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EFOMP policy statement 17: The role and competences of medical physicists and medical physics experts in the different stages of a medical device life cycle

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ABSTRACT

MPPs are trained in the branches of physics associated with the practice of medicine. Possessing a solid scientific background and technical skills, MPPs are well suited to play a leading role within each stage of a medical device life cycle. The various stages of the life cycle of a medical device include establishment of requirements with use-case assessment, investment planning, procurement of medical devices, acceptance testing especially regarding safety and performance, quality management, effective and safe use and maintenance, user training, interfacing with IT systems, and safe decommissioning and removal of the medical devices. Acting as an expert within the clinical staff of a healthcare organisation, the MPP can play an important role to achieve a balanced life cycle management of medical devices. Given that the functioning of medical devices and their clinical application in routine clinical practice and research is heavily physics and engineering based, the MPP is strongly associated with the hard science aspects and advanced clinical applications of medical devices and associated physical agents. Indeed, this is reflected in the mission statement of MPP professionals [1].

Purpose: The life cycle management of medical devices is described as well as the procedures involved. These procedures are performed by multi-disciplinary teams within a healthcare environment. The task of this work-group was focused on clarifying and elaborating the role of the Medical Physicist and Medical Physics Expert - here collectively referred to as the Medical Physics Professional (MPP) - within these multi-disciplinary teams. This policy statement describes the role and competences of MPPs in every stage of a medical device life cycle. If MPPs are an integral part of these multi-disciplinary teams, the effective use, safety, and sustainability of the investment is likely to improve as well as the overall service quality delivered by the medical device during its life cycle. It leads to better health care quality and reduced costs. Furthermore, it gives MPPs a stronger position in health care organisations throughout Europe.

Introduction

During the EFOMP Council meeting in October 2019 in Warsaw, a proposal of the Maltese delegation was accepted to work out a policy statement concerning the involvement of MPPs in the various stages of a medical device life cycle starting from the definition of requirements at the procurement stage to final decommissioning. Up to now, there are no clear EU guidelines for healthcare institutes concerning this issue. According to the European Guidelines on the Medical Physics Expert, MPPs are competent for clinical medical device management, development of service quality and cost-effectiveness, expert consultancy, health technology assessment and innovation [1–3]. All these competences are very valuable in the life cycle management of medical devices.

Life cycle management of a medical device

The life cycle of a medical device can be subdivided into several stages:

- Definition of requirements
- Investment planning
- Purchasing

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- Installation
- Acceptance testing, registration, and commissioning
- User training
- Operation and (preventive and corrective) maintenance
- Quality control and assurance
- Decommissioning

The mission statement of MPP closely follows these stages [2]. However, in all stages other professionals and professions are involved playing their own specific roles. Through collaboration and teamwork, each stage in the medical device life cycle can be managed optimally.

Definition of requirements

To maintain state of the art medical services, a medical device should be replaced before it reaches its end-of-life status. Together with medical specialists and their departments involved, and on indication of the medical technology or biomedical engineering department, the MPP can assess if continuation of the medical services provided by the device is still necessary and estimate which budget should be released to replace the medical device involved. Besides replacement investments, innovations in medical techniques often require new dedicated and highly specialised medical technologies and state of the art devices. In close cooperation with medical specialists and the staff of the department involved, the MPP can define a use-case and derive the specific needs for this technology. A calculation of the budget necessary to implement the innovation can be made and its benefits for healthcare can be estimated. In most cases the total cost of ownership should be forecasted (investments, building costs, installation costs, training costs and maintenance costs).

The roles of the MPP in this stage of the life cycle:

- The MPP advises the medical doctors, management, and board of directors on upcoming investment needs (based on replacement of already existing medical devices) and innovation strategies (based on changing policies or legal requirements).
- Together with the financial department, the MPP draws up forecasts for the budget needed to replace the installed base of medical devices to continue the medical services.
- An MPP plays a primary role in the introduction of new medical technologies through a structured Health Technology Assessment (HTA).

Investment planning

In most healthcare institutes, every financial year only a limited budget is made available for investments in medical devices. Based on the local policy a decision is made to invest in replacement of depreciated medical devices (continuation) and/or new, often innovative medical devices (expansion). Ideally, an investment (or procurement) committee advises on the assignment of the budget for purchasing purposes. It is useful to give MPPs a membership in such an investment committee. Based on convincing use and business cases, including considerations on cost effectiveness and sustainability, the investment committee formulates its advice on allocation of the available budget for the investment of medical devices for the upcoming year.

The role of the MPP in investment procedures:

- An MPP is member of the investment committee.
- An MPP can advise when a medical device is Beyond Economic Repair (BER).
- An MPP can give advice on a medical device that might lead to undue patient harm (e.g., with respect to new and emerging technologies including advanced functionality and increasing safety features).
- An MPP has a broad knowledge about new technologies (e.g., for radiotherapy or diagnostic imaging devices).

Purchasing

As soon as the budget for the investment of a medical device is made available, the purchase of a medical device can start according to local or regional guidelines or regulations of national professional organisations. The medical use-case and all known technical and financial constraints are translated into a set of requirements, considering knowledge from literature or other users and customers and information provided by vendors of medical devices. A prospective risk assessment, based on agreed guidelines, should be carried out to prevent a medical device from being used hazardously or unsafely. Procedures must be defined for cleaning, disinfection, sterilisation, and storage of the medical device. Also, the necessary IT interfacing, when appropriate, must be determined and defined. The medical technology department needs to formulate the specifications on maintenance (by whom and how often) and the service level necessary. Also, procedures for recalls and safety notifications by the vendor must be considered and the proper licences must be obtained if applicable.

Based on all these criteria, a selection of vendors can be invited to offer their solutions, a clinical evaluation can be carried out and finally a selection is made depending on both price and quality. Where possible and feasible, an official tender process is recommended to allow comparison of vendors and medical devices offered. This comparison should consider cost, servicing and maintenance, available options, and differences in makes/models of the medical device.

The role of the MPP in the purchasing phase:

- An MPP participates in the purchasing team for high risk, expensive, or technically complex medical devices.
- An MPP supervises the preparation of technical specifications following an iterative fielding of comments and concerns from stakeholders (clinicians, clinical users, consultants).
- The MPP ensures that tender documents (or other agreements with the manufacturer) include proper application training for the medical technology and the medical physics service.
- The MPP can play a role in the review of submitted tender documents.
- The MPP can help evaluating the bids of the vendors.

Installation

When a medical device is purchased, contracts on maintenance and delivery are formulated by the purchasing or legal department after consulting the project team. After purchasing and delivery, the medical device is installed, following the installation instructions of both vendor and clinical users. There may be regulatory requirements to be considered prior to the installation stage depending on the type of device and country.

The role of the MPP in the installation phase:

- The MPP is member of the installation team.
- The MPP must be involved whenever radiation shielding impacts patient or workers dose. In the case of radiation shielding for occupational and public purposes the MPP should only assume such responsibility if officially appointed also as Radiation Protection Expert.
- The MPP may be consulted in technical issues which are directly related to the medical device to be installed.

Acceptance testing, registration, and commissioning

After installation, for most equipment an acceptance procedure is followed in which both technical and user issues are addressed. The acceptance documents are signed by user, MPP and supplier, causing the medical device being formally accepted for clinical use and ready for financial settlement. Internal registration of the medical device and its

components must be performed by for example the medical technology or biomedical engineering department.

The role of the MPP in the acceptance testing, registration, and commissioning phase:

- Performing acceptance testing on the medical device to ensure that its performance conforms to what was specified in the tender and to the manufacturer statements.
- Supporting the optimisation of default clinical protocols supplied by the manufacturer to those needed for clinical use.
- Performing commissioning of the medical device.
- Once commissioning is performed, the devised protocols should be recorded as part of the Medical Physics Service's protocol management. The MPP should be consulted for advice prior to any change to protocols.

Quality control and assurance

In accordance with the acceptance procedure and its specifications, for some equipment a quality assurance program is defined including routine checks, other assessments, and audits.

The role of the MPP in the Quality Control (QC) and Quality Assurance (QA) phase:

- The MPP is involved in the QA program and collaborates with the QA department, if available.
- An MPP assures the QC of the medical device e.g., by purchasing the proper QC equipment, supervising testing, performing physical measurements, and auditing.
- An MPP is responsible for the QC tests, performed by the MPP himself or by clinicians, other users, or an external company on his behalf.

Training

Before a medical device can be clinically used, the users must be trained on the device to ensure competency. Therefore, training by competent trainers must be defined and performed. Usually, key users are trained by the vendor, and they will train the rest of the clinical team (the Train-the-trainer principle). The trainee participation is registered, and it is recommended training is repeated after updates or upgrades of the medical device, and after a predefined time (e.g., every two years) and/or for new users. Training can be carried out on site (by the vendor or an application specialist), or can be e.g., provided as an e-learning course. Depending on the device, hands-on practical training may also be required. The educational content and user manuals must be made available for the users, either in physical or digital form. Not only training for the users on clinical usage, but also training for the maintenance technicians and quality assurance employees must be performed.

The role of the MPP in the training phase:

- An MPP plays a primary role in the introduction of new medical technologies and can train and educate clinicians and other users of medical devices especially concerning physical principles, safety, and quality control.
- An MPP may be responsible of training programs for users of medical devices and for the maintenance staff.

Operation and (preventive and corrective) maintenance

The medical device must be used according to the clinical needs and should be up to date. Therefore, assessments on the device application needs to be performed and possible improvements including potential updates and upgrades shall be evaluated and installed on a regular basis. Maintenance, both preventive and corrective, must be performed according to manufacturer's specifications and the results and interventions must be registered. Based on the use-case and the maintenance history of the medical device, a risk assessment for the further use of the medical device can be carried out (most likely by the medical technology or biomedical engineering department) to identify the optimal moment for updates, upgrades or even replacement.

The role of the MPP in the regular use and maintenance of medical devices:

- An MPP acts as a guard for the maintenance procedures of the medical technology department.
- An MPP should be informed by the technician performing preventive maintenance of any discovered issues.
- An MPP should be made aware of the preventive maintenance schedule, so that routine QA/QC may be performed after such maintenance is performed.
- An MPP can grant permission to differ from the established maintenance schedule after risk assessment.

Decommissioning

After a medical device has been officially decommissioned, it must be ensured that the medical device no longer can and will be used on patients. When removing the medical device from the medical workspace, it must be cleared of (digital) patient and institutional information to prevent privacy issues and to avoid possible use of the medical device without appropriate recommissioning and installation. Local requirements concerning environment may also be considered at this stage.

In the medical device database, the removal of the medical device must be registered.

The role of the MPP in decommissioning:

- An MPP draws up in close cooperation with the medical technology or biomedical engineering department a protocol for the removal of medical devices and ensures it is adhered to.
- An MPP can perform a final QA on the medical device so that its performance may be quantified. This can be important if the medical device is returned to the vendor or sold to third parties.

Role of the MPP in the management of the life cycle of medical devices

In every stage of the life cycle, multi-disciplinary teams composed of different persons and instances are involved. This includes board of directors, management of departments, purchasers, consultants (data protection officers, cleaning, disinfection, and sterilisation experts), users (physicians and medical staff), trainers, vendors, financial controllers, and medical technicians. An MPP can play an important coordinating role for all those players in the different stages of the life cycle management. In a responsibility assignment matrix, also known as RACI matrix, the participation by various roles in completing tasks or deliverables for a project or business process can be described. RACI is an acronym derived from the four key responsibilities most typically used: responsible, accountable, consulted, and informed. Also, for the processes describing the management of the life cycle of a medical device such a RACI matrix can be used for clarifying and defining roles and responsibilities.

There is a distinction between a role and individually identified people: a role is a descriptor of associated tasks; may be performed by many people; and one person can perform more roles.

The four responsibilities are defined as follows:

R = Responsible (also recommender)
Those who do the work to complete the task. There is at least one

role with a participation type of responsible, although others can be delegated to assist in the work required.

A = Accountable (also approver or final approving authority)

Those ultimately answerable for the correct and thorough completion of the deliverable or task, the one who ensures the prerequisites of the task are met and who delegates the work to those responsible. In other words, an accountable must sign off (approve) work that a responsible provides. There must be only one accountable specified for each task or deliverable.

C = Consulted (sometimes consultant or counsel)

Those whose opinions are sought, typically subject-matter experts; and with whom there is two-way communication.

I = Informed (also informer)

Those kept up to date on progress, often only on completion of the task or deliverable; and with whom there is just one-way communication.

Very often the role that is accountable for a task or deliverable may also be responsible for completing it. It is generally recommended that each role in the project or process for each task receive, at most, just one of the participation types. Where more than one participation type is shown, this generally implies that participation has not yet been fully resolved, which can impede the value of this technique in clarifying the participation of each role on each task.

EFOMP recommends and encourages to involve the MPP through all individual stages of medical device life cycle according to Table 1.

Conclusion

If the right participants are involved and play a correct role in the different stages of the life cycle of a medical device, the use of a medical device is optimized, both in safety of the technology as in cost effectiveness.

Nowadays, in modern medical institutions in the different European countries, the life cycle management of a medical device is not always completely organized as described in this article but differs, not only between countries but also between different medical institutions within a country. For the application of complex medical technology for therapy and imaging with ionizing radiation having a challenging physics component (e.g., radiotherapy, radiology, nuclear medicine), MPPs are involved in all European countries. Nevertheless, only few MPPs are sufficiently involved in the overall life cycle management of the medical devices they support on a daily base. It may be concluded that an optimal level of medical device life cycle management is not implemented yet. In this sense, what is proposed here is the implementation of the management of the life cycle of medical devices where MPPs play a crucial role.

Beside this, in all healthcare institutes also other medical devices are used. They also require safe and appropriate procedures, such as proper risk assessment, for patient or user safety or data security, in which MPPs can play a role. Examples of those medical devices include medical lasers, electrical surgery devices, robot technology, patient monitoring devices, acquisition devices for neurological or pulmonary measurements, medical devices in urodynamics, anaesthesia devices including patient ventilators and infusion pumps, cochlear implants, imaging and measuring devices in cardiology and ophthalmology, and of course the interfaces of all these techniques with hospital IT systems.

For the life cycle management of all these medical devices, MPPs with the relevant knowledge and experience in the above modalities can play an important role, so that the medical performance, the safety of patients and staff, and the efficiency of the institution will improve.

To obtain a balanced and cost-effective life cycle management of medical devices in a healthcare institute, the governance in the life cycle must be defined and procedures must be standardised. MPPs need to play a prominent role in all processes described.

Table 1
MPP's potential roles and degrees of involvements in the stages/procedures within a medical device life cycle.

Stage	*Procedure*	*R*	*I*
Procurement	a. Definition of requirements	r/a	M
	b. Market analysis of potential technical solutions / vendors	r/a	H
	c. Program of requirements / specifications, standardization	r/a	H
	d. Decision criteria / quote evaluation	r/a	M
	e. Business case/Budget	c/i	M
	f. Price; Total cost of ownership; cost effectiveness	c/i	M
	g. Availability of upgrades / improvements	r/a	H
	h. Maintenance options / contracts	a/c	M
	i. Risk management	r	H
	j. Training possibilities	a/c	H
	k. Investment decision / placing order	c/i	L
Quality control / assurance	a. Working procedures	r	H
	b. Assessments	r	H
	c. Audits	r/a	H
Implementation and commissioning	a. Acceptance	r/a	H
	b. Application	a	M
Training	a. (Technical) application training	a	H
	b. Maintenance training	a/c/i	M
Operation	a. Maintenance	c/i	L
	b. Administration / management	a	L
	c. Optimization and training	r	H
	d. Updates and upgrades	r/a	H
Decommissioning	a. Discharge / dissemblance	a	M

Responsible (r), accountable (a), consulted (c), or informed (i); Involvement: High (H), Medium (M) or Low (L).

Recommendation

All EFOMP National Member Organisations should encourage all healthcare institutions and the individual MPPs to closely work together in the management of the life cycle of all medical devices. The goal, as described in this policy statement, is to make sure that medical devices are well managed to ensure effective, safe, and cost-effective use in the interest of patients, staff, and management. MPPs have the knowledge, skills, and competences to play an important role in all the stages of the medical device life cycle. Nevertheless, the actual needs for the involvement of MPP may vary from institution to institution and will be dependent on the processes already in place. Institutions are invited to review their processes and adapt the whole system as described, or the elements thereof which are now missing. By evaluation of the outcome, the need of involvement of MPPs in the different stages of a medical device life cycle can thus be determined more precisely, giving MPPs a stronger position in healthcare organisations throughout Europe.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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