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VALUE-DRIVEN DESIGN OF A HIGH FIDELITY PART-TASK TRAINER FOR UPPER LIMB DISORDERS

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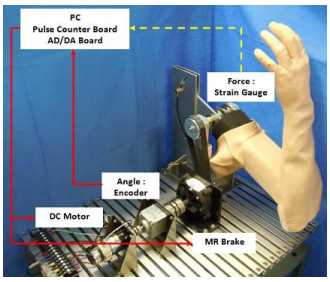
Graphical abstract



Abstract

This paper presents a model-based systems engineering (MBSE) approach to develop an upper limb spasticity part-task trainer for therapy training and clinical education. We adopt a value-driven design proposed by the American Institute of Aeronautics and Astronautics (AIAA) with the combination of specification technique CONSENS™ proposed by Heinz Nixdorf Institute as a framework to guide the team to optimize the perceived system value and the development process. As early as during the conceptual design phase, the specified system models take into considerations the Voice of Customer, the Voice of Business and the Voice of Technology to meet customer expectations, ensure cost effectiveness and enabling new functionality. Following such an approach, clinicians, therapists and engineers work together in order to develop an upper limb disorder part-task trainer which requires knowledge of mechanics, electric/electronics, control technology, software engineering, biology and human anatomy. As an education tool, the part-task trainer can multiply the frequency of novice therapy training at clinical training centres, medical schools and hospitals.

Keywords: Value-driven design, part-task trainer, spasticity, therapist education

1.0 INTRODUCTION

Physiotherapists coordinate and improve balancing of cardio-respiratory system and motor control for better quality of life, while occupational therapists assist people with rehabilitation to overcome disability caused by injury or illness to function in daily life activity.

Figure 1 illustrates the general career roadmap for a novice therapist from their bachelor degree towards board certified occupational therapist or physiotherapist.

However, in current therapy education, there is a concern in increasing frequency of training for novice therapists reported through questionnaire-based

survey by [1] regarding the reliability of the raters' evaluation.

It is reported 72% of the surveyed participants believed that the novice therapists needed a higher frequency of training before engaging with real patients during their 'clinical placement'. This concern is probably due to inter/intra raters variability in extension velocity of spasticity disorder [2].

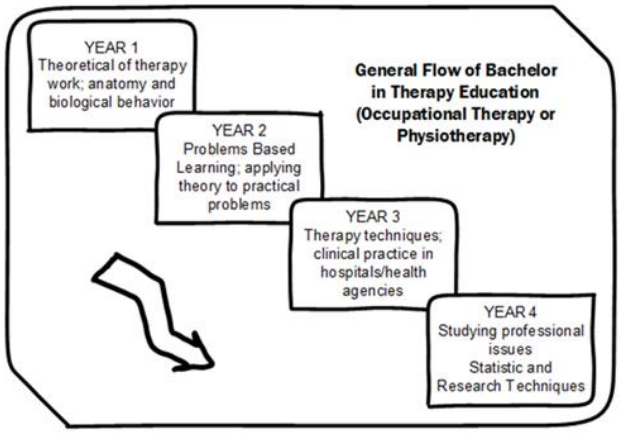


Figure 1 Illustration of study flow for bachelor degree in physiotherapy and occupational therapy

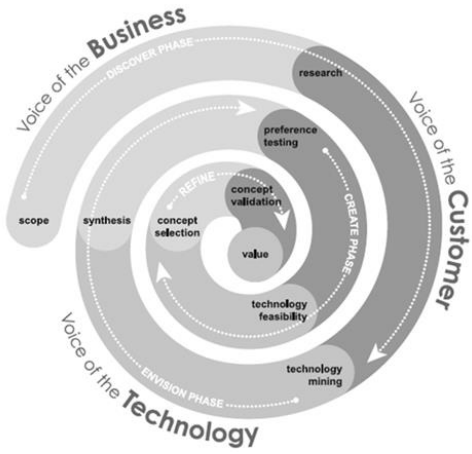


Figure 2 Illustration of Front End Product Development Process referring to [6]

Simulation in therapy education is not a new concept as it has been used in the medical field since over 50 years [3], following the aviation industry. Simulation creates a patient-free environment during pre-clinical training with repeated practice on specific skills, evaluation and decision making [4]. A report for the Health Workforce Australia National Simulated Learning Project indicated that fifteen of the sixteen universities are currently using Simulated Learning Program (SLP) consists of role playing, e-learning programs, low fidelity mannequins, part-task trainers, student/educators as Standardized Patient, medium fidelity mannequins, Standardized Patient actors, high fidelity mannequins, virtual reality and others in their pre-clinical education program [5].

It is reported in [7] that both medical students and must for all medical students. Further discussion has been done regarding ethical issue whether a simulation based education is acceptable from the perspectives of patients, learners, educators and society with the essence of protecting patients whenever possible [8]. Based on the reports above, it is highly significant to develop training simulators for all medical fields including therapy education to maximize training safety and minimize risk.

2.0 UPPER LIMB DISORDER PART-TASK TRAINER

The upper limb part-task trainer emulates the spasticity symptoms at various levels in compliance with the Modified Ashworth Scale and velocity dependent passive joint movement through the Modified Tardieu Scale. Referring to [9], the term upper limb disorder indicates the clinical effects of the tissues covering the region from the tips of fingers to the shoulder extending to the neck. It can be evaluated depending on the abnormalities sign when examined by a clinician. The disorder will affect the quality of life of a person or their caretaker. Spasticity is one of the upper limb disorders with velocity-dependent symptoms when passively stretched by therapists. Despite concerns on the reliability of the Modified Ashworth Scale [10] [11] , the assessment scale is highly applied in assessing patients with spasticity. Due to the high reliability on assessing upper limb disorder [12], the main objective of this innovation is to help the novice therapists to mastering the assessment scale by providing higher frequency of Modified Ashworth Scale and Modified Tardieu Scale [13] training with the implementation of a part-task trainer.

3.0 VALUE DRIVEN DESIGN

The value-driven design proposed by the American Institute of Aeronautics and Astronautics (AIAA) [14] helps balancing the needs of different stakeholders that have different perspectives in evaluating 'good' technologies. Developed based on the value driven design, the Front End Product Development Process for medical device innovation process [6] has been implement in this project. Figure 2 shows the illustrated Front End Product Development Process where various stakeholders are connecting at different levels of innovation process. Different perspectives from stakeholders guided the development team to achieve important value in the part-task trainer development without focusing on specific attributes which only limiting the product design space.

4.0 IDENTIFYING STAKEHOLDERS

Referring to Figure 2, stakeholders are composed into three different groups. For the development of part-task trainer as an education tool, the stakeholders have been identified (refer Table 1). The voices of novice therapists, physicians, and patients are considered as the Voice of Customer (VoC), supported by the education institution, the regulatory bodies (i.e., World Federation of Occupational Therapists-WFOT, World Confederation for Physical Therapy-WCPT) and the medical devices company who works as the representative of Voice of Business (VoB). These voices will then combine with current technology suggested by Voice of Technology (VoT); the Research and Development team and manufacturer vendors as well.

Our research team consists of rehabilitation physician and therapist, both are specialists in their respected area and at the same time giving lecture to the novice therapists. They are representing the Voice of Customer, giving knowledge and idea from their related perspectives. The engineers from mechanical engineering, software engineering and bioscience engineering works as the R&D team along with vendors in accomplishing the required prototype. Considering the Voice of Business; the ethics approval has been obtained from the Research Ethics Committee Universiti Teknologi MARA and the National Medical Research Register Malaysia.

Table 1 List of identified stakeholders

Voice of Customer	Voice of Business	Voice of Technology
Novice Therapists	Education Institution	R&D Team
Physicians, Therapists, Educators	Regulatory Bodies	Vendors
Patients	Government	

5.0 RESEARCH METHOD

The development process was divided into four phases as shown in Figure 3.

5.1 Discovery Phase

In this phase, it is important to extract the right information to form the basis of the research. We started with interviewing our collaborators; the therapist educator from the Division of Occupational Therapist, Tokyo Metropolitan University and the rehabilitation physician from the Faculty of Medicine, Universiti Teknologi MARA. Both educators were asked to discuss their opinions regarding current therapist education and the additional learning tool that could help in their practice. As a result, we have decided to conduct a questionnaire-based survey [1] to collect opinions from therapists and their institutions randomly regarding current therapy education and their opinion concerning part-task trainer as an education tool as reported in the Introduction section. At the same time, the R&D Team was conducting literature review on current technology related to part-task trainer education tool. From time to time, the engineering team seeks consultation with the rehabilitation physician and the therapist educator concerning current practices in therapy education and methods to quantify upper limb disorders characteristics.

5.2 Envision Phase

In the envision phase, the directions of the project has been discussed. The discussion was applying the specification technique CONSENS™ introduced by [15] [16] to define design specification. The upper limb part-task trainer for education tool has been developed previously in [17] before considering various stakeholders' voices. Thus in this phase, we have decided to improve the objectives applying other specifications details. This specification technique CONSENS™ is illustrated in Figure 4 provided a basic concept that could be shared with related stakeholders in each level. System objectives, requirements, functions, shape [18] and active structure of the part-task trainer has been build. Figure 5 shows functions of upper limb spasticity part-task trainer. Main functions are segregated into three functions cut-out; the ability of accurately simulates spasticity symptoms, to be able to emulates human arm trajectory and to provide human-like characteristics to avoid incongruity to the device. One of the details of functions cut-out has been published in [19]. Information flow and needs from stakeholders' voices is described in the active structure illustrated in Figure 6 [20]. Clinical database collection was supported by Voice of Business in order to emulates continuous and loosing stiffness of spasticity symptoms needed by the Voice of Customer. Overall part-task trainer hardware and software development is completed by the R&D team from the Voice of Technology.

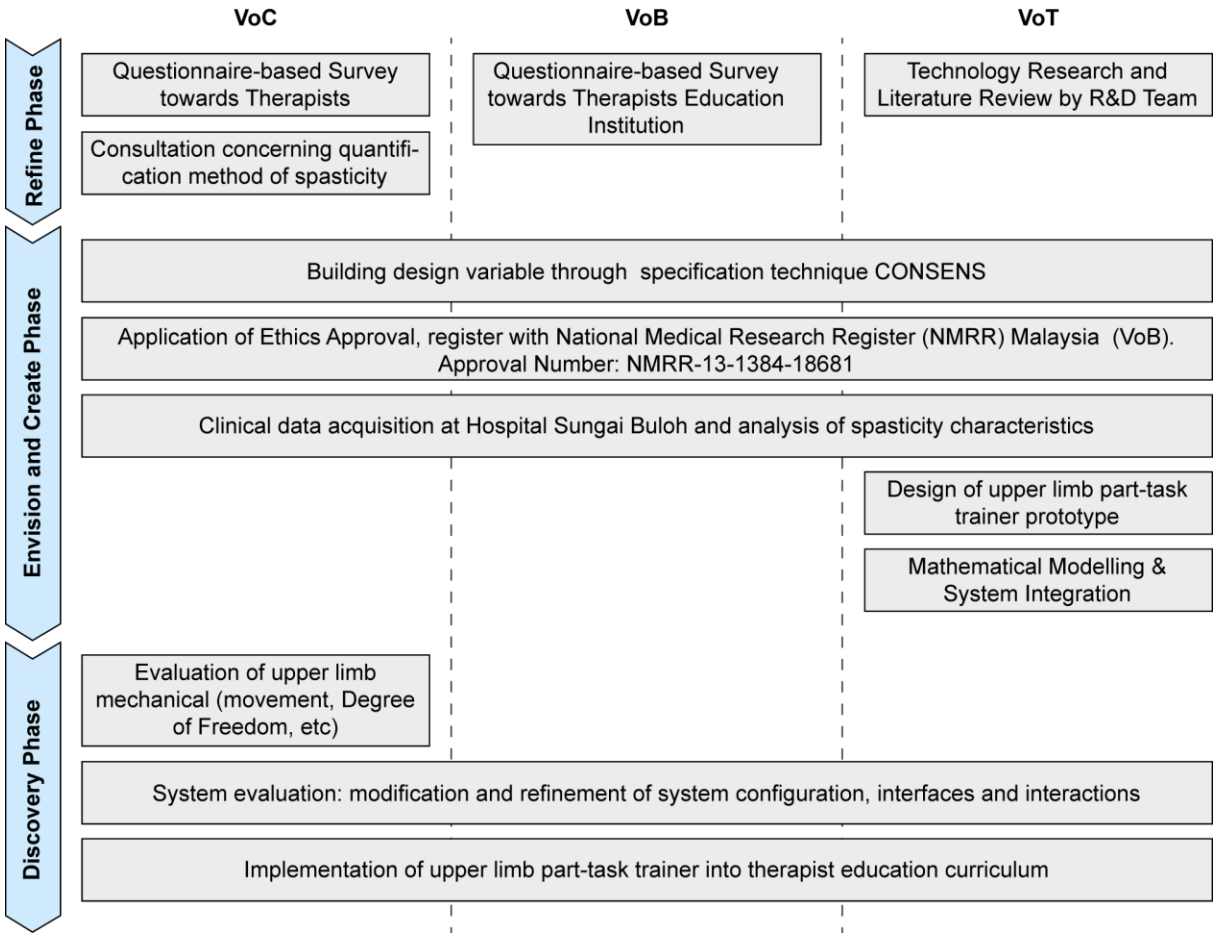


Figure 3 Research activities based on the stakeholders' voices throughout the design process

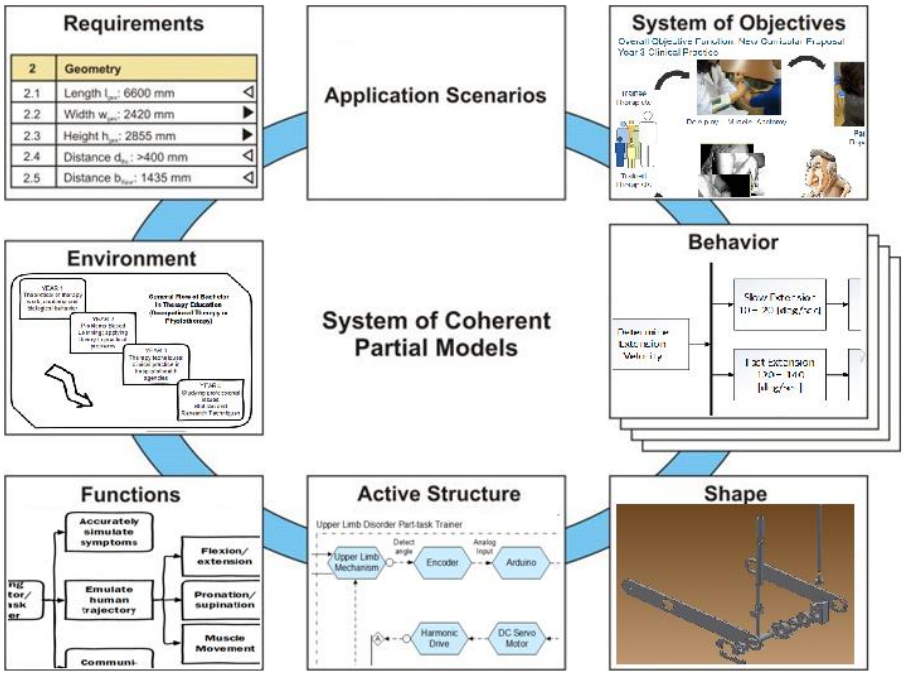


Figure 4 Partial models for the domain-spanning description based on the specification technique CONSENS™

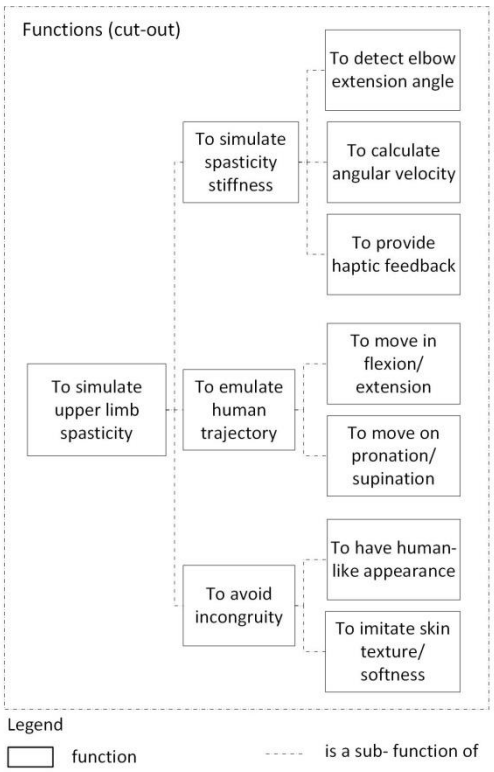


Figure 5 Functions of upper limb spasticity part task trainer built based on the specification CONSENS™

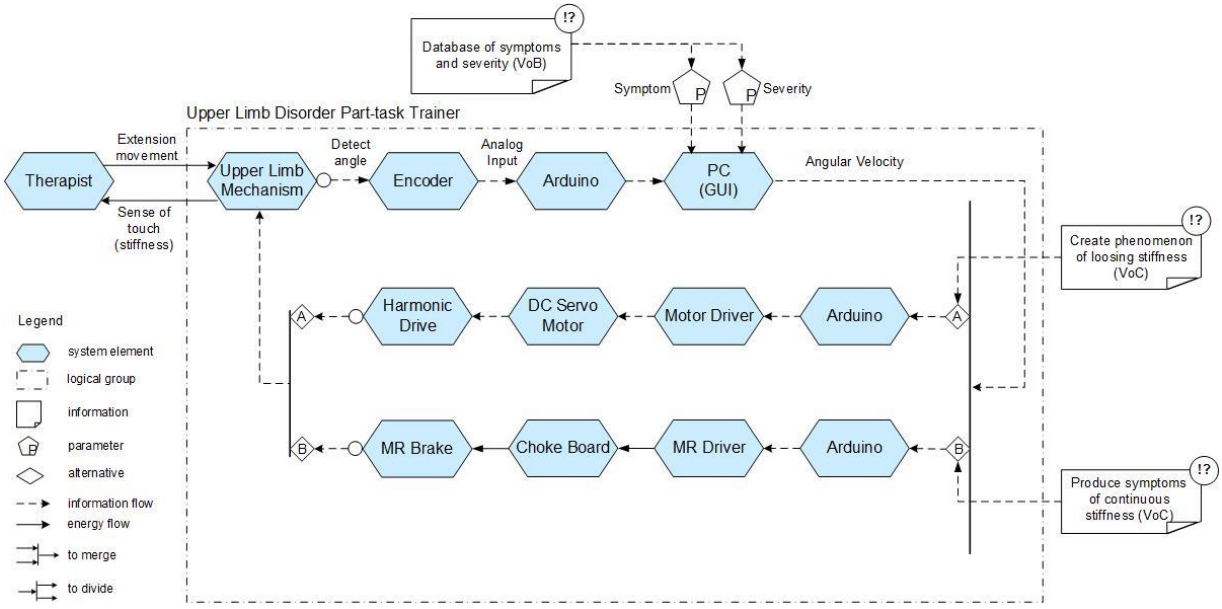


Figure 6 Specification of the active structure taking into account stakeholder's voices

5.3 Create Phase

In this phase, by referring to the information from the specification technique CONSENS™, the previous prototype has been improved. With the purpose of improve the part-task trainer; a set of clinical data is necessitating in developing a mathematical modelling describing characteristics of spasticity disorder. An ethics approval has been given by the Ethics Committee of Universiti Teknologi MARA and the project has been registered with the National Medical Research Register (NMRR) Malaysia. Approval number: NMRR-13- 1384-18681). Clinical Data Collection has been conducted in Sungai Buloh Hospital [21]. From the data acquisition, the behaviour of the system can be designed and the

development of the control system can be completing. The create phase ended with system integration between mechanical prototype and dynamics movement control.

5.4 Refine Phase

In this phase, two parallel evaluations will be conducted. The evaluations are the upper limb mechanical movement (i.e., elbow joint, degree of freedom) and the system evaluation (i.e., spasticity muscle stretch reflex). To validate the concept of applying part-task trainer as an education tool to increase the training frequency, the evaluation will made by physician and licensed therapists including novice therapists in one of the therapist education centre. Once the prototype has been validated, the marketing team would be established to conduct assess survey towards education centre whom would prescribe the part-task trainer in their curriculum.

6.0 SUMMARY

Value-driven design and the specification technique of CONSENS™ has been applied in this work for developing a part-task trainer for education purposes. It streamlines the development process and ensures the final solution satisfying stakeholders' needs as their voices were considered in each development phases. The recommendation received was taken into account to narrowing the design space of the part-task trainer. The team learned the importance of aligning voices of different stakeholders from different perspectives to guarantee the product achieves a commonly agreed conceptual design during the discovery phase. Development of the upper limb spasticity part-task trainer has been started well with clear scope definition and currently under create phase.

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