# Quality of Life Outcome Measures for Upper Extremity Transplantation Research

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  University of Delaware partners: Callie Tyner, Jerry Slotkin, Aaron Boulton, Pam Kisala

# Best Practices when Gathering Patient Reported Outcomes (PRO)

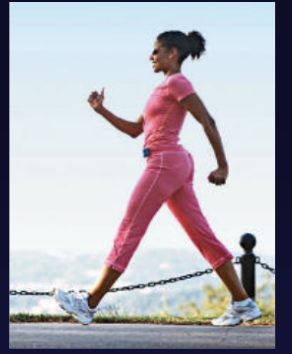
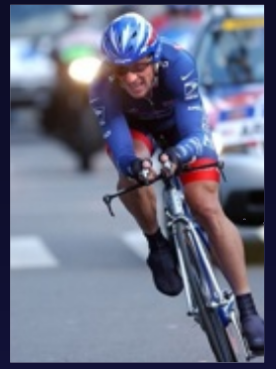
1. Quality of Life is subjective – understood from the patient's (or recipient's) perspective.
2. QOL allows a patient's perspective to be elevated to make important treatment decision or assessment of outcomes. This is critical in VCA research.
3. It is multidimensional – covering broad domains of physical, emotional, and social functioning.
4. There are generic measures that are applicable across medical populations and there are specific measures that are targeted to a specific medical condition.
5. Standards have been set by the American Psychological Association, American Educational Research Association, and National Council on Measurement in Education and the Consensus-based standards for selection of Health Measures Initiative (COSMIN).

# NIH Measurement Initiatives

- In 2004, NIH, as part of the NIH Roadmap (or Common Fund) set out to re-engineer the clinical research enterprise throughout NIH.
- Patient Reported Outcomes Measurement Information System (PROMIS)
  1. was developed to serve as a “Common Data Element”
  2. allow comparison across medical conditions
  3. Multiple domains of functioning – physical, emotional, and social
- Large initiative – $200 million+
- Multiple languages
- Adult and Pediatric
- Utilized advanced psychometrics and computerized adaptive testing (CAT)
  1. Allows assessment of a domain of functioning with minimal items
  2. This technique is very relevant to VCA where there is a concern of overburdening the participant.





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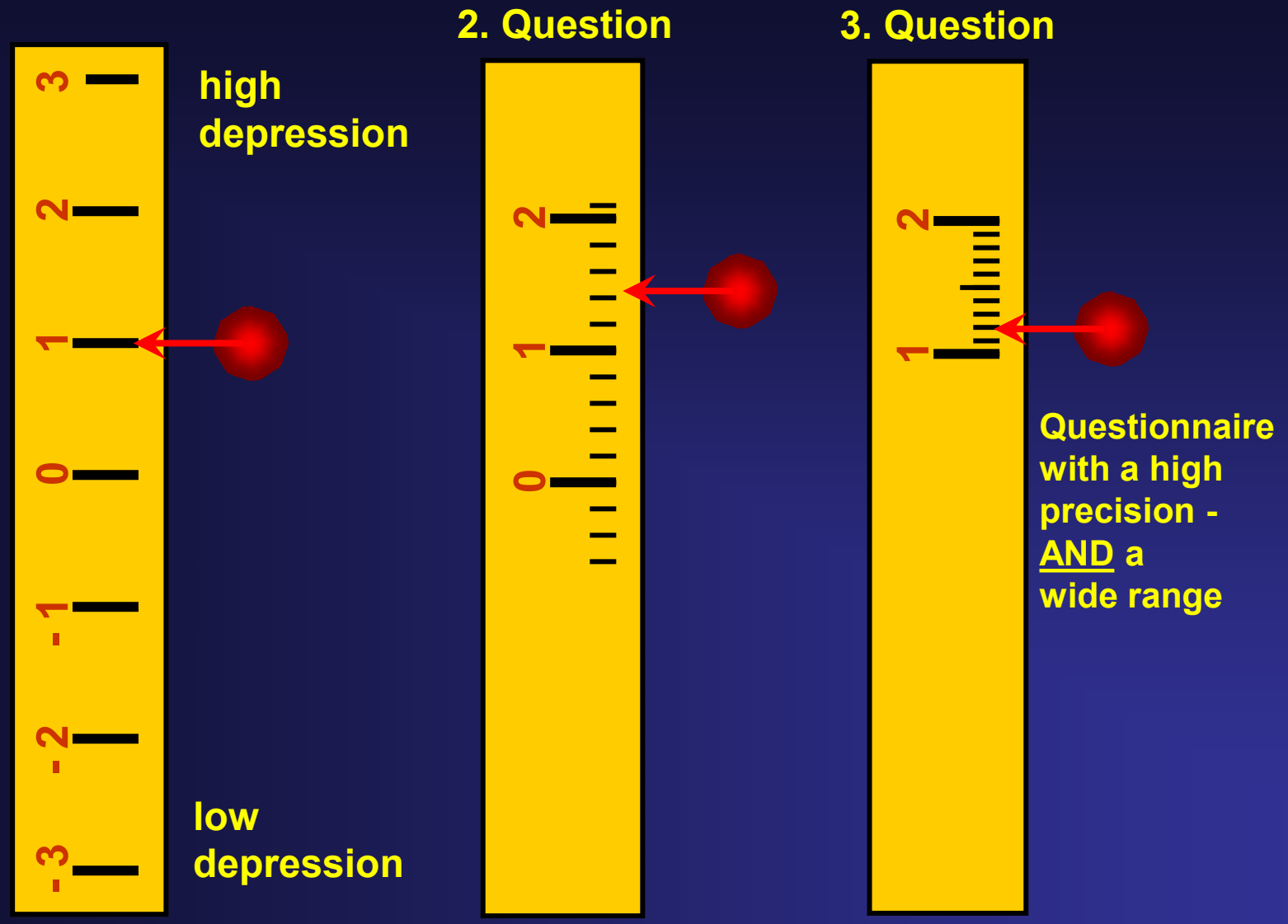
# Physical Functioning Item Bank

Item 1 | Item 2 | Item 3 | Item 4 | Item 5 | Item 6 | Item 7 | Item 8 | Item 9 | Item *n*

Are you able to get in and out of bed?
Are you able to stand without losing your balance for 1 minute?
Are you able to walk from one room to another?
Are you able to walk a block on flat ground?
Are you able to run or jog for two miles?
Are you able to run five miles?

# Computer Adaptive Tests



# PROMIS and PROMIS-Like Measures

1. An advantage of PROMIS is that it is being used widely in medical research
   - Ability to compare across populations
   - Use of a “user-friendly” T-metric
   - Programmed into REDCap and easily integrated into clinical electronic medical records
2. PROMIS set the standard for PRO development (advanced qualitative and quantitative techniques)
3. Standardized administration and scoring – designed for medical research and clinical trials.
4. Several parallel and spinoff projects to assess issues that are specific to certain populations (Neuro-QOL, SCI-QOL, TBI-QOL, LIMB-QOL, NIH Toolbox)

# Outcomes Measures in Upper Extremity VCA

1. What HRQOL domains are important to measure?
2. How can generic domains be combined with wth specific issues and needs of hand transplant recipients?
3. What are existing measurement scales that can be used in an outcome battery?
4. What are measurement gaps and how can new items be developed and validated?

**RTRP award #'s W81XWH-18-2-0068/W81XWH-18-2-0066/W81XWH-18-2-0067**
**RTRP award #'s W81XWH-20-2-0061/W81XWH-20-2-0062**
**Broad Agency Announcement award # W81XWH-17-1-0335**

# PRO Development Process

Goals of RTRP grant:

(1) Use a grounded-theory based qualitative approach to identify the HRQOL outcome domains that are most important to individuals involved in the VCA process

(2) Develop new item pools unique to hand transplantation

(3) Select existing PRO measures (generic) for domains that are relevant to general and/or rehabilitation populations.

# Methods

- Grounded-theory-based qualitative approach
  - Conduct focus groups at TORCH sites **(11 groups; n = 42)**
  - Conduct focus groups at ASRT **(2 groups; n = 17)**
  - Conduct individual interviews with recipients **(n = 5)**
- Prompts:
  - In what ways has your life changed since your hand transplant?
    How have your patients' lives been affected by hand transplantation?
  - How has the hand transplant affected your QOL?
    In what ways does hand transplant change a patient's QOL (for better or for worse)?
- Systematic thematic analysis
  - Open Coding to identify major content areas
  - Axial Coding to develop code hierarchy
  - Selective Coding to tally the frequency of mention of each code

| Emotional Domain | Social Domain | Physical Domain |
| --- | --- | --- |
| Anger | Ability to Participate in SRA | Fine-Motor Function |
| Anxiety/Fear | Satisfaction with SRA | Self-Care |
| Body Image | Independence | Pain Interference |
| Depression | Dependency on Family | Medication Side Effects |
| Grief/Loss | Intimate Relationships | **Sensation** |
| Health-Related Self-Efficacy | Expenses/Economic Hardship | **Satisfaction with Hand** |
| Positive Affect & Well-Being | **Caregiver/Familial Support** | **Post-Treatment Challenges** |
| Psych. Trauma/PTSD | | **Treatment Compliance** |
| Resilience | | |
| Self-Esteem | | |
| Stigma | | |
| **Expectations** | | |
| **“Fitting in”** | | |
| **Integration & Assimilation of Transplant** | | |

# Relevant Existing PRO Measures

- Physical/Medical Health
  - Pain Interference[a,d,e]
  - Upper Extremity Function[b]
  - Fine Motor Function[c]
  - Self-Care[c]
- Social Participation
  - Ability to Participate in Social Roles and Activities (SRA)[a,b,d,e]
  - Social Support [a]
  - Satisfaction with SRA [a,b,d,e]
  - Asking for Help[d,e]
  - Independence[d,e]
  - Economic QOL
  - Intimate Relationships & Sexual Function[a]
- Mental/Emotional
  - Anger[a,e]
  - Anxiety/Fear[a,b,d,e]
  - Body Image[f]
  - Depression[a,b,d,e]
  - Grief/Loss[d,e]
  - Health-related Self-Efficacy[a]
  - Positive Affect & Well-being[b,d,e]
  - Psychological Trauma[d,e]
  - Resilience[d,e]
  - Self-esteem[d,e]
  - Stigma[b,d,e]

[a]PROMIS, [b]Neuro-QoL, [c]SCI-FI, [d]SCI-QOL, [e]TBI-QOL, [f]Item bank in development

# New Hand Transplant Items
# HRQOL measurement Gaps in VCA

| Physical Domain |
| --- |
| Sensation |
| Satisfaction with Hand Functioning |
| Post-Treatment Challenges |
| Aesthetics |

| Emotional Domain |
| --- |
| Expectations |
| “Fitting in” (semblance of normality) |
| Integration & Assimilation of Transplant (sense of wholeness) |

# Experimental Items Specific for Hand Transplant

| Hand Transplant Item Pool | Item Count | Content Coverage | Sample Item |
|---|---|---|---|
| | | | |
| Expectations & Perceived Outcomes | 12 | Assessment of how well the recipients' pre-surgical expectations were met. | *I felt prepared for the risks to my health after hand transplant.* |
| Fitting in | 7 | Comfort in social interactions where other people may view or touch the transplant(s). | *I feel self-conscious about people seeing my hands.* |
| Integration and assimilation of the transplant | 7 | Acceptance and identification of the transplant as one's own; feelings of "wholeness" or having something restored. | *My hand transplant makes me feel more complete.* |
| Post-Surgical Challenges and Complications | 10 | Burdens of post-transplant treatment and therapies; effects on health and personal life. | *I feel bothered by medication side effects.* |
| Hand Sensation | 7 | Ability to perceive sensations with the transplant. | *My sense of touch in my hand(s) is good.* |
| Satisfaction with Hand Aesthetics | 7 | Satisfaction with physical appearance of the transplant. | *I am satisfied with the skin tone of my transplant.* |
| Satisfaction with Hand Function | 6 | Comfort, confidence, and satisfaction with the functional abilities of the transplant(s) in various daily activities. | *I feel frustrated with how my transplant functions.* |
| **Grand Total** | **56** | | |

# Expert Item Review

- Held 5 “Expert Item Review” meetings (via zoom)
  - Included hand surgeons, clinical psychologists, social workers, occupational therapists, and physical therapists
  - leading transplantation centers (e.g., U Penn, U Louisville, Johns Hopkins, Mass General Hospital, Brigham and Womens Hospital, UCLA, & Walter Reed)
- Presented domain definitions and discussed construct that is being measured in the domain.
- Presented each item to the experts and modified based upon content.

# Cognitive Debriefing Review

- Phone interviews with five recipients of hand transplants.
- Administered each item to each participant.
- Discussed wording and “what the individual understood was being asked.”
- As appropriate, recipients discussed how they responded to the item and what they were thinking.
- Items were then modified as needed.

# Potential to Leverage Other Samples

- We have collected data on multiple item banks/domains in people with major extremity trauma including limb-loss.
- We have a sample of 198 individuals collected from 9 performance sites.
- The sample includes 8 people who have had a hand transplant.


Physical Function
Satisfaction with Physical Fitness & Athleticism
Satisfaction with Orthosis/Prosthesis
Fatigue
Physical Function (overall)
Mobility
Upper Extremity
Self Care
Fine Motor
Physical Symptoms
Weight Satisfaction
Pain Interference
Pain Intensity
Mental Health
Body Image
Future Outlook
Health-related Self-Efficacy
Resilience
Self-esteem
Grief/Loss
Anger
Anxiety
Depression
Positive Affect & Wellbeing
PTSD/Trauma
Stigma
Cognition
Social Participation
Vocational Impact
Ability to Participate in Social Roles and Activities (SRA)
Satisfaction with SRA
Independence
Economic QOL
LIMB-QOL Banks
Adapted from SCI-QOL/TBI-QOL/PROMIS/Neuro-QoL Banks
Existing Measures

# Conclusions

- We have identified domains important to people UE transplant recipients.
- We have identified existing item banks that could be administered via CAT technology.
- We have developed eight new experimental item pools important to UE transplant recipients.
- Assuming data from a major upper extremity sample will generalize – we have initial evaluation of the construct validity of some existing measures in a sample of individuals who have had major upper extremity trauma.
- We have data from which we could eventually validate additional measures.

# Improving QOL Measures for VCA

- Next phases of research should include
  - continued evaluation of the construct validity of the new items and existing measures in a VCA sample - including evaluation of the change over time.
  - Examine “group differences” of scores and responses on existing measures between VCA and other sample populations (general population, other disability samples, upper extremity limb-loss sample).
  - evaluate how these items can assist in monitoring symptoms, identifying HRQOL issues, and if they have clinical utility.

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| Physical Function | Physical Symptoms | Mental Health | Social Participation |
|---|---|---|---|
| Hand Function | Post-Surgical Complications | Sense of "wholeness" | Ability to Participate in Social Roles and Activities (SRA) |
| Hand Sensation | Hand Asthetics | Fitting in | Satisfaction with SRA |
| Self Care | Pain Interference | Expectations | Independence |
| Fine Motor | Pain Intensity | Body Image | Economic QOL |
| Upper Extremity | Fatigue | Future Outlook | |
| Mobility | Health-related Self-Efficacy | Resilience | |
| | | Self-esteem | |
| | | Grief/Loss | |
| | | Stigma | |
| | | Anger | |
| | | Anxiety | |
| | | Depression | |
| | | Positive Affect & Wellbeing | |

Existing Item Banks

New items for Hand Transplant Recipients

New "LIMB-QOL" Item Banks

# Thank you

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