The Application of CDIO Standards to Clinical Engineering Education

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ABSTRACT

The task of clinical engineers is the operation, monitoring and maintenance of medical equipment in hospitals. Specifically, they are involved in cardiac and endoscopic surgery, cardiac catheter treatment, cardiac pacemakers, artificial respiration and blood purification therapy, and emergency medical care, amongst other tasks. Required skills involve, but are not limited to, communication skills, decision-making ability and expedient responsiveness.

The curriculum in the new clinical engineering department at Hokkaido Information University (HIU) consists of both medical education (including anatomy and pathology), and engineering education (including basic electrical engineering). Students are provided with an optimal workspace, appropriate medical simulations, and small-group education in an environment conducive to active learning. Hands-on training is conducted in a dedicated clinical engineering practice room, using appropriate medical equipment and/or simulations. The focus is not only on learning the correct response through simulating normal and abnormal situations, but also on how to develop problem solving skills, adopt a team approach, and acquire communication skills.

There is also an ongoing effort to develop an appropriate evaluation method and measure learning outcomes. Furthermore, it is recognized that an amalgam of basic education and practical training, forming an integrated curriculum, is fundamental to the design of the course. In addition, in order to fortify the students' integrated learning, extreme importance is attached to linking theoretical and practical exercises as well as establishing a collaborative system with clinical engineers working in hospitals. The application of the CDIO framework and associated standards to clinical engineering education seems both viable and valuable.

KEYWORDS

Clinical Engineers, Clinical Engineering Education, Practical training rooms, medical simulators, CDIO Standards: 2, 3, 6, 8

INTRODUCTION

Providing on-campus practical training using medical equipment for students enrolled in a clinical engineer training course has significant meaning as it allows an opportunity in a safe environment to learn fundamental equipment principles, operation and troubleshooting techniques. However, there is no binding rule concerning the content and extent, which is left largely to the discretion of each training institution. Methods and training systems vary depending on the school and it is difficult to verify that sound, systematic on-campus practical training is provided for all students (Suzuki, 2017).

This implies that such practical training potentially provides the opportunity for students to develop necessary skills while learning about equipment operation methodology in a clinical situation. As Itoh (2014) notes, social and communication skills of medical personnel are declining, and clinical engineers who work in medical care teams also need to improve such skills while still in training (Itoh, 2014).

In order to address these issues and ensure that skills are being appropriately learned, this paper investigates the feasibility of applying CDIO standards, fast becoming the global standard of engineering education, to clinical engineering education (Takemata, Minamide & Matsuishi, 2011). The main focus will be placed on practical training in the university, in addition to the design and consolidation of educational practice methods.

ROLE OF CLINICAL ENGINEERS IN JAPAN

The work of clinical engineers is defined by the Japanese CET (Clinical Engineer Technologist) Act as the "operation, management and maintenance of life support equipment" (Ishida, Hirose, Fujiwara, Tsuruta & Ikeda, 2014, 329). Such “life support equipment” or “life support systems” refer to devices whose purpose is to replace and/or assist part of the function of human respiration, circulation or metabolism (JACE, 2012). Specifically, examples include artificial heart-lung machines used in cardiac or cardiovascular surgery, artificial respirators that assist respiratory function, or artificial dialyzers which replacing kidney function. Clinical engineers also deal with many other additional medical treatment modalities and biometric devices.

With the qualification of clinical engineer not being introduced in Japan until 1987 (Komasawa, 2005, 50), and specific guidelines on work content being based on the "Clinical Engineer's Operational Guidelines", issued by the Health Policy Bureau, Ministry of Health and Welfare in September 1988 (JACE, 2012), it can be seen that almost 30 years have passed since national clinical engineer regulations came into effect. However, due to advances in medical technology, medical devices have diversified and become more sophisticated, and the role played by clinical engineers in medical care has moved to more of a multidisciplinary team approach. In October 2010, the Joint Clinical Engineering Committee, composed of the Japan Clinical Engineers Association and other professional societies, formulated the "Basic Clinical Engineer's Operational Guidelines - 2010" (JACE, 2012).

The revised guidelines categorize 11 tasks that fall within the ambit of the clinical engineer: respiratory treatment, heart-lung machine operation, blood purification, surgical area assistance, intensive care support, cardiovascular catheter treatment, hyperbaric oxygen therapy, monitoring and care of defibrillators, pacemaker and implantable defibrillators, and general medical device management. Work is further categorized temporally as pre-treatment, immediate, peri-treatment and post-treatment.

The guidelines further add that the "clinical engineer (should) be fully aware that the role of the specialized medical technician concerns the operation, maintenance and management of life support device(s)" (JACE, 2012), and that the "Clinical engineer closely cooperates with doctors and other medical personnel as a member of the medical team to constantly monitor the condition of the patient and to provide medical treatment that responds exactly to the needs of the patient" (JACE, 2012). This means that clinical engineers are not engineering experts who are only familiar with medical devices, but medical professionals who combine knowledge and skills of medicine and engineering, and are able to provide appropriate medical care to patients. It means that the clinical engineer is a member of a multidisciplinary medical team, with concrete tasks that need to be carried out skillfully and efficaciously.

CURRENT STATUS AND PROBLEMS IN CLINICAL ENGINEERING EDUCATION

Education related to the training of clinical engineers is stipulated by rules and regulations issued by the National Clinical Engineering Skills Training Center (JACE, 2012). As such, the curriculum, syllabus, learning contents, necessary facilities (such as classrooms, training rooms, and equipment), and other peripheral requirements are largely controlled.

In order to satisfy the requirements needed to sit the national examination for clinical engineers, the Ministry of Health, Labor and Welfare, stipulates that graduating students must have completed at least 101 credits in 25 designated subjects. Among them, students need to have obtained a basic understanding of the principles, structures, and configurations of medical devices used clinically in the field of medical device science, including the biological function of surrogate devices, the scientific theory of medical and biometric devices, medical device safety management, and the requisite practical knowledge and skills related to proper and safe usage and maintenance.

Appendix 2 of the Operational Guidelines (JACE, 2012) shows machinery and equipment that should be typically available to the training institution. Stipulated devices include a ventilator, an artificial heart-lung machine, an auxiliary circulation device, a hemodialysis machine, a pacemaker, a defibrillator, an electric scalpel, a patient information monitor and infusion pumps.

As such, both the name of the subjects that need to be included in the clinical engineering training courses, and the medical devices that should be accessible to the training facility are clearly specified. However, neither the teaching method for each subject, nor the content of a required hospital internship are specified, being left to the discretion of each training school, institution or host hospital.

Results from a questionnaire by the Japan Clinical Engineers Facility Council (Suzuki, Kudo, Kotaka, Nakahata, Tsukao, Ikenaga, Nakajima, & Kimura, 2017) investigating educational practices concerning the teaching of skills related to life support devices yielded several interesting results and comments. One common theme referred to the effect of employment status of faculty members on teaching quality and experiential knowledge. As few full-time faculty seem to have had actual experience working as clinical engineering technicians, there is a possibility that adequate skills or information may not be correctly conveyed to students, especially before internships. A second issue concerns access to medical equipment for hands-on training. While most training institutions reported having heart-lung machines and various auxiliary circulation devices, access to other medical devices used by clinical engineers concerning circulatory therapy was seen to be remarkably low. This resulted in both a lack of on-campus practical training, and a deficit in experiencing various medical support devices. Still other institutions reported having problems with insufficient lecture time and text inconsistencies.

Prior research on the effect of clinical engineering practicums pointed out the importance of such experiential learning in terms of the attitude of students, the treatment of patients and the ability to communicate among medical professionals (Sasaki & Sato, 2012). Recently, the introduction of objective structured clinical examinations into clinical engineering education has been attempted at several universities (Aikawa, Watanabe, Sugawara, Shimizu & Yamamoto, 2016), which shows how clinical engineering education is evolving towards a professional multidisciplinary team approach.

STATUS AND CONTENT OF ON-CAMPUS PRACTICALS

Medical equipment operation and management

Since the major part of a clinical engineer's work is the operation and maintenance of medical devices, including life support equipment, learning and mastering basic operation skills is indispensable for every student. All students need to learn not only how medical devices function normally, but how they behave in crisis or abnormal situations. They also need to learn about the relative safety of such devices. Associated medical skills can only be developed through providing hands-on experience. This is especially the case with complex vital apparatus, such as heart-lung machines, ventilators and blood purification devices, and extreme importance is attached to students learning from the very basics to more difficult, applied situations. Correct safety procedures, maintenance principles and management of medical equipment is also best learned practically (See Figures 1 & 2)

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Figure 1: Operating Room

Figure 2: Human Simulator

Education and communication skills

In the "Clinical Practice Guidelines" prepared by the Japan Clinical Engineers Association in 2013 (JACE, 2013), a number of skills and qualities involving clinical practice are stressed as having extreme importance. They include: awareness of role in team, patient communication skills, medical safety measures, infection prevention procedures, and desirable traits as clinical engineers. As such, a broad approach is needed when trying to teach or augment skills generally required for medical staff. Things such as social skills and cooperativeness are just as essential as academic and technical skills, even in the preliminary stages of on-campus hands-on clinical training (Itoh, 2014).

CLINICAL ENGINEERING EDUCATION AT HOKKAIDO INFORMATION UNIVERSITY

Outline of clinical engineering education

Clinical engineering education at Hokkaido Information University (HIU) is a newly-introduced degree course. It currently consists of basic liberal arts subjects including foreign languages, mathematics and physics, and more specialized subjects related to medicine, medical information, and medical engineering. Of the latter group, in the practical subjects, students experience using various types of medical equipment in biomedical instrumentation exercises, biomedical equipment experiments, and an artificial organ practical. In addition to these practical courses, a lecture follows or precedes each practical. Students thereby gain basic theoretical knowledge in addition to experiencing practical training, which helps them in acquiring the necessary skills for a clinical engineer. Medical equipment handled in the practical training phases include a wide variety of devices such as heart-lung machines, ventilators, artificial dialysis machines, auxiliary circulation devices, electric scalpels, defibrillators, ultrasonic diagnostic devices, electrocardiographs, biological information monitors and infusion pumps. The hands-on phase is comprehensive, and learning experiences include complex tasks such as how to rapidly respond to a patient's changing state, in addition to more basic items such as powering on the devices, connecting peripheral parts or making rudimentary settings.

On-campus practical training courses

The basic policy in clinical engineering practice at HIU is to give students as much access as possible to practical medical technology by creating environments that approximate actual situations that are liable to be encountered in medical institutions. New, up-to-date medical equipment and/or medical simulators are used to simulate various conditions that can occur in a clinical setting to help improve students' judgment and adaptive abilities. Emphasis is also placed on patient care and communication with other medical professionals, and exercises using either training dummies or more complex simulation mannequins, which respond according to their inbuilt sensors, are frequently used throughout the course. In the process, medical terms and procedures are appropriately introduced and learned.

Simulations in clinical engineering education

Medical simulation education, or hands-on experiential classes in a simulated environment using similar or identical equipment, has been widely used as an educational methodology with both medical practitioners and nurses, but its application in the clinical engineering field has been limited until recently.

A conspicuous difference between clinical engineering education and general engineering education is the presence and role of patients. While it is legally and ethically impossible for unqualified students to actively participate in the treatment of patients at medical institutions to learn and develop related practical skills, this can be remedied to some extent by effective simulation education, which allows students to learn in a safe environment using various medical simulators. This ensures the progress of the learner without compromising the patient, allowing both safe repetition and non-threatening failure. In the case of HIU, newly developed clinical engineering practice rooms serve as a clinical simulation center and allow various types of practical clinical engineering education to be carried out using medical simulators in a safe environment.

THE APPLICATION OF CDIO STANDARDS TO CLINICAL ENGINEERING EDUCATION

The application of CDIO standards to clinical engineering education represents a new approach to considering how clinical engineering may best be taught. As it is necessary to provide clinical engineering students with both the necessary theoretical abilities to successfully pursue their work, (skills related to medical knowledge and equipment, adaptability to situations, decision making ability) and human relations skills (teamwork, leadership, communication skills, ability to cooperate), the CDIO framework seems to offer an appropriate way to further advance education goals and skills in clinical engineering education (Takemata et al., 2011).

Standard 2 - Learning Outcomes

Clinical engineering faculty at HIU make a conscious effort to ensure effective practice by doing exactly what Crawley, Malmqvist, Östlund, Brodeur & Edström (2014, 51) recommend, setting “specific, detailed learning outcomes for personal and interpersonal skills, . . . (encouraging) product, process and system building skills, . . . (and ensuring) disciplinary knowledge, consistent with program goals”. This is shown below in Table 1, where targeted competencies in clinical engineering education are listed. The goal of each specialized subject is set according to the competency. Mastery of necessary clinical engineering skills is achieved not just by learning basic medical device operation, but by extending students to consider how settings may need to be changed to adapt to a patient’s situation or treatment needs. Communication with patients and other stakeholders is also vital to ensure meeting goals. Furthermore, as medical technology is constantly progressing, setting goals and evaluating learning outcomes in conjunction with a practicing clinical engineer will also help ensure validation of the program.

Table 1. Clinical engineering education competencies

Students should be able to apply basic medical knowledge and clinical knowledge stipulated as being necessary for clinical engineers.
Students are expected to be able to understand basic engineering skills necessary for clinical engineers and practically implement safe operation, management and maintenance of life support equipment and related treatment devices. They are also expected to be able to perform biometric measurement and have a sound understanding of medical information technology.
Students will need to have knowledge concerning the management process at medical institutions and an understanding of basic nutrition necessary for maintaining a patient's health. Communication skills will include the ability to convey information to, and obtain information from both patients and other members of the medical care team that the engineer may be working with.

Standard 3 - Integrated Curriculum

The content of the curriculum in clinical engineering courses is set and controlled by a government-advised nationally accredited body. For that reason, there is minimal flexibility in what is taught. There is, however, flexibility in how it is taught. It is important to design and implement a practical education curriculum where medical treatment equipment exercises and hands-on practicums are emphasized and linked to regular classroom theory. In addition, learning from practicing clinical engineers and undergoing off-campus clinical practice in a controlled environment at a hospital, implemented as a follow-up to on-campus programs, will lead to a more effective education.

Standard 6 - Engineering Workspaces

The clinical engineering practice room at HIU simulates an actual hospital environment. Most devices that a clinical engineer would control at a large hospital are provided, some being the genuine article, others simulations or working models. Students learn how to operation the various medical devices in a simulated environment, where either a sensor-fitted smart medical dummy or simulated program enables the students to feel real pressure as they would when working in an actual clinical environment. Table 2 shows medical devices and medical simulators available for hands-on use in the clinical engineering practice rooms.

The practical training rooms are divided into zones, related to the area being studied. In the emergency zone, students learn about such things as cardiopulmonary resuscitation for cardiopulmonary arrest patients, and how to interpret the various monitored data. In the intensive care zone, ventilator usage, information monitoring and emergency responses are covered. In the operating room zone, students take part in an artificial heart-lung simulation to learn how to operate a heart-lung machine during cardiac surgery. Each zone is relevant to a specified need, and students are motivated to learn by doing so in a realistic (but safe) setting.

Table 2. Medical devices and simulators in the clinical engineering practice rooms

Zone	Equipment	Zone	Equipment
Emergency Room	Multifunctional Human Simulator	Operating Room	Artificial heart-lung Machine
	Automated External Defibrillator		Cardioplegia Machine
	Defibrillator		Electric Scalpel
Intensive Care Room	Ventilator		Extra-corporeal Circulation Simulator
	Non-invasive Ventilator	Hemodialysis Room	Hemodialysis Machine
	Cardiopulmonary Support System	Cardiac Catheter Room	Coronary Intervention Simulator
	Intra-aortic Balloon Pumping	Clinical Examination Room	Electrocardiogram
	Vital Sign Monitor		Ultrasonography
	Infusion Pump		Thermography

	Pulse Oximeter		Laser Doppler Flow meter

Standard 8 - Active Learning

In clinical engineering practice, it is necessary for all students to repeatedly operate and practice using medical equipment. To maximize access to resources, it is also desirable to hold practical sessions in small groups. To this end, the clinical engineering practice rooms at HIU are designed to enable small group education. In addition, in order to deepen students' understanding, lesson design focuses on short lectures and ample opportunities to practice with the appropriate medical devices. By presenting various clinical scenarios and situations, students improve their ability to accurately assess and act upon a situation in an appropriate manner. The clinical engineering practice room is open at all times.

Conclusion

The goals of CDIO are to educate students who are able to master a deeper working knowledge of technical fundamentals, lead in the creation of new products, processes and systems, and understand the importance and strategic impact of research and technological development on society (Crawley et al., 2014, 13). These goals are very similar to the aims of the clinical engineering course at HIU, where the object is to graduate technically-able, knowledgeable students who are technologically savvy and eager to continue learning.

The CDIO approach provides the Clinical Engineering Department at HIU with an educational framework that better ensures that students learn necessary skills by establishing an appropriate process for systematic practice, consolidating an integrated curriculum, and allowing the improvement and evaluation of on-campus training. Despite being developed for engineering in general, CDIO standards appear to be suitable for application to clinical engineering education.

The essence of clinical engineering education involves acquiring a complex set of skills from an integrated curriculum, where students acquire hands-on medical equipment operation competency, based on a sound academic knowledge of medicine and engineering. A well-designed blend of classroom lectures and practical training is indispensable to this end.

Practical training focuses not only on standard procedures concerning the operation of medical devices, but also strategies on how to respond to abnormalities of patients and/or medical devices. Skills needed to make prompt decisions and problem solving strategies are also learned through prudent use of various medical simulators.

Also, as medical technology is continually progressing, the educational content and curriculum need to be constantly reviewed, and learning outcomes should be evaluated in terms of the original goals set. To that end, advice from practicing clinical engineers is indispensable, and coordination between medical and educational institutions is paramount.

While clinical engineering is possibly outside the original scope of education initially envisaged by CDIO, application of a number of the standards has been shown to be useful and appropriate in developing and unifying clinical engineering education. It is hoped that the framework can be further applied to improve the quality of education and ensure that future clinical engineers are equipped with the skills necessary for their work.

Final Thought

It is important to note that the CDIO framework has not been applied to clinical engineering education before, and represents a new approach. CDIO formalizes a number of practices, procedures and methodologies that have been loosely used throughout the university in various departments. Adoption of the framework is still very new, as is the clinical engineering program itself. To objectively evaluate the effectiveness of on-campus practical training, in addition to acquired skills and knowledge of students who learn under this framework, it may be beneficial to both monitor pass rates of national certification exams as well as develop an open communication network with hospitals, medical care facilities and other places of employment.
At this stage, it is difficult to document wins or difficulties, failures or successes for the simple reason that the program is still in its infancy. To fully evaluate how well outcomes are reached, further research is needed, and the clinical engineering program needs to be allowed to progress for a few years. The latter is especially important as the program is only in its second year, and no students have yet graduated. The authors look forward to following this up at a latter stage.

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