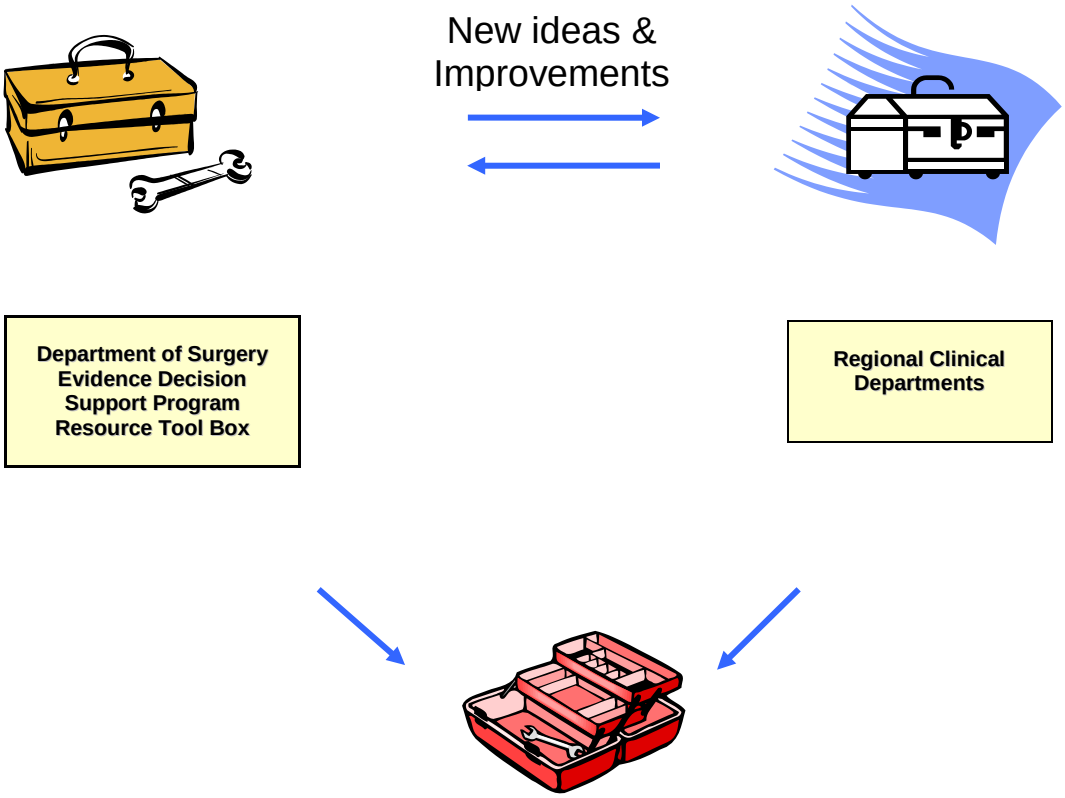
SURGERY STRATEGIC CLINICAL NETWORK

EVIDENCE DECISION SUPPORT PROGRAM

2014 Revision (v3)



New and Improved Evidence Decision Support Program to support the needs of various clinical departments

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The Department of Surgery and Surgical Services, and the Calgary Health Research Portfolio
Alberta Health Services-Calgary and the University of Calgary

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EXECUTIVE SUMMARY

In an era of finite resources and ever-increasing medical possibilities, every health care system faces challenges in determining which new health technologies should be introduced into clinical practice. To assist in making these determinations, various international, national, and provincial agencies provide Health Technology Assessment (HTA) reports. These reports provide health care decision makers with a comprehensive, objective, evidence-based analysis of the clinical effectiveness, cost-effectiveness, and broader impact of health technologies including drugs, devices and procedures.

However, HTA reports produced by such agencies usually do not consider factors that are critical for local decision makers, such as local population health needs, presence of local alternatives and trained personnel, local priorities, infrastructure implications, funding options, and consequent local financial implications of the health technology. Furthermore, HTA reports may not be available for technologies that change quickly, such as medical devices. Even if HTA reports are available, local decision makers may not have a consistent and transparent mechanism in place for integrating research clinical evidence and local resource impact into the decision process.

To address this issue, the Department of Surgery and Surgical Services and the Calgary Health Research Portfolio at the Alberta Health Services-Calgary, with grants support from the Canadian Agency for Drugs and Technologies in Health (CADTH), developed a local decision-support program to provide a process and tools for evaluating new technologies in a systematic, consistent, and transparent manner. To expand the program to other departments, a "Project Group" was formed with members from additional departments, who reviewed, revised and adapted the decision-support program for wider application.

The result is the ***Evidence Decision Support Program (EDSP)***, consisting of a set of Forms and Appendices to assist local decision makers integrate research knowledge into practice when evaluating new technologies in their local context. The ***Forms*** are used to collect information in regard to the safety, efficacy, and organizational impact of requested health technologies and to direct the evaluation process so that all stakeholders are consulted. The ***Appendices*** are a set of guidelines for making decisions at various steps in the process and worksheets for evaluations and prioritization.

The Evidence Decision Support Program has the following key features:

- It creates capacity "from the bottom up" by empowering users to develop their own evidence decision support process.
- It ensures that all stakeholders are consulted and the impact of the technology is considered not only from a research clinical perspective, but also from a financial (resource and infrastructure) perspective in a consistent and transparent manner.
- It provides a single process that encompasses both review of routine technology requests (called the "Technology Request Pathway") and review of technologies (i.e., changes in practice) that are a significant change compared with current practice (called the "EDSP Pathway").
- It supports knowledge and research patient care services innovation by incorporating an outcomes reporting mechanism by which innovative technologies can be tested and evaluated.
- It presents a set of criteria both for evaluating new technologies on a one-by-one basis and also for prioritizing competing technologies for funding or purchase.
- It provides a framework by which technologies can be thoroughly researched prior to submissions for external funding by a Health Trust.
- It integrates with and supports other initiatives such as Patient Safety, Quality Assurance, Capital & Operational Expenditure Processes, Medical Device Safety & Risk Management, Knowledge Transfer and Innovation.

Taken together, the program represents a framework for a consistent and transparent approach to the introduction of technologies that have not been previously used in a department or health facility. It is a work in progress. We hope that physicians, nurses, managers, administrators, researchers, directors, and heads of clinical departments will test and improve the EDSP as a structured method to assist decision making for integrating research knowledge and new health technologies into practice and will adapt it for their specific needs. We thank CADTH for their financial support and the Project Group, whose thoughtful input made this document possible.

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INTRODUCTION

In an era of finite resources and ever-increasing medical possibilities, every health care system faces challenges in determining which new health technologies should be introduced into clinical practice. To assist in making these determinations, Canadian federal agencies such as the Canadian Agency for Drugs and Technology in Health (CADTH) and, in Alberta, the Institute of Health Economics, provide Health Technology Assessment (HTA) reports. These reports provide health care decision makers with a comprehensive, objective, evidence-based analysis of the clinical effectiveness, cost-effectiveness, and broader impact of health technologies including drugs, devices, equipment, and procedures.

However, HTA reports produced by international, national, or provincial HTA agencies usually do not consider factors that are critical for local decision makers. For example, an HTA report may not consider local population health needs, presence of local alternatives and trained personnel, local priorities, infrastructure implications, funding options, and consequent local financial implications of the health technology. Furthermore, comprehensive HTA reports may not be available for technologies that change quickly, such as medical devices. Even if HTA reports are available, local decision and policy makers may not have a consistent and transparent mechanism in place for integrating clinical evidence and local resource impact into the decision process.

To address this issue, the Department of Surgery and Surgical Services and the Calgary Health Research Portfolio at the Alberta Health Services-Calgary developed a decision-support program to provide a process and tools for evaluating new technologies in a systematic, consistent, and transparent manner. In order to expand the program into other departments within the Alberta Health Services - Calgary, a "Project Group" was formed, which included members from additional departments. Over the next 3 years, the Group reviewed, tested, and revised the decision-support program for wider application.

The result is the ***Evidence Decision Support Program, updated in 2014***, consisting of a set of Forms and Appendices to assist local decision makers integrate research knowledge into practice when evaluating new technologies in their local context. The ***Forms*** are used to collect information in regard to the safety, efficacy, and organizational impact of requested new technologies and to direct the evaluation process so that all stakeholders are consulted. The ***Appendices*** are a set of guidelines for making decisions at various steps in the process and worksheets for evaluations, reports, and prioritization.

Program Features

During the extensive consultative process, the Project Group identified key capabilities to be strengthened or incorporated into the Evidence Decision Support Program. As a consequence, the program has the following features:

- It creates capacity "from the bottom up" by empowering users to develop their own EDSP process.
- It ensures that all stakeholders are consulted and the impact of the technology is considered not only from a research clinical perspective, but also from a financial (resource and infrastructure) perspective in a consistent and transparent manner.
- It provides a single process that encompasses both review of routine technology requests (called the "Technology Request Pathway") and review of technologies (change in practice) that are a significant change compared with current practice (called the "EDSP Pathway").
- It supports patient care services innovation by incorporating an outcomes reporting mechanism by which innovative technologies can be tested and evaluated.
- It presents a set of criteria both for evaluating new technologies on a one-by-one basis and also for prioritizing competing technologies for funding or purchase.
- It provides a framework by which technologies can be thoroughly researched prior to submissions for external funding by a Health Trust.

- It integrates with and supports other initiatives such as Patient Safety, Quality Assurance, Capital & Operational Expenditure Processes, Medical Device Safety & Risk Management, Knowledge Transfer and Innovation.

Supporting Innovation

The Evidence Decision Support Program is uniquely positioned to support both innovative, experimental technologies as well as proven technologies that have not yet been used within a particular health system. Supporting innovative technology is often difficult, as a technology early in its life-cycle will inevitably have uncertainties about its clinical and economic effectiveness. Early adoption of an unproven technology may prove to be clinically or cost ineffective. Conversely, avoiding all unproven technology may miss opportunities for gains in health outcomes and cost-effectiveness.

To address these difficulties, in addition to providing a method by which clinical and financial (resource and infrastructure) impact information on a new technology can be collected and assessed (regardless of how these functions are divided provincially and locally), our Evidence Decision Support Program has a built-in method to support innovation. For technologies with little clinical data or those that have not been previously used in the local setting, the EDSP provides the possibility of "Conditional Approval" such as under a clinical trial or an audit. In this case, there is an automatic requirement for outcomes reporting back to the department. Thus, experimental or innovative technologies are subjected to a cycle of trial, evaluation, and re-review. Regardless of whether approval for an experimental technology is given at a provincial or local level, the requirement for outcomes reporting and feedback by those actually using the technology is a critical component for quality improvement. Our EDSP not only provides a method by which such feedback can be provided, but also a method by which suggestions for new technologies can come from the users themselves – a "bottom-up" method of supporting innovation that complements "top-down" methods used by health care administrative bodies. Furthermore, the Evidence Decision Support Program not only facilitates a cycle of technology adoption and evaluation, but supports and interfaces with other initiatives within a health region, as detailed below.

- ***Knowledge Transfer and evidence-based medicine.*** The Program promotes knowledge transfer and evidence-based medicine by ensuring that the best evidence is used to make decisions about a new technology. In Canada, the outcome "Request Independent knowledge synthesis or HTA" would result in a request to independent knowledge synthesis services or CADTH, which offers a variety of independent and objective review services.
- ***Research and Innovation.*** The program supports research and innovation when insufficient evidence about the technology's efficacy or safety exist, usually in the development stage before the technology has received Health Protection Branch approval. The applicant is encouraged to proceed with a clinical trial, with the results to be reviewed by the EDSP Committee and the Department Executive.
- ***Quality Assurance and Patient Safety.*** A decision of "Conditional Approval – Audit" is generally used when a technology's efficacy and safety has been shown, but the technology has not been used in the local setting. A small number of cases are approved for testing, with the results to be reviewed by the EDSP Committee and the Department Executive.
- ***Medical Device Safety and Risk Management.*** The Program ensures that the training and credentialing of medical personnel are adequate for each new technology.
- ***Capital and Operational Expenditure Processes.*** The decision outcome "Conditional Approval – pending funding" feeds the technology application into regional capital and operational expenditure planning processes.
- ***Medical Education and Dissemination.*** Participants in the Evidence Decision Support Program deliver workshops and seminars to a variety of audiences.

Taken together, the Evidence Decision Support Program ensures that patient access to promising and innovative technologies is not prevented by lack of evidence, but is managed in an accountable manner, while also generating new evidence. The Program supports knowledge, research, quality, innovation, continuous improvement, and excellence in health services.

Administrative Structures

The Evidence Decision Support Program can be adapted to a variety of health services administrative structures. In its present form, the EDSP places the responsibility for collecting clinical, financial (resource and infrastructure) impact information at the local level - in the hands of the clinician requesting the new technology, the EDSP Advisory Committee and the local financial experts. However, the Program is also designed for situations in which clinical research evidence and economic analysis evaluations and consequent new technology recommendations can be requested and done objectively and independently at a provincial or national level. In this case, the higher levels of administration recommend technologies based on evaluations of clinical effectiveness and economic analysis, whereas the local administration reviews the technology for local implementation issues such as training, human resource, as well as resources and infrastructure implications in a systematic, consistent and transparent manner, as these issues will be different in each local setting. The information-gathering Forms of the EDSP can be used to reflect this division of labour.

Program History

The initial version of the Evidence Decision Support Program was developed by the Department of Surgery and Surgical Services of the Alberta Health Services-Calgary. Then, with funding provided by CADTH, we embarked on a series of projects including the development of a database in 2004, an interactive education program for health care practitioners in local setting in 2005. Subsequently, in 2006-2009, with the additional support from CADTH and the Calgary Health Research Portfolio, various departments within the Alberta Health Services-Calgary were invited to form the Project Group. This Group was asked to review the Department of Surgery's Decision Support Program and make suggestions for improvements and ways in which it could be adapted to a variety of department's needs.

The Project Group held a series of retreats in December of 2006, May of 2007, November of 2007, and September of 2008. The objectives of these retreats were to share experiences with using the Evidence Decision Support Program, to make recommendations for change, and to develop sets of criteria to guide the decision-making and technology prioritization. The list of grants support and all participants who contributed to the development of this program and their departments are listed in the "Grant Support" and "Project Group" sections of this document.

The current version of the Program is the compilation of these recommendations, and additions. A major change in this version was the introduction of two "pathways" for approving new technologies: 1) the "Technology Request Pathway", for approving minor changes of practice and 2) the "EDSP Pathway", for a comprehensive evaluation of a technology whose impact on clinical outcomes, resources, or finances is uncertain. As well, various Appendices were developed, including a screening guide for deciding which of these pathways to use for a new technology request. In addition, a set of criteria was agreed upon and used to develop guidelines for deciding whether or not a technology should be approved and whether conditions should be attached to the approval. Ways in which the criteria could be used to prioritize competing technologies for funding or purchase were also explored.

The Program is a work in progress. The Project Group intends to convene again to address the needs of the constantly changing world of health care services in Alberta and ensure that peer discussions keep the program flexible, dynamic, and useful. Users are encouraged to use this Program as a starting point to develop their own EDSP process.

PROGRAM OVERVIEW

Overview of Technology Evaluation Pathways

The Program requires the appointment of an "EDSP Advisory Committee" or health professional who fills this role. The EDSP Advisory Committee manages the evaluation process, reviews the application for suitability and completeness, and determines whether the technology represents a minor change of practice and can be approved, or requires further evaluation using the EDSP pathway and makes an objective recommendation to the department's executive committee, who makes the final decision when a technology represents a significant change of practice.

All technology requests begins with filling out the Technology Request package forms (Forms A, B, C): the Applicant (usually a physician) fills out a form (Form A, "Technology Request") that gives basic information about the technology and gets support (Form B) from the Division Chief or Department Head. This information is then checked (Form C) for legal, contractual and cost issues by a designated Contract/Costing Expert.

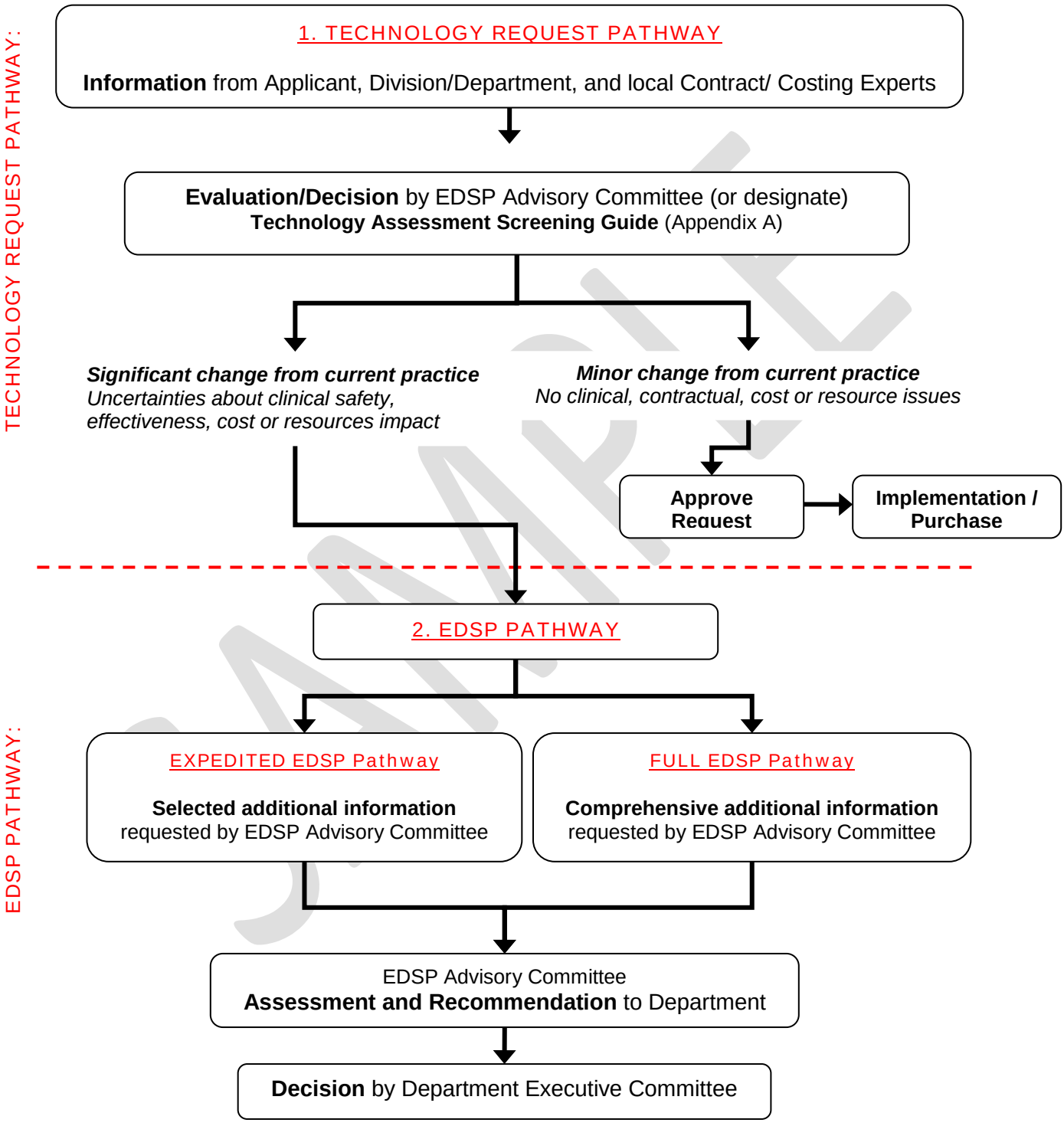
The Technology Request package (Forms A, B, C) is then reviewed by the Advisory Committee who will determine which one of the following two pathways is required for decision:

1. ***Technology Request Pathway*** a rapid pathway under which a technology can be approved for minor change of practice, while ensuring that safety, cost, and legal and contractual issues are considered, or

2. ***EDSP Pathway,*** a more extensive pathway that is used when there are uncertainties about a technology's impact on clinical outcomes, training, resources or finances. In addition to the information contained in the "Technology Request package", extra information is required about the technology, as determined by the department's EDSP Advisory Committee. Depending on the amount of extra information required, the process is sub-divided into the ***Expedited EDSP Pathway*** or the ***Full EDSP Pathway***.

An overview diagram of the evaluation pathways is shown in **Fig. 1**.

Fig. 1: Overview of Technology Evaluation Pathways



Forms and Appendices

Under the Evidence Decision Support Program, ***all technology requests begins with filling out the Technology Request package (Forms A, B, C).*** The Technology Request package (Forms A, B, C) is then reviewed by the Advisory Committee who will determine which one of the following two pathways is required for decision new technologies are reviewed using one of two pathways:

1. ***Technology Request Pathway***, is the starting point for all technology request submissions. It is a rapid pathway under which a technology can be approved for minor change of practice, or
2. ***EDSP Pathway***, a more extensive pathway that is used when there are uncertainties about a technology's impact on clinical outcomes, training, resources, or finances.

The ***Forms*** are used to collect information in regard to the safety, efficacy, and organizational impact of selected new technologies and to direct the process flow so that all stakeholders are consulted. The ***Forms*** required for these two pathways are shown below.

	Form Title	Technology Request Pathway	EDSP Pathway
A	Technology Request	√	√
B	Technology Request Support	√	√
C	Technology Request Contract-Costing Check	√	√
D	Technology Request EDSP Check	√	√
E	EDSP Clinical Information	—	May be required
F	EDSP Financial Impact	—	May be required
G	EDSP Economic Analysis	—	May be required
H	EDSP Recommendation	—	√
I	EDSP Executive Decision	—	√

The following nine ***Appendices*** are a set of guidelines for making decisions at various steps in the process and worksheets for evaluations, reports, and prioritization.

	Appendix Title	Description
I	Technology Evaluation Screening Guide	Gives guiding questions to help determine whether evaluation of a technology should follow the Technology Request Pathway or the EDSP Pathway
II	Levels of Evidence	Gives an explanation of the strength (level) of evidence. Used in Form E when providing evidence for a technology's clinical efficacy.
III	Criteria for Technology Evaluation	Gives a set of pre-determined criteria to help evaluate the merits of a new technology being considered for funding or purchase.
IV	Technology Evaluation Worksheet	Gives a worksheet for members of the EDSP Advisory Committee for reviewing and making recommendations on a technology
V	Decision Guideline Tool	Gives guidelines recommendations and decisions regarding new technologies. For use by the EDSP Advisory Committee and Departmental Executive Committee.
VI	Presentation Template	Gives a template for presenting a technology at Departmental Executive meeting to ensure all evaluation criteria are addressed in a consistent and systematic manner. For use by the EDSP Advisory Committee.
VII	Progress Report	Provide a template for reporting significant follow-up outcomes measures to document the performance (benefits) of a technology. For use by the Applicant.
VIII	One-Off Urgent/Emergent Evaluation Process	Gives a draft process for evaluating requested technologies for patients with few alternatives.
IX	Technology Prioritization Tool	Gives a structured process for rating and ranking several technologies, e.g., when determining which of several technologies should be submitted for funding.

Technology Request Pathway

This pathway provides the starting point for all technology request submissions. It is a rapid method for requesting new technology, while ensuring that safety, cost, and legal and contractual issues are considered. New technology may be approved under the ***Technology Request Pathway*** if the following clinical and operational conditions are met:

Clinical:

- The technology represents a minor change from current practice. ***Appendix I: Technology Evaluation Screening Guide*** is used to help make this determination.
- The technology request has been supported by Division Chief or Department Head (local experts).

Operational:

- The technology does not have legal or contractual issues.
- The item or a similar item may already be on purchase contract and/or utilized within the Region and/or a change of vendor is being requested.
- The technology request is within financial means. The change is budget neutral.

The steps involved in the Technology Request Pathway are as follows (**Fig. 2**):

1) Technology Request (***Form A***) is completed by the Applicant.
2) The form is submitted to the Division Chief or Department Head (i.e. Local Content Experts) for their support of the request. In particular, possible safety and efficacy issues are scrutinized (***Form B***).
3) Forms A and B are then submitted to Contract/Costing Experts to check for possible resources, cost, or legal/contract issues (***Form C***).
4) Then the Technology Request is checked by the EDSP Advisory Committee (or designate) to determine whether an EDSP pathway is required (***Form D***).
5) If no difficulties are found, the request is approved and forwarded to the appropriate personnel for purchase and implementation. (***Form D***).

EDSP Pathway

The EDSP Pathway is sub-divided into the ***Expedited*** and the ***Full*** Pathways.

▪ Expedited EDSP Pathway

The ***Expedited EDSP Pathway*** is used when some clearly identified uncertainties about the technology's clinical safety and effectiveness and/or its impact on finances or resources have been identified. ***Appendix I: Technology Evaluation Screening Guide*** is used to help make this determination.

In this pathway, information gathered using *Forms A-C*, along with additional information, are brought to the EDSP Advisory Committee (or designate) for evaluation and then to the Department Executive Committee for decision. The request for an Expedited EDSP pathway may come directly from the Applicant or may be recommended by the Advisory Committee (or designate). The authority for approving an Expedited EDSP pathwayrests with the EDSP Advisory Committee (or designate). If there is any doubt about the appropriateness of an Expedited EDSP, then the request goes through the Full EDSP pathway.

New technology may be assessed under the Expedited EDSP Pathway if:

- most, <u>but not all</u>, of the conditions for a Technology Request are satisfied,
- the Technology Request-EDSP Check *(Form D*) suggests that a EDSP is required, or
- the request is time-sensitive.

Under these circumstances, the EDSP Advisory Committee may judge that only specific additional information is required in order to assess the request and will seek that information.

The steps involved in the Expedited EDSP Pathway are as follows (**Fig. 2**):

1) The ***Technology Request*** forms (***Forms A-C***) must be completed and submitted to the Chair of the EDSP Advisory Committee (or designate) indicating that an Expedited EDSP has been requested.
2) The Chair of the EDSP Advisory Committee (or designate) will review the documentation and determine whether the request is suitable for evaluation by the Expedited EDSP Process (***Form D***).
3) The Chair of the EDSP Advisory Committee (or designate) may request additional information or seek an *ad hoc* reviewer.
4) After receipt of satisfactory information, the Chair of the EDSP Advisory Committee (or designate) will assess the request and make a recommendation (***Form H***).
5) This evaluation and recommendation will be presented to the Department Executive Committee for decision (***Form I***).

- **Full EDSP Pathway**

The ***Full EDSP Pathway*** may be requested directly by the Applicant or may be recommended by the Advisory Committee (or designate) reviewing the ***Technology Request***.

New technology will be assessed under the ***Full EDSP Pathway***:

- if it represents a significant change of practice
- if there are significant uncertainties about the technology's clinical safety, efficacy or effectiveness and/or its impact on finances or resources. ***Appendix I: Technology Evaluation Screening Guide*** is used to help make this determination.

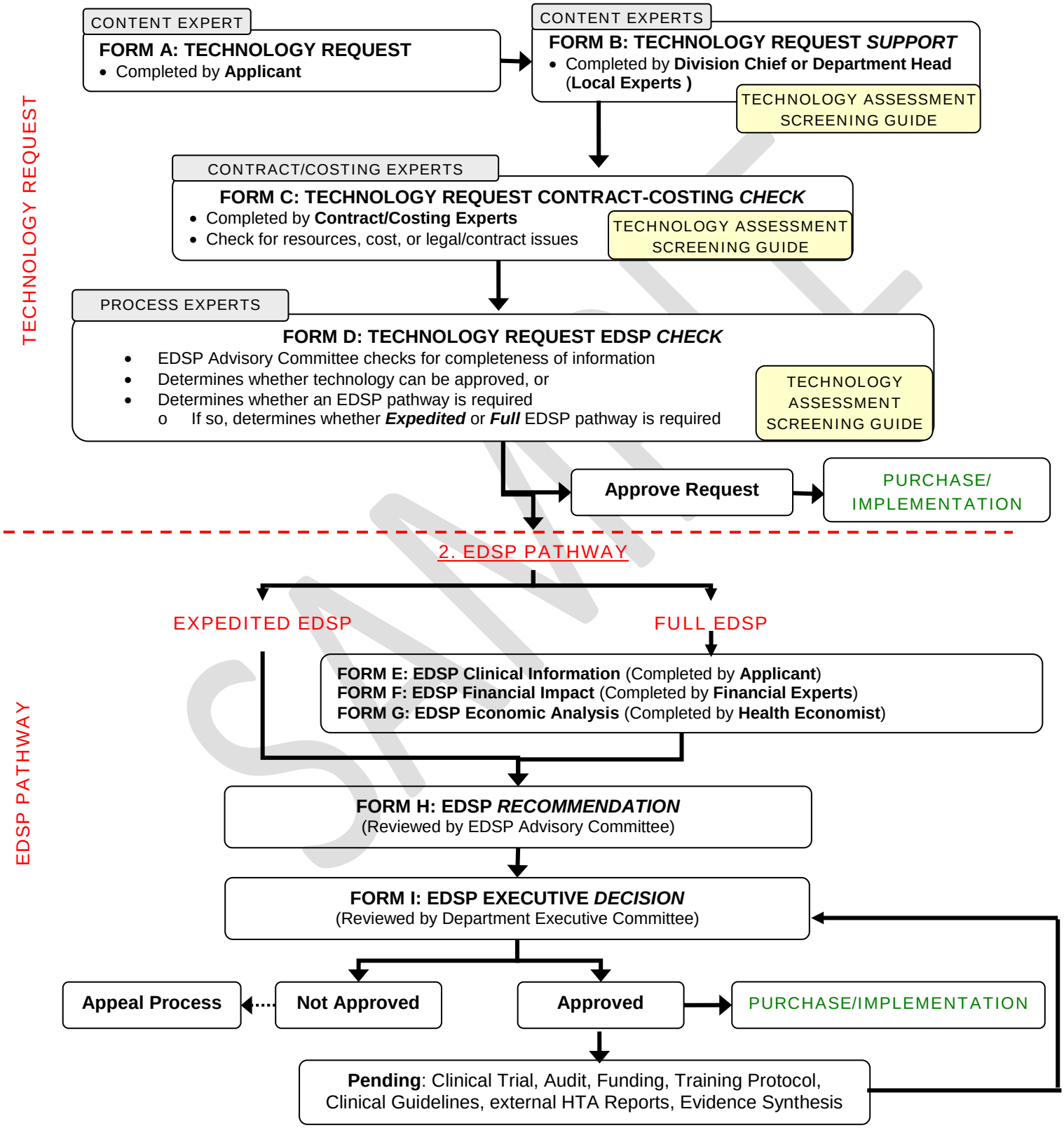
A Full EDSP pathway requires more information (clinical and/or financial resource and infrastructure impact) than an Expedited EDSP or a Technology Request Pathway – that is, *Forms E-G* may be required for a Full EDSP pthway but not for an Expedited EDSP or the Technology Request Pathway.

The steps involved in the Full EDSP Pathway are as follows (**Fig. 2**):

1) The ***Technology Request*** forms (***Forms A-C***) must be completed and submitted to the Chair of the EDSP Advisory Committee (or designate) indicating that a Full EDSP has been requested.
2) Alternatively, the EDSP Advisory Committee (or designate) will review the documentation and determine whether the request requires a Full EDSP Process (***Form D***).
3) The EDSP Advisory Committee (or designate) will request further information:
    a. Clinical Information, completed by the Content Expert(s) (Applicant, ***Form E***)
    b. Financial Impact Information, completed by Financial Experts (***Form F***)
    c. Economic Analysis, completed by Health Economist (***Form G***)
4) The EDSP Advisory Committee (or designate) will assess the technology and make a recommendation (***Form H***).
5) This evaluation and recommendation will be presented to the Department Executive Committee for decision (***Form I***).

Additionally, an evaluation process for one-off, urgent/emergent, compassionate requests is under development. A preliminary version is shown in ***Appendix VIII: One-Off, Urgent/Emergent Evaluation Process***.

Fig. 2: Details of Technology Evaluation Pathways



EVIDENCE DECISION SUPPORT PROGRAM POLICY AND FORMS

Obtaining Program Documents

All documents used in the Evidence Decision Support Program are listed below. They can be provided as individual files or one complete document from paule.poulin@albertahealthservices.ca. To receive more information about the program, you can contact paule.poulin@albertahealthservices.ca.

File #	Document Title
01	Executive Summary
02	Introduction
03	Fig. 1. Overview of Technology Evaluation Pathways
04	Evidence Decision Support Program Details
05	Fig. 2. Details of Technology Evaluation Pathways
06	Policy
07	Form A: Technology Request
08	Form B: Technology Request Support
09	Form C: Technology Request Contract-Costing Check
10	Form D: Technology Request EDSP Check
11	Form E: EDSP Clinical Information
12	Form F: EDSP Financial Impact
13	Form G: EDSP Economic Analysis
14	Form H: EDSP Recommendation
15	Form I: EDSP Executive Decision
16	Appendix I: Technology Evaluation Screening Guide
17	Appendix II: Levels of Evidence
18	Appendix III: Criteria for Technology Evaluation
19	Appendix IV: Technology Evaluation Worksheet
20	Appendix V: Decision Guideline Tool
21	Appendix VI: Presentation Template
22	Appendix VII: Progress Report
23	Appendix VIII: One-Off, Urgent/Emergent Evaluation Process – Draft
24	Appendix IX: Technology Prioritization Tool
25	Grant Support
25	Project Group
26	Glossary

Web-Site

www.ahs.ca/edsp
Application forms can be obtained by contacting Dr. Paule Poulin at paule.poulin@ahs.ca or edsp@ahs.ca

EVIDENCE DECISION SUPPORT PROGRAM POLICY

Subject/Title **Evidence Decision Support Program**	Reference number: Effective date:
Approving Authority: **Department of [*Insert Name*]**	Date Revised:
Classification:	Last Review: Next Review:

Purpose

The primary purpose of the Evidence Decision Support Program is to provide decision-makers with systematically gathered clinical and organizational information on health technologies and their impact on patient health and organization management within the local context.

Underlying Principles

Principles of the Evidence Decision Support Program are:

- To integrate clinical safety and effectiveness, cost, resources, and infrastructure impact
- To achieve consistent, systematic, and transparent decision process
- To support evidenced-informed decisions
- To integrate the interests of all stakeholders including clinicians, administrators, and patients
- To achieve optimal distribution of resources for the greater good
- To ensure quality and safety of new technologies
- To streamline and standardize processes for acquiring new technology within the Region
- To support innovation

Reasons for Policy

- To support and facilitate the evaluation of ***new technologies (including devices, procedures, drugs, medications, and process of care)*** for safety, clinical effectiveness, financial impact on resource allocations before purchase or implementation
- To support the introduction of new technology through the use of a consistent, systematic, and transparent process
- To promote the integration of research evidence into practice
- To facilitate knowledge transfer among a variety of stakeholders within the health organization
- To ensure that an impact evaluation takes place with regards to introducing new technology, i.e. impact on operations

Policy Statement

All new technologies introduced by the Department of [*insert name*], as defined below, will be evaluated by the Evidence Decision Support Program (either following the Technology Request Pathway or the EDSP Pathway) before implementation or purchase.

Applicability

This policy applies to all new technology requested by members of the Department of [*insert name*].

FORM A: TECHNOLOGY REQUEST

To be completed by Applicant

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

This application will be assessed using ***Appendix III: Criteria for Technology Evaluation.***

A-2. Product Manufacturer:_____ **Distributor:**_____ ☐ **N/A**

A-3. Type of proposed technology:

☐ **Device** ☐ **Process of Care** ☐ **Medication**

A-4. Category of proposed technology: [Check **ALL** that apply]

☐ **Innovative/Experimental New**
Little or no safety and effectiveness data is available AND/OR not presently an insured service AND/OR not approved by Health Canada.

☐ **Proven New**
Clinical safety and effectiveness have been demonstrated, but technology has not been used in the local environment AND/OR is not presently an insured service in Alberta.

☐ **Replacement of Existing Technology**
The old version is discarded and proposed version is adopted.

☐ **Upgrade or addition of Existing Technology**
New features are added to existing technology.

☐ **Discard**

A-5. Request for:

☐ **Permanent use**
Estimate the number of patients/devices/procedures **per year:** _____

☐ **Testing a limited number**
Estimate the number of devices or patients that will be tested: _____

☐ **One-Off, Urgent/Emergent Request**. For use on a single patient.

Health Gain

A-6. Efficacy. Briefly describe the proposed technology including:

a) its important features: _____

b) patient characteristics and indications for use: _____

c) its advantages and health benefits (clinical outcomes and QoL) ***over current practice***: _____

d) if this is a replacement, upgrade, addition, or discard of an existing technology as checked in #A-4, describe the existing technology (comparison product) and the ***reason(s) for change***: _____

e) if this benefits cases with few alternatives (One-Off Urgent/Emergent Request as checked in #A-12), describe the circumstances: _____

Service Delivery

A-7. Safety.

a) Please indicate the safety category:

☐ **Risk Profile is the same as comparator procedure(s).** A comparator procedure may be the current "gold standard" procedure or Best Practice, an alternative procedure, a non-surgical procedure or no treatment (natural history).

☐ **Risk Profile is different from comparator procedure**: please describe:

☐ **Risk Profile isUnknown**. Safety has not been determined.

b) Is there known or potential contraindications, product warnings, or risks to:

Patients: ☐ **No** ☐ **Yes** If "Yes", please list? _____

Health care practitioners: ☐ **No** ☐ **Yes** If "Yes", please list? _____

A-8. Users.

Please list additional potential users (other Divisions or Departments) that may use this technology: _____

A-9. Training.

a) Please estimate how many health care practitioners already have the expertise to use this technology?_____

b) Will additional training be required to operate the technology?

☐ **No** ☐ **Yes** If "Yes", please estimate who and how many will require training?

☐ **Physicians** _____ ☐ **Nurses** _____ ☐ **Others** _____

A-10. Location.

Proposed location for use:	Service(s):_____	Site(s):_____

A-11. Change from current practice: [See ***Appendix I: Technology Evaluation Screening Guide***]
Please indicate if this technology represents a:

☐ **Minor change from current practice.**
☐ **Significant change from current practice.**

A-12. Type of review requested (*See,* ***Overview of Evaluation Pathways*****):**

☐ **Technology Request pathway. (**Minor change from current practice or simple vendor change.**)**
☐ **Expedited EDSP pathway.** Additional information may be needed from the Applicant.
☐ **Full EDSP pathway.** Additional Clinical information **(***Form E) may be* required from Applicant.
☐ **One-Off, Urgent/Emergent Request.** Benefits cases with few alternatives. Submit directly to EDSP Committee; [see ***Appendix VIII****:* One-Off, Urgent/Emergent Evaluation Process]
☐ **Don't know**.

Applicant Signature:	**Date:**

(electronic signature and pdf file submission is recommended)

Submit completed *Form A* and accompanying *Form B* to Division Chief or Department Head for support.

FORM B: TECHNOLOGY REQUEST *SUPPORT*

To be completed by Division Chief or Department Head (Local Content Expert)

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

The Division Chief or Department Head will review *Form A: Technology Request*, gather input (formal or informal) from other experts (internal or external), and support/not support the "Request".

Using ***Appendix I: Technology Evaluation Screening Guide***, they will ensure that potential issues have been considered.

B-1. Division Chief or Department Head [Check ONE]:

a. ☐ **NOT Supported.**
Please provide reasons for decision. _____

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b. ☐ **Supported for purchase and/or implementation** (Technology Request Pathway is sufficient).
This indicates that the requested technology:

- represents **minor changes** from current practice
- is safe and effective for patient care
- will improve patient care in the Region
- has good strategic fit with division/department goals and objectives

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c. ☐ **Supported in principle pending further evaluation** (EDSP Pathway is recommended)**.**
This indicates that the requested technology:

- represents a **significant change** from current practice
- is likely to be safe and effective for patient care, but needs further evaluation
- may improve patient care in the Region
- has good strategic fit with division/department goals and objectives

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B-2. Comments
Please provide any additional comments that need to be brought to the attention of the EDSP Advisory Committee._____

Division Chief or Department Head (or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
	PRINT NAME:
	DATE:

Submit completed *Forms A* and *B* to EDSP Advisory Committee: Name: Email:

FORM C: TECHNOLOGY REQUEST *CONTRACT-COSTING CHECK*

To be completed by Contract/Costing Expert

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

Contract/Costing Expert will determine:

- if there are any legal or contractual issues with *Form A: Technology Request*
- if there are cost concerns
- whether a "Request For Proposal" (RFP) is required
- if the Technology Request represents a simple change of vendor

If the Contract/Costing expert feels that there are issues with the Request or that further information is required, then the expert may recommend an EDSP pathway (See ***Appendix I: Technology Evaluation Screening Guide***).

C-1.	**Is the technology Health Canada Approved:**	☐ **N/A**	☐ **No**	☐ **Yes**
C-2.	**Are there any legal or contractual issues with this request?**	☐ **N/A**	☐ **No**	☐ **Yes**
C-3.	**Does the item require a Request For Proposal (RFP)?**	☐ **N/A**	☐ **No**	☐ **Yes**
C-4.	**Is the item or a similar item already on purchase contract?**	☐ **N/A**	☐ **No**	☐ **Yes**
	• If Yes, is the change budget neutral?	☐ **N/A**	☐ **No**	☐ **Yes**
C-5.	**Are there significant cost concerns with this request?**	☐ **N/A**	☐ **No**	☐ **Yes**

C-6. Costing:
Please provide detailed costing evaluation for this request compared to current practice, and indicate if there are any cost concerns: _____

C-7. Comments
Please provide any additional comments that need to be brought to the attention of the advisory committee
_____

Contract/Costing Expert (or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
	PRINT NAME:
	DATE:

Forward completed *Forms A-C* to the EDSP Advisory Committee for review.
Name: E-mail address:

FORM D: TECHNOLOGY REQUEST - *EDSP CHECK*

To be completed by Process Experts (EDSP Advisory Committee or Designate)

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

The EDSP Advisory Committee will check whether ***Technology Request*** pathway is sufficient for approval of the technology, or whether an **EDSP Pathway is required** - [See ***Appendix I: Technology Evaluation Screening Guide*** and ***Appendix IV: Technology Evaluation Worksheet***].

D-1. Is the Technology Request pathway sufficient for approval?

a. ☐ **Yes -Technology Request is sufficient**
EDSP is NOT required; Technology Request is approved in principle and forwarded to purchasing for implementation. Please indicate any conditions of approval: _____

Forward completed *Forms A-D* to Costing/Contract Experts for purchase.
Name: [*insert*] E-mail address [*insert*]

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b. ☐ **No, EXPEDITED EDSP pathway is recommended**
The EDSP Advisory Committee requires the following additional information: [please describe] _____

Forward to appropriate personnel to gather requested information and submit to EDSP Advisory committee for review: Name: [*insert*] E-mail address [*insert*]

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c. ☐ **No, FULL EDSP pathway is required.** [Indicate which of the following forms need to be completed. Check all that applies]

☐ *Form E: EDSP Clinical Information* — Forward *Form E* to applicant
☐ *Form F: EDSP Financial Impact* — Forward *Form F* to financial expert
☐ *Form G: EDSP Economic Analysis* — Forward *Form G* to health economist

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d. ☐ **One-Off, Urgent/Emergent Evaluation Process is requested and is:**
☐ NOT approved
☐ Approved with subsequent critical review. Please describe approval conditions _____
[See ***Appendix VIII: One-Off, Urgent/Emergent Evaluation Process***]

Forward completed *Forms A* and *D* to Costing/Contract Experts for purchase.
Name: [*insert*] E-mail address [*insert*]

EDSP Advisory Committee (Committee chair or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
	PRINT NAME:
	DATE:

FORM E: EDSP *CLINICAL INFORMATION*

To be completed by Applicant

This application will be assessed using ***Appendix III: Criteria for Technology Evaluation.***

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

Health Gain

E-1. Efficacy.

a) Is there evidence that the technology will improve individual patient short-term (< 5 years) or long term (> 5 years) gain in health (clinical outcomes and/or quality of life) as compared with current practice? Please give the best **FIVE** references, including systematic reviews or HTA reports for evidence of clinical efficacy. For each, give the ***title*** and ***authors***, the ***source*** and the ***level of evidence*** (Levels I-V as defined in ***Appendix II: Levels of Evidence***).

b) Summarize the above references, the reasons for change, and the proposed health benefits over current practice. _____

E-2. Population health.

Please describe the incidence and prevalence of the condition, including whether they are projected to change over the next 5 years. _____

E-3. Standard of Care / Best Practice.

Does the proposed technology have the potential to establish a new Standard of Care/Best Practice?

☐ No ☐ Yes [If "Yes", please describe] _____

Service Delivery

E-4. Safety.

a) Please provide additional safety information including known complications and adverse events:

- for the patient _____
- for the health care practitioner _____

b) Please provide information about the risks involved with this technology, additional to that covered in #A-7 of Form A:, or if available, provide a risk/benefit analysis. _____

E-5. Training.

a) Are there staff training implications?

☐ **N/A** ☐ **No** ☐ **Yes** [If "Yes", please describe including number, cost, and time frame]

☐ **Physicians** _____ ☐ **Nurses** _____ ☐ **Others** _____

b) Will credentialing / Certification be required?

☐ **N/A** ☐ **No** ☐ **Yes** [If "Yes", please describe including number, cost, and time frame]

☐ **Physicians** _____ ☐ **Nurses** _____ ☐ **Others** _____

E-6. Access.

a) Will the technology shift services closer to patients?

☐ **N/A** ☐ **No** ☐ **Yes** [If "Yes", please describe] _____

b) Will the technology provide services to under-served populations?

☐ **N/A** ☐ **No** ☐ **Yes** [If "Yes", please describe] _____

c) Will the technology decrease wait times?

☐ **N/A** ☐ **No** ☐ **Yes** [If "Yes", please describe] _____

E-7. Service Coordination.

Will adoption of the technology impact other clinical services either positively or negatively?

☐ **No** ☐ **Yes** [If "Yes", please describe which services will be impacted and how?] _____

E-8. Sustainability.

Will adoption of the technology require additional human resources?

☐ **No** ☐ **Yes** [If "Yes", please describe] _____

Innovation

E-9. Knowledge & Research.

Will the technology improve the generation, transfer, and/or application of new knowledge to patient care services? ☐ **No** ☐ **Yes** [If "Yes", please describe innovation characteristics] _____

E-10. Outcomes Measures [See ***Appendix VII: Progress Report***]

To document the performance (benefits) of this technology to improve patient care services, what Outcomes Measures will be captured [please describe] _____

Applicant Signature:	**Date:**

(electronic signature and pdf file submission is recommended)

Forward completed *Form E* to the EDSP Advisory Committee for review.
Name: E-mail address:

FORM F: EDSP *FINANCIAL IMPACT*

(Resources & Infrastructure Cost) To be completed by Financial Experts

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

Please assess the Financial Impact (Resources and Infrastructure) such as space, equipment, regulatory restrictions, compatibility with existing equipment, maintenance or cleaning routines of the proposed new technology etc. See ***Appendix III: Criteria for Technology Evaluation.***

Information transferred from Form C (See Form C, Contract Costing Check, for further details)

C-5. Is the item or a similar item already on purchase contract? ☐ **No** ☐ **Yes**

- If Yes, is the change budget neutral? ☐ **No** ☐ **Yes**

F-1. Will the technology impact resources or infrastructure?
☐ No ☐ Yes

F-2 Is the technology compatible with existing infrastructure, such as sterilization equipment or information technology systems? ☐ **No** ☐ **Yes [**If No, please describe]:

F-3. Does the technology operate on a stand alone base? ☐ **No** ☐ **Yes**

F-4. Is the new technology an integral part of existing equipment and/or systems? ☐ **No** ☐ **Yes**

- If Yes, can one piece be changed without affecting the work of the whole system? ☐ **No** ☐ **Yes**
  - If No, please describe:

F-5. Equipment Life Expectation:
Please provide an estimate of the expected life of equipment and the likelihood of obsolesces:

F-6. Direct costs [cost of minor and/or capital equipment etc.]	**Direct Cost**
Costs of equipment:	

F-7. One Time & Start up Costs	**One Time & Start Up Costs**
Costs of Engineering, Planning, Renovations and Installation:	
Costs of Staff Training, Orientation and Recruitment:	
One Time Supply, Material Costs:	
Additional Minor Equipment, Software requirements:	
Others, please add:	

F-8. Ongoing costs [yearly costs including cost of personnel etc.]	**Ongoing Costs**
Additional Personnel (increases/decreases to OR set up, tear down and OR time,etc):	
Change in use of: Supplies, Drugs, other Med Surg Supplies, or disposables:	
Ongoing Maintenance/Warranty costs, Software support & Licenses:	
Others, please add:	

F-9 Impact on Other Service Areas	Costs to other Areas
Impact on other service areas such as: Anaesthesia, PACU, In Patient Stays, Processing, Lab, DI, Pharmacy, Physiotherapy, Home Care, etc:	
Others, please add:	

F-10 Alternative or Partial funding sources	Alternative / Partial Funding
If alternative funding sources are available list here (eg: Grant funding to cover equipment, but not operating costs / or two year funding in place for all costs, but no funding after that):	

F-11 Environmental Cost	Environmental Costs
Please describe the environmental cost (environmental impact) of this technology:	

F-12. **Total costs** [sum of F-6 to F-11]	Total Costs
Detailed Costing sheet attached (if required):	

F-13. Is the information presented sufficient for a financial evaluation: ☐ **No** ☐ **Yes**
If No, please describe missing information:

If Yes, please indicate whether the proposed technology is: [check ONE]

a. ☐ **Within budget - recommended**

b. ☐ **Outside budget - costs need Department approval**

c. ☐ **Outside budget – submit request to Region for funding**

d. ☐ **Outside budget – submit request for Province Wide funding**

Financial Expert Signature (or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
	PRINT NAME:
	DATE:

Submit completed *Form F* to EDSP Advisory Committee
Name: E-mail address:

FORM G: EDSP *ECONOMIC ANALYSIS*

To be completed by Health Economist

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

Please conduct an Economic Analysis (Cost-Effectiveness / Cost Benefit Analysis) of the proposed new technology. This application will be assessed using ***Appendix III: Criteria for Technology Evaluation.***

G-1. Is there evidence to support the cost-effectiveness of the technology? ☐**Yes** ☐**No**
If Yes, please describe:

G-2. Is the cost-effectiveness threshold the same for all (e.g., children vs. adults)? ☐**Yes** ☐**No** ☐**N/A**
If No, please describe:

G-3. Is there evidence to support the cost-benefit ratio of the technology? ☐**Yes** ☐**No**
If Yes, please describe:

G-4. Are any potential cost increases associated with the technology offset by significant improvements in quality of life or other patient outcomes? ☐**Yes** ☐**No** ☐**N/A**

If Yes, please describe:

G-5. Comments
Please provide any additional comments that need to be brought to the attention of the advisory committee

Health Economist Signature (or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
	PRINT NAME:
	DATE:

Submit completed *Form G* to EDSP Advisory Committee)
Name: E-mail address:

FORM H: EDSP *RECOMMENDATION*

To be completed by EDSP Advisory Committee

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

Each committee member should evaluate the technology using ***Appendix IV: Technology Evaluation Worksheet.***

H-1. ☐ **RECOMMENDATION** [See ***Appendix V: Decision Guideline Tool***]:

1. ☐ **NOT Recommended**

2. ☐ **Recommended**

3. ☐ **Conditionally recommended**
[Check all that apply]
- **a.** ☐ **Clinical trial**
- **b.** ☐ **Audit**
- **c.** ☐ **Pending funding**
- **d.** ☐ **Pending training protocols**
- **e.** ☐ **Other**

4. ☐ **Recommend request for further evidence review and/or HTA Reports from independent HTA agency or knowledge synthesis services**

H-2. **Conditions of approval:** [If applicable, please describe any recommended conditions of approval. For example, how many cases are allowed, Timeline and significant Outcomes Measures to report to Executive Committee, others] _____

H-3. **Comments:** _____

H-4. ☐ **PRESENTATION TO EXECUTIVE COMMITTEE** [See ***Appendix VI: Presentation Template***]:

a. ☐ **Presentation by Applicant**

b. ☐ **Presentation by EDSP Advisory Committee Chair or Designate**

EDSP Advisory Committee (Committee chair or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
PRINT NAME:	
DATE:	

FORM I: EDSP *EXECUTIVE DECISION*

To be completed by Department Executive Committee

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

I-1. Decision of the Department Executive Committee [See ***Appendix V: Decision Guideline Tool***]

1. ☐ **NOT Approved**

2. ☐ **Approved**

3. ☐ **Conditionally approved**
   [Check all that apply]
   - **a.** ☐ **Clinical trial**
   - **b.** ☐ **Audit**
   - **c.** ☐ **Pending funding**
   - **d.** ☐ **Pending training protocols**
   - **e.** ☐ **Other**

4. ☐ **Request further evidence review and/or HTA Reports from independent HTA agency or knowledge synthesis services**

I-2. Conditions of approval: [Describe conditions of approval. For example, how many cases are allowed, Timeline and significant Outcomes Measures to report to Executive Committee] _____

I-3. Comments: _____

Department Head (Executive Committee chair or designate)	**SIGNATURE:** *(electronic signature and pdf file submission is recommended)*
PRINT NAME:	
DATE:	

Submit Decision letter to Applicant
Name: E-mail address:

APPENDIX I: TECHNOLOGY EVALUATION SCREENING GUIDE

INFORMATION FROM TECHNOLOGY REQUEST FORM

Column 1	Is this technology a change from current practice? If so, answer the following questions (some questions may not be applicable):	Column 2
Content Experts: Patient Impact Questions		
☐ Yes	1. Have the clinical safety and/or rate of adverse events of this technology been clearly described in Form A (or demonstrated elsewhere)?	☐ No
☐ Yes	2. Have the enhanced health benefits of this technology over the current technology been clearly described in Form A (or demonstrated elsewhere)?	☐ No
☐ Yes	3. Has this technology been widely adopted elsewhere?	☐ No
☐ Yes	4. Have the advantages or important features of this technology over current practice been clearly described in Form A (or demonstrated elsewhere)?	☐ No
☐ No	5. Has this technology been categorized as "Innovative/Experimental New" (#A-4) or "significant change from current practice" (#A-11)?	☐ Yes
☐ No	6. Will the addition of this technology require the removal of old technology to minimize the number of choices and the potential for mismatch or error?	☐ Yes
☐ Yes	7. Has the quality of the technology (such as component materials) been demonstrated to be the same or better as that currently used?	☐ No
Content Experts: Health Care Provider Impact Questions		
☐ Yes	8. Are other providers in the Region also in agreement about adopting the technology?	☐ No
☐ No	9. Will the technology require new training for any health care staff?	☐ Yes
☐ No	10. Does the operation of the technology require certification or significant mentored practice time?	☐ Yes
Resource Experts: Resource Impact Questions		
☐ Yes	11. Is the technology compatible with existing infrastructure, such as sterilization equipment or information technology systems?	☐ No
☐ No	12. Will the technology require new maintenance routines?	☐ Yes
☐ No	13. Will the technology require new cleaning routines?	☐ Yes
☐ No	14. Will the technology require more infrastructure (space)?	☐ Yes
☐ No	15. Will the technology require more human resources (staff time)?	☐ Yes
Costing Experts: Cost Impact Questions		
☐ Yes	16. Does the technology fit within the existing budget?	☐ No
☐ No	17. Does the technology require more consumable materials (operational costs)?	☐ Yes
☐ No	18. Will information regarding costing in other areas of health care be needed to determine whether the technology will or will not impact budget?	☐ Yes

All answers in Column 1

Minor change from current practice.
Technology Request Pathway may be sufficient**.**

One or more answers in Column 2

Significant change from current practice.
Expedited/Full EDSP Pathway may be required**.**

APPENDIX II: LEVELS OF EVIDENCE

Levels of Evidence for Primary Research Question[1]				
	Types of Studies			
	Therapeutic Studies—Investigating the Results of Treatment	**Prognostic Studies—Investigating the Effect of a Patient Characteristic on the Outcome of Disease**	**Diagnostic Studies—Investigating a Diagnostic Test**	**Economic and Decision Analyses—Developing an Economic or Decision Model**
Level I	• High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review[2] of Level-I randomized controlled trials (and study results were homogeneous[3])	• High-quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) • Systematic review[2] of Level-I studies	• Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level-I studies	• Sensible costs and alternatives; values obtained from many studies; multiway sensitivity analyses • Systematic review[2] of Level-I studies
Level II	• Lesser-quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level-II studies or Level-I studies with inconsistent results	• Retrospective[6] study • Untreated controls from a randomized controlled trial • Lesser-quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review[2] of Level-II studies	• Development of diagnostic criteria on basis of consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level-II studies	• Sensible costs and alternatives; values obtained from limited studies; multiway sensitivity analyses • Systematic review[2] of Level-II studies
Level III	• Case-control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level-III studies	• Case-control study[7]	• Study of nonconsecutive patients (without consistently applied reference "gold" standard) • Systematic review[2] of Level-III studies	• Analyses based on limited alternatives and costs; poor estimates • Systematic review[2] of Level-III studies
Level IV	Case series[8]	Case series	• Case-control study • Poor reference standard	• No sensitivity analyses
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

1. A complete evaluation of the quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g., with cemented hip arthroplasty) compared with patients treated another way (e.g., with cementless hip arthroplasty) at the same institution.
6. Study was started after the first patient enrolled.
7. Patients identified for the study on the basis of their outcome (e.g., failed total hip arthroplasty), called "cases," are compared with those who did not have the outcome (e.g., had a successful total hip arthroplasty), called "controls."
8. Patients treated one way with no comparison group of patients treated another way.

This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK. For more information, please see www.cebm.net.

APPENDIX III: CRITERIA FOR TECHNOLOGY EVALUATION

The following criteria can be used for evaluating a new technology for funding or purchase.

DOMAIN	CRITERIA	Sub-Criteria Clarifying Questions
Health Gain	**1. Efficacy** (Evidence Based Medicine, Clinical Outcomes & Quality of Life)	1.1 Is there evidence that the technology will improve individual patient short-term (< 5 years) gain in health (clinical outcomes and/or quality of life) as compared with the current practice?
		1.2 Is there evidence that the technology will improve individual patient long-term (> 5 years) gain in health or reduce the likelihood of further disease or complications as compared with the current practice?
		1.3 Can the technology, including risk of adverse events, benefit cases with few alternatives?
	2. Population Health (Burden of Disease)	2.1 Does the technology address a condition with significant incidence and/or prevalence (burden of disease)?
		2.2 Is the incidence or prevalence projected to increase or decrease over the next 5 years?
	3. Standard of Care	3.1 Has the technology become the Standard of Care in other health regions?
		3.2 Will the technology establish a new Standard of Care?
Service Delivery	**4. Safety**	4.1 Is the technology at least as safe as current practice for the patients?
		4.2 Is the technology at least as safe as current practice for the health care providers?
	5. Training	5.1 Will the technology require health care provider training?
		5.2 What is the expected time frame for more health care providers to acquire the expertise to use the technology?
	6. Access	6.1 Will the technology improve accessibility (i.e., shift services closer to where patients reside; geographic equity)?
		6.2 Will the technology provide services to under-served population(s)?
		6.3 Will the technology improve the provision of services at the most appropriate time or decrease wait times? (Timeliness; service efficiency)?
	7. Service Coordination	7.1 Will the technology improve coordination and collaboration with other clinical services or reduce or increase impact on other services (service coordination)? Will the technology reduce load or positively impact other services?
	8. Sustainability	8.1 How many health care providers are demanding this technology?
		8.2 Will the technology be well utilized? How many health care providers have the expertise to use the technology upon acquisition? Will additional human resources be required?
Strategic Fit	**9. Strategic Fit**	9.1 Is the technology aligned with internal (Department/Division) strategic goals?
Innovation	**10. Knowledge & Research**	10.1 Will the technology improve the generation, transfer, and/or application of new knowledge to patient care services? (innovation characteristics)
Financial	**11. Cost** (Resources, Infrastructure)	11.1 Will the technology have Direct costs (purchase of technology)?
		11.2 Will the technology have One Time & Start Up Costs?
		11.3 Will the technology have Ongoing costs?
		11.4 Will the technology impact Other Services Areas?
		11.5 Will the technology have Alternative or Partial Funding Sources?
		11.6 Will the technology have Environmental costs?
	12. Economic Analysis (Cost-Effectiveness, Cost-Benefit)	12.1 Is there evidence to support the cost-effectiveness of the technology?
		12.2 Is the cost-effectiveness threshold the same for all (e.g., children vs. adults)?
		12.3 Is there evidence to support the cost-benefit ratio of the technology?
		12.4 Are any potential cost increases associated with the technology offset by significant improvements in quality of life or other patient outcomes?

APPENDIX IV: TECHNOLOGY EVALUATION WORKSHEET

To be completed by EDSP Advisory Committee or External Expert

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

The EDSP Advisory Committee will use this evaluation when assessing the applicant's request. The Canadian Privacy Act stipulates that, in response to a specific request by the applicant, we must make available a copy of the evaluation.

Reviewer: ☐ **EDSP Committee Member** ☐ **External Expert**

Name: _____ [Please complete Parts A-C]

Part A: Evaluate the **QUALITY AND COMPLETENESS** of the information provided:

(A) Adequate (IN) Inadequate (NA) Not Applicable.

Domain	Criteria	(A) (IN) (N/A)
Technology Description	Is the technology well described (name, type, category) (#A 1-5))?	
Health Gain	**Efficacy** (Evidence-based medicine, Clinical Outcomes, QoL) • Is the number of patients/ devices/ procedures per year clearly estimated? (#A-5) • Are patient characteristics and indications for use, evidence of efficacy clearly described? (#A-6, #E-1) • Are the advantages and health benefits *over current practice* clearly described? (#A-6)	
	Population Health (Burden of Disease, Prevalence) Is the condition incidence/prevalence adequately projected over the next 5 years? (#E-2)	
	Standard of Care Is the potential to establish a new standard of care clearly described? (#E-3)	
Service Delivery	***Safety:*** Are the potential complications or risks to patient or health providers over current practice clearly addressed? (#A-7, #E-4)	
	Training: Are the training implication including number, cost, and time frame clearly described? (#A-9, #E-5).	
	Access / Location for Use: Will the technology improve access to care? Are all potential location for use (services, sites) adequately addressed? (#A-10, #E-6)	
	Service Coordination: Will the technology reduce load or positively impact other services? #E-7	
	Sustainability / Users: How many providers will use this technology & will additional human resources be required? (#A-8, #E-8)	
Strategic Fit	**Strategic Fit**: Does the technology fit with internal (*Department/Division*) *strategic goals*? (#B-1)	
Innovation	**Knowledge & Research**: Are the *innovation characteristics* clearly described? (#E-9)	
	Are the significant O***utcomes Measures*** to document the performance (benefits) of this technology over current practice clearly described? (#E-10)	
Financial	**Cost** (Resources/Infrastructure): Is the information on ***resources and infrastructure impact*** complete? (Form F)	
	Economic Analysis (Cost-Effectiveness, Cost-Benefit): Is the evidence to support the cost-effectiveness or cost-benefit of the technology clearly described? (Form G)	

Part B: a) **Score** the **SIGNIFICANCE and IMPACT** of the technology according to the criteria listed below.

HEALTH GAIN	0 points	1 point	3 points	5 points
Efficacy (#A-6, #E1) Short term health gain Long term health gain Benefits cases with few alternatives	No improvement in patient health gain ☐	Minimal improvement in patient health gain ☐	Moderate improvement in patient health gain ☐	Vast improvement in patient health gain ☐
Population Health (#E-2) Prevalence / Incidence 5-year projected prevalence	The technology address a condition with very low prevalence (rate/ 100,000 < 1) ☐	The technology address a condition with low prevalence (rate/ 100,000 btw 1-10) ☐	The technology address a condition with moderate prevalence (rate/ 100,000 btw 10 -1000) ☐	The technology address a condition with high prevalence (rate/ 100,000 btw 1,000-10,000) ☐
Standard of Care (#E-3) In other Health Regions New Standard of Care	The technology does not represent the Standard of Care in other health regions in Alberta ☐	The technology represents standard of care in some health regions in Alberta ☐	The technology represents standard of care in most health regions in Alberta ☐	The technology represents new standard of care in our health region or Alberta ☐
SERVICE DELIVERY	**0 points**	**1 point**	**3 points**	**5 points**
Safety (#A-7, #E-4)	Controversial documentation of safety ☐	Minimal documentation of safety ☐	Moderate documentation of safety ☐	High degree of documentation of safety ☐
Training (#A-9, #E-5)	Significant training required in terms of cost, time, and number of individuals ☐	Moderate training required in terms of cost, time and number of individuals ☐	Minimal training required in terms of cost, time and number of individuals ☐	No training required ☐
Access (#E-6)	No improvement in access ☐	Minimal improvement in access ☐	Moderate improvement in access ☐	High degree of improvement in access ☐
Service Coordination (#E-7), Reduces load on other services	No reduction in load on other services ☐	Minimal reduction in load on other services ☐	Moderate reduction in load on other services ☐	Vast reduction in load on other services ☐
Sustainability (#E-8) Additional human resources required	High level of additional human resources required ☐	Moderate additional human resources required ☐	Minimal additional human resources required ☐	No additional human resources required ☐
STRATEGIC FIT	**0 points**	**1 point**	**3 points**	**5 points**
Strategic Fit (#B-1**)**	Does not fit department strategic goal ☐	Minimal fit with department strategic goal ☐	Moderate fit with department goal ☐	Fully support department goal ☐
INNOVATION	**0 points**	**1 point**	**3 points**	**5 points**
Knowledge & Research (#E-9)	Not innovative ☐	Small gains in innovation ☐	Moderate gains in innovation ☐	Large gains in innovation ☐
Outcomes Measures (#E-10)	No documentation of follow-up outcome measure ☐	Minimal quality documentation of follow-up outcome measure ☐	Moderate quality documentation of follow-up outcome measure ☐	High quality documentation of follow-up outcomes measure ☐
FINANCIAL	**0 points**	**1 point**	**3 points**	**5 points**
Cost (Resources, Infrastructure; Form F)	Not sustainable or adverse impact on health system funding over time (next 5 years) ☐.	Technology requires significant resource investment in order to be viable and sustainable. ☐	Technology requires start-up funds, but will be viable and sustainable following initial investment. ☐	Technology is viable and sustainable within available resources and/or creates new capacity in the local health system. ☐
Economic Analysis (Cost-effectiveness & Cost-benefit; Form G)	No evidence of cost-effectiveness and/or cost-benefit ☐	Minimal evidence of cost-effectiveness and/or cost-benefit ☐	Moderate evidence of cost-effectiveness and/or cost-benefit ☐	Clear evidence of cost-effectiveness and/or cost-benefit ☐

Part B: b) Please **summarize** the **QUALITY and SIGNIFICANCE and IMPACT** of the technology according to the Domain criteria listed below

DOMAIN Criteria	Overall Information Quality (Score)	Overall Significance and Impact of Technology (Points)	Reviewers' Comments
Health Gain:			
Service Delivery:			
Strategic Fit:			
Innovation:			
Financial:			
Overall			

Part C: RECOMMENDATION

Please give a recommendation on the technology

Technology Request Pathway (See *Appendix I: Technology Evaluation Screening Guide*)		
1. ☐ **EDSP Pathway recommended** (further evaluation required)		
2. ☐ **Approval**		
EDSP Pathway (See *Appendix V: Decision Guideline Tool*)		
1. ☐ **Not Recommended**		
2. ☐ **Recommends Approval**		
3. ☐ **Recommends Conditional Approval**	**a.** ☐	**Clinical Trial**
	b. ☐	**Audit**
	c. ☐	**Pending Funding**
	d. ☐	**Pending Training Protocol**
	e. ☐	**Other**
4. ☐ **Request for Independent knowledge synthesis or HTA Report**		

Comments: _____

APPENDIX V: DECISION GUIDELINE TOOL

RECOMMENTATION OR DECISION		CRITERIA & RATIONALE
1. Not Recommended/Approved		• Negative, poor, or no data on efficacy • Insufficient evidence of safety • Decreases or worsens service delivery
2. Recommended/Approved		• Efficacy and safety well established • Enhanced population health is likely • Sufficient evidence for safety • Will likely improve service delivery • Financial Impact is likely the same or better than current practice • Cost-effectiveness is likely the same or better than current practice • Strategic fit is strong
3. Conditional	**a. Clinical Trial**	• Efficacy has uncertain or controversial evidence • Safety is uncertain • Population health benefit is uncertain • Effect on service delivery is uncertain • May be innovative
	b. Audit	• Efficacy has limited evidence • Good evidence for safety • Cost-effectiveness is uncertain • Advantage over current practice needs to be established • Cost within budget
	c. Pending Funding	• Technology is very expensive • Technology is approved in principle but additional funding is required
	d. Pending Training Protocol	• Detailed training protocol is required • Cost of training needs to be clarified
	e. Other	• Other issues are present that are not already captured (e.g. requirement for detailed clinical use guidelines; approve research protocol, etc.)
4. Request for Independent knowledge synthesis or HTA Report		• Efficacy is controversial or insufficient and summary and interpretation of evidence is necessary • Safety is controversial or insufficient • Cost-effectiveness is controversial or uncertain • May be innovative

APPENDIX VI: PRESENTATION TEMPLATE

Summary for Advisory and Executive Committee Presentation
When a technology request represents a significant change of practice**,** the request requires an **EDSP** and must be presented to the Department Executive Committee for decision. To ensure all important issues are being addressed in a consistent and systematic manner, please discuss the strengths and weaknesses of the proposed technology over current practice using the presentation outline below. Information to be presented can be extracted from the Technology Request (Form A), Clinical Information (Form E), Financial Impact (Form F), and Economic Analysis (Form G).

APPLICANT: Please address the following:

1. **Technology Description**
- **Name** of technology (#A-1); **Type** (#A-3) and **Category** of technology (#A-4):

2. **Health Gain** (#A-6, #E-1, #E-2, #E-3)
- Give a brief summary of clinical efficacy by describing: its important features and the reasons for change, patient characteristics and indications for use, advantages and health benefits **over current practice**, incidence and prevalence of the condition projected over the next 5 years, number of patients/ devices/ procedures **per year.**
- If this is a replacement, upgrade, addition, or discard of an existing technology, describe the existing technology (comparison product) and the reason(s) for change.

3. **Service Delivery**
- **Safety:** (#A-7, #E-4) Please list all known or potential complications, adverse events, contraindications, product warnings, or potential risks to patient or health providers.
- **Training:** (#A-9, #E-5) How many health care practitioners already have the expertise to use this technology? If applicable, describe training implication including number, cost, and time frame.
- **Location for use / Access:** (#A-10, #E-6) List Services and Sites and describe whether it will improve access.
- **Users / Service Coordination** (#A-8, #E-7) List all potential users and whether it will impact other services.
- **Sustainability** (#E-8) Will adoption of the technology require additional human resources?

4. **Innovation**
- Knowledge & Research: Describe the innovation characteristics (#E-9).
- What Outcomes will be measured to document the performance/benefits of this technology? (#E-10)

FINANCIAL EXPERT: Please address the following:

5. **Financial**
- **Financial Impact Information** (*Form F*)
- **Economic Analysis** (*Form G*) Summarize

EDSP ADVISORY COMMITTEE CHAIR: Please address the following:

6. **EDSP Advisory Committee Recommendation (*Form H*)** [EDSP Committee only]
- Summarize (if applicant is not presenting) and describe Committee Recommendations

Return an electronic copy of the presentation to the EDSP Advisory Committee by e-mail.
Name: E-mail address:

APPENDIX VII: PROGRESS REPORT

Name of Applicant:		*(Office use only)* **EDSP ID:**
Department:	**Division:**	**Phone:**
Email:		**Pager:**
A-1. Name of proposed technology (or trade name if applicable)**:**		

Progress Report for Executive Committee Review
When the introduction of a technology has been approved by Executive Committee, the applicant must provide a Progress Report to document the performance (benefits) of the technology. To ensure all important issues are being addressed in a consistent and systematic manner, please address the following using the report outline below.

2. Has the technology been introduced?

☐ Yes [give start date]: _____
☐ No [give reasons]: _____

3. Is the technology continuing to be used?

☐ Yes
☐ No [give reasons]: _____

4. How many procedures have been performed to date? _____

5. Have significant Outcomes been measured?

☐ Yes [Give a summary of key outcomes measured and results – use as much space as needed]: _____

☐ No, give reasons: _____

6. Have there been any adverse outcomes or significant problems?

☐ Yes [Give details – use as much space as needed] _____

☐ No

7. Do you plan to continue using this technology for permanent use?

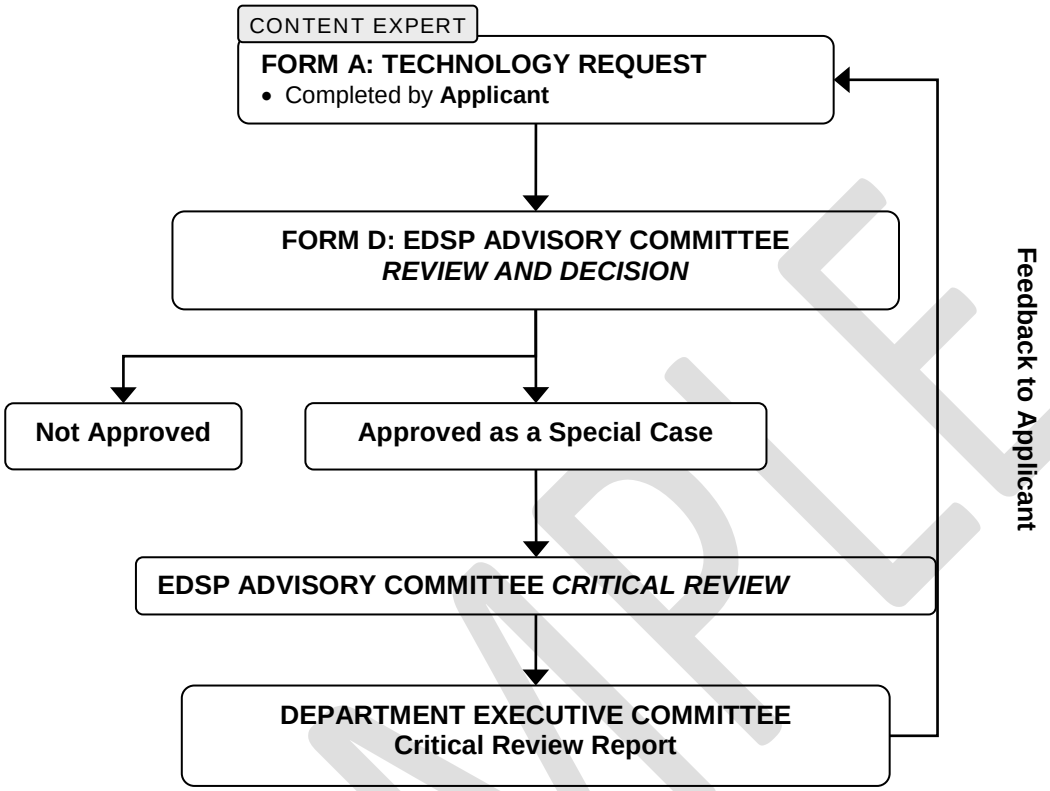
☐ Yes _____

☐ No

Applicant Signature:	**Date:**

(electronic signature and pdf file submission is recommended)

APPENDIX VIII: SINGLE CASE (ONE-OFF) URGENT/EMERGENT EVALUATION PROCESS - *DRAFT*



Suggested process for dealing with Single-Case Urgent/Emergent Requests

- The intent of this process is to allow for legitimate emergency requests while preserving accountability.
- *Form A: Technology Request* should be completed by the requester, preferably prior to the process.
- *Form A* should be is delivered directly to the EDSP Advisory Committee (or designate) for review and approval as a special case (thus by-passing Forms B and C).
- The EDSP Advisory Committee completes *Form D.*
- After the procedure is completed, the EDSP Advisory Committee conducts a Critical Review to assess 1) the outcome with regard to patient safety and clinical effectiveness and 2) whether there was a real emergency as opposed to procrastination.
- The Critical Review is presented to the Department Executive Committee for review and possible follow-up action with the Applicant.
- Note that paperwork for the Critical Review is not yet built into this version of the EDSP.

APPENDIX IX: TECHNOLOGY PRIORITIZATION TOOL

The following "Technology Prioritization Tool" was adapted from Dr. Craig Mitton prioritization tool (personal communication) for use with our decision-making criteria presented in *Appendix III*. It provides one method by which competing technologies can be scored in a way that is consistent and transparent. Technologies can then be prioritized for funding or purchase based on the score received. Please, note this represents a framework to guide a prioritization process and each group should review and revise the list of criteria for their specific needs.

Overview of Steps

Step 1. Compliance Screen. Technologies are screened for their compliance with relevant laws, regulations, and contractual agreements using the Technology Request Form. Only compliant technologies move forward (Form C).

Step 2. Criteria Review. The criteria to be used for prioritization are reviewed and agreed upon (See Appendix III).

Step 3. Criteria Weighting. Some criteria may be deemed to be more important than others, and this relationship may be given a numerical value.

Step 4. Criteria Rating Scales. To assess how well a technology is filling out each criterion, for each criterion, a numerical point scale is developed with clear definitions.

Step 5. Technology Scoring. All technologies are graded on a "matrix", where they are given points for each of the criteria. An overall score is then calculated by using the criteria weights and criteria rating points.

Step 6. Technology Ranking

From here, there are two major streams of analysis, depending on whether costs are considered up front as criteria **(Step 6A)** or whether the criteria consist only of "benefits" and costs are considered later **(Step 6B)**.

Step 6A. Overall Score Used to Prioritize the Technologies. In this case, the cost of the technology is one of the criteria under consideration.

Step 6B. Overall Score Used to Calculate a Cost-Benefit Ratio. In this case, the cost of technology is NOT one of the criteria used to generate the final score. Costs are considered at the final stage, where a calculation of the "cost impact per benefit point" is made.

Whether you used "Step 6A" or "Step 6B", the technologies can now be rank-ordered for funding according to their overall score.

Step 7. Additional Checks

Additional checks, Step 7A and Step 7B can be optionally completed.

Step 7A. System Readiness Check. The technology is checked against four "hurdles" (department capacity, interdependency, risk, and health system impact).

Step 7B. Estimating Success. An estimate of the probability of adoption can be made by considering the System Readiness and System Benefit scores.

TECHNOLOGY PRIORITIZATION DETAILS

STEP 1. Compliance Screen

Technologies are assessed to ensure their compliance with relevant laws or regulations and relevant contractual agreements.

Does the technology request violate any relevant laws, regulations or contractual agreements (See *Form C: Technology Request Contract-Costing Check*)?

☐ **No [PASS – Go to Step 2]**

☐ **Yes [FAIL]**

STEP 2. Criteria Review

It is important that the criteria used be agreeable to all decision-makers. In this regard, the criteria developed for use in evaluating a new technology for funding or purchase and implementation can be used as a starting point (*Appendix III: Criteria for Technology Evaluation*). These criteria are repeated in **Table 1** below**.**

Ideally, the criteria should be independent and non-overlapping, to avoid double-counting. The criteria also should be complete, feasible, and not excessive in number. Please review and revise as needed.

Table 1. Criteria for Technology Evaluation and Prioritization

(repeated from *Appendix III Criteria*)

DOMAIN	CRITERIA	Sub-Criteria Clarifying Questions
Health Gain	**1. Efficacy** (Evidence Based Medicine, Clinical Outcomes & Quality of Life)	1.1 Is there evidence that the technology will improve individual patient short-term (< 5 years) gain in health (clinical outcomes) and/or quality of life as compared with the current practice?
		1.2 Is there evidence that the technology will improve individual patient long-term (> 5 years) gain in health and/or quality of life or reduce the likelihood of further disease or complications as compared with the current practice?
		1.3 Can the technology, including risk of adverse events, benefit cases with few alternatives?
	2. Population Health (Burden of Disease)	2.1 Does the technology address a condition with significant incidence and/or prevalence (burden of disease)?
		2.2 Is the incidence or prevalence projected to increase or decrease over the next 5 years?
	3. Standard of Care	3.1 Has the technology become the Standard of Care in other health regions?
		3.2 Will the technology establish a new Standard of Care?
Service Delivery	**4. Safety**	4.1 Is the technology at least as safe as current practice for the patients?
		4.2 Is the technology at least as safe as current practice for the health care providers?
	5. Training	5.1 Will the technology require health care provider training?
		5.2 What is the expected time frame for more health care providers to acquire the expertise to use the technology?
	6. Access	6.1 Will the technology improve accessibility (i.e., shift services closer to where patients reside; geographic equity)?
		6.2 Will the technology provide services to under-served population(s)?
		6.3 Will the technology improve the provision of services at the most appropriate time or decrease wait times? (timeliness; service efficiency)?
	7. Service Coordination	7.1 Will the technology improve coordination and collaboration with other clinical services or reduce or increase impact on other services (service coordination)? Will the technology reduce load or positively impact other services?
	8. Sustainability	8.1 How many health care providers are demanding this technology?
		8.2 Will the technology be well utilized? How many health care providers have the expertise to use the technology upon acquisition? Will additional human resources be required?
Strategic Fit	**9. Strategic Fit**	9.1 Does the technology fit with internal (Department/Division) strategic goals?
Innovation	**10. Knowledge & Research**	10.1 Does the technology improve the generation, transfer, and/or application of new knowledge to patient care services?
Financial	**11. Cost** (Resources, Infrastructure)	11.1 Will the technology have Direct costs (purchase of technology)?
		11.2 Will the technology have One Time & Start Up Costs?
		11.3 Will the technology have Ongoing costs?
		11.4 Will the technology impact Other Services Areas?
		11.5 Will the technology have Alternative or Partial Funding Sources?
		11.6 Will the technology have Environmental costs?
	12. Economic Analysis (Cost-Effectiveness, Cost-Benefit)	12.1 Is there evidence to support the cost-effectiveness of the technology?
		12.2 Is the cost-effectiveness threshold the same for all (e.g., children vs. adults)?
		12.3 Is there evidence to support the cost-benefit ratio of the technology?
		12.4 Are any potential cost increases associated with the technology offset by significant improvements in quality of life or other patient outcomes?

STEP 3. Criteria Weighting

The Criteria Weighting Tool shown in **Table 2** (adapted from Dr. Craig Mitton, personal communication) uses linear weighting where weightings add up to 100. Other weighting strategies also exist.

Some criteria may be deemed to be more important than others, and this relationship may be given a numerical value (weights). Several methods can be used to determine these weightings:

a) Department members, staff, healthcare providers, and other stakeholders can complete **Table 2** on an individual basis. Weights allocated by respondents are then averaged to generate a Mean weight for each criterion.

b) Department members, staff, healthcare providers, and other stakeholders can meet together and work on a consensus basis to come up with a set of criteria weights for **Table 2** at the group level. This method may be preferable in instances where there are expected value-based disagreements in the weighting of the criteria.

c) If a direction has been given from government on where organizations should be focusing resources, then this may supersede Department decisions on weightings. This is acceptable so long as the rationale for weighting decisions is explicit and transparent.

d) Departments may choose to not weight the criteria. In this case, equal weightings are generated for each criterion in **Table 2**, which must add up to 100.

Table 2. Criteria Weighting Tool

- Allocate a total of 100 points between the criteria listed
- No more than 20 points can be allocated to a single criterion.
- Transfer the weights to Table 3.

Domain	Criteria	Weight
Health Gain	**Efficacy** (Evidence-based medicine, Clinical Outcomes, and Quality of Life)	
	Population Health (Burden of Disease, Prevalence)	
	Standard of Care	
Service Delivery	**Safety**	
	Training	
	Access	
	Service coordination	
	Sustainability	
Strategic Fit	**Strategic Fit**	
Innovation	**Knowledge & Research**	
Financial	**Cost (Resources & Infrastructure)**	
	Economic Analysis (Cost-Effectiveness; Cost-Benefit)	
	TOTAL	**100**

e) Once determined, the criteria weightings are entered into **Table 4**.

STEP 4. Criteria Rating Scales

A Criteria Rating Scale must be developed to allow technologies to be assigned a numerical value (points) based on how well they meet the various criteria. A sample 5-point criteria rating scale based on the criteria of **Table 1** is shown below in **Table 3. Criteria Rating Scale**

Domain	Criteria	0 points	1 point	3 points	5 points
Health Gain	**Efficacy** Short term health gain Long term health gain Benefits cases with few alternatives	No improvement in patient health gain compared with current practices	Minimal improvement in patient health gain compared with current practices	Moderate improvement in patient health gain compared with current practices	Vast improvement in patient health gain compared with current practices
	Population Health Prevalence / Incidence 5-year projected prevalence	The technology address a condition with very low prevalence (rate/ 100,000 < 1)	The technology address a condition with low prevalence (rate/ 100,000 btw 1-10)	The technology address a condition with moderate prevalence (rate/ 100,000 btw 10 - 1000)	The technology address a condition with high prevalence (rate/ 100,000 btw 1,000-10,000)
	Standard of Care In other Health Regions New Standard of Care	The technology does not represent the Standard of Care in other health regions in Alberta	The technology represents standard of care in some health regions in Alberta	The technology represents standard of care in most health regions in Alberta	The technology represents new standard of care in our health region or Alberta
Service Delivery	**Safety**	Controversial documentation of safety	Minimal documentation of safety	Moderate documentation of safety	High degree of documentation of safety
	Training	Significant training required in terms of cost, time, and number of individuals	Moderate training required in terms of cost, time and number of individuals	Minimal training required in terms of cost, time and number of individuals	No training required
	Access	No improvement in access	Minimal improvement in access	Moderate improvement in access	High degree of improvement in access
	Service Coordination Reduces load on other services	No reduction in load on other services	Minimal reduction in load on other services	Moderate reduction in load on other services	Vast reduction in load on other services
	Sustainability Availability of human resources required	High level of additional human resources required	Moderate additional human resources required	Minimal additional human resources required	No additional human resources required
Strategic Fit	**Strategic Fit**	Does not support department strategic goals	Minimal fit with department strategic goals	Moderate fit with department strategic goals	Strong fit with department strategic goals
Innovation	**Knowledge & Research**	Not innovative	Small gains in innovation	Moderate gains in innovation	Large gains in innovation
Financial	**Cost** (Resources & Infrastructure)	Not sustainable or adverse impact on health system funding over time (next 5 years).	Technology requires significant resource investment in order to be viable and sustainable.	Technology requires start-up funds, but will be viable and sustainable following initial investment.	Technology is viable and sustainable within available resources and/or technology creates new resource capacity in the local health system.
	Economic Analysis Cost-effectiveness & Cost-benefit	No evidence of cost-effectiveness and/or cost-benefit	Minimal evidence of cost-effectiveness and/or cost-benefit	Moderate evidence of cost-effectiveness and/or cost-benefit	Clear evidence of cost-effectiveness and/or cost-benefit

STEP 5. Technology Scoring

Once the criteria weightings and criteria rating point scales have been developed, each technology is evaluated for each criterion and given a score according to available evidence. **Table 4, Technology Scoring Tool** provides a tool for entering this information.

For each criterion (1 to n), the points (P) times the weighting (W) is calculated to give a score for each criterion. The total score for each technology is then calculated as follows: $(P_1 \times W_1) + (P_2 \times W_2)\ldots + P_n \times W_n$.

STEP 6A. Overall Score to Prioritize the Technology

The top-ranking technologies can be rank-ordered by their overall score to move forward to the System Readiness Check in Step 7.

STEP 6B. Cost-Benefit Analysis to Prioritize the Technology

In order to calculate a cost-benefit ratio, the overall benefit score for each technology (total score excluding the cost criteria) can be divided by the total technology operating cost with an adjustment for scale by first dividing the operating cost by the total number of patients/ clients served by that technology. As in Step 6A, the top ranked technologies (lowest cost-benefit ratio to highest) would then move forward to the System Readiness Check in Step 7.

Table 4. Technology Scoring Tool

Technology Name:____

Domain	Criteria	0 points	1 point	3 points	5 points	Rating Points	Weights	Score
Health Gain	**Efficacy** Short term health gain Long term health gain Benefits cases with few alternatives	No improvement in patient health gain compared with current practices	Minimal improvement in patient health gain compared with current practices	Moderate improvement in patient health gain compared with current practices	Vast improvement in patient health gain compared with current practices			
	Population Health Prevalence / Incidence 5-year projected prevalence	The technology address a condition with very low prevalence (rate/ 100,000 < 1)	The technology address a condition with low prevalence (rate/ 100,000 btw 1-10)	The technology address a condition with moderate prevalence (rate/ 100,000 btw 10 - 1000)	The technology address a condition with high prevalence (rate/ 100,000 btw 1,000-10,000)			
	Standard of Care In other Health Regions New Standard of Care	The technology does not represent the Standard of Care in other health regions in Alberta	The technology represents standard of care in some health regions in Alberta	The technology represents standard of care in most health regions in Alberta	The technology represents new standard of care in our health region or Alberta			
Service Delivery	**Safety**	Controversial documentation of safety	Minimal documentation of safety	Moderate documentation of safety	High degree of documentation of safety			
	Training	Significant training required in terms of cost, time, and number of individuals	Moderate training required in terms of cost, time and number of individuals	Minimal training required in terms of cost, time and number of individuals	No training required			
	Access	No improvement in access	Minimal improvement in access	Moderate improvement in access	High degree of improvement in access			
	Service Coordination Reduces load on other services	No reduction in load on other services	Minimal reduction in load on other services	Moderate reduction in load on other services	Vast reduction in load on other services			

Table 4. Technology Scoring Tool (continued)

-

Domain	Criteria	0 points	1 point	3 points	5 points	Rating Points	Weights	Score
Service Delivery (continued)	**Sustainability** Availability of human resources required (physicians, nurses, and support staff)	High level of additional human resources required	Moderate additional human resources required	Minimal additional human resources required	No additional human resources required			
Strategic Fit	**Strategic Fit**	Does not support department strategic goals	Minimal fit with department strategic goals	Moderate fit with department strategic goals	Strong fit with department strategic goals			
Innovation	**Knowledge & Research**	Not innovative	Small gains in innovation	Moderate gains in innovation	Large gains in innovation			
Financial	**Cost** (Resources & Infrastructure)	Not sustainable or adverse impact on health system funding over time (next 5 years).	Technology requires significant resource investment in order to be viable and sustainable.	Technology requires start-up funds, but will be viable and sustainable following initial investment.	Technology is viable and sustainable within available resources and/or technology creates new resource capacity in the local health system.			
	Economic Analysis Cost-effectiveness & Cost-benefit	No evidence of cost-effectiveness and/or cost-benefit	Minimal evidence of cost-effectiveness and/or cost-benefit	Moderate evidence of cost-effectiveness and/or cost-benefit	Clear evidence of cost-effectiveness and/or cost-benefit			
						OVERALL SCORE		**/100**

STEP 7. System Readiness Check (Optional)

Mitton's scheme uses a "System Readiness Screen," in which technologies are checked against four "hurdles" (department capacity, interdependency, risk, and health system impact). Whereas these "hurdles" are already mostly embedded within our criteria (**Table 1**), a System Readiness Check is still a useful way of checking the impact of the criteria and predicting the probability of adoption.

- Department capacity: Does the Department have the needed material, financial, and health human resources to support this technology at this time? If the technology is sufficiently important, are there ways to leverage system resources to make the technology viable now or in the future?
- Interdependency: Does this technology depend on the completion of other projects? Are other high-priority projects depending on the introduction of this technology? Is this technology aligned with other projects that would need also to be funded in order for them to be viable?
- Risk: Is the level of risk involved acceptable? Have mitigation strategies been identified to address this risk and are they practical? What are the risks of not funding or endorsing this technology at this time?
- Health system impact: Does this technology raise any considerations of health system impact that were not addressed in the evaluation process? What impact would funding this technology have on other fundable projects in terms of material, financial, and health human resource?

Technologies satisfying the system readiness screen are eligible for funding as per the rank order identified through the scoring process.

STEP 8: Estimating Success (Optional)

Organizations may also want to use a simple probability matrix to estimate the probability of successful adoption using their System Readiness and System Benefit scores (**Table 4**).

System Readiness:

High: Proposal cleared all four hurdles on the System Readiness Check in Step 7
Medium: Proposals cleared two or three hurdles
Low: Proposals cleared zero or one hurdle

System Benefit:

High: Technologies scoring 70-100 in Step 5
Medium: Technologies scoring 40-70
Low: Technologies scoring 0-40

Table 4. Probability Matrix for Success

	Probability of Success		
High System Readiness	30%	60%	80%
Medium System Readiness	25%	50%	60%
Low System Readiness	15%	25%	30%
	Low System Benefit	**Medium System Benefit**	**High System Benefit**

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Paule Poulin, Catherine M. Scott, Judy Seidel, Nadine Gall, René Lafrenière. Local Health Technology Assessment Tools for Local Decision Makers. Health Technology Assessment Capacity Building Grant Program, Canadian Coordinating Office for Health Technology Assessment (2006).

Paule Poulin, Tyrone L. Donnon, Norm Schachar, David Sigalet, Anita Jenkins. Interactive HTA Education Program for Health Care Practitioners in Local Setting. Health Technology Assessment Capacity Building Grant Program, Canadian Coordinating Office for Health Technology Assessment (2005).

Paule Poulin, René Lafrenière, David Sigalet; Tom Noseworthy, Serdar Yilmaz and Guy Maddern. User-Friendly Surgical Health Technology Assessment Database. Health Technology Assessment Capacity Building Grant Program, Canadian Coordinating Office for Health Technology Assessment (2004).

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The individuals listed below have contributed to the review and development of the Decision support program. Their names, titles and department affiliations are listed as current at the time of their contribution.

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Chittick, Mr.	Brian	Regional Business Manager	Surgical Services
Cote, Ms	Joyce	Pharmacist	Pharmacy
Culham, Ms	Patricia	Regional Manager	Cardiac Sciences
De Jong, ms	Mandy	Pharmacist	Pharmacy
De Souza, Ms	Rachel	Program Manager, Interventional services	Surgical Services
Dixon, Dr.	Elijah	Project Co-investigator HT&I Advisory Committee	Surgery
Donnon, Dr.	Tyrone	Assistant Professor, Project Co-investigator	Department of Community Health Science
Dwyer, Ms	Christy	Clinical Product Specialist Product Standards & Evaluation	Medical Device Safety & Risk Management
Flaherty, Ms.	Susan	Facilitator	Retreat Facilitator
Forsythe, Mr.	Darrel	Manager Product Standards & Evaluation	Medical Device Safety & Risk Management
Gall, Ms	Nadine	Manager (Knowledge Transfer) Project Co-investigator	Calgary Health Research
Gervais, Ms	Lori	Patient Care Manager	Peter Lougheed Hospital
Gingues, Mr.	Gilles	Clinical Facilitator (supplies, equip.)	Surgical Services
Hitchison, Ms	Maria	Patient Care Manager	Peter Lougheed Hospital
Hodges, Ms	Mary	Senior Scientific Research Officer	Calgary Health Research
Jajszczok, Mr.	Max	Clinical Product Specialist Product Standards & Evaluation	Medical Device Safety & Risk Management
Jenkins	Anita	Education Coordinator, Project Co-investigator	Surgery

Last Name	First Name	Title	Department
Kortbeek, Dr.	John	Regional Clinical Department Head	Surgery
Kozak, Dr.	Greg	HT&I Advisory Committee	Surgery
Kyle, Dr.	Ann	EDSP Project Scientific Editor	Project Consultant
Lafrenière, Dr.	René	Professor Project Co-investigator	Surgery
Le, Dr.	Ian	HT&I Advisory Committee	Surgery
LeBlanc, Ms	Kathy	Director	Critical Care Medicine / ICU
Lee, Dr.	Robert	Director	HTA Implementation Unit
Maddern, Dr.	Guy	Professor Project Co-investigator	Surgery (Australia)
Mayer, Ms	Anne	Nurse Clinician	Alberta Children Hospital
McEachern, Ms	Marie	Regional Manager	Surgery
McIsaac, Ms	Michelle	Health Economist	HTA Implementation Unit
Mechor, Dr.	Brad	HT&I Advisory Committee	Surgery
Midha, Dr.	Rajiv	Regional Clinical Department Head	Clinical Neurosciences
Mitchell, Dr.	Brent	Regional Clinical Department Head	Cardiac Sciences
Naylor, Dr.	Shanda	Director	Surgical Services
Noseworthy, Dr.	Tom	Director, CHAPS, and Professor, Department of Community Health Sciences Project Co-investigator	Centre for Health and Policy Studies (CHAPS)
Nurani, Ms	Zahra	Project Manager Health Workforce	Research Network of Alberta
Oddone-Paolucci, Dr.	Elizabeth	Project consultant	Medical Education and Research Unit
Perry, Dr.	Mary	Director	Calgary Health Research
Plunkett, Ms	Tracey	Regional Manager	Diagnostic Imaging
Poulin, Dr.	Paule	Project Principal-investigator	Surgery
Poulin, Ms	Michelle	Project Coordinator	Project Consultant
Reader, Ms	Susan	Patient Care Manager	Alberta Children Hospital
Rimmer, Ms	Carol	Pass Director	Calgary Health Research
Ruggles, Ms	Karen	Quality Improvement Consultant	Anesthesia
Schachar, Dr.	Norman	Director, Surgical Education Project Co-investigator	Surgery
Scott, Dr.	Catherine	Director (Knowledge into Action) Project Co-investigator	Calgary Health Research
Seidel, Dr.	Judy	Scientific Director CAH Project Co-investigator	Calgary Health Research
Sevick, Dr.	Robert	Regional Clinical Department Head	Diagnostic Imaging
Sheldon, Dr.	Robert	Vice President Research	Calgary Health Research
Shockey, Ms	Linda	O.R. Projects Manager	Surgical Services
Shrout, Ms	Jeannie	Regional Manager	Critical Care Medicine

Last Name	First Name	Title	Department
Sigalet, Dr.	David	Associate Professor Project Co-investigator	Surgery
Silvius, Dr.	James	VP & Associate CMO	Physician Leadership Portfolio
Stewart, Ms	Janice	Director	Cardiac Sciences
Syverson, Ms	Shawna	Director	Surgical Services
Tang, Dr.	Timothy	Physician Leader, Quality improvement	Anesthesia
Waddell, Dr.	Cam	Executive Medical Director Project Co-Investigator	North West Community Portfolio
Wilkinson, Ms	Shauna	Manager	Cardiac Sciences
Yilmaz, Dr.	Serdar	Professor Project Co-investigator	Surgery
Zarnke, Dr.	Kelly	Director, Pharmacy & Therapeutics	Pharmacy

GLOSSARY

This section provides definitions of the terms used within the Evidence Decision Support Program.

Burden of Disease:

The burden of disease refers to the magnitude of a health problem in an area, measured by mortality (deaths) and morbidity (persons affected by the disease).

Compassionate Request:

A Compassionate Request refers to unusual treatments that are often a "last-ditch" effort. In Canada, there is a "special access" program for the authorization for the sale or import of class III or IV medical devices for emergency use or if conventional therapies have failed, are unavailable, or are unsuitable. The application procedure is set out in the *Medical Devices Regulations: Form 2 "Custom-Made Devices and Medical Devices to be Imported or Sold for Special Access"*. (http://laws.justice.gc.ca/en/showdoc/cr/SOR-98-282/bo-ga:l_2/en#anchorbo-ga:l_2).

Discard of Technology:

The technology is to be discontinued.

Expedited EDSP Pathway:

This is a sub-division of the EDSP Pathway. It is used when some clearly identified uncertainties about the technology's clinical safety and effectiveness and/or its impact on finances or resources have been identified (see *Appendix I: Technology Evaluation Screening Guide*). New technology may be assessed under the Expedited EDSP Pathway if:

- most, but not all, of the conditions for the Technology Request Pathway are satisfied,
- The Technology Request-EDSP Check (Form D) suggests that a EDSP pathway is required, or
- the request is time-sensitive.

Under these circumstances, the EDSP Advisory Committee (or designate) may judge that only specific additional information is required in order to assess the technology and will ask for that information.

In this pathway, information gathered using *Form A: Technology Request*, along with additional information, are brought to the EDSP Advisory Committee (or designate) for evaluation and then to the Department Executive Committee for decision.

The request to use the Expedited EDSP Pathway may come directly from the Applicant or may be recommended by the Advisory Committee (or designate). The authority for approving an Expedited EDSP rests with the EDSP Advisory Committee (or designate). If there is any doubt about the appropriateness of an Expedited EDSP pathway, then the request will go through the Full EDSP pathway.

Full EDSP Pathway:

This is a sub-division of the EDSP Pathway. It is used when there are significant uncertainties about the technology's clinical safety and effectiveness and/or its impact on finances or resources (see *Appendix I: Technology Evaluation Screening Guide*). New technology will be assessed under the Full EDSP Pathway:

- for those technologies whose clinical safety or effectiveness is uncertain or
- for "big ticket" items.

A Full EDSP requires more clinical, resource impact, and costing information than an Expedited EDSP or a Technology Request Pathway – that is, *Forms E-G* are required for a Full EDSP pathway but not for an Expedited EDSP or Technology Request Pathway.

The request to use the "Full EDSP Pathway" may come directly from the Applicant or may be recommended by the Advisory Committee (or designate).

Health Technology:

Health technology includes any method or intervention that is used to promote health; prevent, diagnose, or treat disease; or improve rehabilitation and long-term care. Technologies include drugs, devices, diagnostic agents,

equipment, and medical and surgical procedures. The definition also includes organizational and service systems that provide health care, such as telehealth (Canadian Agency for Drugs and Technology in Health, 2007).

Incidence of Disease:

The number or percentage of NEW CASES arising over a GIVEN TIME PERIOD in a given population.

Innovative/Experimental New Technology:

Technology for which little or no safety and effectiveness data is available AND/OR not presently an insured service AND/OR not approved by Health Canada.

Evidence Decision Support Program (EDSP)

The EDSP is an integrated evaluation of the clinical safety and effectiveness, financial (resources & infrastructure) impact, and broader impact of drugs, medical technologies, and health systems, both on patient care and on the local health care system. During the evaluation, clinical data from research studies and other sources are systematically gathered, integrated with local organizational data, analyzed, and interpreted to inform decisions about the adoption of new health technologies in the local context.

The EDSP is a collection of resources and tools to assist local decision makers in evaluating new health technologies. The role of the EDSP is to collect, integrate and evaluate information with regard to the safety, efficacy and organizational impact of selected new technologies. Recommendations on the new technologies are then produced for consideration by Department Executive Committees for decision.

Our Evidence Decision Support Program makes provision for two major pathways for evaluating new technology:

1. Technology Request Pathway, a rapid pathway for minor change of practice.
2. EDSP Pathway, a more extensive pathway that is used when there are uncertainties about a technology's impact on clinical outcomes, education, resources or finances. The EDSP Pathway requires extra information about the technology in addition to that contained in *Form A: Technology Request*, as determined by the EDSP Advisory Committee. Depending on the amount of extra information required, the process follows either the Expedited EDSP Pathway or the Full EDSP Pathway.

Additionally, a "***One-Off, Urgent/Emergent Request***" technology evaluation process for one-off, urgent/emergent, compassionate case to benefit patients with few alternatives is under development. A preliminary version is shown in *Appendix VIII*.

EDSP Pathway:

This is one of two major pathways for evaluating technology in the Evidence Decision Support Program (the other being the Technology Request Pathway). This pathway is used when there are uncertainties about a technology's impact on clinical outcomes, education, resources or finances. The EDSP Pathway requires extra information about the technology in addition to that contained in *Form A: Technology Request*, as determined by the EDSP Advisory Committee. Depending on the amount of extra information required, the process follows either the Expedited EDSP Pathway or the Full EDSP Pathway.

Manufacturer, Vendor Information:

Manufacturer, Vendor and Supplier information can be a part of the review process to describe the product and to determine the need for Request for Proposal, Health Protection Branch, or legal/contractual issues. However, manufacturers, vendors, or suppliers are not allowed to put forward a technology request application.

Minor change from current practice:

A clear definition of "minor change from current practice" is still under development. However, *Appendix I: Technology Evaluation Screening Guide* can be used to help determine whether a technology is a minor or significant change from current practice. It is recognized that this screening guide needs further revision by appropriate expert working groups.

New Health Technology:

New health technology is defined as a change from current practice (either adoption of new technologies or modification, replacement, or discarding of existing technologies or process of care) that may have a direct or indirect impact on patient care and/or financial aspects of health care services.

From a surgical perspective, "new technology" is also defined as having at least one of the following characteristics: 1) increased cost, 2) different risk profile, 3) needs new training, 4) uses a different anatomical approach.

One-Off, Urgent/Emergent Request:

A One-Off, Urgent/Emergent Request is a request to use a particular technology only once. It may be requested for testing a new technology for a unique circumstance to benefit patients with few alternatives. It may be a time-sensitive Urgent/Emergent Request that needs to be processed quickly for patient safety issues. These requests should not have a resource impact in terms of staff or facilities, but may have efficacy or cost issues. A special process is being developed to deal with these requests (see *Appendix VIII*) and will automatically include a Critical Review Process.

Prevalence of Disease:

The total number or percentage of cases at a given moment in time in a given population.

Principal Applicant:

The Principal Applicant is the lead individual making the technology request. Each technology request must have one designated Principal Applicant (lead technology requestor). The Principal Applicant will receive all official communication from the technology request review process and is responsible to distribute the request status information to his or her co-Applicants.

Proven New Technology:

The clinical safety and effectiveness of the technology have been demonstrated. The technology is in use in other health care systems, but the technology has not been used in the local environment, AND/OR is not presently an insured service in Alberta.

Replacement of Existing Technology:

The old version is discarded and proposed version is adopted. Comparative evaluation may be needed.

Significant uncertainties about the technology's clinical safety and effectiveness:

A clear definition of "significant uncertainties about the technology's clinical safety and effectiveness" is still under development. However, *Appendix I: Technology Evaluation Screening Guide* can be used to help determine whether a technology is a minor or significant change from current practice. It is recognized that this screening guide needs further revision by appropriate expert working groups.

Significant uncertainties about the technology's impact on finances or resources:

A clear definition of "significant uncertainties about the technology's finances or resources" is still under development. However, *Appendix I: Technology Evaluation Screening Guide* can be used to help determine whether a technology is a minor or significant change from current practice. It is recognized that this screening guide needs further revision by appropriate expert working groups.

Technology Request Pathway:

This is one of two major pathways for evaluating new technology in the Evidence Decision Support Program (the other being the EDSP Pathway). This pathway provides a rapid method for requesting new technology, while ensuring that safety, cost, and legal and contractual issues are considered. New technology may be approved under the Technology Request Pathway if the following clinical and operational conditions are met:

Clinical:

- The technology represents a "minor change from current practice."
- The technology request has been supported by Division Chief or Department Head (local experts)

Operational:

- The technology does not have legal or contractual issues.
- The item or a similar item may already be on purchase contract and/or utilized within the Region and/or a change of vendor is being requested.
- The technology request is within financial means.

Upgrade or Addition of Existing Technology:

New features are added to existing technology. Comparative evaluation may be needed.