



# THE SCN-MEDEC INITIATIVE

## A SYSTEMS APPROACH IN THE MANAGEMENT OF HEALTH TECHNOLOGY

**PART 1:** NECESSITY, DESIGN & APPROACH

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Hameed Khan

Blair J O'Neill

Robert Rauscher

Stephen Urquhart

Ulrich Wolfaardt





# EXECUTIVE SUMMARY

Providing high quality care within existing resources is a continual challenge for all health care systems; one that must be overcome to ensure sustainability. Innovative medical technologies can support the aim of health care system sustainability but only if actualized through a deliberate systems management approach; that leverages the value that innovative technology offers by identifying and addressing multiple perspectives concurrently – patient, clinical, system, fiscal and risk.

The health system and the medical technology industry in Canada have historically assumed opposing perspectives surrounding the introduction of innovative medical technologies. Publicly funded systems have limited resources and must maximize health benefit achieved per dollar invested at the lowest cost (price). The industry perspective for medical device technology development also seeks to maximize the value of health technologies. The term value in this case would primarily consider three perspectives: cost, improving patient outcomes and system optimization. Three organizations – Alberta Health Services through its Strategic Clinical Networks™ (SCNs), Alberta Innovates (AI) and MEDEC - partnered around these competing objectives, identifying high value technologies that promote needs based adoption and management within Alberta's Health System. The SCNs are viewed as engines of innovation within the Alberta's Health System, changing the paradigm from external push into the system to a demand-pull model. The SCN membership is multidisciplinary in nature, representing multiple perspectives across the entire patient care continuum. Currently, there are 14 SCNs each based on a specific burden of disease (e.g. Cancer, Cardiovascular Health and Stroke), populations of interest (e.g. Seniors, Maternal, Newborn, Child & Youth) or high cost service areas (e.g. Surgery, Critical Care).

Rallying around the concept of a zero-sum gain environment, and a system management

approach to the planned introduction (and exiting) of medical technologies, it becomes possible to define, measure and validate the true value that an innovative medical technology can offer clinicians, patients; and ultimately, the health care system, based on a three-part Value for Money framework that can be scaled to the scope and complexity of a project.

Based on the identified expressed needs of the SCNs, Alberta Innovates (AI) and MEDEC developed a process that paired potential existing solutions (i.e. health technology innovations) to those needs and then co-developed programs to validate them in a real-world setting within Alberta. The evidence generated from this process will inform the decisions pertaining to adoption and diffusion of these solutions throughout the system. A total of sixteen proposals were received from a variety of large and small companies, from which industry partners with the best aligned proposed solution were selected. The SCN and industry partner(s) jointly completed a needs-based business case template that required content pertaining to various components of what are known as “demonstration projects” including: (A) Business & Operational Impacts, (B) Project Risk Assessment, (C) Implementation Strategy, (D) Evaluation Strategy, and (E) Resources & ROI.

The rapid expansion and evolution of innovative solutions requires a similar momentum to develop the process in which to evaluate the technology, assess system readiness, understand system impacts, and gather evidence for decision making to procure the new solution while identifying disinvestment opportunities and managing scale and spread through change management strategies. This process and the stakeholders involved have demonstrated this innovative approach and achieved initial success in linking needs to outcomes.



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# INTRODUCTION TO ALBERTA'S HEALTH CARE ECOSYSTEM

In Canada, publicly funded health systems are a provincial government responsibility. Each of the ten Canadian provinces and three territories operate independent health care systems that primarily serve the population of that province. According to the Canadian Institute for Health Information, approximately 40% of provincial budgets are earmarked for health care. With an aging population and healthcare spending on the rise, providing high quality care within existing resources is a continual challenge for all provinces – one that must be overcome to achieve sustainable health care systems while continuing to introduce new technological innovation across Canada. Moving to whole system value of innovative solutions – people, product & process – is essential to achieving sustainability.

In most cases, multiple autonomous health care systems exist within each Canadian province. They are managed independently but all are funded by the provincial government. With over 108,000 employees, including more than 9,000 physicians, Alberta Health Services (AHS) is Canada's largest province-wide, fully integrated health authority system, responsible for delivering health services to over four million people living in the province of

Alberta. To develop and implement strategies to improve care across the province while bending the cost of care curve downwards, AHS established Strategic Clinical Networks™ (SCNs), which are provincial structures organized around populations (e.g. Seniors, Maternal, Infant, Indigenous) large disease burdens (e.g. Cancer, Cardiovascular) or high cost service areas (Surgery, Critical Care) to serve as a vehicle for research, knowledge translation and innovation in the health system. The SCNs are comprised of multidisciplinary teams and patient members that embed research initiatives and knowledge translation activities; they have a mandate to design and recommend improvement plans that will drive the achievement of targeted, measurable, and sustainable clinical and operational improvements in health and health care service delivery in targeted populations within Alberta. The SCN structure can be viewed as a built-in incubator within the health system where novel ideas and products can be validated to provide evidence of value for money in the health system. Given appropriate evidentiary thresholds, the key opinion leaders within the networks support the diffusion of these findings across the system, driving scale and spread of the innovation. To date, there are 14 SCNs established.

**Table 1 - Fourteen Strategic Clinical Networks – As of December 2016**

- |                                    |   |
|------------------------------------|---|
| 1. Diabetes, Obesity and Nutrition | 8. Critical Care                            |
| 2. Seniors Health                  | 9. Surgery                                  |
| 3. Bone & Joint Health             | 10. Respiratory Health                      |
| 4. Cardiovascular Health & Stroke  | 11. Maternal, Newborn, Child & Youth Health |
| 5. Cancer                          | 12. Population, Aboriginal & Public Health  |
| 6. Addiction & Mental Health       | 13. Kidney Health                           |
| 7. Emergency                       | 14. Digestive Health                        |

In addition to AHS and the SCNs, Alberta Innovates (AI) provides a critical function of supporting health innovation. AI is an independent provincial government agency that supports cutting-edge research and innovation in Alberta. Working with AHS, AI ensures that research achieves innovation in care, policy and practice, and that the needs of patients and clinicians influence research. AI also develops novel mechanisms to fund projects that facilitate the acceleration of innovation into practice.

This publication is part one of a two-part series that describes the challenges with the current HTA and procurement approach to assessing and purchasing medical devices within Canadian

healthcare systems and the barriers it creates to advance innovation to improve patient outcomes. The most salient consequence of these challenges is often represented by reduced system capacity to adopt the new innovative technologies for the health system. In addition, this publication highlights the partnership based initiative in Alberta that brings together key stakeholders from the health care ecosystem to address these challenges and the introduction of an innovative complementary approach to the existing system. Part 2 of this series will focus on lessons learned from the implementation of this approach, change management, and the ability of real-world evidence to inform decisions.





# ADOPTING INNOVATION: STATUS QUO

The health system and the medical technology industry in Canada have historically assumed opposing perspectives surrounding the introduction of innovative medical technologies. Publicly funded systems have limited resources and must maximize health benefit achieved per dollar invested. That is, health systems are required to maximize the value of money associated with the scarcity imposed by a fixed budget environment. However, in practice health systems often rely on procurement processes as a lever to reduce cost. These procurement practices are arguably misaligned with innovation as the tendency is to focus on lowest acquisition cost, which can obscure value associated with novel and breakthrough interventions. Focusing exclusively on acquisition cost as a decision lever for novel technologies may paradoxically lead to increased system costs. Specifically, acquisition cost represents a single dimension of health technology impact. Additional dimensions of performance include clinical effectiveness and operational efficiency. Therefore, technology A may have a greater acquisition cost but provides a more effective clinical outcome and increased efficiency relative to a lower cost comparator. In this case, focusing exclusively on cost will translate into significant lost opportunity costs to the system.

This status quo must change in order for the system to procure medical technologies based on unmet patient and system needs and with value defined from multiple dimensions. In addition to challenges surrounding procurement, the health technology assessment (HTA) process can also represent a potential barrier to the rapid introduction of innovative health technologies. Through this process, innovative technologies are required to surpass significant evidentiary thresholds and time-consuming reviews to address HTA needs and thus, warrant system adoption. Commercially-driven entities operate in competitive markets where rapid market penetration and expansion are required for success. Within this context, medical technology companies can face significant challenges achieving varying evidence thresholds, while simultaneously meeting key business development milestones. These differing perspectives have arguably impeded adoption of innovation and slowed patient access to promising interventions. Companies admit to bypassing Canada with more recent technologies because of the multiple hurdles compared to the size of other markets and more standardized evidentiary thresholds to introduce new technologies. The contrasting interests between both forces become most apparent when comparing centralized

procurement practices and health technology assessment (HTA) processes within the health system for managing the introduction of innovation relative to industry processes for technology development.

The intent of current HTA mechanisms is to support the health system's need to allocate limited resources in an efficient manner. These systems operate to ensure the health benefit to society associated with a novel technology is greater than cost of technology acquisition and operation. A significant challenge underlying this measured approach for companies producing innovative technologies is the time required to accumulate necessary evidentiary thresholds required by HTA bodies. Within this context and with limited capacity, HTA mechanisms can often be perceived as gatekeepers, controlling technology access to the health system. The process described in this publication addresses this issue by quickly generating value-for-money real-world evidence, with decision-makers engaged throughout the process, to inform the decision pertaining to adoption of a technology. This process is not presented as a substitute to the HTA mechanisms but rather as a system's approach to accelerate the introduction of health technologies that address unmet needs in the health system. The inclusion of multiple perspectives and stakeholders, including HTA groups, represents a balancing process to address the existing challenges in advancing innovation quickly into the health system so that patients receive timely access and the system as a whole, sees improvements in patient outcomes at reasonable incremental cost.

A current substantial challenge in the process is related to the way health systems in Canada procure products and technologies. The procurement divisions of health systems are under pressure to aggregate spending and save costs through various mechanisms such as volume purchasing through joint buying groups across the provinces and territories. The focus on reducing upfront costs for procurement divisions is significant; and is central when considering day-to-day consumables such as cleaning supplies through to complex medical technologies for specific medical conditions.

The caveat to this is that the product considered (i.e. with the lowest cost) and selection is influenced by criteria determined by, and often limited to, basic minimum transactional requirements, which are primarily related to specifications of the product or technology rather than real-world performance in a real world clinical setting. This is a challenge for the system because a focus on reducing upfront costs if a product meets the minimum requirements does not take into consideration the downstream costs / outcomes associated with this approach. Such downstream costs / outcomes may be associated with qualitative product performance related metrics such as, but not limited to, readmission and re-infection rates, inaccurate diagnosis, inappropriate use of medication, premature device failure, and longer length of stays. These costs will likely dwarf any savings that procurement divisions are seeking through this approach. In addition to these direct costs, there are indirect costs which consider lost productivity, burden on non-health care units, or reduced access to care, etc. The focus must change from volume and cost to value, where better patient outcomes (clinical and patient-reported) and improved system efficiencies are considered when assessing a product or technology in the health system over a period of care.

## Industry perspective: Maximizing value

The industry perspective for medical device technology development seeks to maximize the value of health technologies. The term value in this case would primarily consider three perspectives: improving patient outcomes, system optimization and economic.

### ***Improving Patient Outcomes***

The success of most health technologies relies primarily on their ability to improve patient outcomes and/or enhance system efficiencies. It is difficult to develop a viable technology that does not have a point-of-differentiation, with respect to other competing products, or a value proposition focused on improving patient outcomes. This is of paramount importance to industry; however, there is an overwhelming lack of mechanisms that allow health systems and industry to generate real-world



evidence to support the point-of-differentiation or value proposition of health technologies. Without such mechanisms, it is difficult for health systems to engage industry and rapidly assess technologies that address a specific need within the system and more accurately determine their value.

### ***System Optimization***

According to the Canadian Institute for Health Information (CIHI), in 2013, government spending per person after adjusting for differences in population age and sex among provinces/territories is at a national average of \$3,914. Amongst all the provinces, Alberta spends the highest in this category at \$5,210. Total consolidated health spending will account for 39.5 per cent of Government of Alberta consolidated expense in 2015–164. In summary, health care spending continues to increase faster than the rate of economic growth without the corresponding improvements in quality of care. Bending this cost curve is an important matter for government, health systems and taxpayers.

It is critical for the system as a whole to develop mechanisms that allow health organizations to work directly with industry to validate solutions that improve patient outcomes and increase system efficiency. These mechanisms will accelerate innovation within the health system and validate solutions that deliver increased overall benefit. A focus on this is bound to create mutual wins and is of common interest to government, health system, industry, and citizens in general.

### ***Economic Value***

An important component of this objective concentrates on maximizing shareholder value through management of a R&D pipeline focused on cultivating technologies with a high probability

of market penetration and anticipated revenue streams. Decisions to allocate company resources among numerous competing projects are often analyzed through tools such as Net Present Value (NPV) of a venture and potential Return on Investment (ROI). Producing technologies that are adopted by the health system requires significant investment to achieve development milestones. Attainment of these milestones occurs within a context of uncertainty, translating into a high risk of failure. Therefore, a putative technology requires significant forecasted economic benefit to offset the uncertainties associated with product development and the risk of lost capital. Additionally, a novel technology should provide potential for realizable benefit relative to existing competitors in the market. The economic value associated with a novel technology reflects the anticipated financial benefit, potentially realizable through successful commercialization. Specifically, this financial benefit is reflected in anticipated revenue streams aggregated over the lifetime of the project counterbalanced against accumulated R&D investments and anticipated operational expenses.

There is an unexplored opportunity to develop and implement strategies and approaches to synergize the interests of the health system and industry partners. Critically, the sustainability of a continually improving health system requires exploration of methods focused on harmonizing these competing objectives to identify high value technologies that promote needs based adoption and management within the system.





## ENABLING CHANGE – IMPROVING HEALTH SYSTEM VALUE

Health technologies and solutions entering the health system, irrespective of the degree of innovation, should be viewed as “tools” of the medical profession; tools that impact a clinical pathway which resides in the very complicated setting of health care. In order to express the full value of that technology, it must be optimally positioned into an episode of patient care which could be either shorter-term acute episode of care or a longer term chronic disease management program. Assessment of, and decision-making for, these technologies made independent of real world, real time clinical settings lacks the robust considerations needed to ensure appropriate and seamless adoption and outcome effectiveness at the clinical level. Of utmost importance is involving the front-line health care providers as well as

patients in any decision-making processes around new technologies; their insights and participation will facilitate a systems approach to technology management that will encompass several key decision points around clinical and patient outcome impacts, system readiness, opportunity costs and disinvestment strategies.

Rallying around the concept of a “zero sum gain”, in a system’s management approach to the introduction (and exiting) of medical technologies, it becomes possible to define, measure and validate the true value an innovative medical technology can offer the clinicians, the patients and, ultimately, the health care system utilizing these principles and points listed in Table 2.

**Table 2 - Value for Money Principles and Key Points**

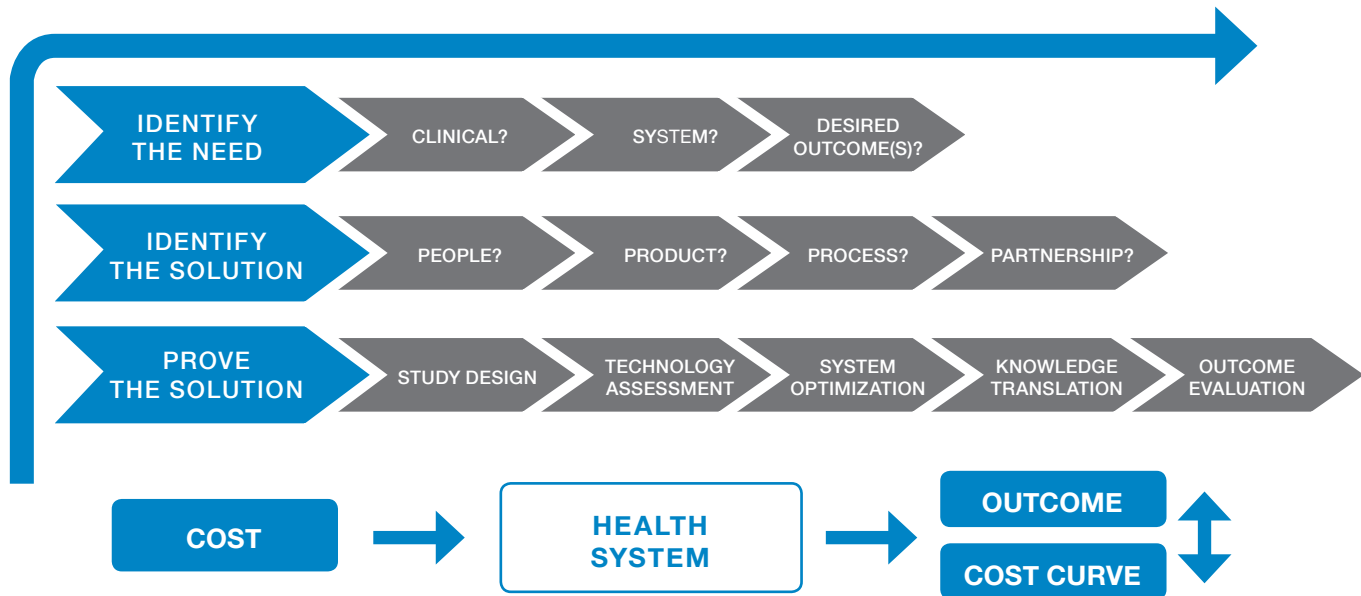
Value for Money Principles	Key Points
Determine complete system impact of adopting medical technologies through a value based approach.	<ul style="list-style-type: none"> <li>• There is a need to develop a full understanding of the impact of the innovation on the total system.</li> <li>• A value based approach is based on outcomes and considers cost and non-cost factors.</li> </ul>
Shift decision making on the value and adoption of medical technologies to a broad collaborative approach.	<ul style="list-style-type: none"> <li>• Engagement of all stakeholders is vital throughout the entire process; some stakeholders within both industry and the healthcare system may need to be re-engaged.</li> <li>• Critical success factors will be cultural change and change management to reduce current risk adversity.</li> </ul>
Provide the optimal level of evidence to determine significant value of a new medical technology versus existing devices or process.	<ul style="list-style-type: none"> <li>• Current HTA systems are congested and unable to provide support.</li> <li>• There is no one size fits all solution.</li> <li>• Need for mutually agreed metrics and fluid models.</li> <li>• Real time evidence and real world outcomes are necessary.</li> </ul>
Establish a complete system support plan to facilitate faster uptake of medical technologies and which includes best practice guidelines, implementation tools and ongoing evaluation metrics.	<ul style="list-style-type: none"> <li>• Planning, training, tools and support for change management contribute to adoption and success of the uptake.</li> <li>• Process should be iterative and constantly re-evaluating, re-inventing</li> </ul>

Within the scope of these principles (Table 2) the SCN-MEDEC projects selected became an extension of a series of deliberate conversations that focused on attempting to create a practical, implementable, scalable and credible framework and technology management model. As noted above, it had to be needs focused, clinically

relevant and gather evidence in a real world setting to address a very wide range of questions across a number of important areas. This is a critical role played by SCNs, with patients, front line clinicians and health system leaders embedded within the health system.



## Value for Money



**Figure 1: Value for Money Framework**

The Value for Money framework (Figure 1) breaks out into three specific parts or steps that can be scaled to the scope and complexity of a project based on the principle that “not one size fits all”:

1. Defining the Need – patient or health system
2. Identify a Solution
3. Proving the Solution

The first step, Defining the Need, is arguably the most important yet one of the most difficult tasks to be undertaken. Certainly, all recognize that health systems have many challenges and a wide range of needs – clinical, outcomes, administrative, financial to name a few. Experience has shown that converging interests into well-defined and actionable need takes effort. Having a clearly defined, realistic and actionable need is an essential starting point.

The second step in the framework, identifying a Solution, requires purposeful, meaningful and facilitated discussions involving the public and private sectors, and in the case of Alberta, between the SCNs and the medical technology sector, to look towards a wide range of potential solutions targeted to meet the stated and validated need.

While this can be achieved any number of ways, the strategy undertaken with the SCNs and the industry partners was to convene a meeting in a facilitated workshop format. The benefit of this approach was multifold: 1) Begin relationship development between the different stakeholders, 2) Clarify and gain agreement on the stated need, including articulating the desired outcomes and 3) Create an objective and transparent starting point for industry that would lead to their next steps of developing solution proposals.

The third step in the framework, Proving the Solution, can be best described as the “change management” step that purposefully moves to align and coordinate what are now largely independent streams of activity under a single project umbrella to realize the concepts of technology and system management. Central to this approach is to keep the end goal (improve and/or enhance patient outcomes) in mind. However, paramount in current fiscal reality, this goal must be achieved within the spectra of other goals such as achieving improved system efficiencies leading to system optimization, translating to cost reductions while increasing the quality of patient care and the patient experience.



# DEVELOPMENT & DESIGN OF THE SCN-MEDEEC INITIATIVE

MEDEEC is the national association created by and for the Canadian medical technology industry. MEDEEC is the primary source for advocacy, information and education on the medical technology industry for members, the greater healthcare community, industry partners and the general public. With a clear recognition of the prevalent HTA landscape in Alberta and the challenges created through the lowest cost mandate of centralized procurement, AI partnered with MEDEEC to develop a mechanism that would allow innovative medical technologies to be validated and potentially introduced into care pathways based on clinical needs identified by the health system. This would be accomplished via demonstration projects that would generate real-world evidence to test the hypothesis of a proposed solution addressing an Alberta specific clinical need. Based on the Value for Money Framework (Figure 1), AI and MEDEEC together developed a process (Figure 2) for a mechanism to accomplish this as an SCN-MEDEEC Initiative.

## ***Needs Identification***

MEDEEC & AI together organized two events over the last year that brought the medical device industry together with the health system and ministries of the Government of Alberta to find ways

to bring innovation into the health system. One of the outcomes of a January 2016 event was the launch of the SCN-MEDEEC Initiative to accelerate the adoption and management of medical technological innovations that improve quality of care for Albertans and are cost-effective for the health system. At this event, four SCNs identified their immediate clinical needs with the intent of having MEDEEC members and other industry players provide technologies that could potentially address those clinical needs. The clinical needs by the SCN's identified were:

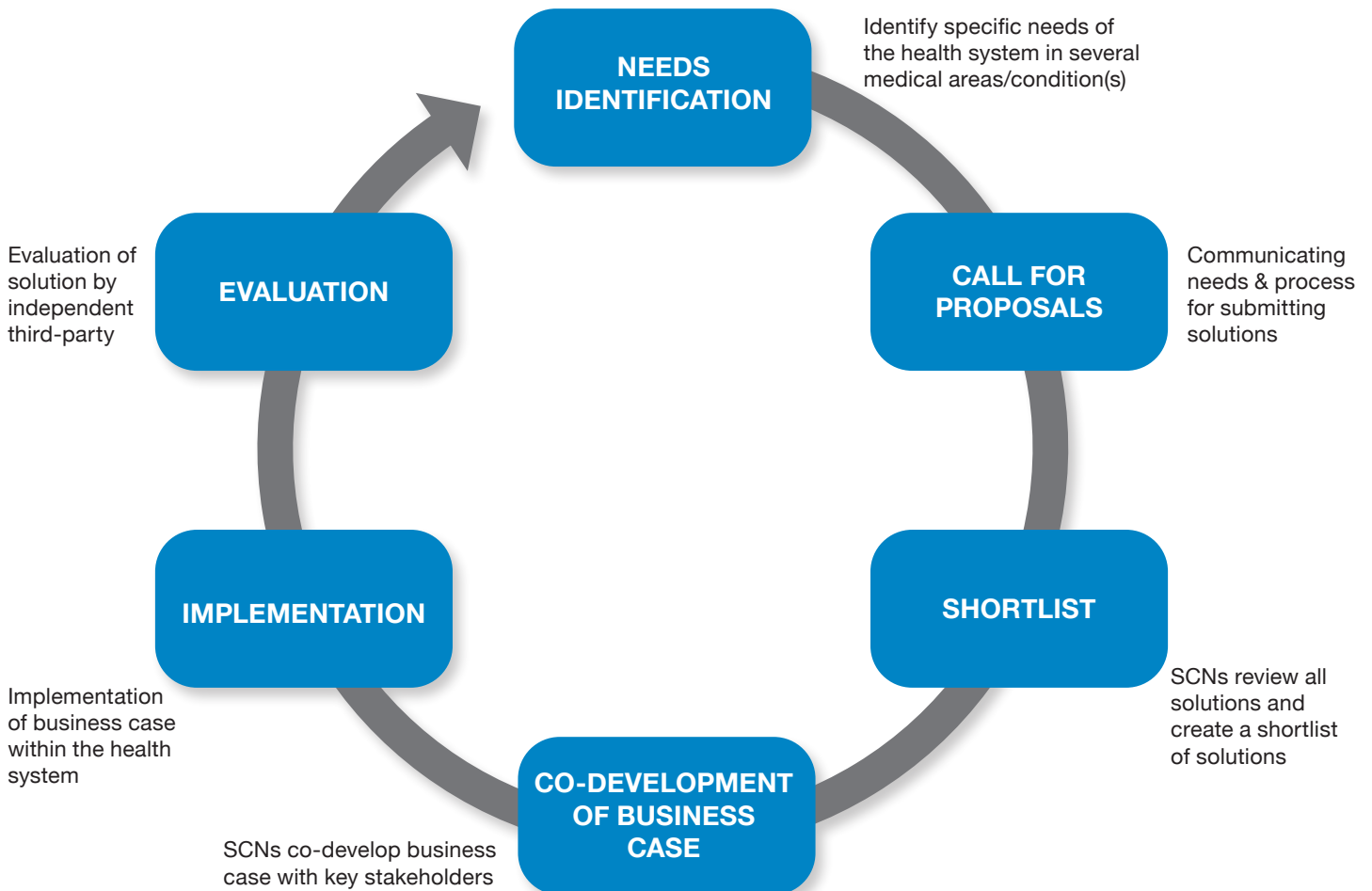
- Cardiovascular Health & Stroke: Technologies for Remote Cardiac Monitoring
- Bone & Joint Health: Biomarkers for Assessing Disease Activity
- Cancer: Remote access to Diagnostic Imaging in Cancer
- Critical Care: Delirium - Technology Related to enhanced Prevention, Diagnosis or Management



Early versions of the SCN needs tended to be high level and lacked the specificity required to move to second step, identifying a Solution. For example, the Critical Care SCN's first defined need was described as identifying and converting best practices in managing delirium into provincial standardized approach. Taking a root-cause analysis approach, this need was redefined as early detection and management of sepsis in the wards of the hospital as delirium is often secondary to sepsis. The need, and therefore the strategy, was to impact delirium through avoidance, thereby reducing the number of delirium patients that find their way to the Critical Care Unit. The companies were given the opportunity to meet with the SCN leadership and explore these clinical priorities further in a 'round-table' format and were informed of a forthcoming process that would allow them

to submit solutions to the clinical needs identified above.

AI and MEDEC developed a process and a template that was to be used by MEDEC members, as well as other health technologies related companies, to submit proposals (referred to as 'solutions' henceforth) for review/evaluation by the SCNs. These solutions were to include information sufficient to determine if there was a strong potential to address the clinical need outlined. These solutions, which are similar to a conventional expression-of-interest/letter-of-intent, were to be submitted to AI by a formal deadline. AI received a total of 16 solutions from a variety of large and small companies including Medtronic, Roche, GE and Philips.



**Figure 2 – SCN-MEDEC Initiative Process**

### **Shortlist**

The SCNs used criteria established by AI and MEDEC to assess, score and rank the proposals. The criteria were focused on the following four topics:

1. *Health System Need*: how well does the solution described in the proposal fully address the identified health system need?
2. *Impact on Identified Need*: is there a line of sight to measurable impact on the identified need?
3. *Value for Money*: does the solution have a clear value proposition compared to current standard of care with respect to patient outcomes, cost savings, and system efficiencies?
4. *Methodology & Deliverables*: is the proposed methodology sound with realistic deliverables?

The SCNs used a mix of clinician, researcher and patient feedback on the proposal to complete the rubric using the criteria listed above. Although this was not listed as a criterion, some of the SCNs considered feasibility and alignment with existing initiatives as additional criteria when assessing solutions. This is important when considering solutions that are strong but incompatible with existing infrastructure and capacity within Alberta, and may require massive system-wide overhaul and thereby deemed unfeasible in the short-term. The SCNs also provided written feedback on all of the solutions, which was relayed to the respective companies via AI.

### **Co-Development of Business Cases**

AI and MEDEC developed a business case template that was to be used by the SCN in collaboration with the company and the Institute of Health Economics (IHE). This co-development process would assure engagement and contribution from the major stakeholders and assure buy-in from them on the project. The template required content pertaining to various components of the demonstration project including: (A) Business &

Operational Impacts, (B) Project Risk Assessment, (C) Implementation Strategy, (D) Evaluation Strategy, and (E) Resources & ROI. These business cases would be reviewed on an 'as required' basis depending on the resources required to successfully implement the project. A more detailed discussion on resources and funding models is available in subsequent sections.

### **Implementation**

This phase of the process is where the solution is applied within the health system in the form of a demonstration project – the implementation strategy described in the business case is employed. The resources (e.g. technology, consumables, human, financial) are secured prior to this phase. The SCNs, in collaboration with the company involved, select specific implementation sites within Alberta Health Services (e.g. emergency department(s) at specific hospital(s) in Alberta) and the target patient population is identified in the business case. Placed within the Value for Money framework's Proving the Solution, the implementation of the potential solution requires an applied research methodology that looks to validate not only the technology through scaled HTA processes and the training effort required for adoption; but this phase also collects the data required to illustrate the impact of the solution on patient outcomes and the health system. Figure 3, Gantt Chart of Activities, illustrates the interdependency of a demonstration project that takes a systems approach where activities historically independent of each other are rolled out in a timed, sequential and interdependent manner. Milestone assessments are established at staged points of the project allowing for real time collection and analysis across a range of predetermined variables that collectively support well informed decision making. A key point to note in this approach is that outcomes and value assessment are integrated in the project plan and conducted by an independent third-party organization such as the Institute of Health Economics. The intent is to obtain a pulse on outcomes and value assessment during the project as close to real-time as possible.



Activity	Months	1	2	3	4	5	6	7	8	9	10	11	12
Study Design		█											
Roll out			█										
System Optimization				█	█	█	█	█	█	█	█	█	
Knowledge Translation					█	█	█	█	█	█	█	█	
Technology Assessment				█	█	█	█	█	█	█	█	█	
Progress Assessments					█			█			█		
Outcome Assessment									█	█	█	█	
Value Assessment										█	█	█	█
Procurement Decision											█	█	█
Disinvestment Decisions									█	█	█	█	

Figure 3 – SCN-MEDEC Gantt Chart of Activities

**Evaluation**

The IHE is an independent organization with proven expertise in health economics. The IHE is commissioned by AI to support the development of an evaluation strategy for all the SCN-MEDEC business cases. This will assure that an independent external agency is tasked with developing the evaluation strategy for the business cases and maintain consistency in the approach to evaluation. The intent is for IHE to evaluate the SCN-MEDEC Initiative as well as the individual demonstration projects. More details pertaining to this section will be available in Part 2 of this whitepaper.

**A Platform for Innovation in Health Care**

The congruency of objectives and outcomes associated with the MEDEC and AI collaboration indicates that a valuable opportunity exists to leverage the current collaboration into a larger platform to stimulate, coordinate and manage projects between the health system and industry. The proposed platform would provide a mechanism for the health system and industry to explore complementary objectives with mutually beneficial outcomes. Once identified, the platform would

allow the entities to co-develop projects with the greatest probability of achieving stated objectives.

**Risk Sharing**

The proposed platform would provide a mechanism to promote risk-sharing for co-developed projects between partner organizations. The degree of risk aversion within the system is largely attributable to the uncertain and unproven benefits associated with early stage innovations and assessment tools to define their true value. By promoting a partnership and moving away from the conventional vendor-buyer approach, there are opportunities to create solutions where the health system and the industry partner share the risk of introducing a technology into the system. Through this model, a company would share the risk by guaranteeing measureable improvements in patient outcomes when their technology is used. Through this partnership approach, the industry partner would take on the responsibility of ensuring adequate clinician training, and would have a certain level of control on deciding the appropriate use of the technology and patient eligibility. The health



system would work to ensure the appropriate infrastructure is in place, the clinician team is engaged, processes are aligned for implementation and the appropriate change management effort is deployed. This approach would add certainty with respect to improvements in patient outcomes in certain areas of the system, would minimize readmission costs, and nudge the system to move towards focusing on improving patient outcomes and not lowest price when assessing the value of medical technologies.

Specifically, shared funding agreements between the health system and industry partners would potentially increase the availability of capital to conduct evaluations and reduce the resources directed away from frontline care. In addition, achieving system optimization through collaboration, while agreeing to who leads and takes responsibility to identify, assess and manage system level co-dependencies moves the risk sharing to a partnership level.

The shared assumption of risk resulting from joint funding and system management suggests consequences are distributed equally between the health system and industry partner. Risk sharing reflects an effective risk management method where project uncertainty is distributed symmetrically among both parties.

The SCN-MEDEC Initiative would also provide significant benefit to industry partners. Increased access to the health system via co-developed

projects would counterbalance much of the uncertainty inherent in the product development process facing industry. Co-developed projects would provide industry a valuable opportunity to evaluate the effectiveness and better define the value of innovations in real-world conditions. Access to these relevant conditions, would provide highly contextualized usability data that is easily generalizable to other care environments.

The application of this knowledge could significantly improve product development processes and eventual rates of adoption among end-users, accelerating patient access to proven innovations. Furthermore, the implementation of a co-development platform would facilitate increased interaction among product developers and end-users, supporting increased exchange of information. The resulting information exchange is expected to stimulate increased adoption of a demand-pull paradigm, where health system practitioners identify unmet clinical need.

The adoption of the demand-pull approach will benefit patients who are currently underserved and industry partners who will be provided new accessible markets.





## FUNDING MODELS

The SCN-MEDEC initiative has been based on a foundation of mutual understanding, clarity and support from all stakeholders involved. It has evolved with an understanding that there will be multiple avenues of benefit expressed throughout this process. In addition to benefits the understanding has always been clearly expressed that financial support of this process is critical.

In continuation of the risk-sharing concept of these co-developed projects leading to exponential benefit to an expanding list of stakeholders, it is similarly proposed that funding for these stated projects evokes a similar shared approach. Specifically, it will be fundamental for all parties involved to have a financial stake in this process.

While innovations have an impact on the clinical care pathway, sustainability and future support will continue and be assessed within a financial setting. To this, funding is a core fundamental and

requires attention. Funding is not only necessary for potential projects to move forward, regardless of individual project dynamics there are minimum requirement of time and support to facilitate these aspects. Funding is also the structure in which to validate and create an ongoing infrastructure to perpetually sustain these initiatives. Defaulting to traditional funding formats and or containing funding in research/grant reference will hinder the spirit and intent; it will be critical that this new shared responsibility of funding be established.

Agreement that shared funding models are an essential component to ongoing impact does require thoughtful clarification before moving forward. Firstly, the medical device sector in Canada is a highly competitive market place with much smaller margins than other jurisdictions, creating limitations on returns. These limitations are noted in the current limited levels of support experienced throughout Canada's academic

network, on projects solely funded by the medical technology industry. Secondly, through this process one of the many outcomes is to define systematic savings, tangible amounts reflective of evolved operational pathways or clinical impact. Third, Alberta is providing a unique perspective on a complex vexing issue but the approach warrants mirroring in other jurisdictions. Certainly, in Alberta there is the perennial mandate to diversify the collective economic engine. Canada has built an impressive network of academic institutions, thoughtful innovators, and educated citizens enabled to fulfill this expanded economy. Capitalizing on the synergy of this innovation framework has been challenging, as current practices noted above do not always favor the innovators. However, a missing partner in this new approach to funding implementation and assessments of technologies in a real world setting possibly leading to adoption, scale and spread, is the Federal Government. While a tremendous amount of Federal funds potentially exist to support the development of novel, medical innovation, known as the “front end”, there is a distinct lack of grant funding to fund the implementation and assessment phase, known as the “back-end”. Innovative solutions require new paradigms and agents of the Federal Government e.g. Industrial

Research Assistance Program (IRAP) claim their inability to fund due to existing policies.

Given these factors and, to cross the hurdles noted above, a unique approach to funding is required to expand the entire continuum of innovation to address the vital component of adoption. Resolution is centred on expanding the responsibility/accountability of funding divided amongst the stakeholders and dependent upon project dynamics.

In addition to this initial strategy, perpetual success of this project will be enhanced by diverting a portion of any systematic savings measured into a defined and restricted trust rather than general budget, to increase participation areas that participate in this initiative.

Given that the range, impact and resources required for each individual business case will vary in accordance with the needs, it is overly restrictive to identify exact percentages required by each body too early in the process. Nevertheless, central are the themes: funding requires a universal partnership approach and efficiencies and savings need to be identified and harvested to support future projects.





## CURRENT STATUS & NEXT STEPS

A total of 16 proposals were received in the form of solutions to the clinical challenges outlined by the SCNs. These 16 were reviewed by the SCN leadership and clinical experts. At the time of publication, the SCN-MEDEC projects are in the Co-Development of Business Case (see Figure 2) phase of the process. The Critical Care, Cardiovascular Health & Stroke, and the Cancer SCNs are developing demonstration project plans with companies such as Philips, Biomerieux, Medtronic & m-Health. These demonstration projects are to be implemented in mid to late 2017.

Moving to a cutting-edge health system will require partnerships with the innovation pipelines of industry and develop processes that use new and collaborative ways to manage health technologies within the system such as the needs-based approach described in this publication. Viable solutions to challenges with procurement and HTA are required for payers to maximize value for money. Alberta is leading the way by demonstrating the utility of innovative approaches to managing health technologies in a complex system to increase value for money. Leaders

of health care systems also must recognize the importance of shifting the organizational culture towards developing and implementing innovative mechanisms to address the prevailing challenges.

Change is constant and ongoing evolution is required to advance and adapt the health system to encourage efficiency and sustainability in the long-term. The rapid expansion and evolution of innovative solutions requires a similar momentum to develop the process in which to evaluate the technology, assess system readiness, understand system impacts, develop the evidence for decision making, move to procure the new solution as/ if evidenced while identifying disinvestment opportunities and managing scale and spread through change management strategies. This process noted above and the stakeholders involved have demonstrated this innovative approach and achieved initial success in linking needs to outcomes. The continuation of this initiative will be demonstrated in progression and documentation; what is clear is that this unique approach is developing a new perspective and one that is beneficial to the system.



# AUTHOR TEAM



**Hameed Khan** is the Lead, Health & Health Care Initiatives, Alberta Innovates, spearheading initiatives that advance innovations to substantially improve value in the health system such as the SCN-MEDEC projects. Dr. Khan has a PhD in biochemical sciences, a MBA and has completed the Value Measurement in Health Care Executive Program at Harvard Business School.



**Stephen Urquhart** has been active in the medical technology and pharmaceutical industry for the past 18 years in a variety of strategic roles. He is the current Chair of the MEDEC's Western Canada Committee and took a leadership role in the planning of the SCN-MEDEC projects. Mr. Urquhart holds a B. Sc. from University of Alberta a MBA from University of Athabasca.



**Blair O'Neill** is a cardiologist, previous Cath Lab Director, and Division Chief as well as Past President of the Canadian Cardiovascular Society. He is currently Associate Chief Medical Officer for the Strategic Clinical Networks for Alberta Health Services. Dr. O'Neill is providing senior leadership to the SCN-MEDEC projects.



**Ulrich Wolfaardt** is the Manager, Health & Health Care Initiatives at Alberta Innovates and has been a primary resource in the development of the SCN-MEDEC projects and processes. His previous roles involved application of health technology assessment and innovation to the health system. Dr. Wolfaardt has a PhD of Psychiatry and a MBA from the University of Alberta.



**Robert Rauscher** has spent his career in health within the public and private sectors, as well as an independent consultant. He is currently the Vice President for MEDEC in West Canada, leads the Value for Money initiative for MEDEC at a national level and for the SCN-MEDEC projects in Alberta. Mr. Rauscher sits on the Alberta Provincial Health Technology Assessment Committee.