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Optimizing Measurement of Health-Related Quality of Life in Adolescents and Young Adults with Cancer

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Running Head: Measuring HRQOL in AYAs: A PROMISing Approach

Portions of this manuscript were previously presented: Salsman JM, Canzona MR, Duckworth KE, Danhauer SC, Patel BG, Victorson D, Sanford SD, Ip EH, Little-Greene D, Howard DS, McLean TW, Zebrack B, Fingeret MC, Tucker-Seeley R, Clayman ML, Moore JB, Reeve BB. Designing conceptual frameworks for financial burden, body image, and fertility and parenthood within adolescent and young adult cancer survivors. Paper presented at the 3rd Global Adolescent & Young Adult Cancer Congress, Sydney, Australia (December 2018).

Precis: To date, the health-related quality of life experiences of adolescents and young adults are inconsistently and incompletely captured by existing patient-reported outcome (PRO) measures. The NIH PROMIS represents the state-of-the-art for measurement science of PROs and provides an optimal approach for addressing these measurement challenges and catalyzing future patient-centered research in AYA oncology.

Keywords: patient-reported outcomes, health-related quality of life, adolescent and young adult, measurement, oncology

COMMENTARY

Adolescence and young adulthood may be characterized as a time of becoming.[1] It is a time of significant personal and professional growth and of recognizing major life milestones such as graduations, jobs, and new relationships. Almost 90,000 adolescents and young adults (AYAs) in the United States are diagnosed with cancer annually,[2] experiencing it as a significantly distressing, widely disruptive, and singularly defining event in their lives. For AYAs with cancer, their "time of becoming" is often characterized by adapting to a wide-ranging number of challenges that compromise their physical, emotional, and social development and health-related quality of life (HRQOL).[3-6] Their lives are less focused on life milestones and more on major

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treatment milestones such as completing chemotherapy, receiving "clean" scans, and returning to work or school.[7-10] Among AYAs, cancer is the most common disease-related cause of death for females, and second only to heart disease for males[2,11] yet the vast majority of AYAs will survive their disease with the average five-year survival rate of >80%.[12-14] Unfortunately, many AYA survivors report poorer HRQOL relative to their healthy peers[3,4] and are at increased risks of cancer-related infertility, financial hardship, recurrence, second primary cancers, and symptom burden for late and long-term effects.[15-17]

Despite the unique needs and challenges of being diagnosed with and surviving cancer as an AYA, the HRQOL experiences of AYAs are rarely evaluated as part of clinical trials,[18] and when they are assessed, they are inconsistently and incompletely captured by existing patient-reported outcome (PRO) measures. In 2013, the National Cancer Institute (NCI) held a State of the Science meeting to review and discuss current gaps in the evidence-base for AYA oncology across epidemiology, basic biology, clinical trials, health services and medical care, and HRQOL research.[14] Key findings and future directions to advance AYA oncology research were summarized in a special "Adolescent and Young Adult Series" published in the spring of 2016 in the journal Cancer. Among the consensus recommendations for "next steps" from the HRQOL working group was the following: "Valid, reliable, developmentally relevant, and psychometrically robust measures of HRQOL, overall and by subdomain, are needed that cross the age spectrum and allow for studies of the full AYA age range."[14]

More recently, the Childhood Cancer Data Initiative (CCDI) highlighted a similar need "to collect, analyze, and share data to address the burden of cancer in children and AYAs."[19] The CCDI has called for a better understanding of the barriers to PRO data collection in pediatric and AYA studies as well as increased use of valid and reliable assessment measures. Common barriers to completion of PROs can occur at both the patient and the clinic levels. At the patient level, factors that decrease completion rates can include respondent burden, measures that are not content or culturally relevant to the patient experience, or are poorly written (colloquial, double-barreled, or have high literacy levels), and are only available in English. At the provider/clinic level, PROs are not always integrated into the electronic medical record or the existing workflow, paper forms can be misplaced, and scoring of measures may not be interpretable or actionable. Collectively, these factors contribute to the relatively low yield of PRO data from AYAs to inform future research and cancer care.

In this commentary, our goal is to highlight the benefit of applying scale development methodologies from the NIH's Patient-Reported Outcome Measurement Information System® (PROMIS®) to the field of HRQOL measurement among AYAs affected by cancer. This can be done in two ways: 1) using existing PROMIS measures that are relevant to the life experiences of AYAs, and 2) using PROMIS methodologies to developing new measures for AYAs where gaps in important HRQOL content domains exist. PROMIS represents state-of-the-art measurement

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science of PROs and is an NIH Roadmap initiative designed to improve assessment of PROs using modern psychometric methods.[20,21] The main focus of the PROMIS initiative has been on developing instruments to assess health status for chronic disease conditions across the age range from pediatrics to adults. Adapting the World Health Organization's tripartite framework of physical, mental, and social health,[22] PROMIS has developed and calibrated measures to capture multiple areas of health and functioning[23-31] and has extensive evidence of its validity and reliability in both pediatric and adult cancer populations.[32-39]

HRQOL measurement in AYAs

AYAs with cancer represent a wide range of both disease types and developmental stages with a correspondingly wide range of HRQOL priorities. The most common cancer types among AYAs are breast, thyroid, hematologic malignancies, germ cell, and melanoma.[40] Developmentally, the AYA age group captures at least three distinct subgroups of adolescents (ages 15 to 17), emerging adults (ages 18 to 25), and young adults (ages 26 to 39).[41] This level of disease and developmental heterogeneity results in an understandably broad range of HRQOL domains impacted by cancer and a lack of consensus regarding standardized assessment of HRQOL for AYAs. A recent systematic literature review identified the following core domains of HRQOL for AYAs: physical, cognitive, emotional, restricted activities, relationships with others, fertility, body image, and spirituality/outlook on life.[42] In an observational study of developmentally diverse AYA patients and survivors, their most important HRQOL domains were physical function, pain, cognitive function, social support, and finances.[43,44] The importance of individual HRQOL domains varied based on age subgroup and treatment status. Pain was more frequently ranked as a priority domain for on-treatment AYAs than for off-treatment AYAs, and finances were more commonly ranked by older AYAs. In the largest, population-based study of HRQOL in AYAs, the NCI's Adolescent & Young Adult Health Outcomes & Patient Experience (AYA HOPE) study,[45] the most common negative psychosocial life disruptions reported by AYAs (regardless of age cohort) were finances, body image, and fertility/parenthood.[46]

Unfortunately, existing HRQOL measures for AYAs are often limited in several important ways: content that is not specific to AYAs' unique HRQOL needs or appropriate for their age group, questions that are not perceived to be relevant to AYAs, summary scores that lack meaningful reference values or norms, and questions that describe concepts in idiomatic or culturally-biased ways or are otherwise not translatable.[43,47-49] Thus, there is a clear need for psychometrically-robust measures of HRQOL to be used with AYAs that capture meaningful constructs. Rather than reinvent the wheel, it is important to provide a clearer delineation of the appropriateness of existing HRQOL measurement frameworks and identify any existing gaps in HRQOL domains for AYAs with cancer. Existing measures of HRQOL may be generic, providing global evaluations of HRQOL across broad domains of physical, mental, and social health, or they may be cancer-specific, incorporating disease- and treatment-specific aspects of HRQOL. Further,

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these measures may be developed for and validated with pediatric and adolescent populations (e.g, ages 8 to 17 years), or adult populations (18 years or older). Applying these tools for AYA research is challenging when the cohort crosses the common threshold of 18 years of age. Instead of using both pediatric and adult HRQOL measures for conducting research on AYAs, a single AYA HRQOL profile measure with a select number of short forms that captures the relevant HRQOL domains from 15 to 39 years of age would be ideal.

An informal review of generic and cancer-specific HRQOL measures for pediatric and AYA populations (Table 1) identified cross-cutting themes of physical, mental, and social HRQOL. Additional areas of relevance to AYAs' HRQOL are not easily captured by these three over-arching themes and comprise a fourth category for "other" HRQOL concerns (e.g., school, work). Only two measurement frameworks cover the entire AYA age range from 15 to 39 years of age: the Pediatric Quality of Life Inventory (PedsQL)[50-52] which has separate, partially overlapping forms for adolescents, emerging adults, and young adults; and the Minneapolis-Manchester Quality of Life Survey of Health (MMQL),[53,54] which has separate, non-parallel forms for adolescents and young adults. Notably, several important aspects of the AYA experience (i.e., financial burden,[48,55] body image concerns,[42,48] and fertility/parenthood concerns[42,47]), are rarely and inconsistently measured by these measures.

Advantages of PROMIS

PROMIS includes over 300 measures of physical, mental, and social HRQOL from among 102 adult and 25 pediatric domains.[56] The PROMIS approach involves iterative steps of comprehensive literature searches, development of conceptual frameworks through concept elicitation interviews, identifying and categorizing items, qualitative assessment of items using focus groups and cognitive interviews, and quantitative evaluation of items using techniques from both classical test theory and item response theory.[20,21,33,57-59] To assist developers in meeting the scientific standard criteria for assessing PROs, the PROMIS investigators created an Instrument Maturity Model.[33] This model describes the five stages of instrument development from latent trait or domain conceptualization to evidence of psychometric properties in multiple clinical samples (Figure 1).

What makes PROMIS stand apart from other established HRQOL measures is that each HRQOL domain measured by PROMIS is captured by an item bank. Other established HRQOL measures have a limited number of questions to assess each HRQOL construct (e.g., 6 questions on fatigue, 8 questions on physical functioning). The PROMIS item banks (one bank for each PRO) include a much larger number of questions that have undergone extensive testing using qualitative and quantitative methods. Every PROMIS measure draws a select number of questions from the item bank to provide a reliable and valid assessment of the HRQOL domain of interest. For example, selecting 10 fatigue questions out of the 95 fatigue questions in the PROMIS Fatigue item bank. PROMIS measures can be administered on paper or electronically

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as fixed-length short forms. This version of the PROMIS measure means that everyone in the study answers the same set of questions (e.g., the 10-question fatigue measure). An alternate way to administer PROMIS measures is through computer adaptive testing (CAT). CAT-based assessment individually tailors the measure to each individual based on her/his responses to each question administered. Compared to fixed-length short forms, the CAT can reduce the number of questions being administered (e.g., maybe 5 instead of 10 questions) and achieve appropriately reliable measurement. Because all PROMIS measures (fixed-length short forms or CAT-based assessment) use items selected from the same PROMIS item bank, the scores can be compared or combined together across the measures.

A particular challenge within AYA HRQOL measurement is that both pediatric and adult perspectives are represented within the 15-39 age range. Previous testing of PROMIS measures was conducted with a broad age range (8-17 years and 18-99+ years) and did not include a specific focus on AYAs. Linking analyses provide an approach to "connect" the pediatric and adult forms in physical and emotional health domains.[60,61] Alternatively, many of the adult items may prove reliable and valid for administration with older adolescents (ages 15 to 17) precluding the need for multiple forms. A unique strength of item banking and CAT is the flexibility in administration within a diverse sample. For example, younger and older AYAs may have different social health needs and priorities. A core set of items could be selected from within the PROMIS social health bank that can form a fixed-length short form across the entire AYA age range and be supplemented with additional items from the bank for specific age groups (younger vs older AYAs) to allow for greater measurement precision. This approach would provide tailoring at the item content level while also preserving comparability of scores within the full AYA age range.

Leveraging PROMIS standards and methodology is an important next step to improve assessment of HRQOL in AYAs with cancer. PROMIS can serve as a blueprint for researchers interested in developing new measures that have the same high standards as PROMIS as well as extending existing PROMIS measures to new clinical populations of interest (e.g., AYAs). Accordingly, developing new item banks to assess financial burden, body image concerns, and fertility/parenthood concerns among AYAs will allow the creation of optimal short forms and CATs. These tools should be designed following the PROMIS Scientific Standards[58] and related COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN).[62-65] By adhering to this rigorous stepwise approach to PRO development and testing, PROMIS can be effectively used to address many of the challenges in measuring AYAs' HRQOL (Table 2).

Conclusion

The NCI issued a clear call for a more psychometrically robust approach to measurement science in AYA oncology, a call that has been echoed by the Childhood Cancer Data Initiative. Advances in the development and validation of PROs for use with AYAs will strengthen

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understanding of the patient experience and may ultimately contribute to a more efficient identification of AYA patients at risk for psychosocial distress and deleterious outcomes. There is growing awareness in the oncology field that PROs are valuable to capture the patient experience to evaluate treatment efficacy and safety and should be routinely collected in trials.[66-71] Additional buy-in and sustained support from funding and regulatory agencies, and from leaders of oncology cooperative groups and review committees is needed to further catalyze PRO research in AYA oncology. A measurement system that is flexible, efficient, reliable, age-appropriate, relevant, comprehensible, interpretable, and translatable holds the potential to significantly elevate AYA clinical care and research pursuits. PROMIS provides this needed framework and approach to move this field forward.

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Table 1 Common Measures and Domains for Assessing HRQOL in AYAs

	MMQL Adolescent & Young Adult Forms	PedsQL 4.0 Generic & 3.0 Cancer Module	PCQL-32 & PCQL Modular	LAYA-SRQL	IOC-CS
for ages:	**13-20 & 21-45 years**	**13-18, 18-25, 25+ years**	**8-18 years**	**18-39 years**	**18-39 years**
Physical	• Physical • **Body Image**	•Physical Functioning •Pain and Hurt •Nausea • **Perceived Physical Appearance**	•Disease and Treatment-Related Symptoms •Physical •Pain •Nausea	•Vitality • **Fertility**	•Body/Health
Mental	•Psychological •Outlook on Life •Cognitive Functioning	•Emotional Functioning •Procedural Anxiety •Treatment Anxiety •Worry •Cognitive Problems	•Psychological •Cognitive Functioning	•Existential/ Spirituality •Coping •Cognition/ Memory	•Personal Growth •Life Challenges •Thinking/Memory Problems
Social	•Social •Intimate Relations	•Social Functioning •Communication	•Social	•Relationship •Dependence •Intimacy/ Sexuality	•Talking with Parents •Socializing
Other		•School Functioning		•Healthcare •Education/ Career	•Health Literacy • **Financial Problems**

Note: Bold font indicates the presence of financial burden, body image, and fertility/parenthood dimensions captured by existing measures.
MMQL Adolescent = Minneapolis-Manchester Quality of Life instrument Adolescent form[53]; MMQL Young Adult = Minneapolis-Manchester Quality of Life instrument Young Adult form[54]
PedsQL 4.0 Generic = Pediatric Quality of Life Inventory Version 4.0 Generic Core Scales[50]; PedsQL 3.0 Cancer Module = Pediatric Quality of Life Inventory Cancer Module[51]
PCQL-32 = Pediatric Cancer Quality of Life Inventory-32[72]; PCQL Modular = Pediatric Cancer Quality of Life Inventory-Modular[73]
LAYA-SRQL=Late Adolescence and Young Adulthood-Survivorship-Related Quality of Life Scale[74]
IOC-CS=Impact of Cancer scale for childhood cancer survivors[75]

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Figure Legend

Figure 1. PROMIS Instrument Maturity Model

Note: For additional details on the PROMIS Instrument Maturity Model, see http://www.healthmeasures.net/images/PROMIS/PROMISStandards_Vers_2_0_MaturityModelOnly_508.pdf

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Table 2 – AYA HRQOL Measurement Challenges and Potential Solutions

AYA HRQOL PRO measures need to be…	**PROMIS provides…**
Flexible	Fixed short forms or computer adaptive testing
Efficient	Minimal response burden by selecting most relevant questions
Reliable	Includes questions that demonstrate high ability to differentiate among individuals HRQOL levels.
Age-appropriate	Adult PROMIS questions are ≤ 6th grade reading level
Relevant	Wide range of HRQOL domains can be assessed by PROMIS*
Comprehensible	Vetted through cognitive interviews with a diverse sample of individuals in respect to age, education, race/ethnicity, and health status.
Interpretable	Uses easily interpretable T-score metric with reference scores to the US general population.
Translatable	Available in Spanish and other languages

Note: *PROMIS HRQOL domains overlap with the majority of important HRQOL domains for AYAs with the exception of financial burden, body image, and fertility/parenthood.

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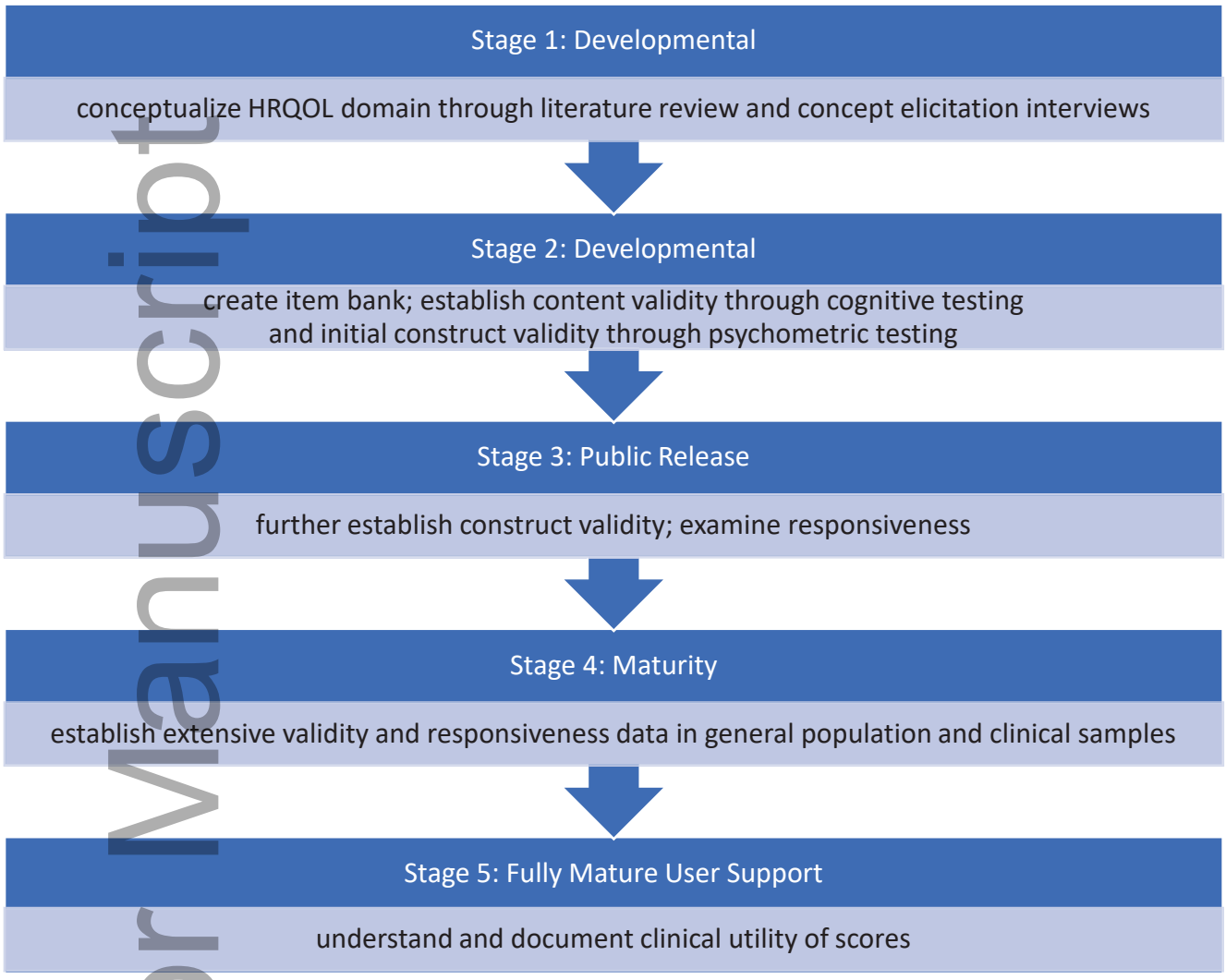

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