

# CORE SERVICES / INFRASTRUCTURE

# EQUIPMENT AND TECHNOLOGY: CRITICAL EXPERTISE AND PROCESSES

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CHAPTER

# EQUIPMENT AND TECHNOLOGY: CRITICAL EXPERTISE AND PROCESSES

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Comprehensive cancer centres have a significant and increasing need for technology and technology infrastructure for cancer care. A wide range of medical equipment and digital technologies are used to provide safe, high-quality patient care, support a safe working environment, inform timely clinical decision-making, and enable efficient operations. These systems range from the most complex systems to deliver highly-conformal radiation therapy (e.g. linear accelerators) to basic communication tools (e.g. email), and allow clinicians to collaborate in care delivery. Increasingly, these technologies are integrated through high-speed networks and oncology information systems, and interoperate to assure safe and efficient operations. In addition, they are important enablers of positive patient engagement and experience.

Equipment and technology cannot be purchased and used in a vacuum. The design, implementation and support of technologies in a cancer centre is of extremely high strategic and operational importance, and requires expertise in medical physics, biomedical engineering and digital technology.

This critical expertise is required to: i) identify the most appropriate equipment and technology that will meet the centre's needs; ii) ensure and maintain optimal functionality and appropriate use; and iii) provide crucial links between the equipment/technology and its end users (i.e., healthcare providers, care teams, clinical and administrative leaders).





# **B. OVERVIEW**

Cancer centre equipment and technology can be categorized into four broad areas, as illustrated in Table 1.

**Major equipment** is a significant capital expenditure for cancer centres. In addition to the initial capital cost, major equipment usually requires a purpose-built physical facility that meets strict and, often, regulated standards, as well as facility utilities such as power, heating, ventilation and air conditioning (HVAC), water, etc. For the physical facility requirements of specific clinical services, see the appropriate *Cancerpedia* chapter.



#### Table 1: Categories of Equipment and Technology in a Cancer Centre

Category		Selected Examples		
1.	Major Equipment	<ul> <li>Computed tomography (CT), positron emission tomo graphy (PET)-CT, and magnetic resonance imaging (MRI) scanners</li> <li>Mammography equipment</li> <li>Orthovoltage and linear accelerators</li> <li>Robotic chemotherapy preparation systems</li> <li>Cyclotron and radiopharmacy equipment</li> <li>Radiation treatment planning systems</li> <li>Surgical robots</li> <li>Brachytherapy afterloaders</li> </ul>		
2.	Minor Equipment	<ul> <li>Surgical and anaesthetic technologies</li> <li>Endoscopes</li> <li>Microscopes and pathology equipment</li> <li>Intravenous (IV) pumps and vital sign monitoring equipment</li> <li>Radiation dosimetry equipment</li> <li>Contrast agent injectors</li> <li>Wheelchairs and beds</li> <li>Servicing equipment for major equipment</li> </ul>		
3.	Consumables	<ul> <li>Protective clothing, gloves and masks</li> <li>Bandages and dressing supplies</li> <li>Disposable syringes and needles</li> </ul>		
4.	Digital Technology	<ul> <li>Oncology information systems (e.g., electronic patient health record, scheduling systems, workflow tools, order entry and reconciliation systems, record and verify systems)</li> <li>Computing and storage hardware and software (e.g., servers, workstations, cloud services)</li> <li>Communication technologies</li> <li>Network infrastructure</li> <li>Cybersecurity software and hardware</li> </ul>		

*Minor equipment* tends to be less physical facility-dependent and has a relatively limited regulatory burden. For example, surgical and anaesthetic technologies can be moved to service numerous operating suites, IV pumps can be moved to various patient care areas, wheelchairs are portable and so on.

**Consumables** are products that are used once and disposed of. They tend to be less costly and are purchased in bulk quantities, but require careful management.

**Digital technology** includes all equipment and services that enable the cancer centre to collect, manage, store, analyze and share data. Digital technology also includes equipment that enables multiple systems to interface with one another and share clinical information, as well as satisfy reporting requirements (e.g., cancer registries). In the cancer centre, digital technology serves multiple purposes, including clinical care, education, research and operations (e.g., scheduling, workflow, billing). Increasingly, these technologies include cybersecurity and business continuity components.

For more information, see the World Health Organization's Core Medical Equipment and List of Priority Medical Devices for Cancer Management.<sup>1,2</sup>



#### C. RESOURCES

There are three major expertise/disciplines are required to design, implement, and support the equipment in a cancer centre.

#### **1. HUMAN RESOURCES**

#### **Biomedical Engineering**

Biomedical engineers apply engineering principles and design approaches to medicine and biology, with the goal of improving healthcare. These professionals are formally educated as engineers, very knowledgeable about human biology and physiology, and well versed in clinical practices. Their expertise – which reflects an understanding of mechanics, electronics, software development, anatomy, physiology and practical clinical applications – is used to design, develop, assess and improve biological and medical systems, products and devices.

In the cancer centre, biomedical engineers work with healthcare professionals (e.g., physicians, nurses, technicians, therapists), scientists, safety and quality assurance managers, and those engaged in research and development. Depending on the jurisdiction and the cancer centre, engineering technicians and technologists may perform selected biomedical engineering tasks.

For information on biomedical engineering global resources – including teaching units, associations, an education and professional database, and a survey of professional and academic profiles on biomedical engineers and technicians – see the World Health Organization's biomedical engineering global resources.<sup>3</sup> These highlight the established role of biomedical engineers in the life cycle of a medical device, from initial conception to routine clinical use. Medical devices are ever more indispensable in cancer care provision and biomedical engineers are among the key experts responsible for their design, development, regulation, evaluation and use training.

#### **Medical Physics**

Medical physicists apply the principles, concepts and methods of physics to medical practice and research, with the goal of improving healthcare. Medical physicists are formally educated in applied physics and have additional specialty training in the medical applications of physics. Specialized medical physics sub-areas usually include the following:

- Medical imaging, including diagnostic and interventional radiology
- Nuclear medicine
- Radiotherapy
- Non-ionizing medical radiation (e.g., MRI, ultrasound)
- Medical health (i.e., radiation protection in medicine)

For more information, see the Cancerpedia: Medical Imaging and Cancerpedia: Radiotherapy chapters.

In the cancer centre, medical physicists work with healthcare professionals in their specialized sub-area, as well as researchers and safety and quality assurance managers. Depending on the jurisdiction and the cancer centre, medical physicist assistants may perform selected medical physics tasks. The medical physicist takes a leadership role in the design, commissioning and ongoing management of major and minor equipment, as well as safety and quality processes in the medical imaging and radiotherapy programs. In addition, medical physicists are responsible for patient-specific dose calculations for radiation treatments.

For additional information on medical physics, see the International Organization for Medical Physics, which includes contact information for many national members and regional organizations as well as links to useful resources for the development of medical physics expertise.<sup>4</sup> The growing need for medical physicists is highlighted by the increasing number of countries establishing national medical physics organizations and certification bodies.



#### **Digital/Information Technology**

A cancer centre's comprehensive information technology (IT) system usually includes:<sup>5</sup>

- An electronic medical or patient health record
- Clinical services subsystems (i.e., imaging, laboratory medicine and pathology, anaesthesia, surgery, radiotherapy, systemic therapy, supportive care)
- Clinical decision-support tools, which may include best practice standards and guidelines, pre-approved drug protocols, treatment prescribing alerts and so on
- Utilization data on services, facilities and equipment
- Utilization data on financial, human and other resources
- Research databases
- Patient portals allowing secure access to one's personal health information

The digital/information technology group is made up of a wide range of skilled individuals who support the cancer centre's comprehensive IT system. These individuals have specialty training and expertise in one or more aspects of IT. The senior digital lead – typically the chief information officer – brings a strategic perspective to the group and oversees multiple areas that provide the following technology support services,

- Hardware purchase, configuration and maintenance (e.g., personal computers, tablets, smartphones, etc.)
- Software applications purchase, development, configuration and maintenance (e.g., clinical service records, comprehensive medical records, materials management, business applications for services such as human resources and finance, etc.)
- Storage purchase, management and maintenance (e.g., servers, cloud services)
- Network engineering and linkages (i.e., wired and wireless, internal and external)
- Cybersecurity policies and practices, monitoring and issues management
- General support (e.g., helpdesk)
- Clinical decision support tools
- Clinical applications that require a high level of digital expertise (e.g., robotic dispensing of chemotherapies, robotic surgeries, electronic delivery of radiotherapy treatment units, image guidance to target tumours, etc.)
- Data science expertise for insights from cancer centre data

In cancer, the quantity and variety of data, the critical nature of decision-making and the extended time frame from diagnosis to follow up define one of the most complex informatics problems in health care.<sup>5</sup> In many ways, the separation of digital technology from major and minor equipment is artificial and biomedical engineering, medical physics and digital/information technologists must work together to ensure safe and highly-reliable cancer services and data analytics.

#### 2. OVERVIEW OF RESPONSIBILITIES

Biomedical engineers, medical physicists and digital/information technologists work closely together to support the same, as well as different, equipment and technologies. There are natural links between these experts and certain clinical areas. For example, medical physicists have a very close working relationship with medical imaging and radiotherapy because of the nature of the equipment used by these services (e.g. imaging, ionizing radiation). Similarly, the relationship between biomedical engineering and surgery/ anaesthesia is also close (e.g., ventilators; surgical robotics).

Table 2 presents a more detailed overview of the roles and responsibilities of biomedical engineers, medical physicists and digital/information technologists with respect to major and minor equipment, consumables and the underlying digital/information technology infrastructure. As the processes of cancer care become increasingly dependent on digital technologies, it is more critical than ever that these three disciplines work closely together. From a safety perspective, it is critical to have biomedical engineering and medical physics oversee the release of new hardware and software to ensure that appropriate testing of clinical systems has been completed. A similar paradigm exists in the engagement of pharmacists in the release and maintenance of digital/robotic pharmacy systems.



#### Table 2: Responsibilities by Expertise

		Human Resource				
	Responsibilities	<b>Biomedical Engineers</b>	Medical Physicists	Digital/Information Technologists		
1.	Advise on the construction of facilities to house equipment/ technology	Surgical facilities; maintenance areas	Imaging and radiotherapy suites	Data centers; network architecture		
2.	Advise on the purchase of equipment/ technology	Pumps; vital signs equipment; patient handling; surgical equipment	Imaging and radiotherapy systems; hardware and software	Storage and computer network gear; computers; generic software		
3.	Advise on the installation of equipment/ technology	As above; participate in procurement	As above; participate in procurement	As above; participate in procurement		
4.	Install, adjust and test equipment/ technology	Pumps; electrical safety tests	Imaging and radiotherapy systems	Privacy and cybersecurity risk assessment		
5.	Ensure/evaluate equipment/ technology safety, efficiency and effectiveness	As above, plus regulatory compliance	As above, plus regulatory compliance	Monitoring/managing internal and external threats; business continuity		
6.	Train clinicians and others on the proper use of equipment/ technology	Typically vendor provided	Significant role in radiotherapy training; practice standards	Cybersecurity risk training; assuring appropriate use of technology		
7.	Maintain, repair and provide technical support	Role in maintaining and managing fleets of small equipment	Typically oversee radiotherapy equipment maintenance/repairs	Manage/maintain downtime procedures due to severe digital dependence of cancer centre		
8.	Investigate equipment/technolo gy failures	Critical role in managing technology failures; proactive/reactive; manage systems for reporting on safety events	Critical role in managing technology failures; proactive/reactive; manage systems for reporting on safety events	Critical role in managing digital technology failures; external cybersecurity threats; architecture; proactive/reactive		
9.	Collaborate on developing diagnostic protocols and decision-support tools	Some responsibilities in medical imaging	Major role in setting standards for medical imaging protocols and radiotherapy practice	Provide tools/resources to allow development and deployment of decision support		
10.	Design and adapt hardware and software for medical applications (e.g., robotic procedures, equipment operations)	Human factors; safety analysis;	Custom design of technologies for patient-specific needs; safety analysis	Limited adaptation for procedures; supporting role		
11.	Develop and use computer tools to collect and analyze data; provide analytic support	For quality assurance /safety systems; procurement strategy/planning	For quality assurance /safety systems; procurement strategy/planning	Major role; data science team; business intelligence tools; manage data governance framework; privacy/consent support		



## D. PROCESSES

The actions and decisions made about equipment and technologies need to be guided by established, standard processes in six areas.

#### Strategic Oversight and Accountability

The cancer centre's leadership team sets a clear strategy for the organization, provides strategic oversight and is ultimately accountable for the centre. For more information, see the *Cancerpedia: Governance and Management* chapter. This strategy shapes the services, programs and activities of the organization, which directly relate to equipment and technologies. Indeed, appropriate investments need to be made to support the organization's priorities.

Management implements the organization's strategic directions and manages the daily operations of the organization, among other tasks. The cancer centre must have a position or function that provides strategic oversight and accountability for equipment and technology at its senior levels. Responsibilities should include, but are not limited to, the following:

- Developing a corporate equipment and technology plan that aligns with the organization's strategy. The plan should identify clear priorities for equipment and technologies in all categories, which may include developing, procuring, maintaining, upgrading and/or replacing equipment, as appropriate.
- Establishing operating procedures related to equipment and technologies, including managing risk, ensuring quality, and supporting privacy and security.
- Establishing procedures on appropriate access to patient information.
- Tracking performance in relation to equipment and technologies, including their effectiveness, efficiency, wait times (i.e., especially for major equipment), and failures and breakdowns.
- Establishing a performance framework that includes clear accountabilities for improvement.

For more information about the selection and regulation of equipment and technology, see the World Health Organization's Needs Assessment for Medical Devices and Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic Medical Devices.<sup>6,7</sup>

#### **Capital Planning**

Capital planning for equipment and technology must be based on the cancer centre's strategic plan. Strategic planning identifies the role of the centre, the services to be provided, the model of care, the number of patients served and so on. A multi-year capital investment plan is best practice, to ensure operational and financial stability while meeting strategic objectives.

Strategic planning decisions must consider affordability and future operating costs, especially for major equipment and technologies. Similar to physical facilities that need to operate at sufficient capacity to achieve efficiencies of scale and make the most effective use of resources, capital planning should optimize the use of equipment and technologies.<sup>8</sup> For example, greater efficiencies occur when multiple radiotherapy machines are located on one site. This maximizes the use of human resources and helps maintain quality and technical skills.

A stand-alone cancer centre must purchase major equipment and technologies or partner with other organizations for shared access. A cancer centre that is part of a larger hospital can leverage equipment and technologies that are not specific to cancer. This includes major equipment, such as diagnostic CT and MRI scanners, computers and servers, and bulk purchasing of minor equipment and consumables.



#### Procurement

Cancer centres need to establish and use efficient and effective procurement policies for each equipment and technology category. These policies will vary depending on whether the centre is purchasing major or minor equipment, consumables or information technologies. Generally, the preferred approach to procurement is a competitive bidding process that includes a request for proposals. Bids are submitted and evaluated using established criteria. Biomedical engineering, medical physics and digital/information technology experts must be engaged in the development and evaluation of specifications associated with the tendering process.

Depending on the jurisdiction, the cancer centre may need to follow procurement policies established by the government, especially for major equipment purchases. Centres may also be part of a central procurement agency or group made up of like organizations that want to buy the same types of equipment and technologies. Generally, group purchasing results in a better pricing and terms. While group purchasing has the advantage of savings, it may sacrifice the specific needs of the organization. The engagement of dedicated expertise from biomedical engineering, medical physics and digital/information technology is critical to ensure that unacceptable compromises are avoided and that any specified requirements are tested following procurement.

It is important to note that all equipment arriving in a cancer centre begins with the procurement process, and therefore proactive support for expertise development, regulatory frameworks and planned commissioning need to be in place to ensure the safe and effective use of these technologies.

#### **Data and Digital/Information Support**

As cancer care grows in its dependence on digital technologies, strategies for data management and support must be developed. This expertise must be centralized if safe and efficient personalized care delivery is to be achieved. In addition, datasets must enable insight-driven strategic planning and efficient reporting. The development of a proper data governance strategy is a growing requirement, given societal expectations with respect to data privacy and consent for the use of patient-derived information.

A framework to support the management of patient, administrative and research- related information is required.

- **Patient information** includes all diagnostic and clinical encounters (i.e., imaging, laboratory medicine and pathology, anaesthesia, surgery, radiotherapy, chemotherapy, supportive care). The sum total of this information is the patient's health record.
- Administrative information includes utilization data on services, facilities, equipment and resources (e.g., financial, human and other).
- **Research information** includes data to support basic, clinical, population-based and translational/ implementation research studies.

The utility of data for future analysis requires investment in data curation. The process for collecting data elements includes two key steps: i) clearly define each data element and develop a data dictionary document, which includes the data element's terms, formats and other characteristics; and ii) develop a process and protocol for data collection, which includes the data elements to collect, how each element will be collected, standard operating procedures as appropriate (e.g., for tissue collection) and other information.<sup>5</sup> As technologies continue to evolve, data aggregation and classification will become more automated; however, the process will still require management for the true benefit to be extracted.

#### **Regulations, Privacy and Cybersecurity**

Cancer centres and other healthcare organizations are regulated by local governments to protect personal health information from disclosure.



In terms of digital/information technology, electronic patient health records must operate on a secure physical network and operations architecture that ensures secure access for a defined set of staff. In addition, facilities must be engineered to isolate the network and networked systems from external access. This is typically achieved through a dedicated interface (i.e., firewall) that limits traffic between the centre's internal systems and external, public-facing systems. This interface facilitates staff and system access to external sources of information, but restricts the ability of external entities to access the centre's systems. These systems are not limited to traditional IT systems, but must now include all technologies attached to the network (e.g. linear accelerators; surgical robots; anaesthesia units, etc.). To enable beneficial data sharing between the centre and external entities or systems (e.g., other hospitals and clinicians, registries, etc.), cancer centres must develop appropriate policies to support interoperability, while assuring the privacy of health information and the safe and controlled operations of devices.

Cancer centres must have a digital/information technology policy on the appropriate use of technology to ensure that staff are aware of the risks and responsibilities associated with having these systems available. The digital/information technology policy should be highlighted in training for all staff and include the risks of cyber attacks (e.g. phishing, ransomware) that can result in a loss of critical functions, impact patient care, and/or violate privacy laws.

### E. FUTURE

The increasing dependence on technology for the delivery of personalized cancer medicine will put greater pressure on the cancer centre to maintain critical expertise and co-ordinate its work. Forethought and investment must be made in the development of the cancer center's technological architecture and the 'tech stack' must be designed, built, and maintained to ensure that cancer services are safe and effective.

Automation is clearly required for the implementation of precision medicine, to ensure that patient-specific treatments can be delivered with confidence. Similarly, automation approaches will be required to support technology, such as quality assurance for medical devices, cybersecurity and the co-ordination of maintenance with zero-tolerance for downtime. Automation frameworks will be further augmented by rapid developments in artificial intelligence and machine learning. Such computational tools will become part of the fabric of the cancer center's 'tech stack', allowing greater efficiency and robustness in almost every domain, including clinical decision support, discovery and operational research, system efficiency and cybersecurity.

Furthermore, the continued growth in robotics for surgery, particle-based radiation therapy, complex drug preparation and, most recently, cellular therapies will push the need for automation capabilities and data science skills even further. This exciting future requires the development and enablement of biomedical engineering, medical physics and digital/information technology to ensure that technologies are fully and safely exploited for the benefit of the cancer patient.

### F. REFERENCES

- 1. Hospital medical equipment. World Health Organization; Available from: http://www.who.int/medical\_devices/priority/core\_equipment/en/.
- 2. WHO list of priority medical devices for cancer management Geneva: World Health Organization; 2017.
- 3. Biomedical engineering global resources. Geneva: World Health Organization; [cited 2018 May 16]. Available from: http://www.who.int/medical\_devices/support/en/.
- 4. International Organization for Medical Physics. York, UK: International Organization for Medical Physics; [cited 2018 May 16]. Available from: http://www.iomp.org.
- 5. Jaffray DA, Hope A, Dwivedi P et al. Cancer informatics. In: O'Sullivan B BJ, D'Cruz A et al., editor. UICC manual of clinical oncology. 9 ed. Oxford: John Wiley & Sons, Ltd.; 2015.
- 6. Needs assessment for medical devices. World Health Organization; 2011.
- 7. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. World Health Organization; 2017.
- 8. Mills A, Rasheed F, Tollman S. Strengthening health systems. In: Jamison DT BJ, Measham AR, Alleyne G, Claeson M, Evans DB, Jha P, Mills A, and Musgrove P, editor. Disease control priorities in developing countries 2ed. Washington, DC: Oxford University Press and The World Bank; 2006.





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