

LIFECYCLE GUIDANCE

FOR MEDICAL IMAGING EQUIPMENT IN CANADA

2013



SUMMARY

PRINCIPAL LEAD:



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.

ACKNOWLEDGEMENTS

MAIN PARTNERS

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

SUPPORT

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1.0 INTRODUCTION

This summary document provides guidance for when and under what conditions selected medical imaging (MI) devices¹ should be considered for replacement, upgrading, and the introduction of new / emerging technologies. The guidance is intended to be comprehensive, based on sound principles, easily applied, and robust enough to be used in a variety of environments such as large or small, urban or rural and public or private. Essential to the development process were thoughtful equipment planning and lifecycle guidance considerations, with a process broader than production of a table of life expectancy numbers. For guidance users, decisions should consider clinical programs and patient needs, staffing, finances and budgets, plus other factors including evidence available via rigorous and unbiased processes such as health technology assessment (HTA).

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 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 strategic plan to augment and assist through established local processes. The guidance is divided into two sections: (1) processes involved and (2) life expectancy advice.

2.1 RECOMMENDATIONS FOR THE PLANNING PROCESS

2.1.1 ESTABLISH A FORMAL PROCESS

In an organization, prior to starting a process for establishing MI guidance, it is essential for leaders to clearly understand their 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.² 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.

2.1.2 ESTABLISH CRITERIA FOR LIFECYCLE PLANNING

To gather useful and practical information for this guidance, key stakeholders in Canada were surveyed to identify how they have used MI equipment planning criteria (e.g., utilization, risk assessment and economics) and which criteria were most important. Clearly organizations must determine the criteria most relevant to their needs which may be weighted to

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- 1 Included are general radiography and fluoroscopy, 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 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.

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 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	

2.1.3 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 with regard to hardware, software and service support (including upgrading). 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.

2.1.4 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 other technology)?
- 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)?
- 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 and employed, i.e., patient exam volumes, workload 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?
- 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?

2.1.5 CONSIDERATIONS FOR UPGRADING EQUIPMENT³

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:

2.1.6 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?

³ 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.

- 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?

2.2 EQUIPMENT LIFE EXPECTANCY

2.2.1 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,

(d) teaching facility or not. Utilization by numbers of examinations⁴ 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.⁵ Low utilization is 50% of the high utilization rate, except for lithotripsy which is 67% of the high rate.

Determining life expectancy: Calculation of life expectancy in years⁶ 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.

2.2.2 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 (Table 1); additional criteria (as above) can be used to justify a request and determine prioritization.

4 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.

5 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.

6 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 ⁷	> 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 ⁸	> 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.

7 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.

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

3.0 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.
- Quality, 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,⁹ 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 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 assessing and discontinuing use of technologies that are no longer practical or meaningful. It should emphasize flexibility to accommodate diverse health care organizations and environments, should be user-friendly, and should be updated regularly.

FOR FURTHER DETAIL, PLEASE REVIEW THE MAIN LIFECYCLE GUIDANCE FOR MEDICAL IMAGING EQUIPMENT IN CANADA (2013) DOCUMENT

⁹ Utilization data is 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).

