Physica Medica 130 (2025) 104923

Contents lists available at ScienceDirect

Physica Medica

journal homepage: www.elsevier.com/locate/ejmp

EFOMP's corner

European Federation of Organisations for medical physics (EFOMP) policy statement no 20: The role of medical physicists and medical physics experts in physiological measurement and related therapies

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ARTICLE INFO

Keywords:
Medical physics
Physiological measurement
Competences
Role development
Clinical physics

ABSTRACT

The role of medical physics professionals (MPPs) (medical physicists and medical physics experts) in physiological measurement and related therapies (PM&T) applied in e.g., critical care, neurophysiology, neurology, physiology, audiology, and neurotology has long been acknowledged. Given that the exact role and medical specialty fields in which MPP are involved vary between countries, this policy statement aims to provide direction towards improved definition, harmonisation, and development of the role. This policy statement considers the surveyed experiences from several European countries, state-of-the-art of PM&T, and anticipated future developments. We also present an inventory of competences, and associated knowledge and skills expected of MPPs working in these areas.

1. Introduction

Developments in electronics and computer technology during the 20th century revolutionised many areas of physiological measurement and related therapies (PM&T), notably electrophysiology, audiology and ophthalmology, but also physiological measurement in a host of other body systems [1]. As healthcare and medical device technology advances, the demand grows for medical physics expertise which spans the interface between the patient and the classes of medical devices that perform PM&T functions, as well as the acting as a bridge between healthcare professionals and medical device technology. The European Federation of Organisations for Medical Physics (EFOMP) in its updated Malaga declaration [2] states that: "*The range of medical devices and physical agents used in hospitals today goes far beyond the use of ionising and non-ionising radiation based imaging and therapeutic devices, and the MPE faces requests for assistance in other areas such as advanced physiological measurements, artificial intelligence and medical nanodevices.*" This recognition signifies a widening of the role from the traditionally acknowledged medical physics fields involving ionizing [3] and non-ionizing radiation. This consequently sets new demands on the knowledge and competences expected of medical physicists (MPs) and medical physics experts (MPEs) – in this PS collectively referred to as medical physics professionals (MPPs). The consideration of advanced PM&T as one of the generally acknowledged European MPPs' role development directions is to be noted. Previously, EFOMP Policy Statement 16, defined the roles of MPP working with radiation safety and ionizing radiation under 2013/59/EURATOM [3]. Given the increased use of physiological measurement devices in radiation medicine (e.g., for cardiac and respiratory gating), the International Atomic Energy Agency (IAEA) recognizes the evolving role of medical physics extending beyond the fields of radiation safety and ionizing radiation in their guidelines for the certification of clinically qualified MPPs [4].

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https://doi.org/10.1016/j.ejmp.2025.104923
Received 8 January 2025; Accepted 30 January 2025
Available online 4 February 2025

MPPs consistently apply their expertise across a range of medical devices in patient diagnostics and therapy. In this context, EFOMP Policy Statement 17 identifies and delineates the role of MPPs in different stages of the hospital medical device life cycle [5]. The present policy statement considers medical devices in physiological measurements to be applied for measuring, modifying, and/or evoking biosignals. This includes devices used in e.g., invasive and non-invasive patient monitoring, devices used in diagnostics and therapy involving the musculoskeletal, cardiovascular, respiratory, nervous, and digestive systems, and therefore necessitating substantial expertise in electrical safety and an understanding of the biological effects of electricity and magnetism on human patients. This aligns with the principles outlined in EFOMP Policy Statement 12.1 [6] which already recognizes physiological measurement, neurology, and audiology within the qualification framework for MPPs. This policy statement considers the surveyed experiences from several European countries, state-of-the-art of PM&T, and anticipated future developments. We also present an inventory of competences, and associated knowledge and skills expected of MPPs working in these areas.

2. Current status

Medical specialties such as clinical neurophysiology, clinical physiology, otorhinolaryngology, audiology, neurosurgery, neurotology and cardiology are integral to MPPs' tasks related to diagnostics and therapy concerning human physiology. These may overlap with more conventional MPP specialties, including diagnostic and interventional radiology, nuclear medicine, and radiation oncology.

A survey was distributed to each the EFOMP national member organization (NMO) to determine the current status of the role in of MPP in PM&T. Eighteen NMOs responded.[1] The survey revealed that MPPs are presently involved in PM&T in 22 % of the countries. Among MPPs working in these countries, 73 % work full-time, and 27 % work part-time in this field. The proportion of MPPs engaged part- or full-time in PM&T varies by country, ranging from 0 % (e.g., Denmark, France, Italy, Spain, Sweden) to 25 % (Finland and The Netherlands).

The most prominent medical specialty fields within PM&T were identified as audiology (74 % of responders), neurotology (37 %), clinical neurophysiology (11 %), and clinical physiology (6 %). Other medical specialties collectively mentioned by less than 4 % of the responders. The total of the percentages mentioned exceed 100 % due to overlap and shared duties between different specialties. Among the surveyed PM&T modalities, electroencephalography (EEG) was identified as the area of most frequent involvement.

In the countries with MPPs working in PM&T, the requirements for MPs within medical specialties involving PM&T were either "*Certification specific to one or more of these medical specialties is required to work as a medical physicist within these fields*" or "*No specific certification to these medical specialties is required, but medical physicist training includes training within one or more of these fields*". Both options acknowledge the need for structured training for MPPs to work in PM&T. National certification authorities, e.g. in Germany, have already defined the MPP qualification as a prerequisite for qualification as a cochlear implant audiologist and a condition for the establishment of a clinical cochlear implant program.

The most important and recognized key activity areas required by MPPs working within PM&T fields identified in the survey include:

- electrical safety for patient-connected medical devices;
- artefact recognition;
- signal processing and analysis;
- expertise in physiology, clinical context and consultancy;
- data analysis and management;
- device specification, evaluation and selection as per medical purpose;
- device life-cycle management;
- quality assurance and control; and
- education and training of medical and healthcare professionals.

Of the respondents, 61 % indicated that expertise required in PM&T fields is often handled by other professionals, predominantly by biomedical engineers/clinical engineers, or physicians. The NMOs emphasized the need to expand the involvement of MPPs in PM&T fields, with the greatest potential at present identified in cardiology, neurology, and respiratory medicine. It was also foreseen by nine of the NMOs that there is a need to increase the number of MPPs working in PM&T, while in five of the countries represented by the NMOs did not have MPPs working within these fields yet.

MPPs require specialized education and training to perform these activities effectively and safely. European consensus dictates that MPPs should hold at least a Bachelor's degree in physics (EQF level 6) or equivalent, followed by a Master's degree (EQF level 7) in Medical Physics or equivalent, and undergo several years of clinical training or residency in a hospital to achieve MPP qualification (EQF level 8) [6]. In some European countries, the minimal acknowledged level for entry to the profession may at present be insufficient to meet the requirements for being fit for practice in PM&T.

3. Overlap and distinction of the roles between of the MPPs and biomedical engineers

Biomedical engineering, clinical engineering, and medical physics are closely related and sometimes overlap as they apply physical science, mathematics, and computing skills in healthcare at the interface between medical devices and the patient. The differences between biomedical engineers, clinical engineers and MPPs lies not only in their professional titles but in the scope and emphasis of *their education and training schemes* and/or *further professional development* within their chosen discipline. Biomedical engineers primarily focus on the needs of the medical device industry by purposeful and safe design and development including post-market surveillance. MPPs and clinical engineers, on the other hand, are focused on providing scientific and technical expertise within hospitals to ensure the on-going and daily effective, efficient and safe application of the medical devices in hospitals. Although clinical engineers and MPPs may have a similar academic background, they are then "moulded" in a different manner by their specific clinical training. Hence, education and training of MPPs has an ever-increasing component of anatomy, physiology, pathophysiology, healthcare management and ethics. Clinical engineers have an emphasis on engineering and device design concepts, device maintenance and troubleshooting. MPPs operate directly in the multidisciplinary clinical environment, facilitating patient-oriented interaction between medical, healthcare, and technical professionals with their deep understanding of PM&T both from technical and from physiological points of view. These different, yet complementary aspects should be reflected in the tasks assigned to these professions and recognized by the organizations and local authorities assigning the tasks in their local context based on their specific needs.

4. Competences

The role of MPPs in the fields of PM&T involves the following competences (assume responsibility in an autonomous manner):

- Assess risks and ensure safe application of PM&T devices with respect to physical agents including electrical safety;

[1] The represented countries of the NMOs that responded to the survey: Albania, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Latvia, Malta, Moldova, Serbia, Spain, Sweden, The Netherlands and Ukraine.

- Manage and ensure clinically effective application of PM&T devices throughout their hospital device life-cycle in accordance with [5] and investment planning;
- Apply and implement signal processing and analysis in PM&T;
- Recognize artefacts and their sources and take steps to prevent and correct artefacts including shielding in biosignal measurements;
- Provide guidance in clinical context and consultancy including: patient counselling, conducting diagnostic and therapeutic procedures, fitting of medical devices and educating other healthcare professionals;
- Participate and consult in patient diagnostic examinations and therapies;
- Set up and manage a quality assurance and control programme for PM&T devices and systems;
- Evaluate, apply, implement and assure the quality of software as a medical device which might include artificial intelligence tools for PM&T;
- Apply data management, visualization, simulation and fusion techniques;
- Apply data integration, communication and archival into different information and telemetric systems;
- Contribute to the development and implementation of new technologies and techniques into clinical practice; and
- Take responsibility for the physiological physics component of the education and training of medical and healthcare professionals.

The application of machine learning and artificial intelligence in medical physics has been considered previously within EFOMP [7], but not in PM&T. Therefore, the field-specific curriculum for PM&T should include artificial intelligence.

5. Knowledge and skills required

To be able to exercise the above competences, the MPPs are expected to possess the knowledge and skills on:

- Diagnostic and therapeutic techniques and technologies based on measurements on biomedical signals by mechanical, electrical, magnetic, radiant, thermal and chemical means. This covers physiological measurements made on most organ systems in the body[2]:
  - o Musculoskeletal system
    - ▪ biomechanical techniques: biomechanics for fields of gerontology and orthopaedics (e.g. motion capture and mechanical biofeedback);
  - o Cardiovascular system
    - ▪ Electrocardiography (ECG) based measurements, blood pressure measurement, blood flow measurement, ankle-brachial index, tilt table test, autonomic nervous system tests and cardiac ultrasound techniques;
  - o Respiratory system
    - ▪ lung function tests (e.g. spirometry, diffusion capacity measurement, cardiopulmonary exercise test, provocation tests),
    - ▪ sleep measurements (e.g. oximetry, polysomnography), and
    - ▪ blood gas analysis;
  - o Nervous system and its functions, e.g. vestibular, ophthalmic and motor systems
    - ▪ Clinical neurophysiology techniques: electroencephalography (EEG), electromyography (EMG) and electroneuromyography (ENMG), magnetoencephalography (MEG), evoked potentials, pain and sensation measurements,
    - ▪ Neuromodulation therapies (e.g. repetitive transcranial magnetic stimulation, transcranial direct current stimulation, transcranial alternating current stimulation),
    - ▪ Intraoperative techniques: intraoperative monitoring (IOM) and robotic surgery (e.g. deep brain stimulation (DBS), stereo-EEG),
    - ▪ Electro- and/or videonystagmography, and
    - ▪ Audiology techniques: acoustics, calibration, psychoacoustic audiometry (e.g. audiogram, psychoacoustics, speech recognition measures), otoacoustic emissions (OAE), auditory evoked responses (AEP), auditory steady state responses (ASSR), closed loop implantable, vestibular evoked myogenic potentials (VEMP), acoustic reflexes, fitting and handling of hearing aids, active middle-ear implants (aMEI), cochlear implants (CI) and/or auditory brainstem implants (ABI); and
  - o Digestive system
    - ▪ Gastrointestinal (GI) tract measurements (e.g. esophageal manometry, ambulatory pH and impedance measurement, anorectal manometry);
- Human anatomy, physiology, biophysics, electrophysiology and pathophysiology;
- Device life-cycle management including Medical Device Regulation [8];
- Electrical safety as well as physical and biological effects of electricity (including knowledge on relevant standards like the IEC 60601 standard-series for the safety and essential performance of medical electrical equipment);
- Data processing, management, visualization, and protection with consideration to data security and cyber security;
- Biostatistics to implement statistical analyses and interpretation of normative/reference values in diagnostics;
- Project management; and
- Clinical trial/medical device trials.

6. Summary recommendations

The authors of the policy statement recommend that:

1. Given their acknowledged high level of expertise in the effective, safe and efficient use of medical devices, MPPs should, in the interest of patients, involve themselves in PM&T.
2. NMOs should ensure that an education and training scheme, continuous professional development programme and recognition mechanism be set up based on the competences, skills and knowledge listed in this policy statement and on the model used for other MPP specialties.
3. It is further recommended that soft skills [9] be given special consideration since MPPs involved in these areas have a high level of interaction with patients and healthcare professionals.

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.

Acknowledgements

We would like to thank the following Medical Physics professionals who have acted as consultants to the policy statement:

Adam Adamopoulos (Greece)
Ciarán Finucane (Ireland)
Constantinos Koutsojannis (Greece)
Jan de Laat (The Netherlands)
Ad Maas (The Netherlands)

[2] list may expand as the field develops.

Cristina Simoes-Franklin (Ireland)
Michiel Sinaasappel (The Netherlands)
Bert van Zanten (The Netherlands).

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