

Clinical training and competency guidelines for using robotic devices

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Abstract— With the increasing popularity of robotic devices in rehabilitation centers worldwide (e.g. Lokomat[®], ZeroG[®], ReoGo, InMotion 2.0, and Biodex System 4), there is a need for guidelines to ensure proper training and evaluation of therapists on the safe and effective use of these devices. Here, we present training tools and guidelines that were based on the recommendations of several device manufacturers and a user-group made up of clinicians and therapists. The training tools consist of a detailed user manual, clinical manual, hand-on training, video training and web based training tools. We also present procedures for evaluating user competency after they have completed detailed training. We believe that the comprehensive training and competency evaluation guidelines presented here will help ensure that rehabilitation robotic devices are used properly. This in turn will lead to more effective interventions and reduce the likelihood of injury.

Keywords- Robotics, Rehabilitation, Training, Competency

I. INTRODUCTION

In recent years, the field of neurologic rehabilitation has been reinvigorated with the finding that the central nervous system (CNS) retains plasticity even into adulthood [1] [2]. The ability of the CNS to reorganize to produce movements in function appears to be highly sensitive to the appropriate training environment [3], which has led to the emergence of “massed-practice” neurorehabilitation. Interventions that utilize massed practice provide a setting in which an individual with CNS pathology performs several hundred repetitions of a behavior using the affected extremity (ies) with the goal of developing skill in the performance of the behavior [1]. Such interventions include body-weight supported treadmill training [4], Constraint-Induced Movement Therapy [5] [6] and robotic therapy [7] [8]. Training that is task specific is essential to the successful outcomes of these interventions ([9].

The ongoing emphasis on cost reduction in health care continues to result in decreased inpatient rehabilitation length of stay [10]. This shortened length of stay plus the evidence that intensity and early intervention are associated with increased functional recovery for individuals with neurological pathologies has resulted in robotic devices moving from the research lab into clinical practice in an increasing rate

[11],[12]. With robotic devices becoming a commonly used tool as a treatment intervention, there is an increasing need to ensure they are being used properly. In the clinical world, turnover of clinicians is frequent, making training and assessment on using these devices challenging at times especially when there are few guidelines in place.

Most robotic devices are built with the assumption that the user has an idea of how a robot can be utilized due to knowledge of movement, purpose of the device, clinical experience, etc. but will not know “the competency of the robot” or how it works. If improperly used, rehabilitation robots may not be used to their fullest potential and consequently outcomes may be hindered. Without proper training and knowledge of the device, safe behavior can be seriously compromised. If robotic devices are to be truly incorporated into daily therapeutic regimes of patients, their users need to be properly trained.

Clinicians are required to prove competency on Cardio-Pulmonary Resuscitation (CPR), Emergency/Safety Rescue procedures, standard Precautions, Patient Privacy Rules etc. but infrequently required to prove competency on Rehabilitation Robotic Devices. This is because currently standards do not exist. Rehabilitation facilities need guidelines and procedures to follow to ensure their clinicians are competent.

In 2006 surgeons had similar concerns with robotic surgical devices. The Society of American Gastrointestinal and Endoscopic surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) felt that guidelines for the usage of robots in surgery were lacking and that the surgical community would benefit from a consensus statement on robotic surgery including guidelines for training and credentialing. To address this issue, SAGES and MIRA developed an international multidisciplinary consensus group to address four areas: 1) Training and Credentialing process 2) Clinical application of robotic surgery – has efficacy been demonstrated 3) What are the risk and cost benefits 4) What direction should future research take to address any unanswered questions on robotic surgery [13].

Although robotic devices used as rehabilitative tools do not lend themselves to the level of risk and possible injury as surgical devices, they can still cause injury to clinicians and patients if the user is not properly trained and the devices are

not properly maintained. The objective of this study was to develop comprehensive training guidelines and competency evaluation tools that therapists could utilize in order to improve their knowledge and skills on using rehabilitation robotic devices to treat their patients.

II. NUMBER OF PARTICIPANTS

Six device manufactures and fourteen clinicians (9 Physical Therapists, 3 Occupational Therapists, and 2 MDs) participated in this project from the United States and Switzerland. (See Acknowledgment section).

III. MATERIALS/METHODS

Guidelines were developed through a consortium of therapists, engineers, device manufactures and clinical organizations. Generalized procedures for each of these components were first developed by the National Rehabilitation Hospital (NRH) in Washington DC, and then circulated through a group of device manufactures to review the training procedures and then through a group of clinicians who specialize in robotic interventions to focus primarily on the competency assessment piece. A series of telephone/web conferencing calls were held to analyze and revise the guidelines.

The first step of this process involved reviewing training and users manuals from several different manufactures identifying the common and unique elements of each and consolidating them. The competency assessment and tracking piece was missing from all samples. The initial development of these tools were based on instruments used in clinical practice to assess clinical competencies, from components used in performance appraisal documents and personal experiences of what techniques were required when training individuals on different robotic devices.

The initial guidelines were sent to six different manufactures (Aretech[®], LLC, Hocoma, Bioness, Motorika, Biodex Medical Systems, and Interactive Technologies) who helped confirm and refine the recommended elements of the User's Manual, Clinical Resource Manual and Hands on Training components. The main comments made by this group were: 1. the need for a User Manual and in some cases a Clinical Resource Manual to guide the clinician 2. the use of videos and webinars for follow-up training 3. providing additional training based on: feedback from technical support, feedback forms from training sessions and feedback from focus groups 4. the importance of hand-on-training 5. The importance of different levels of training (initial and advanced) and when they should occur. These comments were consolidated, the guidelines updated and then forwarded to the clinical specialist. This group helped critique and elaborate on the Clinical Practice section of the Clinical Resource Manual, the Hands on Training and Competency Assessment/Tracking sections. Some items discussed in this group included: 1. identifying the correct domains for competency testing, 2 identifying how individuals will be trained to maintain the device 3. adding a training section on report generation, and how to export them, 4. discussing the need and differences between a User Manual and Clinical Resource Manual 5. the

need for technical support 6. importance of including the population that would potentially benefit from the use of the device. 7. how and in what medium to disseminate the information (most agreed it should be made available via CD and/or online via with the information being disseminated via websites and trade shows). All comments were reviewed by the group and discussed on a telephone/web conferencing call before final revisions were made to the guidelines.

IV. RESULTS

The result of this study is a generalized document outlining training procedures and competency assessment tools that can be used by robotic device manufacturers and/or end users to help them identify what type of documentation and training should be provided with their device. Since some robotic devices are more complex than others and require more in-depth training, the tools outlined in this document can be accommodated to cover easy-to-use systems as well as complex devices. Ultimately the manufacturer will decide which, if any, of the procedures and tools are applicable to their system. Each of the companies involved in this study said there was at least one training tool presented in the guidelines that they did not currently use but plan to modify their training and/or competency plan based on the results of this study.

The document is made up of four major sections: A. Manuals, B. Training Tools, C. Competency/ Assessment Tools and D. Technical Support.

The format of the document is designed as a checklist. The user places a check next to all those items they feel are appropriate for the device. The document directs the user to choose the training tools that should be provided for the device and for each tool general guidelines for content are provided.

A. Manuals

1) *User's Manual*: - The User's Manual is the barebones technical document required by most regulatory agencies however doesn't address clinical needs. This document should include the following sections: (Each of these sections provides a list of recommended content).

- **Introduction**: description of the general purpose of the device, the theory behind it and supporting research as well as administrative/legal requirements regarding installation, liability statement on proper training and adverse events including a sample reporting form for adverse events.
- **Treatment Population**: diagnosis that could benefit from using the device as well as the contraindications and indications for using the specified device.
- **Hardware and Software**: pictures of the device or screen prints of the software and troubleshooting information.
- **Set-Up**: step by step written directions of using the device, including powering on/off, donning and doffing, descriptions of different training modes, cleaning the device, data storage features and providing a quick training check list and/or tip sheets.

- **Emergency Procedures:** listing of emergency switches, step by step procedures on how to use them, pictures with location of switches and how to emergently remove patients from the device.
- **Maintenance:** cleaning and maintenance schedule, a list identifying individuals to perform routine maintenance, common error messages and troubleshooting steps.

2) **Clinical Resource Manual:** The Clinical Resource Manual is designed with the clinician in mind to address; who is appropriate for the device, safe use of the device, suggested documentation for goal writing and billing requirements, clinical problem solving tips in the area of hardware, software, treatment suggestions and how to progress a patient. Critical information that will make the transition of these devices from the research laboratories into clinical practice smoother.

Robotic devices are one of many tools in treating patients. In most cases the robotic device is a treatment tool rather than an orthosis meaning the patient will not be using or wearing it outside their therapy session. Therefore, knowing how to effectively use the device in order to progress the patient as quickly as possible will make the device more useful. Depending upon the clinician’s experience and expertise the need for this additional training may vary. In addition to the initial hands-on training, and videos of treatment techniques, examples of how to progress training in and outside of the device can be very helpful. (See “fig. 1” for an example of this process).

B. Training Tools

Hands on Training is preferred with Video and Web Based as suggested supplements. The hands on training section recommends discussing the purpose of the device, identifying who to train and who should do the training (manufactures representative and/or an identified super user for the facility). The recommend training process is to read the Clinical Resource Manual and view a product training video prior to attending a 1-2 day hands on training course. The course should include an introduction to robotic training (the philosophy behind the science) and the philosophy behind the device. Clinical rationale/supporting research, indications and contraindications for using the device and appropriate patient population should also be discussed. After the lecture portion is complete, a live device demonstration should be provided to the attendees. The users then practice using the software and donning and doffing the device first on each other and then on patients with varying levels of impairments.

The document also prompts the manufacturer/user to think about ongoing training, how often a person needs follow-up training and how that training should be provided (in person or via web based training).

C. Competency/Assessment Tools

It is critical that every user’s competency is evaluated through both written and practical exams, akin to the procedure for obtaining an automobile licenses. A general template for proper training and evaluating user competency with robotic devices is shown in “fig. 2”. Prior to taking a written test/quiz the user should read the User or Clinical

Phase of Training & Sessions	Priorities during training	Body Weight Support	Treadmill Speed	Duration	Guidance Force	Special Notes	Overground Practice
I(1-12)	Improved trunk control; hip and knee extension using biofeedback stance lines; decrease body weight support gradually (less emphasis on treadmill speeds)	40-50%	1.6 km/h (1 mph)	Short bouts up to 20 min total	100%	Progress to removing trunk strap and back support	<ul style="list-style-type: none"> • Coming to standing from progressively lower surfaces; • Standing balance with AD (AFOs may be used)
II(13-24)	Hip and knee extension using biofeedback stance lines; decrease body weight support gradually with moderate treadmill speeds; employ less guidance force as indicated	25-40%	2.0 to 2.4 km/h 1.2-1.5 mph)	20-30 mins	Decrease GF for short periods	May integrate quadriceps FES during stance	<ul style="list-style-type: none"> • Standing with weight shifts (fore-aft, lateral) • Stepping in place • Overground walking if possible with emphasis on stance stability
III(25-36)	Hip and knee flexion using biofeedback swing lines; increasing treadmill speeds	20-30%	2.5-3.2 km/h 1.6-2.0 mph	30-45 mins	Decrease GF	Increase negative hip offset to facilitate hip extension; may integrate use of peroneal FES during swing phase	<ul style="list-style-type: none"> • Overground walking with emphasis on gait speed
IV(37-48)	<ul style="list-style-type: none"> • Dynamic BWS is essential • Decrease guidance force • Use of program for varying speeds • Augmented Feedback if available 	0-20%	Use random or pyramid setting on speed	45-60 mins	Decrease GF	If adequate dorsiflexion, remove footlifters for short bouts (be sure to monitor patient fatigue to avoid an unsafe toe drag)	<ul style="list-style-type: none"> • Practice over ground walking on different terrains, stairs, curbs • Walking tasks such as changing speeds, turns, stepping over obstacles

Figure 1 – An Example of Progressing Training in a robotic device and how to apply that to practice outside of the device. (Author: Patricia Winchester, PhD, developed for the NANRS 2010-Lokomat Workshop “Advanced Training”).

Manual and view the training video if one is available for the device. The focus of a written exam should be based on safety (i.e., proper fitting of the device, possible adverse reactions, emergency removal of the device, safety switches, contraindications for using the device etc.). The practical assessment should include the trainees demonstrating their proficiency of the device on another trainee prior to demonstrating their proficiency of using the device on a patient. Clinicians should not be allowed to use the robotic device on patients without supervision until they have passed both the written and practical exams. In addition to the competency process the document also provides examples of a Competency Evaluation Form, suggestive Test/Quiz content, and Competency Tracking Forms.

Each facility needs to determine who is responsible for assessing and tracking therapist competency. In the United States The Joint Commission (The Joint Commission accredits and certifies more than 18,000 health care organizations and programs in the United States.) may request copies of the competency test and competency tracking forms during their accreditation or recertification visit.

D. Technical Support

Mechanical and software systems may fail occasionally or have error messages. It is critical that technical support is accessible when working with patients. This section recommends knowing contact names, numbers, website addresses, e-mail addresses and having access to a troubleshooting guide.

V. CONCLUSION

We believe that device manufactures and clinicians will find a document like this useful for two reasons: 1) Established guidelines will help save time and money when developing procedures for devices 2) Comprehensive, thorough training procedures will lead to proper use and consequently reduce the risk of injuries.

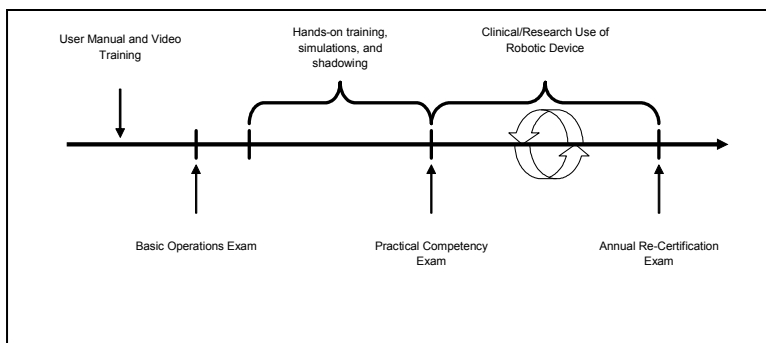


Figure 2. General process for training and evaluating user competency on a rehabilitation robotic device

Our hope is that this document will be made available through manufactures and professional organizations websites for manufactures and users to access freely in an interactive mode which is the next phase of this process. The ultimate measure of success is that manufactures will incorporate these Guidelines into their current training tools and rehabilitation facilities will follow the Competency Guidelines to ensure their therapists are properly trained. This will enable therapist to use robotic assisted interventions effectively.

The current template was presented to an industry-based sub-group of ICORR (International Conference of Rehabilitation Robotics). This sub-group is in the process of creating an industry association or society in the field of new technologies in rehabilitation. The scope of this group is to:

1. Be a worldwide non-profit organization of the industry players in robotics and advanced technologies in rehabilitation.
2. Represent and defend the interests of the industry in the field of robotics and advanced technologies in rehabilitation.
3. Establish standards and best practice in the field of robotics and advanced technologies in rehabilitation.

In the next phase of this project this group will be used to solicit feedback from a wider range of international colleagues. Several companies will assess their training procedures with the current template. Based on their assessments and critique of the template, the current template will be refined further. This group will also be used to determine the best way to make the guidelines available for easy access worldwide.

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