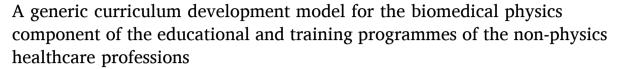
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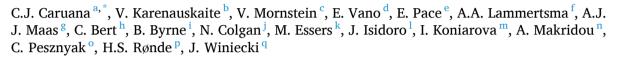
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# ABSTRACT

The objective of the study was the construction of a generic curriculum development model for the use of biomedical physics (BMP) educators teaching the non-physics healthcare professions (HCP) in Europe. A comprehensive, qualitative cross-sectional Europe-wide survey of the curricula delivered by BMP in Faculties of Medicine and Health Sciences (FMHS) was carried out. Curricular content was collected from faculty web-sites, curricular documents and textbooks. The survey data was supplemented with semi-structured interviews and direct observation during onsite visits. The number of faculties studied was 118 from 67 universities spread all over Europe, whilst the number of onsite visits/interviews was 15 (geographically distributed as follows: Eastern Europe 6, North Western Europe 5, and South Western Europe 4). EU legislation, recommendations by European national medical councils, educational benchmark statements by higher education quality assurance agencies, research journals concerning HCP education and other documents relevant to standards in clinical practice and undergraduate education were also analyzed. Best practices and BMP learning outcomes were elicited from the curricular materials, interviews and documentation and these were subsequently used to construct the curriculum development model. A structured, comprehensive BMP learning outcomes inventory was designed in the format required by the European Qualifications Framework (EQF). The structures of the inventory and curriculum development model make them ideally suited for use by BMP involved in European curriculum development initiatives for the HCP.

Abbreviations: BMP, Biomedical Physics/Physicists; CPD, Continuous Professional Development; EQF, European Qualifications Framework; FMHS, Faculty of Medicine and/or Health Sciences (including dentistry, pharmacy when these are separate faculties); HCP, Healthcare Professions; KSC, Knowledge Skills Competences; SWOT, Strengths, Weaknesses, Opportunities, Threats.

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#### 1. Introduction

Biomedical physicists (BMP) from both within and outside universities provide educational services to the non-physics healthcare (including medical and dental) professions (HCP) within most faculties of medicine and/or healthcare sciences (FMHS) and clinical departments in Europe. However, until recently their precise role with respect to the education of these professions was not systematically researched. To address the issue the European Federation of Organizations for Medical Physics (EFOMP) had set up a group 'Biomedical Physics Education for the Healthcare Professions' to conduct research with the aim of producing tools that can be used by members of the profession to advance this component of their role. In a first paper, the group studied the past and present role of the BMP in the education of the HCP and highlighted issues of concern. Although there were indications of increasing interest, the absence of a systematic body of research into the role was deemed a significant handicap that often led to curricula that did not address the actual present and future learning needs of the HCP [1]. A second paper reported the results of a pan-European Strengths-Weaknesses-Opportunities-Threats (SWOT) survey of the role [2]. A third paper presented a strategic development model for the role of the BMP in the education of HCP in Europe based on the results of the SWOT audit. The components of the strategic development model which are most relevant to the present study were an updated mission statement for the role and the urgent need for the construction of a curricular development model based on the mission statement. To ensure the strengthening of the status of BMP departments in the FMHS, BMP educators should focus on those areas in which they are strongest. BMP educators should perceive their role as having a bridging function, spanning the divide between the physics knowledge and skills base underpinning the effective, safe and economical use of medical devices and associated physical agents and the practice-oriented curricula of the healthcare professions. Medical devices and physical agents are welldefined legal terms and our association with these topics is strong, unquestionable and much more evident than with other departments in the FMHS. A more complete discussion about the issues leading to the mission statement can be found here [3]. The complete mission statement reads as follows: "We will make a key contribution to quality healthcare professional education through knowledge transfer activities concerning the technical-scientific knowledge, skills and competences supporting the clinically-effective, evidence-based and economical use of medical devices and safety issues concerning associated physical agents. Our efforts will be guided by an appreciation of the value of all healthcare professions and underpinned by research-based curriculum development" [3]. All curricula should be expressed in terms of knowledge, skills and competence (KSC) statements as required by the European Qualifications Framework (EQF)[4]. Given the ever growing range and sophistication of medical devices this research is increasing critical to avoid an ever widening gap between the physics knowledge and skills learning needs of the HCP and the actual content being delivered and to ensure a harmonized approach across Europe.

The gradual construction of the European Higher Education Area (often referred to as the 'Bologna' process) has encouraged higher education institutions to ensure that their curricula correspond to the present and future learning needs of the professions. The 'Tuning Educational Structures in Europe' initiative has promoted the use of practice-oriented curricula in which programme end-points are expressed in terms of Generic Competences (Tuning terminology for cross-professional competences) and Subject Specific Competences (Tuning terminology for profession-specific competences) that students should acquire by the time they finish their studies. As a result of the

Tuning process, the various HCP have been involved in ongoing pan-European curriculum development [5,6]. The increased importance of multi-professional teams in modern healthcare underscores the need for the different professions to use a common language and have similar attitudes towards the use of medical devices. However, the existing pan-European curriculum development networks are highly profession specific, and the danger therefore exists that, as the different professions design their curricula independently of each other, medical device learning outcomes will be couched using different terminology. The fact that different professions use different devices and that the required level of proficiency even for a particular profession might vary from one country to another, only exacerbates the situation. Furthermore, the number and type of medical devices are also changing rapidly with the swift developments in technology. All this points to a need for the development of a generic learning outcome inventory and a generic curriculum development model for medical devices and physical agents which are device and profession independent and which circumvent the perennial curriculum development problems of future coverage (trying to predict about which medical devices students may need to learn about in the future and to what depth) or rapid obsolescence (as presently used devices become outdated or even totally phased out). In addition, the learning outcome inventory must be expressed in a manner that permits flexible curriculum development yet is structured enough to guide teaching in a systematic and effective way. Unfortunately, no such BMP inventory of learning outcomes or curriculum development model for the education of the HCP has yet been published. Abbey and Shepherd [7] did suggest a basic curriculum model for the general use of medical devices, but their suggestions were excessively general, too biased towards nursing and included very little physics. No attempt was made at developing a framework of specific learning outcomes regarding medical devices and physical agents with the result that the model is of little practical use in the everyday educational arena. The model's main strong point is its emphasis on a systems approach in the sense that appropriate device use is the result of a combination of patient, device, user, facility and environmental factors. A scrutiny of the literature revealed that there has been no further attempt at developing such a model. The objectives of the present study were therefore to identify: (a) principles of best practice for guiding BMP curriculum development for the non-physics HCP (b) the BMP knowledge and skills learning outcomes underpinning HCP competences involving medical devices and safety issues concerning associated physical agents (c) the main steps in constructing, adapting and evolving BMP curricular content for the HCP.

# 2. Methodology

The research strategy consisted of a qualitative cross-sectional Europe-wide survey of the curricula delivered by BMP in Europe. Criteria for the choice of universities included the level of BMP educator activity within the FMHS, geographical position, the range of HCP serviced, higher education structure and level of participation in European initiatives. As a first step, universities within capital cities were chosen; however it was found that surprisingly many other universities from outside the capitals needed to be included as such regional universities very often provided much good practice and many rich curricula. This was particularly the case in the larger European states. Indeed, the level of quality of curricula was largely dependent on the motivational level and enthusiasm of the local individual BMP educator. Curricular content was collected from web-sites, published documents, curricular materials and textbooks. The survey data was supplemented with semi-structured interviews and direct observation during on-site visits. The interviews were also necessary to provide an element of social-constructivism which is essential in curricular development research; this means that curricula should be developed with the participation of relevant stakeholders. Participants and institutions were guaranteed confidentiality. The number of faculties studied was 118 from 67 universities spread all over Europe, whilst the number of onsite visits/interviews was 15 (geographically distributed as follows: Eastern Europe 6, North Western Europe 5, and South Western Europe 4). EU legislation, recommendations by European national medical councils, educational benchmark statements by higher education quality assurance agencies, research journals concerning HCP education and documents relevant to standards in clinical practice and undergraduate education were also analyzed. The competences expected of HCP that included significant BMP features were identified. These competences were in turn carefully deconstructed into component knowledge and skills, and those falling within the BMP learning domain identified. Inventories of best practices and BMP knowledge and skill learning outcomes were elicited from the curricular materials, interviews and documentation and these were subsequently incorporated in the curriculum development model. Very importantly, a structured learning outcomes inventory in the format required by the EQF was designed with the aim of producing a practical curriculum development tool for BMP educators in Europe.

# 3. Results

# 3.1. Good practices for curriculum development identified during the survey

The following best practices were identified during the survey: (a) the inventory should be a pragmatic tool to guide curriculum development for BMP educators teaching HCP at all EQF levels and from initial certification to specialization and subspecialization (b) owing to the rapid expansion of medicine and healthcare there are increasing pressures on curriculum time for both the healthcare curriculum in general and the BMP component; hence, only those BMP learning outcomes specifically required by the clinical learning needs or relevant research contexts should be included [8] (c) owing to the immediate need for employability of First Cycle graduates (EQF terminology for the Bachelor level), learning outcomes necessary for effective and safe performance in the clinical context should be included at the early stages [9] (d) the design should acknowledge that the rolesof many HCP today encompass the use of an ever-widening range of devices, but that the proficiency level (PL) in the use of any specific device within any particular educational level varies from one state to another and in the case of large states even within states (e) the BMP knowledge and skill learning outcome statements should be couched in precise, scientific and up-to-date terminology (f) the BMP knowledge and skills should be formulated in a way that promotes a consistent and harmonized use of physics terminology across devices and professions - this would guarantee an integrated approach to medical devices, a more rapid acquisition of knowledge and skills across devices (cross-device transferability of knowledge and skills) and the avoidance of communication errors in multi-professional teams (g) the inventory should be formulated to allow flexibility for future role and scientific developments - in particular, as the number of medical devices is changing rapidly, the inventory should be devised in a way such that it would be applicable to future devices hence avoiding early obsolescence of the said inventory [10,11] (h) the inventory should not be over-prescriptive to prevent educator and student disempowerment with respect to

Table 1

Operational descriptions of the educational and professional proficiency levels used in structuring the inventory.

Level Proficiency Level (PL) Description

#### PL1 Competences:

Take responsibility for using the medical device effectively and safely within the scope of the profession as stipulated by national legislation in a simulated practice skills-lab context. The term 'safety' here is with respect to the simulated 'patient', user, other workers, general public and others and always with respect to physical agents.

#### Cognitive processes:

Mainly at knowledge retrieval, comprehension and knowledge-utilization levels.

#### PL2 Competences:

Take responsibility for the effective and safe use of the medical device under supervision with patients in the clinical setting and under written protocol, with scope of practice restricted to studies that are basic, routine and predictable. Safety here refers to real patients, users, other workers, general public and others.

#### Cognitive processes:

Mainly at knowledge retrieval, comprehension and knowledge-utilization levels.

#### PL3 Competences:

Take responsibility for the minimally supervised effective and safe use of a medical device with patients, under written protocol with scope of practice widened to include studies that are more complex or somewhat non-predictable.

Take responsibility for supervised research using the device at a basic level. **Cognitive processes:** 

Include fundamental analytical levels.

#### PL4 Competences:

Take responsibility for an autonomous effective, safe and economic use of a medical device at the forefront of current professional practice within the scope of the profession as stipulated by national legislation and in a wide variety of clinical contexts including studies that are complex and unusual all totally guided by a best-evidence and ethical approach.

Take responsibility for contingency preparedness, basic device management, allocation of resources, modification/development of existing protocols and audits of practice, all guided by a best-evidence and ethical approach. Take responsibility for the implementation of research studies concerning new clinical applications of the device.

Participate in routine constancy testing of the device under written protocol as directed by the local biomedical physicist (or Medical Physics Expert or Radiation Protection Expert in the case of ionizing radiations).

### Cognitive processes:

Include analytical, metacognitive and self-system thinking levels.

### PL5 Competences

Take responsibility for a quasi-complete utilization of the scientific knowledge base underpinning the effective, safe and economical use of a medical device in the clinical and research contexts within the scope of the profession as stipulated by national legislation including clinical service development, health technology assessment and the conceptualization, design and implementation of new device applications and user protocols. Cognitive processes:

Include analytical, metacognitive and self-system thinking levels.

curriculum content and allow for diversity hence permitting adjustments to support local curricular targets.

# 3.2. A generic biomedical physics learning outcomes inventory for the HCP based on BMP content identified in the survey and documentation

A practice-oriented, comprehensive, structured inventory of generic (here meaning medical device and HCP independent) BMP learning

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outcomes was developed to guide BMP educators in the determination of syllabus content. The inventory is attached as an Appendix to this article and is designed to ensure that BMP learning encompasses both the physicist's rigorous approach to devices and the practice-oriented educational requirements of the HCP. It was considered essential to avoid the extremes of excessive physics detail on one hand or superficiality on the other which often afflict BMP curricula for the HCP. The inventory is structured as follows: the first column lists the statements of the learning outcomes whilst the second column contains explanatory notes. The order of the learning outcomes is in order of increasing complexity and is intended to guide sequencing during curricular delivery. The best practice guiding principles pointed to the need for a multi-level inventory consisting of device-independent learning outcome statements. The aim of the device-independent nature of the learning outcomes is to circumvent the perennial curriculum development problems of future coverage (that is trying to predict which medical devices students may need to learn about in the future and to what depth) and early obsolescence as conventional medical devices are replaced by newer ones. The proposed inventory was stratified into five proficiency levels (PL) which are PL1 to PL5, where PL5 represents the highest level of educational and professional achievement; a higher level assumes acquisition of learning outcomes at lower levels. Such a framework would guarantee usability throughout the European area and at all levels. It permits flexible curriculum development yet be structured enough to guide curriculum development in a systematic manner.

The operational descriptions of the proficiency levels are shown in Table 1. The descriptions are based on a pragmatic and judicious blend of cognitive, experiential, and career-progression paradigms that incorporates aspects of the proposed cycle descriptors of the EQF [4], the Bloom, Gagne and Marzano taxonomies [12-14] and Benner's noviceto-expert model [15] all of which have been extensively cited in the literature. These frameworks offer complementary perspectives on professional competence and it was considered beneficial to mesh their better aspects into a single set of level descriptors. The benefits of integrating such stratification paradigms in the case of professional education in general have been discussed in the literature and ensure a level structure that would be acceptable to educationalists, professional bodies and employers alike [16]. The levels were formulated in a language to make them easily modifiable to be HCP specific as this would be more desirable at the operational level in the actual teaching environment. In this inventory, levels PL1 to PL3 generally correspond to levels 1 - 6 of the EQF (EQF level 6 is the Bachelor Level), PL4 to EQF level 7 (Masters level) and PL5 to EQF level 8 (research or professional doctorates and high level specialization and sub-specialization levels). Nevertheless it is essential to emphasize that the level of proficiency required at each level varies tremendously across Europe. Very significantly, the nature of the proficiency level structure makes it possible for a particular programme to include different devices at different levels of proficiency according to national and local requirements. An example of the use of such proficiency levels at a very early stage in the research project can be found here [17].

# 3.3. A generic curriculum development model for the teaching of BMP to HCP

The curriculum development model we are proposing is based on the total quality service approach to curriculum design as proposed by Divoky and Taylor [18] (based on client HCP requirements, quality

measurements and on-going design improvements) and the well-established Harden curriculum development model [19,20]. The model can be used as a framework for curriculum development, evaluation, and reform. The process is generic in the sense that it can be applied to curriculum development for any medical device (and any associated physical agents) and any HCP. The model is designed to provide structure, direction, cohesiveness and harmonization; however, it is important to keep in mind that curriculum development needs to be tailored to the national or indeed even local situation.

The main steps in the proposed curriculum development process are:

- a) Research the learning needs of the particular client HCP to ensure relevancy of content. In particular, it is important to avoid the attitude that the physics knowledge and skills for HCP are simply a watered-down version of those for physicists. Every profession has its unique role and characteristics that should be respected.
- Identify those HCP competences which include a significant number of BMP knowledge and skill learning outcomes falling within the remit of the BMP educator as expressed in the mission statement of the BMP. Although many research techniques are possible to carry out the identification of these competences, perhaps the most reliable is documentary analysis. Modern published curricular documents are often the results of well-conducted research studies and wide consultations among various stakeholders and therefore have the advantage of relevance and of being relatively free from individual biases and opinions. Such documents also have the practical advantages of being condensed, easy to use, readily available and inexpensive. Therefore, when time is of the essence, the authors recommend a documentary analysis of the particular HCP educational and role development literature and any relevant EU, national and local legislation associated with the devices and associated physical agents. Well-written documents written by specialized taskgroups and educational and role development research articles in the literature of the particular HCP are ideal sources of KSC data. Such documents should be analyzed from a functional analysis perspective. It is suggested that the Tuning learning outcomes inventories for the particular HCP would be the first documents to analyze if these are available as these documents offer a pan-European perspective, followed by local HCP educational programme benchmark statements and legal requirements. Other methodologies, apart from documentary analysis, can be used for identifying HCP competences (e.g., surveys, focus groups and consensus building methods such as the Delphi and nominal group techniques) however they are often time-consuming, can be expensive to carry out and may entail logistical problems. On the other hand, such techniques become essential when no documentation has yet been developed; in such cases particular attention needs to be given to issues of bias through choice of suitable multi-stakeholder participants [21,22]. The outcome of this step in the process would be a proposal for the consideration of the HCP consisting of a list of devices and an estimate of the proficiency level required for each device.
- c) Communicate your proposal to the educational programme leader (European, national or local according to context) of the HCP asking for feedback. The outcome of this step in the process would be an assessment of the level of HCP satisfaction with the proposal. Revise your proposals according to feedback and iterate if necessary. The final outcome of this step in the process would be a multi-stakeholder constructed and approved document. The results can be converted to

- publishable educational research through the employment of established consensus generating research techniques provided enough time and researchers are available. Examples of comprehensive research studies using such methodologies can be found here [22].
- d) Use the Generic Biomedical Physics Learning Outcomes Inventory to identify the BMP knowledge and skill learning needs for each particular HCP and for each specific device and proficiency level. BMP educators should translate the generic knowledge and skills in the inventory to device-specific knowledge and skills formulated according to the scope of practice of the particular HCP. These device-specific knowledge and skills would then determine syllabus content. The outcome of this step in the process is a syllabus for each medical device used by the particular HCP and at the required proficiency level.
- e) Pool common cross-device syllabus content to avoid repetition and save on curriculum time. Consider also pooling across HCP disciplines as this would create opportunities for shared learning opportunities and use of shared terminology for HCP as well as improving efficiency by freeing unnecessary teaching time which can be used for alternative BMP activities.
- f) Identify local FMHS preferred methods of curricular content organization (outcome-based, theme-centered, problem-centered, case-based etc.), determine desired weighting of breadth versus depth of content, sequencing of content, techniques for curriculum delivery (lecture-based, small group-based, tutor-led, student-led, team-teaching, eLearning, independent learning, problem based learning, inquiry based learning, flipped learning and others) and student assessment methods.
- g) Collect curriculum delivery resources and evaluate them in terms of suitability.
- h) Set measurable programme key performance indicators for assessing the quality of curricular delivery, keeping in mind that the concept of quality in education is complex and requires considerable reflection to ensure that suitable indicators are adopted.
- Evaluate the programme via measurement of the performance indicators and modify the design iteratively for continuous quality improvement.

# 4. Discussion

The strong characteristics of the curriculum development model proposed in this article are the use of proficiency levels and the comprehensiveness of the structured learning outcomes inventory. These characteristics make the curriculum model applicable over the whole span of HCP education from the undergraduate years to postgraduate specialization, sub-specialization, academic and professional doctorate and continuous professional development (CPD) programmes. Indeed the PL and learning outcomes inventory structures are designed to distance future curriculum development from the haphazard nature that has so often dogged BMP curricula for the HCP. Indeed the learning outcomes inventory provides a structured continuum which is applicable both inside and outside traditional university faculty structures including educational and training activities provided by agencies such as national government agencies or professional associations. It is highly advisable to complement the use of the genric curriculum model with the use of any specific documents regarding medical devices and physical agents that may be available which are targeted towards specific professions. There are unfortunately few of these available but an example of just such a document was published by the European Commission in 2014 regarding protection from ionizing radiation ('Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union' Radiation Protection Series, No

175). It is important to emphasize that the curriculum model is aimed at users of medical devices and not those who would say simply use the outputs of such devices. Hence for example family physicians are users of thermometers, sphygmomanometers, pulse oximeters, and small portable ultrasound scanners but although they may need to refer their clients to medical imaging departments they do not acquire the images themselves and hence are not users of such devices. In the case of nonusers relevant elements from the knowledge learning outcomes from the inventory should be used. For example in the case of ionizing radiation, European directive 2013/59/EURATOM (article 18(4)) does state that "Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools." However, one should note that in the case of small dental clinics, dental surgeons do acquire images themselves and therefore should be considered as users. It is crucial to note that although the authors of this article pro-actively encourage that the BMP curriculum for the HCP should be developed with the leaders of HCP educational programmes, the responsibility for the quality of the curriculum content and delivery as well as the assessment must remain with the BMP educator as the expert in the field. It is the experience of the authors and of observations during the survey that when this was not the case the quality often deteriorated.

# 5. Conclusions

The construction of discipline-specific KSC inventories and curriculum development models such as the one presented in this article for BMP education for the HCP is essential for the systematic development and delivery of practice-oriented curricula. These inventories, among other uses, should function as a checklist to ensure that all essential learning outcomes are included within the curriculum and that all are assessed. The curriculum development model may be used irrespective of whether the curriculum is discipline-based or integrated, presentation-based or problem-based. The structures of the inventory and curriculum development model make them ideally suited for use by BMP involved in European curriculum development initiatives not only at the level of initial qualification but also as a tool for structuring and supporting lifelong learning activities in the context of on-the-job training of HCP. Hence, the proposed inventory can be used also in the context of the European Credit System for Vocational Education and Training (ECVET) and any corresponding linking of the ECVET to the EQF. Further research is suggested with respect to student performance criteria that would be tagged to the learning outcomes. This would enable the inventory to be converted into a robust tool for purposes of student assessment and programme evaluation. Another area of research would be investigating the pedagogical techniques for optimal content delivery and in particular how to address the perennial problem of the very low and often heterogeneous level of basic physics (and mathematical) knowledge and skills among HCP.

# **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.

# Appendix

# Appendix

#### Generic Biomedical Physics Learning Outcomes Inventory for the Healthcare Professions

It is important that the level of detail of physics knowledge and skills taught to a particular healthcare profession corresponds to the legal clinical role of the particular healthcare profession and should not go beyond this. In particular, in order to avoid inter-professional conflict one should avoid teaching any physics related to the roles of other healthcare professions, including that of Medical Physicists. Having said this it is important to refer briefly to the role of Medical Physicists in order to heighten awareness and appreciation of the role among the non-physics healthcare professions.

#### Learning outcomes

K = Knowledge (facts, principles, theories, practices); S = Skills (cognitive and practical);

C = Competence (responsibility and autonomy)

#### **Explanatory Notes**

**Illustrative syllabus content** supporting the knowledge or skill in the case of CT scanning for diagnostic radiographers

# Proficiency Level 1 (PL1)

K1. Describe the purpose of the use of the device in terms of the physical properties, structure or function of the tissues, organs, body fluids, etc. which the device seeks to measure, correct, replace etc. including any quantities impacting these properties. Physical properties of tissues can range from temperature, pressure, concentrations, linear x-ray attenuation coefficient, spin density, diffusion coefficient .... Remember, a device can have more than one purpose and different levels of use. Which purposes and levels of use are relevant to the particular healthcare profession at this level in the local situation? If the background of the students in physiology is weak it may be necessary to also address the necessary biophysics e.g., cardiac biophysics for the ECG/EKG.

A CT scanner is an instrument that measures the linear attenuation coefficient of a 3-D slab of patient voxels and converts these values to a CT number in Hounsfield units and into an image using a look-up-table. Tissue contrast is defined as the difference in the linear attenuation coefficient of different tissues. This is to be distinguished from image contrast that is difference in grey-scale level on a monitor. CT number is a function of electron density (atom density and atomic number) and beam energy (kV, filtration). One should here distinguish between the different uses of a CT scanner in diagnostic and interventional radiology, nuclear medicine (PET/CT) or radiotherapy and focus on the learning needs of the particular learner group.

K2. Explain the desired target outcomes relevant to clinical effectiveness in the use of the device in terms of appropriate quality criteria. In the case of instruments this can be expressed in terms of target accuracy and uncertainty; imaging equipment image in terms of desired contrast, noise level, sharpness (however keep in mind that imaging devices are really instruments where the measured physical data is visualized as an image so instrumentation concepts such as accuracy are important); different therapeutic devices would each have their particular quality criteria.

Examples of image quality criteria for CT are visualisation, reproduction and visually sharp reproduction of anatomical structures and pathologies of interest [23].

K3. List and explain the associated risks from physical agents associated with the device to patients, self, workers and the general public from use of the device and target safety criteria. Physical agents include ionizing electromagnetic radiation (X-ray, gamma and particle beams), nonionizing radiations (radio-frequency, IR, visible, UV, lasers), particle beams, mechanical (e.g., vibration), electrical, acoustic, ultrasonic, electrostatic and magnetic fields, elevated body temperatures. Example of target safety outcomes can be diagnostic reference levels (DRLs) in the case of imaging with ionizing radiations, SAR levels for magnetic resonance imaging, thermal and mechanical indices for ultrasound, doses to organs at risk etc.

Target safety criteria with respect to the patient include doses at or below diagnostic reference levels (and ideally optimized) and no damage to eyes from localization lasers. Target safety criteria with respect to the user are: zero to very low occupational dose (and ideally ALARA) and as in the case of electrical equipment avoidance of electric shock hazards.

K4. List and operationally define suitable device performance indicators appropriate for users of the device and their relation to target quality or safety criteria. A performance indicator is a measurable objective quantity that presents an indication of the extent to which a device is performing as it should, when compared to agreed standards. Performance indicators are associated with one or more quality or safety criteria. Such indicators should be restricted to those directly relevant to the clinical situation. In the case of instruments include basic instrument science concepts: accuracy (trueness and precision) [24], SNR, uncertainty, instrument resolution etc. In the case of imaging device accuracy, spatial and tissue contrast resolution are critical.

Examples of performance indicators associated with image quality criteria for CT are: spatial resolution (in line pairs per cm, avoid LSF, MTF), pixel noise, contrast resolution, accuracy of CT-value of water and associated precision (standard deviation), uniformity and absence of artefacts and distortion. Performance indicators associated with patient dose criteria are: CTDIvol and dose length product. Examples of relationships between performance indicators and image quality or safety criteria: spatial resolution and sharpness, noise and contrast, dose length product and patient effective dose.

K5. Describe and explain the general structure and functioning of the device including user determined settings. Use schematic and flow diagrams to aid understanding of how different parts are related to the overall functioning of the device and user settings. Include only necessary details, in particular avoid circuit diagrams. These are rarely necessary and tend to be off-putting to healthcare professionals. Emphasize that user settings may be manufacturer, model and purchase options specific (including post-purchase modifications).

Avoid unnecessary physics details such as different generations of CT scanners, internal structure of scanner, details of reconstruction algorithms, interleaving, z-interpolation etc. User determined settings are: scan type (sequential/spiral), kV, noise index, scan field of view, pitch, beam collimation, mAmax, mAmin, gantry angle, reconstruction algorithm. Include the advantages of retrospective choice of reconstruction increment in the case of spiral CT.

K6. Explain aspects of device design which impact performance indicators and hence quality or safety criteria at a level appropriate for users Consider each performance indicator in turn and list the device design variables that impact the particular performance indicator. Focus on those variables that can be adjusted by the user e.g., focal spot size in the case of projection radiography.

The main device design variables which impact spatial resolution in the scan plane are focal spot size, detector size (in lateral and axial directions), focus to detector distance, minimum focus to isocentre distance, maximum reconstruction matrix size, minimum reconstruction field-of-view size, number of projections per rotation, availability of image filters.

(continued on next page)

condition for subsequent use by self or others.

# Generic Biomedical Physics Learning Outcomes Inventory for the Healthcare Professions

It is important that the level of detail of physics knowledge and skills taught to a particular healthcare profession corresponds to the legal clinical role of the particular healthcare profession and should not go beyond this. In particular, in order to avoid inter-professional conflict one should avoid teaching any physics related to the roles of other healthcare professions, including that of Medical Physicists. Having said this it is important to refer briefly to the role of Medical Physicists in order to heighten awareness and appreciation of the role among the non-physics healthcare professions.

$\label{eq:continuous} \begin{split} \textbf{Learning outcomes} \\ K &= \text{Knowledge (facts, principles, theories, practices); S} &= \\ \text{Skills (cognitive and practical);} \\ C &= \text{Competence (responsibility and autonomy)} \end{split}$	Explanatory Notes	Illustrative syllabus content supporting the knowledge or skill in the case of CT scanning for diagnostic radiographers
K7. Explain basic limitations of the device and their impact on performance indicators (and hence outcome quality or safety criteria) at a level appropriate for users.	Include artefacts, defined as systematic discrepancies between the actual outcomes and desired target outcomes.	CT artefacts: ring, beam hardening, windmill, zebra and stair-step artefacts, metal artefacts, out-of-field artefacts. Main limitations of CT: assumes circular objects (whilst patient is oval), motion artefacts owing to finite rotation speed.
K8. Explain qualitatively the physical principles underpinning facility design, protective barriers, utilization of personal protective equipment, shielding as applied to the protection of patients, self, workers and others when the device is in use.	Personal Protective Equipment (PPE) fall under REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016.	Qualitative explanation of physics of facility design, protective barriers, personal protective equipment and patient shielding in CT.
K9. List and explain use protocol design variables (including appropriate device settings, use of protective accessories and personal protective equipment related to physical agents) which impact performance indicators (and hence clinical outcome quality or safety criteria) at a level appropriate for users	From a device perspective, protocols are designed to ensure that device performance indicators are not degraded, to reduce the effects of the limitations of the device and eliminate or reduce risk to all concerned. It is important to realise that attempts to improve one performance indicator may lead to degradation of another and/or an increase in risk.	Example: the main protocol design variables which impact spatial resolution in the scan plane are focus to isocentre distance, reconstruction matrix size, reconstruction field-of-view size, application of bolus around patient. Important to discuss trade-offs e.g., attempts to increase scan plane spatial resolution by reducing the reconstruction field-of-view or increasing the reconstruction matrix size will lead to an increase in pixel noise and lowering of contrast resolution which may necessitate an increase in mA and hence DLP. Similarly, use of high-frequency filters for increasing edge sharpness will increase pixel noise.
K10. Discuss benefit-risk issues qualitatively.	Every device provides benefits to patients but also risk to the patients themselves and possibly the user, staff and others. Although BMP educators should focus on benefits and risks from physical agents associated with the device, one should expand the discussion to other risks such as those arising from inappropriate use, ineffective quality control of the device, environmental factor effects on the functioning of the device.	CT is a high dose technique. Special care in justification and optimisation is necessary particularly for children and for pregnant women and interventional procedures.
K11. Explain user options for at least one commercially available device	Explain with the help of the user manual so that students become familiar with reading manuals. Important to emphasize that settings are often manufacturer, model and purchase option specific (including post-purchase modifications).	Go through selected relevant sections in the user manual of a CT scanner.
K12. Explain the need for carrying out daily quality control of the device before first use.	In the case of Diagnostic and Interventional radiology, Nuclear Medicine and Radiation Oncology the quality control tests and device care procedures would be specified by the Medical Physics Expert in the particular specialty. In the case of MRI these would be determined by the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.	Certainly, measurements of the CT number of water using a water phantom.
K13. Compare qualitatively the device with devices of similar function in terms of clinical effectiveness and safety.		Qualitative discussion about the relative diagnostic effectiveness and safety of CT with respect to other imaging modalities for detecting a particular pathology in a given region of the patient's body from a physics perspective.
S1. Demonstrate effective and safe use of the device in a simulated practice skills-lab context from a physics perspective.		Suggest assessment is carried out by a team made up of a radiographer and medical physicist.
S2. Demonstrate ability to apply commonly used post- utilisation procedures for enhancing quality or safety outcomes.		Examples would include windowing, zooming, basic image post-processing, and application of edge enhancing or smoothing filters.
S3. Demonstrate the ability to carry out basic daily quality control (daily constancy tests) of the device before use, to care for the device during use and to leave the device in a condition for subsequent use by self or others	In the case of Diagnostic and Interventional radiology, Nuclear Medicine and Radiation Oncology the quality control tests and device care procedures would be specified by the Medical Physics Expert in the particular	Demonstrate ability to measure the CT number of water using a water phantom.

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specified by the Medical Physics Expert in the particular specialty. In the case of MRI these would be determined by the Medical Physics Expert having duties as Magnetic

Resonance Safety Expert.

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#### Learning outcomes

K = Knowledge (facts, principles, theories, practices); S = Skills (cognitive and practical);

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#### **Explanatory Notes**

Illustrative syllabus content supporting the knowledge or skill in the case of CT scanning for diagnostic radiographers

# Proficiency Level 2 (PL2)

- K1. List and explain the physical basis of any contraindications in the use of the device with patients.
- K2. Describe the impact on performance indicators arising from common device malfunction, inappropriate protocol, device misuse, patient factors, facility design, environmental factors and combination of such factors including any artifacts arising from these within their scope of practice and local procedures for reporting such malfunctions.
- K3. Demonstrate knowledge of regional (e.g., EU), national, local and institutional legislation, recommendations, regulations and documentation regarding the use of the device.
- K4. Demonstrate understanding of the physical principles underpinning the effective and safe use of any ancillary medical devices.
- S1. Demonstrate strict adherence to written protocols when using the device with patients in studies that are basic, routine and predictable.
- S2. Demonstrate safe disposal of non-reusable medical devices.
- S3. Demonstrate ability to read and record recommended indicators of risk (e.g., ionizing radiation dose surrogates, SAR levels in MRI, thermal and mechanical indices in ultrasound) and compare the latter to established national reference levels.

### Proficiency Level 3 (PL3)

- K1. Explain the physical mechanisms underpinning procedures which would extend the functionality of the device to studies which are more complex or somewhat non-predictable.
- S1. Demonstrate performance of PL1 and PL2 skills at a level that would require minimum supervision when using the medical device with patients, scope of practice widened to include studies that are complex or somewhat non-predictable.
- S2. Demonstrate ability in carrying out weekly and/or monthly quality control procedures appropriate for users
- S3. Demonstrate understanding of and ability to follow written contingency procedures following an adverse event when using the device.

Patient factors include anatomical (e.g., patient size), physiological (e.g., insufficient skin preparation in ECG, muscle tremor in EEG) and psychological (e.g., anxiety in MRI) factors. Facility design factors include power failures, room size and design, equipment layout, protective barriers and light fittings. Environmental factors include elevated temperatures and humidity. electromagnetic interference and other devices in the

room.

Software is considered as an ancillary device.

Including any basic calculations necessary to adjust the protocol to particular client groups.

For example, contaminated vials and syringes.

In the case of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology risk indicators would be specified by the Medical Physics Expert in the particular specialty. In the case of MRI these would be determined by the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.

The studies which would be considered 'more complex or somewhat non-predictable' would be determined according to the healthcare needs of the local population.

In the case of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology the quality control tests would be specified by the Medical Physics Expert in the particular specialty. In the case of MRI these would be determined by the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.

In the case of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology the applicable contingency procedures would be specified by the Medical Physics Expert in the particular specialty. In the There are no absolute contraindications for CT.

For example, not ensuring patients are centered would be inappropriate protocol in CT.

EU directive 2013/59/EURATOM considers CT as a high dose procedure

Article 61 Special practices

1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure:

(c) involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, COMPUTED TOMOGRAPHY or radiotherapy. Special attention shall be given to quality assurance programmes and the assessment of dose ... for these

For example, contrast media injectors (explain increased linear attenuation coefficient of contrast media), ECG for gated studies, PACS, image viewing and post-processing software.

For example, strict adherence to scan-start and scan-stop locations, patient centering in the gantry, specified adjustments of exposure parameters to obese patients etc.

Safe disposal of non-reusable contrast media injector syringes.

Demonstrate ability to read the dose report of a CT scan and record values of CTDIvol and DLP. Compare these values to national diagnostic reference levels (DRL).

The tests which would be appropriate for users of the scanner will be determined by the local Medical Physics Experts.

Explain local contingency plans relevant to accidental or unintended exposures in CT.

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#### Learning outcomes

K = Knowledge (facts, principles, theories, practices); S = Skills (cognitive and practical);

**Explanatory Notes** 

**Illustrative syllabus content** supporting the knowledge or skill in the case of CT scanning for diagnostic radiographers

C = Competence (responsibility and autonomy)

Proficiency Level 4 (PL4)

- K1 Explain PL1 to PL3 BMP knowledge to a level expected of a user at the forefront of current professional practice with a comprehensive scope of practice in a wide variety of clinical contexts including studies that are complex and unusual all totally guided by a best-evidence and ethical approach.
- S1. Demonstrate BMP based PL1 to PL3 skills to a level expected of a user at the forefront of current professional practice with a comprehensive scope of practice in a wide variety of clinical contexts including studies that are complex and unusual all totally guided by a best-evidence and ethical approach.
- S2. Demonstrate ability to contribute to the formulation of procurement plans for the device in association with the other professionals involved in the procurement process.
- S3. Demonstrate ability to identify and correct causes of below-target quality and safety criteria appropriate for users and recognition of instances when such should be referred to physicists.
- S4. Demonstrate physics knowledge utilization in adjusting protocols to the needs of particular clients in studies which are complex and unusual.
- S5. Demonstrate ability to participate in the conduct of risk assessment, the development of contingency procedures and the creation of a safety culture in association with other professionals.
- S6. Demonstrate ability to liaise with physicists in the development of clinical services (device and risk management, clinical outcome quality improvement, clinical audits).
- S7. Ability to apply physics knowledge and demonstrate the scientific attitude necessary for full effective, safe and economical use of the device in the coordination and implementation of clinical and research programmes.

# Proficiency Level 5 (PL5)

- K1. Explain the underpinning physics (including the basic supporting mathematical) knowledge necessary to envisage new clinical and research applications for the device within own scope of practice.
- S1. Demonstrate PL1 to PL4 skills for a higher utilization of the scientific knowledge base underpinning the effective, safe and economical use of a device in the clinical and research contexts including clinical service development.
- S2. Demonstrate the ability to liaise with physicists in the conceptualization, design and implementation of new device applications and user protocols.

case of MRI these would be determined by the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.

The studies to be considered 'complex and unusual' should be determined according to the healthcare needs of the local population.

In the case of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology the ability to liaise with the Medical Physics Expert in the particular specialty; in the case of MRI liaise with the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.

for overly obese patients and others who do not fit in the maximum scan field of view of the scanner, uncommon pathology or trauma or very low tissue contrast pathologies, CT angiography, interventional, virtual endoscopy, multiplanar reformatting etc.

Important that the user is made familiar with the most

exposure control systems (e.g., mA modulation systems)

Physics necessary for adjustment of the automatic

Important that the user is made familiar with the most important physics technical terms in order to be able to liaise with Medical Physics Experts in the CT procurement process.

This ability should be assessed directly on actual images of below-target image quality and dose reports.

In the case of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology the ability to liaise with the Medical Physics Expert in the particular specialty; in the case of MRI liaise with the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.

In the case of Diagnostic and Interventional radiology, Nuclear Medicine and Radiation Oncology the ability to liaise with the Medical Physics Expert in the particular specialty; in the case of MRI liaise with the Medical Physics Expert having duties as Magnetic Resonance Safety Expert.

The emphasis here is on a complete *scientific* attitude to devices. How can one get the most out of this device yet still keep risk to acceptable levels?

Basics of the mathematics for a higher level of understanding of the use of the device, with emphasis on those aspects required for any particular research project. Important that the user is made familiar with the most important physics technical terms to be able to participate in the conduct of risk assessment, the development of contingency procedures and the creation of a safety culture in association with other professionals particularly Medical Physics Experts.

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S3. Demonstrate the ability to recognize ethical and economic issues regarding the device in research and service development initiatives.  S4. Demonstrate the ability to participate with other professionals in a healthcare technology assessment of the device.	Examples are quantitative risk-benefit analysis, equitable use of resources, and importance of making full use of the capabilities of a device.	

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