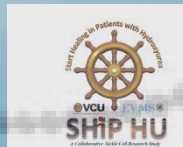


# PROMIS & ASCQ-Me vs. Older SCD-Specific Measures: the SHIP-HU Study

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NHLBI 1R18HL112737

NCT02197845



# Sickle Cell Disease

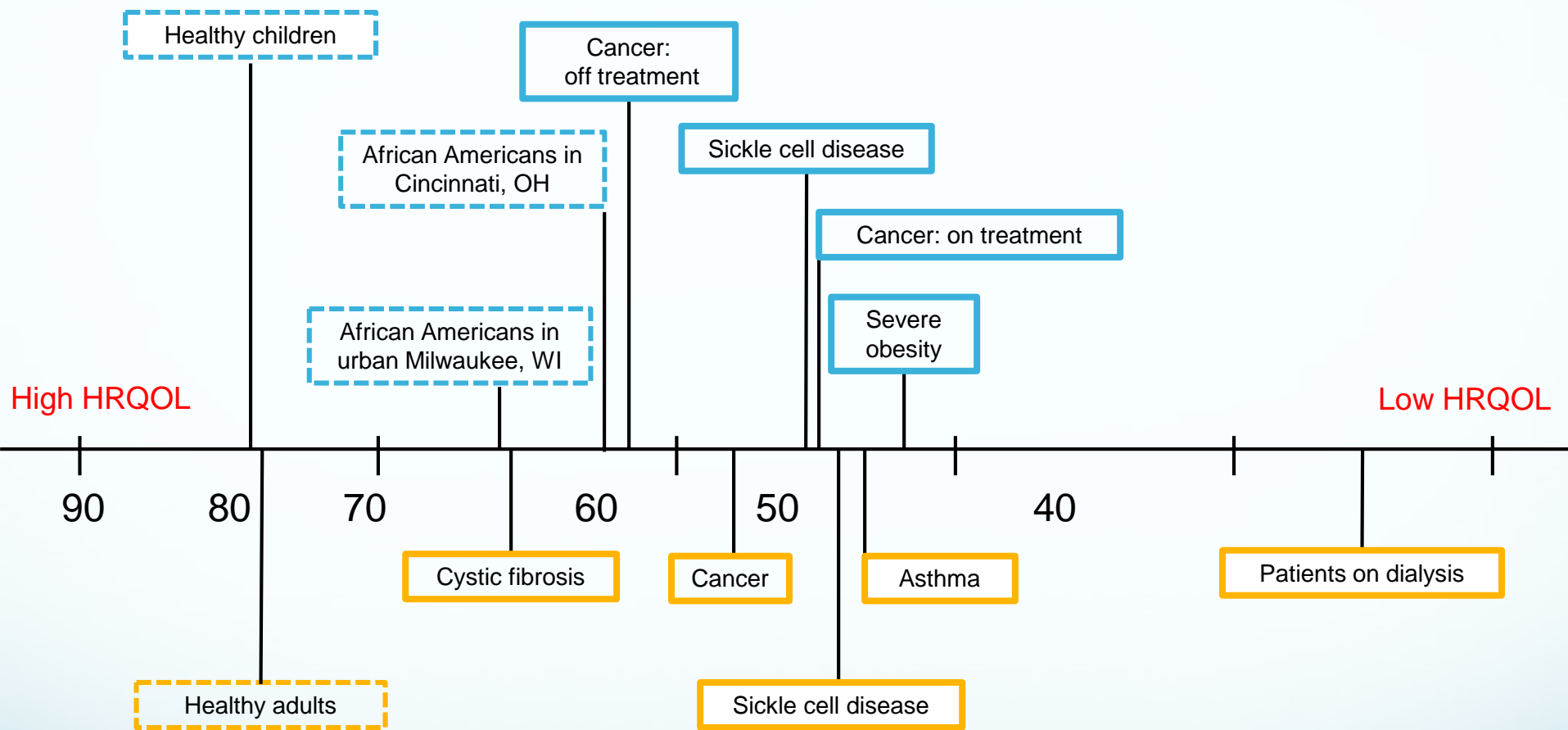
- Worldwide Genetic hemoglobinopathies
- 100,000 in US, predominately African, Mediterranean descent
- Extreme, unpredictable acute → chronic pain
- Vaso-occlusive ischemia, organ failure, early death
- Few treatments



# SCD: A Double Whammy

- Members of a Health Disparities population
- Suffer Chronic Non-Cancer Pain (CNCP)
  - CNCP Common
  - Significant burden to adult patients
  - Known to lower quality of life
    - Kowal, John, et al. "Self-perceived burden in chronic pain: Relevance, prevalence, and predictors." Pain 153.8 (2012): 1735-1741.
    - Ferrell BR. The impact of pain on quality of life. Nurs Clin North Am. 1995;30(4):609-24.
  - May be poorly managed
    - → anxiety and distress related to subsequent treatment
    - → negative long-term psychological effects

# SCD HRQOL State of the Art: Physical Function Means



- Healthy paediatric population
- Healthy adult population
- Children with illness
- Adults with illness

# Places Where PROs Might be Needed in Sickle Cell Disease

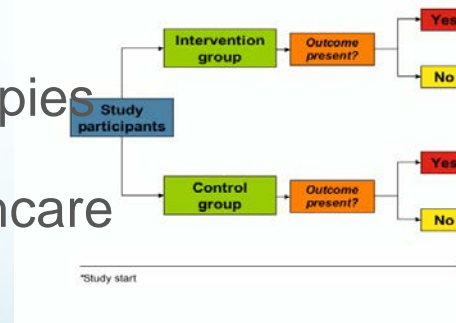
Disease Modifying			Palliative (analgesic)	
Acute	Chronic	Organ preserv	Acute	Chronic

- \*Lopes BL, Flenders P, Davis-Moon L, Corbin T, Ballas SK. Clinically significant differences in the visual analog pain scale in acute vasoocclusive sickle cell crisis. Hemoglobin 2007;31(4):427-432.
- Todd KH, Funk KG, Funk JP, Bonacci R. Clinical significance of reported changes in pain severity. Ann Emerg Med 1996;4(4):485-489.

# Adult Sickle Cell Quality of Life Measurement (ASCQ-Me)

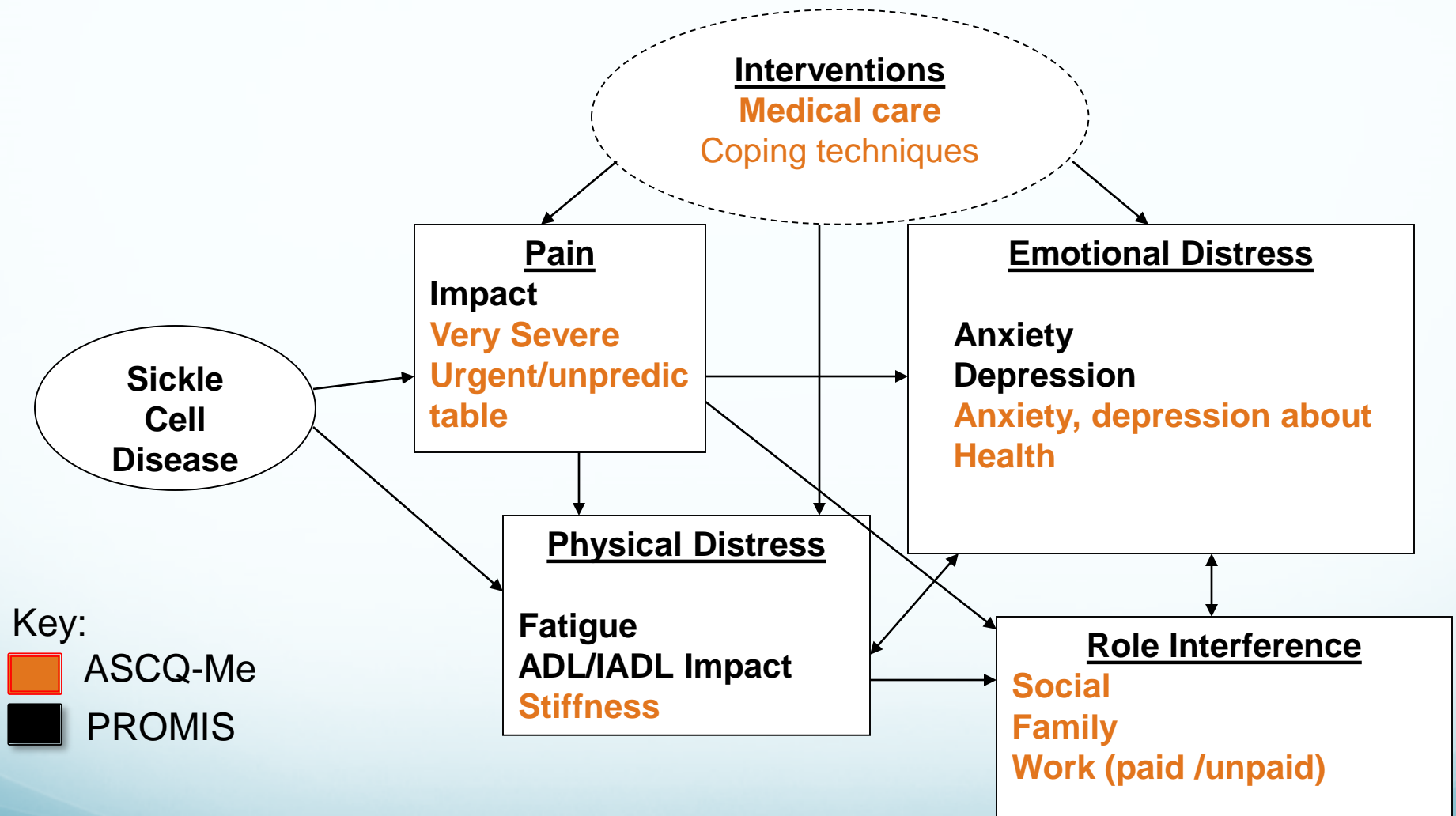
Describes the broader effect of SCD on adult functioning and well being to:

- More fully characterize the efficacy of therapies tested in RCTs
- Evaluate the effectiveness of therapy
- Compare effectiveness of therapies
- Evaluate effectiveness of healthcare delivery system





# ASCQ-Me/PROMIS Conceptual Model



# Objectives

- Test the relationship between function, barriers to care in physical function domain versus those in psychosocial domain, medical skill set domain.
- Compare scores from SCD PROs previously measured and felt important vs. PROs in SCD.
  - Patient Reported Outcomes Measurement Information System, PROMIS
  - Adult Sickle Cell Quality of Life Measurement Information System, ASCQ-Me
- Compare physical function scale scores from PROMIS and ASCQ-Me in a SCD sample.



# Patients

- N=214, 53% female
- Enrolled in **Start Healing in Patients with Hydroxyurea (SHIP-HU) Clinical Trial**
  - NHLBI 1R18HL112737
  - PI Wally R. Smith, MD
- 79% prescribed HU at baseline



# Measures

- PROMIS
  - Global health – physical summary (GPHYS)
  - Physical health (PHYS)
  - Fatigue (FATG)
  - Pain behavior (PAINB)
- ASCQ-Me
  - Sleep/Wake disturbance (WAKE)
  - Stiffness (STIFF)
  - Sleep impact (SLEP)
  - Pain crisis frequency (PAINF)
  - Pain crisis severity (PAINS)
  - Pain impairment (PAINI)
- Smith-Bovbjerg Sickle Cell Stress scale (STRESS)
- Social support (SS)
- Sickle Cell Self efficacy (SCSES)
- Medical Knowledge and Skills (MEDSKILL) scales, Transition Intervention Program - Readiness for Transition
- Three subscales of Coping Strategies Questionnaire (Emotion-focused, Active, Behavioral-- COPEMOT, COPEACT, COPEBEH)

# Results--Correlations

	GPHYS	PHYS	FATG	WAKE	STIFF	SLEP	PAINB	PAINF	PAINS	PAINI
STRESS	-.44***	-.36***	.32**	.34***	-.37*	-0.25*	.25*	0.31	.21*	-.46***
SS	0.04	0.14	-0.08	-0.11	0.04	0.09	-0.12	-0.1	0.01	0.12
SCSES	.29**	.21*	-.28*	-.25*	0.12	0.22*	-0.2	-.23*	-.23*	.27*
MEDSKILL	-0.09	-0.05	-0.03	-0.07	-0.1	-0.02	-0.05	-0.08	0	0.02
COPEACT	-0.12	-0.01	0.12	0.11	-.18*	-0.15	0.11	-0.04	0.1	-0.03
COPEEMO	-.33**	-.23*	.35***	.44***	-.37***	-0.25*	.25*	0.12	0.02	-0.26
COPEBEH	-0.05	0.04	0.13	0.08	-0.1	-0.12	-0.04	0.03	-0.02	0.08

# Results

- The strongest correlations of physical domain PROs were with STRESS, SCSES, and COPEEMOT.
- Physical domain PROs did not correlate with MEDSKILL, COPEBEH, or (usually) COPEACT.
- **Psychosocial domain scores from ASCQ-Me and PROMIS strongly correlated with many scores from older psychosocial measures**
  - **STRESS**
  - **SS**
  - **SCSES**
  - **Emotion-focused Coping**
- Psychosocial domain scores from ASCQ-Me and PROMIS did not correlate with Medical Knowledge/Skills, Active Coping, or Behavioral Coping.

# Conclusions

- In SHIP-HU, Strong relationships were found between ASCQ-Me and PROMIS psychosocial PROs when they were compared to previously validated and reported psychosocial PROs.
- Relationships were also found between physical domain PROs and stress, self-efficacy, and (only) emotion-focused coping.
- Along with these relationships, the relative brevity of the newer measures and the ability to compare PROMIS scores to national norms lends credence to their utility for future SCD research.