Human Factors in Medical Rehabilitation Equipment: Product Development and Usability Testing

DR. AYESHA Mustafa
BSPT (K.E.M.U) PP. DPT (RCRS),
Prototype testing.
The evaluation of a newly developed trial product by the end-users who represent the target market.

Efficacy testing.
A more formal process of performance testing in a controlled setting to determine the effectiveness of the product.

Magnitude estimation.
An experimental technique used in psychophysical experiments that involves having a subject compare his or her current sensation with a reference sensation.
**What Is Usability Testing?**
Usability measures the **quality of a user’s experience** when interacting with a product or system—whether a website, a software application, mobile technology, or any user-operated device.

Usability may also consider such factors as cost effectiveness and usefulness.

**Two international standards further define usability and human-centered design:**
- [Usability refers to] the **extent** to which a product can be used by specified users **to achieve** specified goals with effectiveness, efficiency and satisfaction in a specified context of user.

- Human-centered design is characterized by the **active involvement of users** and a **clear understanding of user and task requirements**; an appropriate allocation of function between users and technology;
What Is User-Centered Design?

“User-centered design (UCD) is the structured process for product development that includes users throughout each phase of the design process. In addition, a macroergonomic approach is often used that includes the overall business mission, goals, and culture, as well as the target audiences’ preferences, abilities, and requirements.”

Usability testing is most well known when used to evaluate the interface between the user and a machine or technology, such as in the computer industry. Examples include evaluating controls and displays on automobile consoles or in aircraft cockpits, designing user-friendly software, and designing human-computer interfaces and websites. However, usability testing also applies to products that are not considered machines, such as workstations.

Both complex equipment (e.g., anesthesia monitors and mammography machines) and simple equipment (e.g., walkers and dynamic splints) can benefit from experimental evaluation that concentrates on users.
PROCESS

If therapists decide to take on the task of consulting regarding the development of a new walker, they must first become familiar with the equipment. This includes the current design and any prior difficulties with this or similar products.

Once familiar with the equipment, the purpose of the equipment, the situations and environments in which the equipment would be used, and the target populations, the team can move on to usability testing.

The first step in the usability testing process is to identify subject matter experts (SMEs) and the user population.

An SME is any person who can be a valid judge of a design by virtue of his or her experience, education, or research of system operations, job performance, or task dimensions.
Second step: SMEs and representatives from the user group meet to define groundwork for development of design objectives and task and function analysis.

Therapists’ expertise on life skills and expectations throughout the life span, human development milestones, disease, and future expectations of the disease process will assist with developing the test objectives and tasks.

Techniques used during meetings with user groups can include focus groups and user workshops, informal discussions, interviews (structured or open-ended), questionnaires, brainstorming, checklists, and observations.
The next two steps, which can occur simultaneously, are to identify design objectives more explicitly and to conduct a task and function analysis. Design objectives focus on product features that affect performance, safety, expense, acceptance, comfort, ease of use, and aesthetics. Inclusion: of these objectives in initial product development helps confirm that the product is effective, safe, and accepted by user groups before expensive investments are made in product creation and large-scale production.

Design should be closely related to task and function analysis provided by investigators, users, and SMEs as a team.

critical success factors:

During a task and function analysis, the task and subtasks to be performed are selected in terms of those that are most demanding, frequent, and essential for the user population.
Fifth step: the development of performance criteria. Performance criteria should closely resemble the requirements of the task and should be performance oriented (action oriented).

sixth step: Measurement techniques include both objective and subjective measurements.

Objective measurements include reaction time, number of errors, and type of error.

Subjective measurements include user ratings of comfort, convenience, ease of use, and aesthetics.

Once the measurement techniques are chosen, subjects are recruited and trained.

Completing steps 1 to 6 before recruiting subjects is important to guarantee full disclosure of the evaluation process.
7th step: A walk-through or trial of the evaluation process should be conducted at this time)

The eighth step: is the actual assessment; in this case it involves a comparison study of several prototype designs. Subjects perform one or more of the reference tasks, and the investigator collects and analyzes objective and subjective information.

Finally, the evaluation process is conducted as either a formal or an informal research project. The results are used to critique or redesign the product.

The process is repeated as new information becomes available or the design is changed. A design is proposed, tested, rejected (or accepted), and revised repeatedly.
One or two design options are then chosen for **rigorous evaluation**. The evaluations can be categorized as experimental or nonexperimental, formal or informal, two-dimensional or three dimensional, and nonperformance or performance oriented.

**An experimental evaluation** requires measurement of subject performance under **contrasting conditions** in a controlled environment and use of experimental and statistical controls.

**A non-experimental evaluation** does not require contrasting conditions or strict controls. For example, evaluating a subject’s reaction time or performance. Having subjects complete a subjective **rating scale** while using a **single product** on the job is non-experimental.

**Formal assessments** have definite procedures and are well defined; **informal assessments** have less well defined objectives and procedures. For example, a questionnaire is formal, but an open-ended group discussion is informal.
Two-dimensional evaluations examine a product’s attributes through checklists, three-dimensional evaluations may use mock-ups or prototypes and can incorporate either nonperformance or performance measurements.

An experimental evaluation of two or more prototypes determines which design is better or best according to user performance and preference.

If only one product is evaluated, the assessment addresses the same design questions of effectiveness, ease of use, accomplishment of the mission, and deficits or areas that need improvement, but only for that one product.
As mentioned, an important aspect of usability testing is that it is performed **during each stage of development**. Even after the product is **on the market**, usability assessment can be conducted to ensure the product remains useful and effective.

If product development occurred **without usability** testing, evaluation may be the first step in determining whether change is needed. The user population, especially clients, may not voice their concerns about the effectiveness of a product. **This leaves the responsibility with the developers and SMEs.**

The information gained from a usability evaluation after the product is on the market can determine the need for product redesign and assist medical personnel in making recommendations.

Information regarding the effectiveness, efficiency, and ease-of-use of a product is important in the recommendation of a product for purchase by a client, a client's family, or a medical facility.
PRODUCT DEVELOPMENT, EFFICACY TESTING, AND COMPARISON TESTING OF AN ASSISTIVE WALKER

Given that therapists have accepted the job as consultants and members of the ergonomic evaluation team, they first review the literature and construction of walkers and re-familiarize themselves with the types of clients who use them. They review the accoutrements that users may want, such as baskets, pouches for carrying small items, and drink holders. They examine the balance characteristics of walkers. Some are balanced at the center handle; these walkers are designed for clients with hemiplegia and thus with limited use of one hand. Wheeled walkers may be especially beneficial during the early rehabilitation process, but it is difficult to know whether one with front wheels only or one with three wheels will best serve a client.

Other important features are the weight, portability, and stability of the walker and the height, shape, and size of the grip handles. Some clients may want a walker with an attached seat.
Given that the New Equipment Company has an idea for a new walker design, the team decides to start there. **They plan for three iterations of the usability process.**

Each phase is considered part of the usability testing. *Usability testing means that the product* is evaluated by obtaining information from representative users, often while they use the product.

The goals of usability testing are to develop a product that accomplishes the purpose for which it was designed, is easy and safe to use, and will be used.
Phase 1----------→phase 2--------→phase 3
Phase 1: product development (pilot testing of walkers)
User or investigator SMEs----->2) Interaction--→3) Establish design objective---→4) Conduct task and function analysis---→5) Develop performance criteria----→6) Establish measurement technique "subjective or objective"--------→7) Walk trough---→8) Assessment---→9) Product

Phase 2: efficacy testing, (walker vs no-walker)
User or investigator---------->2) Interaction--→3) Re-establish design objective--→4) Re-evaluate task and function analysis---→5) Re-establish performance criteria----→6) Re-establish measurement technique “subjective or objective”-----→7) Training---→8) Assessment--→9) Product

Phase 3: useability comparison testing (comparison of walkers)
User or investigator--------->2) Interaction--→3) Establish design objective-→4) Task and function analysis---→5) Develop performance criteria----→6) Establish measurement technique "subjective or objective"--------→7) Walk trough/training---→8) Assessment---→9) Product
THANKS
First Iteration: Product Development
The first step is to identify the SMEs, users, and investigators. This group could include product developers, medical personnel who have prescribed walkers for clients, therapists and nurses who work closely with clients who use walkers, family members of clients who use walkers, and the clients themselves.
A target group, such as those with hemiplegia and those with cerebral palsy, differ. For example, a client who has problems with balance and coordination may not want wheels on his or her walker, and a client who quickly becomes fatigued may need an attachable seat that folds while he or she is walking.
Identification of a target group should be based on demographics; knowledge, skills, and experience; attitude; lifestyle; cognitive and physical abilities; and cultural background.
Design Objectives for Product Development

Primary
Walker, Lightweight, Adjustable height, Adjustable width, Stability, User, Appropriate weight distribution. Ability to maintain erect posture during use

Secondary
Comfort, Ease of use, Ease of adjustment, Ease of storage. Portability, Optimum grip height, Shape, Size

Tertiary
Attractiveness, Convenience

The design objectives and the information gained from the task and function analysis are used to develop performance criteria.
Second Iteration: Efficacy Testing (Controlled Setting)
The goal of efficacy testing is to determine whether the walker improves the user’s ability to walk and maneuver through the activities of daily living—

Therefore, testing consists of having subjects use the walker, as opposed to not using a walker, while performing several representative tasks.

If the investigator believes that walkers have been shown to be effective ambulation tools and that such an evaluation would be superfluous, this phase can be eliminated.

If this phase is eliminated, usability testing begins with a comparison between the new design and existing designs.

The interaction among SMEs, users, and the investigator should focus on the results of the pilot test accomplished during phase 1.

The design objectives for the walker most likely will remain the same as those identified in the development phase.
During efficacy testing, the number of subjects will probably be greater than the number who participated in the pilot test.

Adequate results can be obtained with a relatively small number of subjects, especially because this is a repeated-measurements study. The results should give the investigator clear information about the efficacy of use of the walker (as opposed to no walker) in terms of both the subjects’ performances and their preferences. Efficacy testing provides information on the benefits and limitations of using the walker in three different situations for men and women. Initial results suggest that the walker is beneficial.
Third Iteration: Comparison Field Testing

The second iteration of the usability cycle (efficacy testing) revealed that the walker was helpful in improving ambulation and maneuvering in using a restroom. However, the following concerns were identified during testing:

- The gripping edge of the walker was uncomfortable and caused pain on the thenar eminence during ambulation.
- Subjects requested a handle material that does not feel cold to the touch and comes in different colors.
- Subjects requested detachable accessories, such as a tray for holding objects, a recessed cup holder, and a basket with adjustable sections.
- The fold-up seat was weak and unstable and did not have appropriate contour or padding.

The concerns must be discussed by SMEs, subjects, users, and investigators. The cost of product development and the purchase price must be considered, along with the preferences expressed.
both the old and the new design objectives can be tested by walking, this task is chosen as representative. The purpose of the comparison field testing is to compare one or more designs with one another in a realistic environment.

The task in comparison testing should be similar to the task used during efficacy testing in the laboratory.

The tests can be conducted in nursing homes, rehabilitation centers, or even in a home environment in which throw rugs, narrow halls, and wheelchairs are obstructions.

It can also be conducted in a work setting in which storage cabinets are located in the halls, ramps are located between split-level floors, and low-level ambient light is used.
The results of the comparison test in the example were as follows:
The new design was ranked as the preferred walker compared with the other two walkers. The subjects’ heart rates were lower with the new design. Subjects completed the task faster when they used the new design; however, time to stand and sit was slower.
Subjects found the new design easier to use. Use of the new design increased comfort and decreased pain and strain. No differences were found for ratings of stability, perceived exertion, or performance of ancillary tasks.
These results showed the new design to be superior for ambulatory assistance as measured by user preference and Performance.