

CLINICAL SERVICES

MEDICAL IMAGING

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MEDICAL IMAGING

A. INTRODUCTION	2
B. CLINICAL SERVICES	2
1. Goals	2
2. Scope	3
3. Pathway	4
C. RESOURCES	
4. Facilities and Equipment	6
5. Human Resources	13
6. Information Management	17
D. SPECIAL CONSIDERATIONS FOR INTERVENTIONAL RADIOLOGY	19
E. SPECIAL CONSIDERATIONS FOR MOLECULAR IMAGING AND NUCLEAR MEDICINE	23
F. MANAGEMENT	27
7. Leadership	27
8. Operating Standards and Guidelines	28
9. Policies, Processes and Procedures	31
10. Management of Patient Flow	33
11. Documentation and Data-informed Management Decisions	34
G. QUALITY PERFORMANCE	35
12. Standards, Guidelines and Best Practices	37
13. Performance Monitoring, Reporting and Quality Improvement	43
H. THE FUTURE	
14. Innovative Trends	46
15. The Impact of Innovative Trends	49
I. REFERENCES	50

A. INTRODUCTION

Medical imaging is a fundamental part of comprehensive cancer care. The majority of individuals with suspected or confirmed cancer will have imaging tests to help determine the presence, location and spread of cancer.

Cancer patients may undergo different imaging procedures and repeated examinations over the course of their disease. Imaging can guide the selection of the most appropriate course of treatment and has a therapeutic role via image-guided procedures. It also has a significant role in the early detection of cancers.

This chapter presents the essential elements required to establish and implement medical imaging services as part of a system of cancer care.

B. CLINICAL SERVICES

1. GOALS

Medical imaging serves the following functions in cancer care. ¹⁻⁵

Screening

Medical imaging plays an important role in screening for cancer and precancerous conditions in individuals who appear to be healthy and have no symptoms. For example, mammograms are commonly used to screen for breast cancer, especially in individuals who have high risk factors, such as a family history of breast cancer.⁶ For more information, see the <u>Cancerpedia:</u> <u>Early Detection and Screening</u> chapter.

Informing Diagnosis and Treatment

Medical imaging can detect and confirm the presence of cancer, the stage of a tumour (i.e., size, extent of growth and spread), and a tumour's exact location and relationship to the tissues and organs around it. For example, imaging can show if a tumour has invaded vital organs or tissues, grown around blood vessels or spread to other organs elsewhere in the body. ⁷ Imaging information is often assessed alongside laboratory medicine and pathology results to obtain a definitive diagnosis. Once a diagnosis is obtained, imaging is an effective method to accurately stage cancer. ⁸ The stage of cancer directly influences the types of treatment selected.

Imaging may also be used to guide minimally-invasive biopsies and treatments. For more information, see the *Interventional Radiology* section of this chapter.

Monitoring the Effectiveness of Treatment and the Recurrence of Cancer

Medical imaging is used to assess the effectiveness of treatment. Molecular imaging and advanced biomarker imaging techniques, such as perfusion or diffusion imaging, may also be

used to assess the impact of treatment by monitoring changes in how a tumour's metabolism is changing.

2. SCOPE

The full scope of medical imaging in a cancer centre should include several modalities, as outlined below. The modality selected to address a patient's needs will depend on the location and suspected type of a patient's cancer, a patient's condition and the point in time during the treatment process. Some procedures rely on the use of sophisticated computers to create the medical image.

Medical Imaging Using Ionizing Radiation

X-rays (or radiographs) use radiation to obtain two-dimensional images. In certain instances, X-ray images may be enhanced by administering a contrast medium to the patient orally, rectally or intravenously, which can help to highlight the detail of tumours in the digestive, endocrine and circulatory systems. Traditionally, X-rays have been taken using film, but the digital conversion of X-rays is now standard practice in cancer centres. Digital images are more precise and detailed and allow for image post-processing. In addition, digital images can be shared, stored and retrieved more easily. Dual-energy technology – which uses two X-ray energy levels – is evolving and has shown to be helpful with outlining pathologies; for instance, after automatic bone removal from the image.

Computed (axial) tomography (CT) takes multiple, cross-sectional X-ray images and – with the use of advanced computerized technology that puts the multiple slices together – constructs a three-dimensional image of the body. CT imaging helps determine the presence of a tumour and its exact location, size and spread. It is among the most common imaging tools used to detect and diagnose cancer, and to plan and monitor treatment. ⁵ CT may also be used to guide biopsies and minimally-invasive procedures. For more information about minimally invasive procedures, see the *Interventional Radiology* section of this chapter. As with X-rays, CT is often enhanced with a contrast medium, most commonly administered orally or intravenously.

Molecular Imaging and Nuclear Medicine

Molecular imaging combines medical imaging modalities with the use of radionuclides to detect tumours non-invasively. For more information, see the <u>Molecular Imaging and Nuclear</u> <u>Medicine</u> section of this chapter.

Medical Imaging Using Non-Ionizing Radiation

Diagnostic ultrasound uses high-frequency sound waves and a hand-held device that is moved over sections of the patient's body to create sonographic, computerized images. It can help to diagnose cancer, plan and monitor treatment, and guide minimally-invasive procedures. For more information minimally invasive procedures, see the <u>Interventional</u>

<u>*Radiology*</u> section of this chapter. Contrast-enhanced ultrasound has been demonstrated as helpful with characterizing and staging tumours.

Magnetic resonance imaging (MRI) uses radiofrequency waves and strong magnetic fields to obtain detailed, computer-generated, three-dimensional images of the body. MRI imaging is used to detect and diagnose cancer, determine its stage (i.e., size, location), and plan and monitor treatment. MRI tends to be better than CT for soft tissue imaging, is the standard for imaging brain tumours, and is often the best method for detecting and characterizing cancer in the neck, bones and muscles. ⁵ In addition to diagnosing cancer, MRI is used to guide minimally-invasive procedures. For more information about minimally invasive procedures, see the *Interventional Radiology* section of this chapter. As with X-rays and CTs, MRI images may be enhanced with a contrast medium.

3. PATHWAY

Patients undergoing medical imaging go through a number of key steps, as detailed below and illustrated in Figure 1. ⁹⁻¹¹

A **referral** or requisition is required to perform an imaging examination. The medical imaging service receives the imaging request from the patient's referring clinician. Depending on the jurisdiction, the referral may come from a medical specialist, general practitioner or other healthcare provider. Referrals may originate from multiple sources, including the cancer centre, other hospitals or community-based clinical practices. The referring clinician may consult with a radiologist to determine the most appropriate imaging procedure to obtain a diagnosis. Referring clinicians may also use decision support tools and practice guidelines to determine the appropriate use of various diagnostic tests; for example, the <u>American College of Radiology Appropriateness Criteria</u>.¹²

The medical imaging service verifies the request to ensure that all necessary information has been provided, including the clinical indications for the image. The service contacts the referring clinician if information is missing or if there is a concern that the request may be inappropriate.

Booking and

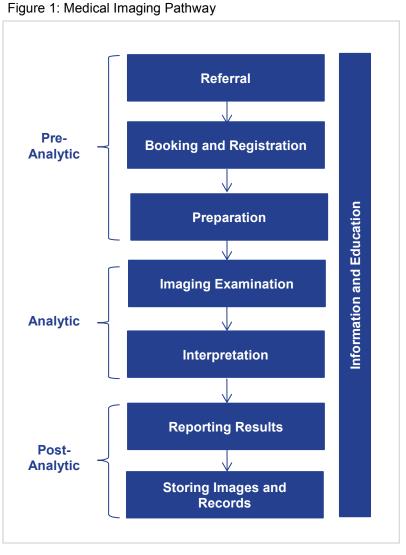
registration begins once a request is verified. The medical imaging service books the patient for his or her examination and provides the patient with instructions on how to prepare for the examination (e.g., eating, drinking, exercising, taking or refraining from certain medications, etc.).

The majority of patients

receive imaging examinations as outpatients. Inpatients may need to be assisted to the medical imaging area or, depending on the procedure, may have portable imaging equipment brought to their hospital room.

A patient arriving at the imaging service checks in and documents his or her health status, medications and medical history, including any implanted devices that could affect the imaging procedure (e.g., pacemakers, pins, plates). The patient's consent is required for most imaging tests. Consent may be given verbally or by means of signing a document that explains the imaging procedure and the associated risks and benefits.

Preparation involves getting the patient ready for the imaging examination. Depending on the type of imaging, this may include removing clothing and/or metal objects (e.g., watches, jewelry, cell phones) or taking medications to relax muscles or reduce anxiety. Patients are also given any additional substances required for a successful imaging examination (e.g., dye or contrast medium to enhance the image, premedication in case of known allergies,





radioactive drug to serve as a tracer, beta blocker to lower and stabilize the heart rate for imaging involving the heart).

The *imaging examination* involves positioning the patient and taking the images. The patient is asked to remain while the quality and anatomical coverage of the images is checked. If there are issues, the imaging examination may be repeated.

Interpretation is typically performed on high-resolution monitors and does not directly involve the patient; rather, a radiologist examines the images and identifies any abnormalities.

Reporting results involves the radiologist preparing and providing his or her report to the referring clinician. In emergency situations, the report may be delivered immediately and verbally, followed by a written report. The radiologist and/or the referring clinician discuss the results and next steps with the patient.

Storing images and records involves maintaining patient records over time. Medical imaging reports are part of the health record. All images and reports should be stored for an appropriate amount of time, which varies depending on the jurisdiction in which the cancer centre is located; for an example, see the Canadian Medical Protective Association's advice. ¹³ For more information, see the <u>Cancerpedia: Health Records</u> chapter.

Information and education are provided to referring clinicians and patients throughout the pathway.

C. RESOURCES

Resources include the facilities and equipment, human resources and information management infrastructure required to provide a comprehensive medical imaging service. The core resource elements required for medical imaging are standard; however, various factors may affect the level and configuration of resources required by a specific cancer centre. For example, increased resources may be needed to support higher patient volumes or highly-specialized medical imaging equipment and tests.

A cancer centre that is part of a larger healthcare facility may configure its medical imaging service to share resources with other clinical programs beyond cancer.

4. FACILITIES AND EQUIPMENT 14-17

Cancer centres must have an adequate and appropriately designed facility infrastructure to support medical imaging. This section describes the facilities and equipment required at each step of the medical imaging pathway, as illustrated in Figure 1.

Referral

The cancer centre may provide clinic space where surgeons and other clinicians can assess their patients and request imaging tests. This space does not need to be co-located with the medical imaging service. Surgeons and clinicians working in other hospitals and in communitybased care offices request tests from their local sites. Receiving and verifying requests – which is ideally done electronically – requires a separate work space, usually in the medical imaging area.

Booking and Registration

The cancer centre may use a main entrance and reception area for all medical imaging outpatients or various entrances for specific types of imaging. Generally, inpatient access to imaging is separate from outpatient access. Registration space usually includes sufficient room for the filing and storage of patient information. Registration work space should be located beside patient waiting areas, while ensuring sufficient privacy for registration. Waiting areas should be located near patient change areas, toilets and imaging rooms.

Preparation

Private cubicles are needed for patients to change their clothing, and to wait for their examination. Storage lockers may be made available to store personal belongings and valuables. Patient change rooms and storage areas should be located beside imaging rooms. Access to washroom facilities is also required.

A separate, supervised area is required for patient preparation prior to imaging; for example, the administration of patient hydration or medications. This area should be distinct from waiting areas and may be gender-specific. The same area may also be used for patient monitoring post-imaging.

Imaging Examination

Each imaging modality has unique physical infrastructure requirements. These are described below, followed by general infrastructure requirements and considerations for the medical imaging service.

X-ray

X-ray machines may be in a fixed location or portable, to allow point-of-care imaging in certain instances. Rooms that house X-ray equipment must be appropriately constructed and shielded according to building and radiation protection standards. They must also be spacious enough to accommodate X-ray equipment as well as patient treatment chairs or beds. While X-rays are being taken, the X-ray technologist must stand behind a protective barrier or leave the room to avoid repeated exposure to low levels of radiation over time.

СТ

Generally, CT units are in a fixed location. These may be single-purpose CT rooms located in the medical imaging service, or within or adjacent to specially-built operating rooms where

real-time CT images are used to guide procedures. For more information about the use of imaging in surgery, see the <u>Cancerpedia: Surgery</u> chapter.

Rooms that house CT equipment must be appropriately constructed and shielded according to building and radiation protection standards. They must also be spacious enough to accommodate CT equipment, and include both a high-energy power supply and enhanced cooling capacity. During imaging, the patient lies on a bed, which continuously moves through the scanner. A separate viewing room is required for the equipment operator, to prevent repeated exposure to radiation. This room must also be appropriately constructed and shielded according to standards. The viewing room should have a window or screen through which the operator can see the patient at all times, as well as a two-way intercom system to enable communication between the operator and patient. This is especially important for monitoring patient adverse reactions, so that medical assistance can be provided quickly if required. Blinds may be installed for patients requiring privacy during their procedure.

CT rooms may also be used for interventional procedures. For more information about the facilities and equipment required for interventional procedures, see the <u>Interventional</u> <u>Radiology</u> section of this chapter.

Molecular Imaging

Molecular imaging procedures require specialized facilities, equipment and supplies. For more information, see the *Molecular Imaging and Nuclear Medicine* of this chapter.

Ultrasound

Rooms that are used for ultrasound procedures must meet building standards and be spacious enough to accommodate ultrasound equipment as well as patient treatment chairs or beds. Generally, ultrasound rooms are located within the medical imaging service area, although some rooms may be located in specialty departments. In these instances, rooms tend to be larger to accommodate ultrasound-guided interventional procedures. For more information, see the *Interventional Radiology* section of this chapter.

MRI

Generally, MRIs are in a fixed location. These may be in single-purpose MRI rooms located in the medical imaging service, or within or adjacent to specially-built operating rooms where real-time MRI images are used to guide surgery. For more information about the use of imaging in surgery, see the <u>Cancerpedia: Surgery</u> chapter. Rooms that house MRI equipment must be appropriately constructed and shielded according to building and non-ionizing radiation protection standards. They should also be spacious enough to accommodate MRI equipment. During imaging, the patient lies on a movable bed that slides into position in the MRI machine. All equipment used in the MRI suite should be certified.

MRI suites must be designed to prevent unauthorized staff from entering areas with a high magnetic field. The <u>American College of Radiology</u>¹⁸ has defined four safety zones within MRI

facilities that correspond to increasing levels of magnetic field exposure and potential safety concern.

A separate viewing room is required for the equipment operator, to prevent repeated exposure to static magnetic fields. This room must also be appropriately constructed and shielded according to standards. The viewing room should have a window or screen through which the operator can see the patient at all times, as well as a two-way intercom system to enable communication between the operator and patient. This is especially important for monitoring patient reactions, so that medical assistance can be provided quickly if required.

General Requirements

Numerous standards and guidelines exist for the physical infrastructure of hospital medical imaging services at the international, national and subnational levels. Depending on the jurisdiction, individual imaging modalities may be required to meet specific mandatory standards.

The design and construction of rooms housing imaging equipment that uses *ionizing radiation* must meet the building and nuclear safety standards of the national and subnational jurisdictions in which they are located. Standards for *non-ionizing radiation* also exist and support the protection of patients, staff and the public.

Examples of organizations that offer international standards and regulations for medical imaging physical infrastructure include the following.

- The <u>International Organization for Standardization</u> develops voluntary global standards in a wide range of areas, including medical imaging.¹⁹
- The International Commission on Radiological Protection develops and maintains the International System of Radiological Protection, a worldwide common basis for radiological protection standards, legislation, guidelines, programs and practice. ²⁰
- The International Atomic Energy Agency sets standards for the protection of people against exposure to ionizing radiation, and develops scientific and technical publications that include infrastructure requirements for imaging e.g., <u>Safety Standards for Protecting</u>
 <u>People and the Environment</u>²¹; <u>Worldwide Implementation of Digital Imaging in Radiology</u>
 ¹⁴; <u>Radiation protection in radiology</u> resources ²²; <u>Radiation Protection of Patients</u>
 resources ²³
- The <u>International Commission on Non-Ionizing Radiation Protection</u> provides scientific advice and guidance on the health and environmental effects of non-ionizing radiation. ²⁴

Examples of organizations that offer national standards and regulations for medical imaging physical infrastructure include the following.

- The <u>Canadian Nuclear Safety Commission</u> reviews and approves infrastructure building plans and grants licenses for the construction and operation of facilities where nuclear energy and materials are used. ²⁵
- <u>Health Canada</u> sets out regulations, guidelines, standards and safety codes pertaining to radiation-emitting devices. ²⁶
- The <u>CSA Group</u>'s Canadian Health Care Facilities standard includes medical imaging

requirements in areas such as workflow and technical and internal design.²⁷

- The <u>Australian Radiation Protection and Nuclear Safety Agency</u> regulates the use of radiation through licensing, compliance, inspection and enforcement, and establishes codes of practice for the medical use of ionizing radiation.²⁸
- The <u>United States Nuclear Regulatory Commission</u> licenses and regulates the use and storage of radioactive materials, including those for therapeutic medical use.²⁹
- The United States Environmental Protection Agency's Interagency Working Group on Medical Radiation develops radiation protection guidance for diagnostic and interventional X-ray procedures. ³⁰
- The United States' <u>National Electrical Manufacturers Association</u> made up of companies that manufacture diverse products, including medical diagnostic imaging systems – develops medical imaging standards. ³¹
- The <u>European Commission</u> provides an overview of radiation protection legislation in Europe. ³²

Ideally, leadership and staff should participate as a team in designing the medical imaging physical infrastructure, especially with respect to how it impacts the effectiveness and efficiency of operations, the flow of patients and patient information, and the safety of the work environment.

In addition to meeting regulatory standards, the design and construction of the cancer centre's medical imaging service should consider the following: ^{27, 33}

Access: The medical imaging area should be secure and accessible only to staff and patients who require imaging procedures. Soundproofing may also be necessary to ensure the privacy and confidentiality of patient information.

Adjacencies: The medical imaging service works with many clinical services that refer patients. If a cancer centre is part of a full-service hospital, the medical imaging service may be located adjacent to the emergency department. These areas should be directly linked or connected. For all cancer centres, the medical imaging service should be connected to the surgical suite, critical care units, and medical/surgical units. The increased use of digital images and point-of-care imaging may make the need for these connections less necessary in the future. Patients should be able to access outpatient imaging areas using public corridors.

Size: The size of medical imaging facilities will vary, depending on the number and types of services provided, the current and projected patient volume, and the size of the imaging equipment used and its requirements. CTs, MRIs and PET scanners are large pieces of equipment that require sufficient space to support safe practices, including separate monitoring rooms. Space must also be available to support imaging modalities that are used in interventional procedures. For more information, see the *Interventional Radiology* section of this chapter.

Flexibility: When planning the medical imaging service, the cancer centre should consider future growth as well as evolving and new modalities and procedures. Flexibility can be built in by locating medical imaging facilities near "soft space" (e.g., administrative offices, storage

space) that can be adapted to accommodate expansion. Mobile workstations and carts and built-in furniture also provide flexibility. The design of medical imaging rooms should maximize space and allow for the easy installation, maintenance and replacement of large equipment. As well, there should be appropriate access to utilities in case space needs to be reconfigured.

Layout: The design and layout of the cancer centre medical imaging service should incorporate LEAN flow principles. Imaging modalities should be located in one area, with separate space for storage (e.g., medications, sterile supplies), treatment preparation (e.g., mixing contrast media), staff facilities and workstations. Depending on patient volume, infrastructure may be organized into dedicated suites for each modality, including change rooms, patient preparation areas, a patient holding area and imaging rooms. Alternatively, imaging modalities that are adjacent to each other may share patient recovery areas and nursing coverage.

Conceptually, the service should be organized by zones, ranging from those that are publicly accessible and uncontrolled (e.g., registration) to those with increasing levels of controlled access. ³⁴ Administrative offices and registration areas should be located on the perimeter and outside of medical imaging areas. Outpatient waiting areas should be close to patient change rooms, toilets and private gowned waiting areas, and adjacent to procedure rooms. Inpatient waiting or holding areas should provide privacy for patients and be close to imaging rooms. Special interventional procedure rooms should include space for short-term, post-procedure observation. For more information, see the *Interventional Radiology* section of this chapter. There should be one direct, controlled-access entrance to medical imaging after hours. Isolation of infectious patients must also be considered; for more information, see the *Cancerpedia: Infection Prevention and Control* chapter.

Sufficient space and equipment are required for staff to check the clinical and technical quality of images. The location of this space and equipment may vary, depending on the imaging modality. For example, digital X-rays and ultrasound images may be checked as soon as they are taken, with the patient in the room or in an adjacent room. The quality of other images, such as CT or MRI, may be checked in a control room. Interventional rooms require large, in-room control monitors, preferably mounted to the ceiling. For more information, see the *Interventional Radiology* section of this chapter.

Safety: Medical imaging physical infrastructure should incorporate various safety design principles, including those outlined by the <u>International Organization for Standardization</u>, relevant national or subnational accreditation and regulatory bodies, and local building codes ³⁵. Safety design features may include:

- Appropriate construction materials, finishes and coatings to maximize safety and infection control (e.g., walls, ceilings, floors, doors, bench tops, workstations, furniture, lighting, etc.)
- Proper shielding of procedure rooms and adjacent spaces (e.g., thickness and density of walls, ceilings and floors)
- Acoustical features that reduce background noise and support voice recognition systems
- Features that minimize vibration that can impact imaging equipment
- Zoning for increasing levels of magnetic field exposure and potential safety concern¹⁸
- Heating, ventilation and air conditioning systems to control temperature, humidity, and air

circulation, exchange and balancing (e.g., removal of radioactive gases, air cycling standards, etc.), including negative air pressure, inward directional airflow and containment barriers in high containment areas

- Appropriate electrical systems and voltage levels, a stable power supply to support the full
 range of medical imaging technologies, an uninterruptable power supply/source (UPS), and
 emergency generator backup to minimize downtime and maintain information systems
- Plumbing systems, including a reliable water supply for water-chilled equipment, drains, sprinkler system, etc.
- A compressed gas infrastructure, including medical gases, vacuums and valves in each
 procedure room
- Appropriate lighting and lighting controls (e.g., electrical outlets for normal and emergency power use, high-quality dimmable indirect fixtures where images are read, etc.)
- Ceiling lifts to transfer patients to imaging equipment tables
- Ceiling mounts for injectors and image control monitors
- Radiation safety devices, such as doors that prevent unauthorized access and emergency controls to shut off the radiation in emergency situations
- Appropriate storage of radioactive substances in secure containers
- Appropriate storage for all other supplies (e.g., medical equipment, sterile supplies, personal protective equipment, flammables, volatile and radioactive products, etc.)
- Separate areas for handling and holding of contaminated/soiled goods, including radioisotopes and radioactive wastes, the disinfection of ultrasound probes, etc.
- Safety devices, such as hand washing sinks at entrances and exits and throughout the department, emergency eyewash stations and showers for immediate access, as required
- Emergency alert buttons
- Access to staff facilities
- Meeting and teaching space

Point-of-care imaging: When point-of-care imaging occurs at the bedside or in an outpatient clinic, space, processes and the use of equipment need to meet all safety requirements.

Information and communication: Infrastructure is required to gather, document and communicate information in the medical imaging service, preferably digitally. ¹⁴ Infrastructure to support communication between the radiologist and other clinical areas or hospitals may include video links, standard and wireless telephones, intranet connections and teleconferencing capabilities.

In addition, imaging procedures that require separate staff control rooms need a staff and patient communications infrastructure, including a telecommunications system that enables visual (i.e., staff to patient) and two-way auditory communications (e.g., intercom, monitors, closed circuit television, telephones, emergency call system, etc.).

Interpretation

Quiet image viewing workstations are required to interpret images. These should be equipped with computers, screens, light boxes (i.e., if films are used), appropriate lighting, airflow and space. The layout of these workstations may vary from individual rooms to a centralized area

for collaborative, specialized imaging interpretation and consultation. ³⁶ Web-based access may allow radiologists to review images remotely or from a home office. Management systems are needed to create and maintain radiologist task lists or worklists of unread procedures ready for interpretation. ³⁷ These may include assigning images according to subspecialists' areas of expertise.

Reporting Results

Once images have been interpreted, the radiologist should record the test results on paper, via dictation or directly in an electronic system. This requires a separate work space, usually in the medical imaging area. The radiologist should review and finalize all dictated reports.

The medical imaging service should use a systematic process to distribute final images and reports to the referring clinician, whether within the cancer centre or in the community. While the electronic distribution of images and reports is ideal, secure physical delivery is also an option. In emergency situations or where there are unexpected results that require urgent action (e.g., findings of pulmonary embolism or bowel perforation), the images and reports should be shared quickly with the referring clinician by electronic and/or verbal communication. It is the responsibility of the medical imaging service to ensure bi-directional communication with the referring clinician to address urgent reports. Successful communication should be documented in the patient health record. It is the responsibility of the referring clinician to read the report and discuss the results and next steps with the patient.

Storing Images and Records

Imaging results must be incorporated into the patient's health record and retained accordingly to the regulations of the jurisdiction in which the cancer centre is located. Images on film or CDs as well as paper records should be stored in facilities that prevent unauthorized access, loss, damage or deterioration due to temperature fluctuations, light, water, fire, etc. Digital images and records should be stored according to the storage, backup and privacy requirements set by the jurisdiction in which the cancer centre is located. Stored images and reports must be appropriately labelled. For more information, see the <u>Cancerpedia: Health</u> <u>Records</u> and <u>Cancerpedia: Equipment and Technology</u> chapters.

5. HUMAN RESOURCES

In a cancer centre, the medical imaging service is provided by a range of professionals. The range of staff needed to support modern medical imaging has risen rapidly, in keeping with increased specialization and subspecialization in imaging.

This section describes the key medical, technical and other professional expertise required by a medical imaging service in a cancer centre. The job titles, education requirements and scope of practice of each role may vary by jurisdiction.

Medical Expertise

Radiologists

Radiologists are medical specialists who advise referring clinicians on the most appropriate imaging examinations, interpret medical images, diagnose diseases from an imaging perspective, recommend disease management approaches and, depending on their subspecialty, perform interventional procedures.

A radiologist is a licensed physician with at least four or more additional years of postgraduate specialty training (i.e., residency) on how to obtain and interpret the full range of medical images and conduct certain image-guided procedures (e.g., biopsies). Radiologists may also complete a fellowship program for additional subspecialty training. Radiologists in cancer centres are becoming more subspecialized and are developing expertise in more complex, minimally invasive image-guided therapies.

Radiologists may subspecialize in medical imaging and diagnosis of particular body areas (e.g., breast, heart and vascular system, gastrointestinal tract and abdomen, reproductive and urinary systems, head and neck, musculoskeletal system, or spine, brain and nervous system). Radiologists may also subspecialize in certain radiology techniques (e.g., interventional radiologists).

Radiologist Assistants

Some jurisdictions recognize radiologist assistants (RAs), or assistant practitioners, as part of a career progression in radiography. ³⁸ The RA role falls between that of the radiologist and the radiology technologist, and the scope of practice for the profession varies by jurisdiction. Working under the supervision of a licensed radiologist, responsibilities may include performing patient assessments, managing patients, performing selected examinations, evaluating image quality and conducting an initial assessment of the image to be sent to the supervising radiologist.³⁹ Education requirements set by the American Registry of Radiologic Technologists (2016) include certification and registration in radiography, completion of a recognized RA education program, a bachelor's degree from an accredited education institution, and at least one year of full-time clinical experience following radiography certification⁴⁰.

Technical Expertise

Technical staff play a significant role in the cancer centre's medical imaging service. The scope of practice of technical staff varies by jurisdiction, as does their status as regulated professionals. The job titles and specific responsibilities of these individuals may also vary by organization.

Medical Imaging Technologist

Medical imaging technologists – also known as radiology or radiologic technologists, medical radiation technologists, diagnostic radiographers, or sonographers – perform medical imaging procedures under the direction of radiologists.

Depending on the jurisdiction, the responsibilities of medical imaging technologists may include the following:

- Explaining the medical imaging procedure to the patient and answering questions
- Positioning the patient properly so an accurate medical image can be taken
- Injecting contrast agents, if required, or administering radiopharmaceuticals via injection, inhalation or ingestion
- Operating medical imaging equipment, including moving it into position and checking all parameters and requirements
- Using mobile, point-of-care imaging equipment in the emergency department, operating room, critical care area(s) or inpatient rooms
- Taking medical images
- Checking the technical and clinical quality of medical images with the radiologist
- Monitoring the patient and reporting if the patient has any reactions

Educational requirements for medical imaging technologists vary by jurisdiction. Medical imaging technologists may specialize in a particular imaging modality. As well, medical imaging technologists in a cancer centre may further specialize in particular parts of the body. Additional training may be required in these instances.

Other Professional Expertise

Radiology Nurses

Cancer centres have radiology nurses who meet the physical, psychosocial and safety needs of patients undergoing imaging tests and procedures. Radiology nurses may review imaging procedures and potential side-effects with the patient and family, administer contrast media, administer and track sedation or pain control, monitor and manage any side-effects or complications, and assist the radiologist or medical imaging technologist.

Radiology nurses are registered nurses with additional specialty training. Depending on the jurisdiction, certification may be required.

Medical (Diagnostic Imaging) Physicists

Diagnostic imaging physicists work with medical imaging staff on the full range of imaging modalities and are responsible for:

- Working with radiologists in selecting the cancer centre's imaging equipment, overseeing
 installation and commissioning, and calibrating and maintaining the equipment according to
 quality control and operational standards
- Overseeing all imaging safety standards, including meeting all physical infrastructure safety

requirements and implementing a radiation protection and quality control program

Diagnostic imaging physicists have general physics training along with advanced postgraduate training in medical physics at a master's or doctorate level and in-hospital clinical training in diagnostic imaging physics. Physicists may also subspecialize (e.g., nuclear medical physics).

Specialized accreditation of medical physics educational programs is available. For example, the <u>Commission on Accreditation of Medical Physics Educational Programs</u> evaluates and accredits graduate, residency and continuing education programs in North America.⁴¹ The <u>European Federation of Organisations for Medical Physics</u> promotes medical physics education in Europe. ⁴²

Human Resource Requirements

The number of staff who have medical, technical and other professional expertise as well as the mix of general and subspecialized staff in a cancer centre's medical imaging service will vary depending on the volume of patients, the imaging modalities provided and the centre's regional role in its jurisdiction. For example, a centre that provides specialized imaging to a wide catchment area may need more specialized staff than a centre that serves a smaller, local population. It is important to note that each subspecialist requires a critical mass of patients to ensure ongoing clinical proficiency.

The workload of radiologists varies based on a number of factors, including: the extent of patient interaction; the complexity of imaging procedures; time spent reporting; the radiologist's level of experience; the radiologist's responsibilities for administration, teaching and research; and the practice setting. ⁴³⁻⁴⁶ In their work to develop a method for quantifying radiologist activities, MacDonald et al. (2013a) determined that diagnostic reporting accounted for approximately 35 per cent of radiologist clinical time, followed by procedures at 23 per cent, trainee supervision at 15 per cent, conferences and tutorials at 14 per cent, informal case discussions at 10 per cent and referral-related administration at 3 per cent. ⁴⁵

Table 1 presents an overview of medical imaging human resource requirements by activity.

Table 1: Medical Imaging Human Re	Resource Requirements
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Professional	Role	Human Resource Requirements
Radiologists	 Review requests for appropriateness May verify clinical quality of images with technologist Interpret images Determine diagnoses Enter results Verify final reports Report results directly to referring clinician if an emergency Consult with referring clinicians and the healthcare team, as required 	 Depends on the volume and type of requests, other responsibilities and other factors ⁴⁵ Influenced by the use of radiologist assistants

Professional	Role	Human Resource Requirements
Medical Imaging Technologists	 May review requests for appropriateness Prepare patients for imaging examinations Conduct imaging examinations Verify clinical and technical quality of images with radiologist, as required May assist in interventional procedures 	 Depends on the number and type of patients/images
Radiology Nurses	 May prepare patients for imaging examinations Ensure adequate medications during and after interventional procedures Monitor and manage side-effects 	Depends on the number and type of patients/images and the type of interventions
Diagnostic Imaging Physicists	 Ensure equipment is working May help in decision-making for new equipment 	 Depends on the types of equipment and the demands placed on each
Nuclear Pharmacists	Prepare compounds for molecular imaging	 Depends on the number of patients undergoing molecular imaging
Administrative Staff	 May review requests for completeness Book and register patients Provide preparation details to patients May transcribe reports (i.e., if dictated) Store images and records 	Depends on the volume of patients
Management Staff	Manage the service	Depends on the volume of patients

6. INFORMATION MANAGEMENT

The cancer centre's information management (IM) infrastructure provides an overarching umbrella for the medical imaging-specific IM infrastructure. Ideally, the corporate-wide and function-specific IM infrastructure is electronic and fully integrated.

The medical imaging-specific IM infrastructure has two interconnected information systems – the radiology information system (RIS) and the picture archiving and communication system (PACS) – as illustrated in Figure 2. Together, these systems support the receipt, storage, management and sharing of medical imaging requests and results. The RIS and PACS are in turn connected to the hospital information system (HIS) and patient health record.

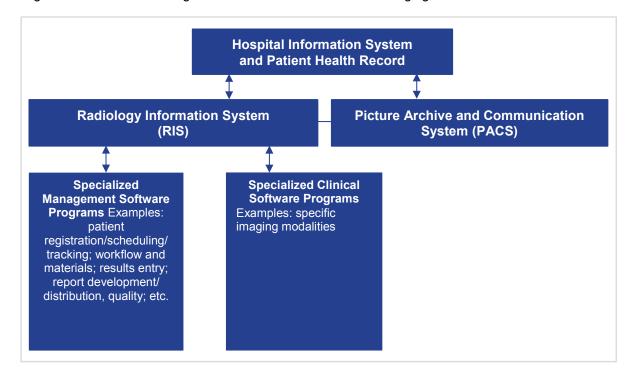


Figure 2: Information Management Infrastructure for Medical Imaging

The RIS is the computerized medical imaging management system. It is usually connected to a series of specialized software programs that are focused on clinical areas or management of the service. The RIS consolidates a wide-range of electronic information in key areas, including: ^{16, 37, 47}

- Requests and approvals for medical imaging tests
- Registration and scheduling of patients, including queue management
- Data on patients who have completed or are scheduled for a medical imaging procedure
- Resource management, including resources required and used (i.e., staff, equipment, etc.)
- Scheduling of exams and work list and workflow planning and tracking (e.g., staff, equipment, transmission of patient information to modality consoles)
- Interpretation of medical images and recording of results, including voice recognition reporting
- Structured reporting and distribution of results
- Storage of medical imaging results
- Tracking and improving performance through business intelligence tools
- Facilitating peer-review programs for quality assurance

Ideally, the medical imaging service should oversee the RIS and its software applications to ensure effective and timely service. Some in-house expertise is required to conduct basic programming and support specialized software systems. For more information, see the *Cancerpedia: Equipment and Technology* chapter.

The PACS enables the cancer centre to receive requests for medical imaging and transfer medical images and reports electronically within the imaging service, throughout the centre to

other members of the care team, to external referring providers, and to central repositories or platforms. Increasingly, jurisdictions are establishing regional medical imaging repositories or platforms that enable cancer centres to work closely with less specialized, smaller hospitals and community-based providers to diagnose and plan treatment for cancer patients. ⁴⁸ The sharing of images between smaller centres or hospitals and the cancer centre using PACS may reduce the need for duplicate testing, assuming that image quality is good and meets the Digital Imaging and Communications in Medicine (DICOM) standard. ³⁵ If the cancer centre performs specialized imaging tests for smaller centres or hospitals, PACS enables the transmission of a timely diagnosis back to the referring provider

Sufficient server space should be appropriately designed and configured to accommodate the RIS and PACS systems.⁴⁷ In addition, medical imaging IM systems need to be closely integrated. RIS and PACS integration enables users to access a wide range of information on the care of patients and the efficient operation of the medical imaging service. ^{16, 37, 49} RIS and HIS integration enables the cancer care team to access the full range of patient information (i.e., imaging and non-imaging) to make a final diagnosis and develop a treatment plan. ^{47, 50} Communication interfaces between RIS, PACS, HIS and other information systems (e.g., pathology) must be bi-directional to enable comprehensive access to patient information, and to reduce the number of steps required to obtain and interpret radiological examinations. While it may require 32 steps to request, obtain and report an ultrasound examination using a traditional paper/film-based system ⁴⁷, a fully integrated digital system requires only nine steps, reduces the number of manual data entries, minimizes errors in patient health records and reduces database fractionation.

D. SPECIAL CONSIDERATIONS FOR INTERVENTIONAL RADIOLOGY

Interventional radiology (IR) is a subspecialty of radiology and refers to the use of imageguided procedures – including X-ray fluoroscopy, ultrasound, CT or magnetic resonance angiography – to precisely target therapy. Most IR procedures are minimally invasive alternatives to open and laparoscopic surgery, meaning reduced pain and risk and a quicker recovery for the patient. Increasingly, interventional imaging techniques are being used to replace traditional, more invasive procedures, with excellent results and additional benefits.

Diagnosis

One of the most common interventional radiology procedures is image-guided biopsy. Under fluoroscopic, CT or ultrasound guidance, small needles are placed in areas of suspicious tissue and samples are taken for cytologic, pathologic or microbiologic testing. ⁵¹ Image-guided biopsy has several benefits. After a surgical biopsy, a delay of 10 days to three weeks is needed to prevent infection and bleeding, and to allow wound healing before other cancer treatments can begin. Image-guided biopsy comes with a lower complication rate and allows patients to begin neoadjuvant chemotherapy and radiotherapy more quickly. In addition, the use of image-guided percutaneous needle biopsy for bone tumours has resulted in a three-to sevenfold improvement in the overall cost-effectiveness of care. ⁵²

Treatment

IR procedures use image guidance in combination with the most current care innovations available to treat cancer while minimizing possible injury to other body organs. Most patients having these procedures are outpatients or require a one-night stay in the hospital. In general, IR procedures provide patients with new therapeutic options, particularly when conventional therapy fails or is deemed unsuitable. IR is essential for patients whose cancer cannot be surgically removed or effectively treated with systemic chemotherapy.

The main types of IR procedures used to treat cancer and its symptoms include the following. 53, 54

- **Venous access**, including the use of temporary ports and peripherally inserted central catheters (PICC) that minimize the number of needle pricks required during diagnostic blood work or chemotherapy.
- *Embolization*, which involves cutting off a tumour's blood supply (i.e., vascular embolization), or targeting it with chemotherapy (i.e., chemo-embolization) or radioactivity (i.e., radio-embolization). This is achieved by injecting microscopic beads into blood vessels that feed the cancer.
- **Radiofrequency ablation, microwave ablation or cryoablation**, which involves placing a needle into the tumour and delivering extreme temperatures to destroy the cancer cells. It is essentially burning or freezing a tumour.
- Vertebroplasty and kyphoplasty, which are used to treat vertebral fractures, a common and painful side-effect of spine tumours. During vertebroplasty, a special type of bone cement is injected directly into a collapsed vertebra to stabilize the spine before surgery or radiation therapy. The cement may also serve as a marker in patients who are treated with image-guided radiation therapy. Kyphoplasty provides spinal support and relieves pain, particularly in patients with spine tumours. A small balloon is inserted into the vertebra and inflated. This creates a space into which bone cement can be injected. Both of these procedures can also help improve patients' mobility.
- Neurointerventional radiology, also referred to as interventional neuroradiology, which is
 primarily concerned with treating life-threatening conditions of the central nervous system
 through endovascular approaches.

IR procedures are frequently used in combination with other therapies provided by the broader cancer team.

Post-Treatment/Surgery

IR is also used in the management of complications post-procedure, including pain, bleeding, blood clots or infection. For example, interventional radiologists can perform percutaneous abscess drainage with CT or ultrasound guidance. ⁵⁵ Patients who undergo surgery for head or neck cancer may also require enteral nutrition through gastrostomy. Percutaneous endoscopic placement is routine in most centres, with interventional radiologists performing the procedure under fluoroscopic guidance. ⁵⁶

Resources

Facilities and Equipment

Designing an IR suite requires special consideration, as they are a major investment. Ultrasound, CT and fluoroscopic guidance are used in 95 per cent of IR procedures. In addition, different procedures can require a variety of additional equipment, such as: ⁵⁷

- Oxygen and suction
- Physiological monitors
- Resuscitation equipment
- Communication equipment

Interventional radiology procedure rooms must meet the building and radiation standards described more broadly in this chapter for each medical imaging modality, and should ideally be co-located with staff workstations for image review and documentation. A dedicated IR day unit is recommended, where patients can be monitored closely by specialized staff post-treatment. Where a dedicated IR day unit is not possible, IR patients may be integrated with other day surgery patients. Consultation rooms are also required to accommodate pre- and post-procedure patient appointments.

In terms of non-clinical facilities, a fully equipped image viewing room is required, along with a readily accessible and secure storage area for commonly used medical/surgical and drug supplies.

For more information about IR facilities and equipment requirements, see the Society of Interventional Radiology's:

- Practice Parameter for Interventional Clinical Practice and Management ⁵⁷
- <u>Resource and Environment Standards for IR</u>⁵⁸

For more information about surgical facilities and equipment, see the <u>Cancerpedia: Surgery</u> chapter.

Human Resources

Interventional radiologists are board-certified, fellowship-trained physicians. They have had additional training in radiology, neurosurgery, neurology, neuroradiology, and interventional neuroradiology, and must show expertise in radiation safety, radiation physics, the biological effects of radiation and injury prevention.⁵⁹ Interventional radiologists are licensed through various national bodies, such as the Royal College of Physicians and Surgeons in Canada, the Royal College of Radiologists in the UK, and the American Board of Radiology in the United States.

Other members of an IR team may include:

- IR technologists, who can conduct simple IR procedures, e.g. PICC insertion
- IR nurses, who are registered nurses with additional specialty training

- IR nurse co-ordinators, IR patient care co-ordinators and IR inpatient flow co-ordinators, who assist with patient navigation and support the administration of the service
- IR clinical nurse educators, who support patient education
- Administrative supports
- An IR supervisor, who manages the service

These positions may be integrated into broader structures in centres with a lower IR patient volume and/or lesser resources.

For more information about IR human resource and staffing requirements, see:

- The Society of Interventional Radiology' <u>Practice Parameter for Interventional Clinical</u> <u>Practice and Management</u> ⁵⁷ and <u>Staffing Guidelines for the Interventional Radiology Suite</u> ⁶⁰
- The Royal College of Physicians and Surgeons of Canada's <u>Objectives of Training in the</u> <u>Subspecialty of Interventional Radiology</u>⁶¹

Other considerations

While interventional radiology has revolutionized modern medicine, it has yet to be made widely available in low- and middle-income countries, primarily due to the significant financial investment required. In addition to the cost of facilities and equipment, there is the cumulative cost of disposables, such as catheters, wires and special needles, as well as funds associated with equipment repair, when necessary.

In addition to the financial obstacles of establishing an IR service, the availability of trained and skill personnel may also be a challenge. The World Health Organization recommends that advanced ultrasound, CT, MRI, fluoroscopy, angiography and nuclear medicine should not be installed unless radiologists and fully-trained technologists are present at the facility to use it. ⁶²

Ultrasound is relatively inexpensive and can be used in most jurisdictions successfully for procedures such as biopsy and image-guided catheterization. ⁶² Human resource challenges can be overcome with medical simulation training ⁶³ or partnerships with foreign institutions, as was the case with Imam Khomeini Hospital in Iran.⁶⁴ In Malaysia, the number of formally-trained interventional radiologists has grown over the last two decades, with much of the training completed overseas (e.g., in the United Kingdom, Australia and Singapore). ⁶⁵ While radiologists from low- and middle-income countries can benefit from educational partnerships with foreign institutions ⁶⁶, an effective training program of local providers should be the ultimate goal in establishing an IR practice within a cancer centre.

Other Suggested Reading

- The <u>Radiological Society of North America</u>⁶⁷
- The Society of Interventional Oncology

E. SPECIAL CONSIDERATIONS FOR MOLECULAR IMAGING AND NUCLEAR MEDICINE

Molecular imaging provides detailed images of the body at the molecular or cellular level. Whereas other types of imaging focus on physical structure, molecular imaging focuses on how the body functions and its chemical and biological processes. ⁶⁹ Molecular imaging includes nuclear medicine, which uses radiopharmaceuticals – also called radiotracers or radionuclides – to release low levels of radiation into the body. Body tissues affected by cancer may absorb more or less of a tracer than normal tissues; if cancer is present, the tumour may show up as a "hot spot" – an area of increased cell activity and tracer uptake – or a "cold spot" – a site of decreased uptake and less cell activity.⁷⁰

Molecular imaging and nuclear medicine contribute to cancer care in a number of ways, including: ⁷¹

- *Early diagnosis:* detecting tumours before they are seen on morphology
- Staging: illuminating the location and extent of tumours more accurately
- **Treatment planning**: providing information on tumour characteristics and prognostic factors as well as functional evaluations of organs and systems before and after treatment
- Treatment: through the use of radioactive materials
- Surveillance: detecting cancer relapses during follow-up

Due to its ability to detect cellular changes that occur early in the course of many types of cancer – well before structural changes can be seen – molecular imaging is lauded as a safe and non-invasive alternative to the pain, trauma and risk associated with invasive surgical procedures. Nuclear medicine can also serve as a non-invasive and targeted treatment for some types of cancer, such as the use of radioactive iodine (I-131) therapy for thyroid cancer.

The full scope of molecular imaging in a cancer centre should include several modalities. The modality selected for a patient is dependent on several factors, such as the location and suspected type of the patient's cancer, the patient's condition and the proposed role of molecular imaging in the treatment process. The main molecular imaging modalities include:

- The gamma camera, a specialized camera that is able to detect the gamma rays emitted by radiotracers. The camera produces two-dimensional images of the body from different angles.
- **Single photon emission computed tomography** (SPECT), which uses a gamma camera that rotates around the patient and creates three-dimensional images of the area under study.
- **Positron emission tomography** (PET), which detects the positrons emitted by radiotracers to create three-dimensional images of the body.

Over the past decade, multimodality imaging has become common. Molecular images can now be superimposed with CT or MRI to perform two imaging studies at the same time, such as PET/CT, SPECT/CT and PET/MR. The merged or fused images can provide more precise information about how different parts of the body function and more clearly identify problems. They can also help rule out false positives and aid specificity.⁷²

Resources

Establishing a molecular imaging and nuclear medicine service as part of a cancer centre requires careful consideration of physical facilities, equipment and supplies, and staffing requirements.

Facilities

While some hospital facilities and systems are shared by the entire medical imaging service, the molecular imaging and nuclear medicine service also requires dedicated physical facilities that meet standards. Generally, these facilities are divided into clinical and non-clinical areas to enable optimal patient care and flow, and to ensure radiation safety.

Clinical areas generally include:

- Waiting areas for nonradioactive and radioactive patients, with seating
- Examination/clinic rooms, where patient vitals can be measured and considered or inputted into the scanner
- Shielded procedure rooms that are large enough to house equipment and patient beds, and that are equipped with oxygen, medical gases and suction
- Shielded control rooms that are adjacent to procedure rooms and that allow for two-way audio communication with the patient
- A shielded post-procedure recovery or uptake room that is adjacent to procedure rooms, is large enough to accommodate beds for three to four patients, and includes a bathroom designed to safely contain radioactive material

Non-clinical areas generally include:

- A hot laboratory, or radiopharmacy, where radiopharmaceutical material is received, prepared, assessed for quality and stored
- A dedicated molecular imaging station that can be used for image processing, interpretation and reporting

Areas that contain radioactive material or are exposed to radiation should be appropriated signed, shielded and secured. Access to these areas should be strictly controlled.

For more information about molecular imaging and nuclear medicine physical facilities requirements, see the International Atomic Energy Agency's <u>Nuclear Medicine Resources</u> <u>Manual</u>. ⁷³

Equipment and Supplies

A key component of the successful operation of a molecular imaging and nuclear medicine service is the on-demand availability of radiopharmaceuticals. Fluorodeoxyglucose (FDG) is the most successful and widely-used imaging agent for PET today, and has a very short half-life of approximately 110 minutes. Many other radiopharmaceuticals may also be used. For more information about radiopharmaceuticals used in cancer diagnosis and monitoring, see

Drodzovitch et al. 2015. ⁷⁴ For more information about radiopharmaceuticals used in cancer treatment, see Yeong et al. 2014. ⁷⁵

Radiopharmaceuticals may be supplied by the cancer centre or manufactured locally by a radiopharmacy. A cyclotron is required to produce the radioisotope Fluorine-18, used in the tracer FDG, as well as other isotopes. If the cancer centre intends to supply radiopharmaceuticals, the choice of cyclotron type and its specific proton beam energy and current will depend largely upon the program's scope and available resources, in particular financial and spatial resources. ⁷⁶ Other equipment required to prepare and store radiopharmaceuticals at the cancer centre include dedicated centrifuges, automatic well counters, liquid scintillation counters, refrigerators and freezers.

Radiopharmaceuticals are typically injected, swallowed or inhaled into the body, and intravenous equipment should be readily available to staff. Once a patient is ready for examination, molecular images are created using gamma cameras, SPECT scanners and PET scanners. As previously indicated, this equipment may be used in combination with CT or MRI to create combined images. Some procedures rely on the use of sophisticated computers to create the medical image.

Finally, appropriate radiation monitoring and personal protective equipment are essential to ensure patient and staff safety. Area monitors may be used in radiopharmaceutical dispensing or storage areas to monitor radiation exposure. Contamination instruments should be available to detect radioactive material on surfaces and people in the event of a spill. Staff should wear rings and whole-body dosimeters to measure radiation exposure, as well as laboratory coats, gloves, face shields and other protective clothing, as appropriate.

For more information about molecular imaging equipment and supplies requirements, see:

- The International Atomic Energy Agency's Nuclear Medicine Resource's Manual and <u>Good</u>
 <u>Practice for Introducing Radiopharmaceuticals for Clinical Use</u> 73 77
- The European Association of Nuclear Medicine's <u>radiopharmacy guidelines</u> ⁷⁸

Human Resources73

Members of the molecular imaging and nuclear medicine team include:

- Physicians who are trained in anatomy, physiology and the interpretation of molecular imaging and nuclear medicine scans
- Technologists who are specially trained in molecular imaging and nuclear medicine, as well as the injection of radionuclides
- Specially-trained booking staff
- A specially-trained radiation safety officer

Nuclear pharmacists, who are specially trained to prepare and dispense radioactive drugs and other supplies, may also be part of the team in some cancer centres.

Molecular imaging and nuclear medicine clinics generally require at least two technologists – one to inject the radionuclide prior to the imaging procedure and another to take

measurements and run the control room during the imaging procedure. All staff in the service must exercise safety precautions that meet radiation standards.

Personnel training should take place before the site is prepared or equipment is procured, and be refreshed on a regular basis.

Other Considerations

Challenges for low- and middle-income countries in establishing a molecular imaging and nuclear medicine service include a lack of local availability of radioisotopes and kits, aged gamma cameras and a lack of resources to service broken equipment, and a dearth of radioactive waste disposal facilities ⁷⁹; however, cyclotron facilities are becoming increasingly common.

More complex and advanced medical imaging tests that require specialized equipment and expertise as well as high capital and operating costs may best be provided in partnership with one or more other centres. Similarly, one large cancer centre may be the referral site for less developed centres that do not have sophisticated imaging on site.

The equipment and supplies required by any cancer centre will depend on the level of molecular imaging and nuclear medicine services to be provided. The three levels of need are:⁷³

- <u>Level 1</u>: This level is appropriate where only one gamma camera is needed for imaging purposes. The radiopharmaceutical supply, physics and radiation protection services are contracted outside the centre. Other services, such as radiology, cover receptionist and secretarial needs. A single imaging room connected to a shared reporting room should be sufficient, with a staff of one nuclear medicine physician and one technologist, with backup. This level is appropriate for a private practice.
- <u>Level 2:</u> This level is appropriate for a general hospital where there are multiple imaging rooms in which in vitro and other non-imaging studies would generally be performed, as well as radionuclide therapy.
- <u>Level 3</u>: This level is appropriate for an academic institution where there is a need for a comprehensive clinical nuclear medicine service, human resource development and research programs. Radionuclide therapy for inpatients and outpatients is provided.

Management and Quality

Radiation protection and safety are essential to the molecular imaging and nuclear medicine service. In addition to developing facilities, equipment and supplies in support of radiation protection and safety, cancer centres must ensure that appropriate policies, procedures and processes are in place to address the following.

- Patient procedures e.g., the provision of patient instructions; patient isolation, clearance and release following radiation exposure; decommissioning of procedure rooms following an imaging procedure
- **Staff training** e.g., practical training in the transportation of dangerous goods and spill response

- Inventory control e.g., tracking radiopharmaceutical receipt, dispensation and disposal; reporting to regulatory bodies
- **Waste disposal** e.g., managing decay to background versus third-party disposal; reporting to regulatory bodies
- **Safety assurance** e.g., spot checks for contamination; planned radiation safety inspections
- *Adverse events* e.g., reporting and managing major spills, contaminated packages, supplies exceeding radiation exposure limits, etc.

The overall goal of radiation protection and safety is to realize an "as low as reasonably achievable" exposure consequence in all cancer centre spaces, while providing optimal patient care. For more information about radiation protection and safety, see the International Atomic Energy Agency's <u>Radiation Protection and Safety of Radiation Sources: International Basic</u> <u>Safety Standards</u> and <u>radiation protection in nuclear medicine resources</u>. ^{80, 81} In addition, standards and regulations may apply at the national or subnational level.

Other Suggested Reading

- The European Association of Nuclear Medicine's <u>publications</u> ⁷⁸
- The Society of Nuclear Medicine and Molecular Imaging's evidence and quality resources⁸²

F. MANAGEMENT

7. LEADERSHIP

The medical imaging service should have a shared clinical-administrative leadership model. Clinical leaders (e.g., radiologists) are primarily accountable for the overall quality and safety of care, clinical management, clinical processes, and clinical staff recruitment and performance. Administrative leaders are primarily accountable for effective and efficient management and operational control processes, business techniques, capital issues, financial performance and project management. The clinical-administrative leadership team must work in partnership to manage all accountabilities, to establish a common vision and unified program with agreedupon goals, and to achieve common objectives in clinical care, education and research. Achievements and successes should be shared, celebrated and rewarded across the service.

The medical imaging service typically includes leaders in the following roles:

- A clinical director (or medical director or chief radiologist) and an administrative/executive director, who should co-lead and be held jointly accountable for the overall service. Ideally, a radiologist should serve as the medical director.
- A division head (i.e., a practicing radiologist) and an administrative/technical director/manager/supervisor for each subspecialty department or program within the medical imaging service, who should work jointly to oversee the operations, quality and safety of their respective department (e.g., abdominal, breast, cardiothoracic, musculoskeletal, interventional, molecular, etc.).
- A *quality manager/supervisor*, who should ensure that quality management processes are being implemented and quality issues are being addressed.

The membership and size of the core leadership team will vary depending on the number of specialized departments, the number and complexity of images performed and the role of the cancer centre as a referral centre. For example, if the centre's medical imaging service has high internal volumes as well as significant external referrals into the centre, the leadership group may include managers with expertise in areas such as:

- Communications and education, to ensure appropriate use of referral processes and requests for images
- Imaging information management/technology, to support information systems (i.e., RIS, PACS), digital imaging, teleradiology, predictive analytics and other technologies
- · Finance and business analysis, to enable appropriate overall and case costing
- Patient flow systems, to support appropriate care pathways for inpatients, outpatients and external referrals

8. OPERATING STANDARDS AND GUIDELINES

Accreditation bodies set out operational standards and guidelines to support a safe and effective hospital and may also include requirements for a medical imaging service. The medical imaging service in a cancer centre should meet national accreditation or internally-recognized accreditation standards, whichever are more stringent. ⁸³ In addition, the medical imaging service must comply with the laws, regulations and licensing requirements of the jurisdiction in which it is located.

Many countries have health service accreditation programs, whereas others adopt or adapt the programs of other countries; for example, see Jimenez et al. (2006). ⁸⁴ Various accreditation and standard-setting organizations specifically address medical imaging operating requirements. At the international level, the International Organization for Standardization – a worldwide federation of national standards bodies – has developed requirements for various aspects of medical imaging.³⁵ As well, the International Atomic Energy Agency has developed standards related to the use of radiation in imaging.⁸⁵ International requirements do not preclude national and subnational bodies from establishing additional medical imaging requirements; for example, see Diagnostic Accreditation Program of British Columbia and the College of Physicians and Surgeons of British Columbia (2014). ⁸⁶

Examples of national accreditation and standard-setting bodies for medical imaging – many of which have an international scope – include the following:

- In Australia, the Department of Health's <u>Diagnostic Imaging Accreditation Scheme</u> (DIAS) sets out mandatory accreditation requirements that are linked to the payment of Medicare benefits for approved diagnostic imaging services. ⁸⁷
- Accreditation Canada is an independent, not-for-profit organization that accredits health organizations across the country, and includes <u>standards</u> for diagnostic imaging services. ⁸⁸
- In the United Kingdom, The Royal College of Radiologists and the College of Radiographers licensed the United Kingdom Accreditation Service to manage and deliver the <u>Imaging Services Accreditation Scheme Standard</u>. ⁸⁹
- In the United States, the American College of Radiology is the principal organization of radiologists, radiation oncologists and clinical imaging medical physicists, accrediting

facilities in 10 different imaging modalities and offering a <u>Diagnostic Imaging Center of</u> <u>Excellence</u> designation that includes a comprehensive assessment of the medical imaging facility. ⁹⁰

 In the United States, The Joint Commission is an independent, not-for-profit organization that accredits and certifies healthcare organizations and programs, including <u>imaging</u> <u>centre accreditation</u>. ⁹¹

For laboratory accreditation bodies, see the <u>International Laboratory Accreditation</u> <u>Cooperation</u>, an international group of laboratory and inspection accreditation bodies, and the <u>Asia Pacific Laboratory Accreditation Cooperation</u>, a group of accreditation bodies in the Asia Pacific region. ^{92, 93}

The following sections present an overview of typical medical imaging accreditation requirements. This information is not meant to reflect all of the complexities of accreditation standards and guidelines; detailed requirements and wording vary by jurisdiction. ⁸⁷⁻⁹⁰

Services

Accreditation standards and guidelines for medical imaging services typically include requirements in the pre-analytic, analytic and post-analytic phases.

Pre-Analytic Phase

- Standard resources and information are provided to referring professionals to assist in choosing the appropriate imaging procedure
- Standard processes are used to verify that imaging requests are appropriate and complete, and to address any issues
- Requests are evaluated and prioritized by the urgency of the patient's condition
- A scheduling system handles requests using standard forms and processes for regular and urgent requests
- Patients and families receive necessary information and education
- Informed consent is obtained
- Standard procedures are used to prepare the patient for the imaging examination (e.g., patient identity and imaging site confirmed; health issues, the presence of implants/devices, medical conditions and potential allergies are verified; contrast media or medications are provided, etc.)
- The patient is appropriately positioned

Analytic Phase

- The image is taken using the policies and procedures appropriate to the specific imaging technique (i.e., using standard operating procedures)
- Any side-effects are monitored, addressed and documented
- The clinical and technical quality of the image is confirmed and the image is repeated, if appropriate
- Patients receive follow-up information in case of complications
- The image is interpreted in a timely manner, in keeping with the priority of the case (e.g., urgent, elective, etc.), commonly referred to as turnaround time for reporting

Post-Analytic Phase

- A standard format is used to document the imaging results (i.e., appropriate, clear, wellpresented)
- The final report is verified and authorized for release
- Reporting turnaround times are established and adhered to, including the reporting of critical test results
- Standard processes are used to communicate results to authorized individuals internal and external to the cancer centre
- Results are documented in the patient's health record
- Images and reports are stored in appropriate environmental conditions (i.e., paper versus digital) and according to appropriate legislative and regulatory requirements
- Images and reports are disposed of/deleted according to appropriate legislative and regulatory requirements

For more information about the storage and disposal of images and reports, see the <u>Cancerpedia: Equipment and Technology</u> and <u>Cancerpedia: Health Records</u> chapters.

In addition, accreditation standards and guidelines for medical imaging in relation to a cancer program may require effective service co-ordination and alignment of activities to support clinical providers, departments, services and organizations (e.g., effective communications, attendance at regular clinical team meetings and rounds, consultation on appropriate tests and interpretation of results, etc.).

Physical Facilities and Equipment

Accreditation standards and guidelines for medical imaging physical facilities and equipment typically include requirements to:

- Meet all planning, design and construction requirements set by regulatory bodies (i.e., subnational, national and international)
- Ensure that the construction, design, layout and physical environment of the service enable tasks to be carried out effectively, efficiently and safely
- Ensure that the layout of required imaging equipment and devices optimize workflow, infection prevention and control, and a safe working environment
- Ensure that appropriate equipment and supplies meet the regulatory requirements of manufacturers and other bodies, are available, in good condition and regularly inspected and maintained

For more information, see the <u>Cancerpedia: Physical Design and Management</u>, <u>Cancerpedia:</u> <u>Equipment and Technology</u> and <u>Cancerpedia: Infection Prevention and Control</u> chapters.

Human Resources

Accreditation standards and guidelines for medical imaging service human resources require an appropriate mix and the right number of fully-qualified and licensed staff to meet the responsibilities expected of them. Education, training and professional development opportunities should be provided to all imaging staff, including radiologists, to ensure ongoing competence.

Quality and Safety

Accreditation standards and guidelines for medical imaging quality and safety tend to focus on requirements to have:

- An effective medical imaging safety program
- Ongoing staff education on quality and safety, which includes safe work practices, and identifying and handling safety issues
- A quality management system that includes reporting, monitoring and improving processes and outcomes, and mitigating risks
- Protocols for ongoing safety, such as medical emergencies, infection control, handling of hazardous waste and substances, etc.

9. POLICIES, PROCESSES AND PROCEDURES

Policies, processes and procedures reflect different and interconnected levels of activity.

- Policies are the mandatory standards of the cancer centre that govern how it operates. The cancer centre's operating policies should reflect accreditation operating standards and guidelines.
- Processes set out what the cancer centre will do to achieve its policies. Processes usually identify who is responsible for performing a process (e.g., department), and the major functions or tasks that will be performed. Processes are high-level actions that drive specific procedures.
- Procedures identify the specific steps that will be taken to perform a task, how they will be done, by whom and when.

Cancer centres need to establish policies, processes and procedures, and make these readily available to all medical imaging service staff, along with the appropriate training. Standard operating procedures (SOPs) should be regularly assessed for their ongoing relevance and effectiveness (i.e., annually, at a minimum) and updated, as required. Document control is critical to ensure that the most updated versions of policies, processes and procedures are being used. An electronic system is preferred as the number of SOPs increases.

Examples of areas in which medical imaging policies, processes and procedures need to be developed include, but are not limited to, the following.

Pre-Analytic Phase

- Verification of requests
- Communication with referring professionals about incomplete or inappropriate requests
- Patient registration
- Scheduling images, identifying underused or released medical imaging time, and addressing instances when scheduled appointments need to be cancelled
- Emergency imaging procedures
- Imaging restrictions

- · Translation and interpretation services
- · Patient instructions before and after imaging
- Informed consent for imaging
- Patient and family education
- Processes before conducting an image (e.g., checks for identity, procedure, health issues, implants/devices, medical conditions, allergies, etc.)
- Medication and contrast media administration
- Documentation of information in the RIS

Analytic Phase

- Conducting imaging examinations
- Managing allergic reactions and respective pre-medication regimens
- Technical and clinical acceptability of images
- Regular imaging protocol review
- Interpretation of images
- Documentation of information in the RIS
- Peer review

Post-Analytic Phase

- Communication of imaging test results, including critical test results
- Imaging report content and presentation
- Documentation of information in the RIS
- Labelling of images (i.e., paper, digital)
- Storage of images and reports

Safety

- Infection prevention and control
- Radiation safety procedures
- Use of personal protective equipment
- Emergency incident procedures
- Violence and harassment
- Safety codes
- Disposal of materials

Adverse Events

- Disclosure of adverse events
- Incident reporting

Equipment and Supplies

- Equipment and supply availability
- Maintenance procedures

Infrastructure

- Access to, and exit from, the imaging service
- Storage of clean and contaminated items
- Electrical failure

Light or fan system failure •

Human Resources

- Responsibilities of all medical imaging personnel
- Staff competency testing and associated documentation
- Continuing education requirements

Privacy

- Appropriate handling and storage of documents containing personal health information
- Data security on digital devices with access to personal health information

Students and Observers

- Medical imaging student practice
- Observers in the service

10. MANAGEMENT OF PATIENT FLOW

Cancer centres must manage the smooth flow of patients across the medical imaging pathway, as illustrated in Figure 1. This includes ensuring that imaging requests are processed expeditiously and that results are communicated back to referring clinicians in a timely fashion.

Table 2 outlines the management of patient flow at each step of the medical imaging pathway.

Phase	Management of Flow	
Pre-Analytic		
Referral	 Requisition sent to medical imaging service from internal or external source Imaging request is assessed by skilled personnel using established protocols Skilled personnel contact the referring clinician to address any issues with the imaging request The request is transferred to booking 	
Booking and Registration	 Booking personnel contact the patient to schedule an imaging appointment and provide preparation instructions Patient arrives for the image; registration personnel positively identify the patient and document his or her health status, medications and medical history, including any implanted devices, etc. 	
Preparation	 Skilled personnel positively identify the patient, review his or her personal information, explain the test and answers any questions Skilled personnel provide instructions to the patient to prepare for the imaging examination (e.g., remove clothes, metal objects, etc.) and administer any additional substances required for successful imaging 	
Analytic		
Imaging Examination	 Skilled personnel escort the patient to the imaging room and position them for the procedure Technologist exits the room, if required Technologist conducts the imaging examination and obtains diagnostic images for review; prepares a preliminary report 	

Phase	Management of Flow
	 Technologist assesses the patient and contacts the appropriate clinical staff to address any urgent patient-related issues Skilled personnel assess the quality of the images and may repeat the imaging procedure, if necessary Skilled personnel escort the patient out of the room and provide instructions (e.g., to change back into clothing)
Interpretation	 Radiologist examines images and identifies any abnormalities Radiologist may need to speak to the patient for additional information regarding medical history Radiologist may be required to re-examine the patient
Post-Analytic	
Reporting Results	 Radiologist records the imaging examination results (i.e., via paper, dictation using voice recognition software or directly on electronic system) Radiologist contacts the referring clinician in emergency or critical situations (i.e., electronically or verbally) Administrative support staff transcribe dictated reports, as required Radiologist reviews and finalizes the imaging report Clinical/administrative staff follow established processes to communicate images and reports to the referring clinician Radiologist and/or referring clinician communicates the results to the patient
Storing Images and Records	 All data, including images and reports, are entered on the RIS and PACS All images and reports are stored for an appropriate amount of time according to legislative requirements

11. DOCUMENTATION AND DATA-INFORMED MANAGEMENT DECISIONS

Cancer centres must collect and analyze standard medical imaging information to ensure that patients receive services consistent with the policies and procedures of the organization, medical imaging resources are being used effectively and efficiently, and medical imaging practices are safe.

Documentation is required throughout the medical imaging pathway, as illustrated in Figure 1. Given that the amount of data collected can be overwhelming, management should develop a minimum data set, with clearly defined indicators to monitor activities and processes and improve performance. Indicators should be analyzed to support data-informed management decisions, and management tactics should be implemented to mitigate risks and make improvements. Improvements can be assessed in various ways; for example, the centre can focus on internal performance improvements, compare its performance in relation to external standards or compare its performance in relation to external peer group benchmarks.

Table 3 presents a suite of medical imaging management indicators that may be considered for a cancer centre's minimum data set. Additional indicators depend on local circumstances. Table 3 also presents potential management analyses targeted at improving performance.

Table 3: Examples of Medical Imaging Indicators and Management Analysis

Area	Indicators	Management Analysis
Requesting Images	 Number of imaging examinations requested by source and location (e.g., cancer centre clinicians, other hospital clinicians, community-based clinicians) Number of incomplete or inappropriate requests by source and reason Number of rejected requests 	 Profile of image sources Analysis of internal/external activity Analysis of request issues (i.e., incomplete, inappropriate, etc.)
Imaging Volumes	 Number of imaging examinations completed (e.g., total by machine, body type) Number of no-shows and re-bookings Number of late cancellations Number of imaging examinations deemed unacceptable and that need to be redone due to technical and/or clinical issues Number of emergency requests received in a defined time period 	 Tracking of imaging volumes over time along with utilization and cost analyses (i.e., financial, human, capital, operating) to determine operational efficiency rate, identify resource gaps and find opportunities for improved efficiencies Analysis of unacceptable images and reasons why, and improvement tactics Analysis of impact of emergency cases on imaging resources and scheduling, and improvement tactics
Information Flow	• Start and end times of each point in the imaging flow process, beginning with booking and ending with imaging report receipt by referring clinician	 Analysis of delays and blockages in flow, and improvement tactics Analysis of actual wait times against wait time targets, and improvement tactics
Quality Practices	 Percentage of imaging examinations taken correctly Completeness of imaging reports Adoption of structured reporting Compliance with quality and safety regulations and requirements 	 Assessment of correct imaging procedures, and improvement tactics Identification of incomplete report issues, and improvement tactics Rate of compliance with quality and safety regulations and requirements
Report Communication	Percentage of reports communicated within acceptable turnaround times, including reports on urgent cases	Analysis of report turnaround against targets, and improvement tactics
Image and Records Storage	 Number of stored images and reports Number of stored images and reports compromised due to storage issues Number of images and reports disposed that have met regulatory retention requirements 	 Identification of storage issues, including issues that compromise the integrity of images, and improvement tactics Identification of long storage times and improvement tactics to free up space (i.e., image compression, off-line storage)
Use of Resources	Volume of equipment and supplies used in the medical imaging service in relation to activity	• Tracking of volumes, resource utilization and costs (i.e., financial, human, capital, operating), and identification of resource gaps and opportunities for improved efficiencies without compromising the service

G. QUALITY PERFORMANCE

Quality performance in medical imaging is critical, given that the majority of individuals with suspected or confirmed cancer will have some type of imaging examination. Diagnostic errors

are an important source of preventable harm, although it must be recognized that not all misdiagnoses result in harm.⁹⁴

There are many potential sources of medical imaging error, including the following. ⁹⁵⁻⁹⁹

- Radiologist-related causes: poor imaging technique; cognitive issues (e.g., finding is attributed to the wrong cause, lack of knowledge); perceptual issues (e.g., findings missed, review prematurely stopped when one abnormality is found); ambiguity in reporting
- Referring clinician-related causes: gaps in knowledge; provision of inadequate or incorrect clinical information to the radiologist
- System-related causes: staff shortages; excessive workload; poor working conditions (e.g., inadequate equipment); long wait times for the most appropriate test; lack of communication between the radiologist and the referring clinician; lack of a universal digital health platform

In addition, many factors may contribute to inappropriate requests for imaging. These factors may include the above sources of medical imaging errors as well as various influences that have contributed to the growth of medical imaging, such as: ^{97, 100}

- · The introduction and increased availability of new technologies
- Scientific advances that enable medical imaging to be used for a wider range of clinical indications
- Public, patient or clinician demand

Significant international efforts have been made to improve medical imaging quality and safety. As noted earlier, the International Organization for Standardization has voluntary global standards in medical imaging ³⁵, the International Commission on Radiological Protection maintains and develops the International System of Radiological Protection²⁰, the International Atomic Energy Agency sets standards for the protection of people against exposure to ionizing radiation ^{22, 23}, and the International Commission on Non-Ionizing Radiation Protection provides scientific advice and guidance on the health and environmental effects of non-ionizing radiation. ²⁴ The work of these international bodies has been adopted and adapted, and has influenced many national and subnational efforts to ensure medical imaging quality and safety; for example, see the European Society of Radiology (2014)¹⁰¹, Kanal et al. (2013)³⁴ and Eurosafe Imaging²⁸.

Electronic systems, such as decision support or computerized provider order entry tools, have been identified as useful in reducing unnecessary and duplicate diagnostic imaging examinations. ^{102, 103} Additionally, clinical-radiological consultations have been shown to have beneficial diagnostic and therapeutic impact. ¹⁰⁴ found that consultations led to changes in initial clinical diagnoses in 50 per cent of cases and substantial changes in therapy in 60 per cent of cases on the basis of further radiological investigations and clinical-radiological discussions.

The following section describes strategies and tools for preventing medical imaging errors and improving the quality of the medical imaging service.

12. STANDARDS, GUIDELINES AND BEST PRACTICES

Medical imaging quality standards, guidelines and best practices are common across a hospital and are not specific to cancer centres. Some cancer-specific medical imaging standards and guidelines may exist for diagnosing cancer. Standards, guidelines and best practices used by a cancer centre may originate from different sources, such as international, national and subnational organizations and bodies. Although cancer centres may develop local best practices, those should align with the national and subnational standards and guidelines of the jurisdiction in which the cancer centre is located.

Diagnostic Management

Standards and guidelines for medical imaging diagnostic management are based on evidence or expert consensus. Standards and guidelines can be developed by medical imaging-specific organizations or by larger health bodies. A number of organizations make available a wide range of cancer-related standards and guidelines, including those for medical imaging.

Physical Facilities and Equipment

Cancer centres must have an adequate and appropriately designed medical imaging facility infrastructure. In addition to ensuring that all infrastructure, equipment and supplies meet building and biosafety standards and requirements set by national and subnational bodies, a quality control program for infrastructure – including equipment performance and maintenance – is essential to ensuring quality.

Equipment must meet mandatory specifications and be properly commissioned for clinical use in the cancer centre. Quality control tests must be conducted to ensure that imaging equipment is performing properly. In addition to the initial set up, ongoing, regular quality monitoring of imaging infrastructure is required to make sure that machines, equipment and computers are consistently performing correctly.

Human Resources

A quality medical imaging service must meet human resource requirements and ensure that all staff meet ongoing quality standards. All healthcare professional groups develop professional care standards and recommended practices for their members, including ongoing competency and continuing education. Examples of professional bodies that address medical imaging human resource standards, practices and education include the following.

Radiologists

- International Society of Radiology ¹⁰⁵
- European Society of Radiology ¹⁰⁶

Radiologist Assistants

- American Registry of Radiologic Technologists ¹⁰⁷
- The Society of Radiographers¹⁰⁸

Medical Imaging Technologists

- <u>College of Medical Radiation Technologists of Ontario</u>¹⁰⁹
- International Society of Radiographers and Radiological Technologists ¹¹⁰
- European Federation of Radiographer Societies ¹¹¹

Radiology Nurses

Association for Radiologic & Imaging Nursing ²⁸

Diagnostic Imaging Physicists

International Organization for Medical Physics ¹¹²

Work Practices

Cancer centres should implement quality medical imaging work practices throughout the medical imaging pathway, as illustrated in Figure 1, and in collaboration with clinicians.

Throughout the Medical Imaging Pathway

A great deal of effort is needed to plan, prepare and co-ordinate medical imaging services so that patients and referring clinicians receive the right imaging results in a timely fashion, and so that resources (i.e., human resources, financial resources, equipment and facility infrastructure) are optimized. Poor flow results in delays in diagnosis, increased waits, high levels of patient and staff stress, and suboptimal resource use.

Examples of quality performance within each phase of the medical imaging pathway are illustrated in Figure 3.

Attention to process and process improvements in the medical imaging service is critical, especially given the increasing demand for imaging. Although digital imaging has resulted in workflow efficiencies, medical imaging processes have become more complex with the significant shift from inpatient to outpatient cancer services. The fact that many inputs – both internal and external to the cancer centre – feed into the medical imaging service highlights the importance of standard operating procedures for requesting tests, verifying and tracking patients, communicating with multiple care providers, measuring and monitoring the time of each step in the imaging process and meeting all documentation requirements. The use of process improvement methodology is a major tactic for improving medical imaging quality and efficiency.

Many programs are available to help hospitals improve the quality and efficiency of the medical imaging service. For example:

- The American College of Radiology offers a comprehensive range of <u>practice</u> <u>management</u>, <u>quality and informatics</u> resources and tools. ¹¹³
- The Canadian Association of Radiologists develops <u>practice guidelines</u> to promote safe, efficient and quality healthcare.¹¹⁴

- The Australian Department of Health provides <u>diagnostic</u> <u>imaging quality</u> <u>programs</u>. ¹¹⁵
- The Royal Australian and New Zealand College of Radiologists provides <u>quality and</u> <u>standards</u> resources. ¹¹⁶

The medical imaging service also needs to ensure safety within and across all analytic processes. Numerous international and national bodies have developed extensive guidelines and recommendations that cancer centres can use to develop safety protocols in such areas as the use of radiation in medicine, radiation protection for patients, the handing of radioactive substances. infection prevention and control, and the handling of hazardous biomedical waste and substances. These bodies include:

- <u>Australian Radiation</u>
 <u>Protection and Nuclear</u>
 <u>Safety Agency</u>²⁸
- International Atomic Energy Agency ^{22, 23}
- International
 Commission on
 Radiological
 Protection²⁰
- <u>World Health</u>
 <u>Organization</u>¹¹⁷

Figure 3: Examples of Quality Performance Within Each Phase of the Medical Imaging Pathway

Pre-Analytic Phase

- Test requests are complete and appropriate
- Test requests are entered
- The patient arrives on time and meets the requirements for the imaging examination (e.g., restrictions on eating, drinking, medications)
- The patient provides consent and is correctly identified, and information that might affect the imaging process is verified (e.g., health status, medications, implanted devices, etc.)
- The patient is appropriately prepared for the imaging examination (e.g., medications, information, etc.)
- Medical and hospital staff have the training to meet preanalytic requirements
- The patient is in the imaging room on time
- Clinical staff arrive on time

Analytic Phase

- Images are taken on the correct patient and body part using standard procedures
- The clinical and technical quality of the images is confirmed
- Appropriate and sufficient supplies and equipment are available
- Equipment is well-maintained and functions
 appropriately
- Sufficient time is scheduled for the imaging process
- Flexibility is built in for emergency cases
- Imaging staff are qualified and meet professional competency standards
- Communications and teamwork are excellent
- Imaging results are interpreted correctly using appropriate standards and results/reports are of high quality
- The medical imaging service and each area within the service meet the safety and operating standards and guidelines required by relevant regulatory and accreditation bodies

Post-Analytic Phase

- Reports of imaging results meet quality standards and guidelines
- Reports are clear, accurate and communicated to the referring clinician(s) within established timelines
- Data is entered correctly
- Images and reports are used appropriately to make final diagnostic and treatment decisions
- Imaging and reports are stored appropriately

For more information, see the Cancerpedia: Infection Prevention and Control chapter.

Collaborative Standards in the Cancer Centre and Beyond

A number of medical imaging quality work practices should be developed and implemented in collaboration with clinicians in the cancer centre and beyond. Five key practices are highlighted below.

Priority Rating System

The medical imaging service requires a priority rating system to help guide decisions about timely access to imaging services, based on clinical need. The system should:

- Define what is meant by an imaging wait (i.e., time from when a completed imaging request is received to when the referring clinician receives the imaging report)
- Establish standard priority levels (e.g., urgent to least urgent)
- Develop standard clinical assessment criteria and recommended wait time targets for each priority, which may vary by type of image

In addition to a total wait time target, turnaround time targets should be set for each step of the medical imaging process (e.g., time from when a request is received to when the final request is completed; time from when a request is finalized to when the patient is scheduled; time from when the patient is ready to when the image is taken; time to analyze the image, etc.). This enables the medical imaging service to identify exactly where delays are occurring and to address issues.

All clinicians within and outside of the cancer centre who request test results should be made aware of, and understand, the priority rating system and associated turnaround times. Cancer centres may use medical imaging priority rating systems that have been developed at a national or subnational level. Generally, these systems are not specific to oncology. For example, the Canadian Association of Radiologists recommends national maximum wait time targets for CT and MRI to guide practice, as illustrated in Table 4.

		Maximum Time Target (Calendar Days)		
Priority	Measure	Time from Completed CT or MRI Order Received to Imaging Examination Finished	Time from CT or MRI Finished to Report Signed Off by Radiologist	
P1	Emergent: To diagnose and/or treat disease or injury that is immediately threatening to life or limb.	Same day (i.e., maximum 24 hours). Some patients require imaging in less than an hour, based on clinical judgment.	Immediate to a maximum of one hour. Direct verbal or immediate written communication is the practice standard.	
P2	Urgent: To diagnose and/or treat disease or injury and/or alter a treatment plan that is not immediately threatening to life or limb.	Maximum seven days. In most instances, the exam should be completed as soon as possible after the referral is received. In some cases, seven days	Maximum 12 hours. Direct verbal or immediate written communication may be required due to medical need or the clinical situation.	

Table 4: Target Wait Times for CT and MRI ¹¹⁸

		Maximum Time Target (Calendar Days)	
Priority	Measure	Time from Completed CT or MRI Order Received to Imaging Examination Finished	Time from CT or MRI Finished to Report Signed Off by Radiologist
		may be medically acceptable.	
P3	Semi-urgent: To diagnose and/or treat disease or injury and/or alter a treatment plan, where clinical information requires that the examination be performed sooner than the P4 benchmark.	Maximum 30 calendar days.	Maximum four calendar days.
P4	Non-urgent: To diagnose and/or treat disease or injury where no negative long-term medical outcome related to a treatment delay is expected if the exam is within the benchmark.	Maximum 60 calendar days.	
Specified Procedure Date	For the purpose of disease surveillance.		

Multidisciplinary Cancer Conferences

The majority of cancer patients require a number of different clinical services from a range of healthcare providers. The multidisciplinary cancer conference (MCC) – also known as a multidisciplinary meeting – is a quality practice that guides complex, evidence-based, shared decisions about treatment. For more information, see the <u>Cancerpedia: Clinical Management</u> chapter.

Clinical Decision Support Tools

Various clinical decision support tools, increasingly based on predictive analytics, can be used to help improve the quality of medical imaging. For example, referring clinicians should be able access real-time information to guide them in selecting the most appropriate test. ^{12, 119} Accessing this information using computerized provider order entry systems or through electronic health records makes decision support part of the referring clinician's normal workflow. ¹²⁰ For more information, see the <u>Cancerpedia: Clinical Management</u> chapter.

Peer Review

Peer review is a process of self-regulation by a profession or an evaluation process involving qualified individuals within the relevant field. ¹²¹ Generally, peer review involves departmental meetings to discuss and report discrepancies. For example, in the United Kingdom the majority of radiology departments have discrepancy meetings, as recommended by the Royal College of Radiologists. ¹⁰⁰ Before meetings, discrepancies between reports and other findings are

collated. At the meetings, discrepancies are acknowledged and discussed, and lessons learned are identified in an open, constructive and blame-free environment.

The ideal approach to peer review is one of continuous quality improvement. Medical imaging peer review should be proactive, educational, non-punitive, part of a broader quality management program ¹²², and aimed at maintaining standards and improving diagnostic ability, quality and patient care. ^{121, 123, 124} The use of peer review scoring and information management systems must ensure that the data facilitates discussion and meaningful performance improvement, rather than tracking individual discrepancies. ¹²⁴ Medical imaging peer review can be within the cancer centre or can be expanded to include a number of facilities.

Quality of care conferences (QCCs) – also known as morbidity and mortality rounds or morbidity and mortality conferences – are an integral part of quality assurance, especially in interventional radiology. These conferences may be held within the medical imaging service or jointly with other clinical departments. The aim is to discuss problematic treatment situations, unfavourable clinical outcomes of imaging and treatment procedures, and concerns around quality and safety. Similar to peer reviews, the environment should be educational and non-punitive. For more information, see the <u>Cancerpedia: Clinical Management</u> chapter.

Reporting

Successful medical imaging reporting assumes ongoing, effective communication between referring clinicians and medical, technical and other imaging staff. This reciprocal duty of information exchange ¹²⁵ includes providing the radiologist with patient-related information to help inform the imaging process and interpretation (e.g., previous reports and images, relevant clinical information, working diagnosis, pertinent clinical signs and symptoms, etc.), and two-way communication to determine a definitive diagnosis and address any issues.

Patient death or serious injury resulting from failure to follow up or communicate radiology test results is a serious reportable event in healthcare, as defined by the American-based National Quality Forum (2011)¹²⁶. In addition to failing to follow-up or communicate results, presenting results inappropriately or results that the clinician cannot understand can lead to inappropriate interpretation of imaging results by the clinician, misdiagnosis and the wrong treatment.

The ultimate purpose of the final imaging report is to facilitate clinical decisions and patient care. Generally, the radiologist is responsible for interpreting the images and developing and approving a final report. Depending on the jurisdiction, other professionals may conduct initial assessments of images and forward these to the supervising radiologist ¹²⁷, or may assess images within clearly stipulated parameters (e.g., single organ investigation, single suspected pathology and a yes/no answer within the context of working in a team, with access to a radiologist for advice). ¹²⁸

There is widespread agreement that radiology reports need to be well-organized, clear and present complete information in a succinct and understandable manner. Many organizations

have developed best practices for developing final radiology reports and communicating findings. ^{125, 128-130} Report content should include:

- Patient demographics
- Relevant clinical information
- Imaging procedures/techniques
- Findings and any abnormalities
- Impressions (i.e., conclusions, opinions, diagnosis, and advice on additional investigations and follow-up)

Referring clinicians may not read whole imaging reports; as a result, the impressions or conclusion section is critical ¹³⁰, as is the overall report format. Although there appears to be agreement on the content of radiology reports, there is less consensus about how the information should be presented.¹³¹ The referring clinician may not pick up key clinical information if reports are not well-organized or are too long.

Increasingly, clear and succinct standard report templates are being developed and used to structure imaging information. Structured or synoptic reporting presents information using a standard format, content and structure. For example, the Radiological Society of North America has created <u>RadReport</u>, a library of radiology report templates.⁶⁷ Templates can be adapted to local practice circumstances. As well, Cancer Care Ontario has developed the architecture of a cancer imaging synoptic report.¹³¹

The report is an essential link between the diagnosis and treatment of a patient's illness and part of the patient's health record. ¹³² The final report should meet any legislative requirements of the jurisdiction in which the cancer centre is located. Protocols to communicate approved imaging results may vary by jurisdiction and the type of test. To ensure patient confidentiality, images and reports should be released to patients and referring clinicians by authorized staff only. The referring clinician should be contacted immediately if there are emergency or unexpected findings that may require urgent action, such as more evaluation or treatment. Cancer centres need to establish a policy for notification of emergency or unexpected findings.

Digital images and verified results are typically entered into the RIS. As noted earlier, cancer centres should ideally have electronic medical imaging systems that store, manage and support the sharing of digital images and reports to referring clinicians, both within and outside of the cancer centre. PACS and medical imaging repositories/platforms may be shared by a number of facilities.⁴⁸

Finally, an important part of medical imaging reporting is the availability of a medical imaging expert to answer questions and discuss cases with the referring clinician.

13. PERFORMANCE MONITORING, REPORTING AND QUALITY IMPROVEMENT

The medical imaging service must establish a system for quality and performance management and continuous quality improvement. As noted earlier, various international and national organizations have identified quality requirements and systems for medical imaging. These systems should inform the cancer centre's overall medical imaging quality performance

efforts, as well as directly influence quality activities within the service. Quality improvement includes the following elements.

Quality Framework

The cancer centre's medical imaging quality framework should include broad domains for performance improvement, such as patient safety, staff satisfaction, and care that is timely, efficient, patient-centred, effective, accessible, equitable and appropriate. ¹³³ These broad domains should align with the cancer centre's priorities and reflect the particular priorities of the medical imaging service. The selection of domains may be influenced by international, national and subnational medical imaging standard-setting bodies, as well as by the priorities of national or subnational health ministries or organizations that focus on quality in cancer care. Examples include the following:

- Agency for Healthcare Research and Quality ¹³⁴
- Canadian Partnership Against Cancer ¹³⁵
- Cancer Quality Council of Ontario ¹³⁶
- European Partnership for Action Against Cancer ¹³⁷
- National Quality Forum ¹³⁸

Quality Performance Indicators

The cancer centre's medical imaging service should select quality performance indicators within each broad domain. As with the selection of domains, the selection of indicators should align with the cancer centre's objectives, reflect the priorities of the medical imaging service and may be influenced by the priorities of external bodies. A wide range of clinicians and managers should have input into selecting the indicators, and should have confidence in both the process used to select the indicators and the indicators themselves.

Indicator definitions may be adopted or adapted from other reliable sources. Indicators must be clearly defined, measurable and reliable, incorporate the use of evidence or benchmarks, and be used to manage and improve the quality of chemotherapy.

Generally, quality performance indicators should consider structures, processes and outcomes. ¹³⁹ For the medical imaging service:

- Structures are the settings where services are provided and the related supports (e.g., procurement, registration areas, imaging areas, point-of-care imaging areas, intraoperative imaging areas, analysis areas, storage areas, equipment and supplies, human resources, administrative structures, program operations and policies, etc.).
- Processes refers to the full range of medical imaging services that patient and referring clinicians receive, and how they are provided (e.g., appropriate, complete, technically competent, guideline-based, safe, co-ordinated, acceptable, etc.).
- Outcomes refer to complete and comprehensive medical imaging examinations and reports.

Numerous medical imaging performance indicators can be selected. The medical imaging service should select a manageable number of indicators to track. Table 5 presents examples quality performance domains and indicators for medical imaging.

Domains	Examples of Quality Performance Indicators
Accessible	 Wait times within priority rating targets Equitable access to medical imaging expertise (i.e., internal and external referrals) Equitable access to medical imaging tests (e.g., age, gender, income, ethno-racial background, etc.) Availability of medical imaging services to the population
Appropriate	 Use of priority rating scale Appropriate number and mix of staff to meet demands Appropriate equipment and technologies to meet demands Rate of imaging requests that are deemed unnecessary or inappropriate
Effective	 Rate of pre-analytic errors (e.g., wrong patient, etc.) Rate of images that are technically and/or clinically unclear Use of evidence-based medical imaging services High-level team performance Equipment functioning appropriately Rate of downtime of the RIS Achievement of accreditation requirements
Efficient	 Turnaround times for all indicators in pre-analytic, analytic and post- analytic phases Turnaround times for each type of imaging examination Turnaround times for overall medical imaging process (i.e., beginning to end) Flow between pre-analytic, analytic and post-analytic phases First case and subsequent case on-time start accuracy, and reasons for delay Time between scheduled appointment and start of medical imaging Imaging time booked compared to imaging time used Turnover time of medical imaging room Total number of medical imaging resources (i.e., actual vs. budget) Average cost per medical imaging unit hour
Patient-centred	Patient satisfaction levelsPatient education and information
Safety	 Complications or allergic reactions in the medical imaging process Adverse events in the medical imaging process Near misses in the medical imaging process (e.g., unplanned events without injury, illness or damage, but with the potential for any or all of these adverse outcomes) Percentage of staff quality assurance reviews performed Discrepancy rate between initial and subsequent image analysis Equipment malfunction Staff injuries due to safety breaches Percentage of staff meeting continuing education and competency requirements
Staff Work Life	 Staff satisfaction Staff absenteeism Staff efficiency

Table 5: Examples of Quality Performance Indicators for Medical Imaging

Domains	Examples of Quality Performance Indicators	
	Staff turnoverOvertime hours	

Quality Infrastructure

A quality infrastructure with the following elements is needed to measure, monitor and improve medical imaging service performance.

First, information management support is needed to collect, analyze and report on indicators. The timing of indicator collection may vary from just-in-time to weekly, monthly, quarterly, semi-annually or annually. Regular access to medical imaging data and the ability to develop customized reports is critical to driving improvements. Customized performance reports may focus on discrete phases, particular activities, groups of staff or individual staff. It is best to provide performance feedback quickly and frequently, so that care and process improvements can be made.¹⁴⁰

Second, a medical imaging performance accountability team – made up of key medical imaging leaders (e.g., administrative, medical and scientific leaders, supervisors/managers, quality specialists and representatives of partner facilities) – should review the indicators in relation to evidence- and consensus-based benchmarks and best practice standards and guidelines. The team should engage staff to identify areas for improvement, establish improvement targets with associated timelines, develop action plans, support the implementation of change and track improvements.

Third, medical imaging staff should receive ongoing training in quality improvement and patient safety, including best practices, adverse events (i.e., recognize, respond, report, disclose) and human factors. The latter includes factors that can influence people and their behaviour. In the cancer centre, these are environmental, organizational and job factors, and individual characteristics that influence behaviour at work.¹⁴¹

Finally, to promote transparency and continuous quality improvement, performance information should be communicated to those working in the medical imaging service and, more broadly, to everyone in the cancer centre. Communication should include commentary on the data, expected plans of action and successes improving performance.

H. THE FUTURE

The medical imaging field is advancing significantly and having a profound impact on the diagnosis and treatment of cancer. These changes affect facility infrastructure and design, as well as equipment, human resources and training requirements.

14. INNOVATIVE TRENDS

Several major trends are expected to influence the evolution of medical imaging.

Advances in Imaging Technologies and Techniques

Since medical imaging depends on technology, the ongoing development of technology is vital to the progress of the discipline. ⁸ Existing imaging modalities, such as ultrasound, CT and MRI, will continue to improve in terms of resolution, precision, speed, computing power and the level of detailed functional and physiologic information generated to detect cancer and inform diagnosis and treatment. ^{142, 143}. For example, ultra-high resolution CT imaging is allowing for a spatial resolution of less than 0.14 mm, and deep-learning image reconstruction is providing superior image quality that will allow for the use of CT at a dose level similar to that of a conventional X-ray. ^{144 145} While most MRI devices today operate at a magnetic field-strength of 1.5 and 3 tesla, strengths of up to 11 tesla have been achieved, with extremely high image quality.⁸ Such strengths may not only become the norm in the future, they may also become the benchmark to exceed. Another example is the development of quantitative ultrasound, which detects cell death and can be used to monitor and evaluate the impact of cancertargeting chemotherapy and inform subsequent treatment decisions. ¹⁴⁶

Imaging technologies will also continue to become safer. For example, radiation dose reduction strategies are being used to minimize the potential risks of radiation in X-ray-based imaging, without compromising image quality. ⁸ Another example is the use of a standard MRI to detect glucose in cells by labelling them magnetically with bursts of radio waves, rather than having patients ingest a radioactive isotope and conducting a PET scan. ¹⁴³

Emerging molecular imaging modalities, such as the use of multimodality imaging – also known as fusion or hybrid imaging – will increase in the future. This involves the use of CT or MRI with ultrasound and molecular imaging modalities to produce a single set of images taken from different types of scans. This advancement provides more complete diagnostic information ¹⁴⁷ and far superior images.⁸

These increasingly sophisticated imaging technologies and multimodality approaches will produce increasingly more complex digital images for study. Advanced computerized systems are helping to translate volumetric patient image data in to three-dimensional anatomical renderings that can greatly enhance clinical interpretation. In addition, it is expected that more sophisticated and sensitive computer-assisted detection and diagnosis systems will be available to help clinicians analyze images and identify cancer patterns more quickly and accurately.¹⁴⁷

Advances in Cancer Treatment

With the increase in image-guided procedures, a new hybrid medical discipline is emerging that combines the expertise of specialists, such as interventional radiologists, nuclear medicine specialists, surgeons and radiation oncologists.

Areas for continued future growth include image-guided surgery and radiotherapy. Imageguided surgery uses real-time CT and MRI images to see exactly where cancerous and healthy tissues are located and to guide surgical procedures. Image-guided radiotherapy – also known as adaptive radiotherapy – provides information on a tumour's changing size and location and the surrounding organs at risk, precisely delineates a tumour, aims radiotherapy at the tumour as it moves in real time and differentiates the most aggressive areas of the tumour to be treated. ¹⁴⁸ Adaptive radiotherapy also makes it possible to assess the tumour's response to treatment while it is being delivered, and to modify the patient's initial treatment plan. ¹⁴⁹ The overall effects are more precise and accurate treatment, less damage to healthy tissue, less treatment-related morbidity, improved clinical outcomes and fewer radiotherapy sessions required. The development of more sophisticated image-guided radiotherapy techniques will likely grow in the future.

High-intensity focused ultrasound (HIFU) is increasingly being used in the treatment of certain tumours. It acts by killing cancer cells with very high frequency sound waves. HIFU is non-invasive, targeted and causes very few side-effects. It is expected that the application of this treatment will continue to expand.

Molecular imaging and nuclear medicine are, and will continue to be, promising enablers of precision medicine, and will continue to improve the effectiveness of healthcare by pinpointing "the right treatment at the right time in the right dose with reduced side-effects and maximum efficiency." ¹⁵⁰ Theranostics is an emerging field of nuclear medicine, with the aim to apply a specific, targeted therapy based on precise diagnostic tests. It bridges nanoscience with diagnostic and therapeutic applications to generate a single agent to facilitate diagnosis, drug delivery and treatment response monitoring. ¹⁵¹ While targeted radionuclide therapy has been used for some time, the field is evolving; for example, alpha-emitters are showing promise for the highly-targeted treatment of microscopic tumours. ¹⁵²

Artificial Intelligence and Machine Learning

As healthcare organizations have come to amass vast amounts of data, funding for artificial intelligence (AI) and machine learning approaches to medical services has grown substantially. ¹⁵³ Currently, AI is being used primarily for back office functions (e.g., scheduling) as well as predictive measures (e.g., risk of readmission). Moving forward, it is expected that AI will play an increasing role in real time clinical management and workflow.

Although medical imaging reports typically contain measurements of the size of a tumour, the description of the finding remains largely qualitative. It has been broadly recognized that quantitative image analysis can provide more diagnostic information and help further characterize cancer tissue.

Radiomics is the high-throughput extraction of large amounts of image features from radiographic images and has been recently enabled by the increased availability of high-performance computing power. ¹⁵⁴ Radiogenomics investigates the relationship between a disease's genetic and gene-expression characteristics and its imaging phenotype. ¹⁵⁵ Taken together, AI approaches have demonstrated remarkable potential for image-recognition tasks and, by extension, promise with respect to advancing precision and personalized medicine. ¹⁵⁶

Despite progress and initial clinical testing, the use of AI in clinical practice remains experimental and should be considered an augment to human capabilities. Technology-driven

initiatives must be given proper oversight by human resources to verify the accuracy of AI outputs and to ensure clinical decisions are appropriate to each patient.

For more information about the potential of AI, see:

- Artificial Intelligence, Machine Learning and Radiomics in Radiology ¹⁵⁷
- Artificial intelligence in healthcare: past, present and future ¹⁵⁸
- Artificial intelligence (AI) and global health: how can AI contribute to health in resource-poor settings? ¹⁵⁹

15. THE IMPACT OF INNOVATIVE TRENDS

Innovative trends have an impact on designing, planning and developing the medical imaging service.

From a physical facilities perspective, infrastructure must be designed to accommodate the capacity for medical imaging innovations, such as those described in this chapter. Overall, less physical space may be required to house imaging equipment in the future. Advancements in miniaturization technologies and increases in processing power and storage capacity will continue to reduce the size of imaging devices. ¹⁴⁷ Regardless, the widespread use of digital imaging will require more powerful image processing and storage systems. As well, specially-built rooms may be needed to accommodate and operate specialty equipment. When image-guided surgery and radiotherapy are being conducted, procedure rooms require additional capacity to accommodate imaging equipment along with space for additional professionals to work.

In terms of cost, precision medicine necessitates a significant increase in the number of medical imaging examinations performed and the volume of data gathered and analyzed. The associated investments required for technological upgrades, structural changes and education of staff may be offset by savings due to more appropriate and effective treatments, reduced days of incapacity and shorter hospital stays for patients.¹⁶⁰

Training in advanced imaging techniques and the computer-assisted analysis of digital data is critically important, especially for existing staff who need continuing education to become proficient in new techniques and analysis. Given that innovative trends will impact all professionals who are involved in medical imaging, ongoing skills development is required.

The growth in molecular imaging may influence the composition of the imaging team. For example, molecular biologists, cell biologists and synthetic chemists may increasingly become part of this specialty area. ¹⁴² In addition, strong computer science researchers will have increasing opportunities to collaborate with those in the medical imaging field to develop high-powered medical image processing and analysis applications. ¹⁴⁷

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