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## Spinal Cord Injury-Movement Index (SCI-MI) Fine Motor Item Pool: Development and Preliminary Validation

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## Introduction

- Spinal Cord Injury (SCI) clinical trials with novel therapeutics and neuro-technologies need clinical outcome assessments (COAs) that are standardized, observation-based, disallow compensations, and are sensitive to improvement with functional relevance.
- Most clinical trial COAs do not have this capability:
  - Not developed as clinical trial measures<sup>1</sup>
  - Fail to address important aspects of physical functioning<sup>1,3</sup>
  - Do not adequately reflect functional tasks<sup>2</sup>
  - Poor sensitivity to change in motor recovery<sup>3</sup>
  - Lack rigorous measurement properties<sup>4</sup>
- Lack of robust COAs creates serious problems for SCI clinical trial programs.

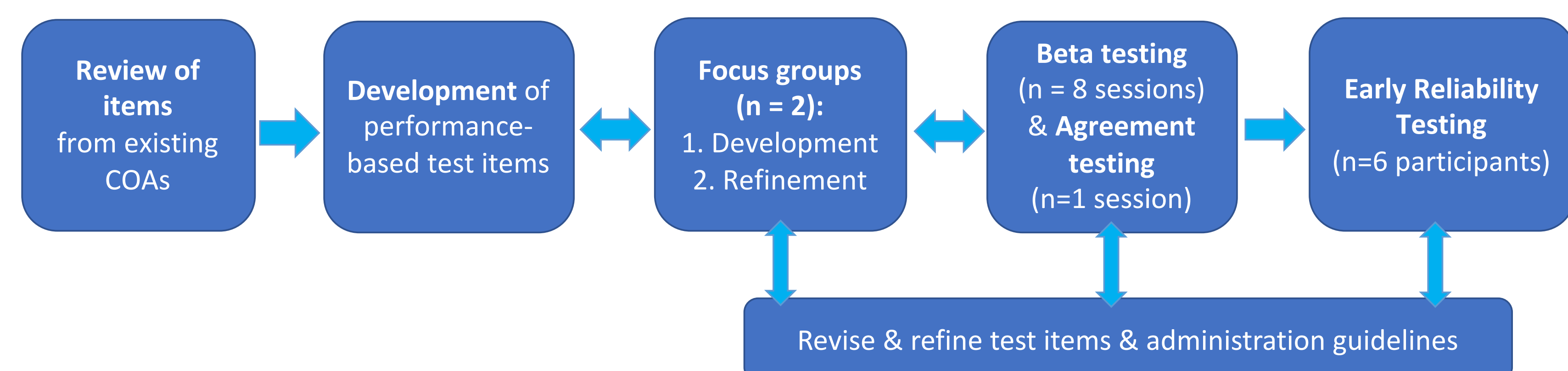
## Spinal Cord Injury-Movement Index (SCI-MI)

- Currently under development as a clinical trial COA
  - Item Response Theory
  - Intended to assess movement in the context of function
- Item pools: Fine Motor & General Movement

## Purpose

Describe the conceptual framework and preliminary results from pretesting for content validation of the Fine Motor Item Pool of the SCI-MI.

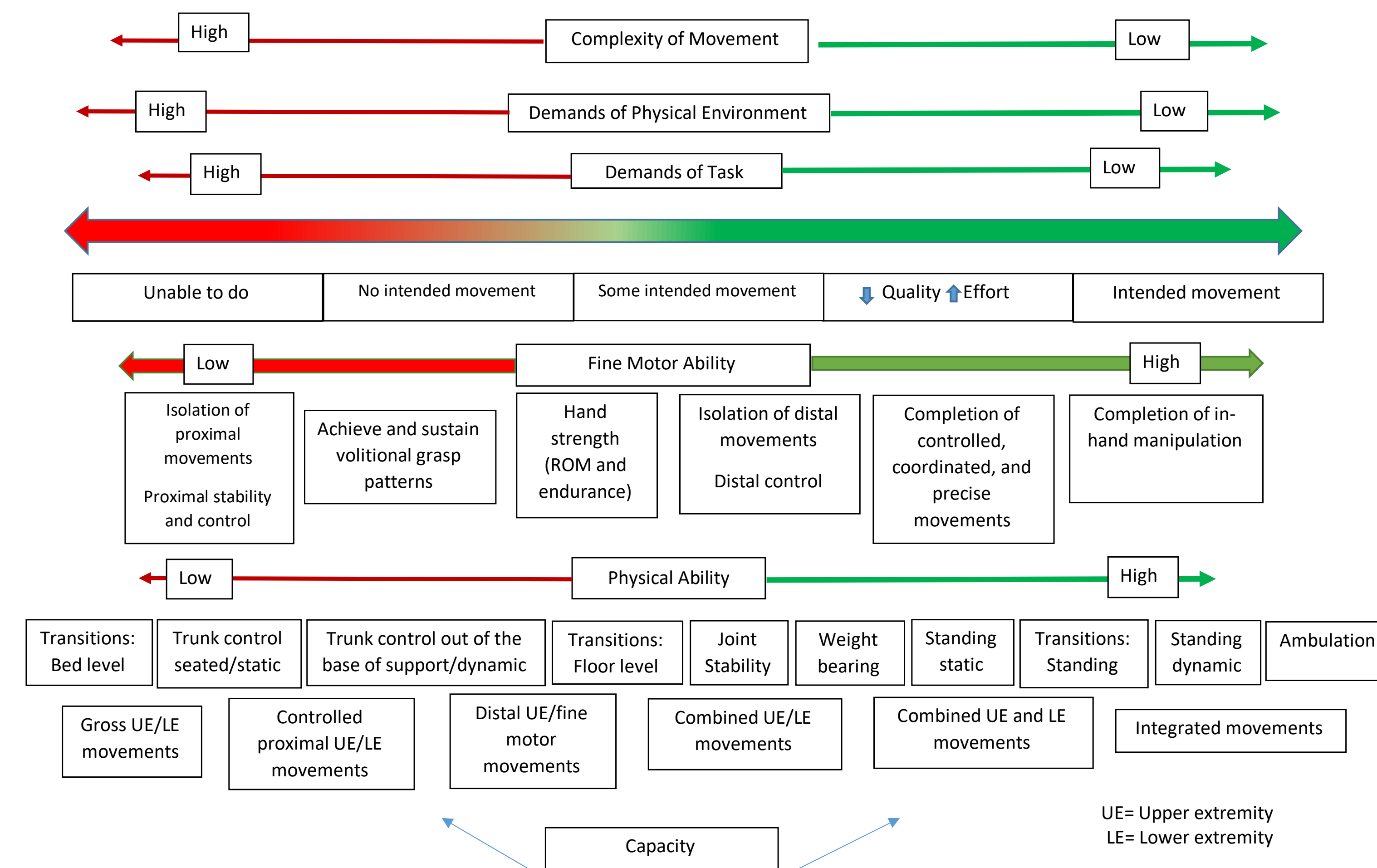
**Figure 2: Iterative Process for Development and Initial Validation of SCI-MI Fine Motor Item Pool.**



## Methods & Results

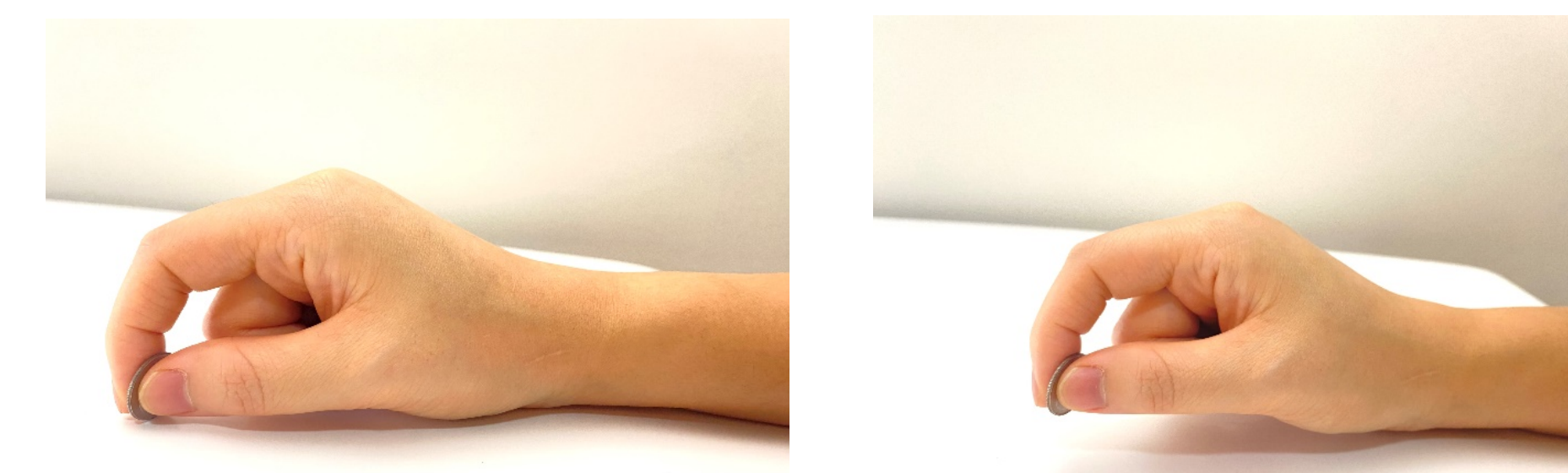
- Conceptual Framework developed via conceptual map & nomological network (Figure 1)
- Test items were developed via an iterative process using mixed methods (Figure 2).
- Consensus meetings (n=10) identified candidate items from existing COAs, such as the Spinal Cord Injury-Functional Index (SCI-FI)<sup>5</sup> that were amendable to administration and scoring by observation of performance. New items were added by the team to cover gaps in content.
- The team developed administration guidelines, item intents, and scoring procedures for each test item through iterative focus groups (n=2), testing sessions with 7 individuals with SCI, and input from experts in SCI rehabilitation.
- Bi-weekly study team meetings refined the procedural guidelines for administration and scoring.
- Test items (n=8) that demonstrated high burden or decreased relevance during early reliability testing were eliminated.

**Figure 1: SCI-MI Conceptual Framework.**



**Figure 3: Example Administration Guidelines for SCI-MI Test Item.**

Administration Guidelines		Item Intent
<b>Required props:</b> timer; dime (2) <b>Set-Up:</b> The administrator is to <u>sit across</u> from the participant. Dime placed on tabletop in front of participant at the midclavicular line of tested side.	<b>Pick up Dime</b> <i>Using your thumb and index finger, pick up the dime from the tabletop and hold for a count of 5 seconds. Do not drag the dime from the tabletop.</i> Timer starts at word "begin;" administrator to <b>count out loud for 5 seconds</b> , then tell participant to stop after 5 consecutive seconds.	<i>Pincer grasp to pick up dime from tabletop and hold for a count of 5 seconds</i> <b>Note:</b> Forearm may rest on tabletop for test item completion, but this is not required.



**Figure 4: Scoring Guidelines for the SCI-MI.**

Full Volitional Movement		Some Volitional Movement	No Volitional Movement	
Intended Movement		Compensation & Intended Movement	All Compensations	Unable to Complete
5	4	3	2	1
Completes using intended movement(s)	Completes using intended movement(s) with increased effort or decrease in quality or fluidity of movement	Completes with some intended movement (some compensations)	Completes with no intended movement (all compensations)	Unable to complete (or uses substitutions)

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## Discussion

- The SCI-MI Fine Motor Item Pool (including administration guidelines & scoring criteria) has been developed (Figure 3).
- The item pool consists of 31 items: 23 unimanual items & 8 bimanual items.
- Scoring is based on intended movement, accounts for compensation and disallows substitution (Figure 4).