

Terms of Reference

Feasibility Testing and validation of the Flexible Interview for ICD-11 (FLII-11) Adult Epi version for the Mental Health Survey in Sri Lanka

1. Background and context

Mental health is a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well, work well, and contribute to their community. Mental health conditions include mental disorders and psychosocial disabilities as well as other mental states associated with significant distress, impairment in functioning, or risk of self-harm (1).

The burden of mental health conditions, which is a portrayal of the tip of the iceberg is increasing. The gap between prevalence and treatment remains unacceptably large globally as well as locally, where the WHO estimates show that only 29% of people with psychosis receive mental health services (2). Globally, the prevalence of mental health disorders is estimated to be 13.0%; 970 million people, 82% of whom are in Lower Middle-Income Countries suffer from mental health conditions. Among both males and females, anxiety disorders and depressive disorders are the two most common mental disorders (2). According to recent data, in general, people with mental illnesses are increasing in Sri Lanka in par with the global situation. Mainly, mood disorders have become a critical issue in the Sri Lankan context, particularly in the past decade. Further, persons with mental and behavioural disorders due to the use of alcohol and other psychoactive substances and neurotic, stress-related somatoform disorders have also increased (3).

Though there is an existing information system for data collection in Sri Lanka through which outpatient and inpatient data, as well as outreach clinic data, are collected, the availability of updated information and lack of data on the prevalence of mental and neurological disorders has long been recognized as a deficiency.

Assessment of the true burden can address the mental health needs by taking the appropriate policy decisions to reduce suffering and improve the quality of life, social functioning, and life expectancy of people with mental health conditions in Sri Lanka. Hence, at this juncture, it is imperative to conduct a rapid assessment survey to assess the mental health burden in Sri Lanka during the available time duration as an initial step to obtain evidence to be used for the development of evidence-based policies on mental health interventions for Sri Lanka for the next national health plan 2026.

WHO is collaborating with several countries to conduct feasibility testing and validation of tools to conduct mental health assessments in the population. The Ministry of Health Sri Lanka has shown its interest to partner in this exercise, with a view to have validated tools developed for conducting mental health assessment in the country subsequently.

(1). [Mental health \(who.int\)](https://www.who.int/mentalhealth).

(2). World mental health report: transforming mental health for all. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/356119>).

(3). Ministry of Health (Sri Lanka). Sri Lanka Annual Health Bulletin 2020. Colombo, Sri Lanka.

WHO Sri Lanka wishes to seek support of a suitable national technical partner to conduct this feasibility assessment and validation study of the tools in Sri Lanka. The proposed assessments are being carried out in various countries, and the outcomes will inform the finalization of global applicable tools for mental health assessment. Additionally, the national feasibility assessment and validation will also help Sri Lanka have an adapted version of tools that could then be used to conduct an estimation of the mental health burden in Sri Lanka.

2. Purpose of the consultancy:

The purpose of this consultancy is to work with the WHO technical team, its technical partners, and the Mental Health Directorate of the Ministry of Health to devise methodology, conduct feasibility assessment (phase 1) as well as validity assessment (Phase 2) in a phase-wise manner. The phase 2 will additionally include a qualitative needs assessment exercise through interviews and focus group discussions (FGDs) to identify the unmet needs of mental health in Sri Lanka, assess treatment gaps, and challenges continuity of care for mental health conditions in Sri Lanka.

3. National and international collaborators:

- Directorate General of Non-Communicable Diseases (NCD) and the Directorate of Mental Health, Ministry of Health as the primary beneficiary of this project.
- World Health Organization as the main technical collaborating partner.
- WHO Collaborating Center at Columbia University as data management and analyses support.

4. Roles of national and international collaborators:

- The proposed work will be commissioned and coordinated by WHO Country Office Sri Lanka.
- The selected agency will be responsible to plan and implement the two phases of work in accordance with the terms of reference proposed below.
- Ethical clearance certificate will be obtained by the selected agency.
- Regional ethical clearance certificate will need to be obtained through the WHO Country office Sri Lanka.
- The office of the Deputy Director General (DDG) NCD, Ministry of Health will obtain administrative clearance to conduct the study.
- The DDG NCD, Ministry of Health will appoint a Technical Advisory Committee (TAC) and facilitate regular (monthly) meetings of the TAC.
- The proposed tools for feasibility testing component will be provided by WHO.
- The selected agency will need to communicate and work in close collaboration with WHO and the WHO Collaborating Center at Columbia University throughout the project period.

- WHO will provide the proposed draft tools (FLII 11 Adult Epi version) and Interview Experience Questionnaire, (IEQ)) to be used for the feasibility assessment and validation exercise.
- Phase 1 of the project should be followed by Phase 2. Phase 2 can only start if the previous phase 1 has been successfully completed and the results are delivered.

5. Proposed timelines

Phase 1- Six months

Start date: 01.05.2024

End date: 31.10.2024

Phase 2- Three months

Start date: 15.11.2024

End date: 15.02.2025

6. Work to be performed by selected agency:

Phase 1 (Feasibility testing exercise)

1. To translate the FLII 11 Adult Epi version for mental health diseases and the 'Interview Experience Questionnaire (IEQ) for Sri Lanka.
2. To conduct the feasibility testing (testing of FLII-11's feasibility, clinical utility and acceptability) component using the translated FLII 11 Adult Epi version and the Interview Experience Questionnaire (IEQ)
3. To provide a comprehensive report of the feasibility testing.

Phase 2 (Phase 2 consists of 2 components)

Component 1 (validation study)

1. To validate the 'FLII 11' Adult Epi version to adapt culturally and to identify the measures of diagnostic accuracy (Sensitivity, Specificity, Predictive values) and reliability
2. To provide the validation study report.

Component 2 (needs assessment)

3. To conduct a qualitative needs assessment for assessing the perceived needs, unmet needs, continuum of care, community-based care, gaps at facility level, community level and gaps in the continuum of care based on an appropriate methodology developed.
4. To provide a comprehensive report of the needs assessment exercise.

7. Methodological considerations:

Phase 1: Feasibility testing

- 1) Develop an appropriate methodology adjusted from the recommended general methodology for the feasibility testing (testing of FLII-11's feasibility, clinical utility and acceptability) component of the FLII 11 Adult Epi version.
 - a) General methodology developed for the Global Implementation Group will be shared with the selected agency and the methodology need to be developed aligned with this.
 - b) Recommended to conduct a minimum of 100 of adult interviews
 - c) Participants should be drawn from clinical settings as well as participants not identified as mental health service recipients
 - d) Participants not identified as mental health service recipients will include accompanying family members or friends and participants recruited directly from the community
- 2) Two types of tools require feasibility testing, FLII-11 interview and Interviewer Experience Questionnaire (IEQ) which will be at the end of the FLII-11. The latter consists of two parts the participant portion and the interviewer portion.
- 3) Develop interviewer guides for the data collectors in English language.
- 4) Translation of the tools in Sinhala and Tamil language
 - a) The forward-backward translation methodology to be utilized in the translation of the study instrument.
 - b) Forward translation (English to Sinhala and English to Tamil)
 - c) Backward translation (Sinhala to English and Tamil to English)
 - d) Translation should be done for the FLII 11 Adult Epi version as well for the feasibility testing Interviewer Experience Questionnaire (IEQ) with the supervision and reviews of Consultant Psychiatrists
- 5) Selection and training of data collectors using the developed interviewer guides
 - a) Data collectors need not be a mental health professional or clinician but should have some background in mental health as there are instances in which a decision may have to be made based on the interviewer's understanding of the concept being investigated.
 - b) Training should be conducted with the supervision of Consultant Psychiatrist with periodic reviews
- 6) Obtain the Ethical Clearance Certificate for conducting the two phases of the study (Ethical clearance need to be obtained for both phase 1 and phase 2 together)
- 7) Obtaining approval for the above from the Technical Advisory Committee (TAC)

- 8) Inclusion of the translated approved Sinhala and Tamil versions of FLII 11 Adult Epi version and the IEQ questionnaire to the provided software (Qualtrics platform) in both languages (in collaboration with the WHO collaborating Centre in Columbia hosting the software platform)
- 9) The team lead of the selected agency will need to coordinate with the Consultant to WHO HQ in close collaboration with WHO HQ, through the WHO Collaborating Center at Columbia throughout the complete study period. The initial coordination will be conducted via WCO SL
- 10) Conduct the data collection
 - a) The FLII-11 interviews are expected to take approximately 45 minutes per participant followed by the IEQ which has 15 questions for one participant.
 - b) Data collectors should collect data with informed written consent.
 - c) Data should be fed to the Qualtrics platform in Sinhala or Tamil language
 - d) Data collection can be conducted with any device with internet connection
 - e) Data will be stored in the programmed database owned by WHO HQ and raw data will be shared
- 11) Data analysis in collaboration with WHO HQ and WHO collaborating center team.
- 12) The report of the phase 1 should be submitted to the TAC and obtain approval prior to the conduction of phase 2.

Time frame – Six months

Specific area of work	Duration
Propose a study plan, methodologies and obtain approval from TAC	By 10 th of May 2024
Obtain Ethical clearance	By 30 th June 2024
Translation of questionnaires, development of interviewer guide, selection, and training of data collectors with the TAC approval	By 31 st of July
Conduct the feasibility testing component	By 30 th of September 2024
Submission of final technical report and statement of expenditure with original invoices related to phase 1 (Soft and hard copies)	By 31 st October 2024

Phase 2:

Component 1: Validation Study (to be considered upon completion of phase 1)

- 1) Develop an appropriate validation methodology to validate the 'FLII 11' Adult Epi version to adapt culturally and to identify the measures of diagnostic accuracy (Sensitivity, Specificity, Predictive values) and reliability in Colombo district. (Minimum of 100 cases and 100 controls should be taken as the sample size while, gold standard for the criterion validity study should be the diagnosis of consultant psychiatrist)
- 2) Implementation of the validation study as per the developed methodology in Colombo district. The translated 'FLII 11' Adult Epi version should be used in the Qualtrics electronic platform for collecting data similarly to the phase 1. Already trained data collectors recruited in phase 1 could be used for phase 2. The team lead of the selected agency will need to coordinate with the Consultant to WHO HQ in close collaboration with WHO HQ, through the WHO Collaborating Center at Columbia throughout the complete study period.
- 3) Data analysis of the validation component.

Component 2: Needs Assessment study (can be initiated in parallel with validation component)

- 4) An appropriate methodology (qualitative) and tools for the qualitative assessment should be developed to assess mental health perceived needs, unmet need, continuum of care, community-based care, gaps at facility level, community level and gaps in the continuum of care among the people with mental health disease and/or symptoms for the conduction of the qualitative needs assessment exercise.

Key questions to assess the unmet need, treatment gap, gaps at facility level and gaps in continuity of care are as follows:

1. *What are the perceived mental health needs of the people (need for counselling, need for information, need for medication, need for practical support, need for professional support etc.)?*
2. *What is the 'Unmet Need' for receiving mental health services for the people with mental health diseases?*
 - a. *Of those people who have the need for care, whether they have their needs fully met*
 - b. *Of those people who have the need for care, whether they have partially met needs*
 - c. *Of those people who have the need for care, whether they have unmet needs*

3. *What is status of people receiving facility based follow up or continuum of care of the people with mental health diseases?*
4. *What is the community-based support received for the people with mental health conditions?*
5. *What are the major gaps and perceived barriers at facility level, community level and continuum of care?*
6. *What are the reasons for not accessing care/service utilization barriers/perceived barriers?*
(Self-reliance, pessimism, ignorance, stigma, cost of the treatment was too high, Problems with transportation, could not take time off work, whether any previous bad experiences with healthcare, The healthcare professional did not have sufficient skills or the appropriate treatment or medication was not available etc.)

5) Data analysis of the need assessment component

6) Obtaining approval for the above from the Technical Advisory Committee (TAC)

Time frame – Three months

Specific area of work	Duration
Propose a study plan and methodology and obtain approval from TAC	By 15 th of November
Conduct the validation component and the need assessment component	By 15 th January 2025
Submission of final technical report and statement of expenditure with original invoices to the WHO (Soft and hard copies) related to phase 2	By 15 th February 2025

8. Reporting Requirements:

Deliverables of phase 1:

- Translated copies of the 'FLII 11' Adult Epi version and the IEQ
- Submission of final technical report and statement of expenditure with original invoices related to phase 1

Deliverables of phase 2:

- The translated and validated 'FLII 11' Adult Epi version
- The detailed report of the validation study (including measures of sensitivity/specificity/diagnostic accuracy/reliability)
- The detailed report of the need assessment study
- Submission of final technical report and statement of expenditure with original invoices related to phase 2

Monthly updates and touch base meetings

The contacting partner/focal point should share monthly updates of activities to the Technical Advisory Committee (TAC) and as required organize touch base meetings to discuss any issues/concerns.

9. Performance monitoring:

Performance monitoring will be done by the TAC.

10. Ownership of the work:

WHO, NCD Bureau and the Directorate of Mental Health, Ministry of Health will have the ownership of the work done as per the WHO policy and the contracting partner can't publish/present the findings of the survey in any manner without the approval of the Ministry of Health and the WHO SL.

11. Competencies, qualifications, and experience:

Agency/survey team should have following qualifications and experience.

Mandatory qualifications:

The survey team should consist of minimum of following experts.

- 1) At least one expert in public (community) health with MD/PhD in Public Health. Having more than one expert is an added advantage
- 2) At least one expert in Psychiatry with MD in Psychiatry. Having more than one expert is an added advantage.
- 3) At least one specialist in ICT

Mandatory experience of team members:

- 1) Expertise in public (community) health with MD/PhD in Public Health should have more than 5 years' experience as a public health specialist.
- 2) Expertise in Psychiatry with MD in Psychiatry should have with more than 5 years' experience as a consultant psychiatrist.

Desirable qualifications of additional team members

- 1) At least one expert in statistics.
- 2) At least one expert in report writing.

3) Desirable experience of team members

- 1) Experience in carrying out surveys related to Mental health.
- 2) Experience in carrying out other assignments related to Health.
- 3) Experience in working with UN agencies and Government Agencies.

12. Submission of Quotation:

Interested agencies/ organizations must submit **separate** technical and financial proposals for evaluation. **Technical and financial proposals to be submitted to: (Subject: Feasibility Testing and validation of the Flexible Interview for ICD-11 (FLII-11) Adult Epi version for the Mental Health Survey in Sri Lanka)**

The proposal shall include:

- 1) A technical proposal with timelines
- 2) A **separate financial proposal (not combined with technical proposal) describing details of the budget for the two phases separately,**
- 3) Updated profile of agency and CVs of all experts of the team- highlighting requested expertise and experiences

13. Instructions for bidders

Bidders should follow the instructions set forth in this RFP when preparing and submitting their proposal to WHO. Proposals which are not prepared according to the instructions will be rejected.

14. Language

The proposal prepared by the bidder, and all correspondence and documents relating to the proposal exchanged by the bidder and WHO shall be written in the English language.

15. Place of assignment:

Sri Lanka