

LIFECYCLE GUIDANCE

FOR MEDICAL IMAGING EQUIPMENT IN CANADA

2013



MAIN REPORT

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Canadian Association of Radiologists
L'Association canadienne des radiologistes

PARTNERS:



Canadian Association of
Medical Radiation Technologists
Association canadienne des
technologues en radiation médicale



**Canadian Cardiovascular
Society**
Leadership. Knowledge. Community.

**Société canadienne
de cardiologie**
Communauté. Connaissances. Leadership.

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MAIN PARTNERS

The Canadian Association of Radiologists was the principal lead on the project, with the Canadian Association of Medical Radiation Technologists (CAMRT) and the Canadian Cardiovascular Society (CCS) as partners.

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1.0 INTRODUCTION

- The focus of this guidance report is to help organizations determine when and how to upgrade or replace existing medical imaging (MI) devices or add new / emerging technologies.
- Optimizing MI equipment is an essential consideration for establishing best practices and managing capital equipment budgets – but striking a balance between replacing and upgrading the tools needed for clinical excellence and strained health care budgets is an ongoing challenge.
- Lifecycle planning is an essential part of optimal use. Key stakeholders in Canada have taken the lead in developing updated, comprehensive lifecycle guidance (LCG) for MI equipment in Canada. This initiative has resulted in more relevant LCG to replace the 2001 LCG produced by the Canadian Association of Radiologists. It appears that there is a lack of comprehensive LCG nationally and internationally and this gap supports the potential benefits of this initiative.
- Key principles for the 2013 MI LCG were derived in part from a literature review and an environmental scan (survey and interviews) carried out early in the project.
 - The literature review included national and international literature. Evidence (i.e., clinical studies) appears to be limited; rather, experts in various fields describe their experiences and observations including factors to consider when creating tailored LCG for a jurisdiction, e.g., finances, equipment age and utilization, demand / wait lists, history of maintenance, and technology evolution.
- An environmental scan surveyed Canadian stakeholders and communicated with experts nationally and internationally. The survey showed variability in awareness of and experience with MI LCG. Regarding technology change, respondents overwhelmingly felt that technology advancement is important when deciding to upgrade / replace / adopt new technologies. Assessment criteria were confirmed as essential to a business case for equipment planning.
- As a final LCG product, it was determined that a simple table of number of years of life per modality cannot provide adequate guidance for equipment management. To best accomplish thoughtful equipment management and lifecycle considerations a broader process and stakeholder participation are required.
- Decisions involving technologies should ideally include considering the evidence available, such as health technology assessment (HTA), in addition to examining clinical programs, staffing, budgets, etc. The link with evidence should include examples of how MI technology decisions positively impacted patient management and improved patient outcomes; however, this research is sparse.

This advice provides ‘guidance’. Selection of assessment criteria and weighting of importance are unique to each environment. It is the responsibility of the user to assess his or her equipment based on an intimate understanding of the technology, clinical requirements, risk, fiscal limitations, etc.

A common standard for lifecycle guidance should be applied to all medical imaging devices within an organization, regardless of their location.

2.0 PROJECT MANDATE AND PHILOSOPHY

The purpose of this document is to provide guidance for when and under what conditions selected MI devices¹ should be considered for upgrade or replacement, including consideration of new technologies. In developing the guidance, it was determined that it should encourage the use of evidence in a practical way. The guidance should be comprehensive, based on sound principles, and robust enough to be used in a variety of environments (large/small, urban/rural, public/private), yet easily applied.

To accomplish thoughtful equipment management that includes lifecycle issues a process broader than production of a table of numbers is required. Ideally, decisions involving upgrades or replacement with new technologies should examine clinical programs, staffing, budgets, etc. and also consider the evidence available via rigorous and unbiased processes such as HTA. Stakeholder feedback should be monitored and the guidance revised on a regular basis.

3.0 PROJECT METHODS

Development of this guidance took into account the broad spectrum of stakeholder² requirements. Guidance development was informed by a literature review (Section 4.0), followed by stakeholder input via an environmental scan (Section 5.0) consisting of a survey and communication with key individuals and organizations nationally and internationally. Valuable input was provided by a 14-member multidisciplinary Advisory Committee (AC).

The survey was distributed to about 500 stakeholders including academic heads of radiology; cardiac chiefs from academic sites; managers from the Canadian Association of Medical Radiation Technologists (CAMRT); and representatives from ministries of health, colleges of physicians and surgeons, radiation health and safety organizations, and AC committee organizations. Knowledgeable contacts from Canada, Australia, the United States and the United Kingdom were also interviewed by phone, e-mail or both.³

Main guidance and summary documents were drafted and a validation process was initiated to ensure exposure to the views of key stakeholders. Participants were members of the sponsoring organizations (CAR, CAMRT and CCS) and ministry of health representatives. CADTH also requested broad input via their newsletter, liaison offices and twitter. A number of experts responded with suggestions. These were reviewed and changes made to the reports.

4.0 LITERATURE REVIEW

As background to guidance development, a literature review was conducted. The research questions were:

- What does the published and unpublished / “grey” literature (medical and other) report about existing lifecycle guidelines or guidance for imaging equipment, nationally and internationally?
- What does the literature report about LCG under-way or planned?
- What does the published / “grey” literature report about financial models for MI?
- What sources were used or are being used to develop LCG?

1 Included are general radiography and fluoroscopy (fixed & mobile); digital radiography; angiography/interventional; catheterization laboratories, ultrasound, CT, MRI, bone densitometry; mammography; NM (gamma and SPECT); SPECT/CT, PET, PET/CT; and lithotripters. Excluded are cancer treatment and simulation equipment, dental equipment, RIS/PACS and cyclotron equipment.

2 Examples of stakeholders: federal, provincial and territorial governments; hospital administrations and financial officers; clinicians; patients; MI providers; quality and safety officials; accreditation organizations; and equipment manufacturers.

3 Alberta Health Services, American Association of Medical Imaging Management, American College of Radiology, Australian Ministry of Health and Aging, BlueCross BlueShield, Canadian Institute for Health Information (CIHI), Canadian Medical and Biological Engineering Society, Canadian medical equipment manufacturers (MEDEC), Canadian Organization of Medical Physicists, Quebec Ministry of Health, Saskatchewan Ministry of Health and the United Kingdom National Health Services (NHS).

The literature review report is found in Appendix 1. The review focussed on replacing / upgrading technologies, and introducing new and emerging technologies. Of almost 1,400 records screened, 52 were identified as potentially relevant and were obtained in full text and assessed for eligibility; 34 were included in a qualitative synthesis. Useful material was identified (primarily from the US and Australia) but the amount of ‘evidence’ underlying LCG was sparse, as were examples of life-cycle guidelines. Experts in various fields described factors to consider when creating tailored LCG for a jurisdiction, e.g., demand, technology evolution / new technologies, history of use, changes in safety considerations (e.g., radiation doses), and availability of parts and service. This practical advice was used to design the ‘rules’ around use of LCG.

Ideally the body of evidence will grow in future to link changes in imaging technology with changes in patient management and improved outcomes, although research in this area is complex and sparse. A key contribution of the literature review was to identify the lack of LCG nationally and internationally – this served to support this initiative and the potential utility of MI LCG.

5.0 ENVIRONMENTAL SCAN

The environmental scan report is found in Appendix 2. Its objective, including a stakeholder survey followed by focused interviews, was to understand the views of a cross-section of MI stakeholders such as those from professional associations; ministries of health; monitoring organizations, e.g., accreditation and radiation safety; administration; and industry.

- *Survey:* A letter of invitation and on-line stakeholder survey (38 questions plus 18 subset questions) were distributed to about 500 stakeholders. Response rate was 16.4% (82 respondents, some were groups). Responses ranged from 4 to 82 per question. The survey showed variability in awareness of and experience with MI LCG. Although 39% of respondents were aware of the 2001 CAR MI LCG, only 2/3 of these (26% of respondents) had used them. Also, 16% of respondents were aware of MI LCG produced by others. A third of respondents had developed their own LCG; of the remainder, 50% plan to do so. Respondents overwhelmingly feel technology advancement is important when deciding to upgrade or replace equipment and whether to consider new or emerging technologies.

Considerations include, for example, reduced radiation dose, standards and safety code compliance, improved image quality, clinical pathways, suitability for upgrade, and likelihood of obsolescence.

- The most common criteria currently in use for justifying equipment replacement or upgrade are: life expectancy criteria (age, functionality, operational cost, etc.); prioritization criteria (clinical program requirements, etc.); replacement criteria (safety, efficiency, etc.); risk assessment criteria; and government policy related criteria (licensing, radiation safety, etc.). Currently, financing is the single biggest factor affecting decision-making. Other key factors are ‘purchase versus lease’, recovery of cost, future revenue potential and utilization history.
- *Interviews:* Communication with national and international stakeholders helped to identify further examples of how one might apply LCG and other processes to help maintain the quality of existing MI equipment and contribute to strategic planning and decision-making. A number of key observations arose from the interviews:
 - National MI LCG would be useful.
 - Quality, patient care and patient / staff safety are paramount.
 - Equipment planning should consider upgrades, replacement, and integration of new and emerging technologies. (Upgrades can be a workable option and should not be overlooked.)
 - When planning for equipment replacement, important factors include the age of equipment, utilization, advances in technology, financing and evidence. When examining an organization’s past experience, utilization data should be based on annual exams (also consider patient numbers and visits).
 - Equipment planning should look forward for a minimum of 5 years with annual updating of equipment plan(s). Prioritization of equipment can be based on type of facility. An emergency replacement process should be included. Consider weighting the various important criteria to help determine priority levels. Organizations will tailor to meet their unique needs.

- The LCG resulting from this initiative must be flexible enough to accommodate diverse environments; consider ranges for technologies including three utilization ranges (high, mid, low); and be 'user-friendly'.
- The LCGs should be updated regularly (suggested every 3 years).

6.0 KEY PRINCIPLES UNDERLYING DEVELOPMENT OF THE GUIDANCE

Based on knowledge gleaned from a literature review and an environmental scan that included a survey of Canadian stakeholders and interviews with national and international experts, these principles underlie the guidance:

- The objective of the guidance is to integrate replacement criteria, prioritization and life expectancy based on a reasonable range of years specific to each modality. The project scope was to focus on diagnostic (not therapeutic or research) MI equipment.
- Patient care and patient / staff safety are paramount (including radiation safety).
- Organizations should plan equipment 5 years forward, updating annually. Planning processes should consider replacement factors such as equipment age, degree of utilization,⁴ safety, clinical utility, financing, advances in technology, and evidence. A detailed MI inventory and independent assessment form the basis for planning.

- Equipment is only replaced (or changed to new technology) if there is a demonstrated need for its continued use. As each device approaches its replacement timeframe an internal discussion should occur to decide whether the device can continue as-is, be replaced or be upgraded.
- Equipment planning prioritization processes should consider type of facility (classification) and / or mission-critical needs; 'emergency replacement' and other unique circumstances should be addressed. Development of weighting criteria may assist in prioritization.
- Financial considerations and depreciation should be taken into account when planning for upgrade or replacement with new or emerging technologies.
- Conceptually, the guidance should consider a number of different strategies including upgrading versus replacing equipment, acquiring new / emerging technologies, and discontinuing use of technologies that no longer have practical or meaningful use. The guidance should emphasize flexibility to accommodate diverse health care organizations and environments, should be user-friendly, and should be updated regularly.

7.0 EQUIPMENT PLANNING GUIDANCE

Based on information garnered from a literature review and environmental scan (national stakeholder survey and national / international interviews) the following MI equipment planning guidance provides process tools to assess and prioritize equipment for upgrade or replacement. It can also assist in developing a 5-year equipment and financial strategic plan to augment and assist established local processes. The guidance is divided into two sections: (1) processes involved and (2) life expectancy advice.

⁴ Utilization data are generally based on number of examinations but may consider patient numbers or visit numbers where appropriate and can be integrated into planning based on degree of use, e.g., high, mid, low.

7.1 RECOMMENDATIONS FOR THE PLANNING PROCESS

A brief introduction and list of suggested questions are provided to help each site apply the guidance to its unique environment, i.e., large / small, urban / rural, public / private, academic and research.

7.1.1 ESTABLISH A FORMAL PROCESS

Prior to starting up a process for establishing MI guidance for an organization it is essential for leaders to clearly understand their own mandate, timelines (including how far to plan into the future), deliverables, processes, funding and limitations. The next step is to establish an equipment planning committee of primary stakeholders.⁵ It is important to reflect on the past, examine the present, and consider the future in order to determine the impact of strategic directions on needs and services.

7.1.2 ESTABLISH CRITERIA FOR LIFECYCLE PLANNING

To gather useful and practical information for this guidance, key stakeholders in Canada identified how they have used MI equipment planning criteria (e.g., utilization, risk assessment and economics) and which criteria were most important (see Appendix 2 for more detail). Clearly organizations must determine the criteria most relevant to their needs which may be weighted to compare and prioritize each device. These criteria may change over the years and some organizations may have unique criteria as well. In the survey, of the criteria considered important to stakeholders, the table below shows respondents' impressions (red = most important, orange = important, yellow = least important).

Most important	Important	Least important
Replacement criteria	Life expectancy	Weighting assignment
Utilization	Technology upgrades	College of Physicians & Surgeons
Risk assessment	Strategic & financial	Academic and research
Mission critical vs. patient risks	Upgrade criteria	Government policy-related criteria
Finance and economics	Prioritization assignments	

7.1.3 CONSIDERATIONS FOR INITIAL PURCHASE OF EQUIPMENT

During the initial purchase process, it is wise to determine when an original equipment manufacturer (OEM) equipment platform was first established and how long the technology platform will continue to be developed and supported (including upgrading) with regard to hardware, software and service support. It can also be beneficial to understand (a) the hardware / software updates to be provided as part of the original purchase, as well as those involving additional cost; and (b) the hardware / software considered optional, how long these will be available, and at what cost. This knowledge will be helpful when evaluating each device for equipment lifecycle planning.

7.1.4 CONSIDERATIONS FOR REPLACING EQUIPMENT

As part of annual equipment planning, stakeholders should have a common understanding of their own planning processes (e.g., how funding is to be applied; priority toward replacing equipment, adding additional equipment or upgrading existing equipment; priority toward type of facility or clinical service; and funding realities). Addressing the following questions can be helpful in developing a strategy:

- Are processes and funding solely for replacement (versus upgrading) of existing equipment? If yes, what is the process for acquiring new equipment in addition to current inventory?
- Is there a site classification system identifying where MI technology can be located and operated (e.g., based on clinical programs, hospital size, academic versus community setting)?
- For existing services being provided by a facility, can alternate equipment be considered (e.g., can fluoroscopy be replaced with a general radiography unit [or something else])?
- Must equipment be replaced on a 'like-for-like' basis only or is there a process to upgrade to higher capabilities (e.g., replacing a SPECT camera with SPECT/CT)?

⁵ Consider the benefits of an independent review of equipment (i.e., by BioMed, Medical Physics, OEM, Consultant or other third party) to help with strategic planning.

- May upgraded equipment be redeployed to another location if all requirements are met?
- Does the existing equipment meet or exceed equipment life expectancy guidance?
- Will the equipment selected for replacement be funded for value and installation expenses?
- Is there an equipment age range when considering relocating equipment to another site and what are the conditions (e.g., low versus high volume sites?). What must be fulfilled to do this?
- Must redeployed equipment have been operational for a minimum length of time at the new location before it is eligible for replacement?
- Prioritizing:
 - Is prioritization carried out on a site, organization, or provincial / territorial basis?
 - Are certain facility classifications given ‘first priority’ for equipment replacement (e.g., provincial, regional, tertiary, or specialty)?
 - How are second-priority facilities designated?
 - Is the age of a piece of equipment the primary factor generally considered?
 - How is utilization considered/employed (i.e., patient exam volumes, work load units or patient numbers)?
 - How is long-term sustainability of MI services at specific locations considered?
 - Are efficiencies that can be gained from new technology considered?
 - Is equipment compatible with existing and future information technology such as RIS / PACS and upcoming XDS and SNOWMED DICOM standards?
 - Are ongoing intermittent issues with equipment a consideration?
- Have renovation costs been considered?
- Does the existing equipment have any residual value for trade-in?
- Are relocation or decommissioning costs taken into consideration?
- Does image quality meet today’s best practices requirements?
- Is there an incremental benefit of upgrading the equipment?
- What is being done to assess and discontinue use of technologies that no longer have practical or meaningful use via appropriateness, education, change management, etc.?
- What are the economic implications of upgrading equipment in terms of installation, renovations, maintenance, consumables, or training?
- What are the economic implications of introducing new or emerging technologies in terms of installation, renovations, maintenance, consumables, or training?

7.1.5 CONSIDERATIONS FOR UPGRADING EQUIPMENT⁶

To upgrade a device is to raise the device to a higher standard or to improve the equipment by adding or replacing components. An upgrade can add capabilities and / or improve patient safety, quality of care, and / or efficiency. It can be carried out early in the life of a device or later to help increase clinical relevance or to extend its expected life (e.g., a software upgrade to a CT scanner might reduce exposure to ionizing radiation thus improving patient safety and quality of care). Refurbishing a device is also a consideration as it may restore a device to its original condition and performance. A major upgrade can include full replacement of the device although the cost may be somewhat less than that of a new purchase (depends on what was replaced, its new capabilities, etc.). Addressing the following questions may be helpful in developing an appropriate strategy:

⁶ Upgrading processes and funding may differ from those for technology replacement and emerging technology adoption. Upgrading equipment should be considered part of the arsenal for equipment management and planning although often it is given second priority after replacement of existing equipment.

- How do responses to the points for replacing equipment apply to upgrading existing technology?
- Is there a different process and funding source for upgrading versus replacing equipment?
- What priority are upgrades given versus replacement or introducing new or emerging technologies?
- What criteria must be met to apply for and receive approval to upgrade equipment and is the process consistent across MI technologies?
- Does an upgrade include software and / or hardware and can / should it change or enhance the original functionality of the original device?
- Is there a threshold of the original purchase price that is considered an upgrade?
- For a 'major upgrade', is emerging technology a consideration within the organization, especially if there is an argument for clinical / operational benefit?

7.1.6 CONSIDERATIONS FOR ADOPTING NEW / EMERGING TECHNOLOGIES

There is an onus on stakeholders involved in the ongoing operation and /or use of MI devices to stay up-to-date with new and emerging technologies, including hybrid technologies, and to assess how and when these may be a consideration as part of a department's strategic and equipment planning process. The following questions may be helpful in developing an appropriate strategy:

- What are the current MI-related best practices for each modality?
- Does the type of technology fit with the organization's strategic plan, programs, etc.?
- What is the process to obtain the necessary approvals?
- What provincial / territorial, regional and organizational requirements must be addressed?

- What level of evidence is required to meet these requirements (i.e., are HTA or forms of other evidence review a component of your evaluation process)?
- Is there an incremental benefit of newer technology and are advanced features really needed?
- Does timing of this process differ versus replacement processes?
- Do sources of funding differ including capital and operating funding?

7.2 EQUIPMENT LIFE EXPECTANCY

7.2.1 DEFINITIONS OF UTILIZATION AND LIFE EXPECTANCY

Table 1 was developed based on all resources accessed for this initiative. In particular, stakeholders indicated a need to assess a device's utilization to evaluate its impact on aging devices.

Measuring utilization via numbers of examinations:

Utilization of a technology is useful to assess its safe and continued effective use and when or whether to upgrade or replace it. It can be assessed from different perspectives such as (a) number of examinations, patients or patient visits, (b) number of shifts / days used per week, (c) number of staff rotating through the equipment, and (d) teaching facility or not. Utilization by numbers of examinations⁷ is common as the information is readily available and measurable.

Comparisons between low and high utilization calculations are based on minimum use of technology 8 hours per day / 250 days per year. High utilization is based on information obtained through the literature review, environmental scan, the 2001 Canadian Association of Radiologists lifecycle guidelines, previous Canadian radiology administrative directors' data, and other ProMed projects in Canada.⁸ Low utilization is 50% of high utilization rate, except for lithotripsy which is 67% of the high rate.

7 An examination is a defined technical investigation using an MI modality to study a body structure, system or anatomical area that yields one or more views for diagnostic and/or therapeutic purposes. Exceptions include routinely ordered multiple body structures that by common practice or protocol are counted as one exam. Source: CIHI MIS Standards available at www.cihi.ca.

8 High utilization may exceed that identified here in cases of 24/7 use; this must be considered when planning. Increased equipment use up to 24/7 can increase exams by 3 times that stated, placing a higher emphasis on early replacement.

Determining life expectancy: Calculation of life expectancy in years⁹ was determined using the resources noted above. Technologies have a range of life expectancy based on utilization, age, and other factors. Each technology has been assigned a ‘high, mid and low’ category for replacement.

7.2.2 MI EQUIPMENT LIFE EXPECTANCY BASED ON UTILIZATION AND AGE

With due consideration to the preceding information, a life expectancy range is proposed based on equipment age according to utilization; additional criteria (as above) can be used to justify a request and determine prioritization (Table 1). Comparison to other jurisdictions is shown in Appendix 3.

8.0 PROJECT LIMITATIONS

- The literature search was limited to material published from 2000 forward and available in the public domain. This inevitably limited the information available. However, more than 1400 citations were reviewed for relevance and the documents selected were fairly consistent in their approach.
- True ‘evidence’ related to LCG for MI is scant with most publications providing expert opinion and local experience. This LCG will add to the existing body of literature that others can reference.
- The link with evidence should ideally include examples of how MI technology decisions impacted patient management and ultimately improved patient outcomes. However, these linkages are complex to track (particularly for MI) and may require long-term follow-up across multiple clinical domains beyond MI. As a result, documentation about patient benefits is sparse.

9 Input was obtained from a number of experts in the environmental scan interviews.

TABLE I: MI EQUIPMENT LIFE EXPECTANCY GUIDANCE (UTILIZATION AND AGE RELATED)

Device type (analogue or digital)	Device life expectancy based on utilization: HIGH - MID - LOW (see columns to the right)	Utilization based on exams / year		
		HIGH , e.g., 24 hours 5 days / week or 750 8-hour shifts/ year	MID , e.g., 16 hours 5 days / week or 500 8-hour shifts/ year	LOW , e.g., 8 hours 5 days / week or 250 8-hour shifts/ year
Radiography, general	10 - 12 - 14	> 20,000	10,000 - 20,000	< 10,000
Radiography, mobile	10 - 12 - 14	> 6,000	3,000 - 6,000	< 3,000
R/F fluoroscopy (conventional/remote)	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
R/F interventional integrated c-arm	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
R/F urology	8 - 10 - 12	> 1,500	750 - 1,500	< 750
Mobile C-arm (all types including O-Arms)	8 - 10 - 12	> 2,000	1,000 - 2,000	< 1,000
Angiography (1/2 plane)/ interventional	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
Cardiac suite (single/biplane)	8 - 10 - 12	> 3,000	1,500 - 3,000	< 1,500
CT scanner	8 - 10 - 12	> 15,000	7,500 - 15,000	< 7,500
MRI scanner	8 - 10 - 12	> 8,000	4,000 - 8,000	< 4,000
Ultrasound	7 - 8 - 9 ¹⁰	> 4,000	2,000 - 4,000	< 2,000
SPECT/gamma	8 - 10 - 12	> 6,000	3,000 - 6,000	< 3,000
SPECT/CT	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
PET (likely replace with a different technology such as PET/CT)	8 - 10 - 12	> 6,000	3,000 - 6,000	< 3,000
PET/CT	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
Bone densitometry	8 - 10 - 12	> 10,000	5,000 - 10,000	< 5,000
Mammography	8 - 9 - 10 ¹¹	> 7,000	3,500 - 7,000	< 3,500
Lithotripter	8 - 10 - 12	> 3,000	2,000 - 3,000	< 2,000

NOTES:

- Maximum life expectancy and clinical relevance should be no longer than 15 years for any technology
- New and emerging technologies should be integrated into equipment and financial plans within the organization.

10 Some ultrasound scanners may be subject to a faster rate of obsolescence. Ultrasound requires a high level of diagnostic capability and optimum technology is considered essential.

11 Mammography units require a high level of diagnostic capability and optimum technology is considered essential.

APPENDIX I: LITERATURE REVIEW REPORT

1.0 OBJECTIVE OF THE LITERATURE REVIEW

Through appraisal of the national and international literature, to provide a narrative review as background to the creation of updated, comprehensive LCG for MI equipment in Canada.

2.0 RESEARCH QUESTIONS FOR THE LITERATURE REVIEW

The research questions for the literature review included:¹²

A. Related to the medical literature

1. What does the national and international published medical literature report about existing LCG for imaging equipment and what sources were used to develop these?
2. What does the unpublished / “grey” literature report about existing LCG for imaging equipment and what sources were used?
3. What does the published and “grey” literature report about LCG for imaging equipment that are underway or planned and what sources are being used?

B. Related to the literature in non-medical fields

1. What does the national and international published literature report about existing LCG in non-medical fields, how might these be applied to MI equipment and what sources were used to develop these?
2. What does the “grey” literature report about existing LCG for equipment in non-medical fields and what sources were used?

3. What does the published and “grey” literature report about LCG for equipment in non-medical fields that are underway or planned and what sources are being used?

C. Related to the financial literature in medical and non-medical fields

1. What does the published and “grey” literature report about financial models for MI (e.g., how are replacement versus new purchases prioritized, upgrades planned and funded, new technologies introduced, etc.)?

3.0 METHODS

A literature search identified key published material in English related to equipment lifecycles in health care and other industries. Peer reviewed articles and papers were identified by searching health-related databases with international coverage. Where subjects were well indexed, subject headings were used to increase relevance and precision of search results and to ensure a manageable number of items were retrieved. Where subjects were less well-indexed, or had not yet been assigned subject headings, key words were added to increase recall. Subject headings used were database dependent, but analogous to the Medical Subject Headings (MeSH) used in PubMed (search strategies in Appendix A).

Specific search parameters (e.g, inclusion/exclusion criteria, jurisdictions, time frame, languages of publication) were developed in consultation with ProMed researchers during initial planning stages. Literature inclusion criteria are contained in Table 1. Records from database searches were downloaded and imported into a Reference Manager database to facilitate removal of duplicates. Database searches were conducted August 3-13, 2012, with “grey” literature searching extending to August 31. Informal on-line searches were also conducted by ProMed team members as the draft report was being developed.

¹² This project requires thinking beyond experience expressed in the medical literature so resources that explored LCG for other technologies and situations were sought, e.g., engineering, information technology and the military.

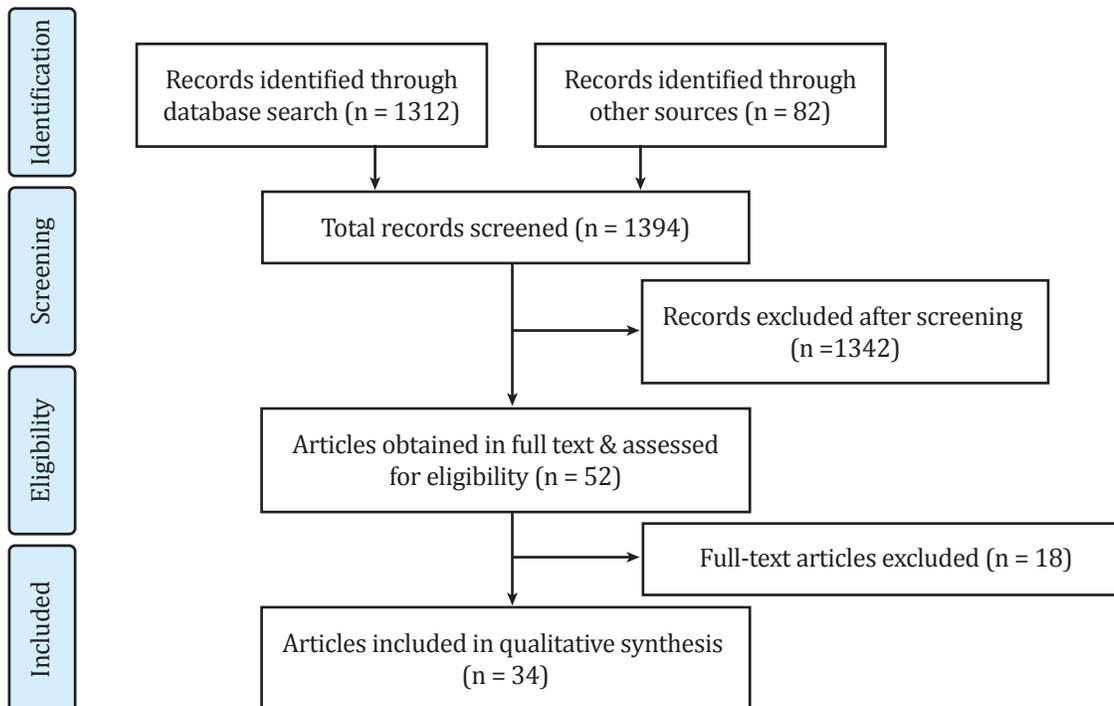
TABLE 1: LITERATURE INCLUSION CRITERIA

Studies	Secondary research (i.e., systematic reviews, meta-analyses and other high level evidence-based synthesis studies); guidelines; primary research (i.e., clinical trials, observational studies); expert opinion; and economic evaluations
Jurisdictions	Canada (provincial and federal), USA, UK & Europe, Australia & New Zealand
Languages	English; French only if Canadian
Dates	Published 2000 to August 2012

4.0 FINDINGS OF THE LITERATURE REVIEW

The qualitative nature of the information retrieved was best handled via a narrative review, describing the observations of others and the evolution of thinking over time. The retrieved literature focused on: (a) replacing / upgrading technologies, and (b) introducing new and emerging technologies. These categories have, therefore, been employed to present our findings. Also, references are presented from oldest (within our 12-year time limit for the literature search) to most current as thinking, experience, and policies / processes are evolving over time. The flow of literature selected for the report is illustrated in Figure 1 as a PRISMA diagram.

Limitations: Only free resources available on the Internet were searched. This included PubMed and other evidence-based health care resources. The search was focused on the medical literature within PubMed, expanding to other types of literature in the non-database search, as needed. Also, the literature search was constrained by time and budget limitations.

FIGURE 1: PRISMA FLOW DIAGRAM¹³

13 Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

General observations:

- The term 'lifecycle guidance' has different meanings and applications to different authors.
- True 'evidence' is limited (and there are views on why there is so little evidence and what might be done to improve this in the future).
- While much of the retrieved literature focuses on medical technology in general, much is applicable to imaging requirements.
- Most literature is from the US, augmented by materials by authors from Australia, New Zealand, Canada and Europe.
- Although literature from the US often focuses on financial and business cases, this may complement literature from other sources with different service delivery models.
- The literature provides insight in areas such as:
 - Medical equipment management planning using patient risk and mission criticality
 - Frameworks for technology adoption at a hospital level
 - Factors and criteria to monitor during equipment operation
 - Regulatory and patient / staff safety considerations
 - Alternatives to equipment replacement, upgrades or new / emerging technologies
 - Determination of when to replace, upgrade or introduce new / emerging technologies
 - Multi-source age considerations for life expectancy of MI equipment
 - Recommendations for collaboration and process methods for strategic planning
 - Questions senior management may want to ask
 - Examples of lifecycle expectancy
 - The evolution of thinking around replacing, upgrading and introducing new technologies over the past 12 years
 - The challenges of finding high quality evidence to support decision-making

4.1 WITH RESPECT TO REPLACING OR UPGRADING TECHNOLOGY

To accommodate escalating equipment requirements it is important to develop a strategy about how best to meet these needs (Bluemke, 2002). Optimizing the use of equipment will be an essential component of an organization's strategy to stretch the capital equipment budget. This can include establishing a capital equipment committee of key stakeholders to review requests and consider alternative methods for acquiring assets including:

- Redeploying and reallocating existing equipment
- Purchasing previously-owned equipment
- Leasing equipment
- Cash flow and balance sheets
- Lifecycle management

In 2003, a medical equipment manager with the US military described "a simple method of equipment replacement planning" (Dondelinger, 2003). He noted that there are many ways to determine what needs to be replaced immediately. This could be as simple as choosing the oldest pieces of equipment and developing a list in replacement sequence. However, consideration should also be given to the pieces of equipment that are the most logical and defensible and understood by the key players. A simple list can reveal patterns that then require further follow-up. Additional information like life expectancy and operating costs can help in a justification for replacement.

A year later the same author published an "advanced action plan" for replacement of medical equipment (Dondelinger, 2004). The plan focussed on equipment failure rate and cumulative cost of repairs. These factors, plus the age of a device, were considered to be quantifiable, historical and defensible information. In addition to the objective factors, two subjective factors were created including "advancement in technology" and "fits into 5-year plan". A Likert scale was suggested to quantify opinions and weighting each factor can bring it in line with the "normal" numbers of the other factors. An "Order of Merit number" = age factor + repair work order factor + repair cost factor + advancement in technology factor + fit into 5-year factor.

A 2003 publication reported on an audit of 19 public hospitals in Australia, examining the efficiency and effectiveness of the management, maintenance and replacement of major medical equipment (Victoria [Australia] Auditor General, 2003). It included an assessment of the medical equipment's current condition and life expectancy. It was noted that factors other than age can influence the life expectancy of medical equipment (or extent of use beyond its projected life expectancy) including:

- Utilization levels (i.e., is the equipment used at full capacity)?
- Maintenance practices (i.e., has the equipment been maintained in accordance with generally accepted standards)?
- Technological change (i.e., has the equipment become obsolete due to technological advances)?
- Availability of replacement parts (i.e., are parts available as and when required)?
- Changes in clinical practices (i.e., are clinicians required to use the equipment in the normal course of treatment)?

In 2004, US-based clinical engineers David and Jahnke noted that it was essential in an environment of constant change to have an equipment management program that:

- Provides for a guiding strategy for allocation of limited resources
- Maximizes the value provided by resources invested in medical technology
- Identifies and evaluates technological opportunities or threats
- Optimizes priorities in systems integration, facility preparation, and staff planning
- Meets or exceeds standards of care
- Reduces operating costs
- Reduces risk exposure

For several decades, the US Air Force has worked with the ECRI Institute¹⁴ (an independent, non-profit health services research agency with a particular focus on HTA based near Philadelphia) to disseminate patient safety medical device information to key staff at Air Force hospitals worldwide. In 2004, a collaborative document, *Best Practices for Medical Technology Management*, was published (Keller, 2004). Observations were that proper management can help extend life expectancy, while lack of effective management can quicken end of life, and determining the time at which the technology should be replaced is very challenging. Factors to take into account are cost, safety, efficiency, standard of care, and device performance. Safety-related considerations include device recall and hazard alerts, objective device performance information, standardized device inspection, and preventive maintenance procedures.

The US Joint Commission (a major accrediting body) has issued medical equipment management standards for over 25 years. Wang et al. (2006) noted that the standards initially focused on electrical safety but have now evolved to flexible criteria that fit an individual institution's needs (e.g., a device located in an area that is used on a 24/7 basis by many individuals may need more frequent inspection and maintenance than an identical device used in a location used less frequently by one individual). There is, therefore, an onus on each organization to determine its own requirements, taking into account local conditions. An example of inclusion criteria using patient risks and mission criticality for planning preventative maintenance (PM) and safety and performance inspection (SPI) activities is illustrated in Table 2. This type of exercise can allow for a more efficient allocation of resources and an elevated level of operation, while those applying the same level of PM and SPI on all equipment with limited resources may struggle to cope with equipment-related issues.

14 The government-funded Canadian Agency for Drugs and Technologies in Health (CADTH) in Ottawa houses similar expertise and could be a valuable resource for Canadians, particularly through its rapid response program.

TABLE 2: A MEDICAL EQUIPMENT MANAGEMENT PLAN USING PATIENT RISKS & MISSION CRITICALITY (ADAPTED FROM WANG ET AL., 2006)

Mission criticality		Patient risks as per US Joint Commission “Elements of Performance”		
		High	Medium	Low
	Critical	Include	Include	Include
	Important	Include	Optimal*	Exclude
	Necessary	Include	Exclude	Exclude

* Some may benefit from scheduled service depending on failure rate, effects analysis, etc.

Observations from reviews in Australia (Victoria and Western Australia plus three major metropolitan health centres in Melbourne) led Brown et al. (2006) to generate a report titled *Managing medical technology in Australia’s health care systems – planning, prioritisation and procurement*. They reported that 5-year planning exercises are carried out on an ongoing basis and funding is allocated based on actual data derived from major equipment surveys. Some of their comments:

- There are separate requirements for pre-existing backlog, routine replacement of existing items (varies year to year), additional items expected to be required within the 5-year planning period (varies year to year), and minor items. Additional complexities are modelled such as single year funding injections, revenue raised from other sources, annual growth in the service, introduction of new technology, and leasing options.
- Prioritization is required when equipment replacement requirements exceed available funding – the paradigm is to replace equipment when needed while extending the life of lower priority items. To ensure fairness in fund distribution, the model used at state and hospital levels provides objective prioritization (categories = above normal, normal, or below normal priority) using factors such as equipment age, patient, operator and business risk factors; support status; operational efficiency and cost; and strategic factors at enterprise and state levels.
- As no single purchasing model suits everyone’s needs, five possible options can be considered: (1) *status quo* position, (2) *ad hoc* purchasing groups, (3) centrally negotiated contracts, (4) pre-

ferred suppliers, and (5) a centralized purchasing body. The best model is decided based on the number of suppliers in the market, frequency of purchase, level of variability across the different hospitals, and level of control required by health service.

Another useful resource from Australia is a *Medical equipment asset management framework / Medical equipment business case package* generated by the State of Victoria Department of Human Services (VGDHS, 2007). The report authors noted the following:

- In evaluating and reviewing equipment performance, consider equipment condition, utilization, critical risk assessment, functionality/clinical efficacy, costs, age/effective life, disposal and the importance or criticality of the medical equipment to the health service.
- A review ideally includes qualitative, financial and overall analyses, facilitated by data captured in resources like an asset management system.
- Options going forward include “do nothing”, replacement, refurbishment / upgrade, consolidation / reconfiguration, or alternate service delivery. The preferred option is determined by comparing the benefits resulting from a specific option with its lifecycle cost from the overall option analysis. A business case documents the preferred option and reasons in terms of cost and benefits with the rationale for the chosen option clearly stated and supported by the outcomes of an analysis.

Around this time, Griffin and Dubiel (2006), for the Association for Medical Imaging Management, emphasized the need to be strategic about imaging capacity

and capital examining influences such as factors driving rapid growth; procedure forecasting; inpatient, outpatient and ER forecasts and capacity; imaging capacity; aggregate capacity modelling; time-phase modelling; impact of modelling policies; and multi-year planning including prices, replacements, upgrades, expansion, new technology and facilities.

Priority setting of technology adoption at the hospital level (versus a national / regional level) was explored in a literature review performed by Italian engineers Lettieri and Massera (2007). From the 20 relevant studies they retrieved, two main assessment perspectives were identified:

- How a technology can create value at a hospital level: Through the creation of social value, economic value and medical/technical knowledge.
- Level of sustainability in the implementation phase: Related to at least five sources: financial, organizational, technological, resource and context.

Proposals for new technology could be vetted through a framework for priority setting (Table 3).

TABLE 3: REFERENCE FRAMEWORK FOR TECHNOLOGY ADOPTION AT A HOSPITAL LEVEL (ADAPTED FROM LETTIERI & MASSERA, 2007)

» Value »	High	Mirage health care technology	Target health care technology
	Low	Resource wasting health care technology	Incremental health care technology
		Low	High

» Level of Sustainability »

Once again the Australians produced useful work in a document called *Best practice in integrated engineering asset management* (AAMCoG, 2008). Its aim was to facilitate collaboration among interested organizations to promote and enhance asset management for Australia. A comprehensive process for equipment management is described in their document.

At Hamilton Health Sciences Centre, the manager of biomedical technology reported on a framework for prioritizing equipment for replacement based on data – not perception – particularly in a strained financial

climate (Capuano, 2010). The process is described as being based on simplicity, leveraging the data contained in the equipment database and other available resources to accomplish a detailed analysis. All equipment was included in the prioritization process, thus offering a means for comparing all devices.

Considerations:

- Custom-build assessment criteria (e.g., device use, physical condition, risk, and repair history).
- Replacement cost considerations include obtaining quotes from manufacturers or using a previous purchase as a guide.
- Items with a higher capital value should be flagged sooner as funding approval may be more challenging.
- Depending on historical funding, a cut-off point of the first 20 items might be highest priority. These items might be segmented into price groups (e.g., < \$15,000 and > \$100,000).
- Other factors: equipment condition, product discontinuation (can influence the level of priority), age and vendor support.
- Lifespan is sometimes identified as an exclusive indicator for replacement as reported by the AHA and the American Society for Healthcare Engineering (ASHE). Many accountants use 7 years for depreciation. Other factors determining lifespan depend on how the equipment was used, how much it was used, quality of the product, failure rate, repair hours, if supported by the vendor, and if similarly efficacious to new products.
- Risk was also considered to prioritize equipment replacement included function, consequence, lethality, frequency of use, required maintenance and protective safeguards. Some used a rating of 1 to 5 where 5 indicated serious injury or death.
- Factors such as price, labor, parts, risk and utilization are not time dependent. By eliminating these, a practical method of prioritizing for consideration could be realized.
- Using equipment to recruit / retain medical staff or other political factors was eliminated from consideration.

Texas technology consultants Evanoo and Cameron (2010) promoted the adoption of a capital equipment strategic planning (CESP) philosophy that moves from opinion-based to data-driven. A snapshot of the efficacy of each clinical device includes such factors such as maintenance history, risk associated with ongoing/extended use, remaining device support and serviceability, level of technology sophistication, clinical utilization and impact and industry benchmark data. Their model reviews equipment from several points of view and moves forward as follows:

- Perform technology assessment / HTA of clinical equipment (may gather data from user departments, accounting, clinical engineering, and executive management plus employ interviews with key constituencies), prioritize and integrate into the facility's strategic plan.
- Maintain the process (i.e., a plan means nothing unless it is implemented and updated on an ongoing basis).
- Assess whether the plan is right for the organization.
- Determine state of readiness (i.e., no formal process, ineffective process, distressed process).

Additional resources / opinions published in 2010:

- Gresch (2010): This clinical engineer at a network of hospitals in Wisconsin promotes business intelligence over 'anecdotal information and flowery justifications' maintaining that, in order to develop a sensible and sustainable capital equipment planning program, four components must be in place:
 1. Data regarding cost to maintain, obsolescence/ end of life, and safety information.
 2. Clinical input to cover appropriate level of technology, appropriate level of software / hardware, and patient volumes and utilization.
 3. Strategic direction from senior management focussed on market growth opportunities and reflecting on whether technology renewal or upgrade of is a consideration.
 4. Financial alternatives such as lease, estimated useful life, and replacement cost.

- Taghipour et al. (2010): University of Toronto engineers maintain that in order to mitigate functional failures, significant and critical devices should be identified and prioritized for consideration. Their first requirement is to determine the criteria required to evaluate devices (e.g., function, 'mission criticality', utilization, availability of other devices, failure frequency, and cost of repair). The second is to determine weighting values for criteria and sub-criteria. The third is to set up grades and intensities for each criterion and the fourth is to rank the medical devices. Evaluation of the information is conducted to test the model. Based on the list of devices according to criticality, classification and maintenance strategies are explored and developed in order to prioritize attention to particular equipment and assign limited resources.

Resources / opinions published in 2011:

- Clinical engineers in Indiana, Hockel and Hughes (2011) focussed on an equipment management life-cycle plan that included a number of steps:
 - Capital equipment planning → Selection and procurement (including 1-2 upgrades in the purchase that extends clinical relevance) → Implementation → Management → Monitoring and end of life management

In their report titled *Bottom-line booster: Extending medical equipment life without compromising care* they also noted cost saving measures like ensuring that clinical engineering / IT collaborate, giving due attention to contract management, leveraging buying power and considering software updates versus upgrades – making a point to distinguish between update and upgrade.
- Reasons for purchases of major equipment were discussed by McConnell (2011):
 - *Required by regulation or accreditation:* Equipment purchase may be needed to bring an institution into compliance with regulations (legal operation) or loss of accreditation may be a possibility – such situations justify a purchase on their own.
 - *Replacement of existing equipment:* Justification requires demonstrated need.

- *Addition of new equipment to perform a new function:* This often involves provision of a new service with the equipment just being part of the plan.

To determine corporate requirements, departments will ideally create their own prioritized list of equipment for consideration, describe their general assessment of need, provide an assessment of clinical implications, and identify personnel requirements. Tentative cost information should also be articulated describing total cost, estimated useful life, estimate of personnel costs, estimated costs of materials, and the annual volume of work to be serviced.

- A biomedical / clinical engineer at Johns Hopkins Medical School in Baltimore, Robert Steifel reflected on a relatively new US Joint Commission standard (EC.02.04.01) which states *“the hospital solicits input from individuals who operate and service equipment when it selects and acquires medical equipment”*. His interpretation is that there should be a seat at the purchasing table for clinical engineering and he goes on to advise how the contribution should be high quality. Further, the most important contributions to replacing or upgrading technologies are to:
 - Maintain complete and accurate information.
 - Be willing to provide advice when needed.
 - Ensure that all requests for new equipment include explanation or justification and consider age, equipment history, safety, standards and regulations.
 - Include information on the “end of support” from the original equipment manufacturer (OEM).
 - Consider retiring technologies that do not meet internally established standards.
- The European Commission issued a report called *Criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy* (EC, 2011). The criteria

were produced in response to ‘Directive 97/43/ Euratom’ (1997) that focussed on health protection related to dangers of health-care-related ionizing radiation. Criteria were based on levels of performance that, if not corrected, should prompt intervention and result in equipment use being curtailed or terminated as necessary.

Finally, an ECRI publication provided advice for when health systems have cut back on spending (Maliff, 2012). As capital spending has fallen behind technical innovation, biomedical staff members have gone to great lengths to maintain equipment operation – even purchasing spare parts on eBay! Efforts to extend life can include integrating devices planned for replacement in the near future, updating software versions or developing electronic medical record device interfaces. The author notes that a good capital plan and process can help manage change and accommodate stakeholder requirements.

4.2 WITH RESPECT TO NEW / EMERGING TECHNOLOGIES

Priority setting for the consideration of acquiring new medical technologies was described by Singer et al. from the University of Toronto. The setting included two committees for two organizations with a total of 26 representatives. Outcomes were assessed via accounts of priority-setting decision-making gathered by review of documents, interviews and proceedings of meetings. Their priority setting model included six domains:¹⁵

- The institutions in which the decision are made
- The people who make the decisions
- The factors they consider
- The reasons for the decisions
- The process of decision-making
- The appeals mechanism for challenging the decisions

¹⁵ NOTE: There could be a role for HTA here.

The University of Washington Medical Center (UWMC) in Seattle has committed to installation of the “latest and best” MI technology in order to deliver its academic, teaching and research responsibilities (Alotis, 2003). Staff members develop forecasts via “sensitivity analysis” to determine the equipment required, when it is needed, and how it should be acquired. Sensitivity analysis lays out existing and projected business operations with volume assumptions displayed in layers. Each layer of current and projected activity is plotted over time and placed against a background depicting the capacity of the key modality. The analysis considers:

- Necessity (capacity and clinical efficacy).
- Economic assessment (business plan and break-even analysis).
- Performance (patient safety, image quality, processing speed, ergonomics, and other technical measures).
- Compatibility (fully integrated into existing or planned IT systems).
- Reliability and service.
- Training (off-site and on-site training of technical and biomed staff and medical representatives).

Acquisition of new imaging equipment at UWMC is generally triggered in one of two ways:

1. Need for increased capacity due to growing wait times (i.e., a significant gap between demand and the capacity to meet it, or a growing demand based upon trends in care).
2. Release of a breakthrough or substantially improved technology that will clearly have a positive impact on clinical efficacy and efficiency, thereby benefiting the patient.

The logistics around adoption of new medical technologies, including linkage to use of evidence,¹⁶ were examined by Professor Rita Redberg at the University of California (Redberg, 2007). She examined conditions that are ideally satisfied (at least in the US) before widespread adoption of a new medical technology can take place:

- *Approval by the US Food and Drug Administration (FDA):* This requires evidence of safety and effectiveness but, due to demands for early adoption from industry and patients, surrogate / intermediate outcome measures are often employed meaning true patient benefits are unclear.
- *Coverage by major insurers, particularly the Centers for Medicare and Medicaid Services (CMS):* For CMS, coverage is based on whether the treatment is ‘reasonable and necessary’ (terms that are not defined and specifically do not speak to a need for evidence of improvement in quality or length of life).
- *Access to high-quality evidence of clinically meaningful benefit:* Randomized controlled trials (RCTs) with clinically meaningful outcomes are considered to be the ‘gold standard’ of evidence. However, RCTs are often not practical for assessment of new devices.
- *Clinical practice guidelines (CPGs):* Although CPGs can be an excellent guide to physician practice, they have limitations (e.g., not all CPGs are created equal (some rely on evidence more than others); they do not address larger policy issues such as cost/benefit analysis or appropriate use of a new technology; and CPGs do not exist for all interventions and conditions).
- *Development of appropriateness criteria:* Consideration of appropriateness provides recommendations on when the use of a technology is indicated by determining whether benefits of use exceed risk. Ideally, criteria for appropriateness include cost-effectiveness and a risk-benefit analysis of available alternatives. If these criteria can be assessed early enough, they may be used to guide coverage decisions.

In Australia, consideration was given to developing a ‘National Medical Devices Policy’ equivalent to the country’s ‘National Medicines Policy’ (Smith & Faunce, 2009). In the process of their review, the authors described device lifecycle in Australia including three phases:

¹⁶ Examination of evidence should be rigorous and unbiased (i.e., not ad hoc, where special interests could interfere); HTA could be of assistance here and relationships with HTA organizations / experts would be ideal.

1. *Manufacturing*: This involves a need for a viable manufacturing industry with high standards. Themes were: developing world-class capability, increasing speed to market, and expanding market opportunities. This paradigm does not differ much for drugs versus devices.
2. *Equitable and affordable access*: At the national level, the Department of Health ensures affordable and equal access to medical devices through an HTA program. The HTA assesses the clinical and economic appropriateness, and relative value of technologies. Again, this paradigm does not differ much between drugs and devices.
3. *Quality use*: The final lifecycle phase is where policy frameworks between drugs and devices. In the previous two lifecycle phases – manufacture and access – similarities exist. Like the device manufacturers, drug manufacturers use quality- and risk-management processes along with state-of-the-art standards during production – but drug use and device use differ as drugs are prescribed and devices are applied. Currently there is no national strategy for the quality use of devices despite the inherent complexity of device use within the health care setting – and device use includes considerations such as training, operation, integration, maintenance, reliability and disposal.

Once again, the ECRI Institute¹⁷ contributed publications in the area of medical technology planning (Montagnolo, 2011; Montagnolo, 2012). These opinion pieces query what governing boards are to do when faced with huge demands for investment in the face of declining reimbursement – at a time when the variety of systems continues to expand. With respect to emerging technologies in MI, questions for decision-makers include (Montagnolo 2011):

- Which emerging technologies are worth special consideration?
- Are advances worth the investment and should the focus be on luxury, workhorse or economy?
- Where does imaging technology fit within specific clinical pathways and how will these change over time (e.g., MRI in the operating room)?
- What is the right mix of imaging technologies to meet a facility’s mission today and tomorrow (e.g., CT in the emergency department or, with respect to radiation, CT versus MRI for children)?

With respect to medical technologies in general, decision-makers, working with health care managers, should consider the following when striving to be ‘smarter buyers’ (Table 4) (Montagnolo, 2012):

TABLE 4: STRATEGIC EQUIPMENT PLANNING CONSIDERATIONS

Question	Detail	ECRI’s ‘bottom line’
What is the state of our clinical technology infrastructure compared (a) with our peers and (b) with our strategic intent?	Address this via a clinical technology scorecard that is kept up-to-date and reviewed at least annually by the board and the senior executive team.	‘If you run an airline, you had better know the state of your planes.’
Do we understand the major clinical technology changes that may cause a seismic shift in our ability to thrive?	Keep an eye on emerging technologies and paradigms in order to capture those representing huge leaps in patient care innovation.	‘Past performance is no guarantee of future performance, and clinical technology changes like the weather. Check the forecast often.’
Do we have a sustainable financial plan to fund our clinical technology needs for the next 5 years?	Review access to capital and operating margins precisely and accept that care is becoming more technology-intensive.	‘Visioning without financial understanding results in wishing, and wishes do not make dreams come true. This is health care, not Hollywood.’
Are we confident that our clinical technology decision process is evidence-driven, free from bias and in sync with our strategic priorities?	Review the technology decision process examining areas like adequacy of required data, players at the table (including conflicts-of-interest) and breadth of OEM sources.	‘The road to bad technology is paved with good intentions, while the road to good technology is paved with good processes.’

17 A US institute with a solid foundation in assessment of evidence via HTA.

Via a literature review and interviews with key informants, Sorenson and Kanavos (2011) examined current procurement policy for medical technologies across five European countries: England, France, Germany, Italy and Spain. They were interested in the potential impact of procurement policy on the diffusion of medical devices. (Sample devices focussed on implantable devices.)

Findings:

- National procurement policies can support the efficient and timely uptake of new medical devices.
- All surveyed countries have introduced regulatory and policy mechanisms to influence or control procurement practices, from lists of devices for purchase and use to changes in financing systems.
- A greater, more formalized role for physicians and governments can ensure that technologies best meet the needs of patients and align with national health care priorities.
- A dominant theme is cost containment but quality and health outcomes might better allow governments to achieve value for money and support patient access to beneficial innovations.
- Movement towards centralization of purchasing (bidding or public tendering) allows for increased negotiating power and economies of scale; however, specific needs should not be overlooked.

Escalating US government requirements may delay approval of imaging advances (Kaplan, 2011). Reasons provided include increased regulation and reimbursement and adoption issues. Compared to earlier introductions of radiology 'staples' (e.g., X-ray, CT, MRI, and ultrasound), innovations are incremental in scope, i.e., developers must prove why updates are superior to current technologies. Academic researchers and practicing radiologists concerned with various aspects of innovation, from work flow and radiation exposure for patients or technicians, to novel features, applications, and quantitation may be impacted. Basic science may not be translated as quickly into product features or applications that improve or expand procedures to help patients.

5.0 EQUIPMENT LIFE EXPECTANCY INFORMATION

MI equipment life expectancy was sparsely reported in the literature (i.e., actual numbers of estimated years of useful life). Often it was not clear on what basis numbers had been chosen¹⁸ and, as can be readily seen (Table 5), variation is the norm.

Device Type	US Army (1993)	American Hospital Association (1998)	CAR (2001)	ASHE Report (Australia, 2002)	TB Med7 Army (2005)	Ohio-US Army reference (2011)	State of Nevada (2012)	Florida Dept. of Revenue (date NR)
Radiography, general	8-12 years	5 years	5-10 years		8-12 years	8-12 years	5 years	10 years
Radiography, mobile	8	5	5-10		8	8	5	10
R/F fluoroscopy (conventional / remote)	10	5/5	5-10		10	10	5	10
R/F interventional			7				5	10
R/F urology			10				5	10
Mobile C-arm (all types)	8		5-10		8	8	5	10
Angiography (single/ biplane)			7	8			5	10
Cardiac suite (single/biplane)			7				5	10
CT scanner	8	5	8	8	8	8	5	10
MRI scanner	5	5	6	8	5	5	5	10
Ultrasound	8	5	6				5	10
SPECT/gamma	8 for gamma	5/5	10		8	8 for gamma	5	10
SPECT/CT								10
PET		5		8			5	10
PET/CT							5	10
Bone densitometry			6				5	10
Mammography		5, 8 if mobile	5-7		10	10	5	10
Lithotripter	5	5	7		5	5	5	10

Note: Excludes cancer treatment and simulation equipment, dental, RIS/PACS and cyclotrons.

¹⁸ It appears that '5 years' was often chosen based on accepted depreciation practices. Planning for the US Military was carried out in conjunction with ECRI and updated periodically (details not provided but ECRI has an evidence-based philosophy). Australia / New Zealand choices were regional and national health initiatives.

6.0 LIMITATIONS OF THE LITERATURE

True ‘evidence’ for replacing / upgrading equipment and introducing new technologies is scant – much is expert opinion and local experience. This may limit informed decision making. Evidence-based HTA can help answer critical questions concerning safety, effectiveness and appropriateness and can be used to avoid the promotion of ineffective technologies and the premature diffusion of unproven technologies (Ziegler et al., 2005). In addition, the link with evidence should ideally include (where available) examples of how imaging technology decisions impacted patient management and ultimately improved patient outcomes.¹⁹ However, applying evidence can be a challenge. Califf (2006) noted that we are “entering an era in which the success of biomedical science and the increasing understanding of the value of evidence for practice are in a state of tension...especially in the device arena in which the short lifecycles and iterative nature of development are at odds with current design constructs of the types of clinical trials that provide evidence for medical decision-making.”

7.0 IMPACT OF LIT REVIEW ON THE ENVIRONMENTAL SCAN

The purpose of the literature search was to find useful information to contribute to the process of an environmental scan (seeking further information from stakeholders) and the development of LCG. As part of the environmental scan, a survey provided insight from key stakeholders, drawing on their experience using LCG themselves.

8.0 DISCUSSION

To develop contemporary LCG it is important to understand the environment when the previous CAR LCG was developed and how the environment today may influence requirements. In September 2001, the CAR conducted an inventory of MI technologies in

Canada and prepared a special ministerial briefing. It noted that more than 50% of MI devices exceeded ‘useful life’ guidelines (Table 6) and required immediate replacement – only one third had the potential for future upgrades at that time.

Over the past decade this field has faced a number of challenges (e.g., legal challenges to the *Canada Health Act*, proliferation of free-standing imaging facilities, increasing conversion to a digital environment, growing patient expectations, and wait time pressures). Such challenges mean that the development of LCG for the replacement/upgrade of existing MI technologies and for the introduction of new/emerging technologies must be robust enough to be used regardless of the environment type (large/small, simple/complex, urban/rural). The LCG should be comprehensive yet easily applied to ensure their use. They should encourage the use of evidence – but in a practical way HTA could play an important role here and relationships with HTA organizations and researchers would be ideal.) Periodic audit should be conducted to verify use of the LCG and provide updates if required.

TABLE 6: CAR LIFECYCLE GUIDELINES FOR SELECTED TECHNOLOGIES (2001)

Equipment years after which equipment is considered to be outdated	
General radiography unit	5-10
General radiography mobile	5-10
General radiography tomography	5-10
Fluoroscopic R/F	5-10
Mobile fluoroscopy C-arms	5-10
Angiographic suites	7
Cardiac catheterization labs	7
CT scanners	8
MRI scanners	6
Ultrasound	6
Nuclear medicine (including SPECT & gamma cameras)	10
Bone densitometry	6
Urology	10
Mammography	5-7
Lithotripter	7

¹⁹ For example, advocates claim that advanced diagnostic equipment such as multi-slice CT scanners, more-powerful MRI machines and PET/CT scanners allow for greater accuracy, speed and efficiency in diagnosis, often facilitating changes in management, e.g., treatment of earlier disease stages and use of less invasive procedures (MEDEC, 2010).

Historical lifecycle replacement criteria have evolved with technological changes. In the 1970s and early 1980s, technology was well engineered and functioned on the principle of electro-mechanical systems. Devices were reliable and low-cost maintenance was achievable; however, limited advancement in equipment technology resulted in limited clinical applications. The advancement of more sophisticated technology; the conversion of general radiography to digital technology; and the introduction of integrated (fused, merged) technologies means new clinical applications and means of communication are now available. It is important to determine what processes stakeholders have in place, how these processes work for them, and what they need now and anticipate in the future.

9.0 CONCLUSIONS

With other stakeholders, CAR has taken the lead in developing comprehensive 2013 MI LCG to replace CAR's 2001 LCG. To provide background and ideas, a literature review focussed on LCG nationally and internationally, including the complex processes involved in their development. Useful material was identified (primarily from the US and Australia) but the amount of 'evidence' underlying LCG was sparse, as were examples of LCG itself. Instead, experts in various fields described factors to consider when creating tailored LCG for a jurisdiction, e.g., demand, technology evolution / new technologies, history of use, changes in safety considerations (e.g., radiation doses), and availability of parts and service. Ideally the body of evidence will grow in future to link changes in imaging technology with changes in patient management and improved outcomes, although research in this area is complex and sparse. A key contribution of the literature review was to identify the lack of LCG nationally and internationally – this serves to support the current guidance initiative and its potential utility.

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LITERATURE SEARCH STRATEGIES

TERMINOLOGY FOR PUBMED SEARCH

Search Terms	
Subject Headings	Text Words*
Concept 1: Lifecycle – Guidelines, Planning	
<ul style="list-style-type: none"> • “Guidelines as Topic” • Policy • Standards [as subheading] • Benchmarking <p>AND</p> <ul style="list-style-type: none"> • “Equipment and Supplies” • Instrumentation [as subheading] • Biomedical Technology • [equipment textwords] 	<ul style="list-style-type: none"> • (lifecycle* OR life cycle*) (guideline* OR standard OR standards OR policy OR policies OR criteria OR benchmark*) • (lifecycle OR life cycle) (planning OR assessment) • (equipment OR technology OR technologies OR device* OR apparatus OR instrument*) (lifecycle* OR life cycle*) • (equipment OR technology OR technologies OR device* OR apparatus OR instrument* OR inventory OR inventories) (management OR condition OR sustainability OR priorit* OR maintenance OR repair* OR replacement OR planning OR acquisition OR procur*) • (prioritizing OR prioritising OR maintaining OR repairing OR replacing OR acquiring OR procuring OR managing) (equipment OR technology OR technologies OR device* OR apparatus OR instrument* OR inventory OR inventories) • “planning for equipment” OR “planning for technology” OR “planning for technologies” OR “planning for device*” OR “planning for apparatus” OR “planning for instrument*” • (equipment OR technology OR technologies OR device* OR apparatus OR instrument* OR inventory OR inventories) AND (life expectancy OR utilization OR utilisation OR asset management) • OR (expanded due to low retrieval) • [equipment textwords] • AND • standard OR standards or policy or policies or mission critical OR best practice* OR leading practice* OR promising practice* OR evidence based
Concept 2: Juridictions	
<ul style="list-style-type: none"> • Canada • United States • Great Britain • Australia • New Zealand • Europe 	<ul style="list-style-type: none"> • canada OR canadian • united states OR america* • great britain • united kingdom • england • scotland • wales • australia* • new zealand • europe*

* Truncation was used where appropriate for text word searching – indicated by asterisk.

GREY LITERATURE RESOURCES

Government and International Agencies
Canada
Government of Canada publications http://publications.gc.ca/site/eng/home.html
Other Jurisdictions
Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov/
Australia and New Zealand Horizon Scanning Network (ANZHSN) http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/technologies-assessed-lp-2
Catalog of U.S. Government Publications http://catalog.gpo.gov/
Environmental Protection Agency (EPA)
Life Cycle Assessment (LCA) page http://www.epa.gov/nrmrl/std/lca/lca.html
LCA Resources page http://www.epa.gov/nrmrl/std/lca/resources.html#EPA_Documents
National Guidelines Clearinghouse http://www.guideline.gov/
International
WHO – Lifecycle of medical equipment webpage http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/health-technologies/lifecycle-of-medical-equipment

Organizations, Research Institutes and Specialized Databases/Search Engines

Canada

CADTH <http://www.cadth.ca/>

Ontario Health Technology Advisory Committee: Health Technology Policy Reviews
http://www.hqontario.ca/en/mas/mas_ohtas_mn.html

Canadian Association of Radiologists <http://www.car.ca/>

Other Jurisdictions

Aetna Clinical Policy Bulletins http://www.aetna.com/cpb/cpb_alpha.html

American College of Radiology <http://www.acr.org/>

Anthem Blue Cross <http://www.anthem.com>

Australian Institute of Radiography <http://www.air.asn.au/>

Blue Cross Blue Shield Association <http://www.bcbs.com/>

CIGNA <http://www.cigna.com>

ECRI <https://www.ecri.org/>

Euroscan <http://www.euroscan.bham.ac.uk>

Humana <http://www.humana.com/>

Institute for Healthcare Improvement <http://www.ihl.org/ihl/>

International Institute for Sustainable Development <http://www.iisd.org>

International Society for Magnetic Resonance in Medicine <http://www.ismrm.org/>

Medical Technology Management Institute <http://www.mtmi.net/>

NIHR Health Technology Assessment Programme / NHS National Institute for Health Research
<http://www.hta.ac.uk/>

Radiological Society of North America <http://www.rsna.org/>

Regence Group <http://www.regence.com/>

Technology Evaluation Center (TEC), Blue Cross and Blue Shield Association
<http://www.bcbs.com/blueresources/tec/>

UnitedHealthcare <https://www.unitedhealthcareonline.com>

Wellmark Blue Cross Blue Shield <http://www.wellmark.com/>

Search Engines and Specialized Databases

Cochrane Library <http://www.cochrane.org>

Centre for Reviews and Dissemination (CRD) databases <http://www.york.ac.uk/inst/crd/index.htm>

Google <http://www.google.com>

Google Scholar <http://scholar.google.com>

PQD Open (ProQuest Dissertation and Theses – Open Access) <http://pqdopen.proquest.com/>

TRIP Database <http://www.tripdatabase.com/>

APPENDIX 2: ENVIRONMENTAL SCAN REPORT

1.0 OBJECTIVE OF THE ENVIRONMENTAL SCAN

The objective of the environmental scan, consisting of a stakeholder survey followed by focussed interviews, was to augment the information obtained through a literature review and to gain a clear understanding of the views of a cross-section of MI stakeholders such as those from professional associations; ministries of health; monitoring organizations (e.g., accreditation and radiation safety); administration; and industry. The aim was to understand stakeholders' knowledge of and experience with LCG, their current needs, and their anticipated future requirements, to inform development of the 2013 MI LCG.

2.0 THE SURVEY

2.1 SURVEY METHODS

2.1.1 DEVELOPMENT OF THE SURVEY

A letter of introduction and invitation to participate, plus suggested survey questions for an online stakeholder survey, were drafted and shared with Advisory Committee members. Following feedback, final versions were developed (available under separate cover).

The survey focused on the following areas:

- Demographic information
- Awareness of existing CAR / other MI LCG
- General experience with CAR / other medical imaging LCG
- Detailed experience with CAR / other medical imaging LCG
- Technology change requirements
- Financial and economics requirements
- Impact of academic and teaching roles on the need for LCG
- LCG criteria important to stakeholders
- Suggestions as to best value or application of MI LCG

Respondents were also asked about their willingness to be interviewed to explore further details, if necessary.

2.1.2 SURVEY PROCEDURE OVERVIEW

The online survey was released in late November 2012 with a 3-week turn-around requested. The package, including a letter of invitation, was sent electronically by ProMed to:

- Canadian Heads of Academic Radiology (CHAR) : n=16
- Cardiac chiefs from academic sites: n=23
- Relevant Canadian national associations / organizations : n=10

Canadian Agency for Drugs and Technologies in Health (CADTH)
Canadian Organization of Medical Physicists (COMP)
Canadian Association of Medical Radiation Technologists (CAMRT)
Canadian Association of Nuclear Medicine (CANM)
Canadian Association of Radiologists (CAR)
Canadian Cardiovascular Society (CCS)
Canadian Interventional Radiology Association (CIRA)
Canadian Medical and Biological Engineering Society (CMBES)
Canadian Society of Diagnostic Medical Sonographers (CSDMS)
Northern Alberta Institute of Technology (NAIT)

- Selected MI managers/directors from multi-facility academic sites : n=19
- MOH representatives (Deputy Ministers or staff dealing with MI issues): n=18
- MEDEC (representing 'Canada's medical technology companies'): n=1
- Original Equipment Manufacturers (OEMs): n=4 (GE, Philips, Siemens and Toshiba)

- Colleges of Physicians and Surgeons (e.g., registrar, director, program head) and Accreditation representatives (Accreditation Canada, Manitoba Quality Assurance Program, Diagnostic Accreditation Program of BC): n=13
- Radiation health and safety related organizations: n=17

ProMed issued 102 invitations to stakeholders to participate in the survey process; reminders were issued to non-respondents. In addition, ProMed made arrangements with the CAMRT to distribute an invitation to about 400 members in the 13 Canadian jurisdictions. As the CAMRT was unable to selectively distribute the request by email, a blanket request was sent to all CAMRT registered directors / managers of MI departments in public and independent health facilities. Follow-up emails were sent.

2.2 RESULTS OF THE SURVEY

The survey included 38 questions and 18 subset questions. Of approximately 500 people contacted for the survey, 82 responded (16.4% response rate).²⁰ Some answered all questions while some answered only some. Responses ranged from a maximum of 82 responses per question to a minimum of 4.

2.2.1 RESPONDENTS

68%	MI managers / directors
13%	Professional associations / organizations
4%	MOH
15%	“Other” included provincial MI directors / managers, supervisors, technologists, instructors, equipment / informatics, regulatory organizations, ministry of labour, and a physician. One response was from an integrated provincial group response of 11 MI managers and two MOH representatives.

2.2.2 AWARENESS OF LCG

Question	YES (70 respondents)	Notes
Are you aware of the CAR LCG?	39%	—
Are you aware of other LCG for MI?	16%	COCIR ²¹ (2003, 2009); ECRI, ²² Ontario IHF ²³ and Saskatchewan AESB ²⁴
Are you aware of single modality LCG?	10%	Ontario IHF (MRI, CT, NM, and PET/CT), OEMs end of life determination, and CIHI MIS guidelines ²⁵
Are you aware of LCG for non-MI?	7%	ECRI; computers; and AHS criteria for CR readers, printers, ECG and NM lab support equipment

20 The primary objective of the survey was to seek input and generate ideas and it was successful in this regard.

21 European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry.

22 A not-for-profit health services research agency in Philadelphia.

23 Independent Health Facilities, i.e., private facilities; quality is overseen by the College of Physicians and Surgeons.

24 Saskatchewan Acute and Emergency Services Branch.

25 Canadian Institute for Health Information (CIHI) Management Information Systems (MIS).

2.2.3 GENERAL EXPERIENCE WITH USE OF LCG

Question	# respondents	YES	Notes
Have you used the CAR LCG?	61	26%	16% for all modalities; 10% for selected modalities; 13% answered 'not applicable'
Have you developed your own LCG?	61	33% ²⁶	17% answered 'not applicable'
• If no, are you planning to develop your own or use others in future?	40	50%	
Do you use MI LCG developed in-house or by others?	60	45%	28% in-house, 17% other organization; 13% not applicable
Does your organization maintain records on rationale/ processes for replacement / upgrade?	60	37%	17% answered 'not applicable'
• If yes, are you able to share this information with the project?	21	19%	35% answered 'not applicable'

26 For those who answered yes, the distribution of in-house LCG in use was:

- General radiology / fluoroscopy (86%)
- Digital radiography (77%)
- Angiography / interventional (51%)
- Cardiac catheterization labs (17%)
- Lithotripters (20%)
- Ultrasound (89%)
- CT (74%)
- MRI (63%)
- BMD (63%)
- Mammography (71%)
- Gamma / SPECT (51%)
- SPECT / CT (49%)
- PET (11%)
- PET/CT (37%)
- Others (9%)

Note: Areas with higher percentages aligned somewhat with a higher distribution of those technologies.

2.2.4 DETAILED EXPERIENCE WITH USE OF LCC

Question: Have you used criteria for justification of upgrades, replacement, etc.?

(Highlighted are responses where $\geq 50\%$ answered 'yes')

CRITERIA (WITH EXAMPLES)	RESPONSES (n=48)
UPGRADE CRITERIA: clinical functionality and relevance; life expectancy; quality of care; utilization, efficiency; asset based requirements; refurbishment, operational affordability; meets strategic needs, etc.	Yes: 58%
	No: 9%
	NA: 33%
REPLACEMENT CRITERIA: end of life determination by OEM; clinical functionality; age of equipment; safety (patient/staff); operating costs; utilization, efficiency; performance reliability; upgradeability; upgrade in comparison to replacement and clinical benefits; accreditation and regulatory requirements; etc.	Yes: 62%
	No: 2%
	NA: 36%
STRATEGIC AND FINANCIAL ALTERNATIVES: purchase, lease, managed equipment service, individual offsets, P3, etc.	Yes: 40%
	No: 23%
	NA: 37%
WEIGHTED ASSIGNMENT CRITERIA: level of importance in terms of weighted value to strategic plans of site, organization, region and province/territory, etc.	Yes: 40%
	No: 20%
	NA: 40%
RISK ASSESSMENT CRITERIA: immediate and long term risk to patients and staff, quality of service, organization, etc.	Yes: 60%
	No: 6%
	NA: 33%
PRIORITIZATION CRITERIA: prioritize upgrades, replacements, new and emerging technologies, clinical program requirements, technologies, etc.	Yes: 64%
	No: 2%
	NA: 34%
MISSION CRITICALITY VS PATIENT RISKS: critical, important, necessary	Yes: 50%
	No: 12%
	NA: 38%
LIFE EXPECTANCY CRITERIA: age of equipment, functionality, operational costs, parts availability, patient activity, performance, redundancy, relevance, reliability, replacement costs, safety, space, upgrade costs, upgradeability, utilization, workload requirements, criteria for acceptability, upgrades.	Yes: 65%
	No: 2%
	NA: 33%
COLLEGE OF PHYSICIAN AND SURGEONS CRITERIA: criteria for acceptability, accreditation, clinical practice parameters and facility standards, etc.	Yes: 42%
	No: 23%
	NA: 38%
GOVERNMENT POLICY-RELATED CRITERIA: licensing, radiation safety, criteria for acceptability, etc.	Yes: 60%
	No: 6%
	NA: 33%

Question: Would these types of criteria be reasonable considerations for LCG?

- Response (n=39): 100%

Question: Should additional elements be considered in the development of new LCG?

- Responses (n=8):
 - Radiation dose, image quality, workflow and lifecycle cost
 - Volume and distance to next site with same technology
 - Impact of managed equipment services
 - Availability of local funding
 - Patient / exam volumes (urban / rural) and population demographics
 - Standards of practice
 - Consider factors but in more informal way (avoid being rigid and complicated)

2.2.5 TECHNOLOGY CHANGE REQUIREMENTS

Question (number of respondents)	Responses
Do you consider technology advances? (n=45)	Yes = 93%
How do you factor in advances in technology? (n=34)	Current standards of care, clinical pathways, efficiency, trends, improved patient care, reduced radiation dose, image quality, ability to be upgraded and support new software, availability of parts and software, value for money, costs of extending the lifecycle, depends on timing of an upgrade
How do you factor in obsolescence? (n=32)	Patient / staff safety; threat / risk assessment; site tolerance; mission critical determination; vendor end of life determination; rationale for replacement; reprioritizing capital requirements; weighted higher; becomes a part of risk analysis; critical replacement; consider contingency funding; biomed assessment and ranking to help determine risks, continued use, prioritization
How often is equipment rotated through your facility? (n=33)	Should not be age only, depends on use and budget, no systematic approach, evergreen for ultrasound only, MES agreements (4 years) in a couple of cases otherwise ranged between 5 and 15 years, equipment died
Does this vary by modality? (n=40)	Yes = 68%
What guidelines are used to extend lifecycle? (n=34)	No guidelines; varies depending on criteria; uptime, reliability and utilization; parts and software; vendor support; Ontario IHF guidelines; MRI and CT planned mid-life; many variables
Can lifecycle be extended if platform is newer and continues to be developed? (n=36)	70% felt this could be considered depending on upgrade path which varies by product and vendor; consider IHF standards and HARP requirements in Ontario.

2.2.6 FINANCIAL AND ECONOMIC FACTORS

Question (number of respondents)	Responses				
	5 (very important)	4	3	2	1 (not important)
Do you include “full” lifecycle costing in an economic assessment? (n=39)	54%	18%	23%	—	—
To what extent is replacement, upgrade and new and emerging technology a factor in decision making? (n=39)	39%	44%	21%	—	—
To what extent is financial impact considered, e.g., improvement or increase in operating costs, allocation of capital resources, increase in debt structure, etc.? (n=33)	67%	23%	8%	—	—
How does the financing strategy to acquire a piece of equipment or technology affect the decision-making process? (n=33)	Most agreed financing is the single most important factor; another is related to purchase versus leasing. Other considerations are recovery of cost and future potential of revenue. Financial weighting may be 25-30% (or more). Foundation or similar funding can factor in occasionally.				
How is “efficiency” factored into decision-making? (n=33)	Efficiency allows greater throughput that would enable shorter wait times, faster patient access and staff changes that could aid in operating costs. However, there is some indication that it is not considered a factor at all in some organizations.				
How is utilization factored into decision-making? (n=29)	Most indicated it is a very important factor and utilization is monitored closely to aid in obtaining financing for future purchases.				
How would you measure the “expected life” of equipment? (n=41)	Years in operation	Number of tests	Quality of deliverable service	Combination of the first three	Other
	17%	—	—	78%	5%
Why do you think one approach would be more useful to a decision-maker? (n=22)	Most seemed to think that the more factors used in the process of accessing “expected life” the more accurate the result; economics is the primary factor but years in operation, number and type of examinations, and quality of service are also important and fairly easily monitored.				
If you have an economic model, are you willing to share it with this project?	Yes = 10				

2.2.7 IMPACT OF ACADEMIC AND TEACHING ROLES ON NEED FOR LCG

Question: Does the need for academic resources and teaching affect the decision-making process to upgrade, replace or acquire technology?

- Responses: 34% said it was more critical in an academic and teaching environment; 51% indicated it was equally critical in all environments; 15% indicated that equipment becomes obsolete faster in the academic/teaching environment.

2.2.8 LCG CRITERIA IMPORTANT TO STAKEHOLDERS

Exercise: Rate the importance of factors in the development of MI LCG

- Response: The number of responses for each factor ranged between 35 and 40 participants. Also, 34% noted that consideration of factors in the development of LCG is more critical in an academic and teaching environment.
- Specific criteria to rate:

- Upgrade criteria*
- Prioritization assignments*
- Technology upgrades*
- Replacement criteria*
- Mission critical vs patient risks*
- Finance and economics*
- Strategic & financial*
- Life expectancy*
- Academic and teaching*
- Weighting assignment*
- College of Physicians & Surgeons*
- Utilization*
- Risk assessment*
- Government policy related*
- Other criteria or factors*

Responders identified the following as very important:

- Replacement criteria
- Utilization
- Risk assessment
- Mission critical vs patients risks
- Finance and economics

Responders identified the following as important:

- Life expectancy
- Technology upgrades
- Strategic & financial alternatives
- Upgrade criteria
- Prioritization criteria

Responders identified the following as least important:

- Weighting assignment
- College of Physicians & Surgeons
- Academic and research
- Government policy-related criteria

The table of criteria is reorganized here and colour-coded to reflect respondents' ideas about importance: red = most important, orange = important, yellow = least important

Most important	Important	Least important
Replacement criteria	Life expectancy	Weighting assignment
Utilization	Technology upgrades	College of Physicians & Surgeons
Risk assessment	Strategic & financial	Academic and research
Mission critical vs. patient risks	Upgrade criteria	Government policy related criteria
Finance and economics	Prioritization assignments	

Other criteria mentioned as worth considering: ergonomic impact on staffing, radiation safety, ease of use and standards of practice.

2.2.9 SUGGESTIONS AS TO BEST VALUE OR APPLICATION OF MI LCG

Survey participants were requested to identify where they 'see the best value' of MI LCG.²⁷ There were 27 responses including:

- Sorting out one's capital equipment inventory, creating priority listings based on multiple factors, and developing a rationale and evidence of need for upgrades and replacement.
- Providing health care organizations with an authoritative voice and the due diligence to develop capital plans; provide a framework of accountability, evidence, quality, safety, value for money; and present a valid and defensible position to the board.

²⁷ A question arose as to whether cancer therapies could be included in the LCG; however, from the outset of this project, in order to contain its scope, cancer treatment and simulation equipment, dental equipment, RIS/PACS and cyclotron equipment were specifically excluded.

- Assisting in acquiring the best technology to provide increased throughput and upgradeability.
- For health regions / Local Health Integration Networks (LHINs) and MOHs to better understand equipment realities.
- Providing an evidence base to support decisions.
- Prompting government to budget.
- Providing standards for the industry.
- Providing a consistent model across the provinces, i.e., providing LCG where none exist.
- Determining when to upgrade and replace.
- Independent source to help justification as equipment is required.

2.2.10 WILLINGNESS TO BE INTERVIEWED

Twenty individuals identified a willingness to be interviewed, if needed.

2.3 SUMMARY OF SURVEY RESULTS / OBSERVATIONS

- To assess knowledge and use of MI LCG in Canada, a survey of diverse stakeholders was conducted; survey questions were developed with input from an Advisory Committee. About 500 individuals were contacted; response rate was 16.4%.
- Contacted were a wide-ranging group of stakeholders including independent health facilities plus one integrated provincial response. Of these, 68% were MI managers or directors, 13% were from professional organizations, 4% were from MOHs, and 15% were 'other' (e.g., technologists and regulators). This diversity provided various perspectives and requirements.
- The survey showed variability in awareness of and experience with MI LCG across the country. Although 39% of respondents were aware of previous Canadian MI LCG (released by CAR in 2001), only 2/3 of these (26% of respondents) had used them. Also, 16% of respondents were aware of MI LCG produced by others. A third of respondents have developed their own LCG primarily for general and digital radiography, ultrasound, CT, MRI, BMD and mammography; of the remainder, 50% plan to

do so. A third maintain records on their processes for replacement or upgrade although only half are willing to share this material more broadly.

- The most common criteria currently in use for justifying equipment replacement or upgrade are: life expectancy criteria (age, functionality, operational cost, etc.); prioritization criteria (clinical program requirements, etc.); replacement criteria (safety, efficiency, etc.); risk assessment criteria; and government policy related criteria (licensing, radiation safety, etc.) Currently, financing is the single biggest factor affecting decision-making; some other key factors are purchase versus lease, recovery of cost, future revenue potential and positive utilization history.
- Regarding technology change, respondents overwhelmingly feel technology advancement is important when deciding to upgrade or replace equipment and whether to consider new or emerging technologies. Considerations include, for example, reduced radiation dose, improved image quality, clinical pathways, suitability for upgrade, and likelihood of obsolescence.
- With respect to decision-making for academic and research MI equipment, about 1/3 of respondents feel LCG is particularly important; 50% feel guidance is equally important for everyone.
- Examples of assessment criteria for determining upgrade or replacement of equipment were confirmed essential to help build a business case for equipment planning. Of LCG criteria considered important to stakeholders going forward, the table below shows respondents' impressions (red = most important, orange = important, yellow = least important):

Most important	Important	Least important
Replacement criteria	Life expectancy	Weighting assignment
Utilization	Technology upgrades	College of Physicians & Surgeons
Risk assessment	Strategic & financial	Academic and research
Mission critical vs. patient risks	Upgrade criteria	Government policy related criteria
Finance and economics	Prioritization assignments	

3.0 FOLLOW-UP INTERVIEWS

Follow-up communication (telephone or e-mail) was conducted between ProMed team members and representatives of the following organizations or groups. It was anticipated that these contacts may have had experience in developing or using MI LCG.

In Canada:

- Alberta Health Services (AHS)
- Canadian Institute for Health Information (CIHI)
- Canadian Medical and Biological Engineering Society (CMBES)
- Canadian Organization of Medical Physicists (COMP)
- MEDEC (Canadian medical technology industry)
- An Ontario Independent Health Facility (IHF)
- Quebec Service des technologies biomédicales (STB)
- Saskatchewan's Acute and Emergency Branch (AESB)

Outside Canada:

- American College of Radiology (ACR)
- Association for Medical Imaging Management (AHRA)
- Australian Ministry of Health and Aging
- Royal College of Radiologists (RCR-UK)
- US military, previous equipment planner

HIGHLIGHTS OF INTERVIEWS

CANADA (ordered alphabetically):

- a) *AHS*: Each year a manager's working group sorts devices according to replacement, deferral, upgrade or no replacement needed, preparing justifications based on the 2001 CAR LCG, subjective criteria, and a 'common sense approach' where necessary.
- b) *CIHI*: Sources of CIHI data could be the MIS guidelines (Fixed Assets Sub-ledger) and the Medical Imaging Technologies (MIT) Survey. A consideration is whether to count examinations and / or patients versus patient visits to determine utilization.
- c) *CMBES*: Members actively participate in the ongoing maintenance of MI equipment with participation in equipment planning varying by institution. They have considered creating a reference LCG document but have not yet developed one.

d) *COMP*: A number of MI physicists shared their experience. Depending on the organization, MI physicists contribute to strategic / equipment planning, get involved in research, and teach future medical physicists, residents, medical students and technologists. At some sites, equipment planning is contributed by biomedical engineering and / or consultants. It was noted that consideration should be given to changes in technology as well as age and usage and that LCG should be developed for linear accelerators as well as diagnostic equipment.

e) *MEDEC*: LCG exists in various parts of Canada but the interviewee could see the benefit to national LCG with flexibility to allow for the different environments. This would allow OEMs to better plan upgrade and replacement scenarios. Comments were that 'life expectancy' often becomes a main focus and upgrades might be considered to increase clinical relevance; however, upgrades may be accompanied by unreasonable extended life expectations.

f) *Ontario IHF Clinical Practice Parameters and Facility Standards (2012)*: If devices exceed specified age limits the owner must demonstrate that the equipment continues to meet the *Healing Arts Radiation Protection Act* (HARP) requirements and/or has been upgraded. The IHF standards set out expectations for ultrasound, general imaging and fluoroscopy, BMD and mammography: ultrasound is to be replaced after 7 years and general imaging and fluoroscopy after 20 years; BMD and mammography must meet accreditation requirements (i.e., Canadian BMD Accreditation Program and CAR Accreditation Standards, respectively).

g) *Quebec's STB*: Quebec created LCG for hospitals (single replacement age only versus a range) as a guide for the replacement of hospital technology, including MI. Timelines were determined by observation and some input by user groups and manufacturers. Shorter lifecycles were identified for newer technologies due to limited experience with those technologies.

h) *Saskatchewan's AESB*: AESB uses its own LCG with 6-10 year ranges for equipment replacement that consider high and low utilization as determined by annual exam volume. A core document outlines MI equipment management and LCG processes, *Medical Imaging Capital Equipment Acquisition Policies* (June 13/2012). Developed in 2006/07 by a

provincial committee of provincial MI managers and administrators, the policies provide three reasons for MI acquisition: replacement of existing equipment, DICOM compliance, and upgrade for technological / functional requirements. Priority focusses on RIS/PACS (DICOM related) first, then replacement. The process has been active for 7 years and has significantly lowered replacement costs per device. All regional health authorities must agree to participate in group purchasing to receive funding. Upgrades due to technical / functional requirements may be considered with a number of caveats.

INTERNATIONAL (ordered alphabetically)

- a) *ACR and AHRA*: To the knowledge of the interviewees, MI LCG has not been developed or even considered on a national or state level; however, with changing dynamics within the US health care environment, this may become more important in the future.
- b) *Australian Ministry of Health and Aging*: Australia does not have MI LCG but rather has ‘capital sensitivity’ for the delivery of services, applied to all MI technologies except PET. Considered are (i) new effective life age and (ii) maximum extended life age. Documented maintenance and operation of the equipment plus significant upgrades typically add 5 years to the ‘maximum extended life age’ (currently excludes CT and angiography which are being considered).
- c) *RCR-UK*: ‘Good practice guidelines’ were released in 1999 and updated in 2012. The guidelines focus on national guidance, hospital and department responsibilities, and individual responsibilities and also touch on MI equipment replacement. Replacement age varies from 5 years (ultrasound) to 10 years (mobile and standard x-ray) with all other modalities having 7-year replacement ages. In contrast, a 2011 national audit report set CT and MRI life expectancy at 7-10 years and government budgeting is based on the replacement of machines after 10 years.
- d) *US military, previous equipment planner*: An interview with this author described the use of subjective and weighting factors to help determine replacement priorities.

POINTS FROM RELEVANT DOCUMENTS

1. College of Physicians and Surgeons of Ontario: IHF clinical practice parameters

- College guidelines have set LCG for some MI modalities.
- Equipment in facilities must be replaced when it does not meet established Standards of Practice.
- The age of equipment should not be older than 7 years for ultrasound equipment. The age of general imaging and fluoroscopy equipment should not be over 20 years. The age of CT equipment is a maximum of 7 years; MRI 10 years.
- BMD and mammography equipment must meet CAR standards.
- Equipment must be upgradeable to future standards and the facility must have a clear pathway to replacement of aged equipment. Any equipment remaining in service beyond the recommended lifecycle must still meet Ontario *Healing Arts Radiation Protection Act* (HARP) standards.

2. COCIR draft (2003) Age Profile Medical devices (Third Edition):

http://cocir.trynisis.com/site/fileadmin/Publications_2003/ageprofile2003.pdf

- Snapshot by the OEMs of the age of equipment in EU member states.
- Advises why “age” matters.
- Some rules for their evaluation support upgrades up to 5 years.
- Equipment 6–10 years is still fit for use but only 30% should be in the installed base.
- Any equipment over 10 years should be considered ‘no longer state of the art’ and no more than 10% should be > 10 years old.
- Suggest:
 - At least 60% be younger than 5 years
 - 30% be between 6–10 years
 - No more than 10% be over 10 years old

3. COCIR European Co-ordination Committee of the Radiological, Electromedical and Healthcare IT Industry

The COCIR has published documents on the age of MI equipment in Europe. The latest study was published in 2009 with previous publications in 1998, 2001, and 2006. 'Golden rules' have been developed for the evaluation of medical equipment, based on the premise that equipment that is up to 5 years old reflects the current state of technology; 6 to 10 years old is still fit for use but already requires replacement strategies to be developed; and > 10 years is no longer state-of-art and replacement is essential (see 2003 draft, above). A 'rule of thumb' is that CT, MRI, PET-NM, and angiography medical diagnostic equipment has a reasonable economic life expectancy of between 6 and 10 years depending on the type of equipment and technical progress in the field. Because the advances in technology now occur at a more rapid rate, a high percentage of equipment aged 6 years and older indicates a poor age profile. The study does not comment on factors other than the age of the MI equipment.

European Commission – Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy

- Report is to update existing criteria for acceptability
- Updates and extends criteria for acceptability for new types of MI equipment
- Range of systems includes CT, DXA, PET, combined modalities, and digital radiography and fluoroscopy
- Identifies an updated and more explicit range of methods to better assess the criteria for acceptability
- Provides criteria for acceptability (that are achievable throughout the Member States)
- Provides advice on: implementation and verification in practice, how to deal with situations where criteria for acceptability do not exist, and rapid innovation in equipment
- Deals with special issues like screening techniques, pediatric examinations, and high dose examinations

- Promotes methods that are consistent with those employed by the Medical Devices Directive (MDD) (Council Directive 93/42/EC (1993)), industry, standards organizations and professional bodies.
- Apparently 26 of 27 member states had signed off on this updated report and it was still under review in the 27th member state.
- Criteria focus on qualitative and quantitative aspects of performance.
- The report is aimed toward owners and end users of the equipment as well as regulators.
- There are special considerations (equipment for screening, equipment for pediatrics and high dose equipment (CT, interventional angiography and therapy); exceptions (old equipment) and exclusions (rapidly evolving technologies plus others).
- The report goes on to focus on each category of equipment and the various technical aspects for testing quality and safety, etc.

4. Canadian Medical and Biological Engineering Society (CMBES)

Communications with CMBES confirmed they do not have any current study on hand. However, they have been discussing creating some reference document(s) for Useful Life of Medical Devices.

5. Canadian Institute for Health Information (CIHI)

CIHI was contacted for ideas relevant to LCG and two possibilities were noted:

- The annual National Survey of Selected Medical Imaging Equipment: This survey collects data on 10 different modalities across Canada, reported by site-specific stakeholders. The data include age of equipment and may be helpful when comparing the age of equipment to that of other sites with similar modalities.
- Management Information Systems (MIS) reporting: Many organizations have a fixed asset sub-ledger where they can record the purchase of each piece of equipment. For an organization, this could be reviewed to calculate amortization regarding what is reported in their MIS data as well as age of equipment and possible replacement dates.

APPENDIX 3: 2013 LIFE EXPECTANCY GUIDANCE COMPARED WITH OTHER GUIDELINES

The table below presents the 2013 life expectancy guidance compared with selected national and international MI guidelines identified via the literature search and interviews.

Device Type	CAR (2001)	Ohio-US Army reference (2011)	UK Royal College of Radiologists (2012)	Province of SK (current)	Province of QC (current)	CAR LCG ^{28,29} (2013)
Radiography, general	5 – 10	8 – 12	10	10 – 15	10 – 16	10 – 14
Radiography, mobile	5 – 10	8	10	10 – 15	10 – 16	10 – 14
R/F fluoroscopy (conventional / remote)	5 – 10	10	7	8 – 10	16	8 – 12
R/F interventional	7		7	8 – 10	12	8 – 12
R/F urology	10		7	8 – 10	10	8 – 12
Mobile C – arm (all types)	5 – 10	8		8 – 15	10 – 16	8 – 12
Angiography (single/ biplane)	7		7	8 – 10	12	8 – 12
Cardiac suite (single/biplane)	7		7	8 – 10	12	8 – 12
CT scanner	8	8	7 ³⁰	8 – 10	10	8 – 12
MRI scanner	6	5	7 ³⁰	8	10	8 – 12
Ultrasound	6		5	6 – 8	8	7 – 9
SPECT/gamma	10	8 (gamma)	7	8 – 10	12	8 – 12
SPECT/CT				8 – 10	12	8 – 12
PET					10	8 – 12
PET/CT					10	8 – 12
Bone densitometry	6			8	18	8 – 12
Mammography	5 – 7	10		6 – 8	15	8 – 10
Lithotripter	7	5		10	N/A	8 – 12

28 Maximum life expectancy and clinical relevance for all technologies must not be longer than 15 years.

29 Range dependent on utilization.

30 A UK national audit report gives a range of 7–10 years; government budgeting is based on replacement of devices at 10 years.

