Chapter 21

Healthcare Technology Management in Zimbabwe

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Introduction

Healthcare Technology Management (HTM) is the most prominent biomedical engineering-related activity in Zimbabwe. Little to no medical device development currently takes place, primarily due to the country's economic priorities and to limited understanding of the potential role of a local medical device industry. A strong bias of clinicians towards internationally branded and certified equipment has also had a negative impact on local development activities.

Medical technology adopted in Zimbabwe's public sector is predominantly donor driven, with equipment, systems and methods of implementation being dictated by donors. The private sector has more autonomy, but few entities can afford new equipment, and therefore refurbished equipment is a common choice. Donor funded or refurbished equipment, however, presents a technology management challenge in the form of short life cycles. Skills gaps, inadequate technical support, locally unavailable spare parts and disposal challenges also add to the difficulty in managing healthcare technology, both in the public and in the private sector.

This chapter provides an overview of HTM in Zimbabwe. The HTM role is discussed, models of HTM support and training are presented, and the role of regulatory bodies is reviewed.

The HTM role and its challenges

The anchoring professional role for HTM in Zimbabwe is that of the biomedical engineering technician (BMET).

Established clinical facilities typically employ BMETs of strong electronic and mechanical aptitude who receive on-the-job training. Everyday activities include equipment, air-conditioning, plumbing and lighting repairs, first line support for major equipment and related software systems, communication with suppliers for support, as well as assisting suppliers with installation, commissioning and decommissioning of hospital equipment. The BMET team is headed up by a more experienced technician who typically has 8 or more years of experience with general service and maintenance of the equipment. No medical device development activities take place.

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In the private sector, procurement is a collaborative exercise between a more experienced technical staff member, often referred to as the chief or head BMET, and staff with financial, executive and end-user roles within the hospital. The role of the head BMET is crucial in the procurement process, and involves research and engagement of suppliers of equipment to establish technical specifications and cost, and to guide internal decision making. Part of the procurement exercise also involves workshop and conference attendance to understand product ranges and technological advances, as well as attending demonstrations by various potential suppliers, especially for new equipment.

The availability of foreign currency for procurement is key, especially for larger equipment, but is not always guaranteed. This implies an unpredictable wait time for allocation and remittance to foreign suppliers who have strict 100% payment policies prior to shipment. While technical planning remains one of the functional areas of BMETs, planning for repairs, replacements and associated down-time is unpredictable where foreign imports are concerned.

Another major procurement-related challenge faced by BMETs is that of unforeseen failure on commission. Technical manuals are often excluded from shipments as they provide a future source of income for the supplier. While this makes business sense for the supplier, the scarcity of local agents to assist with troubleshooting further increases clinical down-time. This consequently incapacitates in-house BMETs who revert to bringing in technicians from the supplier company to resolve what is sometimes discovered to be a minor technical fault.

Power supply quality and load shedding cause frequent failure of operational equipment. This escalates the cost of repairs and maintenance. Voltage fluctuations cause a myriad of electronic faults, which result in the bulk of the work carried out by BMETs being related to repair and replacement of damaged parts. Additionally, unforeseen phase rotations on the power grid cause problems for larger three-phase equipment, which relies on the correct phase sequence delivery for functionality. Facilities with reasonable cash flow invest in the installation of voltage regulators, phase correction units, and uninterruptible power supplies where possible. However, facilities without budget for such investments continue to run equipment on inconsistent and/or poor-quality power supply, shortening equipment lifespan.

Given the limited scope of work imposed on BMETs by the structural and health system challenges they face, there is heavy reliance on support services for the equipment for which the BMETs are responsible.

Models of HTM support

Two loosely defined models are observed to support the activities of the BMET, referred to here as *Outsourced Services* and *Shared Services*.

Outsourced services

Where there is a skills gap internal to a healthcare service company or clinical facility, services are contracted out to an external company. This includes both foreign and domestic services. For locally available expertise such as artisanry, architectural design, construction, power upgrades and corrections, equipment installations, computer networking and telephony configurations, local companies may be contracted for once-off major projects and/or ongoing support.

Foreign contracted services are usually manufacturer-based. One such example is the country's single private radiation therapy treatment centre, established in 2016, Oncocare Zimbabwe[1]. Oncocare outsources major installations, repair, calibration and servicing of its linear accelerator through the Swedish equipment supplier, ELEKTA, which has a sizeable footprint for cancer treatment equipment in Africa. To complement the remote technical support of the manufacturer, staff operating the equipment and systems receive training on troubleshooting and correctly communicating faults for assistance from BMETs who are also manufacturer trained.

Medical facilities with foreign parent companies rely on foreign based agents of the parent company or sister companies for repairs and maintenance, unless repairs are minor and parts are locally available. Such is the case with Lancet Zimbabwe[2], which has no in-house trained staff and receives support from the Lancet Laboratories group. However, it is possible that with such a model, travel and accommodation costs for foreign staff may exceed repair costs. Down-time is sometimes unpredictable as several factors, such as the availability of spare parts at the supplier, transportation, and import expenses and restrictions, all affect overall down-time.

Outsourcing typically follows a needs-based approach. Alternatively, annual maintenance contracts (AMCs) and/or service level agreements (SLAs) are employed. These routes are often reserved for preventative maintenance of more complex equipment or services and training of first line support personnel where available. In other cases, such contracts are used to secure a priority response for major faults.

More established clinical practices have such agreements with South African manufacturers and suppliers such as TECMED Africa as well as South African satellite

[1] Oncocare Zimbabwe Cancer Treatment Centre, 1 Walmer Drive, Harare, Zimbabwe, http://oncocare.co.zw/
[2] Lancet Clinical Laboratories Zimbabwe, www.lancet.co.zw

offices of foreign companies. Traditional medical equipment giants in the industry also offer and strongly encourage such agreements. However, challenges presented by the shortage of US dollars in the economy attract tighter terms of agreement, such as 100% payment prior to dispatch of skilled personnel.

Strong commercial objectives of the private sector compel agreements that ensure maximal use of assets and adequate support. A generally sound appreciation of AMCs and/or SLAs for fields using complex, high-valued equipment can therefore be argued for the private sector. This is seen at oncology, radiology and pathology service centres across the country, whose business is highly dependent on uptime of equipment and related systems. Relationships between clients and manufacturers allow for a degree of training of resident BMETs on an ongoing basis.

Contracts established at time of sale ensure maximum up-time and safe operation of equipment. A common strategy employed by healthcare facilities, however, is to wait out a warranty period before drafting and signing contracts of agreement. Such contracts outside the warranty period can be costly, with the result that some facilities take on the risk of running without necessary measures for quality assurance, maintenance and repair, which impacts on service delivery when equipment or systems are down.

Shared services

In the shared services model, one unit provides services to multiple facets of the healthcare facility, with the aim of consolidating business operations. This may extend to a group of healthcare facilities that share services through an established shared services centre. In addition, costs are shared between various cost centres in the healthcare enterprise or group of facilities. Typical services that can be shared include human resources management, information technology, security, procurement, logistics and legal services. Typing pools, which are a common establishment in various clinical entities for the generation of patient reports, may also be a shared service.

The challenge presented by this model, is striking a balance between priority response, efficient use of skilled labour, and cost containment. Where efficient systems are in place in healthcare facilities with more experienced technical staff, the mean time between failures can be so long that it may not justify full-time employment of staff within one company. The skills-to-equipment ratio therefore needs to be taken into consideration.

Training

Formal BMET training methods and curricula are increasingly being introduced in Zimbabwe. In-service training is available and academic programmes are emerging.

In-service training is typically conducted by more senior technical personnel. Technicians with instrumentation, information technology, telecommunications, and electrical or

electronic engineering qualifications are typically recruited. Activity towards device development is limited, as technicians spend years in training to bridge the gap between engineering/information technology and medicine.

Manufacturer-based training is offered by suppliers and/or manufacturers of various technologies at a cost to the company. Levels of training vary depending on the technical competence of the resident technicians and engineers. Conditions of SLAs are also considered, where training is limited to areas excluded in the agreement.

Student attachments or internships offer technical development and clinical exposure to students studying towards mechanical, electronics and instrumentation qualifications. Students are often from smaller technical training institutions. Employment prospects post-training are a large deciding factor for students considering technical attachments in a clinical setting. In general, internship programs lack structure and post-internship retention rates are low.

Academic programmes offering formal training to address the BMET training gap are being introduced, particularly at institutions with a technical bias. The Harare Institute of Technology (HIT), for example, has introduced a BTech in Biomedical Engineering, housed in the Electronics department, with strong ties to large clinical facilities in the public sector.

Regulatory bodies

The Medicines Control Agency of Zimbabwe (MCAZ) is a statutory body established by the Medicines and Allied Substances Control Act of parliament (MASCA) [Chapter 15:03]. MCAZ follows guidelines of the International Organization for Standardization (ISO) as well as WHO guidelines to ensure quality, safety and efficiency. The MCAZ Chemistry and Medical Devices Laboratories have been accredited by the Southern African Development Community Accreditation Service.

Medical device regulation in Zimbabwe is done by the medical device regulation unit housed in MCAZ. The unit's mandate is to ensure quality and market safety of medical devices. While regulations for imports and exports of medical equipment have been drafted by MCAZ, they have not yet been implemented. As there are no formal regulations as yet, government tenders reference the CE mark or FDA approval. However, MCAZ is progressing towards a tiered risk-based approach for classifying medical devises based on priority, with the initial focus being in-vitro diagnostic devices.

Due to the infectious disease burden, mainly HIV/AIDS, malaria and TB, as well as clinician protection imperatives, the primary focus of MCAZ medical device regulation since 1998 has been imported male condoms and latex gloves. Standards applied include ISO 4074 for natural rubber latex male condoms and ISO 11193 for single-use medical examination gloves. New brands entering the country are also registered through MCAZ.

Standards applied to other MCAZ activities include ISO 17025 for verifying competence of testing and calibration laboratories.

MCAZ is generally mandated with regulating all clinical trials, and with product testing as well as participating in research, documentation and policy creation, with healthcare technologies included in the scope. The body would therefore form a natural link with academic, scientific, clinical, government and industrial bodies to support the development of a medical device industry in Zimbabwe.

There is also scope for the regulatory body, in collaboration with local distributors and service providers, to play a more active role in the standardization of donor-based purchases for more focused management of healthcare technologies. The WHO has highlighted the challenges associated with donated medical devices, and offers guidelines for the planning and coordination of donations[3]. With thorough assessment of equipment and regulation of donation protocols, Zimbabwe and other African countries may be able to mitigate the problem of inheriting equipment with a short life-cycle and unpredictable operational safety.

Radiation protection

The Radiation Protection Authority of Zimbabwe (RPAZ) came about in 2014 through the Radiation Protection Act of Parliament [Chapter 15:15]. Legislation and guidelines have been formalized for ionizing radiation emitting devices.

RPAZ provides regulatory inspection to ensure compliance of radiation sources to legal guidelines and provides dosimeter services to all personnel exposed to ionizing radiation. Licensing of radiation services is also provided, authorizing protection and safe use of radiation sources based on Section 4 of the Radiation Protection Act [Chapter 15:15].

RPAZ is one of the few bodies to have conducted thorough needs assessment for ionizing radiation equipment across Zimbabwe, from which standards were developed for accreditation, installation and training as well as company registrations.

Although RPAZ is a well-established regulatory authority, there is still room for tighter regulation towards calibration and annual maintenance of equipment. This would improve HTM repair and maintenance standards of radiation equipment, as would partnerships between RPAZ, MCAZ and suitably identified research and training institutions.

[3] "Medical device donations: considerations for solicitation and provision" available at http://www.who.int/medical_devices/management_use/manage_donations/en/

Conclusion

At present, Zimbabwe is focused on appropriate management of healthcare technologies, while other aspects of biomedical engineering have not yet been explored. Attention to the broader field of biomedical engineering could benefit the healthcare system by addressing the context-specific health technology needs of the country. Biomedical engineering education, strategic collaboration, expansion of regulatory activities, and streamlined management of existing technologies, would contribute to the overall growth of biomedical engineering and improve the availability and implementation of medical devices.

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