Home-based Assessment of Patient Reported Outcome Measures Using a Smartphone App Platform: A Feasibility Study

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Conflict of Interest

Grant/Research Support:

- Agency for Healthcare Research and Quality (AHRQ), NU-PATIENT K12 (PI)
- Northwestern University Clinical and Translational Sciences Institute (NUCATS) (PI)
- Pfizer ASPIRE Sickle Cell (PI)
- PCORI Implementation Research (Co-I)

Memberships:

- ASPHO / ASH, Pediatric Hematology Choosing Wisely Panel, Member
- ASH, Committee on Quality, Subcommittee on Stewardship, Member
- Journal of Medical Interest Research (JMIR) Pediatrics and Parenting, Editor-in-Chief
- U.S. Health Resources and Services Administration, Using Technology to Prevent Childhood Obesity in Low Income Families and Communities, Expert Panel Member

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Objectives

- Review a brief background of sickle cell disease (SCD).
- Review HRQOL in SCD and the challenges of PROs assessment.
- Review pros and cons of e-PROs assessment.
- Preliminary data from a pilot feasibility study.
- Future directions.

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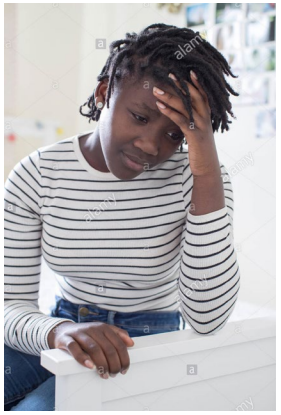
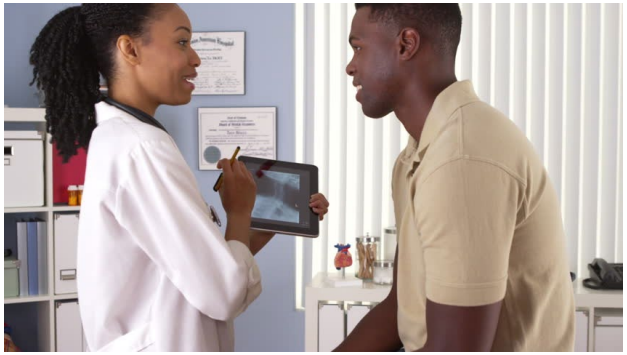
The Challenge





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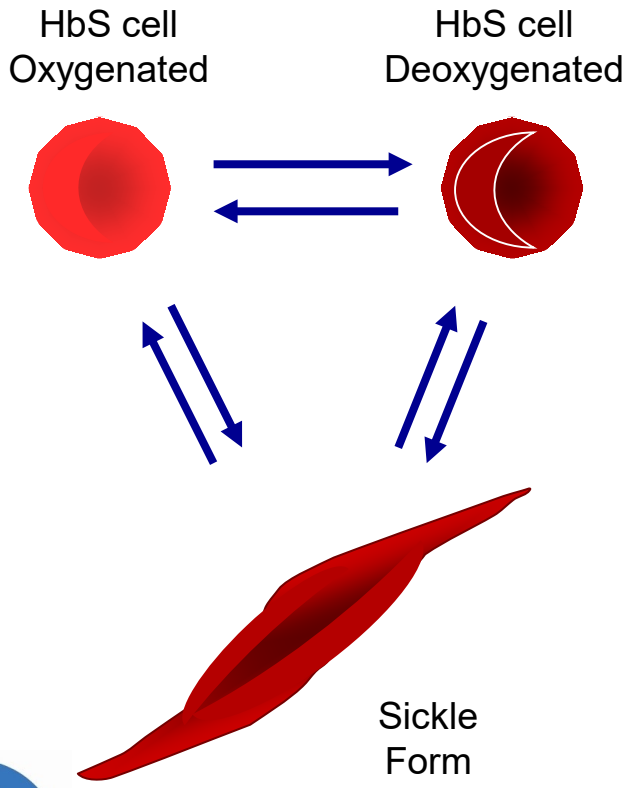
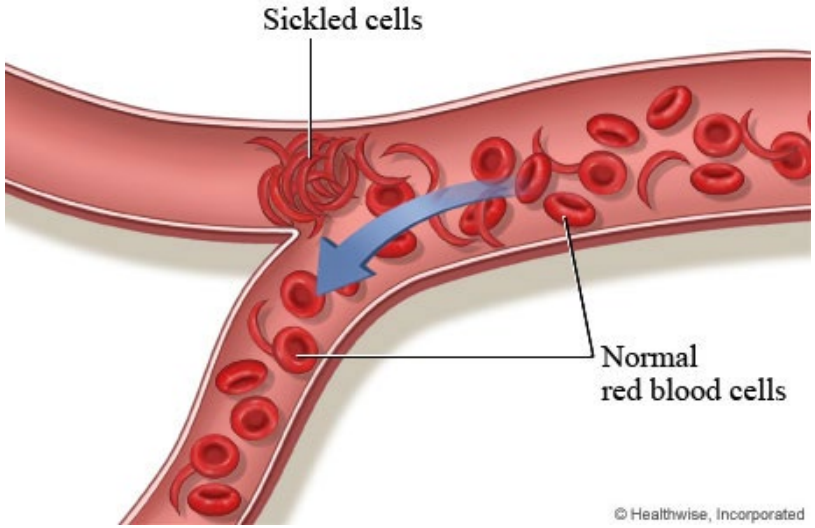
Sickle cell disease is common in Blacks

- SCD is the most common genetic disorder in the USA, affecting about 100,000 Americans and 1 in 350 AA. (NHLBI; Hassell KL, 2010)





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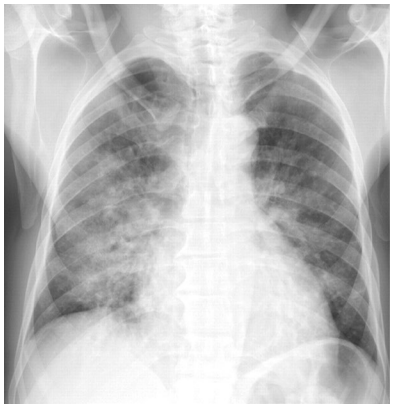
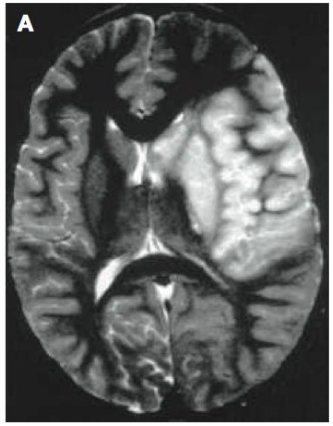
SCD is a devastating chronic illness

- Complications: pain, acute chest syndrome, pulmonary hypertension, stroke, end organ damage... (Rees et al, 2010)
- Patients have poor quality of life (QOL) (Panepinto and Bonner, 2012; Palermo T et al, 2002)

Pain Episodes



Heart and Lung



Stroke

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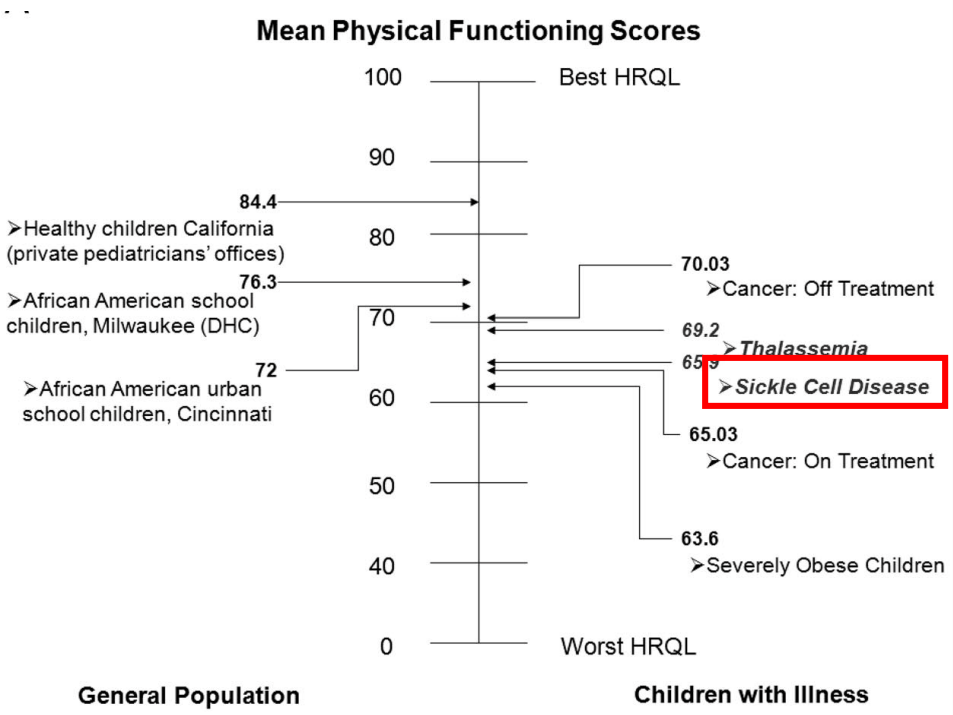
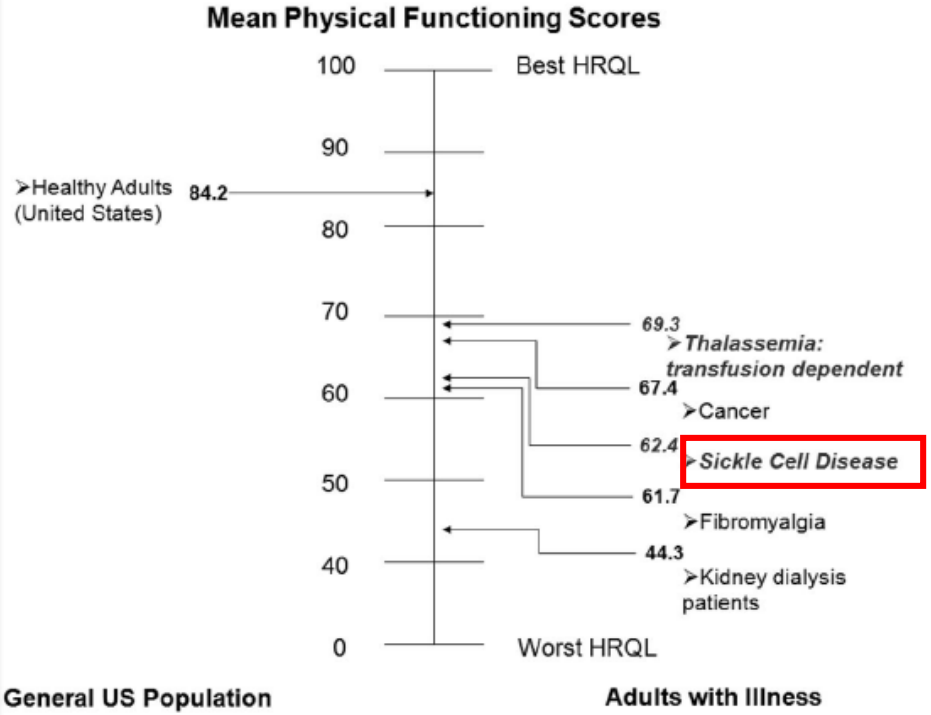
PROs / HRQOL in SCD

Children



Adults



Panepinto JA. *Hematology Am Soc Hematol Educ Program.* 2012;2012:284-289.

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PROs in SCD

- Symptoms are the main manifestations of SCD and disease control.
- Lack of disease biomarkers that show disease improvement.
- Emerging issues in SCD: (1) Neuro-cognitive deficits; and (2) Co-morbid psychiatric conditions.
- We have good measures (e.g., ASCQ-Me, PROMIS), not perfect yet.
- When to use the measure (i.e., what time points to use in a clinical trial), we may be guessing when therapeutic effect will occur.

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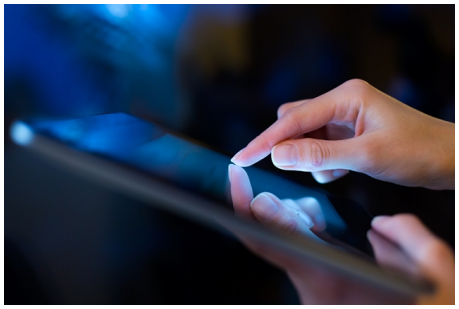
e-PROs



- More accurate, complete, high quality data
- Reminders and real-time monitoring
- Minimize recall bias and secondary data entry errors
- Adaptive testing
- Easier implementation of skip patterns
- Less administrative burden and potential cost savings
- Encouraged by regulators (FDA), ISPOR, and e-PRO consortium

1. Gwaltney CJ, et al. *Value Health*. 2008;11(2):322-333.
2. Coons SJ, et al. *Value Health*. 2009;12(4):419-429.

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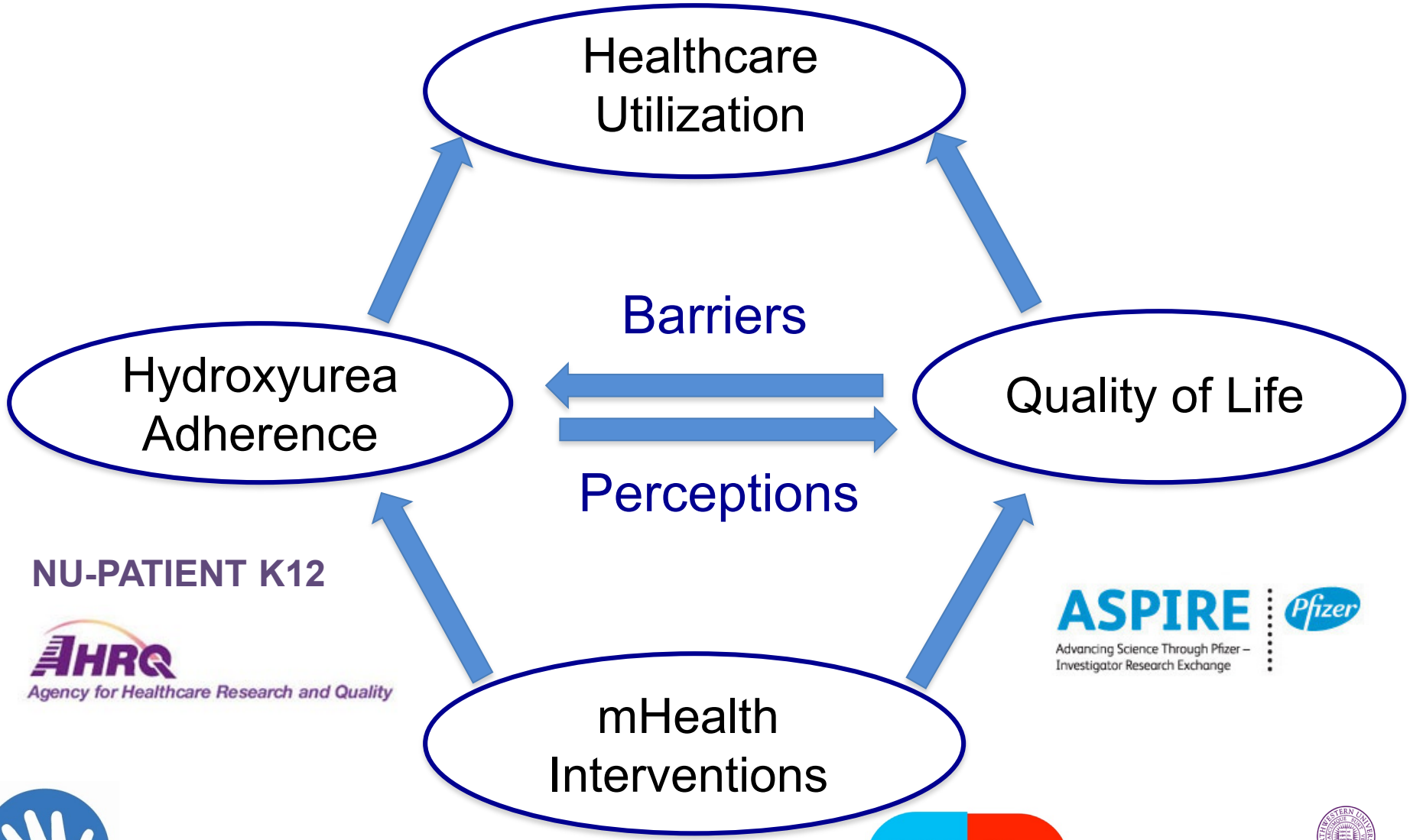
Sickle Cell Disease



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AHRQ
Agency for Healthcare Research and Quality

ASPIRE
Advancing Science Through Pfizer – Investigator Research Exchange
Pfizer

Mobile App

HU Go

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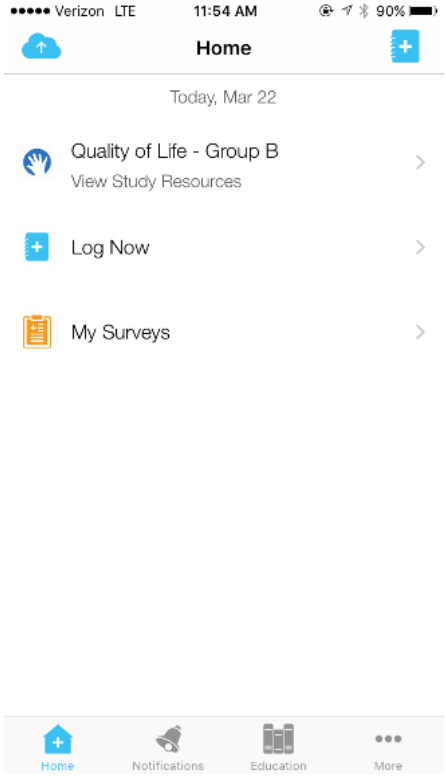
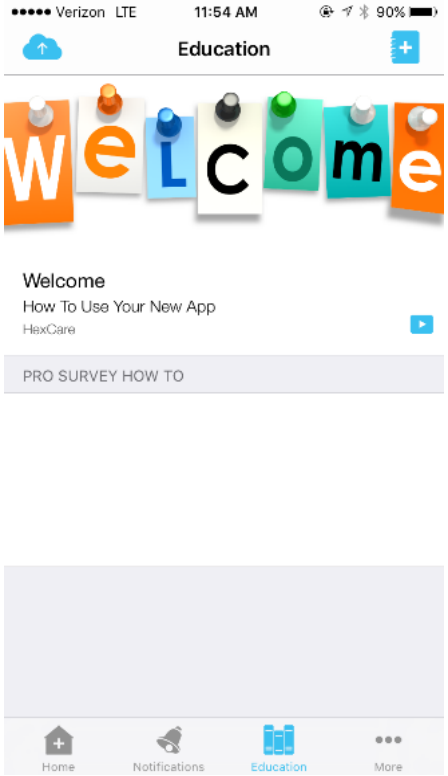
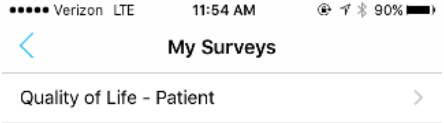
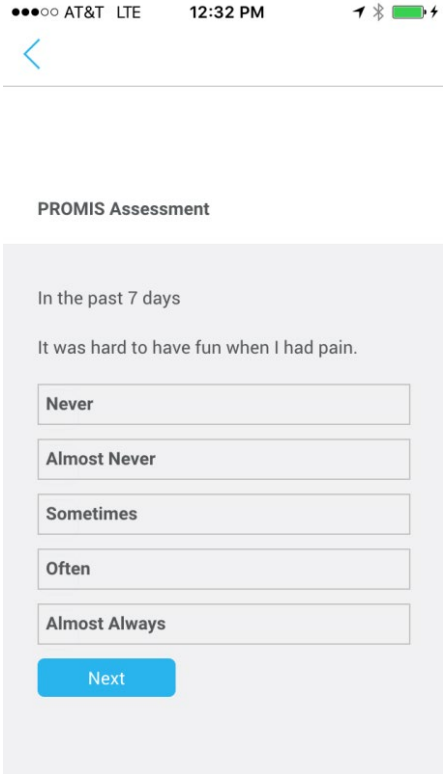
Home PROs (PROMIS) - BYOD









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Specific Aim 1

- To evaluate the feasibility and acceptability of the assessment of patients HRQOL at home using smartphones with PROMIS®-CAT measures integrated into a SCD-app.

  Hypothesis 1: The assessment of patients' HRQOL at home using a SCD smartphone app platform is feasible and acceptable.

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Specific Aim 2

- To examine the effect of the frequency of HRQOL assessments on participants' completion rate over 24-week period, every 2 weeks (Group 1) vs. every 4 weeks (Group 2).

  Hypothesis 2: Less frequent assessments of HRQOL at home will have an overall higher completion rate when compared to more frequent ones.

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Specific Aim 3

- To explore participants' experience and preferences with the process and the frequency of HRQOL assessment at home using a SCD-app.

  Hypothesis 3: Patients will have valuable insight into the process and the frequency of HRQOL assessment at home using a SCD-app.

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Study Methods

- Outpatient SCD clinic at Lurie Children's Hospital of Chicago.
- Eligibility : SCD, 12 years and older and English-speaking.
- Patients/Parents dyads randomized to:
  - Group A (every 2 weeks) or Group B (every 4 weeks), 6 month.
- 5 pediatric PROMIS measures (fatigue, pain interference, physical function mobility, depression and anxiety)
- Other surveys: (1) Demographics; (2) Technology Comfort; and (3) Usability and Acceptability Questionnaires.
- Exit semi-structured interview at the end of the study.

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Participants Characteristics

Patients (N=42)	
Age, mean ± SD (years)	15.7 ± 3
Males	57%
Black or African American	91%
Highest Level of Education	
6th - 8th Grade	41%
9th - 12th Grade	38%
HS Diploma	7%
Some College or University	12%
Bachelors Or Associates	2%

- Enrollment rate: 94%

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Technology Comfort Questionnaire

Item	Agree
I can usually deal with most difficulties I encounter using smartphones	81%
I find working with smartphones very easy	95%
I am very sure of my abilities to use smartphones	85%
I have no difficulties with most of smartphones apps I have tried to use	88%
I enjoy working with smartphones	100%
Smartphones make me much more productive	81%
I have no difficulties when trying to learn to use a new smartphone app	83%
I consider myself a skilled smartphone user	93%

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PROs Completion Rates

	Patients	Parents
Group A (every 2 weeks)	59.3%	37.5%
Group B (every 4 weeks)	71.7%	58.3%
iPhones	56.6%	40.1%
iPads	100%	100%
Overall	**65.3%**	**47.9%**

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PROs Completion Rates - Overall

Completion Rates	Patients	Parents
100%	37.5%	12.5%
50% - 99%	25%	37.5%
< 50%	37.5%	50%

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PROs Completion Rates - Frequency

	Group A (2 weeks)	Group B (4 weeks)	P-value
Patients only	59.3%	71.7%	**0.005**
Parents only	37.5%	58.3%	0.09
Patients and Parents	45.5%	65.4%	**< 0.001**

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PROs Completion Rates - Devices

	iPhones	iPads	P-value
Patients and Parents	45.2%	100%	**< 0.001**

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PROs Completion Rates - Setting

	Clinic	Home	P-value
Patients and Parents	47%	83.3%	**< 0.001**

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Satisfaction / Acceptability Questionnaire

	Patients	Parents
The quality of the app is good/excellent	100%	100%
I would recommend this app to a friend	100%	100%
I felt the app was useful to me	79%	83%
I am satisfied with the app	86%	100%
I would come back for another app study	86%	100%
I would like to continue using the app after the study	79%	67%

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Usefulness and Ease of Use

	Patients	Parents
I can use the app without written instructions	100%	83%
I learned to use the app quickly	100%	100%
I easily remembered how to use the app	100%	83%

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System Usability Scale (SUS)

	Patients	Parents
I think I would like to use the app frequently	100%	83%
I think the app was easy and simple to use	100%	100%
I found different functions of the app well designed	93%	100%
Most people would learn how to use app quickly	93%	100%
I felt very comfortable and confident using the app	100%	100%

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Conclusions

- The completion of HRQOL assessments at home using PROMIS®-CAT measures integrated into SCD-app is feasible and acceptable.
- Completion rates were significantly higher with less frequent HRQOL assessment (every 4 weeks compared to every 2 weeks), and using iPads rather than iPhones, when possible.
- Satisfaction with app platform was high among patients and parents.
- Future longitudinal studies to integrate HRQOL assessments as part of routine care for patients with SCD in between clinic visits are warranted.

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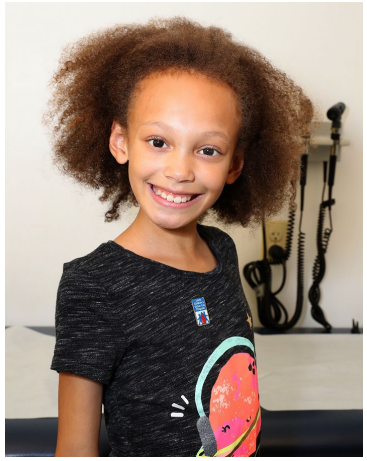
Acknowledgment – Patients



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Acknowledgment – Team / Funding

Leonardo Barrera, MPH
Clinical Research Coordinator
Lurie Children's Hospital

Zeinab Alward, MBBCh
Clinical Research Coordinator
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ASPIRE
Advancing Science Through Pfizer – Investigator Research Exchange
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Questions

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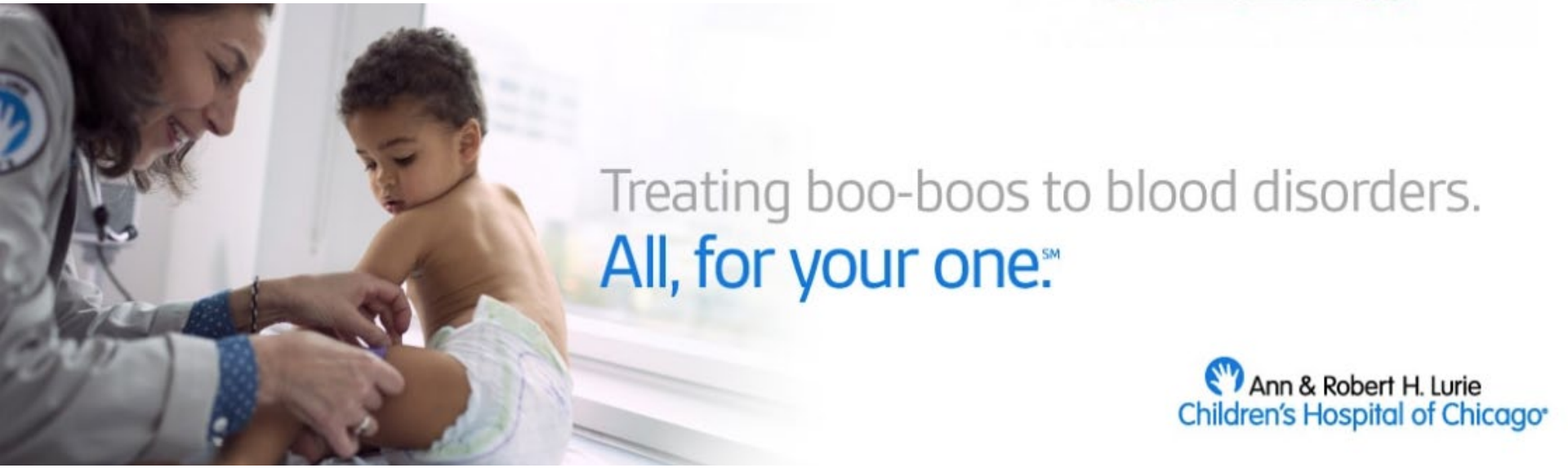

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