for data entered into the Cardiac Registry-STS Database. The Glossary of Terms (Appendix 9) is a quick reference for the terminology and acronyms used in the Registry.

There are cases that need additional information beyond what is provided in the data dictionary. In order to decrease data entry variation for these procedures, the following section provides detailed clinical scenarios and instructions on how they are to be entered into the Registry.



Data entry into the Registry should follow the standard process and timelines outlined in Section VI to ensure accurate prioritization of select cardiac procedures and volume reconciliation of all procedures at month end. Furthermore, records must be as complete as possible by month end with no or minimal missing and 'unknown' values.

## I. Cardiac Procedures

#### A. Cath (Cath), PCI (PCI), and Cardiac Surgery (CS)

Procedures performed to diagnose and/or treat coronary artery disease (CAD) such as cardiac catheterization (or coronary angiogram), PCI, and CABG surgery require the completion of a referral. For a diagnostic coronary angiogram procedure, the primary reason for referral would be either CAD or 'other'. If CAD is chosen, the type of CAD is entered as stable angina, STEMI, NSTEMI, unstable angina or rule-out CAD. Unless the indication for coronary angiogram is 'Other' (e.g., biopsy, right heart cath, research), patients referred with no known CAD are assigned a 'rule-out' CAD referral reason.

It is important to note that the patient's main medical diagnosis (e.g., aortic stenosis, heart failure) is not necessarily the primary reason for a cath referral. This information may be the secondary reason for referral and entered in the 'secondary reason' field, for example, valvular disease or heart failure. Similar referral reasons apply for PCI procedures and CABG surgery. With consultation with the medical team, it may be necessary to change the referral reason for a patient recently discharged from a hospital who is scheduled for an elective procedure. For example, a discharged STEMI or NSTEMI/UA patient waiting at home for an outpatient PCI should be assigned 'stable CAD' as the primary referral reason.

#### 1. Documentation of inpatient/outpatient (I/O) status. (Cath, PCI)

**Case Scenario:** An inpatient NSTEMI patient from a non-PCI community hospital was transferred to a PCI hospital for an outpatient cath +/- PCI (i.e., 'flyer' patient). **Question:** What is the I/O status of this patient at the PCI hospital? **Answer:** The I/O status of patient is determined at the time of registration at the PCI hospital. This patient would be documented in the Registry as an 'outpatient'. **Rationale/Intent:** A patient can only be registered as an 'inpatient' in one hospital. In this scenario, the patient is a 'flyer' which means that he/she remains as an inpatient at the sending hospital until it has been decided otherwise.

#### **Data Entry Instructions:**

- On the 'Bookings' tab, enter the booking date
- Select 'Outpatient'



- Admission Date: Enter the date of initial admission at the referring hospital (i.e., non-PCI hospital)
- Admission Location: Enter the name of referring hospital
- Enter transfer date

### 2. Documentation of conversions from outpatient to inpatient. (Cath, PCI)

**Case Scenario:** An inpatient NSTEMI patient from a non-PCI community hospital was transferred to a PCI hospital for an outpatient cath +/- PCI (i.e., 'flyer' patient). During the procedure, the physician decided to admit the patient on the telemetry ward at the PCI hospital for further tests and observation.

Question: What is the I/O status of this patient at the PCI hospital?

**Answer:** The I/O status of patient is determined at the time of registration at the PCI hospital. This patient would be documented in the Registry as an 'outpatient'.

#### **Data Entry Instructions:**

- On the 'Bookings' tab, enter the booking date
- Select 'Outpatient'
- Admission Date: Enter the date of initial admission at the referring hospital (i.e., non-PCI hospital)
- Admission Location: Enter the name of referring hospital
- Enter transfer date
- Check 'Converted from outpatient to inpatient'

## 3. Documentation of coronary angiogram in the setting of scheduled/staged PCI. (Cath, PCI)

**Case Scenario:** A patient is booked for a scheduled or staged PCI as an outpatient. The interventional cardiologist performs a coronary angiogram prior to the PCI.

**Question:** How do we properly document a scheduled/staged PCI case in which the interventional cardiologist decides to repeat the cath prior to procedure date?

**Answer:** The decision to perform a repeat cath **must be made prior** to the patient being taken to the cath lab for the PCI procedure. A scheduled or staged PCI must be onlisted and offlisted as such i.e., not as a SSPCI.

#### Data Entry Instructions:

- Change Service Detail 1 and 2 to Coronary Angiogram
- Reassess Priority in WLE or patient's record
- Complete procedural information for cath +/- PCI



#### 4. Documentation of cases with 'rule-out CAD' indication. (Cath, PCI)

**Case scenario:** Patient with chest pain presented to the hospital ED. The ECG indicates nonspecific ST elevation and the chest discomfort remains. Upon further assessment the patient is diagnosed with acute heart failure. Patient has angiogram with or without SSPCI.

Question: What is the primary reason for referral?

**Answer:** The primary reason for referral is 'rule-out CAD' with heart failure as the secondary reason for referral.

**Rationale:** There are many causes of chest pain and since the diagnosis was not CAD, the reason for performing the angiogram is to determine if indeed the patient's chest pain is caused by CAD or not.

#### Data Entry Instructions:

- Primary Reason for Referral: Rule Out CAD
- Secondary Reason for Referral: Heart Failure
- Complete the Offlisting Details: Coronary Angiogram; SSPCI (if performed)
- Do not complete the STEMI activity form

#### 5. Referral of patient in cardiac arrest for a cath lab procedure. (Cath, PCI)

**Case Scenario:** A patient experiencing cardiac arrest was brought to the cath lab for an emergent procedure. The cause of cardiac arrest has not been determined and there is no qualifying ECG. The angiogram shows no or non-significant CAD and the patient was subsequently treated with medical management.

**Question:** What is the primary reason for referral?

**Answer:** For any patient brought to the cath lab emergently without a qualifying STEMI ECG the primary reason for referral is 'rule out CAD'.

**Rationale:** Unless evidence for STEMI exists, the cause of this patient's cardiac arrest is not known.

#### Data entry instructions:

- Primary Reason for Referral: Rule Out CAD
- Complete Offlisting Details: Coronary Angiogram
- **Do not** complete the STEMI Activity form.

#### 6. Documentation of late STEMI. (Cath, PCI)

**Case scenario:** Patient presents via Paramedic or self-transport to a non-PCI or PCI hospital. ECG confirms STEMI. Patient receives no treatment for >24 hours. Patient is referred for and receives a coronary angiogram and SSPCI.



#### Question: How is this case captured?

**Answer:** This should be documented as a STEMI case. This was a missed STEMI due to a system delay.

#### Data Entry Instructions:

- Onlist with Primary Reason for Referral = STEMI
- Complete Offlisting Details: Coronary Angiogram; SSPCI; Late PCI
- Complete the STEMI Activity tab

#### 7. Documentation of STEMI with fibrinolysis with or without PCI. (Cath, PCI)

**Case scenario 1:** Patient presents via Paramedic or self-transport to a non-PCI hospital. ECG confirms STEMI. Due to distance from PCI hospital, patient receives fibrinolytic therapy. Patient is transferred to PCI hospital for coronary angiogram within 24 hours of symptom onset and arrival to cath lab. No PCI is performed.

#### **Data Entry Instructions:**

- Onlist with Primary Reason for Referral = STEMI
- Complete Offlisting Details: Coronary Angiogram; STEMI PCI Not Completed Reason
- Complete the STEMI Activity tab

**Case scenario 2:** Patient presents to a non-PCI hospital. The ECG confirms STEMI. Due to distance from PCI hospital, patient receives fibrinolytic therapy. ST elevation on ECG does not resolve and/or patient continues to experience chest pain. After 24 hours, patient is transferred to PCI hospital emergently for coronary angiogram which results in a SSPCI. **Data Entry Instructions:** 

- Onlist with Primary Reason for Referral = STEMI
- Complete Offlisting Details: Coronary Angiogram; Rescue; SSPCI; Late PCI
- Complete the STEMI Activity tab

# 8. Documentation of a STEMI patient who subsequently had an ECG non-diagnostic of STEMI. (Cath, PCI)

**Case scenario:** A patient is transported from the field or transferred from a non-PCI hospital to a PCI hospital by Paramedics. The 12-lead ECG performed by the Paramedics or from the sending non-PCI hospital shows ST elevation. Repeat ECG at PCI hospital shows no ST elevation; assessment of patient now indicates NSTEMI. Patient has angiogram with or without SSPCI.

Question: Does STEMI remain the primary reason for referral?

**Answer:** The clinical status of the patient has changed to NSTEMI which should be reflected on the referral form.

#### Data entry instructions:



- Primary Reason for Referral: NSTEMI
- Complete Offlisting Details: Coronary Angiogram; SSPCI (if performed)
- Do not complete the STEMI Activity form.

#### 9. Documentation of referral for CABG plus valve surgery. (CS)

**Case Scenario:** A patient is referred for a combined CABG and valve surgery. **Question:** What is the primary reason for referral?

**Answer:** Based on the referral, determine the main diagnosis that drives the operation, whether coronary artery disease or valve disease. The alternate reason is listed as secondary reason for referral.

#### **Data Entry Instructions:**

- Select Primary Reason for Referral: CAD (Stable Angina, STEMI, NSTEMI or UA) or 'Other'
- Secondary Reason for Referral: Valvular disease (if primary reason is 'Other')

#### 10. Documentation of surgical site infection. (CS)

**Case Scenario:** A patient had a CABG surgery and developed sternal wound infection requiring an intervention.

**Questions:** How is this captured in the Registry? Are sternal wires/pectoralis flaps related to sternal wound infection entered as a separate entry?

**Answer:** Sternal wound infection is a complication of CABG and should be documented as part of the original CABG surgery record. Postop infection complications are documented in the Cardiac Registry-STS Database. Interventions related to sternal wound infection do not need to be entered as separate records.

**Rationale/Intent:** Note that all cardiac surgery centres should be entering case details into the Cardiac Registry-STS Database.

#### Data Entry Instructions:

- Open original CABG record (associated with infection) in Cardiac Registry-STS Database
- In Section P: Indicate 'Yes' to 'Surgical Site Infection within 30 days of operation'
- Deep Sternal Wound Infection/Mediastinitis = within 30 days or greater than 30 days after procedure
- Wound Intervention Procedure = Yes
- Indicate what procedure was done including secondary procedure muscle flap



# 11. Documentation of surgical complications that occur in hospital or following discharge. (CS)

#### **Case Scenarios:**

- a. A post CABG patient had hemorrhage requiring reoperation while in hospital.
- **b.** A post CABG patient had an acute graft occlusion that required re-do bypass following discharge.

**Question:** Are the two examples for complications entered the same way, i.e., in the original waitlist entry (WLE)?

**Answer:** Post CABG patients who had complications with or without intervention while still in hospital are documented in the original surgical record or WLE under Section P, and those complications occurring following discharge are entered in Section S: Readmission.

**Rationale:** Complications may or may not require intervention. Cardiac Registry-STS Database captures complications postoperatively up to 30 days.

#### Data Entry Instructions:

#### For scenario a:

Cardiac Registry-STS Database:

- In-hospital postoperative events are captured in Section P
- For Bleeding, check 'Yes' for 'Re-op for Bleeding/Tamponade'
- Indicate bleeding times as 'acute or late'.

#### For scenario b:

Cardiac Registry-STS Database:

- Open original CABG record
- Section S: Readmission
- Readmit Primary Reason Check = Coronary Artery/Graft Dysfunction
- Section P: Re-intervention for Myocardial Ischemia = Yes
- Indicate vessel: Native coronary, Graft or Both
- Enter Intervention Type: Surgery, PCI or Both

#### 12. Documentation of pericardial window. (CS)

**Case Scenario:** A cardiac patient had a pericardial window performed to treat a complication following cardiac surgery.

**Question:** Are pericardial windows captured in the Cardiac Registry-STS Database? **Answer:** Pericardial windows and pericardiectomies that are performed to treat cardiac tamponade are entered as a 'bleeding complication' (see below).



**Rationale/Intent:** Documentation of a surgical complication is more important than the procedures to treat a complication. Pericardial window and pericardiectomy are procedures performed to treat a complication or pericardial disorder. However, only those procedural data associated with a complication of previous cardiac surgery are entered into the Registry.

#### Data Entry Instructions:

Cardiac Registry-STS Database:

- Open associated original (or index) cardiac surgery record
- In hospital postoperative events are captured in Section P
- For Bleeding, check 'Yes' for 'Reop for Bleeding/Tamponade'
- Indicate bleeding times as acute or late.

If patient has been discharged and readmitted for bleeding:

- Check 'Pericardial effusion and/or Tamponade'
- Readmit Primary Procedure: OR for Bleeding

#### **B.** Heart Rhythm Procedures

(Cardiac Devices (Devices), Lead Procedures (LP), EP study (EPS), Ablation (EPA))

#### 1. Documentation of CRT LV lead insertion. (LP)

**Case Scenario:** A patient with a CRT device is returning to have LV lead inserted. **Questions:** How is this case onlisted? Is this considered a CRT upgrade? What is the Implant Indication?

**Answer:** Patients with a CRT device returning for LV lead insertion are coming for a Lead-Only procedure; therefore is not considered an upgrade. The implant indication for any lead-only procedure, pocket revision, device explant or DFT testing is 'OTHER'. **Rationale/Intent:** The original WLE would have indicated an 'upgrade'. It should be mentioned in the 'Notes' section that the LV lead port was capped with the intent of having a LV lead insertion at a later date.

#### Data Entry Instructions:

- Service Detail 1 = Electrophysiology Service; Service Detail 2 = Lead Insertion
- Offlist as 'Lead Insertion' and check 'LV Lead'
- Document details of LV lead in the 'Notes' section.
- Documentation of pacemaker patient receiving an ICD or CRT device. (Devices)
   Case Scenario: A patient with existing permanent pacemaker had an ICD or a CRT device implanted.



**Questions:** Is this case onlisted as New or Upgrade?

**Answer:** This case is onlisted as a 'New' procedure into the Registry.

#### Data Entry Instructions:

- Service Detail 2 = ICD or CRT Implant
- On Heart Rhythm tab, select for implant indication = New (U)
- Then select 'Yes' to 'Current Intracardiac Device' and select 'Permanent Pacemaker (P)' from list
- Select appropriate description of pacemaker: single or dual
- When offlisting, document details of explanted pacemaker in the 'Notes' section

#### 3. Documentation of device replacement. (Devices)

**Case Scenario:** A patient had a dual chamber ICD implanted 3 weeks ago and has been readmitted for removal of device and leads because of infection. Two weeks later the patient receives a new dual chamber ICD.

Question: Is this case onlisted as New or Replacement?

**Answer:** This device is the patient's second device, therefore Onlisted as a 'Replacement'. Note that **only the first device** a patient receives can be classified as 'denovo' or new. **Rationale:** Previously, devices that were implanted after a total system extraction were classified as 'new' which caused a problem in identifying the true denovo (first device). Moving forward, <u>only</u> the first device implantation is "New" and all other subsequent devices are replacements or upgrades. However, a pacemaker that is replaced with an ICD or CRT is entered as 'New'.

#### Data Entry Instructions:

- Service Detail 2 = ICD Implant
- On Heart Rhythm tab, select for implant indication = 'Replacement' (R)
- Then select 'Replacement Infection/Erosion (R)'
- Then select 'Yes' to 'Current Intracardiac Device' and select 'ICD' from list
- Select appropriate description of ICD: single, dual or CRT
- When offlisting, document details of explanted device on the 'Notes' section

#### 4. Documentation of a device upgrade. (Devices)

**Case Scenario:** A patient with a previous VVI or DDD ICD is referred for a CRT-D device. **Question:** How should this be onlisted and documented in the Registry? **Answer:** An ICD replaced with a CRT-D is entered as an 'Upgrade' in the Registry. **Data Entry Instructions:** 

• Onlist as Service Detail 2 = CRT



- On Heart Rhythm tab, select for implant indication = Upgrade (U)
- Then select 'Device Upgrade to CRT-ICD (I)
- Then select 'Yes' to 'Current Intracardiac Device' and select 'ICD' from list
- Select appropriate description of ICD: single or dual
- When offlisting, document details of explanted device on the 'Notes' section.

#### II. Vascular Procedures

(Open Aortic Aneurysm Repair (OAR), Endovascular Aneurysm Repair (EVAR), Open Lower Extremity Revascularization (OLR), Endovascular Lower Extremity Revascularization (ELR))

#### 1. Documentation of aborted or abandoned procedures. (OAR, EVAR, OLR, ELR)

**Case Scenario:** A patient with an abdominal aortic aneurysm was undergoing an EVAR; however, the procedure was aborted after failed attempts to insert the delivery sheath through the femoral artery.

Question: Is this procedure documented in the Registry?

**Answer:** Currently there is no field in Vascular Registry to capture aborted or abandoned procedures. These procedures will be tracked through 'site specific elements' page until appropriate changes in the Registry are completed.

#### Definition:

An aborted procedure or surgery is one in which the skin has been cut or punctured with the intent to perform aortic or lower extremity repair but the procedure has been abandoned prior to its completion (i.e., the patient did not have aneurysm repair, or did not receive a device (e.g., stent, graft)).

#### Data Entry Instructions:

- Enter the procedure date on the procedure details tab along with as many details about the procedure as possible
- Enter 1 in numeric field #9

#### 2. Documentation of removal of previously implanted EVAR graft. (EVAR)

**Case Scenario:** A patient who had an EVAR procedure 3 weeks ago was readmitted with an infected graft. An urgent surgery is scheduled to remove the previously implanted graft.

Question: How is this procedure included in the Registry?

**Answer:** Currently there is no option in the 'Indication for Procedure – Aortic Aneurysm' field to select removal of previously implanted EVAR graft. These procedures will be tracked through 'site specific elements' page until appropriate changes in the Registry are completed.



#### **Definition**:

Removal of EVAR Graft is an open surgical procedure for the removal of a previously implanted aortic stent-graft.

#### Data Entry Instructions:

- Enter the procedure date on the procedure details tab along with as many details about the procedure as possible
- Enter 1 in numeric field #10
- Enter the date of initial graft implantation in date field #10

#### 3. Documentation of hybrid procedures. (OAR, EVAR, OLR, ELR)

**Case Scenario:** A combined EVAR and open surgery was scheduled for a patient with symptomatic infrarenal abdominal aortic aneurysm.

**Question:** How do we enter combined or hybrid procedures into the Registry? **Answer:** Details of open surgical and endovascular portions of a hybrid procedure are entered into the 'open repair' and 'endovascular repair' tabs respectively, within the aortic repair page. Both procedures must be entered using the same vascular entry and encounter number.

#### **Definition:**

Hybrid procedures are planned combined open surgical and endovascular procedures that are performed at the same time i.e., same sitting.

#### Data Entry Instructions:

- Enter both procedures as a single vascular entry
- Complete both 'Open' and 'Endovascular' tabs

#### 4. Documentation of conversion procedures. (EVAR, ELR)

**Case Scenario:** During an EVAR procedure, the physician decided to convert to an open surgery due to inability to deploy the endograft percutaneously.

**Question:** How do we document immediate conversion procedures in the Registry? **Answer:** The above scenario is an immediate conversion procedure. Conversion procedures are documented in the Registry; however, for greater clarity, conversion procedures that occur immediately (during the same sitting as the endovascular procedure) will be differentiated from conversions that occur after the completion of the index endovascular procedure. Immediate conversion procedures will be tracked through the 'site specific elements' page until appropriate changes in the Registry are completed.

Definition:



Conversion procedures are open surgical procedures performed to correct a complication or device-related adverse event of the index endovascular repair. Conversion procedures are organized into three groups according to the time from endovascular intervention to surgical repair.

- a) Immediate: occur while in the procedure room for the EVAR. The EVAR is unsuccessful and an open surgical procedure is done to complete the repair. Immediate conversions may be necessary due to inability to deploy a graft, vessel rupture, device, equipment or technical error, etc.
- b) Early: open surgical procedures that are performed between 1-30 days after an EVAR in order to correct a complication or device-related adverse event (e.g. graft thrombosis, endoleak, graft migration or kinking). For example, a patient who received an EVAR was discharged and readmitted 20 days later for an open surgical repair of previously repaired aneurysm.
- c) Late: open surgical procedures that are performed >30 days after an EVAR in order to correct a complication or device-related adverse event (e.g. graft thrombosis, endoleak, graft migration or kinking).

#### Data Entry Instructions:

Immediate conversion procedures:

- Enter the index procedure as an EVAR procedure
- For the 'Conversion to Open' field, select 'Yes'
- Complete as many EVAR procedure details as possible
- Complete procedural details in 'Open Procedure' tab
- For the 'Conversion from EVAR' field, select 'Yes'
- For the 'Time to Conversion' field, leave blank
- Go to the Site Specific Tab
  - Enter 1 in numeric field #6
  - Enter date of 'open' procedure in date field #6

Early and Late conversion procedures:

Note: early and late conversion procedures will be a separate entry from the index EVAR procedure.

- Enter procedure as an open AA procedure
- For the 'Conversion from EVAR' field, select 'Yes'.
- Select appropriate choice for 'Time to Conversion' field: either '≤30 days' OR '>30 days'
- 5. Documentation of procedure complications. (OAR, EVAR, OLR, ELR)



**Case Scenario:** A patient experienced a myocardial infarction (MI) one day following a femoral-popliteal bypass surgery.

Question: How do we document a MI following a procedure?

**Answer:** MI may occur as a complication following surgery. To document one or more complications, select 'Yes' to 'Complications' field. This opens up a list of possible complications. From this list, select the complication (or complications) by clicking on 'Yes' then click 'No' for ALL other selections in this list.

#### Data Entry Instructions:

- Select 'Yes' to 'Complications'
- Select Yes to 'Myocardial Infarction'; Ignore the 'Cardiac Troponin' and 'Maximum Reference Range used' fields
- If no other complication, select 'No' for the rest in the list of complications

## 6. Documentation of radiation dose if the unit reported is not mGy. (EVAR, , ELR)

**Case Scenario:** A patient underwent a lower extremity endovascular procedure that took 1½ hours to complete and the patient was exposed to 250 mGycm<sup>2</sup> of radiation. **Question:** How do I document radiation dose not reported in mGy? **Answer:** Currently, the 'Radiation dose' field in the Registry is captured only in mGy. Radiation doses reported in other units (e.g., mGycm<sup>2</sup>), will be tracked through the 'site specific elements' page until appropriate changes in the Registry are completed. **Data Entry Instructions**:

- If mGycm<sup>2</sup> is used, Enter 1 in numeric field #7
- If Sievert (Sv) is used, Enter 2 in numeric field #7
- If millisievert (mSv) is used, Enter 3 in numeric field #7
- If gray (Gy) is used, Enter 4 in numeric field # 7
- Enter radiation dose value in numeric field #8

## 7. Documentation of a radiation dose that is greater than 3000 mGy. (EVAR, ELR)

**Case Scenario:** A patient underwent an EVAR to repair an extensive thoracoabdominal aneurysm. The source notes indicate that the patient was exposed to 5500 mGy of radiation.

**Question:** The registry only accepts entry of radiation doses in the range of 1-3000 mGy. How should I enter a dose of 5500mGy?

**Answer:** Once you have confirmed that the dose is accurate and above 3000mGy, you can enter the dose on the 'site specific elements' page using gray (Gy) as the unit of measure. **Data Entry Instructions**:

• Convert the radiation dose from mGy to Gy by dividing the dose (in mGy) by 1000. In this example, 5500 mGy = 5.5 Gy



- Go to the Site Specific Elements page
- Enter 4 in numeric field #7. The number 4 indicates that the units of measure is gray (Gy)
- Enter the radiation dose value (in Gy) in field #8

#### 8. Documentation of multiple segments bypassed in a single procedure. (OLR)

Case Scenario: During a lower extremity bypass case, an aorto-bifemoral bypass and a

left femoral-anterior tibial bypass was performed. **Question:** How do I document both of the bypassed segments?

**Answer:** Enter each bypass into the proximal and distal bypass attachment site fields using the available checkboxes. For this example, select the following:

- Bypass 1 (red circles): Proximal attachment site = Aorta; Distal attachment sites = Left & right CFA; Left CFA
- Bypass 2 (green circles): Proximal attachment site = Left CFA; Distal attachment sites = Left AT

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#### 9. Documentation of staged and supplementary procedures. (OAR, EVAR, OLR, ELR)

Case Scenario: A vascular patient underwent an EVAR procedure (the index procedure in this scenario) to treat an aortoiliac aneurysm. At the same time, an external to internal iliac artery bypass was performed as a supplemental procedure.
Question: Are these two procedures entered in two separate records?
Answer: Since the two procedures were performed at the same time, they are entered as a single vascular entry.

**Rationale/Intent:** Concomitant or supplemental procedures are documented in the same record as the index procedure i.e., same vascular entry. Supplemental procedures performed at a different time than the index procedure (i.e., requires a return trip to the OR) are entered as a new vascular entry. Likewise, staged procedures are documented as a separate entry from the index procedure because the later stage is performed at a later time, requiring a separate scheduled OR trip. **Definition:** 



**Staged procedure:** This is a scheduled follow-up procedure similar to the index procedure. A staged procedure can be performed within the same hospital admission (as the index procedure) or as a separate hospital encounter.

**Supplementary procedure:** Also called adjunct procedure; is performed in addition to the index procedure to increase efficacy and ensure optimal results of the index intervention. Supplemental procedures are usually performed concomitantly or within the same hospital encounter as the index procedure.

#### Data Entry Instructions:

- Enter details of the EVAR procedure
- Select 'Adjunct (conduit) Procedure': 'Other' (O)
- Enter type of conduit (bypass) as free text: External-internal iliac bypass

#### 10. Documenting revascularization of previous bypass conduit. (ELR)

**Case Scenario:** A patient had a right femoral-popliteal bypass 15 years ago. The bypass conduit has become stenotic and is going to be treated with angioplasty.

**Question:** How do I document that the angioplasty occurred at the level of the previous bypass conduit?

**Answer:** When documenting revascularization of a previous bypass conduit, select the vessel at the sight of the proximal anastomosis of the previous graft as the current target vessel.

#### Data Entry Instructions:

In the Procedures Tab

- Indication for Procedure field: select all relevant indications AND select other.
- In other text box, enter "stenosis of previous graft".

| Asymptomatic      | Candication                   | E Rest/Night Pain | Hajor Tissue Loss |
|-------------------|-------------------------------|-------------------|-------------------|
| Minor Transe Loss | 📋 Acite Ischenia              | E Aneurysm        |                   |
| Other             | three sectors of account work |                   |                   |

• Lesions Treated table: Select the vessel at the sight of the proximal anastomosis of the previous graft. In this example, select the right femoral artery as the sight of the current revascularization.

| Lesion(s) Tre   | sated            |                |                 |                                    |                   |     |
|-----------------|------------------|----------------|-----------------|------------------------------------|-------------------|-----|
| Vessel Trutted  | Occlusion Lenath | Lesion Length  | Lesian<br>Count | Treatment Types(s)                 | Technical Outcome | Add |
| Poplet OFA (10) | 🥥 - 5 cm (1)     | < ≤ 5 cm (1) ~ | Single (1 🗸     | Baloon Expandable Stert, Uncovered | Success (S) 🗸 🗸   | √×  |



#### 11. Difference between occlusion length and lesion length. (ELR)

**Question:** When completing the lesions treated table, I see that there is a field for 'occlusion length' and a field for 'lesion length'. What is the difference between these two fields?

**Answer:** A lesion is any area along an artery where there is atherosclerotic plaque deposits between the middle and inner layers of the artery wall. As the plaque builds, it will reduce the lumen of the artery and decrease the amount of blood flowing past that point. If known, the total length of the lesion (or sum of lesion lengths if there are multiple) in a vessel should be entered into the 'Lesion Length' field. If blood flow becomes 100% blocked, it is called a total occlusion. If known, the total length of the vessel that is 100% occluded should be entered into the 'Occlusion Length' field. Occlusion length may be equal to or less than the lesion length. Below are examples of single and multiple lesions with and without occlusion.

A) A single lesion with no total occlusion.



B) A single lesion with total occlusion.



C) Multiple lesions where one lesion is totally occluded, one lesion is not totally occluded and both lesions are treated.

| Variant Treated | Doheset Lendy | Local Local | Lauko Inselment | thempti | Tuchnood Oxform | 444 |
|-----------------|---------------|-------------|-----------------|---------|-----------------|-----|
| *[Left \$PA (7) | v cimiii      | 1-11-00 V   | TRACK W         |         | × .             | ~ × |

#### **12.** Translating descriptive details into numeric values.

There are data fields in the Registry in which numeric values are required or selection from a range of values (e.g. estimated blood loss (ml) or Left Ventricular Ejection

Fraction (percent range)). In some circumstances operative notes or other source data may only contain descriptive details and not numeric values (e.g. "minimal blood loss" of "normal" Left Ventricular Ejection Fraction). Below is a list of data fields with direction for translating descriptive details into acceptable numeric values.

• Hemoglobin (g/L) (OAR, EVAR, OLR, ELR)

If hemoglobin is described as 'normal', for females enter 140 g/L, for males enter 155 g/L

• Left Ventricular Ejection Fraction (LVEF, %) (OAR, EVAR, OLR, ELR)

If LVEF is described as 'normal', select ≥50% from the dropdown list

• Estimated Blood Loss (ml) (OAR, EVAR, OLR)

If estimated blood loss is described as 'minimal', enter 30 ml

• Ankle Brachial Index (ABI) Value (OLR, ELR)<sup>15</sup>

If ABI is described as 'normal', enter 1.00 If ABI is described as 'borderline', enter 0.91 If ABI is described as 'non-compressible', enter 1.41

• Toe Brachial Index (TBI) Value (OLR, ELR)<sup>15</sup>

If TBI is described as 'normal', enter 0.71

## 13. Documentation of a planned repair of a large iliac aneurysm with a small aortic aneurysm. (EVAR)

**Case Scenario:** A patient underwent a planned repair of aortoiliac aneurysm, in which the aortic segment was considered a small aneurysm (35mm) and the iliac segment was in the internal iliac artery and was considered large (41mm). The diameter of the iliac aneurysm warranted the repair. For the procedure, an iliac branched graft (IBG) endovascular device was used. The surgeon has documented on the operative notes that the indication for the procedure was the size of the iliac aneurysm. The patient had no symptoms. Due to the challenges in cannulating the iliac artery, the procedure was prolonged and it was decided to complete the procedure in two stages:

• On November 10<sup>th</sup>, the first stage was the insertion of a branched right internal iliac artery endovascular device.

<sup>&</sup>lt;sup>15</sup> Gerhard-Herman, M.D., Gornik, H.L., Barrett, C., Barshes, N.R., Corriere, M.A., Drachman, D.E.,... Walsh, M.E. (2016) 2016 AHA/ACC guideline for lower extremity peripheral artery disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Executive Summary, *Journal of the American College of Cardiology* (2016), doi:10.1016/j.jacc.2016.11.008.

- CARDIAC CARE NETWORK
- The second stage was performed 5 days later while the patient was still an inpatient. The procedure involved the insertion of the main body of an AA EVAR graft in the infrarenal location.

**Question:** How is this staged procedure involving aortoiliac artery documented in the Registry?

**Answer:** This case is documented as two separate vascular entries with the same indication for procedure and the same encounter number (or visit number).

#### **Data Entry Instructions:**

For Stages 1& 2:

- Service Detail 1: Aneurysm Repair
- Service Detail 2: Endovascular
- Complexity of procedure: Moderate, then select 'aortoiliac'
- Indication for procedure: Aneurysm
- Size of aneurysm: 41mm

For Stage 1:

- Indicate zone(s) of graft attachment i.e., zone 10 and/or zone 11
- In the Notes section, indicate that this is the first of 2 stages, document the size of abdominal and iliac aneurysms, other relevant details



For Stage 2:

- A. Indicate zone of graft attachment i.e., zone 9
- B. In the Notes section, indicate that this is the second of 2 stages (the first stage was done on November 10, 2016), document the size of abdominal and iliac aneurysms, other relevant details

#### 14. Documentation of a pseudoaneurysm repair. (OLR)

**Case Scenario:** A patient underwent a repair of a pseudoaneurysm located in the right common femoral artery. The patient had a recent percutaneous coronary intervention (PCI). The operative notes indicate that the aneurysm sac was resected and the defect was repaired using sutures.

**Question:** Is pseudoaneurysm the same as aneurysm? How is this case documented in the Registry?

**Answer:** Pseudoaneurysm, also called a 'false aneurysm', is a blood clot formed between the two outer layers of an artery. This is entered into the Registry. **Data Entry Instructions:** 



- Service Detail 1: Lower Extremity Repair
- Service Detail 2: Bypass (Open)
- 'Indication for Current Procedure' field = 'Other', then type
   'pseudoaneurysm' in the text box
- 'Procedure Type' field: Select the appropriate response if available (e.g. bypass or graft implant). If the appropriate procedure type is unavailable this field may be left blank
- If field left blank, add details of procedure in the Notes section

## VIII Data Quality

Registry data is used in various ways to inform and support the decisions, recommendations, and quality improvement initiatives made by multiple stakeholders. As such, it is essential to have data that is complete, accurate, and entered according to CCN guidelines. CCN has developed processes and tools to help promote data quality. The maintenance of quality data contained within the Registry requires a continuous and collaborative effort between CCN and hospital stakeholders. Data quality consists of four dimensions: completeness, accuracy, consistency, and timeliness.

#### Completeness

Completeness is defined as the capture/entry of all appropriate data into the Registry. Data completeness consists of two components: 1) capture of all appropriate cases, and 2) for every case, all required information is entered into the Registry. Completeness of data is important since incomplete data cannot be reported upon and it is difficult to make recommendations or draw conclusions from partial data.

To support hospitals to achieve complete data entry, CCN has developed the following reports:

a. Cardiac Utilization Reports and Vascular Case Reconciliation Report

The cardiac utilization report and vascular case reconciliation report display all case entries for a specific hospital within a one-month period. These reports can be filtered by service detail and by physician type (e.g. cardiac surgeon, vascular surgeon or interventional radiologist, or combination). Utilization or reconciliation reports can be run at any time; however, CCN recommends that these reports are run as part of the month-end activities (see CCN Data Verification and Reconciliation Requirements in Section VI).

b. Missing Data Report



The missing data reports are designed to help users of the Registry determine which elements are not completed and address those data quality issues. A summary of completeness is also found on the data quality report cards that are submitted to Registry users on a monthly basis. The goal is to have 10% or less missing and 'unknown' values.

#### Accuracy

Accuracy is defined as the proportion of data entered into the Registry that matches the source data. Accuracy is important because the data in the Registry is used to inform decisions and recommendations. Data collected are meant to represent or capture real-world events and if data is inaccurate conclusions drawn from it will be incorrect.

Support for this dimension is provided in the data dictionaries and data standards. These documents provide reference and guidance to the Registry user in how and where to find data that are captured in the Registry.

#### Consistency

Consistency is defined as the likelihood that a value entered into a data field has the same meaning across multiple users and/or facilities. Consistency is important to the credibility of data as it ensures that the data will maintain its integrity when pooled across hospitals and when comparing results between hospitals. To achieve consistency of data, different users must be able to understand and interpret data definitions in the same meaningful way, resulting in uniformity of data entry across data entry users.

Tools to support accurate and consistent data entry include the data dictionaries and this Data Standards document. The data dictionaries are a reference for interpretation of the meaning of each data field and element. The data standards document provides guidance about case entry and is intended to reduce variability in case interpretation and decision making when entering case details into the Registry.

Through monitoring help desk calls as well as through the monthly RCCC/data clerk teleconferences, CCN determines if the interpretation of a data definition or clinical scenario is consistent across Registry users. Based on this activity, clarification to help promote consistency can then be communicated to all Registry users. A clear and concise data dictionary that defines what each element in the Registry represents also helps to promote consistency. Achieving and maintaining accurate and consistent data entry is a continual learning and a collaborative process between CCN and Registry end-users. Through facilitation of open communication between CCN and Registry end-users, CCN is committed to ensuring that the data entered is complete and accurate.

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December 2016 (Rev Sept 2017)
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#### Timeliness

Timeliness is a measure of how soon data are entered into the Registry after they are available. Timeliness of data is essential to avoid negatively impacting the completeness of current data in the Registry and, as an extension, negatively impacting the completeness of reports that CorHealth shares with stakeholders. There are stakeholders who may have time-sensitive needs for the registry data. Sharing incomplete data may carry negative consequences, for example, patient case counts and wait time reporting being inaccurate. Up-to-date and timely data helps to ensure that any data request can be fulfilled quickly and with confidence.

Before month end, CorHealth sends a reminder to Registry users about completing all records entered into the Registry. Guidelines around quality data entry are reinforced in this Data Standards document. The dimensions of data quality are also reflected in the report cards that are distributed monthly.

## IX Reporting and Analytics (Under development)

## X CCN Help Desk

The CCN Help Desk provides support to all Registry users. Any questions regarding data entry and extraction or technical issues with the Registry are directed to the help desk which ensures that questions and issues are handled properly and consistently. All questions received are logged and reviewed for recurring themes and issues which are then addressed systematically by the CCN team.

The CCN helpdesk can be reached Monday to Friday 9:00am-5:00pm by:

Telephone: 416-512-7472

Email: <u>help@ccn.on.ca</u>

#### **XI** Appendices

- 1. CCN Cardiac Wait Times Patient Triage
- 2. Figures A-D; F-L: Clinical Pathways
- 3. Figure E. Algorithm for Cardiac Procedure Referral and Data Entry Management
- 4. <u>Cardiac Data Dictionary</u>
- 5. TAVI Data Dictionary
- 6. Vascular Data Dictionary



- 7. STS Data Dictionary
- 8. STS Adult Cardiac Surgery Database Training Manual
- 9. Glossary of Terms



#### Figure A. Stable Coronary Artery Disease (CAD) Clinical Pathway<sup>16</sup>

<sup>&</sup>lt;sup>16</sup> Cardiac Care Network of Ontario (CCN) & Ministry of Health and Long Term Care (March 2016). Quality-Based Procedures Clinical Handbook for Coronary Artery Disease. Toronto: CCN.





### Figure B. Acute Coronary Syndrome (ACS – NSTEMI) Clinical Pathway<sup>16</sup>

\* CICU = Cardiac Intensive Care Unit; IABP = Intra-Aortic Balloon Pump





#### Figure C. Acute Coronary Syndrome (ACS) – STEMI Clinical Pathway<sup>16</sup>

\*\*\*\*IMPORTANT: The STEMI patients who are discharged home with arrangements for an outpatient scheduled/staged PCI should be reclassified as stable angina patients.

**Note:** STEMI pathway includes post cardiac arrest and cardiogenic shock patients (with or without STEMI). STEMIs with or without an event are admitted to CICU. An event is any cath/PCI with heart failure, cardiac arrest, cardiac tamponade, transfusion for bleeding, etc.; with or without IABP\*, ventilator, inotropes, temp pacer, mechanical circulatory support, dialysis, etc.

\* CICU = Cardiac Intensive Care Unit; IABP = Intra-Aortic Balloon Pump





## Figure D. Isolated Coronary Artery Bypass Graft (CABG) Clinical Pathway<sup>16</sup>

a. New or re-CABG on/off CPB\* with or without IABP\*, dialysis, inotropes, etc. b. Patient may require transfer to a convalescent or long-term care facility. \* CVICU = Cardiovascular Intensive Care Unit; CPB = Cardio-Pulmonary Bypass; IABP = Intra-Aortic Balloon Pump





Figure E. Cardiac Procedure Referral and Data Entry Management





Figure F. Isolated Surgical Aortic Valve Replacement (SAVR) Clinical Pathway<sup>17</sup>

AS = Aortic Stenosis; BAV = Balloon Aortic Valvuloplasty; CVICU = Cardiovascular Intensive Care Unit

<sup>&</sup>lt;sup>17</sup> Cardiac Care Network of Ontario (CCN) & Ministry of Health and Long Term Care (March 2016). Quality-Based Procedures Clinical Handbook for Aortic Valve Disease. Toronto: CCN.





## Figure G. Surgical AVR with CABG Clinical Pathway<sup>17</sup>

a. Includes a small number of aortic valve repairs.

b. Valve prosthesis may be mechanical, biological, or sutureless. Patients may need long-term anticoagulation requiring longer hospital stay, i.e., due to arrhythmia (e.g. atrial fibrillation) and/or valve prosthesis.

c. Patient may require transfer to a convalescent or long-term care facility.

\* CVICU = Cardiovascular Intensive Care Unit





## Figure H. Transcatheter Aortic Valve Implantation (TAVI) Clinical Pathway<sup>17</sup>

a. Patient may require transfer to a convalescent or long-term care facility.

Note: PCI or BAV\* may also be performed at any time prior to completion of the TAVI procedure.

\* AS = Aortic Stenosis; CICU = Cardiac Intensive Care Unit; CVICU = Cardiovascular Intensive Care Unit; BAV = Balloon Aortic Valvuloplasty





#### Figure I. Asymptomatic Aortic Aneurysm Repair Clinical Pathway<sup>18</sup>

<sup>&</sup>lt;sup>18</sup> Cardiac Care Network of Ontario (CCN) & Ministry of Health and Long Term Care (MOHLTC). (April 2016). Quality Based Procedures Clinical Handbook for Repair of Aortic Aneurysm. Toronto: CCN.





#### Figure J. Symptomatic Aortic Aneurysm Repair Clinical Pathway<sup>18</sup>



#### Figure K. Claudication (Stable) Lower Extremity Occlusive Disease Clinical Pathway<sup>19</sup>

<sup>&</sup>lt;sup>19</sup> Cardiac Care Network of Ontario (CCN) & Ministry of Health and Long Term Care (MOHLTC). (April 2016). Quality Based Procedures Clinical Handbook for Repair of Lower Extremity Occlusive Disease. Toronto: CCN.





#### Figure L. Critical Limb Ischemia (Unstable) Lower Extremity Occlusive Disease Clinical Pathway<sup>19</sup>

- 1. Patients with severe symptoms (excluding trauma patients): critical limb ischemia, embolus, severe pain, or gangrenous changes.
- 2. Ancillary foot surgery includes: toe or foot amputation, and foot debridement.
- 3. Location of lesion determined: aortoiliac or infrainguinal as defined in the LEOD Quality-Based Procedures (QBP) Clinical Handbook.
- 4. Selection of intervention approach (surgical or open vs endovascular) is based on patient characteristics, clinical judgement and an informed patient decision.
- 5. Other location may include repatriation to another hospital or transfer to a long-term care facility or complex care facility.

6. Patient seen at one month post-procedure for a clinical evaluation by the most responsible physician.

7. Vascular Specialists are medical, surgical or radiologic specialists with specialty specific training and expertise in the diagnosis and medical, percutaneous and surgical management of patients with vascular disease. This term does not currently represent a separate certification status by the Royal College of Physicians and Surgeons of Canada.