VALIDATION OF CLINICIAN REPORTED OUTCOME MEASURES OF PEDIATRIC SEDATION

A qualitative study aimed at assessing the content validity of clinician reported pediatric sedation measures via cognitive interviewing.

Pro00102030

Version 1.2

Date
28 March 2019

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Table of Contents

List of Abbreviations

Study Summary

Title	Validation of Clinician Reported Outcome Measures of Pediatric Sedation
Short Title	Pediatric Sedation
Protocol Number	Pro00102030
Phase	N/A
Methodology	Qualitative: Cognitive Interviewing
Study Duration	1 hour
Study Center(s)	Single-center
Objectives	Validation of clinician reported measures of pediatric sedation
Number of Subjects	24
Diagnosis and Main Inclusion Criteria	Pediatric anesthesiologists and pediatric critical care physicians will be enrolled
Statistical Methodology	Qualitative: Thematic Analysis

1 Introduction

This document is a protocol for a human research study. This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

1.1 Background

Anesthesia and analgesia are increasingly recognized as integral parts of inpatient and outpatient management of infants, children, and adolescents.[1] However, many anesthetics and analgesics are not approved by the US Food and Drug Administration for use in children due to inadequate information on drug efficacy, safety, and dosing in pediatric populations.[2,3] In order to assure optimal pharmacotherapy, it is imperative to select the correct drug dose. The Pediatric Trials Network (PTN) seeks to complete safety and efficacy studies of understudied but commonly-administered anesthetics to children, The studies will help define an optimal dosing regimen for pediatric populations. In order to complete these studies and submit data to the US FDA for update of pediatric labeling, the PTN requires outcome measures for sedation levels that have been thoroughly validated. Existing clinician report pediatric sedation scales do not have adequate qualitative evidence to support content validity for any of these scales to be used as outcome measures.

This Study

This study will conduct qualitative interviews to provide evidence for the content validity and comprehension of existing physician-reported measures of sedation levels of children receiving anesthesia to facilitate a diagnostic or surgical procedure. Information gained from this study will inform the use of the measure in studies that are part of the PTN.

2 Study Objectives

Primary Objective

To assess the content validity and physician understanding of the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS) via cognitive interviewing methods.

3 Study Design

3.1 General Design

This is a qualitative, questionnaire validation study using 1 hour, phone-based cognitive interviews with pediatric anesthesiologists and pediatric critical care physicians. Participation will last for the duration of the 1 hour phone interview.

3.2 Primary Study Endpoints

The two co-primary study endpoints are physicians' 1) comprehension of items and response options on clinician reported pediatric sedation scales, and 2) evaluation of the relevance of the scale to capture sedation levels.

4 Subject Selection and Withdrawal

4.1 Inclusion Criteria

1. Is a practicing clinician in a clinical care environment
2. Cares for pediatric patients >50% of their time
3. Treats or works with pediatric patients who are sedated/anesthetized for diagnostic and/or therapeutic procedures
4. Holds one of the following titles/positions
    a. Anesthesiologist
    b. Pediatric critical care physician
    c. Clinical pharmacist (PharmD)
    d. Nurse anesthetist
    e. Nurse practitioner
    f. Physician assistant
    g. Nurse (with a BSN/RN or higher)
5. Is over the age of 18 years
6. Can speak English
7. Is capable of giving informed verbal consent

4.2 Exclusion Criteria

1. Lack of access to a telephone for interview

4.3 Subject Recruitment and Screening

Participants will recruited via phone and email.

Emails will be sent to clinicians by Pediatric Trials Network (PTN) staff members and study staff. The email will contain brief information about the study (recruitment materials), a Study Information Sheet attachment (in place of a consent form with approval of a waiver of documentation of informed consent), and contact information for study personnel. Clinicians interested in participating may use the information in the email to contact study personnel.

Phone calls will be made by study staff to PTN member clinicians. An approved IRB phone script will be used by study staff making calls to potential participants.

Because clinicians are busy, we expect that recruitment for the study will require a number of contacts before we can schedule physicians for the interview. We will keep a list of any clinicians who refuse participation so that they will not be subsequently contacted during the recruitment period.

Study staff will review the Study Information Sheet with potential participants, answer any questions the clinician has about the study, and screen interested clinicians for eligibility using self-reported information obtained over the phone or via email.

4.4 Subject Consent

Given the design and topic of this interview study (content validity and comprehension of clinician reported outcome measures of pediatric sedation), we believe this study qualifies for Exempt Research status under 45 CFR 46.104(d)(2)(ii) because:

- The research involves only the use of standard interview procedures; and

- We will have robust confidentiality protections in place to protect the data—but even in the unlikely event of participants' responses being disclosed in identifiable form, we do not believe participants would reasonably be placed at risk of criminal or civil liability or that the responses would be damaging to the subjects' financial standing, employability, or reputation. Our topic is neither personal nor sensitive, and the questions posed to participants are intended to ascertain whether the design of a survey is adequate to assume content validity and comprehension of survey items and responses by users of the questionnaire, not right or wrong answers.

This study does not involve patients; participants will be health care professionals. Participants will be provided with a Study Information Sheet that includes a brief description of the study objectives and procedures, along with information on data safety and confidentiality.

Agreement to participate in the survey and/or interview will serve as consent to participate in the study.

4.5 Early Withdrawal of Subjects

4.5.1 When and How to Withdraw Subjects

As this study is a qualitative interview study lasting for only 1-hour, we do not anticipate having to withdraw subjects from the study based on safety or non-compliance. However, there may be instances in which a participant needs to end the interview early. In these instances, we will work to schedule a new time to complete the interview within the following two weeks. If the interview cannot be scheduled for completion within 14 days, we will retain the already collected data from the participant and consider any uncollected data as missing.

5 Study Procedures

Participants will take part in a semi-structured qualitative interview (~1 hour).

One day before the interview, the participant will receive a reminder email with details about their phone interview time, the study information sheet, and three documents for use during the interview: Definitions (of sedation levels), Scale A (PSSS), and Scale B (UMSS).

At the start of the interview, the interviewer will ask the participant if they received the email with the attachments and ask them to pull the email up as the materials will be referenced during the interview. The interviewer will send a new copy of the materials if the participant cannot locate them.

Participants will then be given a demographic survey, which will be read aloud to them over the phone and completed by the interviewer based on answers given by the participant.

After the demographics survey, the interviewer will begin the interview using the interview guide. The interview will consist of cognitive interviewing questions related to the survey instructions and the surveys' items and response options on 2 different clinician report pediatric sedation scales, the Pediatric Sedation State Scale and the University of Michigan Sedation Scale.

Example questions may include:

1. Which scales have you previously used to measure sedation levels in your pediatric patients?
    a. **[For any scale mentioned]**
        i. How long have you used the [name of referenced scale]?
        ii. What strengths do you think the [name of referenced scale] has?
        iii. What limitations do you think the [name of referenced scale] has?
2. How clear are the scale instructions?
3. Looking at the sedation level categories in this scale, how clearly do you think each level is defined?
    a. How distinct do you think each category's definition is from the others?
    b. Are there any terms or phrases that are unclear or might create confusion when scoring a child on these levels?
    c. Are they appropriate for pediatric patients in the following age ranges?
        i. <2 year
        ii. 2-6
        iii. 6-12
        iv. 12-18

At the conclusion of the interview, the interviewer will thank the participant for their time and send the participant the forms to complete for participant payment. Once forms are completed and returned, the interviewer will process an AP check request to have the participant paid.

6 Statistical Plan

6.1 Sample Size Determination

Cognitive interviewing seeks to assess the way in which questionnaire content is understood to ensure that what is expected to be measured is actually being measured. The type of logical and

structural problems that we wish to identify are relatively independent of sample size and approximately 5-15 interviews per round is a generally accepted guideline for cognitive interviews.[4] Multiple rounds may be needed if questions need to be revised and retested. Our sample minimum sample size will be 18 and the maximum will be 24. This will provide a more than adequate sample size. Additionally, the sample will include a minimum of 2 anesthesiologists, 2 critical care physicians, and 2 nurses to ensure we obtain responses from a variety of clinical care professionals.

6.2 Statistical Methods

Qualitative research does not incorporate standard statistical methodology, but rather uses qualitative analysis methodologies. In this study, at least two analysts will independently review transcripts and debriefing forms. During the initial transcript reviews, transcripts will be double coded (the same transcript independently coded by two analysts) and coding results compared. This will continue until an inter-coder reliability of at least 90% is reached on double coded transcripts. After inter-coder reliability is reached, transcripts will be coded individually by only one analyst with the exception of every 6th transcript, which will be double coded to ensure the continuation of inter-coder reliability. Once review and coding is complete, we will create an item-tracking matrix to document changes to the measure, as well as reasons for those changes. A summary report will be compiled with our analysis, detailing our process and our findings from the cognitive interviews.

6.3 Subject Population(s) for Analysis

All participants enrolled into the study who complete phone interviews will be included in the study analysis.

7 Data Handling and Record Keeping

7.1 Confidentiality

Information about study subjects will be kept confidential and managed according to Good Clinical Practice (GCP) guidelines. All paper based data will be stored in a locked filing cabinet in the locked file room of the Population Health Sciences Department. All electronic data will be stored on the secure network server of the Department of Population Health sciences where study space accessible to only IRB approved study personnel will have access to the study space. Identifiable information such as names, phone numbers and email addresses will only be recorded for the purposes of scheduling and tracking enrollment/refusals and will be destroyed once enrollment is complete. Audio recordings will be destroyed at the completion of data analysis.

This study does not collect protected health information (or health information of any kind).

7.2 Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda,

subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

7.3 Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

7.4 Records Retention

It is the investigator's responsibility to retain study essential documents for at least 3 years after the study is completed, in compliance with NIH policies. Essential documents include financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant. Individual participant data will be retained, at a minimum, through the completion of data analysis, but no longer than 3 years. Study results will be retained in participant's research record for at least six years after the study is completed. At that time the research information will be destroyed or information identifying participants will be removed from such study results at DUHS. No information from this study is entered into DUHS Medical Records.

8 Study Monitoring, Auditing, and Inspecting

8.1 Study Monitoring Plan

This study will be monitored via weekly data review meetings and quality control (QC) reviews of data files. Weekly data review meetings will include review of study operations including enrollment progress, recruitment issues, and review of data summaries from interviews completed in the previous week. Data summary reviews will include discussion of completeness of data, quality of data, and how effective the interview guides are at collecting the desired data. Weekly QC checks for the study will include checking that enrollment logs, participant identifiers for scheduling and for the do not re-contact" list, all audio recordings, and all transcripts are stored in the appropriate folder on the secure DPHS server. Consent will be obtained verbally, so no consent form review will occur. All encrypted audio recorders will be checked weekly to ensure no audio files are left on them after being moved to the DPHS secure folder for this study. Additionally, the first 3 interview transcripts obtained on the study and 10% of subsequent transcripts will be checked to ensure that interviewers are not deviating from

interview scope and are completing interviews as planned. The investigator and Research Program Leader will allocate adequate time for such monitoring activities.

The investigator will permit study-related monitoring, audits, and inspections by the EC/IRB, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

9 Ethical Considerations

Given the study design (qualitative interview) and the study topic (content validity and comprehension of questionnaire items), we believe this study may qualify for Exempt Research status under 45 CFR 46.104(d)(2)(ii). This is because the research involves only the use of standard interview procedures. In addition, no personal health information will be collected, and the audio-recordings will be destroyed after publication of the interview findings. In the unlikely event of interviewees' responses being disclosed in identifiable form, we do not believe they would reasonably be placed at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted independent Ethics Committee (EC) or Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the EC/IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The investigator should provide a list of EC/IRB members and their affiliate to the sponsor.

Per the waiver of documentation of informed consent obtained by this study, all subjects for this study will be provided a Study Information Sheet and allowed to ask questions about the study prior to agreeing to participate in the study. Agreement to participate in the study will constitute consent. The Study Information Sheet will be submitted with the protocol for review and approval by the EC/IRB for the study.

10 Study Finances

10.1 Funding Source

This study is funded by a grant from the National Institutes of Health, NICHD, awarded to the Pediatric Trials Network.

10.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. .

10.3 Subject Stipends or Payments

Participants will be paid $100 for participating in the study.

11 Publication Plan

The Duke Center for Health Measurement (CHM) acknowledges that this study is funded by the Pediatric Trials Network (PTN) and that any publication resulting from this study must undergo review by a PTN publication committee.

The study team in CHM shall submit all proposed publications, abstracts and oral presentations to the Publication Committee for review and comment at least thirty (30) days prior to submission for publications, seven (7) days for abstracts, and thirty (30) days for oral presentations, and shall consider in good faith all comments provided by the Publication Committee during that review period. Should this review determine that the manuscript contains patentable matter requiring protection, the Duke CHM team shall delay publication for a period of not longer than an additional sixty (60) days to allow such protection to be sought.

Publications and Publicity shall be governed by the requirements set forth in HHSAR Clause 352.227-70 of Exhibit A.. In addition, all publications shall comply with the NIH Public Access Policy (http://publicaccess.nih.gov/) and acknowledge NIH support whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows: "This project has been funded in whole or in part with Federal funds from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN275201000003I."

Where registration is required for publication of the results in International Committee of Medical Journal Editors ("ICMJE") journals, or if otherwise required to be registered by law or regulation, DUKE shall insure that the STUDY is registered with either www.clinicaltrials.gov, or another registry meeting the requirements of the International Committee of Medical Journal Editors ("ICMJE") in effect at the time the STUDY is initiated.

12 References

1. Mahmoud M, Mason KP. A forecast of relevant pediatric sedation trends. *Current opinion in anaesthesiology.* 2016;29 Suppl 1:S56-67.
2. Sachs AN, Avant D, Lee CS, Rodriguez W, Murphy MD. Pediatric information in drug product labeling. *Jama.* 2012;307(18):1914-1915.
3. Wang LA, Cohen-Wolkowiez M, Gonzalez D. Advances in Pediatric Pharmacology, Therapeutics, and Toxicology. *Advances in pediatrics.* 2016;63(1):227-254.
4. Willis GB. *Cognitive Interviewing: A Tool for Improving Questionnaire Design.* Thousand Oaks, California: Sage Publications; 2005.

13 Attachments

Attached Documents:

- Appendix A – Study Information Sheet
- Appendix B – Recruitment Email
- Appendix C – Recruitment Flyer
- Appendix D – Phone Script
- Appendix E – Definitions
- Appendix F – Scale A (PSSS)
- Appendix G – Scale B (UMSS)
- Appendix H – Demographics Form
- Appendix I – Interview Guide – PSSS First
- Appendix J – Interview Guide – UMSS First

14 Appendix A – Study Information Sheet (SIS)

Duke University
School of Medicine

INFORMATION SHEET

PEDIATRIC SEDATION STUDY

Principal investigator: Bryce Reeve, PhD
Co-investigator: Christina Zigler, PhD

This form describes a research study that is being conducted at Duke University by Drs. Bryce Reeve and Christina Zigler, Department of Population Health Sciences.

The purpose of this study is to assess the content validity and physician understanding of the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS) via cognitive interviewing. We are interested in assessing physicians' comprehension of items and response options, as well as their evaluation of the relevance of these clinician reported pediatric sedation scales.

The interview will assess the clarity / comprehension of response options for each scale and evaluate the ability of the scale to validly capture different sedation levels. Participants will be compensated for their time.

You are being asked to take part in this research study because you are a practicing clinician in a clinical care environment who cares for pediatric patients over fifty percent of your time and treats or works with pediatric patients who are sedated/anesthetized for diagnostic and/or therapeutic procedures.

If you decide to participate in this study, your agreement to participate in this study will serve as your consent. Study staff will first contact you via email or phone to schedule your phone interview time and send you study related information. Then, a member of our research group will conduct a phone based cognitive interview with you that will last approximately 1 hour. During the interview, the research group member will ask you questions to assess your comprehension of questionnaire items and response options on the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS), as well as your evaluation of the relevance of the scales to capture sedation levels. These questions are to assess the quality of the sedation scales. Interviews will be audio recorded.

This is a minimal risk study with little perceived risk. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may stop your participation at any time.

There is little chance you will benefit directly from your participation in this study. We hope that the information learned from this study will allow clinicians to use a validated clinician reported outcome measure of sedation to be used in clinical care and research.

Duke University
School of Medicine

All of the information we collect, as well as the audio recordings of the phone interview, will be stored on a secure server and only study team members will have access to it. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Results of the research may be presented at meetings or publications, but your name will not be used.

This study is funded by a grant from the National Institutes of Health, NICHD, awarded to the Pediatric Trials Network.

You will be compensated $100 for your participation in this study. In order to receive the $100, you will need to provide your social security number. You may choose not to provide your social security number and still participate in the study, but you will not receive the $100 compensation for your time. There will be no cost to you to participate in this study.

Your participation in this study is completely voluntary. You can choose not to participate or withdraw at any time, for any reason. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled.

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, you can contact Dr. Bryce Reeve (Primary Investigator) or Courtney Mann (Research Program Leader) at 919-613-7857 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

FOR MORE INFORMATION, PLEASE CONTACT

Alexy Hernandez
alexy.hernandez@duke.edu
(919) 668-6864

15 Appendix B – Recruitment Email

Dear [Clinician],

We wanted to let you know about an upcoming opportunity to participate in research focused on validating clinician reported outcome measures.

We are looking for practicing clinicians who regularly treat pediatric patients to participate in a 1 hour phone interview. The goal of the interview is to assess the validity of two measures of pediatric sedation: the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS).

You may be eligible for this research study if you:

- Are a practicing clinician in a clinical care environment.
- Care for pediatric patients > 50% of your time.
- Treat or work with pediatric patients who are sedated / anesthetized for diagnostic and / or therapeutic procedures.
- Hold one of the following titles / specialties:
  - ☐ Anesthesiologist
  - ☐ Pediatric critical care physician
  - ☐ Clinical pharmacist (PharmD)
  - ☐ Nurse anesthetist
  - ☐ Nurse Practitioner
  - ☐ Physician Assistant or
  - ☐ Nurse (with a BSN/RN or higher)
- Are over the age of 18 years.
- Can speak English.
- Are capable of giving informed verbal consent.
- Have access to a telephone.

The interview will assess the response options for each scale and evaluate the ability of the scale to validly capture different sedation levels. Participants will be compensated for their time.

For more information, please contact Alexy Hernandez at (919) 668-6864 or alexy.hernandez@duke.edu.

Thank you,

[Name/Signature from PTN staff]

Department of Population Health Sciences
Duke University School of Medicine

16 Appendix C – Recruitment Flyer

Pediatric Sedation

We are looking for practicing clinicians who regularly treat pediatric patients to participate in a one hour phone interview. The goal of the interview is to assess the validity of two measures of pediatric sedation: the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS).

You may be eligible for this research study if you:

- Are a practicing clinician in a clinical care environment.
- Care for pediatric patients > 50% of your time.
- Treat or work with pediatric patients who are sedated / anesthetized for diagnostic and / or therapeutic procedures.
- Hold one of the following titles / specialties:
  - ☐ Anesthesiologist
  - ☐ Pediatric critical care physician
  - ☐ Clinical pharmacist (PharmD)
  - ☐ Nurse anesthetist
  - ☐ Nurse Practitioner
  - ☐ Physician Assistant or
  - ☐ Nurse (with a BSN/RN or higher)
- Are over the age of 18 years.
- Can speak English.
- Are capable of giving informed verbal consent.
- Have access to a telephone.

The interview will assess the response options for each scale and evaluate the ability of the scale to validly capture different sedation levels. Participants will be compensated for their time.

For more information, please contact:

Alexy Hernandez
(919) 668-6864
alexy.hernandez@duke.edu

DukeHealth

Version Date: 2019_03_28 Pro00102030

17 Appendix D – Phone Script

Pediatric Sedation Study Phone Script

Voicemail:
"Hi, my name is [study staff name]. You were previously sent an email about a research study at Duke University regarding the validity of clinician reported outcome measures of pediatric sedation levels and I'd love to tell you more about the study. If you are interesting in learning more, give me a call back when you have 15-20 minutes and we can talk about it more. My phone number is [study staff phone number]. Thanks, and have a great day!"

Answer:
Hi, is this [clinician/nurse name]?

My name is [study staff name]. Our study team sent you an email about a research study at Duke University called the Validation of Clinician Reported Outcome Measures of Pediatric Sedation. I'd like to tell you more about the study if you're interested in learning more. Do you have 15-20 min to talk?

[If yes, continue with script. If no, schedule a time to speak with the participant. If they don't want to know more, thank them for their time and say goodbye. Record their name on the opt out list for no future contact.]

Great. I first want to tell you a little bit more about the study. Feel free to ask me any questions at any time. The study is called the Validation of Clinician Reported Outcome Measures of Pediatric Sedation or Pediatric Sedation Study for short. What we are looking to do in this study is to assess the content validity and physician understanding of the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS). We are interested in assessing physicians' comprehension of items and response options on both of these clinician reported pediatric sedation scales, and assessing physicians' evaluation of the relevance of each scale to capture sedation levels. Our goal is to use the information from these interviews to provide evidence for the content validity of existing physician-reported measures of sedation levels in children to inform the use of the measure in studies that are part of the PTN.

Do you have any questions so far?

[If yes, answer questions. If no, continue with script.]

If you decide to participate in this study, you will participate in a 1 hour phone interview. During this time, you will be able to ask any additional questions you have about the study before getting started. You will then be asked a series of questions about the Pediatric Sedation State Scale (PSSS) and the University of Michigan Sedation Scale (UMSS).

The interview will assess the response options for each scale and evaluate the ability of the scale to validly capture different sedation levels. Participants will be given $100 as compensation for their time.

I know that was a lot of information. Do you have any questions at this point?

[If yes, answer questions. If no, continue with script.]

Does this sound like something you might be interested in participating in?

[If no, thank for their time and say goodbye. If yes, continue with script.]

Okay, then we'll just need to verify your eligibility for the study.

To do this, we'll need to ask you about your clinical background. Answering these questions is completely voluntary. If you choose not to answer them, you will not be eligible to participate in this study.

Because this will be an exempt study, there will be a waiver of documentation of informed consent. Therefore, if you qualify for the study and agree to participate, your agreement to participate will be your consent to participate, and you will not sign a physical consent form. You will be sent a study information sheet that will include information about the study, risks, benefits, and confidentiality before the phone interview and you will be able to ask any questions before or at the beginning of the phone interview. The personal information you give me today will become part of our research records and will be reviewed by Dr. Reeve and the research staff. Your name will be kept on a separate file on a secure server and will not be attached to the eligibility information. If you do not qualify for this study, or you choose not to participate, no information you give us today, except your name, will be kept. Your name will be kept through the end of recruitment for the study for people who are ineligible or do not wish to participate in the study. It will be deleted from our files once recruitment is over.

Would you like to continue with the screening questions?

[If no, thank them for their time and say goodbye. If yes, continue with script.]

Question	**Eligibility Requirement**
1. "Are you a practicing clinician in a clinical care environment?"	Yes
2. "Do you care for pediatric patients >50% of your time?"	Yes
3. "Do you treat or work with pediatric patients who are sedated/anesthetized for diagnostic and/or therapeutic procedures?	Yes
4. Do you hold on of the following titles/positions? a. Anesthesiologist b. Pediatric critical care physician c. Clinical pharmacist (PharmD) d. Nurse anesthetist e. Nurse practitioner f. Physician assistant g. Nurse (with a BSN/RN or higher)	Yes
5. How old are you?	18 or older
6. Can you speak English?	Yes
7. Do you give verbal consent to participate in the study?	Yes

If not eligible: Unfortunately, you do not meet the criteria for our study, but we do appreciate your interest and time. Thank you.

If eligible: You are eligible for participation in this study.

If you are still interested in participating, do you have time now to schedule the interview?

[If no, ask when would be a good time. If yes, continue with script. If they would like to go ahead and do the interview at that moment, continue with the interview guide.]

We generally schedule interviews between 8am-6pm during weekdays, but if you need something outside of that, we will be more than happy to work something out with you. What date(s) and time(s) are you available to participate in this hour interview?

Great, so I have you down for **[say date and time].** You may have previously received a copy of our study information sheet, but I would like to send you another copy to review between now and the interview in case you have trouble locating the one from our previous email. You can contact me if you have any questions about it or you can ask them the day of the interview. Again, your agreement to participate in this study is your consent.

[If participant agrees, get email address to send study information sheet. Send as soon as the call ends.]

Do you still have my contact information from the email you received?

[If no, provide contact information. If yes, continue with script.]

Do you have any other questions I can help you with today?

[If yes, answer questions. If no, continue with script below.]

Thank you so much for your time today. Remember, I will be sending you a study information sheet. If you have any questions after reviewing the study information sheet, please feel free to ask. You have my phone number and my email address.

And just to confirm, I have you scheduled for **[say date and time].**

Great! Thank you again, and have a nice day!

18 Appendix E – Definitions

Sedation Definition:

Sedation is a state of drug induced depression of consciousness.

The American Academy of Pediatrics (AAP) guidance[1] states

"The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are as follows:

1) To guard the patient's safety and welfare;
2) To minimize physical discomfort and pain;
3) To control anxiety, minimize psychological trauma, and maximize the potential for amnesia;
4) To modify behavior and/or movement so as to allow the safe completion of the procedure, and;
5) To return the patient to a state in which discharge from medical/dental supervision is safe."

-p. 64. AAP.

Sedation Level Concepts:

1) Minimal sedation (anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
2) Moderate Sedation/Analgesia (conscious sedation) is a drug-induced depression of consciousness during which patients respond purposefully[1] to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
3) Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully[1] following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
4) General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

19 Appendix F – Scale A

Pediatric Sedation State Scale (PSSS)

	RATER	Definition?
0	Deeply asleep with ABNORMAL physiological parameters (oxygen desaturation/hypotension/tachy or bradycardia (more than 30% off from baseline))	0: Sedation associated with abnormal physiologic parameters that require acute intervention (ie, oxygen saturation <90%, blood pressure is 30% lower than baseline, bradycardia receiving therapy).
1	Deeply asleep with normal vital signs – REQUIRES some airway intervention to maintain breathing (chin lift, nasal/oral airway, mask vent, etc.) Physiological parameter are NORMAL	1: Deeply asleep with normal vital signs, but requiring airway intervention and/or assistance (eg, central or obstructive apnea, etc).
2	Patient is quiet (awake or asleep) and not moving, no frown, no verbalization, no crying	2: Quiet (asleep or awake), not moving during procedure, and no frown (or brow furrow) indicating pain or anxiety. No verbalization of any complaint.
3	Patient has an expression of discomfort on the faces or is crying/verbalizing discomfort but NOT moving or impeding the completion of the procedure. May require positioning, but NO restraining to stop movement. May be awake or asleep	3: Expression of pain or anxiety on face (may verbalize discomfort), but not moving or impeding completion of the procedure. May require help positioning (as with a lumbar puncture) but does not require restraint to stop movement during the procedure.
4	Patient is moving during the procedure and requires gentle immobilization or positioning. May appear uncomfortable, verbalize discomfort, or may be crying but this is not a requirement.	4: Moving during the procedure (awake or sedated) that requires gentle immobilization for positioning. May verbalize some discomfort or stress, but there is no crying or shouting that expresses stress or objection.
5	Patient is moving (purposefully or non-purposefully) in a manner that impedes the proceduralist and requires forceful immobilization. Patient may be sedated or awake. Patient may be crying or shouting (not required however).	5: Patient is moving (purposefully or nonpurposefully) in a manner that impedes the proceduralist and requires forceful immobilization. This includes crying or shouting during the procedure, but vocalization is not required. Score is based on movement.

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20 Appendix G – Scale B

University of Michigan Sedation Scale (UMSS)

Prior to scoring, assess the child's response to voice, light stimulation, such as stroking the face, and deeper physical stimulation, such as massaging the upper back or tickling the chest or axilla.

0	Awake and alert
1	Minimally sedated: tired/sleepy, appropriate response to verbal conversation and/or sound
2	Moderately sedated: somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command
3	Deeply sedated: deep sleep, arousable only with significant physical stimulation
4	Unarousable

21 Appendix H – Demographics

Pediatric Anesthesia Study

Protocol Number: _____ Patient Study ID: _____ Date: _____
(MM/DD/YYYY)

SOCIODEMOGRAPHIC FORM – CLINICIAN

Please answer the following questions. Complete the blanks or check the boxes next to the category that best describes your situation.

1. What is your age? _____

2. What is your gender: ☐1 Male ☐2 Female
☐3 Self-identify:_____ ☐4 Prefer not to say

3. Are you of Spanish/Hispanic/Latino origin? ☐1 No ☐2 Yes

4. What is your race? *(Please check all that apply)*
☐1 White
☐2 African-American or Black
☐3 American Indian/Alaska Native
☐4 Asian
☐5 Middle Eastern
☐6 Native Hawaiian/Other Pacific Islander
☐7 Other _____

5. What is your state of residence: _____

6. What are your current professional credentials? *(Please check all that apply)*

☐1 MD ☐2 OD ☐3 PharmD
☐4 BSN ☐5 MSN ☐6 PhD/DNP

7. What is your medical specialty:_____

8. How many years and months that you have worked in this specialty (including fellowship years):

Years / Months: _____/_____

9. In an average week, how many hours per week do you spend treating / observing anesthetized or sedated pediatric patients?

Hours: _____

Version Date 03/21/2019

22 Appendix I– Interview Guide – PSSS First

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

Participant ID: _____ Randomization Group: ☐ PSSS 1st ☐ UMSS 1st

Clinical Outcomes Assessments of Pediatric Sedation

Cognitive Interview Guide

Introduction

Thank you for taking the time to talk with me today. As we talk, I'm going to ask you questions about two Clinician Reported Outcome scales used to assess sedation level in pediatric populations from birth up to 18 years of age. The questions we ask during this interview will help us to assess the clarity / comprehension of response options for each scale and evaluate the ability of the scale to validly capture different sedation levels. We are particularly interested in how the scales perform for assessing sedation levels related to diagnostic and therapeutic procedures.

I'm here to learn from you during this interview. There are no right or wrong answers and everything you say in this interview will be kept confidential. Our discussion will last about an hour and your participation in this interview is completely voluntary. If at any time you need to stop the interview, just let me know. As a busy clinician, we know that things may come up, so if we do need to end the interview early, but you wish to reschedule to complete the interview in the next 2 weeks, let me know that as well.

Before we get started, I just need to verify that you received our reminder email yesterday and that you have a copy of the materials needed for the interview today. You should have 4 attachments. We will use three of them in the interview: the definitions file, the Scale A file, and the Scale B file. Do you have these materials or should I send you a new copy now? [Send files if needed.]

☐ **[If previously agreed to audio recording]**

Lastly, as we discussed earlier, I will be audio recording our conversation. I just want to check in and confirm that audio recording the interview is still fine with you.

☐ Yes

Great. I'll start the recorder now.

☐ No

Okay. Instead of audio recording, I'll take detailed notes. I will be writing a lot and may need to pause between questions, but I want you to know that I am listening to you even when I am writing. Let's get started.

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Lastly, as we discussed earlier, I will not be audio recording our conversation. However, I will be taking detailed notes of our conversation. I will be writing a lot and may need to pause between questions, but I want you to know that I am listening to you even when I am writing. Let's Get Started.

Version Date: 2019_03_21
Interviewer Name: _____

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

Participant ID: _____ Randomization Group: ☐ PSSS 1st ☐ UMSS 1st

Interview Start Time: _____

Questions:

Sedation Level Definitions

To start, let's pull up the Definitions document that I sent you with your interview reminder email yesterday. I'll give you a few moments to review them and then we will discuss them.

1. Let's start with the definition for sedation. What are your general thoughts about the provided definition for sedation level?
    a. Do you agree or disagree with definition?
    b. Would you add or remove anything?
    c. Applicable from birth to 18 years?
2. Now let's move to Sedation Level Definitions in this document. What are your general impressions of these levels for sedation with regard to how well they define progressive sedation levels? [concept levels]
    a. If there things about these definitions you would change, what would you change?
    b. Applicable from birth to 18 years?

Prior Use

3. Which scales have you previously used to measure sedation levels in your pediatric patients?
    a. **[For any scale mentioned]**
        i. How long have you used the [name of referenced scale]?
        ii. What strengths do you think the [name of referenced scale] has?
        iii. What limitations do you think the [name of referenced scale] has?

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

Participant ID: _____ Randomization Group: ☐ PSSS 1st ☐ UMSS 1st

Scale Specific Questions – PSSS

Great! Now let's move on to out specific scales we are considering in this study. I am going to have you pull up the [first scale for randomization group] now. After you've had a couple of minutes to read through it, we'll go through some questions regarding that scale.

4. There are no instructions for this scale. How do you think the scale should be completed?
5. Looking at the sedation level categories in this scale, how clearly do you think each level is defined?
    a. How distinct do you think each category's definition is from the others?
    b. Are there any terms or phrases that are unclear or might create confusion when scoring a child on these levels?
    c. What information / patient interaction do you need to assess each level of sedation on this scale.
        i. What actions would you take to obtain this information?
            1. Not moving vs. Moving vs. movement that requires immobilization
                a. gentle vs forceful
            2. Discomfort
                a. Facial expression / frowning
                b. Verbalization/crying vs. no verbalization or crying
            3. Quiet / Asleep / Deeply asleep
            4. Vital signs and physiological parameters (oxygen saturation, blood pressure, bradycardia)
                a. Normal vs. Not Normal
            5. Requires airway intervention
    d. Are they appropriate for pediatric patients in the following age ranges?
        i. <2 year
        ii. 2-6
        iii. 6-12
        iv. 12-18

6. Are each of these levels easily distinguishable based on your clinical experience observing patients?
    e. How would your clinical decisions or actions change at each of the sedation levels on this scale? **[ensure they speak about all levels]**
    f. Have you observed patients who fit some criteria for one sedation level on this scale and some criteria for another sedation level?
        i. Which sedation level would you assign the child in this scenario / when they fit into multiple levels?
        ii. What factors do you consider when making this decision?
        iii. How can the scale be modified to minimize this problem? [To level description or instructions]
            1. Would you add any instructions to the scale?

Scale Specific Questions – UMSS

Great! Now let's move on to out specific scales we are considering in this study. I am going to have you pull up the [first scale for randomization group] now. After you've had a couple of minutes to read through it, we'll go through some questions regarding that scale.

7. UMSS: How clear are the scale instructions?
        i. How helpful are the instructions?
8. Looking at the sedation level categories in this scale, how clearly do you think each level is defined?
    b. How distinct do you think each category's definition is from the others?
    c. Are there any terms or phrases that are unclear or might create confusion when scoring a child on these levels?
    d. What information / patient interaction do you need to assess each level of sedation on this scale.
        i. What actions would you take to obtain this information?
            1. Awake/Alert vs. tired/sleepy vs. somnolent/sleeping vs. deep sleep
            2. Appropriate response to verbal conversation or sound

3. Easily aroused with light tactile stimulation or a simple verbal command
4. Arousable only with significant physical stimulation.
5. Unarousable

e. Are they appropriate for pediatric patients in the following age ranges?
   i. <2 year
   ii. 2-6
   iii. 6-12
   iv. 12-18
      2. Are each of these levels easily distinguishable based on your clinical experience observing patients?

f. How would your clinical decisions or actions change at each of the sedation levels on this scale? **[ensure they speak about all levels]**

g. Have you observed patients who fit some criteria for one sedation level on this scale and some criteria for another sedation level?
   i. Which sedation level would you assign the child in this scenario / when they fit into multiple levels?
   ii. What factors do you consider when making this decision?
   iii. How can the scale be modified to minimize this problem? [To level description or instructions]
      1. Would you add any instructions to the scale?

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

Participant ID: _____ Randomization Group: ☐ PSSS 1st ☐ UMSS 1st

Head to head comparison of PSSS and UMSS

Now I would like us to consider both the PSSS and the UMSS scales. I'm going to ask you some questions regarding their similarities and differences as well as your preferences.

9. What strengths do you think each of the scales has?
    a. [Probe on both scales.]
10. What limitations do you think each of the scales has?
    b. [Probe on both scales.]
    c. Does one scale have more ambiguity that might lead to difficulty scoring a child's sedation level?
11. Which of these scales do you think aligns better with the Sedation Level Definitions from the definitions file that we discussed earlier?
12. The PSSS has more categories than the UMSS.
    d. What do you see as the major differences between the ways these categories are differentiated in each of the scales?
        i. How important is it to measure levels of sedation with regard to patient safety?
    e. The PSSS has more categories for deeper sedation levels to assess not only efficacy of the sedation treatment but also safety with regard to sedation level. The UMSS only includes sedation levels with regard to efficacy. How important is it to measure levels of sedation with regard to patient safety?
13. Which of the two scales do you prefer?
    f. What is it about this scale that you like more than the other?
    g. Is this preference true for each of the following age groups?
        i. <2 year
        ii. 2-6
        iii. 6-12
        iv. 12-18

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

Participant ID: _____ Randomization Group: ☐ PSSS 1st ☐ UMSS 1st

Mapping

For our last topic, I want to talk with you about how well the sedation categories on each of these scales coincides with our defined sedation levels and with each other.

14. Let's go through each level on the PSSS and map them to the Sedation Level Definitions we discussed earlier. You will need the Scale A and Definitions File for this activity. The PSSS is reverse scored as compared to the UMSS, so make sure you are referring to the correct scale as we talk through the levels. For level 1 on the PSSS, which level definition does that coincide with? **[Continue through each level on the scale.]**

Minimal sedation	5
Moderate Sedation/Analgesia	4 3
Deep Sedation/Analgesia	2
General anesthesia	1 0

15. Let's go through each level on the UMSS and map them to the sedation level definitions we discussed earlier. You will need the Scale B and Definitions File for this activity. Remember to check the scale and make sure you are looking at the UMSS as we begin. For level 1 on the UMSS, which level definition does that coincide with? **[Continue through each level on the scale.]**

Minimal sedation	0
Moderate Sedation/Analgesia	1 2
Deep Sedation/Analgesia	3
General anesthesia	4

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

Participant ID: _____ Randomization Group: ☐ PSSS 1st ☐ UMSS 1st

16. Now, we're going to do the same sort of mapping between the PSSS and the UMSS. Let's pull up the Scale A and Scale B files and talk through how each sedation level on the PSSS maps to a sedation level on the UMSS. Remember that these are reverse scored compared to one another as we work through this activity.

PSSS	UMSS
5 (Awake)	0 (Awake)
4	1
3	2
2	3
1	4
0	

17. That concludes the questions that we have for you today. Is there anything else you would like to tell us about the PSSS, the UMSS, or other sedation scales that you think it important?

Thank you so much for your time.

Interview End Time: _____

Version Date: 2019_03_21
Interviewer Name: _____

23 Appendix I– Interview Guide – UMSS First

Protocol No.: Pro00102030 Protocol Name: Pediatric Sedation Study Date: _____

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Clinical Outcomes Assessments of Pediatric Sedation

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            2. Appropriate response to verbal conversation or sound
            3. Easily aroused with light tactile stimulation or a simple verbal command
            4. Arousable only with significant physical stimulation.
            5. Unarousable
    e. Are they appropriate for pediatric patients in the following age ranges?
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        ii. 2-6
        iii. 6-12
        iv. 12-18
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Minimal sedation	5
Moderate Sedation/Analgesia	4 3
Deep Sedation/Analgesia	2
General anesthesia	1 0

15. Let's go through each level on the UMSS and map them to the sedation level definitions we discussed earlier. You will need the Scale B and Definitions File for this activity. Remember to check the scale and make sure you are looking at the UMSS as we begin. For level 1 on the UMSS, which level definition does that coincide with? **[Continue through each level on the scale.]**

Minimal sedation	0
Moderate Sedation/Analgesia	1 2
Deep Sedation/Analgesia	3
General anesthesia	4

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Interviewer Name: _____

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PSSS	UMSS
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2	3
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0	

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