INTerventional Cardiac Services
Needs Assessment and Options Analysis
Overview

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EXECUTIVE SUMMARY

The Needs Assessment and Options Analysis, is the result of a joint project of Alberta Health (AH) and Alberta Health Services (AHS), that utilized a coordinated and evidence-based approach to assess (through review of the literature, best practices and data) options for the future provision of interventional cardiac services within Alberta. This work was completed under the guidance of the Interventional Cardiac Services (ICS) Oversight Committee which included clinical and operational stakeholders from across Alberta along with patients/family advisors (see Appendix).

Public Health Agency of Canada publications (2017)\(^1\) state that, in Canada, heart disease is the second leading cause of death. The good news is that over a ten-year period from 2000/01 to 2012/13, the number of Canadian adults newly diagnosed with heart disease declined from 221,800 to 158,700 and the death rate, or the number of deaths per 1,000 individuals with a known heart disease decreased by 23%. The early detection and management of medical conditions such as high blood pressure, diabetes and high cholesterol reduces risk of heart disease. Mounting evidence suggests that early intervention in managing the cardiovascular risk factors is more important than treating the cardiovascular disease (CVD) itself. CVD complications take years to develop, therefore, this affords ample time for early intervention and treatment of the various cardiovascular risk factors\(^2\).

What has become apparent through this needs assessment process is that there is no one right way to provide specialty cardiac care. Evidence suggests that primary Percutaneous Coronary Intervention (pPCI), when it can be delivered under very specific conditions and received within 120 minutes of the onset of symptoms may reduce mortality from AMI. Indeed, the 2006 Swedish Registry study\(^3\) concluded significantly better outcomes for primary PCI versus a pharmaco-invasive strategy and current clinical consensus supports that primary PCI is the preferred strategy provided it can be performed expeditiously within the 120-minute window. The vast geography of Alberta presents a significant challenge to delivering high quality pPCI within this window. This challenge not only presents itself in our rural areas, but also in our increasingly sprawling and traffic congested urban centres. The current approach in areas outside of the 120-minute corridor is to administer fibrinolytics followed, in select cases, by PCI after transfer to Calgary or Edmonton. The evidence, however, may be changing with some recent evidence suggesting that benefits of pPCI may not be as significant as once thought when compared to the alternative of lower dose fibrinolytics, transfer then PCI. A very recent (September, 2017) randomized control trial found that a pharmaco-invasive strategy with a PCI delay did not result in inferior outcomes (including 30-day mortality) than a primary PCI strategy with the former actually resulted in superior restoration of blood vessel flow\(^4\). Several additional recent studies (though not randomized control) also report clinical outcomes up to a 5-years that show few if any differences between a pharmaco-invasive strategy and a primary PCI Strategy. In addition, the Calgary experience in moving from fibrinolytic therapy

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to primary PCI also found only a small 1% improvement in mortality rates. While mortality rates may not be significantly impacted, experience in Calgary and Edmonton suggests that primary PCI patients have a shorter length of stay than those receiving fibrinolytic therapy followed by PCI (approximately 1 day).

The above evidence focuses on a particular type of heart attack (STEMI). The absence of ST-segment elevation (n-STEMI) is currently understood to require a less immediate need for invasive restoration of blood flow. There is considerable discussion in the literature about the optimum approach for treatment of n-STEMI patients, with differing conclusions and uncertainty regarding the long-term benefits. In n-STEMI patients there continues to be debate whether early/urgent/immediate cardiac catheterization and restoring blood flow to the heart muscle is beneficial compared to a more selective invasive and conservative approach. Early intervention has the potential to prevent further events during the time from event to the restoration of blood flow. Conversely, a delayed intervention may help avoid procedure-related complications. More recent studies have been more supportive of the early invasive strategy for n-STEMI patients.

The appropriateness of interventional cardiac interventions has been a major topic of investigation around the world, in part driven by the volumes and cost of PCI. This has led some to conclude that there will always be inadequate evidence, disagreement among experts, and new research rendering current knowledge obsolete, which makes it difficult to assess appropriateness of implementation in new settings based on patient outcome evidence.

The ICS Oversight Committee met on September 21, 2017 to review data, identify foundational elements that would need to be in place prior to implementation of a catheterization lab and to identify and evaluate options for consideration. Foundational elements identified include strong primary and secondary prevention, zone-wide access to cardiac rehabilitation, better support for transitions of care, and a quality improvement strategy (see page 7 for a complete list). Based on the needs assessment, potential volumes and existing personnel, only two sites (Red Deer and Lethbridge) would be in a current state of readiness to fully proceed with the development of the ICS foundational requirements prior to full ICS implementation.

Data indicate that reducing the incidence in AMI would result in significantly greater improvements in AMI mortality than those that would result from access to local PCI. The outcome evidence suggests that the availability of catheterization and primary PCI capability alone would have marginal impacts on patient outcomes in comparison to the current pharmaco-invasive alternative. While the direct impact of enhancing coverage of interventional cardiac services on patient outcomes is likely quite small, some believe that the indirect benefits include an enhanced ability to support strong cardiac care teams and access to more comprehensive cardiac services in and around regional centres. These benefits can be realized as foundational elements are established or strengthened.

Notwithstanding the outcome evidence, there is a stronger argument to be made for cardiac catheterization and PCI availability in our regional centres to improve access and the patient experience. Adding catheterization diagnostic capability could mean an additional 8-10% of residents have access closer to home in areas surrounding Red Deer and Lethbridge. Adding PCI capacity (considered clinical standard) would increase the percentage receiving care within recommended protocols by 5.4% and 3.7% in Red Deer and Lethbridge respectively.

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A summary of the methodology, the needs assessment findings, the options analysis and a high level next steps roadmap are provided below.

**METHODOLOGY**

The project methodology had multiple components that were synthesized together as guided by the key principles articulated within the Quadruple Aim. These included a focus on a) improving the health of the population, b) improving the patient experience, c) decreasing the per capita cost of health care; and d) improving the work life of health care clinicians. The methodology included:

- Review of published literature
- Review of recognized standards, guidelines and Accreditation requirements
- Review of previous internal reports
- Exploration of approaches used in British Columbia and Ontario
- Key informant discussions
- Patient focus groups
- Data collection, validation and analysis
- Capital costing and an assessment of space availability
- System costing and financial analysis.

The ICS Oversight Committee was struck to provide oversight to the planning process, with broad representation from the regional facilities and urban zones (clinical and administrative).

**NEEDS ASSESSMENT OVERVIEW**

The needs assessment focused on patient perspectives, clinician perspectives, examination of variation in patient outcomes (mortality and morbidity) across the province, assessment of estimated volumes to support stand-alone catheterization labs and the financial implications of doing so. Summarized below are the key findings.

**Patient & Family Member Perspective:**

Patients largely focused on receiving care closer to home and better transitions of care and access to follow-up care. An important rationale for a stand-alone PCI lab expressed by some patients, family members and AHS operational leaders is the burden placed on patients when having to travel to access care. Patients and family members emphasize that the travel for care happens at a time when patients are not only physically vulnerable but also emotionally vulnerable due to the shock of their diagnosis and/or confrontation with a potentially life-threatening event. This is a time when patients are in most need of support from family. Improving access to services for patients also decreases the financial and quality of life burden on patients. In addition to the financial burden, participants in this needs assessment also identified a social cost to families when services are accessed at a significant distance from home.

Patients and family members are of the opinion that there is a need to:

- Increase access for all Albertans and to invest in rural communities.
- Build a stronger emphasis on pre- and post-interventional services and on communication in rural areas.
- Enhance transitions of care and follow up care particularly in rural areas.
- Be more responsive to the needs of all Albertans – not just those living in the major urban centres.
• Build capacity for more specialized health care for rural Albertans (including interventional cardiac labs) to bring care closer to the patient and reduce travel.
• Build capacity for more specialized health care for rural Albertans to increase confidence in health service quality in these centres.
• Be mindful that population growth is occurring outside of the two large urban centres.

Clinicians’ Perspective:

Clinical representatives agreed that improvement in patient outcomes is an important driver underpinning any recommendation to establish Interventional Cardiac Services in a regional centre. Some clinical representatives on this project, however, felt that potential effects on patient outcomes is, in their view, not the primary driver for establishing interventional services in regional centres. These representatives suggested that local access to Catheterization and PCI is justified based on improved patient experience, accessibility (i.e., reduced travel and wait times) and the availability of other enhanced services that come with the establishment of a PCI. Other clinical representatives either on Oversight or interviewed as key stakeholders maintain that the preponderance of evidence supports primary PCI as the gold standard of care and that the effects on patient outcomes may be understated in this needs assessment. Notwithstanding this area of disagreement, Clinicians are of the shared opinion that there is a need to:

• Provide more equitable access to the current accepted standard of care (primary PCI) closer to home.
• Enhance the quality of cardiac care in regional hospital facilities and local confidence in care quality.
• Make it easier to recruit or retain cardiologists by offering cardiac interventional services at regional sites.
• Enhance cardiac care capacity to raise the standard of care for all patients and support local clinical consultative services.

Patient Outcomes Evidence:

Variation in mortality and morbidity rates across the province identified the areas of greatest need for improving the cardiac care continuum of services. The data indicate the greatest potential need for:

• Primary and secondary prevention (as indicated by increased AMI incidence and mortality rates) in North Zone, Central Zone, followed by South Zone.
• Stronger transitions of care following an AMI (as indicated by the percentage of individuals progressing to heart failure within 2-years) in Central Zone and other localized areas across the province.
• Stronger foundational cardiac care including cardiac rehabilitation (as indicated by mortality rates following partial artery blockage) in the North Zone, Central Zone and South Zone.
• A standardized approach to the administration of the fibrinolytics and transport protocol in the South Zone and Central Zone.

Patient outcome evidence suggests that the availability of catheterization and primary PCI capability alone would have marginal impacts on patient outcomes in comparison to the pharmaco-invasive strategy. Stronger cardiac care programs overall, including the building of foundational services where they can be well supported would provide more opportunities to affect better outcomes in our regional centres. The evidence that Interventional cardiac services (e.g., Catheterization and PCI capability) that goes beyond primary prevention, secondary prevention and other foundational elements in the South Zone and Central Zone remains in question with recent evidence suggesting that a pharmaco-invasive strategy with a PCI delay may not result in inferior outcomes than a primary PCI strategy. A summary of estimated effects of strategies to reduce heart attack mortality is found in the Figure A below.

As indicated in this figure it is estimated that, in Central Zone for example, approximately 20 lives per year could be saved through stronger primary and secondary prevention, 7 lives per year through enhancement...
to existing cardiac programming, and approximately 1 per year through more specialized availability of Catheterization and primary PCI services.

Figure A - Estimated Effects of Interventions for Reducing Heart Attack Mortality in Rural Zones: Number of heart attack deaths per year

Access and Critical Mass Evidence:

An annual minimum standard of 150 PCI cases/operator and 400-450 cases/ interventional cardiac lab was set as the minimum threshold for a stand-alone PCI lab. A stand-alone lab is an interventional cardiac lab, but it is situated in a hospital facility without cardiac surgery back-up. Only two regional hospital sites have sufficient estimated volumes to support a stand-alone PCI lab, that being Red Deer and Lethbridge. Currently 68.2% of the Alberta population 40+ years of age appropriate for pPCI is currently served within the distance recommended by protocols. This percentage would increase by 5.4% and 3.7% if capacity was added in Red Dear and Lethbridge respectively. Currently, wait times for all cardiac interventional services are within acceptable benchmarks and residents of rural zones do not experience longer wait times than residents of Calgary and Edmonton zones. Median wait-times for less urgent outpatient services currently range between 13-14 days for those accessing services in Calgary and 24-29 days for those accessing services in Edmonton. Additional capacity would presumably reduce these wait times.

In Alberta there are approximately 5000 hospitalized AMI events (37% STEMI and 62% n-STEMI) and just over 900 hospitalized cases of unstable angina. In the vast majority of these cases as well as others (e.g., abnormal stress tests, new onset heart failure, some cardiac dangerous cardiac arrhythmia) cardiac catheterization is used to diagnose and plan treatment. There were just over 9300 cardiac catheterizations performed in Alberta in 2016-17. If diagnostic catheterizations were offered in both Red
Deer and Lethbridge, approximately 8-10% patients surrounding each site would receive this diagnostic procedure closer to home.

Based on criteria set by Canadian Cardiovascular Society, cardiac catheterization could presently be supported in both Red Deer and Lethbridge. These volumes are supported by heart attack patients, (both STEMI and n-STEMI), as well other non-acute coronary syndrome patients that would benefit from this important diagnostic procedure.

**Financial Implications:**

In this phase of the work, costing analyses focused on the costs of establishing catheterization and PCI capabilities in regional centres with a two lab set-up per site. Capital costs are estimated at $19.0-$21.5M and annual operating costs of $7.0-$8.5M in those centres with estimated volumes sufficient to support PCI capabilities. These costs do not include the costs of developing and ensuring foundational elements that are in place. Validating and completing this cost assessment is an important next step towards foundational and ICS planning and implementation.

**OPTIONS ANALYSIS OVERVIEW**

The option of continuing the current provincial models of service was not considered viable by the Oversight Committee. Two viable options were identified by the ICS Oversight Committee based on the review of data and criteria developed in advance to inform the decision process.

- **Option 1** – Cardiac Care foundational services in all five regional centres including diagnostics with a focus on primary and secondary prevention including cardiac rehabilitation and improving transitions of care. This option would not include implementation of peripheral catheterization labs at this time.
- **Option 2** – Foundational elements developed plus additional peripheral cardiac catheterization lab(s) in other locations: Phased in implementation of Cardiac Catheterization in regional site(s) that meet the minimum volume thresholds adopted. Both Red Deer Regional Hospital and Chinook Regional Hospital (Lethbridge) could meet minimal volumes currently (Red Deer) or by 2020 (Lethbridge). Includes primary, secondary and transitions of care built in as foundational elements.

ICS Oversight Committee members felt the higher incidence of acute myocardial infarction (AMI) and related mortality rates in the rural zones compared with Edmonton and Calgary Zones requires further interventions to improve health equity of Albertans. The Oversight Committee was largely split on the two options and expressed views as below:

- **Proponents of Option 1** believe this option would result in significant benefit to patient health outcomes, greater equity (health and healthcare) for more Albertans (greater number of Albertans would benefit compared to adding one or two additional interventional labs) and believe only marginal impacts on patient health outcomes would be realized if the focus was on PCI capacity in regional centres. Proponents of this option feel the cost of building this capacity could be better spent in other areas to promote better cardiac care. Proponents of Option 1 also believe that a focus on transitions of care would support the greatest opportunity for improving patient experience and follow-up care and was expressed as a significant need by patient/family focus group participants at most sites.

- **Proponents of Option 2** believe primary PCI is the accepted standard of care and its availability in the regional centres under consideration will achieve better health outcomes. Proponents of Option 2 also
believe the value of PCI capability in regional centres goes beyond direct effects on patient health outcomes directly related to PCI. This includes care closer to home, enhanced patient access, and ability to recruit cardiologists and other medical specialists to enhance cardiac care overall through enhancements of services that would accompany this interventional capacity.

**Foundational Elements:**

The ICS Committee was in agreement that specific elements of cardiac care are foundational to the establishment of an interventional cardiac program. Foundational elements identified as pre-requisites needing to be in place within a zone, before seeking approval in concept to open an interventional cardiac lab, include:

- Strong primary prevention programs. Adoption of health life habits remains the cornerstone of primary prevention including the avoidance of tobacco (including second hand smoke), healthy dietary patterns, weight control and regular appropriate exercise. An important role of health care providers including primary care teams (e.g., Primary Care Networks) is to support and reinforce these public health recommendations for all patients. A zone-wide approach to the management of patients with acute coronary syndrome, including the appropriate use of fibrinolytics and compliance with all cardiac clinical guidelines and care pathways.
- Comprehensive cardiac outpatient services for the diagnosis and secondary prevention services for patients with coronary artery disease.
- Zone-wide cardiac rehabilitation capabilities.
- A plan to actively engage patients in their recovery by providing clear information on care pre-procedures, what to expect during and after procedures, and supportive discharge information.
- Mechanisms to enhance transitions of care for patients being repatriated back to their home community and/or upon discharge, regardless of where procedures are performed.
- A comprehensive quality improvement strategy to assess performance of the overall cardiac care program to ensure quality outcomes.
- Support from Diagnostic Imaging for other imaging testing requirements needed to support the specialty cardiac patient.

Additional foundational elements and associated phasing were identified for the business planning and approval phase for a stand-alone PCI lab, and for the pre-implementation phase. These elements are outlined in greater detail in the supplementary technical document to this report.

**Important Considerations:**

- The broad geography in Alberta, coupled with the challenges of weather, affect the availability of PCI, so by necessity, the current provincial approach is a combination of primary PCI and fibrinolysis; this will need to continue. This is characteristic of all Canadian provinces.
- The evidence collected for this project indicates a potential in reducing mortality rates through strong primary and secondary prevention strategies. A strong foundation of cardiac care will positively impact outcomes by reducing the number of AMI events; reducing events will also reduce mortality rates.
- Current clinical guidelines recommend primary PCI, performed within the recommended timelines (i.e., 120 minutes between symptom onset and procedure), should constitute the default strategy for patients that experience a complete blockage in a coronary artery, as it offers the best chance to reopen the blocked vessel, without increasing the risk of hemorrhagic stroke. The pharmaco-invasive (fibrinolysis) strategy, however, is a valid alternative when seen early after the onset of symptoms and when the time to primary PCI is likely to exceed the limits suggested in the guidelines.
• The Calgary experience in moving from fibrinolytic therapy to primary PCI found a small 1% improvement in mortality rates. Recent literature indicates that changing from the current alternate approach (fibrinolytic therapy followed by PCI) to primary PCI results in few differences in outcomes, though the evidence is not definitive.
• Given the expected learning curve associated with establishing stand-alone PCI unit, it is expected that a progression of capacity and skill sets may take several years to avoid mortality risks. In Ontario, for example, PCI capability was enhanced following catheterization capacity was already established. Significant training and mentorship opportunities need to be implemented to build an effective team over time.
• In Alberta, there is not strong evidence to support that driving distance to PCI is a significant contributor to AMI in-hospital mortality rates, but there is evidence of increased AMI emergency department mortality as a function of driving time to PCI. It is uncertain at this time as to whether this is due to driving time, the variation in the use and timing of fibrinolytic therapy, or the practice of transporting to a regional hospital prior to being transported to Calgary or Edmonton.
• Enhancing foundational cardiac services in all three rural zones would result in benefit to patient health outcomes, and greater equity (health and healthcare) for more Albertans.
• Both options under consideration would have direct and indirect benefits on patient care. The option that includes the building of a standardized catheterization lab may better enable recruitment of cardiologists in regional centres and promote care closer to home.
• There is a need to enhance transitions of care, regardless of option chosen.
• More detailed plans and budget estimates would be required to proceed to establishing the foundational cardiac care elements identified in this report. Subsequent plans and more detailed budget estimates would also be required before proceeding to a subsequent stage of Catheterization and PCI implementation in Red Deer and Lethbridge.
• As AHS budgets are not anticipated to exceed increases associated with expected rates of population growth and aging, identification of services that are recommended be stopped or slowed will need to be part of the next stages of planning.
• As AHS is committed to enhancing care in the community, all enhancements considered need to align with new service models that best promote this strategic objective.

KEY LIMITATIONS

There are important limitations to the needs assessment work that should be highlighted. These include:

• An absence of literature examining interventional cardiac services effects on patient outcomes in rural settings. The patient outcome effects cited are largely drawn from the urban context.
• The costing analyses was based on average estimated capital and implementation costs in our regional centres. These costs may vary at the individual site level based upon existing space or service provision. A deeper costing assessment is recommended at each site if a decision is made in support of developing a full business case for Catheterization Lab implementation.
• The needs assessment focused on the outcome implications of catheterization lab and PCI enhancements on patients with Acute Coronary Syndrome. There are likely additional outcome benefits to implementing catheterization lab diagnostics outside of this patient population that were not fully explored in this needs assessment.
CONCLUSION AND NEXT STEPS ROADMAP

The Oversight Committee was largely split on the two options described in a previous section. (see page 6) The Oversight Committee was unable to reach a consensus on whether or not to recommend implementation of Catheterization Lab services in Lethbridge or Red Deer.

The ICS needs assessment and options analyses has provided significant insights into the disparity in AMI incidence and related population outcomes across the province and the evolving evidence for treatment of AMI. At this point, the outcome evidence in comparing the effectiveness of primary PCI versus the alternative of fibronolitics, transfer then PCI is not definitive. Indeed, most recent evidence suggests outcomes may be equivalent and may actually favour a pharmaco-invasive strategy with delayed PCI. Experience in Calgary and Edmonton, however, does suggest that primary PCI patients have a shorter length of stay than those receiving fibrinolytic therapy followed by PCI (approximately 1 day).

Primary PCI is currently considered the preferred standard of care. The relative benefit of primary PCI in comparison to newer alternatives (e.g., a lower dose pharmaco-invasive strategy with delayed PCI) requires further research, discussion and consensus. Less controversial is the conclusion that catheterization diagnostic capacity and PCI capacity in our regional centres will enable access closer to home, improve the patient experience and local resident’s confidence with the quality of care available in our regional centres. Also less controversial, is the identified need to build stronger, and more equitable access to foundational cardiac services in our rural zones.

Though there was no consensus on whether or not to introduce Catheterization Labs in Lethbridge and Red Deer, the following planning and implementation roadmap is recommended:

Phase I:

1. Conduct gap analyses and costing to implement foundational cardiac services. The foundational elements have been identified. It is recommended that Central, South and North Zone Leadership each undertake the following:
   a. Conduct gap analyses identifying foundational elements currently in place and the additional personnel and programming infrastructure required.
   b. Provide high level costing of gap requirements and high-level timelines for implementation.
   c. Identify potential funding sources and requirements with AHS Finance for 2018-19 budget planning.
   d. Develop engagement plan to work with Primary Care Networks and other key stakeholders to identify the most effective primary and secondary prevention strategies that can be implemented within each Zone.
   • While North Zone may not be in a state of readiness to build all foundational elements, it is recommended that North Zone also conduct similar planning work to enhance services to optimize patient outcomes within existing constraints.
Phase II:

1. Develop cardiac service foundations implementation plan:
   a. Central, South and North Zone leadership develop foundations implementation plans to include:
      i. Detailed implementation activities and timelines including required work with Zone Primary Care Networks
      ii. Detailed operational costing and identification of funding sources
      iii. Recruitment and training plans
      iv. Anticipated timelines for foundations implementation
   b. Present proposed plans for implementation of services to fill remaining gaps in foundational cardiac services to AHS ELT and to Alberta Health

Phase III:

1. Zone cardiac services foundations implementation
   a. Central, South Zones and North Zones implement foundational cardiac services improvements.
2. SCN/South Sector Implementation of Vital Heart Response Program.
   a. This program has been implemented in North Zone, Edmonton Zone and parts of Central Zone. It provides a coordinating function for the care of STEMI patients, particularly related to the administration of the fibrinolytics protocol and transport to an appropriate centre.

Phase IV - Planning for Option 2-upon decision to proceed:

1. ICS Implementation Planning:
   a. Central and South Zones develop full ICS implementation Plans including:
      i. Master Planning to support capital needs in Lethbridge and Red Deer
      ii. Identification of Capital funding sources including Foundation contributions
      iii. Detailed capital plans and timelines for construction
      iv. Identification of diagnostic imaging requirements and implementation timelines
      v. Detailed implementation activities and timelines
      vi. Detailed operational costing and identification of operational funding sources with AHS Finance for 2019-2020 and beyond forecasting
      vii. Recruitment and training plans including mentorship arrangements
Appendix 1 – Interventional Cardiac Services - Governance and Support

Executive Sponsors
- Dr. Ted Braun, VP & Medical Director, Central & Southern Alberta
- Deb Gordon, VP & Chief Health Operations Officer, Northern Alberta
- Sohaib Khalid, ADM Health Standards, Quality and Performance (HSQP), Alberta Health

Project Oversight Committee
- Tom Briggs, AHS Planning & Performance (co-chair)
- Sherri Kashuba, Alberta Health, Health System Planning (co-chair) (replaced by Jonathan Kim)
- Shelley Valaire, AHS Cardiovascular Health & Stroke Strategic Clinical Network
- Dr. Todd Anderson - Clinical Lead – Cardiology & Internal Medicine, Calgary Zone
- Robert Stratychuk – Patient Advisor, South Zone
- Donna Leontowicz, Patient Advisor, Central Zone
- Allan Sinclair – Executive Director, Red Deer Hospital
- Dr. Colm Murphy, Red Deer Cardiologist
- Dr. Sayeh Zielke, Lethbridge Cardiologist
- Dr. Yolande Westra, Area 9 &QEI ZZCFC Internal Medicine (replaced by Dr. Tafi Madzimure)
- Mishaela Houle, Executive Director, Cardiac Sciences, Edmonton
- Andy Chuck – AHS Financial Planning (Health economist)

Project Manager and Lead
- Brenda Fischer – Consultant

Project Support Team
- Jeannette Lawrence – Sr. Practice Consultant SCN
- Colleen Norris – Scientific Director CvHS SCN
- Olexsandr Shlakhter – Analyst (Analytics)
- Diane Galbraith, APPROACH
- Lisa Pilon – Finance, Case Costing
- Alka Patel –GIS Support
- Capital Costing Support – Janette Gescher, Director Strategic Capital Planning
- Stafford Dean – Chief Analytics Officer, AHS
- Dee-Jay King – Executive Director, Health Economics & Funding, AH

Additional Expert Advisors
- Dr. William Hui - Cardiology, Internal Medicine
- Dr. Paul Armstrong – Professor & Director, Department of Medicine, Division of Cardiology
- Dr. Christopher McCabe - Executive Director & CEO, IHE