The role of biomedical physics-engineering in the development of medical device education for the healthcare professions

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Introduction

Biomedical physics-engineering involves the development of medical devices and their effective, safe and efficient application in the clinical milieu. Modern healthcare relies heavily on the twin pillars of pharmaceutical and medical device technology. Unfortunately, whilst pharmaceutical education has been given a lot of attention in healthcare professional curricular development, medical device education has been sorely lacking. Meanwhile, the array, variety and complexity of medical devices have been increasing rapidly with the swift advances in technology. On the other hand, as device education has not kept pace so have underutilization of devices and the number of instances of improper and unsafe use.

Legal definition of a 'medical device'

The EU medical device directives define a medical device as "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" (EC, 1993).

This definition is very broad and the list of medical devices ranges from simple tongue depressors and thermometers, to stethoscopes, hepatitis test kits, contact lenses, breathalyzers, heart valves and pacemakers, physiological monitoring devices, x-ray imaging machines and the complex intricacies of MRI scanners and radiotherapy accelerators.

The role of biomedical physics-engineering in the development of medical devices - a historical perspective

The importance of the contribution of physics-engineering to healthcare has a long history. As long ago as 1856, Fick edited a book called 'Medizinische Physik' whilst Brockway published a book with the title 'Essentials of Medical Physics' in 1891. However the influence of physics in medicine registered a quantum leap after the discovery of x-rays by Roentgen (1895) and radioactivity by Becquerel (1896). Stieve (1991) reports that the first two x-ray laboratories were established in Berlin in 1896, one at the Institute of Orthopedics and Pneumotherapy of a certain

Dr Max Immelmann - only one year after the discovery of x-rays. Immelmann also promoted the 'Roentgenvereinigung' consisting of 14 medical doctors, physicists and engineers. The first chairperson of this first 'Roentgen society' was Walter Wolf, a physicist (Stieve, 1991, citing Goerke, 1980). The first radiological society in England was formed in 1897 - that is only 2 years after the discovery of x-rays, and the first president was Silvanus Thomson, a professor of physics. The developments in the first ten years were mostly in radiodiagnosis. The involvement of physicists in radiotherapy started in 1910 (Stieve, 1991). Stieve citing Cook (1972) states that the first full time physicist in radiotherapy was employed in 1912 in the radiotherapy department of a hospital in Munich. From then onwards, the involvement of physicists-engineers in medicine increased rapidly. The first society of medical physicists (the Hospital Physicists' Association, UK) was set up in 1943. The first comprehensive medical physics text was the three volume encyclopedia 'Medical Physics' by Glasser (1944 -1960) who listed 23 domains of medicine which required close collaboration between physicists-engineers and medical specialists. Laufman (2002) who has reviewed the role of engineering in medical progress cites in detail the milestone contributions of Roentgen in radiology, Bovie in electrosurgery and Greatbatch in implantable cardiac pacemakers. Today medical physics and engineering play a part in all areas of medicine. Established areas are continuously being developed and new areas emerging (Sharp & Perkins, 2000). The future holds devices for biomolecular, cell, tissue and organ engineering, optical imaging, nano-instrumentation and lab-on-a-chip systems for laboratory and home diagnostics (Griffith & Grodzinsky, 2001). Indeed medical physics and engineering have come a long way since those early days of radiodiagnosis and radiotherapy! The advice of a biomedical physics-engineer is today considered essential in ensuring effectiveness, safety and efficiency in the adoption of new medical devices (Bergmann, 2003), and regulatory bodies are increasingly making the presence of a biomedical physics-engineer mandatory in various areas of healthcare. For example, EC Directive 97/43/Euratom regarding the use of ionizing radiation in healthcare states that:

> *"In radiotherapeutic practices, a medical physics expert shall be closely involved. In standardized therapeutical nuclear medicine practices and in diagnostic nuclear medicine practices, a medical physics expert shall be available. For other radiological practices, a medical physics expert shall be involved, as appropriate, for consultation on optimization including patient dosimetry and quality assurance including quality control, and also to give advice on matters relating to radiation protection concerning medical exposure, as required."*

Scales (1965) emphasized the importance of collaboration between the disciplines of biology, medicine, physics and engineering, whilst Adelstein (2001) in describing the development of radioiodine studies of the thyroid makes the remark that "the cooperation between physicists and physicians that made their accomplishments possible stands as a model example for interdisciplinary collaboration".

The role of biomedical physics-engineering academics in the development of medical device education for healthcare professionals

Although there have been many instances of interdisciplinary collaboration between biomedical physics-engineering practitioners on one side and healthcare professionals on the other in the clinical and research environments, and although most biomedical physics-engineering organizations e.g., European Federation of Medical Physics (1984), European Society for Engineering in Medicine (2006) do speak of the importance of the educator role with regard to the healthcare professions within their policy documents, there is very little published evidence regarding such activities. The references that do exist are mainly confined to undergraduate medicine, radiography, radiation therapy, and the postgraduate medical specializations of radiology and radiotherapy. There are very few instances of published work for the other healthcare professions and such studies are long overdue. For example, although there is a biomedical physics-engineering component in most physiotherapy undergraduate courses in Europe, curriculum development in the area is practically inexistent. Again Wilkes & Batts (1996) acknowledge that nurses' understanding of the physical science component of the knowledge underpinning nursing competences is very inadequate.

Biomedical physics-engineering curricula in courses of medicine

Biomedical physics-engineering education for medical students has had a long and chequered history. Hayter (1996) describes the work of J. K. Robertson, professor of physics teaching at the Queen's University Faculty of Medicine in Canada in the years 1909 to 1951. Robertson started teaching medical students in 1909 at a time when the physics component in the medical curriculum was minimal. The number of lectures was two per week for a single term and concerned general non-applied physics (mechanics, properties of matter, heat, light, sound, electricity and magnetism) with some laboratory work added in 1911. Robertson considered this inadequate and following an intra-mural report regarding the inadequacy of instruction in the uses of radiation and radioactivity in medicine instituted a course entitled 'X-Rays and the Physics of Electro-Therapeutics' as an option for final-year medical students also with a frequency of two sessions per week. A second objective of the course according to the same report would be to ensure that future physicians would be able to make informed decisions regarding the purchase and use of such equipment. The course was very comprehensive and also included radiation doses, radiation protection and a comparison of various forms of devices. However this course was not a success. The reasons given by Robertson were two. First, he found that students who had learned their electricity and magnetism in the first year course of physics had forgotten everything by the final year. Secondly, final year students perceived that this final year course would be similar to the non-applied first year course and preferred to attend classes in areas directly relevant to their clinical practice. Robertson solved the problem by convincing the faculty to move the final year course to the second year of the course. He then transformed this second year course into a combination of scientific principles with clinical practical application in a single course. Robertson stressed the applications of physics as opposed to pure theoretical principles and used a lot of demonstrations as opposed to chalk-and-talk methods. Hayter considers that Robertson's second year course combining pure and clinically applied physics in one course "challenged the linear, rigidly structured medical curriculum of the day, with its strict separation of basic and applied science" and that Robertson himself considered his work as an experiment in medical education. Hayter quotes Robertson's advice to fellow physicists:

> *"The physicist who teaches medical students should recognize that the mental approach to a scientific subject by those whose primary interest is medicine is not the same as that of the physicist and he should govern himself accordingly" (Robertson, 1954).*

> Hayter finally affirms that:
> "Robertson's success in this endeavour was based largely on two factors: his sympathetic understanding of the needs of medical students and his innovative combination of basic and applied science in one course - factors that are as important to medical teaching today as they were 50 years ago".

Fasce et al. (2001) report an interesting attempt at introducing problem-based-learning and team-teaching in the physics teaching of medical students. First year medical students were separated into two groups, one group being taught in the traditional manner and the second group using problem-based-methods by a team of physicists, a biochemist and three medical doctors.

The European Federation of Medical Physics has published a syllabus for medical undergraduates. This syllabus, confined in scope to radiation protection issues only (Dendy, 2005), was the response of the federation to a call by the European Commission that "Member states shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools" (EC Directive, 97/43/Euratom, Article 7).

Of particular significance is an appeal by Mornstein (2005) for biomedical physics-engineering educators to include many more lectures on medical devices apart from established topics like molecular biophysics, biophysics of perception, and microscopy in their curricula for medical students. The author particularly is of the opinion that principles of biosignal instrumentation and processing should be considered as fundamental.

At the moment there is a biomedical physics-engineering component in medical student curricula in practically all European countries (the only exceptions being the UK and Malta).

Biomedical physics-engineering curricula in radiography programmes
Physics has been included in the curriculum for radiographers since the beginning of formal radiography education. Snelling (1963) speaks of "an estimation of the necessity for physics in the training of the radiographer". This seems to have led to a symposium on the subject (Franklyn, 1964) and finally a basic syllabus (Mussell, 1965). The College of Radiographers, United Kingdom (2003) includes sections on 'physical sciences' and 'technology' in its curriculum framework for radiography. However given the of necessity broad nature of the document further specification is required to produce learning outcome competence statements that are directly usable in the educational environment. Most schools of Radiography publish a locally developed physics syllabus under such diverse names as 'radiation physics', 'principles of radiation science', 'imaging equipment', 'imaging science and instrumentation', 'radiation protection' and others (Price, High, & Miller, 1997) but there is no evidence of a systematic and studied approach. At the moment there is a strong biomedical physics-engineering component in radiography curricula in all European countries.

Biomedical physics-engineering teaching in radiation therapist programmes
Radiotherapy is an area in which physicists and other healthcare professions have worked together in a concerted and systematic manner and on a European scale to produce curricula and educational

materials. An extensive curriculum development programme has been carried out as part of the project ESQUIRE (**E**ducation, **S**cience and **Q**uality **A**ssurance for **R**adiotherapy) which is run under the auspices of the European Society for Therapeutic Radiology and Oncology (ESTRO) and financed by the EC (Europe Against Cancer initiative). Important outcomes of the project included endorsed guidelines for European core curricula for all three professions within radiation therapy i.e., medical physicists, radiotherapists and radiation therapists (Heeren, 2005). The project led to a European core curriculum for radiation therapists which included a physics component (Coffey, Vandervelde, Van der Heide, Adams, Sundquist & Ramalho, 1997). A revised version has an improved biomedical physics-engineering component under the headings of 'physics' and 'equipment' (Coffey, Degerfalt, Osztavics, Van Hedeld, & Vandervelde, 2004). A weakness of the curricula is that they are not outcome competence based (as required by the Bologna process) but simply present a list of topics to be covered. At the moment there is a very strong biomedical physics-engineering component in radiation therapist curricula in all European countries.

Biomedical physics-engineering curricula in the postgraduate specializations of radiology and radiotherapy

In 1989, The Committee on Training of Radiologists of the American Association of Physicists in Medicine, published the results of a survey conducted among recently certified radiologists regarding their perceptions of radiological physics training and the importance of the various physics topics included in the radiological physics curricula at the time. The most important results of the survey for this study were the following:

(a) 72% of the respondents had a negative opinion of physics as presented in their programs at the time, however, the same percentage continued to attend physics training even after graduating and notwithstanding the fact that they were not obliged to do so for certification reasons! This clearly indicated that "radiologists actually do consider physics to be a worthwhile endeavor".

(b) The respondents indicated that they would have liked to have "an emphasis on subjects that are directly relevant to everyday practice" as they felt that "although they acknowledged the need for an understanding of basic physics principles, they clearly perceived that theory had been overemphasized". The respondents wanted a greater emphasis on those topics relevant to the production of quality images and means of reducing radiation doses to patients.

The results of the survey triggered a discussion that has gone on unabated in some form or another since then. Saba & Poller (1999), argued that it is indeed the superior knowledge that radiologists have of physics that gives radiologists an edge over other clinicians who attempt to read medical images, as medical images are "a combination of both anatomical and physical information" and that the "anatomic and physical information form an inseparable unit". Moreover:

> "It is the job of the radiologist to combine his knowledge of anatomy, disease, and image production in formulating an interpretation. If one of these elements is missing, the interpretation is at best incomplete, if not incorrect. This is what

> happens when a clinician who has a thorough knowledge of the specific anatomy and disease process attempts to interpret radiologic images without an understanding of image production".

Saba & Poller then go on to give several convincing examples of the misdiagnoses that can occur through an inadequate knowledge of imaging physics. Balter (1992) echoes similar sentiments in saying that "radiologists may be able to use their equipment in a safer and more effective manner than would be possible without such knowledge".

Frey (Frey, Dixon, & Hendee, 2002) in a point-counterpoint discussion argued that owing to the pressures on radiologists' learning time only physics knowledge that is derived from the clinical practice should be taught. This has the advantage of demonstrating directly the relevance of physics knowledge. The best educators of physics for radiologists and by extension all healthcare professions are those who have both physics and clinical knowledge, as the physicist must "translate" the physics to the clinical situation. Another advantage of this approach is that the student is more likely to retain the material after graduation. But perhaps the greatest advantage is that this approach "preserves the image of the physicist as possessing valuable and occult knowledge" and that when complex situations arise in their practice the radiologists would feel the "need to consult with their medical physics colleagues". Dixon countered these arguments by saying that it is more important to use the time available to build firm broad conceptual foundations as there are physical concepts which though not relevant at the time of learning could become relevant later in particular with the rapid expansion of technology. He cites as example the case of magnetic resonance imaging (MRI) by saying "in the 70s who would have thought that nuclear spins would play any role in radiology?"

Current developments in biomedical device education for the healthcare professions at the IHC

Biomedical Physics at the IHC is taking a leading role in researching and developing biomedical device physics curricula for the healthcare professions at the European level. Our research programme over the last four years has resulted in seven research papers (Caruana & Plasek, 2006a, 2006b, 2006c, 2005a, 2005b, 2004a, 2004b) and several presentations at international meetings. Learning outcome competence inventories (in the format required by the Bologna process) for biomedical device physics education in Europe have already been published for diagnostic radiography, nursing and medicine (Caruana & Plasek, 2006a, 2006c, 2005a). These were developed following a survey of healthcare professional curricula across Europe and an in-depth study of associated themes gleaned from the professional literature (e.g., role development in the various professions). Inventories for other health professions are in the pipeline. The European Federation of Medical Physics has invited the author of this article to set up a European Special Interest Group to work with other healthcare professional groups to produce suitable European curricula for them. Through a collaboration with the Faculty of Medicine and Healthcare, University of Brno, Czech Republic (which houses all the healthcare professions under one roof) the unit 'Principles of medical device science' offered at the IHC and currently undertaken by B.Sc. Radiography and B.Sc. Medical Laboratory Science students will this year be further developed so that it can be offered as a shared cross-disciplinary unit to the other healthcare professions at both the IHC and the Faculty of Medicine. The Department of

Biomedical Physics at Brno has one of the best-developed student medical device laboratories in Europe. This collaboration would lead to the first systematically researched shared cross-disciplinary medical device curriculum in Europe. The resulting papers will be presented at the first European Conference on Medical Physics organized by the European Federation of Medical Physics in Pisa, Italy in September 2007.

References

Adelstein, S. J. (2001). Robley Evans and what physics can do for medicine.
Cancer Biother Radiopharm, 16(3), 179-185.

Balter S. (1992). Why (continue to) study physics? *Radiographics*, 12(3), 609.

Barnes, J. E., Berry, P. C., & Dennis, M. J. (1999). *Report 64: a guide to the teaching of clinical radiological physics to residents in diagnostic and therapeutic radiology.* Madison WI, US: Medical Physics Publishing.

Bergmann, H. (2003). The need for independent physics advice. *Eur J Nucl Med Mol Imaging,* 30(4), 491-493.

Brockway, F. J. (1891). *Essentials of medical physics.* London: Saunders.

Caruana, C. J., & Plasek, J. (2006a).
An inventory of biomedical imaging physics elements-of-competence for diagnostic radiography education in Europe.
Published in the journal *Radiography* (Elsevier), 12(3), 189-202. doi:10.1016/j.radi.2005.07.005

Caruana, C. J., & Plasek, J. (2006b).
A SWOT audit for the educator role of the biomedical physics academic within Faculties of Health Science in Europe.
Proceedings of the Groupe International de Recherche sur l'Enseignement de la Physique (GIREP) Conference 2006. Modeling in Physics and Physics Education. Amsterdam, Netherlands. ISBN Not yet available.

Caruana, C. J., & Plasek, J. (2006c).
An initial biomedical physics elements-of-competence inventory for First Cycle nursing educational programmes in Europe.
Proceedings of the Groupe International de Recherche sur l'Enseignement de la Physique (GIREP) Conference 2006. Modeling in Physics and Physics Education. Amsterdam, Netherlands. ISBN Not yet available.

Caruana, C. J., & Plasek, J. (2005a).
A biomedical physics elements-of-competence inventory for undergraduate medical education in Europe.
Proceedings of the 14th International Conference of Medical Physics, Nuremberg, 2005. Published in *Biomedizinische Technik* Vol 50 Supplementary vol.1 Part 1. ISSN 0939-4990

Caruana, C. J., & Plasek, J. (2005b).
A systematic review of the biomedical physics component within undergraduate medical curricula in Europe.
Proceedings of the 14th International Conference of Medical Physics, Nuremberg, 2005. Published in *Biomedizinische Technik* Vol 50 Supplementary vol.1 Part 2. ISSN 0939-4990

Caruana, C. J., & Plasek, J. (2004a).
Generic learning objectives in the domain of medical device physics
Proceedings of the Groupe International de Recherche sur l'Enseignement de la Physique (GIREP) Conference 2004. Teaching and learning physics in new contexts. Ostrava, Czech Republic. ISBN 80-7042-378-1.

Caruana, C. J., & Plasek, J. (2004b).
An initial set of exploratory case studies regarding the role of the biomedical physics-engineering educator as practiced in health science faculties in Europe
Proceedings of the Groupe International de Recherche sur l'Enseignement de la Physique (GIREP) Conference 2004. Teaching and learning physics in new contexts. Ostrava, Czech Republic. ISBN 80-7042-378-1.

Coffey, M., Degerfalt, J., Osztavics, A., van Hedeld, J., & Vandevelde, G. (2004)
Revised European core curriculum for RTs. *Radiotherapy and Oncology*, 70, 137-158.

Coffey, M., Vandevelde, G., van der Heide Schoon, R., Adams, J., Sundqvist, E.,
Ramalho, M. (1997). The European core curriculum for radiotherapy technologists. *Radiotherapy and Oncology,* 43, 97-101.

College of Radiographers. (2003). *A curriculum framework for radiography.* London: CoR.

Committee on Training of Radiologists, American Association of Physicists in Medicine. (1989). Radiologic physics instruction for diagnostic radiologists: results of an opinion survey. Committee on Training of Radiologists, American Association of Physicists in Medicine. *Am J Roentgenol.,* 152(2), 393-7.

Cook, H. F. (1972). *Medical Physics - past, present and future. WHO / IAEA seminar on the Education and Training of Medical Physicists* (Kiel, 10-22 April 1972). Geneva: WHO.

Dendy, P. P. (2005). *Radiation protection in the basic curriculum of medical students.* Retrieved April, 8, 2005, from EFOMP website: http://www.efomp.org/docs/ear_syll_stud.html

EC. (1997). Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. *Official Journal* L 180, 09/07/1997, pp. 0022 - 0027.

EC. (1993). Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. *Official Journal* L 169, 12/07/1993, pp. 0001 - 0043.

European Federation of Medical Physics (1984). *Policy Statement Nr. 2: The Roles, Responsibilities and Status of the Clinical Medical Physicist.* Retrieved *March, 20, 2006,* from EFOMP website: http://www.efomp.org/policy/policy2.html

European Society for Engineering in Medicine. (2006). The Goals and Mission of ESEM. Retrieved March, 20, 2006, from ESEM website: www.esem.org

Fasce, E., Calderon, M., Braga L, De Orue, M., Mayer, H, Wagemann, H, & Cid, S. (2001). Problem based learning in the teaching of physics to medical students - Comparison with traditional teaching. *Rev Med Chil,* 129(9), 1031-1037.

Fick, A. (1856). *Medizinische Physik. Supplementband in Muller-Pouillet's Lehrbuch der Physik fur Mediziner.* Braunschweig: Vieweg.

Flexner, A. (1910). *On Medical Education in the United States and Canada.* New York: Carnegie Foundation for the Advancement of Teaching.

Franklyn, P. P. (1964). Physics in the training of radiographers - a symposium. *Radiography,* 30, 252-254.

Frey, G. D., Dixon, R. L., & Hendee, W. R. (2002). Point-Counterpoint. Physics concepts that cannot be explained from a clinical context should be omitted in physics courses for radiologists. *Med Phys*, 29(2), 255-256.

Glasser, O. (1944 -1960). *Medical Physics Vol 1 - 3*. Chicago: Year Book Pub.

Goerke, H. (1980). *Funfundsiebzig Jahre Deutsche Rontgengesellschaft*. Stuttgart: Gg Thieme.

Griffith, L. G., & Grodzinsky, A. J. (2001). Advances in biomedical engineering. *JAMA*, 285(5), 556-61.

Hayter, C. R. (1996). Physics for physicians: integrating science into the medical curriculum, 1910-1950. *Acad Med,* 71(11),1211-7.

Heeren, G. (2005). The bright but ephemeral life of a rainbow. A chronicle of seventeen years of intensive ESTRO-EU cooperation. *Radiotherapy and Oncology*, 75 253-257.

Laufman, H. (2002). Are engineers unsung heroes of medical progress?: the historic bond between physics, engineering, and medicine. *Biomed Instrum Technol,* 36(5), 325-334.

Mornstein, V. (2005). Medical biophysics yesterday, today and tomorrow. *Scripta Medica (Brno),* 78(4), 203-204.

Mussell, L. E. (1965). Physics in the training of radiographers: a basic physics syllabus. *Radiography*, 31, 61-64.

Price, R., High., J, & Miller, L. (1997). *The developing role of the radiographer: issues affecting the future curriculum.* London: University of Hertfordshire.

Robertson, J. K. (1954). An experiment in medical education: Thirty third Silvanus Thompson memorial lecture. *Br J Radiol,* 27, 593-603.

Saba, P. R, & Poller, W. R. (1999). Physics for radiologists: now more than ever! *Acad Radiol,* 6(5), 261-263.

Scales, J. T. (1965). Collaborating disciplines: biology and medicine-physics and engineering. *Br Med J,* 5459, 470-472.

Sharp, P. F., & Perkins, A. C. (eds.). (2000). *Physics and engineering in medicine in the new millennium*. York: Institute of Physics and Engineering in Medicine.

Snelling, O. D. (1963). An estimation of the necessity for physics in the training of the radiographer. *Radiol Technol,* 36, 302-8.

Stieve, F. E. (1991). Medical physics, in the past, today and in the future--the development of medical physics from the point of view of a radiologist. *Phys Med Biol,* 36(6), 687-708.

Wilkes, L. M., & Batts, J. E. (1996). Nurses' understanding of physical science in nursing practice. Nurse Education Today, 18, 125-132.