ISCTM SIB Consensus Statements for the Instrumentation & Special Populations Working Group

Description/Overview: This workgroup focused on the following areas of importance to the selection and utilization of instruments assessing SIB: Basic Education for SIB raters, SIB instrument selection, Rater training for scales administration, and Special Populations. We developed 31 statements during the face-to-face meeting that reflected the consensus of the large working group and brought 6 statements forward for a vote in the joint workgroup meeting. Items voted on by the large combined group were considered to be those most likely to have a diversity of opinion. The workgroup agreed not to focus on any one instrument as the field will likely continue to progress and new instruments may be developed.

Statements Voted on at F2F Meeting on Nov 18

Statement	Total n	Yes n	Yes %	No n	No %	NK* n	NK* %
1. When selecting an instrument and method of administration for a study, one should consider the research settings (e.g., academic, hospital, CRU), study teams (e.g., psychiatric vs. non-psychiatric, level of experience) and patient populations (e.g., youth, elderly, cognitively impaired, acutely ill).	79	74	93.67	3	3.8	2	2.53
2. Evidence of validity must be provided for formal use of an instrument in clinical trials. Reliability and validity of an SIB instrument must be demonstrated for the population to be studied, taking into account vulnerable populations and cultural relevance. (This does not apply to experimental measures, which may be included alongside established measures.)	83	64	77.11	15	18.07	4	4.82
3. When assessing outcome for treatment of SIB, two or more perspectives for assessing SIB can provide more comprehensive and clinically meaningful information than a single instrument. Perspectives may include different methods of assessment, instruments and/or sources of information.	83	59	71.08	19	22.89	5	6.02
4. One perspective may be sufficient for determining eligibility to participate in a clinical trial.	74	69	93.24	5	6.76	-	-

5. One perspective may be sufficient for determining treatment emergent events	80	61	76.25	11	13.75	8	10.00
6. Assessment tools for suicidal ideation and behavior must be translated taking cultural factors into account and ideally have demonstrated reliability and validity for use within the selected population.	73	66	90.41	7	9.59	-	-

*Not Knowledgeable enough

Statements Not Voted On by Entire Group

Basic Education for SIB Raters

7. General training about suicidal ideation and behavior, assessment and contributors to suicide risk must be broad-based and ongoing.
8. Training should include information about the specific population being studied and the scales being used with attention to vulnerable populations.
9. Training regarding safety procedures is important.

SIB Instrument Selection

10. The 4 broad categories of clinical trials research employing SIB instruments are: Description of clinical and demographic characteristics, Measurement of treatment outcomes, Identification of treatment-emergent SIB, and Assessment of risk for suicidal behavior.
11. One instrument may not be adequate to cover all 4 categories of use in clinical trials (Description of clinical and demographic characteristics, Outcomes, Treatment-emergent SIB, Risk for Suicidal Behavior). The choice of instruments for clinical trials will be based on focus of the research.
12. When choosing an instrument, risks and benefits for the participant must be considered.
13. The instrument must have reliability and validity for the time frame of interest.
14. Different methods of SIB assessment are available including face to face or remote clinician interview, participant self-reports by pen/pencil or other devices, prompted computer-based interviews and behavioral assessments. The rationale for the choice of method(s) used needs to include strengths and limitations as well as feasibility of administration.
15. Different sources of information include medical records, clinician interview and participant or informant. The source of information needs to be considered when selecting an instrument.
16. The instrument must have reproducibility as demonstrated by relevant measure(s) of reliability (e.g., inter-rater, test-retest and/or alternate forms).
17. Internal consistency alone is not sufficient as an assessment of reliability.
18. Evidence of content validity should be provided by quantitative and qualitative research that demonstrates the concepts and domains assessed.

19. Given the low occurrence of suicide attempts and suicide it is understood that predictive validity will be hard to demonstrate. When suggested by data, both sensitivity and specificity must be reported since one without the other is meaningless. Sample base rates must also be presented.
20. When used longitudinally, instruments must demonstrate the ability to detect change.
21. Standardized instruments require manuals with specific instructions about administration, scoring and interpretation as well as provision of evidence of reliability and validity.
22. It is desirable that an SIB instrument have established norms for the population being studied.

Training and Administration

23. Interviewers need to be trained to adhere to each scale's definition of key variables, such as suicidal behavior.
24. Initial training, monitoring and regular follow-up training of interviewers is recommended to maintain reliability and prevent drift.
25. Training should focus on specific definitions of key terms, such as suicide attempt, and non-suicidal self-injurious behavior.
26. Identification of acute risk and safety procedures must be specified and included in training for in-person and remote assessments.
27. Informants' knowledge of the participant's state of mind must be taken into account when evaluating the validity of the informant's report.
28. Informed consent and assent and documentation issues are very important and adaptations for vulnerable populations might be necessary.
29. Information should be available about the minimum level of education required for each SIB scale so that researchers can determine if the scale is applicable to the population of interest.

Special Populations

30. Studies with special populations need raters trained in the communication techniques consistent with the mode of communication used by the participant and their caregiver.
31. Each population needs an environment that is conducive to comfortable and effective communication.