

Technical Report

December 2010

Project Quality of Life for Deaf and Hard-of-Hearing Children and Youth

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FINAL REPORT		GRANT NUMBER 1 R01 DC008144
PERIOD COVERED BY THIS REPORT		
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Donald L. Patrick, PhD, MSPH	FROM 03/06/2007	THROUGH 01/31/2010
APPLICANT ORGANIZATION University of Washington		
TITLE OF PROJECT Hearing Loss and Quality of Life of Children and Youth		

Introduction

The overall goal of this study was to use qualitative methods to identify and quantitative methods to assess the important QoL issues relevant to children and youth who have hearing loss. Results of the proposed qualitative work (Phase I) were used to determine content for hearing loss-specific outcome module of the Youth Quality of Life Instruments (Edwards et al, 2002; Patrick et al., 2002): 1) Youth Quality of Life- Deaf and Hard-of-Hearing Module (YQOL-DHH), for youth ages 11-18 and 2) Deaf and Hard-of-Hearing Parent Reported Observation of Behaviors & Events (DHH-PROBE) for children ages 5-10 years versions were created.

To achieve these overall goals, the specific aims were as follows:

Study 1 YQOL-DHH and DHH-PROBE Module Development:

- 1) **Aim 1:** To identify key QoL issues and develop QoL items specific to youth with hearing loss by conducting in-depth interviews and focus groups with youth ages 11-18 years. The YQOL-DHH module will be developed using the data from youth themselves.
- 2) **Aim 2:** To identify observable behaviors and events that are association with their child being deaf or hard-of-hearing that parents of children ages 5-10 year of age think have an impact on their child's quality of life. The PROBE will be developed from parents' interviews and, reviews of existing measures and literature, and in consultation with an expert panel.

Study 2 YQOL-DHH and DHH-PROBE Module Testing:

- 3) **Aim 3:** To validate the cross-sectional measurement properties of DHH specific QoL module using classical and modern test methods of item-response theory.
- 4) **Aim 4:** To explore association of degree of DHH with QoL and known or expected correlates, using a clustered sample design (see conceptual model).
- 5) **Aim 5:** To revise the draft youth- and parent-report DHH Modules using validation results and to disseminate the new DHH Modules.

The fulfillment of these aims is summarized below with supplemental documents provided in the enclosed Technical Report of the study, including instruments developed in the study and project manuscripts (see Appendices). The Technical Report will be available at the Seattle Quality of Life Group website (www.seaqolgroup.org)

B. Study Design Summary

This study was a multi-site observational cohort study. Youth ages 11-18 who are deaf or hard of hearing and parents/guardians of children ages 5-10 who are deaf or hard of hearing completed survey at one timepoint. Data were collected from 230 youth and 271 parents/guardians regarding general and hearing specific quality of life, depression, and general health status and communication questions.

The study cohort was recruited through local, regional and national associations, organizations, professional networks and schools by the following sites:

- a. The University of Washington, Seattle Quality of Life Group, and Seattle Children's Hospital;
- b. The University of Colorado, Boulder.

The final Youth Quality of Life for Deaf or Hard-of-Hearing Youth (YQOL-DHH) module for self-administration to youth 11-18 was developed at a 4th grade reading-level, in written English and American Sign Language (ASL). The Deaf or Hard-of-Hearing Parent Reported Observations of Behaviors and Events (DHH-PROBE) for administration to parents of 5-10 year old children, was developed at a 4th grade reading level in written English and U.S. Spanish and ASL.

The technical report included in Appendix A details the study procedures, methods and analysis steps.

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Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Hearing Loss and Quality of Life of Children and Youth
 Total Enrollment: 501 Protocol Number: _____
 Grant Number: 1 R01 DC008144

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	30	47	0	77 **
Not Hispanic or Latino	209	209	0	418
Unknown (individuals not reporting ethnicity)	0	0	6	6
Ethnic Category: Total of All Subjects*	239	256	6	501 *
Racial Categories				
American Indian/Alaska Native	8	8	0	16
Asian	4	5	0	9
Native Hawaiian or Other Pacific Islander	4	6	0	10
Black or African American	11	9	0	20
White	163	167	0	330
More Than One Race	19	14	0	33
Unknown or Not Reported	30	47	6	83
Racial Categories: Total of All Subjects*	239	256	6	501 *
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	30	47	0	77
Racial Categories: Total of Hispanics or Latinos**	30	47	0	77 **

* These totals must agree.

** These totals must agree.

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Study Aim 1: To identify key QoL issues and develop QoL items specific to youth with hearing loss by conducting in-depth interviews and focus groups with youth ages 11-18 years. The YQOL-DHH module will be developed using the data from youth themselves.

Objective: Existing quality of life instruments for adolescents have not included the important voices of youth of different age, sex, hearing levels, modes of communication and school placement types. Youth with various level of hearing loss participated in the simultaneous development of the Youth Quality of Life-Deaf and Hard-of-hearing (YQOL-DHH) using the needs-based model

Design: Purposive and theoretical sampling of youth ages 11-18 years who were deaf or hard-of-hearing was conducted in the U.S. Semi-structured interviews probed youth's perceptions of their quality of life. Interviews were coded in Atlas-ti 5.0 by pairs of researchers. Items were written based on interview text, compiled into a long-list by hypothesized domains: self, social, environment. Items were crafted using needs-based criteria. The item list was reduced iteratively by consensus and in consultation with an expert panel. Cognitive interviews were conducted to assess readability and clarity of survey items.

Participants: Adolescents ages 11-18 who were deaf or hard-of-hearing recruited through Seattle Children's Hospital, University of Washington, and University of Colorado, Boulder participated in this study.

Main Outcome Measure(s): Concepts of DHH-specific Quality of Life

Results: Forty nine interviews were conducted with youth ages 11 to 18 with mild/moderate (26%), mod-severe/severe (26%), and profound (47%) hearing impairment. From an initial list of 100 crafted items, 54 items were nominated for a short list, of which 43 were assessed in cross-sectional sample: n=12 Self, n=18 Social, n=13 Environment. Thematic analysis revealed 4 main themes: acceptance, confidence, perceived stigma and participation and were examined in relation to the a priori hypothesized instrument factor structure.

Conclusions: The DHH-specific quality of life instrument has established content validity based on a sample of youth with varying degrees of hearing loss and diverse backgrounds.

Products/Publications/Presentations for Study Aim 1:

- [Poster presentation: Phase 1 development poster presentation "Perceptions of Quality of Life among Youth who are Deaf or Hard-of-hearing" accepted for ISOQOL 2010 Conference in London October 30, 2010.](#)
- Manuscript "Qualitative development of quality of life survey instrument for Youth who are deaf or hard-of-hearing" in preparation.
- Oral Presentation "Quality of Life Among Children and Youth who are Deaf and Hard of Hearing" American Society for Deaf Children, Sulphur, Oklahoma, June 24-28.

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Study Aim 2: To identify observable behaviors and events associated with a child (ages 5-10 years) being deaf or hard-of-hearing that parents believe have an impact on the child's quality of life. The resulting instrument, the Parent Report of Observations of Behaviors and Events (PROBE) will be developed with parent interviews, reviews of existing measures, and in consultation with an expert provider panel.

Objectives: 1) To conduct in-depth semi-structured qualitative interviews with parents of children who are deaf or hard-of-hearing, in order to identify through content analysis the DHH-specific issues they feel are important to their child's well-being and adjustment. 2) To review the research literature for applicable instruments in order to incorporate appropriate existing items. 3) To convene a panel of expert providers in order to gain its' input on the relative importance of the items to be included in the new instrument.

Design: Self-administered cross-sectional questionnaire available via paper-and-pencil, web survey, ASL DVD.

Participants:

Phase 1: 46 parents of DHH children ages 5-10.

Phase II: 126 parents of DHH children 5-7 year olds. 185 parents of DHH children 8-10 year olds

Main Outcome Measure(s): Parent observation of hearing-specific quality of life of children.

Results: TO BE COMPLETED PENDING FINAL ANALYSIS

Conclusions:

Products/Publications/Presentations for Study Aim 2:

- Oral Presentation "*Development of a Deaf and Hard of Hearing Specific Quality of Life Instrument for Youth and Parent Observational Report for Children.*" International Congress on Education for the Deaf (ICED), July 18-22.
- Manuscript in preparation "*Development and validation of a parent-observation instrument for assessing quality of life of 5-10 year old children who are deaf or hard of hearing (DHH-PROBE).*"

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Study Aim 3: To validate the cross-sectional measurement properties of DHH specific QoL module using classical methods.

Objective: To evaluate the measurement properties of a new 32-item deaf and hard-of-hearing-specific quality of life instrument for adolescents – Youth Quality of Life Instrument – DHH Module (YQOL-DHH).

Design: Self-administered cross-sectional survey available via paper-and-pencil, web survey or ASL DVD.

Participants: n=230 adolescents ages 11-18 who were deaf or hard-of-hearing were enrolled through Seattle Children's Hospital, University of Washington, and University of Colorado, Boulder.

Main Outcome Measure(s):

We analyzed data from 230 adolescents ages 11-19 with bilateral hearing loss, of whom 51% were male, 61% Caucasian, and 43% attending mainstream public schools in the Midwestern (25%), Southern (30%) and Western (42%) regions of U.S. Hearing levels for sample were 11% mild, 20% moderate/mod-severe, 41% severe/profound and 28% had a cochlear implant. Example items are: "I feel it is hard for me to understand what people are saying because I am d/hh" and "I know how to stand up or speak up for myself." Items were administered with an 11-point response scale ranging from 0-10, coded such that 10 indicated the best quality of life.

Results: Forty of 43 items were retained for analysis. Item means ranged from 4.37 to 8.45 and standard deviations from 2.00 to 3.81. The percentage of responses in the lowest (0) and highest categories (10) ranged from 0.87% to 14.97% and from 10.0% to 76.6%, respectively. Exploratory factor analyses yielded support for three sub-factors corresponding to self-acceptance and advocacy (14 items; $\alpha=0.84$), participation (10 items; $\alpha=0.87$), and perceived stigma (8 items; $\alpha=0.85$), but no overall score, based on the inter factor correlation, parallel analysis, and review of item content. Children's Depression Inventory-Short Form total score was inversely correlated with the YQOL-DHH self-acceptance and advocacy ($r=-0.40$), participation ($r=-0.49$) and perceived stigma ($r=-0.50$) scores. Re-administration of the YQOL-DHH approximately 7 days after baseline yielded intra-class correlation coefficients of 0.70, 0.92, 0.78 for the self-acceptance/advocacy, participation, and perceived stigma factors respectively.

Conclusions: The YQOL-DHH demonstrates good reliability and validity for assessing deaf and hard-of-hearing-specific quality of life in adolescents.

Products/Publications/Presentations for Study Aim 3:

- [Phase II validation poster presentation "Measurement properties of a quality of life instrument for youth who are deaf or hard-of-hearing \(YQOL-DHH\)" ISOQOL 2010 Conference in London, England, October 30, 2010.](#)
- [Patrick, D.L. "Validation of a quality of life measure for deaf or hard of hearing youth" in press Otolaryngology, Head-Neck Surgery.](#)

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Study Aim 4.1:

To explore association of degree of DHH with QoL and known or expected correlates, using a clustered sample design (see conceptual model).

ANALYSIS 1:

Objective: 1) Compare youths' generic and hearing loss-specific quality of life across their preferred mode of communication, and 2) Compare the impact of youths' perceptions of their ability to understand parents' communication upon youths' generic and hearing-loss specific quality of life.

Design: A convenience sample of 230 youth with a wide range of hearing level were surveyed on communication-related issues, generic and hearing loss-specific quality of life, and depression symptoms.

Participants: Adolescents ages 11-18 who were deaf or hard-of-hearing recruited through Seattle Children's Hospital, University of Washington, University of Colorado, Boulder, and parent communities in Texas

Main Outcome Measure(s): YQOL, YQOL-DHH, CDI-S

Results: The mean age of participants was 14.1 years old (SD=2.2). A majority of youth reported high quality of life, regardless of preferred communication modality, degree of hearing loss or cochlear implant usage, adjusting for multiple comparisons. Higher youth perception of their ability to understand parents' communication was significantly correlated with perceived quality of life related to self, in relationships, and participation, as well as lower reported depressive symptoms and lower perceived stigma.

Conclusions: These data demonstrate the importance of youths' perceptions of communication with their parents on generic and hearing loss-specific youth quality of life. Consistent with previous research, communication modality and degree of hearing loss were not shown to have impacts on youth perceived quality of life in this sample.

Products/Publications/Presentations for Study Aim 4.1:

- Manuscript "*Mode of communication, perceived level of parent-youth understanding and perceived quality of life among youth who are deaf or hard-of-hearing.*" Under revision after 1st review, Journal of Deaf Studies and Deaf Education.

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Study Aim 4.2: To explore association of degree of DHH with QoL and known or expected correlates, using a clustered sample design (see conceptual model).

ANALYSIS 2: School Placement and Perceived Quality of Life in Youth who are Deaf or Hard-of-hearing

Objective: 1) Examine association among school placement and the three YQOL-DHH domain (Participation, Acceptance & Advocacy, Perceived Stigma), adjusting for age, gender, hearing loss, and depression scores; 2) Examine the differences in YQOL-DHH scores between youth with hearing families versus those with families with at least one parent with hearing loss; and 3) Compare quality of life measures in students with hearing loss and hearing students on a generic quality of life instrument, YQOL-R.

Design: Self-administered cross-sectional survey available via paper-and-pencil, web survey or ASL DVD.

Participants: Adolescents ages 11-18 who were deaf or hard-of-hearing recruited through Seattle Children's Hospital, University of Washington, and University of Colorado, Boulder participated in this study.

Main Outcome Measure(s): *Youth Quality of Life Instrument - Research Version* (YQOL-R) and Youth Quality of Life: Deaf and Hard-of-hearing (YQOL-DHH)

Results: For each YQOL-DHH factor, Participation, Self-Acceptance & Advocacy, and Perceived Stigma across the three different school placements (School No DHH, School with DHH, and School for DHH). For school placement, there were no significant differences for any of the three YQOL-DHH factors (Participation, $p = .967$; Self-Acceptance, $p = .712$; Perceived Stigma, $p = .492$). For age groups, there were significant differences for Participation between the younger age group (11-14 years) and the older age group (15-19 years), in that the younger group demonstrated higher Participation scores (higher is good/positive) than the older group ($p < .001$). However, the effect size for age was very small indicating that the magnitude of the differences were small (partial eta squared = .046). There were no significant differences by age for Self-Acceptance ($p = .415$) or Perceived Stigma ($p = .911$). When hearing level was entered as an independent variable, this did not result in significant differences in any of the three domains (Participation, $p = .889$; Self-Acceptance, $p = .095$; Perceived Stigma, $p = .532$).

There were very few DOD youth in schools with DHH programs so only schools with no DHH program and schools for DHH were analyzed. Separate ANOVAs were calculated for each of the three domains of the YQOL-DHH (see Table 5). There were no significant differences between DOH and DOD youth in schools with no DHH program in any domain. However, there were significant differences between DOH and DOD youth in schools for DHH in the Participation domain ($p = .003$) with a small effect size (partial eta squared = .137). DOD youth reported higher Participation scores than DOH youth (DOD: Mean = 76.61, SD = 15.26; DOH: Mean = 57.04; SD = 23.08). There were also significant differences in the Perceived Stigma domain ($p = .005$; partial eta squared = .124). DOH youth reported higher scores for Perceived Stigma than DOD youth (DOH: Mean = 31.82, SD = 20.73; DOD: Mean = 14.89; SD = 16.14). There were no differences between the DOH and DOH youth on Self-Acceptance.

We compared the scores from the DHH youth with data from previous studies on typically developing youth (general population) and on youth confirmed to have a medical diagnosis of ADHD and receiving support services in public schools (Patrick, Edwards, & Topolski, 2002). In comparison with the general population, the DHH group differed significantly on the domains of Self-Acceptance ($p = .036$) and Relationships ($p = .003$), with lower scores than the general population, but DHH youth did not differ on the Environment domain, or Total Score. When comparisons were made between the general population and the DHH grouped by type of school however, differences found were mostly lower YQOL-R scores for DHH youth in the schools with DHH programs. These youth differed significantly from the general population in all four domains of the YQOL-R (range of p values $<.001$ to $.008$.) There were no significant differences between the general population and DHH youth from schools with no DHH program. DHH youth from schools for DHH differed from the general population in one domain, Relationships ($p = .007$).

Conclusions:

In general, school placement is not associated with overall DHH-specific quality of life. The YQoL-DHH will allow future research regarding specific subdomain differences in quality of life related to school placement.

Products/Publications/Presentations for Study Aim 4.2:

- “*The Quality of Life of Youth with Hearing Loss*” *American Speech-Hearing Association (ASHA) Leader*, December 21, 2010, <http://www.asha.org/Publications/leader/2010/101221/Quality-of-Life-of-Youth-With-Hearing-Loss/>
- Manuscript “*School Placement and Perceived Quality of Life in Youth who are Deaf or Hard of Hearing*” in preparation.

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Study Aim 4.3: To explore association of degree of DHH with QoL and known or expected correlates, using a clustered sample design (see conceptual model).

ANALYSIS 3 : Cochlear implant use and quality of life in youth with severe to profound sensorineural hearing loss

Objective: Evaluate whether use of “technology” is associated with self reported quality of life using validated generic and condition specific quality of life instruments, YQoL-R and YQoL-DHH respectively.

Design: Prospective cohort study; convenience sampling.

Participants: Subjects, 11-18 years of age, with SNHL, were recruited from multiple sites around the United States.

Methods: Demographic and audiological data, technology use and communication preferences were recorded. The Clinical Depression Index-short, YQoL-R and YQoL-DHH were administered in the youth’s preferred communication mode. Subjects were stratified by type of technology (none, hearing aids or cochlear implant/s) and school setting (mainstream without DHH program, mainstream with DHH program or school for the deaf).

Main Outcome Measure(s): YQOL-DHH, YQOL-R

Results: 157 subjects, overall mean age 14.1 years(SD 2.3) and F:M 82:75, participated. 49(31%) were not using any technology; 45(28%) were using hearing aids; and 63(40%) were using cochlear implant/s. Average age of unilateral or first CI was 62.9 months. 53 (33.8%) subjects attended schools with DHH programs; 37(23.6%) attended schools without DHH programs and 57(36.3%) attended schools for the deaf. There were no statistically significant differences in YQoL-R, YQoL-DHH (participation, self/advocacy or perceived stigma) between the groups.

Conclusions: Although there were significant differences in preferred mode of communication, language used and school placement between the groups, there were no differences in self-reported quality of life in this cohort of youth with severe to profound SNHL as a function of technology used. This may be related to the relatively older age of cochlear implantation in this cohort.

Products/Publications/Presentations for Study Aim 4.3:

- [Abstract “Quality of life amongst youth and adolescents with severe to profound sensorineural hearing loss” accepted to American Society of Pediatric Otolaryngology meeting in May 2011.](#)

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Study Aim 5: To revise the draft youth- and parent-report DHH Modules using validation results and to disseminate the new DHH Modules.

Objective: Create YQOL-DHH and DHH-PROBE instruction manual, instruments and scoring programs for dissemination for public use.

Design: NA

Participants: NA

Main Outcome Measure(s):

- Youth Quality of Life- Deaf and Hard-of-hearing Youth (YQOL-DHH) User manual & Interpretation Guide
 - YQOL-DHH Instrument Module
 - ASL DVD of YQOL-DHH & answer booklet
- Deaf and Hard-of-hearing- Parent Report of Observation of Behaviors and Emotions (DHH-PROBE) User manual & Interpretation Guide
 - DHH-PROBE 5-7 Instrument Module
 - DHH-PROBE 8-10 Instrument Module
 - ASL DVD of DHH-PROBE 5-7 & answer booklet
 - ASL DVD of DHH-PROBE 8-10 & answer booklet

Results: NA

Conclusions: NA

For complete details of this study see the manuals and instruments provided in Appendix IV of the Technical Report.

Products/Publications/Presentations for Study Aim 5:

- [Youth Quality of Life – Deaf and Hard of Hearing \(YQOL-DHH\) User Manual and Interpretation Guide, 1st Edition & scoring programs.](#)
- [Self-report quality of life instrument for use in 11-18 year old adolescent populations "Youth Quality of Life – Deaf and Hard of Hearing" \(YQOL-DHH\) module English version.](#)
- Parent-report of observations of behaviors and events for deaf and hard of hearing 5-10 year olds (PROBE-DHH), User Manual and Interpretation Guide, 1st Edition & scoring programs.
- Parent-report of observation and events of children 5-10 years old who are deaf or hard of hearing "Parent-report of Observations of Behaviors and Events (PROBE-DHH)".

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Final Progress Report
Research Supplement to Promote Diversity in Health-Related Research

Poorna Kushalnagar, Ph.D., Postdoctoral Co-Investigator

Donald L. Patrick, Ph.D., MSPH, Principal Investigator

Summary of the entire supplement research experience from the mentor's perspective

Dr. Poorna Kushalnagar, who is deaf, was provided support from May 1, 2008 to June 30, 2010, to strengthen her ability to conduct qualitative and quantitative research with deaf and hard of hearing youths in the U.S. as a postdoctoral co-investigator. We introduced her to a new set of research skills including qualitative interviewing and data analysis, item writing and measure development, and psychometric analysis including classical and modern test theory (item response theory) methods. She participated fully in all aspects of the parent grant, and was exposed to new research skills at the various stages of the study. **1. Qualitative Research and Instrument Development:** During the first phase of this study, Dr. Kushalnagar received valuable training and exposure to methodological expertise in the area of culturally appropriate development of a patient reported outcome (PROS) measure, specifically, a quality of life measure for youth who are deaf or hard of hearing. **2. Cross-Sectional Validation of YQoL-DHH measure:** Dr Kushalnagar worked with Dr. Patrick and his team of researchers to validate the YQOL-DHH instrument, (developed in the parent grant) among the deaf and hard of hearing youth participants. **3. Coursework:** As part of the learning contract, she was expected to complete a psychometrics course at the University of Houston. Unfortunately, the professor who taught this course felt that having a team of interpreters interfered with her teaching effectiveness. This resulted in Dr. Kushalnagar's enrollment in my course via long distance learning. The goals were to:

- identify and evaluate the role and limitations of patient-reported outcomes in research and practice,
- describe the theoretical foundations, methods, and applications of outcomes assessment in health and medicine,
- evaluate the measurement properties of new or existing health outcome measures, and
- design an outcomes assessment, including specification of the theoretical framework, identification, evaluation, and measurement of the outcomes, and application to evaluating treatment effectiveness

Dr. Kushalnagar completed the readings and exercises in the syllabus from my course. She sent written answers to the questions for each reading as an email attachment for review by her project committee.

Summary of the entire supplement research experience from the candidate's perspective

During my postdoctoral training on the diversity supplement, I developed methodological expertise in the area of culturally appropriate development of a patient reported outcome (PROS) measure, specifically, a quality of life measure(s) for youth who are deaf or hard of hearing. For example, I performed semi-structured qualitative interviewing and data analysis, item writing and development, and participated in reviewing psychometric analysis including classical and modern test theory (item response theory) methods. I was invited to present at conferences and meetings targeted at parents of deaf and hard of hearing children as well as members of the deaf community, particularly those with Latino background. I co-authored several manuscripts from this project.

The following specifies new techniques that were learned during support on the diversity supplement:

1. Conceptual understanding and development of patient-report outcome measures
 - a. Qualitative interviewing
 - i. Form conceptual model from literature review
 - ii. Establish sample group criteria and sample size
 - iii. Develop semi structured questions for qualitative interviews
 - iv. Develop protocols for telephone and videophone interviews
 - v. Recruit eligible participants
 - vi. Conduct interviews with probing techniques
 - vii. Translate from ASL to English text
 - viii. Code thematic quotations
 - ix. Evaluate inter-rater agreements on coding
 - x. Develop items from quotations and revise
 - xi. Evaluate the goodness of items (i.e. ability to distinguish groups)
 - xii. Consult with expert panel for item selection and recommendations
 - xiii. Conduct cognitive debrief interviews
 - xiv. Revise and finalize questions
 - b. Standardization
 - c. Coordinate development of ASL and PSE DVDs
 - d. Develop protocols for different administration modes
 - e. Develop standardized recruitment and invitation letters to schools, camps and clinics
 - f. Develop protocols for parent screening to determine eligibility
 - g. Develop protocols for in-person and online survey administrations
 - h. Monitor cell saturation and recruit specific group of participants where needed
 - i. Ensure that all forms are complete before sending out survey and payment
 - j. Developed broad understanding of factor analysis and IRT procedures
 - i. Importance of ceiling items for elimination
 - ii. Team work necessary for factor analysis and determination of domain names
 - k. Development of test manuals

I. Group manuscript

Summary of participation at national and local meetings, workshops, poster sessions, and presentations. List any publications experience (as author or as part of the research team).

1. **Kushalnagar, P.**; Topolski, TD; Schick, B; Edwards, TE; Skalicky, AM; Patrick, DL. Mode of communication, perceived level of parent-youth understanding and perceived quality of life among youth who are deaf or hard-of-hearing. *Journal of Deaf Studies and Deaf Education*
2. Skalicky, AM; **Kushalnagar, P.**; Topolski, TD; Schick, B; Edwards, TC; Sie, K.; Patrick, DL. Qualitative development of quality of life survey instrument for youth who are deaf or hard-of-hearing.
3. Edwards, TE, et al. Development and validation of a parent-observation instrument for assessing quality of life of 5-10 year old children who are deaf or hard of hearing (DHH-PROBE).
4. Patrick, DP, Edwards, TC, Skalicky, AM, Leng, M, Topolski, T, Schick, B, **Kushalnagar, P.**, Sie, K. Measurement properties of a perceived quality of life instrument for youth who are deaf or hard of hearing (YQOL-DHH). Archives of Otolaryngology: Head and Neck Surgery
5. Schick, B; Topolski, TD; **Kushalnagar, P.**; Skalicky, AM; Edwards, TC; Patrick, DL. School placement and perceived quality of life among youth who are deaf or hard of hearing.
6. Skalicky, AM; **Kushalnagar, P.**; Topolski, TD; Schick, B; Edwards, TC; Sie, K.; Patrick, DL. Perception of Quality of Life among Youth who are deaf or hard of hearing. Poster session at 2010 ISOQOL conference, London, England.
7. **Kushalnagar, P.**, Mathur, G., Moreland, C., Napoli, D., Osterling, W., Padden, C., Rathmann, C. (2010). Infants and Children with Hearing Loss Need Early Language Access. *Journal of Clinical Ethics*
8. **Kushalnagar, P.**, Topolski, T., Skalicky, A., & Patrick, D. (2009). *Quality of Life Among Deaf and Hard of Hearing Youths from Spanish-speaking Families*. Invited talk at the University of Texas at Brownsville, Texas.
9. **Kushalnagar, P.**, Patrick, D., Topolski, T., Edward, E., Schick, B., Skalicky, A., & Garafalo, M. (2009). *Quality of Life Among Deaf and Hard of Hearing Children and Youth*. Paper presented at the American Society of Deaf Children conference, Sulphur, OK.
10. **Kushalnagar, P.**, Topolski, T., Skalicky, A., & Patrick, D. (2008). *Quality of Life Among Deaf and Hard of Hearing Youths from Spanish-speaking Families*. Invited talk at the Texas Latino of the Deaf and Hard of Hearing conference, McAllen, Texas.

The impact the supplement program has had on future career plans; indicate all research support being sought or already obtained; professional appointments and honors; brief description of any new research responsibility the individual will assume.

Appendix A

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STUDY TECHNICAL REPORT

Quality of Life among Youth with Hearing Loss

Prepared by:

Project Hearing Quality of Life Study Team

Donald L. Patrick, PhD, MsPH – Principal Investigator

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Section 1: Study Overview

1.0 AIMS AND OBJECTIVES

1.1 *Project goal*

Previous studies of QoL among youth who are deaf or hard-of-hearing (DHH) have focused more narrowly on individual aspects of QoL, such as functional status and psychological well-being (Huber, 2005; Hawthorne et al., 2004), peer relationship, self-esteem and inclusive education (Hintermair, 2000). These studies compared youth with hearing loss to children with normal hearing. Although generic measures are useful, instruments used with hearing youth may not accurately reflect the perspective of youth with hearing loss themselves. Using measures of outcome that reflect the “voices” of persons with hearing loss is important to the development and evaluation of interventions that are culturally and socially sensitive and inclusive. More recently researchers have examined what they called HrQoL in a group of children ages 5-14 years, with a self-report measure that assessed the perception of the benefits of a cochlear implant among children who were deaf from birth and had used an implant for between 0.19 and 10.6 years (Schorr, 2009).

We define “quality of life” as an individual’s “perception of their position in life in the context of the culture and value systems in which they live, in relation to their goals, expectations, standards, and concerns” (WHOQOL Group, 1994). This definition requires that youth and parents or guardians define the concepts and items, that the measure use subjective self-report whenever possible, and that the items be developmentally appropriate. It focuses on a positive emphasis on health enhancing aspects of life rather than a negative orientation found in most mental health assessments. Parent-child reporting agreement has been documented to be generally low, especially with regard to subjective perceptions such as quality of life and emotions (Waters et al 2003). Therefore, when parent measures are considered to be proxy measures for child perceptions, they must be regarded with great suspicion. Nevertheless, parents are the principal decision makers for the young child’s well-being, including use of aids (e.g., cochlear implants), school type (residential, private, and public) and communication style (Aural vs. Visual). Thus understanding parents’ perceptions of their children’s QoL in regard to hearing loss is important. Parent perceptions may be measured without considering them proxy reports, similar to caregiver measures used with adult populations.

Our goal was to use qualitative methods to identify and quantitative methods to assess the important QoL issues relevant to children and youth who have hearing loss. Results of the proposed qualitative work (Phase I) were used to determine content for hearing loss-specific outcome module of the Youth Quality of Life Instruments (Edwards et al, 2002; Patrick et al., 2002): 1) Youth Quality of Life- Deafness and Hard-of-hearing Module, for youth ages 11-18 and 2) Parent Report of Observation of Behaviors and Events (PROBE) for children ages 5-10 years versions were created.

1.1.1 Research questions/aims

Study 1: Phase I Module Development:

- 6) To identify key QoL issues and develop QoL items specific to youth with hearing loss by conducting in-depth interviews and focus groups with youth ages 11-18 years. The YQOL-DHH module will be developed using the data from youth themselves.
- 7) To identify observable behaviors and events that are association with their child being deaf or hard-of-hearing that parents of children ages 5-10 year of age think have an impact on their child's quality of life. The PROBE will be developed from parent interviews and reviews of existing measures and literature, and in consultation with an expert panel.
- 8) Diversity Supplement Goal: To identify key QoL issues specific to deaf and hard-of-hearing children and youth from Spanish-speaking families, and provide descriptive summary on key QoL issues for this subpopulation.

Study 2: Phase II Module Testing:

- 1) To validate the cross-sectional measurement properties of DHH specific QoL module using classical and modern test methods of item-response theory.
- 2) To explore association of degree of DHH with QoL and known or expected correlates, using a clustered sample design (see conceptual model).
- 3) To revise the draft youth- and parent-report DHH Modules using validation results and to disseminate the new DHH Modules.

1.2 Diversity supplement project goal

A two-year diversity supplement was obtained to support and train a postdoctoral fellow who is deaf. The goal for the diversity supplement was to use qualitative methods to identify the important QoL issues relevant to deaf and hard-of-hearing children who come from Spanish speaking families. Because the number of participants in this subpopulation will be small, the qualitative data from Hispanic/Latino deaf and hard-of-hearing children will be used only to provide a descriptive summary on key QoL issues that are specific to this subpopulation. Because this information will be pertinent to the greater DHH population their qualitative data will be included in the larger sample of the general deaf and hard-of-hearing youth population and used for the development for the deaf and hard-of-hearing module of the Youth Quality of Life instruments (Edwards et al, 2002; Patrick et al., 2002).

2.0 BACKGROUND AND SIGNIFICANCE

2.1 *Definition of Hearing Loss and Prevalence*

Current estimates of hearing loss from the Better Hearing Institute (Kochkin, 2005) indicate that approximately 31.5 million people (10.6%) people in the US are DHH. Severe to profound hearing loss diagnosed in infancy or early toddlerhood is estimated to occur in 1 to 3 of every 1000 births and is thought to produce the most deleterious impact in the development of speech, language, and communication skills (Greenberg & Kusche, 1989; ASHA, 2006). Ninety-two percent of infants and children with hearing loss have parents with normal hearing (Mitchell and Karchmer, 2003; Holt, 1994). Through its effect on the ability to communicate, socialize and cultural identity, hearing loss poses enormous challenges to children and their families. The current literature available to families mainly focuses on how interventions enhance auditory abilities, speech, and language skills (Greenberg, 1993; Harris 1978; Jackson, 2001; Marschark, 1997).

2.2 *How Common is Hearing Loss among Children and Youth?*

At least one in 1000 children are born with bilateral sensorineural hearing loss ≥ 40 db putting them at risk for speech, language and psychosocial dysfunction (Smith, Bale & White, 2005). Although objective measures of hearing status, speech production, language development and psychosocial function exist, the impact of hearing loss on an individual's evaluation of his/her position in life, referred to as quality of life (QoL) has rarely been studied. Quality of life is the ultimate outcome of any intervention because it expresses subjective well-being. For children and youth with hearing loss this outcome is particularly important because it reflects successful communication, a critical part of normal development (Mason, 1996; Steward, 2000).

2.3 *Healthy Communication*

Approximately 90% of children with profound hearing loss are born to hearing parents, many of whom have never met or interacted directly with a person with hearing loss. This interfamilial discontinuity creates major dilemmas for children with hearing loss and their hearing families (Pipp-Siegel, 2002; Mohr, 2000). Most children with hearing loss do not have access to professional people who are Deaf, or family members who can introduce them to the minority culture and language of the Deaf community, which they may eventually adopt (Mar, 1995). Meanwhile, family members face unusual challenges in one of the most fundamental aspects of human life, communication with their child (Geers & Schick, 1988). In general, it is thought that the QoL of children with profound hearing loss is lower than that of their hearing peers because the body of evidence showing that children with profound hearing loss are at much higher risk for poor adjustment as reflected by increased behavior problems, academic delays, and poor problem solving skills, as well as parental reports of greater stress and poor family adjustment (Schlesinger & Meadow, 1972; Luterman, 1987; Russell, 1998) (although a causal association between hearing loss and these factors has not been established). On the other hand, there are many children and youth with hearing loss who do not have these problems, function very well, and become successful adults. Thus, it appears that it is not hearing loss per se that leads to deficits (Calderon, 1988 & 1999).

2.4 *Limited Knowledge for Decision-Making*

Children and parents need reliable and relevant information with which to make important life choices (Eccles, 1993; Harris, 1978 & 1995; Lee 1995). Parents and children report that the range of information available for use in making these choices is sorely limited. Parents typically make decisions (often with guidance and input from hearing professionals specializing in hearing loss e.g., surgeons, teachers, audiologists, counselors) on the basis of potentially

sensori-centric information (i.e., often solely from a hearing person's perspective without the consideration and sensitivity to the experience of deafness). This will not necessarily guide parents in the direction of fulfilling their primary desire to optimize well-being for their child with hearing loss. Further, due to differences between hearing parents' and children with hearing loss' life experiences, it may be difficult for the parent to fully understand what their child might define for him or herself as optimal QoL (Gilman, 2004; Mohr 2000). Thus it is important for the child with hearing loss, particularly older teens, to give voice to their perspective as to what constitutes and contributes to QoL.

2.5 Theory and Research on Quality of Life in Youth with Hearing Loss

Our approach toward measuring QoL starts with the World Health Organization (WHO) general definition of QoL as people's "perceptions of their position in life in the context of the culture and value systems in which they live, in relation to their goals, expectations, standards, and concerns" (Bonomi et al., 2000; WHOQOL Group, 1994). This definition of QoL is broader and more global than the concept of "subjective well-being" in reflecting the cultural and social context that defines the good life (Kahneman, Diener, & Schwartz, 1999, p. x) or health-related QoL (HRQoL), which focuses on functional limitations. This definition also requires that youth define the concepts and items, that the measure use subjective self-report whenever possible, and that the items be developmentally appropriate. It focuses on a positive emphasis on health enhancing aspects of life rather than a negative orientation found in most mental health assessments.

Few studies have examined the broad impact of hearing loss on QoL of children and youth with hearing loss, although health-related QoL (HRQoL) has been included in a few studies (Huber, 2005; Wake, Hughes, Collins, & Poulakis, 2004; Hawthorne et al., 2004; Karinen, Sorri, Valimaa, Huttunen, Loppo 2001). The QoL concept is important to the investigation of children and youth with hearing loss, because of the centrality of communication issues in normative development and the saliency of communication to everyday life.

An appropriate context for the assessment of QoL specific to hearing loss in children and youth is that of promoting the health of people with disabilities. At the University of Washington Center for Disability Policy and Research, we have developed a conceptual model for health promotion that includes important influences extrinsic to the individual (the environment), influences that are intrinsic to the individual, and the progression from impairment to functional status and perceptions within the context of the Americans with Disabilities Act (Patrick, 1997b; Patrick et al., 1997; Patrick & Chiang, 2000). We have modified this model, based on DHH literature, to highlight the role communication plays in the lives of these children and youth (see Figure 1).

Summary

Hearing loss in early life can have a significant impact on the development of speech, language, and communication skills, interpersonal relationships, and social development adversely affecting a child's well-being. Measures for determining the important issues for children and youth with hearing loss are needed for use in, needs assessment, education placement, and for program design and evaluation.

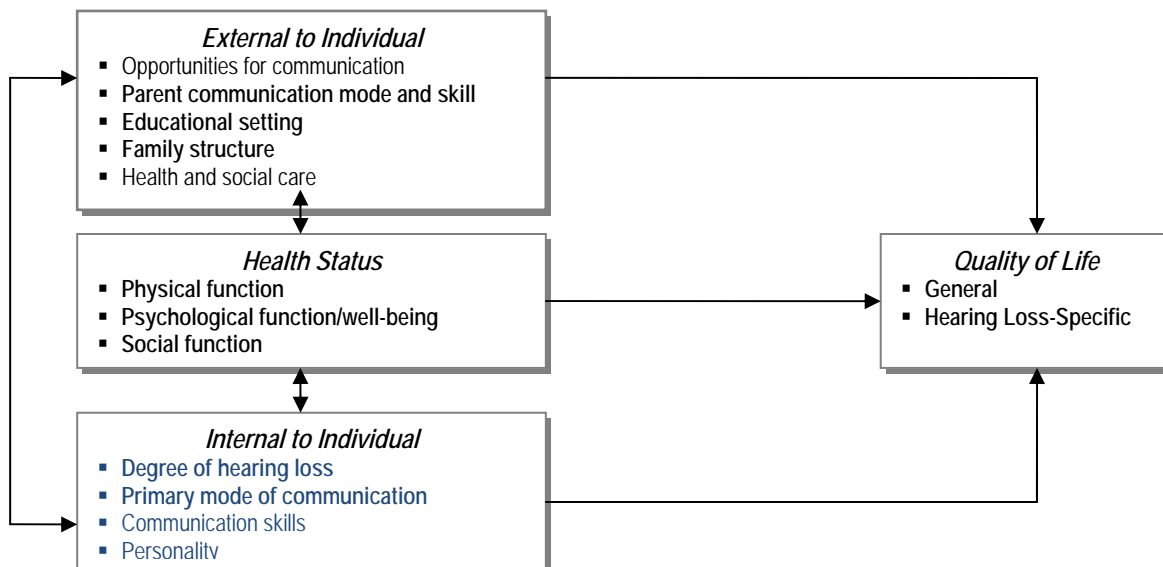
The effects of different interventions on the QoL of children and youth with hearing loss are highly relevant and understudied. We proposed to apply solid methodological approaches toward the goal of developing valid and reliable outcome measures that can inform and be used to understand the factors leading to positive QoL for children and youth with hearing loss. With strong ties to an extensive network of hearing loss education programs, clinical programs, and a

diverse population of families, we have successfully conducted this research in Washington State, Colorado, Arizona, and New Mexico, as well as in a national sample.

Culturally, developmentally appropriate measures of outcome grounded in the populations affected by hearing loss are needed for research studies and for evaluation of interventions.

3.0 Conceptual Model of Hearing Loss and Quality of Life

Figure 1. Conceptual Model of QoL and Correlates for Children and Youth with Hearing Loss*



* Correlates that were assessed in this study are bolded

4.0 STUDY ADMINISTRATION & TIME LINE:

The research study was conducted from April 1, 2007 to March 31, 2010. The below project activity milestones were met, except with some delays and changes to timeline and protocol which are explained in more detail below.

Table 1: Overview of Time Line for Phases I and II

Activity	Year 1	Year 2	Year 3
Obtain IRB approval at sites	Prior to Award	Renewal at Year 2 start	Renewal at Year 3 start
Convene project meetings	Weekly	Weekly	Weekly
Recruit youth	Qualitative: within 2 months of funding	Quantitative: Will coincide with the annual survey in AZ. In WA and NM it will begin as soon as YQOL-DHH is finalized	Complete by 9 months of Year 3 to permit analyses
Questionnaires/Measures	Prepare in months 8-12 of study add DHH module month 12.	Administer months 13-24 of grant	Administered through month 9 of Year 3

<i>Test-retest</i>		Within 1 week after baseline and 4 weeks complete by month 24 of grant	Administered through month 9
<i>Analysis/Data Entry</i>	Months 3-12 for creation of measure (YQOL-DHH)	Begin Data Entry in month 14 complete by month 25 of grant	Month 33 data cleaning and verification. Months 33-35 final analysis
<i>Manuscript Preparation and Final Report</i>			Months 33-36

5.1 MULTI-SITE COORDINATION

During the course of the study, we conducted weekly project conference calls to facilitate the development of study materials and track recruitment progress during phases 1 and 2 of the study. Weekly recruitment reports were created and distributed to group during phase 2. Calls will continue during the analysis phase to review collected phase 2 data and organize manuscript production.

5.2 Overview of Protocol Changes

Personnel & staffing:

During the three-year study period the project adjusted to several personnel and staffing changes which had the effect of delaying study activities at several intervals. The phase 1 timeline was lengthened in order to take into account hiring challenges for the research coordinator position. Additionally, in phase 2 the project manager (Tari Topolski) required medical leave and a new project manager was identified (Anne Skalicky). In the analysis phase, the collection, reading and determination of audiological records was delayed due to scheduling changes for Melissa Garafalo, ASHA certified audiologist.

Interpreter Interviewer Hiring and Training:

In the original protocol we intended to hire interviewers who are native signers/Spanish speakers or certified interpreters. This staffing plan proved to be not possible due to budgetary shortfalls and also not practical due to the involvement in the study of Dr. Poorna Kushalnagar, a fluent deaf researcher who joined the project in 2007 with a NIH diversity supplement.

Diversity supplement:

In 2008, Dr. Kushalnagar joined the project with a NIH diversity supplement to study the issues related to quality of life among Hispanic youth whose primary language in the home is Spanish. Additionally, the diversity supplement will allow validation and test the cross-sectional psychometric and practical measurement properties of the Youth QoL Deafness and Hard-of-Hearing Modules in Texas.

Study 1:

Focus groups:

Focus groups had been included in the original study proposal as a method to supplement the information gained from the qualitative interviews. Focus groups were to include parents of youth with hearing loss ages 5-18 years and young adults with hearing loss ages 19-22 years. Parents who participate in the focus groups were to be hearing, hard-of-hearing or deaf. Focus groups were to be conducted with young adults, because it was foreseen that because they have just finished the adolescent period they would be able to look back retrospectively and

identify themes, topics, areas that adolescents may have felt were too sensitive to discuss. Additionally, the focus group participants were to review the content areas and proposed items for the YQOL-DHH modules derived from the parent and youth in-depth interviews. Participants were to examine and prioritize the issues and to discuss any issues they feel have not been thoroughly covered.

A determination was made during phase I of the study to not conduct focus groups with 30 young adults 19-22 and 30 parents of children ages 5-18. The research team considered several factors in cancelling the focus groups: study timeline, cost/effort in convening focus groups, and the information to be gained from focus groups. After review of the diverse and rich nature of the qualitative interviews with 11-18 year olds and determined that the cost in time and effort to convene and conduct focus groups would outweigh the benefit of the information to be garnered from them. The content, themes and issues discussed by parents and youth in the qualitative interviews was extensive and more than adequate for instrument development.

Study 2:

Sample size:

In the original phase 2 sample size calculations from the grant, we proposed appending the YQOL-DHH module to annual school-based surveys conducted in Arizona and Colorado. Unfortunately, before the phase 2 study was initiated, the Arizona and Colorado Departments of Education cancelled the annual school-based surveys due to state budget cuts. The annual survey was a critical component of subject recruitment in Colorado. Therefore, the initial sample goal of recruiting 550 youth and 550 parent participants in phase 2 of the study was reviewed and power calculations were re-run to predict the number of participants needed to recruit through convenience sampling. A sample of 300 participants for both the youth and parent surveys was determined (see section X for sample size methods).

Mild-moderate	80
Moderately severe-severe	67
Profound	153

Recruitment strategy:

In addition to recruiting participants through schools and organizations serving deaf and hard-of-hearing children in Arizona, Colorado, New Mexico, Texas and Washington, recruitment was expanded to include participants from other states. Presentations on the overview of our study and recruitment needs were given at the Texas Latino Council of the Deaf and Hard-of-hearing and American Society of Deaf Children conferences. Letters of introduction were sent to 3,000 members of the American Speech-Hearing Association (ASHA) and over 500 listserv members of the Educational Audiology Association (EAA) and Cochlear Implant Associations. Likewise, invitations were sent to parent organizations (Hands and Voices; Listen and Talk), cochlear implant and deaf community websites (The ASL-Cochlear Implant Community; Cochlear Community; Facebook social pages), summer camps for deaf or hard of hearing, and D/HH consultants at state departments of education. Advocacy groups, such as AG Bell, Hearing Loss Association, and others were approached for free advertising via their online forums, magazines and newsletters. Published study advertisements were released from March 2009 dates to October 2009.

Section 2:
Qualitative Phase 1 Development

6.0 Qualitative Study-Phase I Module Development of DHH QoL Modules

6.1 Study I Design

A qualitative study with purposive sampling was conducted using the methodologies of literature and instrument review, and in-depth semi-structured interviews in item generation, expert consultation, inductive text analysis, cognitive debriefing, and readability. The primary objective was to identify the issues and life situations that children and youth who are deaf or hard-of-hearing perceive as important to their quality of life and to develop specific quality of life measures for children and youth who are deaf or hard-of-hearing. A parent observational measure of events and behaviors was developed for children ages 5-10 and a self-report QoL version for youth 11-18.

6.2. Study I Sample

A total of 49 youth ages 11-18 and 46 parents of children ages 5-10 participated in Phase I of the study including in-depth semi-structured interviews and cognitive debriefs. For the diversity supplement, 11 youth and 3 parents from Spanish-speaking families participated in interview. The in-depth interviews elicited potential items for the new modules.

To ensure applicability to all youth with hearing loss, we recruited as diverse a sample as possible (spoken/signed English, ASL, use of aids e.g., cochlear implant, hearing aids, FM, location, rural, urban, and ethnicity) to identify the salient issues for this heterogeneous population. We also monitored the sex and ethnicity of the sample to ensure the relevance of the content to all groups in the study design.

In this study, because of the complexity of communication with youth with hearing loss, we proposed conducting interviews with 45 youth ages 11-18 and 45 parents of children ages 5-10. In previous studies we noted that after 30-35 in-depth interviews we had achieved information saturation. We monitored the interview data and looked for information saturation throughout the interview process. The interview process was terminated when information saturation regarding quality of life issues was reached.

6.3. Study 1 Recruitment

Table 2 outlines the study recruitment goals for study 1 conduct of qualitative interviews.

Table 2. Target Participant Numbers for Phase I Module Development

	In-depth Interviews with Youth ages 11-18	Interviews with Parents of children ages 5-10	Cognitive interviews with Youth ages 11-18	Cognitive Interviews with Parents of children ages 5-10
Seattle	20	20	6	6
Texas	10	10	2	2
Colorado	5	5	2	2
Total	45	45	10	10

6.3.1. Informed Consent

Consent and assent was obtained by site staff prior to the time the participant was interviewed. All members of the team who obtained informed consent completed Human Subjects training and were trained in obtaining informed consent. The consent forms were reviewed with the parents and the assent forms with the adolescent during the telephone screening interview. Parents and youth returned the consent/assent form directly to the study coordinator or project manager via mail or during the face-to-face interview.

A toll-free dedicated phone number was provided for youth and parents who were interested in the study. Accommodation for youth and parents with hearing loss included, relay service, web-cam, videophones and interpreters or staff ASL, signed English, spoken Spanish, so that youth/parents with hearing loss could be screened and have their questions about the study answered. If youth or parents called the study office, the study coordinator obtained oral consent and then conducted the eligibility screen with a primary caregiver. This strategy has been used successfully by the Seattle Quality of Life Group (SeaQoL) in past studies involving youth with and without chronic conditions.

Children's Hospital and Regional Medical Center Hearing Loss Clinic

Patients were informed and invited to the study when they came into the Hearing Loss Clinic or Audiology Clinic for a routine follow-up visit. Either during their visit at the clinic or a telephone call follow-up, patients were informed by clinic staff. Where possible, clinic staff handed out to prospective participants an information packet giving an introduction to the study, and asked for their oral consent/assent to be contacted by the study recruiter. For those who provided oral consent/assent, clinic staff recorded the patient's and parent's contact information on the contact form and faxed it to the study office. The study recruiter then called these families, and conducted a telephone screen with primary caregiver of those youth who were interested in participating and orally consent to the interview.

During the initial recruitment phone call the study recruiter went through the consent/assent forms and asked the participant if they had any questions about the consent/assent to ensure that the participants understood the study and study requirements. For participants for whom it was determined that they had not received an information packet prior to the time of the initial recruitment phone call, the study coordinator sent a packet to the participants in the mail. The study coordinator then contacted the participants again prior to their appointment to go through the consent/assent forms, to ensure that the participants understood the study and study requirements prior to their study session.

Washington school sites

Information packets included a Recruitment Letter, Fact Sheet, Flyer, release of information form with a copy of the Verification of Degree of Hearing Loss, Consent/Assent forms, preaddressed postage paid envelopes, and names of the investigators. The packets were provided for school staff to send to the parents. In the Edmonds School District, and at the Northwest School for the Hearing Impaired, packets were mailed in postage pre-paid envelopes to the parents by school staff. In the Tacoma and Seattle Public School Districts, only flyers were sent to the parents via the students. Interested parents and youth were directed to contact the UW study coordinator, go to our website or return the interest card in the preaddressed postage paid envelope included in the packet to obtain additional information.

Schools identified youth who have an IEP or 504 Plan because of a hearing impairment. Packets or flyers were distributed to parents of all youth in the school who met the age criteria

and have an IEP or 504 Plan due to a hearing impairment. Youth with hearing loss and parents of children with hearing loss were recruited from Washington School for the Deaf (WSD), Northwest School for the Deaf and the school districts of Seattle, Edmonds, Tacoma, Colorado and Texas and through community advertising/networking (these sources are described below).

In the schools, flyers were mailed or given to the students to take home to the parent, with instructions for interested parties to contact the study coordinator who obtained verbal consent to conduct the eligibility screener. Community recruitment was pursued through channels targeting the Deaf community using methods we have used in the past with success including distributing flyers through community centers and churches, Deaf organization list serves and advertising on teen and deaf-oriented web sites and in local teen and deaf oriented newspapers. We also attended community events and passed out flyers and talked with interested parties.

At the Listen and Talk program and the WSD the packets were provided to schools in postage-prepaid envelopes that the schools will then mail to the parents (approximately 190 packets). To help increase participation, as a follow-up to the mailing, WSD provided space for a booth for UW project staff to set-up and talk with parents about the project during registration for the 2007-2008 academic years. The UW project staff distributed information packets and obtained contact information for follow-up with interested parents and youth at that time.

Colorado sites

Information packets that include a Recruitment Letter, Fact Sheet, Flyer,-and interest cards and preaddressed postage paid envelopes were mailed (or during presentations to youth, given) to students identified by the participating Colorado School Districts. Interested parents and youth were directed to contact the CU study coordinator for additional information, or return the interest card in the preaddressed postage paid envelope included in the packet.

Schools identified the youth who have an IEP or 504 Plan because they had a hearing impairment. Packets were sent to parents of all youth in the school who meet the age criteria and have an IEP or 504 Plan due to a hearing impairment.

Texas sites

The Texas recruitment for Latino/Hispanic group included students from Spanish speaking households. These students used primarily ASL or English or preferred to communicate using PSE or Signed Exact English but their parents speak primarily Spanish at home. Students and parents were recruited from the Regional Day Schools for the Deaf in Houston, Dallas, El Paso, Brownsville, Harlingen, McAllen, San Antonio and Austin. A study presentation with emphasis on recruitment issues was also given at the Texas Latino Council of the Deaf and Hard-of-hearing conference in McAllen, Texas. Interested participants were immediately scheduled for screening interview. If they met eligibility, they were asked to complete and sign a packet of parent consent, youth assent and audiology information release forms before participating in semi-structured qualitative interviews.

Recruitment Letters, Flyers, Fact Sheets and Interest Cards about the study were given to the students either in person to take home to share with their parents or via mail. Youth signers who were interested in participating in the study were instructed to contact Dr. Kushalnagar via videophone or email. Parents who speak Spanish were directed to contact Ms. Skalicky. The interviewer provided additional information about the study and for those interested; a telephone screen was conducted with the parent who provided oral consent. For eligible students and

parents who chose to participate in the study, a complete packet of information and forms was mailed. A survey appointment was scheduled upon receipt of the signed forms.

Community recruitment

Through channels targeting the communities of deaf and hard-of-hearing individuals, we solicited participation using methods that we have used in the past with success. Methods included distributing flyers through word of mouth in the community, community centers and churches, deaf organizations and advertising on teen and deaf-oriented web sites and in local teen and deaf-oriented newspapers. A toll-free dedicated phone number (videophone) was provided for youth and parents who were interested in the study. Questions were answered by the study coordinator who was well trained in communicating with deaf or hard-of-hearing persons. If a participant under the age of 18 contacted the study recruiter, they were given a brief description of the study including information about the inclusion and exclusion criteria. The recruiter spoke with the youth's parent/guardian, explained the study procedures, inclusion and exclusion criteria, obtained oral consent to conduct the eligibility screener and asked for verbal consent to speak with their child further regarding the study and/or schedule a time to meet at the project site or in the family's home. If a parent/guardian was not available, the study recruiter informed the youth that since they are under the age of 18, they were not eligible to participate unless they had parental consent. The recruiter asked the youth for a contact telephone number and a best time to reach his/her parent or guardian. No other information was collected.

Communication regarding recruitment took place through email, webcam, videophone, as well as regular mail. At the project website, study information was made available in English text, Spanish text and ASL videos.

Study 1 Recruitment Steps:

1. **Telephone Screening.** We receive a list of candidates from Seattle Children's Hospital, or a permission to contact form, and then we call participants. The telephone screening is conducted to determine eligibility.
 - a. **Reviewing the consent form.** For every candidate, we review the consent form step-by-step to explain the study including the risks and benefits. We will do this regardless of whether the candidate says they have read the consent/assent forms or not.
 - b. **Ten Screening Questions.** Eligibility is determined from these ten questions. The questions and answers are straight forward, except for secondary disabilities. It is important to keep in mind that as long as the deafness or hearing impairment is the major issue affecting quality of life, then it is okay for someone to participant with another condition. There is a list of conditions that are related to hearing loss.
 - c. **Verification of hearing loss form.** For eligible participants, we collect contact information and explain the verification of hearing loss form (to be completed by CHRMC or participant's Audiologist/Otolaryngologist preferably, School personnel secondarily). If CHRMC or the participant's Audiologist/Otolaryngologist is completing the form, we need the parents to sign the release of medical information form and either fax or return in the reply-envelope that's in the packet.
 - d. **Talk with the Youth.** Lastly, we contact the youth (if the child is 11 – 17 yrs of age). It's important to determine that the youth is interested in participating and to give them an opportunity to ask us any questions they might have. The youth assent is reviewed with them step-by-step.

2. **Verification of Hearing Loss Form.** Every attempt should be made to obtain the parent permission and the form mailed prior to the appointment. Permission to obtain this information **MUST** be given by the parent prior to their participation in the project. Ideally the parent will mail the signed form to the Study Coordinator; however, it can be obtained at the time of the face-to-face meeting.
3. **Schedule Appointment.** Once eligibility is determined, schedule the appointment. If possible allow at least 10 days between screen and the appointment time to allow the receipt of the VHL.
 - a. **Appointment Mailing.** We will send a letter that describes the date and time of the appointment, the contact information for the interviewer (cell phone, etc.), and other pertinent information (such as for parents to bring a book or something to entertain themselves for about an hour). Consent/Assent forms and Directions to the location (Fremont or CHRMC) will also be included in this mailing.
 - b. **Reminder Calls.** Reminder calls are conducted the day before the appointment. Parents are called until we are able to physically get a hold of them. Messages are left only as a last resort.

6.3.1 Inclusion Criteria

Phase I –Module Development:

Inclusion criteria for children/youth

- Ages 11-18 and meets the definition of deaf or hard-of-hearing in their school and have an IEP
- Able to communicate in English/ASL/SEE/Total Communication

Inclusion: criteria for parents

- Has a son or daughter ages 5-18 years who meets the definition of deaf or hard-of-hearing in their school district and have an IEP.
- Able to communicate in English/Spanish/ASL/SEE/Total Communication

Inclusion criteria for young adults

- Able to communicate in English/ASL/SEE/Total Communication
- Between 19 and 22 years old with a hearing loss as verified by their clinician or audiologist

Exclusion Criteria

Phase I –Module Development:

Exclusion criteria for children/youth

- Child/Youth with normal hearing level
- Presence of other known stigmatizing conditions, such as impaired mobility, or craniofacial anomalies
- Inability to communicate and participate in a personal interview
- Multiple sensory disorders (e.g., deaf-blindness)
- Parental report of a history of other physical conditions (e.g., impaired mobility, craniofacial anomalies, chronic disease that have a greater impact than their hearing loss, or mental health condition(s) (e.g., bi-polar, schizophrenia, severe depression, generalized anxiety disorder, ADHD, obsessive compulsive disorder) that have had an impact upon their child's quality of life.*

Exclusion criteria for parents

- Inability to communicate in spoken English, Spanish, ASL, signed English, or Total Communication to participate in a personal interview or focus group

Exclusion criteria for young adults

- Normal hearing level
- Inability to communicate in spoken English, ASL, signed English or Total Communication
- Inability to participate in a focus group
- Multiple sensory disorders (e.g., deaf-blindness)
- Self report of as history of other physical conditions (e.g., impaired mobility or craniofacial anomalies) or mental health condition(s) (e.g., bi-polar, schizophrenia, severe depression, generalized anxiety disorder, ADHD, obsessive compulsive disorder) that have had an impact upon their quality of life.*

* Exclusion criteria are designed to ensure that we capture salient issues to children and youth who are deaf and hard-of-hearing and not issues related to other disorders.

6. 4 Study 1 Methods

Overview of Steps:

1. *In-depth Interviews* were conducted with 37 youth ages 11-18 and 35 parents of 5-10 year old children who are deaf or hard of hearing.
2. *Cognitive Debriefings* were conducted with 13 youth ages 11-18 and 12 parents of children ages 5-10 to ensure the understandability of the instrument.
3. *Item Ranking Activity-Modified Delphi surveys* were conducted with an advisory board expert review panel with our list of final items to review content, intelligibility and importance of items.
4. *Readability Analysis* was conducted using the Flesch-Kincaid and Homan-Hewitt methodologies and the Living Word Vocabulary.

Qualitative Interview Methods

In this study, because of the complexity of communication with youth with hearing loss, we proposed to conduct interviews with 45 youth ages 11-18 and 45 parents of children and youth ages 5-10. We followed methods outlined by Glaser & Strauss in developing questions and conducting the qualitative interviews (Glaser & Strauss, 1967). In previous studies we have noted that after 30-35 in-depth interviews we have achieved information saturation. We monitored the interview data for information on saturation throughout the interview process. Item development was monitored and the interview process was terminated when there were no new items generated from the last 3 interviews. Items were assessed for content and whether the item content was new or redundant with previously written items. The interview process was terminated after 37 youth interviews and 35 parent interviews.

A team of experienced researchers and experts developed the qualitative interview protocol with the study aims in mind. The semi-structured interview included a series of questions that asked the youth to share their perspectives on how, if at all, being deaf or hard-of-hearing impacted their quality of life at home, school and in the community. Participants were told that responses were confidential and their identity would be concealed in the final analysis. The interview schedule was used for exploration as a starting point but the respondents determined

interview content, allowing them to introduce relevant themes not included in the initial interview protocol.

For in person interviews, a video camera was used to capture data delivered in ASL or PSE by the participant and interviewer. These individual interviews were conducted in a private large room with two chairs. The room was examined to ensure minimal or no distractibility to the participant. The clock was visible to both interviewer and participant to keep track of interview length. For videophone interviews, either webcam software with built-in recording or a videophone with a DVR recording device was used to capture both interviewer and participant's data for transcription. The interview began after the interviewer explained the interview process and obtained the youth's assent and permission to record the interview. When the interviewer started recording, a recording status appeared on the interviewer's screen. This recording status was visible to the youth participant that the recording had started and was in progress until the interviewer ended the recording.

Table 3. Phase 1-YQOL-DHH Module Development Sample

Hearing Status	Number of Interviews*		
	Youth	Parent	Total
Mild	5	3	8
Moderate	8	5	13
Mod-Severe	6	9	15
Severe	7	7	14
Profound	23	20	43
	49	46	

Table 4. DIVERSITY SUPPLEMENT:

Hearing Status	Number of Interviews		
	Youth	Parent	Total
Mild	1	0	1
Moderate	2	0	2
Mod-Severe	2	2	4
Severe	2	0	2
Profound	4	1	5
	11	3	14

Transcription/Coding methods

Audiotaped interviews

English and Spanish Audiofiles were uploaded using a secured FTP site to GMR transcription service <http://www.gmrtranscription.com/> for production of transcripts and then downloaded by Seattle site for coding assignment. Audiofiles were retained in password secured server files until the end of the study. Spanish interviews were first transcribed in Spanish and then translated into English. Each English audiofile and transcription was checked for accuracy by Tari Topolski, (Spanish audiofile & transcripts by Anne Skalicky) and videofile with transcripts by Brenda Schick.

Videotaped interviews

Two deaf researchers (one team member and one contractor) with high proficiency in ASL and English were assigned to review and transcribe videotaped interviews into written English. Confidentiality training was provided to the contractor before the videotapes were shown. At the time of transcription, the contractor reportedly did not recognize any deaf youth participants in the interviews.

Coding procedure

Transcripts were reviewed and coded for hearing loss themes related to self, social and environment domains and assigned domain-specific codes by two separate researchers. Two researchers were assigned transcripts to code by hand or using MS word. A tracking spreadsheet was maintained to be able to assign and review the qualitative process. Researchers were provided a coding sheet with domains, subdomains and themes (see table 6.4 below). The first series of transcripts were coded at the level of subdomains and themes, while subsequent coding was coded with domains and subdomains. The decision to code primarily using domain names was to facilitate organizational groupings of items for analysis. Coding assignment was determined by rotating transcripts to assure that workload was evenly distributed between two junior coders and three senior coders, with two coders assigning codes to text in each transcript. Each team member highlighted relevant quotations within a transcript according to 3 principal coding domains 1) Self; 2) Social; 3) Environment; as well as subdomains based on YQOL-DHH coding structure (see below). Two individuals coded each transcript separately (one junior, one senior) using highlighting or comment function in MS word document or scanned hard paper copy mark-up and send to Seattle. Seattle coded directly into Atlas-ti.

The team as a whole worked by consensus to revise and consolidate the final coding frame. Coders worked in pairs and coder discrepancies were arbitrated at the same time as the development of the coding frame and the categories or domains of importance. Codes were continually reviewed and consolidated when appropriate. The team worked by consensus to organize codes into themes, to organize themes around a conceptual model, and to identify concepts and items that are specific to children and youth with hearing loss. After the text was coded and sorted, the research team will work together to generate a long list of items based upon the coded material, expert input, and existing instruments. Care was taken to represent all relevant data and domains with items. Some items were taken verbatim from interviews, others were also written based upon the material, keeping the items in the language of the participating youth as closely as possible.

Specific instructions, as follows, were provided to coders:

1. Coder will review the transcript for information and highlight relevant sentences that provide an indication of the “youth’s perception of their position in life in the context of the culture in which they live, and in relation to their goals, expectations, standards and concerns” and for this project the context of their hearing loss/deafness.
2. Coder will write the name of the relevant code in the right hand margin
Relevant text should be:
 - a. specific to hearing or hearing loss
 - b. relevant to all youth with hearing loss or relevant to all youth who are deaf
 - c. frequently mentioned by youth with hearing loss
 - d. evaluate a feeling, sensation or perception
 - e. is a basic human need (Maslow, 1954; Doyal & Gough, 1991)

Table 5: Youth and Parent Coding Schema

<u>Domain</u>	<u>Subdomain</u>
Self	Belonging Sense of self Identity Spirituality Felt stigma

	Self-esteem Physical
Relationships	Family Peers Friends Teachers Inclusion Enacted stigma Social stigma Social isolation Participation
Environment	School Future Engagement Neighborhood Community Communication

Coded transcripts were uploaded into an Atlas Ti database. AtlasTi permits manipulation of coded text using queries and reports. A final query of youth and parent coded text was then exported for item writing into a spreadsheet format which was posted onto a study Google docs work space where the research team was able to craft items. Once items were crafted for coded text and duplicate material was identified in the google spreadsheet, a “long list” was reviewed by the research team and evaluated for consistency with quality of life criteria.

To select the *best* quality of life items for inclusion and testing in the YQOL-DHH module the following criteria were used:

- A the item evaluates a "quality" (perception/sensation/feeling),
- B the item represents an area of importance to people who are DHH,
- C the item is in the language of the people with the condition, and the item is translatable conceptually,
- D the item is likely to change with successful treatment of the condition (cochlear implant, hearing aid),
- E the item is likely to discriminate with severity of condition (hearing level),
- F the item discriminates between known population groups (hearing level),
- G the item is frequently mentioned by participants,
- H the item is relevant to everyone with the condition,
- I the item has semantic equivalence with other languages (ASL, SEE),
- J the item has been found in the literature written by experts in DHH,
- K valence of item is clear,
- L includes how “well” things are going, as well as “badly.”

Elimination of items that do not assess QoL, are poorly worded, or are redundant were arrived at by team consensus. The remaining items were then reviewed, domains tightened, and confirmed that all essential categories included items. A major issue was to evaluate overlap between the generic YQOL items and new items specific to hearing loss. From prior experience, we anticipated that new items would be elicited on social stigma and hearing loss that are not currently contained in the YQOL. However, we also anticipated overlap in concerns of youth without deafness and youth with this condition. Another area of attention led to the examination of whether there are QoL issues that are distinct between deafness and hard-of-hearing. We anticipated that this may be the case as the communication issues between these groups are

somewhat different from one another. We also anticipated however, that there would be QoL issues that overlap between these groups. Each item on the long list was categorized as generic or specific and related to the participant representation by hearing status. Based on each team members' evaluation they rated the item "yes" or "no" whether it qualified as a quality of life item.

The next step in the coding process six team members nominated their ~20 top candidate items from each of the domains: self, social, environment. The pooled list of nominated items was then examined for items with 3 or more nominations and a final list for each domain was retained to continue on to the next phase of analysis.

Role of advisory board

An advisory board meeting was convened to review youth and parent team nominated items on two separate calls. Advisory board members were oriented to the qualitative work and analysis process and then advisors were invited to select and rank 1 (highest) to 5 (lowest) their top 5 items from each domain. In addition to the study team, 5 advisors participated in the ranking exercise.

The number of draft items was then reduced based upon investigator and advisory board rankings.

Table 6. Process of drafting and selecting items

YOUTH	Total ranked	Highest count/rank retained
Self	22	14
Social	15	4
Environment	14	5
<i>Total Youth items</i>	<i>51</i>	<i>23 (45%)</i>
PARENT		
Self	35	7
Social	27	4
Environment	23	4
<i>Total Parent items</i>	<i>85</i>	<i>15 (18%)</i>

Cognitive interview methods

Cognitive Debriefing Procedure (Audiotaped Sessions)

Draft items were cognitively debriefed through 3 waves of interviews with approximately 3 youth and 3 parents per waive. Review of cognitive debriefing notes and observations were reviewed by team and items were edited.

Cognitive Debriefing Procedure (Videotaped Sessions) Semistructured cognitive interviews with signers were conducted either through videophone or on instant messaging. Each session lasted for approximately 1 hour. First, the instrument was sent to the parent and youth via email attachment immediately prior to scheduled appointment. When the interviewer and participant connected on videophone or online, the youth was asked to open the document and instructions were then given to the youth. The interviewer clocked the start time until the participant stated that he or she finished the questionnaire. The interviewer proceeded to ask the participant specific questions regarding concepts, clarity and wording of the items. Due to the semistructured nature of the interview, the youth was encouraged to comment or ask questions at any time during the session.

Table 7. Cognitive Debriefing

	Round 1	Round 2	Round 3
Youth	4	5	4
Parents	5	4	3

Table 8. Item development process, count of items

	Total Items Generated	Qualifying items-reduced list	Advisory Board Review	Cognitive Interview Review	Final Items fielded
Youth:					
Self	111	50	23	14	12
Social	165	20	16	15	20
Environment	75	30	15	13	11
TOTAL	351	100	54	42	43
Parent:					
Self	310	36	13	13	8
Social	278	28	10	6	11
Environment	184	24	12	3	7
TOTAL	772	88	35	22	22

Reading Analysis

Draft items were word-smithed, maintaining original language as much as possible. Flesch-Kincaid and Homan-Hewitt analysis was run on items to determine grade level of items (Homan-Hewitt, 1994). Items with grade level at or above 4th grade are assessed for word selection and discussed. Reduced list of draft items is presented to the advisory committee and further reduced to a set suitable for final draft.

Table 9. Overall item readability

Item	Whole Sentence Flesch-Kincaid Reading Ease	Main clause only Reading Ease	Whole Sentence Flesch-Kincaid Grade Level	Main clause only Grade Level	Whole Sentence Homan-Hewitt Grade Level	Main Clause Homan-Hewitt Readability Grade Level*
TOTAL READABILITY	68.3	80.6	7.83	4.51	4.27	3.53

Flesch-Kincaid formula takes into account total syllables/total words = average number of syllables per word (ASW), and total words/total sentences = average sentence length (ASL).
 $(.39 \times ASL) + (11.8 \times ASW) - 15.59$

Whole sentence Avg, Flesch-Kincaid
 Main Clause Only, Flesch-Kincaid

Main Clause Only, Homan-Hewitt

Homan-Hewitt formula takes into account number of words per thought unit, number of words unfamiliar (below 75% 4th grade level of Living word Vocabulary), and number of words with 7 letters or more

$$1.76+(0.15*WPTU)+(0.69*WU)-(0.51*W7L)$$

Final Items for Field Testing

Final domain facet structure is determined and contextual-perceptual mapping was completed.

Final survey was pretested in 2 youths and 2 parents to determine whether survey is of a suitable length to avoid participant burden.

Table 10. Pretest of Instrument

	DHH Youth	DHH Parent
Survey 1	47 minutes (8:15 pm – 9:04 pm)	47 minutes (1:07 pm -1:50 pm)
Survey 2	47 minutes (11:58 pm – 12:45 pm)	
Time Average	47 minutes	47 minutes

The below items are included in the Parent 8-10 version, but not in 5-7 version.

During the *past 4 weeks*:

1. How often did you observe or learn that your child...
...**spoke up** for him/herself as someone who is deaf or hard-of-hearing? (*please circle your answer*)

During the *past 7 days*, concerning your child who is deaf or hard-of-hearing:

2. How often did you observe or learn that your child...
...**had a hard time** communicating with family members because s/he is deaf or hard-of-hearing? (*please circle your answer*)

During the *past 4 weeks*, concerning your child who is deaf or hard-of-hearing:

3. How often did you observe or learn that your child...
...**communicated** for him/herself outside of the home and school? (*please circle your answer*)

During the *past 4 weeks*, concerning your child who is deaf or hard-of-hearing:

4. How often did you...
...**have to take over** communication for your child outside of the home? (*please circle your answer*)

6.6.1 Preparation of Study 2 materials

Youth booklet development

YQOL-DHH items were randomly ordered in survey. All outcome measures were compiled into booklets and formatted according to guidelines suggested by Dillman (2000) and Fowler (1993).

Parent booklet development

All outcome measures were compiled into booklets and formatted according to guidelines suggested by Dillman (2000) and Fowler (1993).

Development of a Spanish parent survey

We produced a linguistic validation of the English parent questionnaire for 5-7 and 8-10 year old children which is not a literal translation of the original instrument, but the production of a

translation that is conceptually equivalent to the original and culturally acceptable to U.S. Spanish speakers.

Two bilingual, fluent translators will produced an independent forward translation of the original English YQOL-DHH instruments' instructions, items and response choices into U.S. Spanish. Both translators and the HQL investigator reconciled translation discrepancies to create a final and forward translation. The aim of the forward translation was the production of a conceptually equivalent translation of the original questionnaire and the language used should be colloquial and easy to understand. One additional independent bilingual, fluent translator then conducted a back translation from the Spanish forward translation to English (blinded to the original English text). This final process was then reviewed between forward translators and HQL investigator to produce the second reconciliation of the forward translation of the original survey into Spanish.

ASL and PSE Video Development

Forward ASL and PSE translations of the survey items were done by Drs. Kushalnagar and Schick, both fluent in ASL and English. Each person uploaded videos to a secure website for the other person to preview for consistency in choices of signed translation. On items that had different dialectical sign vocabulary, they met on videophone and discussed until an agreement on a translation was reached. After full agreement was reached by both team members for all signed translations, Dr. Kushalnagar proceeded with the next step of selecting youth model signers. Dr. Topolski coordinated schedule and contract with a video production company.

Two youth model signers were needed to produce two sets of DVDs, one in ASL and another in PSE. Dr. Kushalnagar interviewed three youth who were recommended by a team of administrators at the Washington School for the Deaf (WSD). Two youth were selected on basis of their ability to sign in ASL and PSE, level of interest in the project, and time availability. A female high school student was selected to be the model signer for the ASL DVD. Both of her parents and all siblings as well as extended relatives are deaf. American Sign Language was the primary language used in this female youth's household. A male high school student was selected to be the model signer for PSE. He was the only deaf person in his family, and used mostly PSE/Signed English to communicate with his peers and teachers at previous mainstream school. He enrolled at WSD when he was in the 11th grade.

Dr. Kushalnagar met with both youth to prepare and review translation of survey items to ASL and PSE prior to actual taping. During the taping session, the written items were projected on a white screen in front of the youth model signer who faced the video camera. The youth first reviewed the item in English and then watched Dr. Kushalnagar sign the translation. The youth practiced the translation a few times until sign accuracy was accomplished. When the actual taping began, Dr. Kushalnagar stood slightly behind the video camera and signed the items in front of the youth. The youth continued to look at the camera but was able to see Dr. Kushalnagar in the visual periphery field and copy her signed translation of the item. The entire video session took approximately 5 days to complete. The youth model signers were paid for their time.

The contracting video company provided editing and production work. All clips were reviewed and corrected via WebEx by the DVD team, consisting of the video production point-of-contact on contract, Drs. Kushalnagar, Topolski, Schick and Ms. Skalicky. Copies of DVDs were then mailed to the members for double-checking and accuracy prior to final production.

Section 3:
Study 2 Module Testing of DHH QoL Modules

7.0 Quantitative Study Design (Phase II Module Testing of DHH QoL Modules)

7.1 Study 2 Design

In the quantitative study we conducted a cross-sectional study design to examine quality of life of youth with hearing loss to validate the newly developed study instruments. Youth ages 11-18 and parents of children and youth ages 5-10 were recruited to participate in the study.

Based on Clark (1981) degree of hearing loss guidelines, our recruitment strategy sought to recruit equal numbers in each of the following categories. Audiologic records were requested for all participants. An audiologist certified by the American Speech, Language, and Hearing Association reviewed all received audiograms and classified the participant's degree of hearing loss based on the better ear pure tone average (PTA), or the average unaided air conduction thresholds at 500 Hz, 1000 Hz, and 2000 Hz. Degree of hearing loss is categorized as "mild" (PTA = 26-40 dB), "moderate" (PTA = 41-55 dB), "moderate-severe" (PTA = 56-70 dB), "severe" (PTA = 71-90 dB), or "profound" (PTA > 90 dB) (Clark, 1981). A participant with normal hearing in the better ear (PTA = -10-25 dB) but had any degree of hearing loss in the contralateral ear (PTA > 25 dB) was categorized as "unilateral". If a participant used a cochlear implant, they were characterized as "cochlear implant". Children or youth who had a PTA = <26 dB but who had significant hearing loss in the higher frequencies only were classified as "high-frequency only" but were entered as "mild". Please note that cochlear implant users were separated from their severe or profound peers.

Mild loss = 26 dB HL to 40 dB HL AND High Frequency Hearing Loss,
Moderate loss = 41 dB HL to 55 dB HL,
Moderate-severe loss = 56 dB HL to 70 dB HL,
Severe loss = 71 dB HL to 90 dB HL,
Profound loss = 91 dB HL or more,
Cochlear Implant User

7.1.1 Protocol deviations—Study 2

Sampling method:

Phase 2 proposed embedding the YQOL-DHH module in the annual school-based surveys conducted in Arizona and Colorado. However, the Colorado and Arizona Departments of Education unexpectedly cancelled the annual school-based surveys due to state department budget cuts. The annual survey was a critical component of subject recruitment in Colorado. Instead, a listing of all Colorado school districts and the DHH contact person was used to contact all school districts who provided services to a DHH student. This individual distributed information to all eligible students and parents, who then contacted the Colorado site manager.

Recruitment sources:

Although the superintendent of the Texas School for the Deaf (TSD) provided a letter of support for Dr. Kushalnagar's diversity supplement application, TSD later declined to participate due to heightened concerns that the student participants may get upset when they see some survey items that ask about feeling left out from family communication, bullying, and other sensitive issues associated with being deaf or hard-of-hearing.

Mode of administration:

The study developed a Pidgin Signed English DVD for administration, but was unable to recruit participants who needed this mode of administration. Additionally, the study was designed for a 4th grade reading level, however, due to lower reading ability of some prospective deaf study participants we modified the protocol to allow for interviewer-assisted administration in our Texas site.

Audiogram assessment: Quality of audiogram

To expedite recruitment and completion of surveys, a web version of the study questionnaires were launched through the Catalyst website for both parents and youth. Additionally, a Spanish translation of the parent survey was created for the paper-and-pencil booklet only.

7.1.2 Sample size recalculations

Revised Sample size Determination

In our previous studies of adolescents with facial differences and Tourette syndrome, we observed effect sizes for YQOL-R total rating scores between .4 and .6 based on self-reported severity of their condition. We anticipate that in the study of youth who are deaf or hard-of-hearing that we will observe similar effect sizes. Our sample will yield 90 youth who are deaf and 60 youth with a cochlear implant. Using the harmonic mean this will yield an effective sample size of 72 per group for independent sample paired t-tests. Thus with an effective sample size of 72 we will need to an effect size of at least .47 to observe 80% power. For an effect size of .6 we would have over 99% power to detect a difference. For our mild and moderate groups our anticipated sample sizes are 30 per group. This would provide 44% power to detect a significant difference between these groups.

Means and standard deviations for the YQOL-R scores from the validation study were used to compute a small effect size (.20) (Cohen, 1988) for the using the procedure described in Howell (1992). Based on this information a sample size of 300 would provide 93% power for a small effect size, while a medium effect size (.50) would provide 99% power to detect a significant difference in YQOL-R scores. This translates into a difference in mean scores of 2.5 to 5.2 by severity ranking to detect a significant difference in YQOL scores.

For the parent data, we do not have previous YQOL-R data on which to base a power calculation. However, given a sample size of 300 we would have 80% power to detect an effect size as small as .165.

Power Calculation for Multiple Regression R^2

Power Calculation for R^2 was calculated using the program cited above. The underlying model is that we have a sample of N iid multivariate random vectors of length p , and that the p th variable is regressed on the first $p-1$ variables. $R^2 = 1 - SS(\text{error}) / SS(\text{total})$ is the coefficient of multiple determination.

The usual way to test a hypothesis about R^2 is to transform it to an F statistic:

$$F = \frac{(n - k - 1) R^2}{k (1 - R^2)}$$

for our sample this would be

Predictors are: age, sex, degree of hearing loss, school type, communication mode. .04 would be 4% of the variation explained by the predictor. This was a somewhat arbitrary figure, but anything less that 4% explained by one of these predictors seems inconsequential to me.

$$F = \frac{(300 - 5 - 1) \cdot .04}{5(1 - .4)} = 11.84/4.85 = 2.46 \text{ critical value of } F \text{ at } \alpha = .05 \approx 2.45$$

This is the usual ANOVA F. The distinction that makes this dialog different from the one for regular ANOVA is that the predictors are random. The power computed here is unconditional, rather than conditional. However, in the FD we observed R² values of .04 to .26 (Add reference to Kathy Kapp-Simon paper).

The GUI components of the program used are as follows:

Alpha: The desired significance level of the test	Values Input
True rho ² value: The population value of R ² at which we want to compute the power.	.04
Sample size: The number of N multivariate observations in the data set.	300
No. of regressors: The value of k = p - 1.	4
Power (output only): The power of the test.	.8092

Power for the Difference Between 2 Means With Unequal Ns
 First we calculated the harmonic mean sample size.

Harmonic mean sample size (m)

$$m = \frac{k}{\sum \frac{1}{n_i}}$$

Assuming that we want to look at the mean differences between mid-mod, moderately severe-severe and profound, the calculations were based on the proportions in each category observed in Phase I. The sample sizes would be as follows:

Mild-moderate	80
Moderately severe-severe	67
Profound	153

The harmonic mean would be

$$\frac{3}{\frac{1}{80} + \frac{1}{67} + \frac{1}{153}} = 88.5$$

For a sample size of 88 with 3 groups the power to detect a difference between groups would be equal to

$d \approx \sqrt{\frac{N}{3}} ES = d \approx \sqrt{\frac{264}{3}} .3 \approx 2.82$ Power is approximately 80% to find a difference between any 2 groups.

Observed Effect sizes for the YQOL-R in other groups have ranged from .41 to .6. Being conservative and estimating that we will find smaller effects of the YQOL-DHH, we arbitrarily choose an effect size of .3. For an effect size of .2 we only have 44% power to detect a difference.

7.2. Study 2 Proposed Sample

In our initial recruitment plan, we had enlisted the Colorado Department of Education and the Arizona Schools for the Deaf and Blind to field the YQOL-DHH and the Parent Observational of Events and Behaviors that Impact their children as part of their regularly schedule annual survey of children and youth in their respective DHH programs. In late 2008 we learned that Colorado and Arizona were not going to conduct their annual surveys in the 2009-2010 school years. Recruitment goals were revised and a new target goal of 300 youth and 300 parents from all sources. This goal was based on a power calculation done on 7-9-09.

Table 11. Recruitment goal by mode of administration Youth 11-18

Hearing Status	Mode of Administration		Minimum Total
	Self-Administration		
	English-Written (web & paper)	ASL/PSE- Signed	
Mild	30		30
Mod/Mod-Sev	30		30
Severe/Profound	30	30	60
CI	30	30	60
	120	60	180

Table 12. Recruitment goal by mode of administration Parents of 5-10 year olds

Hearing Status	Mode of Administration			Minimum Total
	Self-Administration			
	English-Written (web & paper)	Spanish- Written (paper)	ASL - Signed	
Mild	30	7		37
Mod/Mod-Sev	30	8		38
Severe/Profound	30	7		37
CI	30	8		38
	120	30		150

Colorado Department of Education (Denver, Co), The Exceptional Student Services Unit currently serves approximately 800 students in Colorado. Our colleagues at the University of Colorado Boulder are working with the school districts in the greater Denver Metro area that have programs for children and youth who are deaf or hard-of-hearing to recruit participants. Additionally, they are working with several camp programs to recruit and anticipate recruiting 70 youth and 70 parents.

Arizona School for the Deaf and Blind (Tucson, AZ) and **Phoenix School for the Deaf** (Phoenix, AZ). Provides services to approximately 2200 deaf and blind students in Arizona, of which 1200 would be eligible for participation in this study. They have made contacts to students at the Tucson School for the Deaf and the Phoenix School for the Deaf, who were available to us for recruitment. Additionally, they sent out postcards to parents and youth who were enrolled in one of their regional DHH programs and serviced by itinerant teachers. It was anticipated that 95 youth and 95 parents will participate from this source.

New Mexico School for the Deaf (Santa Fe, NM). Provides services to approximately 500 deaf and hard-of-hearing students through their outreach program. They assisted with identifying and recruiting eligible youth who come from Spanish-speaking homes for the qualitative portion of Phase I interview. However, the point-of-contact did not cooperate in the follow up emails and phone calls for Phase II recruitment and study participation.

Table 13. Module Testing Proposed Sample, n=60

	Youth Re-test	Parent Re-test
<i>Recruitment Site</i>		
Washington		
7-day	15	15
4-week	15	15
Colorado		
7-day	15	15
4-week	15	15
Total	60	60

7.3 Study 2 Recruitment

7.3 Study 2 Recruitment Procedures

Recruitment through Seattle Children's Hospital Hearing Loss Clinic

Patients were recruited when they come into the Hearing Loss Clinic or Audiology Clinic for a routine follow-up visit. Either during their visit at the clinic or a telephone call follow-up, patients were informed of the study by clinic staff. Where possible, clinic staff will give an introduction to the study, and ask for their oral consent/assent to be contacted by the study recruiter. For those who consent/assent, clinic staff will record the patient's and parent's contact information on the contact form and fax it to the study office. The study recruiter will then call these families, and conduct a telephone screen with primary caregiver of those youth who are interested in participating and orally consent to the interview.

During the initial recruitment phone call the study recruiter will also go through the consent/assent forms and will ask the participant if they have any questions about the forms to ensure that the participants understand the study and study requirements.

Washington Recruitment through school sites

Information packets that included a Recruitment Letter, Fact Sheet, Flyer, Medical Release of Information Form Consent/Assent forms with names of the investigators, HIPAA form, participant payment form, and preaddressed postage paid envelopes, were provided for school staff to send to the parents. In the Edmonds School District, and at the Northwest School for the Hearing Impaired, packets were mailed in postage pre-paid envelopes to the parents by school staff. In the Tacoma, and Seattle Public School Districts, only flyers were sent to the parents via the students. Interested parents and youth were directed to contact the UW study coordinator, go to our website or return the permission-to-contact form by mail or fax to obtain additional information.

Schools identified youth who have an IEP or 504 Plan because of a hearing impairment. Postcards and/or flyers were distributed to parents of all youth in the school who met the age criteria and have an IEP or 504 Plan due to a hearing impairment.

At the Listen and Talk program and the Washington State School for the Deaf the packets were provided to schools in postage-prepaid envelopes that the schools will then mail to the parents (approximately 190 packets). The UW project staff distributed information packets and obtained contact information for follow-up with interested parents and youth at that time.

The School sites that have agreed to participate in the study were contacted Schools were sent flyers and/or postcards to distribute to the youth. Youth and parents who were interested in participating in the study then contacted the study recruiter. The recruiter provided full details of the study and with verbal consent from the parent conducted the screening telephone interview to determine eligibility. Youth and parents who passed the telephone screener were then provided information on the steps to complete the study. Youth were required to take a reading screener to assess their ability to read at the 3rd grade reading level. Youth who did not pass the reading screener and used ASL/PSE as their primary mode of communication were given the option to have an interviewer assisted administration of the survey questionnaire. Parents and youth who participated in the study were given the option of completing the survey online or as a paper and pencil option.

Packets for parents of children 5-10 will also contain the study questionnaire, which parents were asked to complete and return to the study coordinator along with the Consent form, HIPAA

form, Medical Release of Information, and participant payment form in the enclosed prepaid preaddressed envelope. The study coordinator will then forward the Release of Information ~~along~~ to the child's school or clinic to obtain recent audiologic records for child.

Colorado Recruitment through school sites

Information packets that include a Recruitment Letter, Fact Sheet, Flyer, and interest cards and preaddressed postage paid envelopes were mailed (or during presentations to youth, given) to students identified by the participating Colorado School Districts. Interested parents and youth were directed to contact the CU study coordinator for additional information, or return the interest card in the preaddressed postage paid envelope included in the packet.

Schools will identify the youth who have an IEP or 504 Plan because they have a hearing impairment. Packets were sent to parents of all youth in the school who meet the age criteria and have an IEP or 504 Plan due to a hearing impairment.

Texas Recruitment through school sites and community

Students and parents were recruited from the Houston Speech and Hearing Center and Regional Day Schools for the Deaf throughout Texas. Study announcement was posted periodically on Texas Deaf Network and Texas Parents of Deaf Children listservs. A study presentation with emphasis on recruitment issues was also given at the University of Texas in Brownsville, which is close to Mexico border. Both audiences included Latino deaf professionals, parents, youth, and teachers who serve deaf and hard-of-hearing children and youth in the surrounding area. Interested participants were immediately scheduled for screening interview. If they met eligibility, they were asked to complete and sign a packet of parent consent, youth assent and audiology information release forms before completing the survey.

Recruitment Letters, Flyers, Fact Sheets and Interest Cards about the study were given to the students either in person to take home to share with their parents or via mail. Youth signers who were interested in participating in the study were instructed to contact Dr. Kushalnagar via videophone or email. Parents who speak Spanish were directed to contact Ms. Skalicky. The interviewer provided additional information about the study and for those interested; a telephone screen was conducted with the parent who provided oral consent. For eligible students and parents who chose to participate in the study, a complete packet of information and forms was mailed. A survey appointment was scheduled upon receipt of the signed forms.

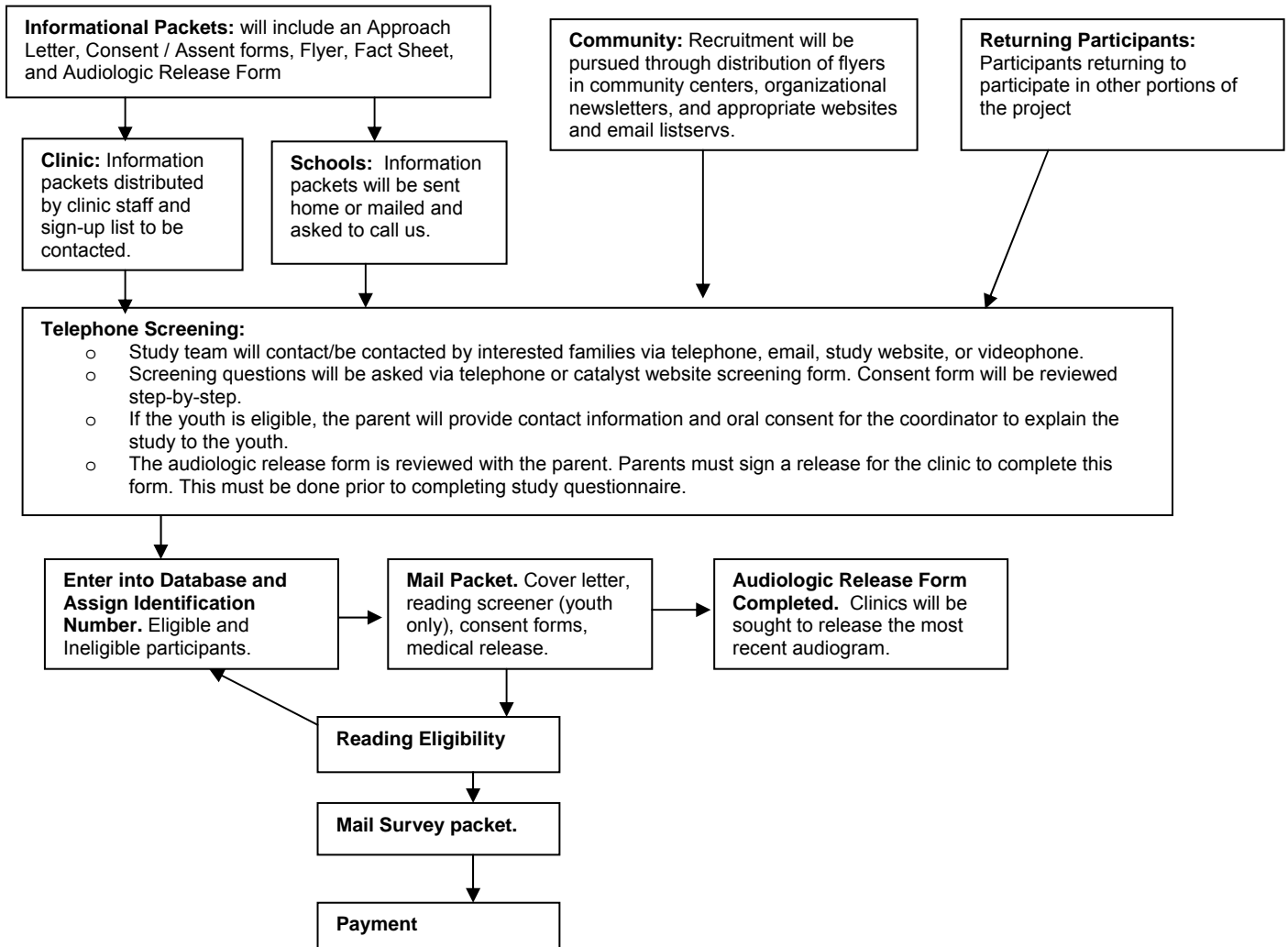
Community recruitment

Through channels targeting the Deaf and hearing impaired communities using methods we have used in the past with success, we solicited participation in the study. Methods will include distributing flyers and postcards through community centers and churches, deaf organizations and advertising on teen and deaf-oriented web sites and in local teen and deaf-oriented newspapers. A toll-free dedicated phone number were provided for youth and parents who are interested in the study. This strategy has been used successfully by the Seattle Quality of Life Group (SeaQoL) in past studies involving youth with and without chronic conditions. Questions were answered by the study coordinator who were well trained in communicating with deaf or hard-of-hearing persons. If a participant under the age of 18 contacts the study recruiter, they were given a brief description of the study including information about the inclusion and exclusion criteria. The recruiter WILL speak with the youth's parent / guardian, explain the study procedures, inclusion and exclusion criteria, obtain oral consent to conduct the eligibility screener and ask for verbal consent to speak with their child further regarding the study and/or schedule a time for them to come in. If a parent / guardian is not available, the study recruiter

will inform the youth that since they are under the age of 18, they are not eligible to participate unless they have parental consent. The recruiter will ask the youth for a contact telephone number and a best time to reach his/her parent or guardian. No other information was collected.

Communication regarding recruitment was conducted through email, webcam, videophone, as well as regular mail. A website provided information to families and students. Written materials were also available in Spanish on the website for parents of children ages 5-10.

7.3.0 Figure 2. Recruitment Procedures Flow Diagram



7.3.2 Informed Consent

The consent forms were reviewed with the parents during the telephone screening interview. Parents participating or providing consent for their adolescent to participate returned the consent form directly to the study coordinator or project manager via mail. The cover letter indicated that should they have questions regarding any of the study materials enclosed they should contact the study coordinator or the project manager. The letter indicated that the youth should complete the assent form and return it with the parental consent form.

Parents were assured that all information provided by them or their child will be kept confidential and only shared with members of the research team, or presented in aggregate so that no person is identifiable.

7.3.3 Inclusion/Exclusion Criteria

Inclusion Criteria:

Inclusion criteria for children/youth:

- Ages 11-18 and meets the definition of deaf or hard-of-hearing in their school and have an IEP.
- Is recruited through U.S.-based outlets and is schooling in the U.S.

Inclusion criteria for parents

- Has a son or daughter ages 5-10 years who meets the definition of deaf or hard-of-hearing in their school district and have an IEP.
- Is recruited through U.S.-based outlets and 5-11 year old child is being schooled in U.S.

Lost to Follow-Up breakdown

- 1) No screener: We received a permission to contact from somewhere and never were able to screen them; they never returned our calls or were part of the “survey first, screen later” madness from ASD or WSD.
- 2) Unreturned forms group: They were sent the study forms and reading screener and did not return the forms to then get the survey booklet itself. Some of these kids didn’t have a resounding “yes” when their parents were asked about their reading level and so were sent forms first to determine eligibility.
- 3) DVD waitlist group: These kids were sent forms and reading screener initially to determine DVD eligibility and never responded or sent back forms to then get the DVD. Some of them were recruited way early before the DVD was created, and then months and months later when recontacted, they didn’t respond. These are for the self-administered
- 4) LTFU group: These youth were screened, determine eligible, and they indicated they wanted to participate. So we sent forms and the survey to them, and then did follow up calls and/or emails to make sure they received the survey and remind them to complete, but we never received anything back from them. After 3 or 4 calls/emails with no response, they were marked LTFU.

Eligibility criteria for Youth Participant:

- Youth is Deaf or hard-of-hearing and 11-18 years of age
- Parent permission and consent.

- No presence of other known stigmatizing conditions, such as impaired mobility, or craniofacial anomalies
- No multiple sensory disorders (e.g., deaf-blindness)
- Bilateral hearing loss
- Permission to contact audiologist to confirm hearing status
- No parental report of a history of other physical conditions (e.g., impaired mobility, craniofacial anomalies, chronic disease) that have a greater impact than their youth's hearing loss, or mental health condition(s) (e.g., bi-polar, schizophrenia, severe depression, generalized anxiety disorder, ADHD, obsessive compulsive disorder) that have had an impact upon their youth's quality of life.*
- Youth schooling or residing in the U.S.
- Ability to read English OR sign ASL, or PSE at ≥ 3 rd grade reading level (AGS screener)
- Access to DVD or web technology or ability to fill out paper & pencil/web questionnaire.

Eligibility criteria for Parent Participant:

- Ability to read English or Spanish or sign ASL.
- Son/Daughter is deaf or hard-of-hearing and 5-10 years of age.
- Son/Daughter has bilateral hearing loss
- Son/Daughter without multiple sensory disorders (e.g., deaf-blindness)
- Parent reports NO history of other physical conditions (e.g., impaired mobility or craniofacial anomalies) or mental health conditions (e.g., bi-polar, schizophrenia, severe depression, generalized anxiety disorder, ADHD, obsessive compulsive disorder) that have had an impact upon their child's quality of life.*
- Parent reports no attention, vision, or learning disabilities that would interfere with their ability to complete a 45-minute survey
- Permission to contact audiologist to confirm hearing status.
- Child schooling or residing in the U.S.
- Access to DVD or web technology or ability to fill out paper & pencil questionnaire.

Siblings:

- When you have multiple children from a family and interview all the children, they get analyzed in a probabilistic way. We can only use 1 child per family with parent report.
- We do not want to weight the data. It is not an issue of the individual differences. In the future we need to ask them what the names of the kids are and then select the oldest child in the family with a hearing loss. The thought behind this is that the parent was a "different" parent for the 1st vs 2nd child who was DHH.
- We cannot have the same person giving multiple reports that artificially skews the data.

Parent-Youth Participant from same household:

- We can have a parent and a youth from the same family.

7.4. Study 2 Methods:

Recruitment Methods:

1. Networking Contact. Email and phone contacts to recruitment sites was made to introduce them to the study and invite them to assist with recruiting youth to share their important views about quality of life as a deaf and hard-of-hearing person, as well as recruit parents to document observations of their children's behaviors through our study questionnaires. The invitation letter contained details on following the OFFSITE or ONSITE recruitment procedures.

2. Study Flyers. Prospective participants viewed flyer and contacted us to learn more about the study. The researcher met with the parent to screen for eligibility and then sent a packet of forms.
3. Study Website. Prospective participants were given the option of viewing information in English, or Spanish at <https://depts.washington.edu/projhql/> or <http://slhs.colorado.edu/hql>, and following link to complete an online screening form. They were given Custom ID “*platypus2009*” to begin the login process.
4. Permission to contact form. For school or camp recruitments, interested participants were asked to fill out “permission to contact forms.” These forms were forwarded to the site Study Coordinator, who initiated contact with participant via telephone screening or on-line screening form.
5. Official Study Letter: After initial networking contact and arrangements have been worked out with a recruitment site, an official study letter with Dr. Patrick’s signature was edited for the particular recruitment site which outlines the steps for recruiting prospective participants at that site and formalizes the relationship. The letter was saved for tracking and reporting purposes.

Steps to Recruitment:

[Telephone/Videophone]. The telephone screening was conducted with parents of children and youth to determine eligibility. The screening form contained questions about youth or child’s eligibility. Once eligibility was determined, the study coordinator explained the consent process and mailed out consent/assent form(s) and the medical release form to the youth and/or parent.

[Online]. Interested parents or youth initiated contact with HQL study via the study website which was posted on HQL advertisements and flyers (<https://depts.washington.edu/projhql/>). The online forms and main study website was managed by the WA study site. CO and TX HQL site personnel are contacted by WA HQL site when participants from their respective sites signed on and completed the online screening form. The password for the screening forms was *platypus2009*, and participants used this password to log into the secure screening form.

Parents 5-10 Years: <https://catalysttools.washington.edu/webq/survey/hqlweb/70229>

Parents of Youth 11-18 Years: <https://catalysttools.washington.edu/webq/survey/hqlweb/70225>

Youth 18 years: <https://catalysttools.washington.edu/webq/survey/hqlweb/70226>

Determining Eligibility:

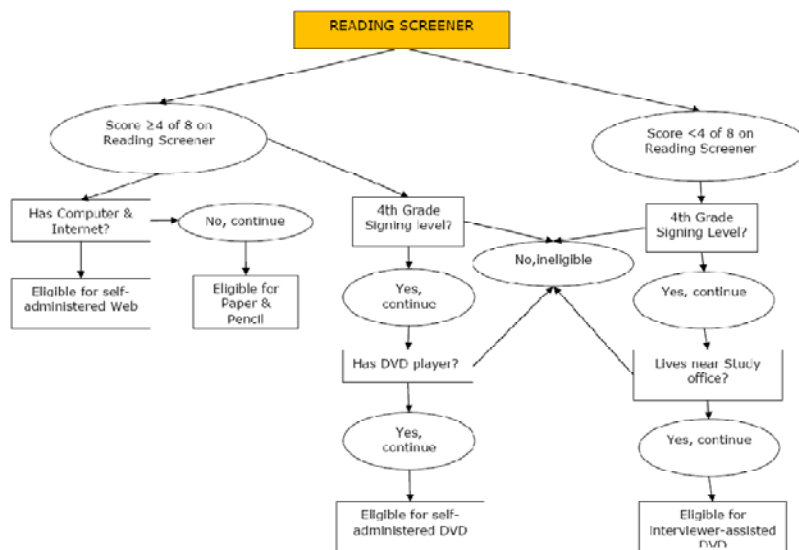
The specific steps to the screening are outlined below:

1. Telephone screening Questions. Eligibility is determined from two preliminary questions, as well as having bilateral hearing loss and parent report of greater than 4th grade reading level.. Individuals who are not eligible bypass the remaining questions are thanked for their time. Eligible participants continue the screening process for categorization of participants for sampling frame (hearing level, etc) and for determination of preferred mode of administration (English or Spanish paper-and-pencil for parent), web-survey or DVD (ASL and PSE for youth, ASL for parent).
2. Reading screener. The youth must be able to answer a predetermined number of reading questions before they can participate in self-administered survey. The 8-question adaptation of the AGS reading screener used in this study captures primarily reading comprehension from 3rd to 8th grade. The 8-question screener has three

sentences (# 1,7,8) which represent simple sentences, four sentences (#3,4,5,6) represent complex sentence structure and, one (#2) which represents complicated sentence structure. The 8-question AGS reading screener was sent to ALL YOUTH study participants to determine reading level. A self-addressed stamped envelope with reading screener was sent to prospective participants to return immediately upon completion. A web-screener is available online for youth with internet connections and was automatically completed for those youth who were filling out the permission to contact form online.

1. A cut off score of 4 is required to take the self-administered survey online, on paper or DVD.
2. Youth who score below 5 may participate in interviewer-assisted DVD administration, which is limited to Houston region.

Figure 3. Youth Participant: Determination of Reading Eligibility & Mode of Administration



3. Determination of Mode of Administration: The study recruiter must assess what mode of administration and language is to be provided to participants based on the results of the reading screener and in consultation with parent & youth about preference.

- Parent participants who have less than 4th grade English reading level, but who do not sign at or above a 4th grade signing level were excluded from the study.
- Spanish speaking parents were given the option of Spanish vs. English paper and pencil versions.
- Only those prospective participants passing 4 out of 8 questions on the reading screener are eligible for the self-administered paper & pencil or web-online surveys options.
- Self-administered DVD surveys are available to youth passing 4 out of 8 questions on the reading screener if they sign ASL or PSE at 4th grade level.
- Only those participants answering correctly <4 of 8 reading screener questions AND who able to communicate in ASL or PSE at 4th grade level (as reported by parent)

AND live in the Houston areas can participate in the interviewer-assisted DVD survey administration.

Type of Administration: Self-administered surveys and interviewer assisted surveys (on a select group) were conducted in this study. A decision to NOT conduct group administration surveys has been determined due to the complexity of creating a standardized administration by different administration types. Only those prospective participants passing ≥ 4 answers in the reading screener are eligible for the self-administered surveys options. Interviewer-assisted DVD surveys are only available to youth living in Seattle, Denver or Houston areas.

Consent form/Medical Release.

- i. Reviewing the consent form. For every participant, we reviewed the consent form step-by-step to explain the study including the risks and benefits. This was done prior to the mailing of the consent form. The assent and/or consent form(s) were sent to the youth and/or parent to read and provide signature. The parent then mailed the signed form (in stamped-enclosed envelope) to the Study Coordinator. These forms were received (or collected in-person) by Study Coordinator prior to their participation in survey.
- ii. [Instructions for online screening form] The Seattle HQL Screening Coordinator reviewed the on-line screening form to determine what mode of administration and what site is best suited to initiate study procedures with participant. The site study coordinator confirmed eligibility for requested mode of administration either through an additional screening phone call or via email. A study coordinator/research assistant in CO and TX checked the catalyst platform as well for screening forms relevant to their sites. A follow-up phone call was initiated within 5-7 days of the mailing of the consent/release forms to see if parent and/or participant had any questions and to provide a reminder to return the forms for survey administration.
- iii. Medical Release form. For eligible participants, we collected contact information for child's/youth's Audiologist/Otolaryngologist or school audiologist to request child's/youth's Audiogram record. During the screening process, site screeners requested contact information for medical release form. The medical release form is sent to the parent to fill out contact information for audiologist and signature. The medical release form was received (or collected in-person) by Study Coordinator prior to participation in the study.
- iv. Study ID. Each site was responsible for creating site ID numbers according to the numbering protocol for HQL study (20,000-WA, 21,000-CO, 22,000-TX, 23,000-Arizona). Participants from other states were incorporated into the numbering protocol of the HQL site doing the recruiting.
- v. Tracking Database. An Access database was maintained in Seattle for the Seattle participants. A separate database was maintained for Colorado and Texas for recruiting Colorado and Texas participants. A unique site-specific study ID number was generated for each participant. The database maintained the study recruitment information of each prospective participant, for those eligible, ineligible, and those who declined to participate. Responses to the participant screening form were entered along with participant and audiology contact information. Fields necessary for the recruitment reports were noted in red on the study 2 data entry form. CO and TX sites were requested to send their de-identified participant information via Catalyst <https://weblogin.washington.edu/> FTP site every Wednesday afternoon. Recruitment

reports were generated on a weekly basis on Thursdays to determine site progress to attaining recruitment goals.

For more detailed information on merging data for the recruitment report, see W:\Project – HQL\Databases\HQL Tracking Database Information 7.8.09.docx.

Weekly Report (see appendix)

Step C: Survey Administration. The Study Coordinator in each site (CO, WA, TX) determines with the participant's parent which type and mode of administration was conducted for youth surveys. The methods for each type and mode of survey administration are listed below.

MODES OF ADMINISTRATION:

A. PAPER & PENCIL ADMINISTRATION-MAIL-IN SURVEY ADMINISTRATION:

1. Eligibility. Only parent participants who have been assessed by telephone screen interview with parent to have >4th grade reading level can participate in this mode of administration. Youth eligibility is determined by performance on the reading screener.
2. Reading screener (Youth). The reading screener was sent to the household with consent forms, medical release, and prior to the survey mailing. Reading screener must be scored and participant must answer at least 4 out of 8 correctly in order to receive paper & pencil survey. If the youth fails the reading screener, they were eligible for interviewer-administered DVD if they live in Houston ONLY and the parent indicated that the youth signs \geq 4th grade level in ASL or PSE. All forms must be returned before participant can complete the survey.
3. Survey Mailing. We will send a letter that describes the instructions for taking the self-administered paper & pencil survey. We approximate that the survey will take about 60 minutes of the youths' time and 45 minutes of parents' time. Participants were asked to complete the survey within 1-3 days of receiving the packet and to complete the survey, to the degree possible, in one sitting or at the minimum in one day (a 12 hour period). A self-addressed, stamped envelope was provided to the participant to return the survey.
4. Reminder Calls/E-mails. Reminder calls and/or e-mails were conducted 4-6 days after the survey has been mailed to participant. Parents were called until we are able to physically get a hold of them. Messages were left only as a last resort.

B. WEB SURVEY ADMINISTRATION:

1. Eligibility.
 - a) Only parent participants who have been assessed by telephone screen interview with parent to have \geq 4th grade reading level;
 - b) Only youth participants who received \geq 4 out of 8 on the reading screener; and
 - c) Only participants with access to a computer and high-speed internet are eligible for this mode of administration.
2. Reading screener. The reading screener was sent to the household with consent forms, medical release, prior to completing the web survey. An online reading screener was made available to this group. Reading screener must be scored and participant must answer at least 4 out of 8 correctly in order to continue with web survey. If the youth fails the reading screener, they were eligible for interviewer-administered DVD if they live in Seattle, Denver or Houston ONLY and the parent

indicated that the youth signs $\geq 4^{\text{th}}$ grade level in ASL or PSE. All other forms must be returned before participant can complete the survey.

3. Web Survey procedure. We will send a letter and/or email that describes the instructions for taking the self-administered Catalyst web survey. We approximate that the survey will take about 45 minutes of the youths' time and 30 minutes of parents' time. Participants were asked to complete the survey within 1-3 days of receiving the web login instructions. The participant were instructed to complete the survey, to the degree possible, in one sitting or at the maximum in one day. The instructions will also include the https address of the survey, and the individual study password (their participant ID#) that they were prompted to enter before taking the survey. Each HQL study site is responsible for recruiting from start-to-finish their site participants (i.e. providing individual study passwords for online survey, etc).

Parents 5-7 Survey: <https://catalysttools.washington.edu/webq/survey/hqlweb/71381>

Parents 8-10 Survey:

<https://catalysttools.washington.edu/webq/survey/hqlweb/71382>

Youth 11-18 Survey: <https://catalysttools.washington.edu/webq/survey/hqlweb/71383>

4. Web Survey instructions. The web survey has been set up to be equal and parallel to the paper booklet to the greatest degree possible. Participants have the option to stop and restart the survey (saving their answers), to backtrack if needed, and to review their responses at the end before submitting their survey. No question on the web survey has a required response, and they can discontinue the survey at any point. When the participant has completed the secured online survey, they can choose to submit their secured data to the Study or cancel. Within seconds of submitting data to the Study, the Seattle Study Coordinator receives an email notification that someone has completed the online survey form and the Study Coordinator is able to log-on to the secured Catalyst server to access the participants' information. Data from the surveys are saved in the Catalyst program, and can only be accessed by a project researcher using the UW login and password specific to the Catalyst surveys. Survey data are downloaded to an excel spreadsheet where no identifying information is attached and is then entered into the study database. Participant data was removed permanently from the Catalyst server once downloaded to the study database.
5. Reminder Calls/E-mails. Reminder calls and/or e-mails were conducted 4-6 days after the online survey information has been sent to participant. Parents were called until we are able to physically get a hold of them. Messages were left only as a last resort.

C. DVD SELF-ADMINISTRATION:

1. Eligibility.

- (a) Only youth participants who have been assessed by telephone screen interview with parent to have $\geq 4^{\text{th}}$ grade ASL or PSE signing skills, who received a ≥ 4 out of 8 on the reading screener, and have a strong preference for DVD are eligible for this mode of administration;
- (b) Only parent participants who indicated during the telephone screen interview that they have $\geq 4^{\text{th}}$ grade ASL signing skills and had a strong preference for DVD are eligible for this mode of administration; and
- (c) Only participants with DVD players at home are eligible, either with a TV or a personal computer.

2. Reading Screener. The reading screener was sent to the participant prior to DVD & booklet mailing to determine if the prospective participant is eligible for the self-administered DVD. In order to be eligible for the self-administered DVD the prospective participant will need to answer at least 4 out of 8 reading screener questions correctly. If the youth fails the reading screener, they will be eligible for interviewer-administered DVD if they live in Houston ONLY.
3. *DVD & Booklet Mailing.* We will send a letter that gives instructions for taking the self-administered DVD, the DVD, and the survey answer booklet. We approximate that the survey will take about 90 minutes of the youths' time and for the parent-version we approximate it should take about 45 minutes of the parents' time. Participants will be asked to complete the DVD booklet survey within 1-3 days of receiving the packet and to complete the survey, to the degree possible, in one sitting or at the maximum in one day (12 hours). See survey methods instructions on page 48.
4. A self-addressed, stamped envelope will be provided to the participant to return the booklet and DVD. Participants will not be paid unless the consent, HIPAA, medical release, payment form and the DVD is returned to the study office.
5. Reminder Calls/E-mails. Reminder calls and/or e-mails will be conducted 4-6 days after the DVD & booklet has been mailed to participant. Parents will be called until we are able to physically get a hold of them. Messages will be left only as a last resort.

D. INTERVIEWER-ASSISTED DVD SURVEYS:

1. Eligibility.
 - a. Only participants who have been assessed by reading screen to have <3rd grade reading level (score of 3 or less of 8 questions) AND have ASL or PSE signing skills reported by parent at or above the 4th grade;
 - b. Only participants who live in Houston or Seattle are eligible to participate in the interviewer-assisted DVD questionnaire.
 - c. Interviewers will use project laptops, so it is not necessary for participants to have a DVD player.
2. Appointment Mailing. We will send a letter that describes the date and time of the in-person appointment, the contact information for the survey administrator (cell phone, videophone, etc.), and other pertinent information (such as for parents to bring a book or something to entertain themselves for about 2 hours). Consent / Assent forms and Directions to the study meeting location will also be included in this mailing.
3. Reminder Calls/E-mails. Reminder calls and/or e-mails will be conducted the day before the appointment. Parents will be called until we are able to physically get a hold of them. Messages will be left only as a last resort. An additional reminder call on the day of the appointment is often necessary to confirm with parent/participant.
 - a. For in-person interview administered ASL or PSE surveys, the researcher will bring a laptop to the interview meeting that is set-up to run the DVD.
4. DVD administration. To assure that participants in this group receive the same exact ASL or PSE signing of the questions as the self-administered participants, the interviewer will follow the following protocol. The DVD will be used for administration of questions, but the answer responses will be signed in ASL or PSE using standardized response options by the interviewer.
5. Instructions for Interviewer-Assisted DVD.
 - a. The participant will record his/her answers in the booklet.

- b. No extra help will be given to participants to help them better understand or answer questions.
- c. Youth will watch the question on the video screen. After which the youth will be given signed answer options by interviewer.
- d. Youth selects answer to matching question # in the answer booklet.
- e. Interviewer can repeat the signed answer options if needed.
- f. No one is able to help you answer the questions.
- g. If youth has any difficulty, interviewer can instruct "Please answer the questions to the best of your ability."
- h. If youth does not understand a question, they should leave it blank.
- i. It is OK for youth to take a break
- j. See survey methods instructions on next page.

TYPE OF ADMINISTRATION:

SELF-ADMINISTERED SURVEYS:

Eligibility. Only participants who have been assessed by telephone screen interview with parent to have >4th grade reading level and have passed 4 of 8 reading screener questions are eligible for self-administration surveys.

Reading screener. The reading screener will be sent to the household prior to the survey mailing. Reading screener must be scored and participant must answer 4 out of 8 correctly in order to complete the paper & pencil and web-online survey.

We will send a letter that describes the instructions for taking the self-administered paper & pencil, online, or DVD survey with answer booklet. We approximate that the survey will take about 60 minutes of the youth participants' time and 45 minutes of parents' time using the written English version, and approximately 60 minutes of parent participants' time using the DVD survey with answer booklet and 90 minutes of youth participants' time using the DVD survey with answer booklet. Participants will be asked to complete the survey within 1-3 days of receiving the packet and to complete the survey/DVD booklet, to the degree possible, in one sitting or at the maximum of one day. A self-addressed, stamped envelope will be provided to the participant to return the survey/answer booklet and the enclosed DVD (if applicable). To ensure the return of the DVD, participant payment will be contingent on receiving DVD.

Reminder Calls/E-mails. Reminder calls and/or e-mails will be conducted 3-4 days after the packet has been sent to participant. Parents will be called until we are able to physically get a hold of them. Messages will be left only as a last resort.

Survey & DVD Standardization:

Survey Administration: The goal of standardization is to help minimize data collection error in order to yield better quality data. As much as possible, the survey administration setting and conditions must be consistent between individuals participating individual self-administered administration. Privacy and autonomy must be maintained for each individual participating. The survey administration setting must allow for quiet and for each participant to have their own space where they can complete the survey questions without risk of having their answers looked upon by others. A quiet room or workspace is needed to complete the questionnaire. Parents were discouraged from trying to help their youth complete the survey. Participants were instructed to complete the survey to the best of their ability and to answer the questions as they understand them. Study personnel did not provide information to a participant that is not on the questionnaire or that is not provided to all participants.

For a more complete review of interview methods see <http://www.socialresearchmethods.net/kb/survey.php> and Fowler FJ Survey Research Methods –Chapter 7 [1988 Sage Publications, Volume 1]

RETEST SURVEY ADMINISTRATION:

1. Random Number Selection. Subsets of youth and parents will be randomly selected from the list of study IDs to complete the YQOL-DHH module (youth) and YQOL-DHH module (parents) 4-5 days prior to one-week anniversary and 7 days prior to the 4 week of completion of the baseline questionnaire at any site. Retest recruitment will be conducted at Washington and Colorado sites. The DVD will not be available for the retest so only youth participants with above 4th grade reading skills will be able to participate in retest. Additionally, there will not be a retest booklet available for the parent Spanish paper-and-pencil surveys. Random selection will be facilitated by using a random number generator without replacement to select random numbers signifying order of invitation and recruitment of participants to retest.
2. Screening. Study recruiters in CO and WA sites will have a list of random numbers corresponding to next in line order for parent or youth retest. During screening of potential participants, the recruiter will assess eligibility for 7-day and 4-week retest (insufficient time, refusal) and obtain oral consent for participation in the 7-day and 4-week retest.
3. Retest Mode of Administration. The retest participants will be administered the survey via the same mode of administration used for baseline survey. The retest will be administered through the mail or web and surveys or permissions to log-on the website will be sent 4-5 days after sending baseline questionnaire for the 7-day retest or 1 week prior to 4-week retest anniversary. If the youth or parent selected to do the retest is unable to complete the questionnaires for any reason (e.g., insufficient time, refusal) the next eligible youth or child/parent on the list will be selected as a replacement.
4. Reminder Calls/E-mails. Reminder calls and/or e-mails will be conducted at the 7-10 day interval of the 7-day retest period and on the 4-week anniversary date to remind parent or youth participants to complete the retest on those days.

Test-Retest

Participants completed the retest using the same mode of administration used during baseline. Determination of 7-day vs. 4-week was randomly determined, and respondent consent/assent was received as to whether s/he was able to complete 7-day or 4-week. Additionally, study personnel made their best effort to do complete 7-day retest with mail-survey participants within 7-day window using phone follow-up and reminders. Seventeen youth were randomly retested at the 7-day interval administering the YQOL-DHH perceptual questions and 7-day recall contextual questions (Projected- 15 WA-15 CO). An additional twenty-nine youth were randomly administered the retest survey at the 4-week interval (Projected- 15 WA-15 CO), administering the YQOL-DHH perceptual questions and contextual questions which have a 4-week recall period. For parents we will administer 7-day recall and 4-week retest questionnaires to fifty parents each (Projected 50 WA- 50 CO). Out of those eligible for a retest, 40 parents from WA and CO completed the 7-day retest, and 40 additional parent participants completed the 4-week retest.

Additional youth and parents were administered the 7-day and 4-week retests, after determination that the retest had primarily been taken during the summer, and the school questions were only answered for a small percentage of the retest sample. An attempt was

made to increase the number of retest numbers for the school questions due to shortfall from summer survey administration.

Retest shortfall was due to a combination of factors, but primarily due to staffing shortage in Colorado.

Table 14: Retest results

PARENT

	7-day Retest	4-week Retest
WA Recruitment	26	28
CO Recruitment	14	12
Total	40	40

YOUTH

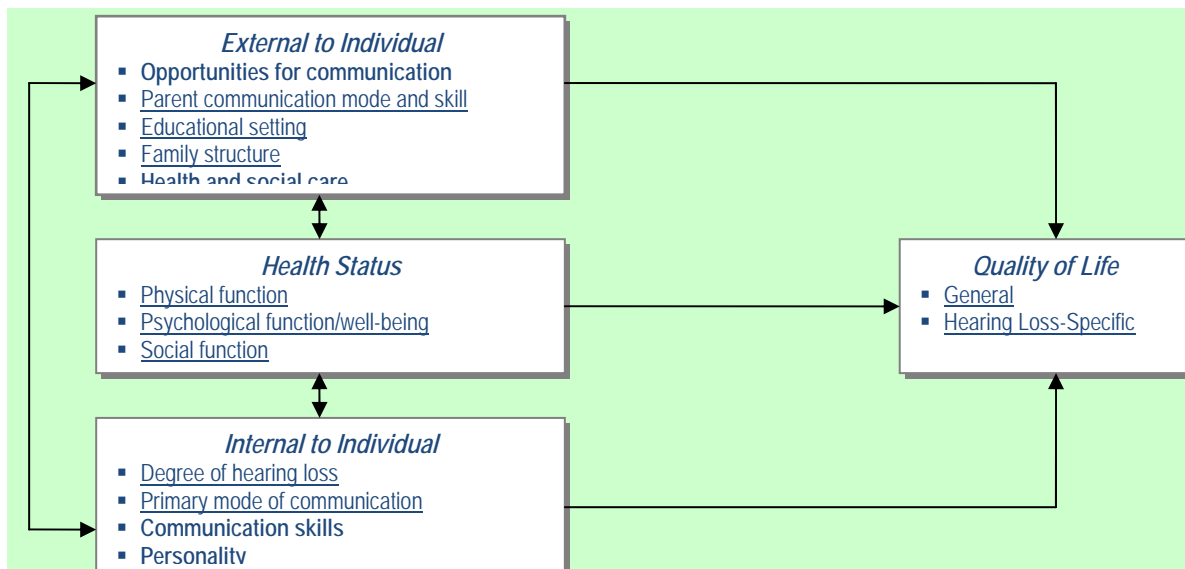
	7-day Retest	4-week Retest
WA Recruitment	15	23
CO Recruitment	2	6
Total	17	29

Step D. Payment. An incentive of \$25 is available to all participants after completing the main survey or \$15 after completing the retest survey. Payment can be made to participant only when consent forms, medical release, and completed surveys are received by Study Coordinator. Payment is administered by check for either \$25 (survey only) or \$40 (survey and baseline).

7.5 Study 2 Outcome Measures

Copies of the study instruments may be found in the appendix of the protocol. The total time to complete the questionnaire booklet is between 45 – 60 minutes. Four subscales of the CHQ and the CDI and CIPP were administered in the Youth survey.

From Figure 1. Conceptual Model of QoL and Correlates for Children and Youth with Hearing Loss*



*** Bolded-Underlined Items are the correlates we are assessing in this study**

Child demographics: Questions regarding child/youth age, birth date, sex, ethnicity, grade in school were collected in both Phase I and Phase II. Parents provided age, sex, ethnicity, degree of hearing loss and mode of communication as part of the telephone eligibility screener.

External Factors

Parent/Child Communication: Were assessed via the demographic form in Phase I or as part of the questionnaire booklet (Phase II) using previously validated questions from the Colorado Individual Performance Profile (2002a; CIPP) parent version of the student and family information and language modality usage sections.

Educational setting: Education program type, school placement, percentage of time in regular education classrooms will be obtained via questionnaire and verification of hearing loss. (see internal factors section below).

Family structure: Parent marital status, with whom the child/youth lives, mother/father age, education, occupation, is being assessed as an indication of SES. Other family members who are DHH, primary language used in the home by family members, and location of child/youth primary residence (e.g. urban, suburban, rural/small town) will be obtained via parent/youth reports these variables are being included as they are indicators of opportunities for the youth to socialize, which may have an impact on QoL.

Health Status

Physical/psychological/social function: *Pediatric Quality of Life Inventory 4.0 (PedsQL)* (Varni, Seid, & Kurtin, 2001) parent and youth age specific versions (5-7; 8-12; 13-18). The PedsQL assesses: Physical functioning, Emotional functioning, Social functioning and School functioning in both self and proxy reports, and consists of 23 items in each of its age specific versions. It is a well validated instrument. Psychometric analyses have shown it to be internally consistent and reliable with Cronbach's alphas in the .70 to .90 range. Scores are transformed to 100-point scales.

Self Rated Health: Assessed by a single item: "How would you rate your health?" (Response options: excellent, very good, good, fair, poor).

Depressed Affect: – The Children's Depression Inventory (CDI; Kovacs, 1992). The 10 item short version designed for self report with youth will be fielded on the questionnaire for youth ages 11-18. The 17-item CDI-Parent's Version will be used for Children ages 5-10. The CDI-S and CDI-P are brief screening measures that allow the quantification of depressive symptoms. The CDI-S correlates 0.89 with the longer 27 item CDI. The CDI scores are compared with normed data by age and gender. The CDI will be used to control for depressed affect in index youth/siblings, which has a strong correlation with quality of life (Patrick et al., 2000).

Internal Factors

Degree of Hearing Loss: Questions from the Colorado Individual Performance Profile (CIPP), which is part of the survey from the other sites, were fielded on the youth and parent questionnaires. age of first hearing loss and diagnosis, age of first severe or profound hearing loss, current functional level of hearing loss (as assessed by parent as none/mild/moderate/severe/profound), type of hearing loss (stable, progressive and/or sudden), history of therapy, use of hearing aids (none, unilateral, bilateral), FM system (at school, home,

social situations), length and type of school placement, use of an educational interpreter, use of cochlear implant, primary mode of communication used by child/youth at home and school, day-to-day health concern.

Verification of Hearing Loss: Parents were asked to provide permission for the schools/audiologist/physician to obtain their child's most recent audiologic records. Youth who want to participate, and have parental consent, were allowed to complete the questionnaire with or without audiogram information so that those for whom complete information could not be obtained do not feel left out or discriminated against.

Child/Youth primary mode of communication: Assessed during the telephone screen (Phase I) or via questionnaire (Phase II) using previously validated questions from the Colorado Individual Performance Profile (2002a; CIPP) youth version of the student and family information and language modality usage sections.

Quality of Life

Generic QoL: *Youth Quality of Life Instrument - Research Version* (YQOL-R) (Edwards et al, 2002; Patrick et al, 2002) Perceptual module (41 items) was fielded in the youth questionnaire at all study sites. The YQOL-R is a validated generic QoL self-report instrument for youth ages 11-18 assessing: Sense of Self, Social Relationships, Environment, and General Quality of Life. Psychometric analyses on the YQOL-R perceptual scales have yielded scores with acceptable internal consistency (Cronbach's alpha = 0.77 to 0.96), reproducibility (ICCs = 0.74 to 0.85), expected associations with other measured concepts, and ability to distinguish among known groups. It takes approximately 15 minutes to complete.

Deaf/Hard-of-hearing-specific QoL: *Youth Quality of Life Instrument – Deafness and Hard-of-hearing Modules* (YQOL-DHH) developed in Phase I. A self-report module for youth ages 11-18 and a parent proxy-report module for children ages 5-10 assessed quality of life areas of concern for DHH children and youth. Based on development of other QoL specific modules it is anticipated that these modules will be 30 items or less with a 10 minute completion time.

7.6 Protocol for Collecting Verification of Degree of Hearing Loss

Collecting Verification of Degree of Hearing Loss

Verification of degree of hearing loss will be collected for all participants. Initial information will be obtained from the parent. This information will be verified either from school records, the youth's audiologist, or otolaryngologist. Verification of Degree of Hearing Loss forms will be sent to the appropriate reference provided by the parent with a signed release form with a postage paid return envelope. For the Qualitative interviews and the focus groups verification of degree of hearing loss will be obtained prior to the meeting. For the youth questionnaire participants, those for whom the parent did not return the Parent questionnaire booklet and release of Information form, a second packet will be sent home with the youth after completion of their questionnaire booklet. For parent participants parents will complete the Degree of Hearing Loss Information as part of their questionnaire booklet. A medical release form to obtain information from the school, audiologist or otolaryngologist along with postage paid return envelope will be included in the questionnaire packet.

Audiograms will be collected for all participants from their audiologist, physician, or school district after the parent/guardian has completed the audiologic release form. Audiological information will be analyzed and entered onto an abstract form, and then entered into a FileMaker Pro database. Data will be entered and checked for data entry errors. From

the database, participant identification number and degree of hearing loss category will then be exported into Excel to be managed within the statistical program. An audiologist certified by the American Speech, Language, and Hearing Association (ASHA) will complete all analysis of audiologic information.

Assessment of Audiological Status

After signed audiology/medical release forms were obtained from parents/guardians, we first communicated with audiologists and then sent release forms to schools or clinics to obtain the participant's most recent audiological records. This information was used to determine participant's hearing level in the better ear for the purpose of hearing level categorization. The progress in obtaining the audiograms was tracked on an excel spreadsheet. These reports were then sent via Catalyst Sharespace to an audiologist certified by the American Speech, Language and Hearing Association (ASHA), who analyzed the information and entered them onto a summary audiological form. The hearing loss information was then entered into a FileMaker Pro database. From the database, participant identification number and degree of hearing loss category were exported to Excel to be managed within SPSS.

Ear specific unaided air conduction results were necessary in order to determine the degree of hearing loss. Additionally, cochlear implant status was determined by the audiologic report.

Unaided Information:

Pure-tone air conduction thresholds will be recorded onto the audiological abstract form. Separate fields will be entered for the right ear (RE), left ear (LE), and soundfield (SF) results. Pure-tone averages (PTA), or the average at 500, 1k, and 2k Hz, will be automatically calculated at the time of entry into the FileMaker Pro database. Additionally, all high-frequency pure-tone average (HF PTA), or the average at 3k, 4k, and 6k Hz, will also be automatically calculated at the time of entry into the FileMaker Pro database. The HF PTA will be used if the PTA does not represent the participant's degree of hearing loss in the professional judgment of the audiologist, such as the case of a precipitously sloping high frequency hearing loss. If the HF PTA is to be used, it will be indicated on the audiological abstract form.

Degree of hearing loss will be determined by the better ear PTA, or the lower number PTA (or HF PTA, if applicable). A numerical category will be assigned to each degree of hearing loss. Degree of hearing loss will be classified as follows:

- Normal (0): 0-20 dB HL
- Mild (1): 20-40 dB HL
- Moderate (2): 40-55 dB HL
- Moderate-severe (3): 55-70 dB HL
- Severe (4): 70-90 dB HL
- Profound (5): 90+ dB HL
- Unilateral (6): Better ear PTA is within normal limits but a mild or greater hearing loss is present in the other ear.
- Cochlear Implant (7): Cochlear implant users
- Missing (999): Cannot be determined by the information available on the audiogram

Information will also be recorded regarding the type of hearing loss (sensorineural, conductive, mixed, or unknown). Other characteristics of the hearing loss will be noted as well, including symmetry and progression of hearing loss. Type of amplification will be recorded if

available, including hearing aids, cochlear implant, FM system, other amplification, no amplification used, and unknown.

After repeated efforts to contact parents and clinicians, 53 of the remaining youth and 68 of the 5-10 year olds' parent participants did not have hearing level categorization due to insufficient or missing medical record information. In order to fulfill missing audiological data, the project team used the following procedure to determine classification of hearing level for the remaining participants. Two separate spreadsheets were created for youth and parent participants. The spreadsheet included entries from the parent's report of the child/youth's hearing level at time of screening interview as well as the participant's survey response to the survey question that asked about their hearing level. A decision was made to re-classify hearing level as a new variable based on several criteria (outlined in Table 2 as groups 2-4). Below is a description of hearing level determinations made on available audiogram and study data for different groups:

Criteria for classification of hearing levels (see Table 2):

- 1) **Group 1:** *For those subjects with an audiogram where a clear determination of hearing level was available, then the categorization of hearing level remained that of the audiogram.*
- 2) **Group 2:** *In the case of concordant parent' report of hearing level and youth/parent survey response of hearing level then the concordant parent/youth determination of hearing loss became the new classification.*
- 3) **Group 3:** *In the case where an audiogram was inconclusive but the parent indicated the child/youth had (and was actively using) a cochlear implant, the child/youth was categorized as CI.*
- 4) **Group 4:** *If parent's report and parent/youth survey response were NOT concordant for hearing level, then degree of hearing loss was determined by agreement of three researchers based on the available evidence:*
 - a. *available audiogram data regardless of date of medical record (post-dated 2+ years from survey date),*
 - b. *type of school placement, sign or speech preference (as indicated by parent's report at time of screening interview; (i.e. Mainstream- not in DHH program, Mainstream- in DHH program, or attending Deaf School),*
 - c. *Youth/parent responses to survey items from CIPP questions regarding amplification and classroom assistive devices (i.e.: "What type of personal amplification do you/does your child currently use at home?"; "What type of assistive listening device do you use at school?"; and "What type of interpreter does your child use?")*

For all participants in group 4, we aimed to correlate these communication and hearing level variables with parent and youth report to determine hearing level. However, when these variables were inconclusive, we deferred to parent report for categorization.

- For the youth participants, a final determination was made using the parent's report of the youth's hearing level at time of screening interview, as the parent was thought to be more reliable than the youth.
- For the parent participants, a final determination was made using the parent's report of the child's hearing level indicated in their completed survey. This decision was made on the assumption that the parent would provide a more accurate answer given the additional time to think about the question. (The exception being if parent survey question was not answered, and then we defaulted to the screening data).

Table 15: Group breakdown for classification of hearing levels

Surveys completed	Youth	Parent
Total surveys completed	233	271

Audiology/Hearing Level completed	Youth	Parent
GROUP 1: Audiograms completed	180	202
GROUP 2: No audiogram-- Hearing level concordance	30	38
GROUP 3: No audiogram-- Screener/Survey indicated CI	10	17
GROUP 4a: No audiogram-- Parent Screener used	13	4
GROUP 4b: No audiogram-- Parent Survey used	0	10
TOTAL	233	271

Table 16: Final hearing level distribution for recruitment sample

Hearing Level	Youth Completed	Parent Completed
High Freq	1	2
Mild	19	21
Mod	20	25
Mod-Sev	26	55
Severe	30	27
Profound	65	29
CI	64	104
Unilateral	7	5
Normal	1	3
TOTAL	233	271

Analytic groupings are discussed in SAP.

7.7 Data Management

7.7.1 Participant ID Numbers

Each potential participant will be assigned a 4 or 5-digit identification number, which will be attached to all forms and instruments. The assigned ID numbers will increase in numerical order in the order they are contacted for recruitment. The use of identification numbers ensures confidentiality.

The key which links names to the data will be stored in a locked office at each site for one year after the study ends, with access only to research staff. After this time, it will be destroyed. If a participant chooses to withdraw from the study, we will destroy the key linking their name to the data at that time. The data without identifiable information will be kept indefinitely at the Center for Disability Policy and Research. Access to this data will be controlled by the research staff at the Center for Disability Policy and Research. No names or other identifying information will be used in any publications or presentations which may result from this study.

7.7.2 Participant Files

All completed forms, instruments, and coordinator notes will be kept in separate participant files ordered by ID number. Each participant will have a file folder organized in this order: eligibility screener, copies of any important e-mail/IM communications with participant, consent form(s), HIPAA form, medical release, audiogram, and payment requisition form.

Files with identifying information are divided by site in colored hanging folders: Texas, red; Colorado, blue; Seattle, turquoise, Arizona, purple. Each site has the following folder sections: *Screened*, *Scheduled*, *Materials Needed*, and *Completed*. Participant files are created, and travel through these folder sections as documents are returned and are completed.

Files will be kept in a file cabinet and the security of the data will be maintained at all times. Only researchers associated with this project will have access to the data.

As mentioned above, consent forms will be kept separate from the questionnaires. A year following the end of the study, the consent forms will continue to be kept in a secure locked place without any link to an ID number. After a period of 10 years, the consent forms may be destroyed. Each site will be responsible for securely storing this information until it is appropriate to be destroyed.

7.7.3 Data Entry

All questionnaire and corresponding data will be entered into the database. To assure accuracy of data input a sample of 25% will be double entered and matched as an additional 10% spot checked.

The security of the data will be assured by keeping the original questionnaires in a locked filing cabinet, and electronic data in password protected server. Files which contain subject identifiers will be stored separately from data files. One year after the close of the project all links between the data and identification information will be destroyed.

Site reports will be generated weekly in the Seattle Coordinating Center. The weekly recruitment reports include information as to site, hearing level, school type, type of administration (parent or youth, survey or retest), audiograms and mode of administration.

Sensitive study information will be shared via the UW Catalyst Sharespace, which is allows for file transfer with password protection over a secured network server. Specific database query and report procedures for MS Access tracking database as well as audiogram database are available. Specific instructions for downloading data from the UW catalyst server are additionally available.

Table 17. Study 2 Final Recruitment Results by Hearing level, Youth 11-18

Hearing Level	<i>Youth Completed</i>	<i>Parent Completed</i>
Mild/ High Freq	20	23
Mod/Mod-Sev	46	80
Severe/Profound	95	56
CI	64	104
<i>TOTAL</i>	<i>225</i>	<i>263</i>

<i>Unilateral</i>	7	5
<i>Normal</i>	1	3

Table 18. Study 2 Final recruitment results by School placement

School Placement by Hearing Level	Youth		Parent	
	Mainstream	DHH School	Mainstream	DHH School
Mild/High Freq	19	1	22	1
Mod/Mod-Sev	42	4	68	12
Severe/Profound	43	52	25	31
CI	48	6	84	20
TOTAL	152	73	199	64

<i>Unilateral</i>	7	0	5	0
<i>Normal</i>	1	0	2	1

Table 19. Study 2 Final recruitment results by Mode of administration, Youth 11-18

Youth Mode by Hearing Level	Mode of Administration			Total Completed
	Self-Administration		Interviewer-assisted	
	English-Written (web & paper)	ASL/PSE-Signed	ASL/PSE-Signed	
Mild/High Freq	20	0	0	20
Mod/Mod-Sev	44	2	0	46
Severe/Profound	66	20	9	95
CI	59	5	0	64
TOTAL	189	27	9	225

<i>Unilateral</i>	7	0	0	7
<i>Normal</i>	1	0	0	1

Table 19. Study 2 Final recruitment results by Mode of administration, Children 5-10

Parent Mode by Hearing Level	Mode of Administration			Total Completed
	Self-Administration			
	English-Written (web & paper)	Spanish-Written (paper)	ASL - Signed	
Mild/High Freq	23	0	0	23
Mod/Mod-Sev	73	6	1	80
Severe/Profound	51	1	4	56
CI	101	3	0	104
TOTAL	248	10	5	263

Unilateral	5	0	0	5
Normal	3	0	0	3

7.9 STUDY ANALYSIS PLAN

Prior to analyses the distribution of scores will be assessed for departure from the assumptions of univariate and multivariate normality. Variables that show marked departures from these

assumptions will be appropriately transformed. Individual cases that are shown to be univariate or multivariate outliers will be screened, and a determination as to the appropriateness of inclusion or elimination will be assessed.

7.9.1 Study Aim # 2

Aim 2: To test the cross-sectional psychometric and practical measurement properties of the Youth QoL Deafness and Hard-of-hearing Modules.

Preliminary data cleaning and logical/error checking will be conducted. The frequency and pattern of missing values will be examined. Any outliers will be carefully evaluated with statistical and clinical judgment to determine their validity for use in the analyses. Descriptive statistics of each variables involved in the analyses will be calculated to learn the distributional properties of each variable. For continuous measures, mean, median, standard deviation, percentiles (5%, 25%, 75%, 95%) and range (minimum and maximum) will be computed. For categorical measures, frequency and mode will be obtained.

Measurement Model: Standard classic psychometric analyses will be used to validate the instrument in this cross-sectional study. We shall use the Multi-trait Analysis Program (MAP-R) to investigate the scaling properties of the YQOL-DHH modules, including the overall score and any subscale scores that are derived from the measure (Hays et al., 1988). Item reduction statistics will be assessed for the YQOL-DHH modules. These include: 1) items with greater than 5% missing data; 2) items that demonstrate a ceiling effect (more than 50% of respondents selecting the “lowest” response option, which would suggest a high degree of “non-relevance”); 3) an item-to-total correlation lower than 0.40 (suggesting the item may measure something belonging to a different scale); and 4) an item-to-item correlation of greater than 0.70 (indicating redundancy among the individual items). A discrimination index will also be calculated for each item. The index will be constructed by looking at the endorsement of the item by those who scored in the top 27th percentile on the scale compared with those who scored in the lowest 27th percentile. An item will be considered to have been endorsed if the respondent chooses a value of 7 or greater on the 11-point scale or a value of 4 or greater on a 5-point scale. We shall also use principal components analysis using SPSS to look at linear combinations of items in association with expected a priori hypotheses of inter-relationships and the association of items to domains or “traits” (Hambelton & Slater, 1997). We propose using exploratory and confirmatory factor analyses to examine the dimensionality of our scales. One-factor models will be imposed on our data and model fit will be assessed by examining scree plots, the Tucker-Lewis index, the root mean square error of estimation and practical fit indices such as the comparative fit index. If one-factor model does not fit, we will determine how many factors to retain by examining the scree plot from the principal components factor analysis specifying squared multiple correlation in the diagonal of the identity matrix. If there is no clear breakpoint in the scree plot then we will examine the set of possible solutions based on the numbers of factors around which the scree plot crosses factors with eigenvalues of 1.0. To assist interpretation of each set of solutions, we will use Promax rotation, which first orthogonally rotates the solution and then rotates it again to allow correlations among the factors. This rotation is used because the simple structure is maximized by clarifying which variables do and do not correlate with each factor. Promax was selected because it is highly likely that the factors will be correlated.

Measurement Model

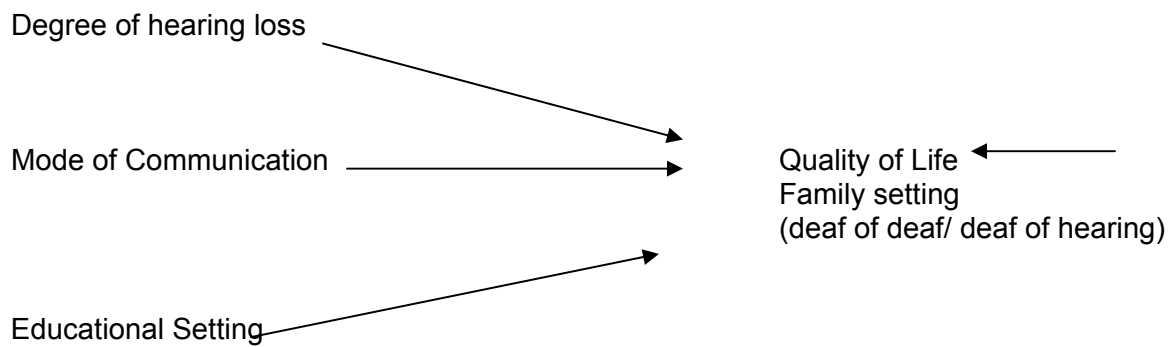
Hypothesis 1: Degree of hearing loss will be associated with quality of life.

Hypothesis 2: Youth who have better school support will report better quality of life.

Hypothesis 3: Deaf youth from deaf families will report better relationships with their family members than deaf youth from hearing families.

Hypothesis 4: Youth with severe to profound hearing loss with CI who are mainstreamed will report better quality of life than youth with severe to profound hearing loss who are mainstreamed and use alternative technologies for communication.

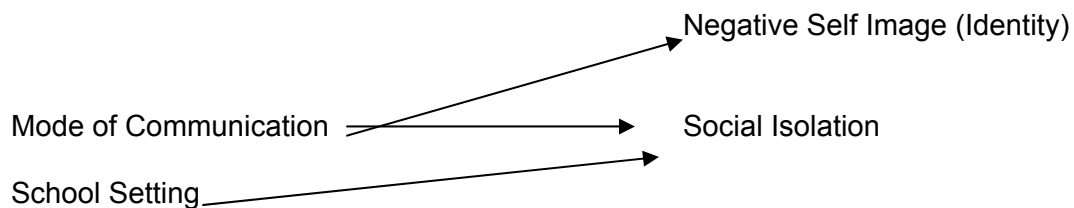
GENERAL MODEL



QOL SPECIFIC MODEL

Hypothesis 1: Youth with poor speech, those who wear hearing aids or CI will report a more negative self image and greater social isolation.

Hypothesis 2: youth who use sign language as their primary mode of communication and are in mainstream schools will experience greater social isolation



IRT models will be used to estimate item difficulties (locations) and item slopes (discrimination) (Hays, Morales, & Reise, 2000). Although multidimensional IRT models have been described (e.g., Reckase, 1997), most applications of IRT assume unidimensionality. Therefore prior to applying IRT, a key issue is to assess whether a scale is unidimensional "enough" to allow for the valid scaling of examinees on a common latent trait (see one-factor model above). IRT models will also be used to evaluate items for differential item functioning (DIF) (i.e., bias). DIF occurs when the probability of endorsing an item (in the case of a dichotomous item) differs by subgroup (or time for drift assessment) after controlling for the latent attribute (e.g., level of health-related quality of life). We will evaluate items for DIF by communication mode (ASL, signed English, Spoken English) and race/ethnicity (Hispanic versus Caucasian). When using a 2-parameter IRT model, items can be evaluated for DIF by contrasting the IRT slope (a_i) and difficulty or location (b_i) parameters among subgroups. Uniform DIF is present when the probabilities of endorsing an item are uniformly higher for one group than another across the latent trait range. In contrast, non-uniform DIF occurs when the probability of endorsing an item is higher for one group than the other in some parts of the trait range and lower in other parts of the trait range. We will evaluate items in our scales for both uniform and non-uniform DIF.

Reliability: Cronbach's alpha coefficient will be used to assess internal scale consistency. A minimum coefficient of 0.70 will be considered necessary to claim the instrument is internally consistent for use in group comparisons. The reproducibility (test-retest reliability) will be ascertained using the intraclass correlation coefficient (ICC) to evaluate the relationship between the baseline and 1-week measures. The ICC ranges between 0.00 and 1.00, and the minimal acceptable level for group comparisons is 0.70.

Construct Validity: Convergent and discriminant validity will be assessed determine if the logical relationship between the YQOL-DHH and other similar and dissimilar concepts. If predictions of association are accurate then convergent and discriminant validity will be achieved. To assess convergent and discriminant validity, Pearson's correlation will be computed to measure the association between the domains of the YQOL-DHH, and the four YQOL-R domains, CDI, and PedsQL 4.0, scales.

It is hypothesized that

The YQOL-DHH will be positively correlated with the domains of the YQOL-R, the Social and Emotional scales of the PedsQL 4.0, will be more highly correlated with the domains of the YQOL-R than the scales of the Physical scales of the PedsQL and will be negatively correlated with depression and anxiety, as measured by the CDI.

Respondent burden: will be assessed by timing self administration of the YQOL-DHH module reporting mean, median, and ranges.

Alternate forms: The YQOL-DHH modules will be available in ASL, Signed English DVD formats. A Thurstone scaling analysis will be conducted to examine response choice equivalence between the three forms.

Cultural and language adaptations: The new modules are being culturally adapted during development for use with the three functional communication groups. Youth who use sign language exclusively (Visual communication), youth who use spoken English as their primary means of communication (Audio), and youth who use a combination of sign and spoken English (Audio/Visual) The development of the instrument will include youth who use these forms of communication. We are also targeting both Hispanic and African American youth in the

development of the instruments to ensure its cultural relevance to the Deaf/deaf communities in the U.S.

Power Analysis for Aim 2: The sample design will provide 550 youth who are DHH, 550 parents of youth who are DHH to complete the instruments. The power calculations are based on differences between two correlations. A sample size of 90 allows the detection of significant differences between two correlations of 0.11 or greater with 80% power. Based on previous studies with the YQOL-R, it is anticipated that the correlation between the Depression Scale and the YQOL-D will be in the 0.5 range and correlations between the YQOL-D and the physical scales of the PedsQL 4.0 will be in the 0.3 range which will allow for assessment of construct validity.

7.9.2 Study Aim #3

Aim 3: To explore of degree association of DHH with QoL and known or hypothesized correlates using a clustered sample design.

The associations between degree of hearing loss (DHL), QoL and other covariates will be evaluated with cross-sectional data. First we will conduct descriptive analyses, consisting of cross-tabulations, comparisons of means and variations, and correlations to examine bivariate associations between the following sets of covariates in the conceptual model: internal factors (primary mode of communication, DHL and demographic characteristics), external factors (educational setting, family structure), health status (physical, psychological and social function), and quality of life (general and DHH specific).

Intra-cluster correlation will be taken into account in all statistical testing and modeling using Huber sandwich estimates (Huber, 1967) or a Generalized Estimating Equation (GEE) approach. Generally, a positive correlation is found within clusters (i.e., students within schools are more alike than across schools, so they tend to respond similarly) which usually results in overdispersion or the introduction of extra variation in the responses beyond what would be expected under independence. Clusters can, however, result in underdispersion. To assure that this non-independence is accounted for in these analyses, we will use a GEE regression model with site as a cluster or a regression model with robust estimates of standard errors through Huberization. Specific statistical software such as STATA (StataCorp 2003) or SUDAAN (RTI, 1999) will be used.

Comparisons between Mild, Moderate, Severe, Profound and Deaf Youth:

Mean differences in outcome measures between the groups will be assessed using pairwise comparisons on the YQOL-R perceptual domains, total score and the YQOL-DHH. The analysis will be conducted using a GEE regression model controlling for age, sex, and SMFQ depression scores, which previously have been shown to be associated with QoL (Patrick et al., 2002; Topolski et al., 2001). The covariation of health status with QoL will also be explored. A sequential discriminate function analysis of age- and sex-residualized data (known correlates of QoL) will be performed. This analysis will provide information regarding whether the groups can be correctly classified based on their YQOL-R and YQOL-DHH domain scores as well as information on the relationship between hearing-loss severity and the set of predictors. By using a sequential discriminate function analysis it can further be determined whether adding scores on the SMFQ (depression), PedsQoL (health/functional status), and school placement to the model provide significantly better classification among the groups than that afforded by YQOL scores alone. Where appropriate a Bonferroni type adjustment for multiple comparisons will be made to ensure the effective type I error at the level intended.

Comparison between Males and Females: First we will conduct descriptive analyses to explore the associations between QoL, age, psychosocial factors, health status and school placement by gender. Mean differences between males and females will be assessed using a hierarchical *GLM* or *GEE* regression model. The covariate age will be entered at the first step. In the next step, the covariates depression (SMFQ score) and family structure and school placement will be entered. The association between health status and functional status with QoL will also be explored. *If non-independence is found, it will be accounted for in these analyses, by using a GEE regression model with site as a variable or a regression model with robust estimates of standard errors through Huberization.*

Comparison between Ethnic/Racial Groups:

We will conduct descriptive analyses to explore whether the associations between QoL and degree of hearing loss (DHL), demographic characteristics, educational setting, family structure, health status, and depression, differ between racial and ethnic groups. For example, we will analyze the bivariate association between QoL and DHL separately by ethnic group using correlations and marginal regressions to see if the nature and strength of the associations are similar. If differences emerge in these associations, it will suggest the need for stratification or interaction terms in subsequent multivariate analyses.

To assess the independent associations between DHL and quality of life, demographic characteristics, family structure and school placement, health status, and psychosocial factors, we will fit a series of multivariate regression models. These regression models will have the following general form:

$$YQOL - DHH_i = f(D_i, X_i, H_i, PS_i,) \quad (\text{eq. 1})$$

where the dependent variable will be YQOL-DHH_i, represents the YQOL-DHH score for the ith youth. The main explanatory variables in these models are as follows: D_i is the degree of hearing loss; X_i is a vector of demographic characteristics; Y_i is a vector of family and school characteristics; H_i is a vector of health characteristics; and PS_i is a vector of psychosocial factors.

Racial and ethnic group differences will be explored by testing the significance of interaction terms between indicators of race and ethnicity and each explanatory variable. For example, we will test interaction terms between QoL and indicators of race and ethnicity. We will retain statistically significant interaction terms in our final models. Given our sample size, however, we recognize that the statistical power may be limited for detecting the significance of multiple interactions terms between QoL and racial/ethnic groups. We will try to use parsimonious models when it is possible. We will use ordinary least squares (OLS) regression models for these analyses. In general, our OLS regression models will be of the form:

$$YQOL - DHH_i = \alpha + \beta_x D_i + \beta_x X_i + \beta_x Y_i + \beta_x H_i + \beta_x PS_i + \varepsilon_i \quad (\text{eq.2})$$

where YQOL-DHH_i is the outcome measure for the ith youth; D_i, X_i, Y_i, H_i, and PS_i, are as described in equation (1); α is the regression intercept to be estimated; the β 's are vectors of regression coefficients to be estimated; and ε_i is an error term for the ith youth. As described above, we will estimate models with interaction terms in preliminary models and retain significant interactions terms in subsequent models if they are statistically significant. All standard errors will be estimated using the Huber-White sandwich estimator, which provides robust estimates of standard errors under clustering data structure and heteroskedasticity (STATA, 2003).

7.9.3 Study Aim #4

Aim 4: To revise the draft module and disseminate the Youth Quality of Life Deafness-Specific Module 2.0.

Results of analyses from the module testing will be used to evaluate the draft deafness module. Items will be revised according to the psychometric data. Input will be sought from our expert consultants and local advisory panel. A final version of the YQOL-DHH will be produced and available for use from the SeaQoL Group website (www.seaqolgroup.org). Results shall be presented at meetings of child and adolescent auditory clinicians and researchers and publish as appropriate in peer-reviewed journals. A manual, including scoring instructions, shall be prepared for distributing the modules.

Study Limitations Resulting from Design and Methods Decisions:

This project entails primarily observational methods with cross-sectional assessment. As such, we shall not be able to assess the ability of the YQOL-DHH to detect minimally important changes with intervention. This objective awaits further studies, ideally with randomized designs, to be able to attribute changes in the QoL scores to intervention. Randomized trials or large epidemiological observational studies are more suited for investigating these important correlates. The study populations are currently limited to the Washington State, Colorado, New Mexico and Arizona area and may not be representative of the national population. We are seeking participation from other school districts in the US with the hope to be able to recruit sufficient participation to all generalizability to the entire US population of school age youth with hearing loss.

The conceptual model of characteristics that predict adolescent communication status and thus possibly QoL contain several characteristics that will not be measured in this study. We have augmented current models and selected those that we feel are most salient for this investigation.

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