# REVIEW REPORT

**Title:** Barriers in accessing treatments for cleft lip and cleft palate in Bangladesh

**Authors:** Tanzila Rafique, Rakia Ishra, Sharlin Akter, Shahriar Mohd Shams

## Round 1

**Reviewer F:** Ahsan Aziz Sarkar, **ORCID:** 0000-0002-8800-8669, **COI:** None, **AI disclosure:** ChatGPT was used to assist in correcting the grammar and improving the clarity of the written feedback

**1. Comment** Completeness and accuracy of the Abstract. The abstract states the sample size was 106, but the methods and results section of the main text stated 105.

**Response:** Thank you for your comments. The correct sample size was 105. The sample size written in the abstract was a typo. Line no.46-47

**2. Comment** The conclusion ("Increasing social support... may enhance self-esteem") is too generic.
On what basis do the authors claim that social support will increase self-esteem, given that this outcome was not directly measured in the study?

**Response:** The conclusion has been changed focusing the study findings. Now it reads, "Socio-cultural stigma, economic constrains and health system limitations continue to impede access to cleft lip and palate treatment in Bangladesh. Addressing these barriers is therefore essential to improve equitable access and health outcomes for affected individuals. Line no.61-63

**3. Comment** Clarity and appropriateness of the Objective(s). A clear statement of objectives at the end of the introduction section is essential to guide the reader and align the methodology with the intended purpose of the research.

**Response:** Objectives have been given at the end of the introduction section.

Now it reads, "This study examined the barriers to treatment for CL/P in Bangladesh, utilizing a mixed-methods approach." Line no.115-116

**5. Comment** The Methods are not described in sufficient detail to ensure reproducibility.
Key deficiencies include: No sample size calculation

**Response:** The study included the adult cleft lip and cleft palate patients and the participants were recruited purposively. The selection was intentional and strategic. Patients with medically handicapped conditions or those unwilling to participate in the study were excluded. Line no.141-145

**6. Comment** Inadequate explanation of how stigma and psychological variables were measured

**Response:** Interviewer administered questionnaire and a semi-structured interview were carried out to assess the socio cultural, socio economic barriers and personal factors related to access of the healthcare services. Line no.134-136

**7. Comment** Lack of justification for adapting the SAGE questionnaire

**Response:** WHO's World Health Study on global Ageing and adult health (SAGE) survey were used to collect socio-demographic data. Line no.130-131

**8. Comment** No description of questionnaire used, and no description of interviewer qualifications or saturation determination for qualitative data.

**Response:** The questionnaires used to collect the quantitative data were described in the study design and setting sections of the manuscript.

- WHO's World Health Study on global Ageing and adult health (SAGE) survey were used to collect socio-demographic data. Line no.130-131

- Self-administered questionnaire was used to assess the perceived barriers reported by the patients in accessing health care services. This section included seven questions employing 5 point Likert scale from "No" (1) to "Most"(5). Line no.131-133

- Both interviewer-administered questionnaire and a semi-structured interview were carried out to assess the socio cultural, socio economic barriers and personal factors related to access of the healthcare services. Line no.133-135

**1. Comment**    Appropriate and thorough description of the Statistical methods. The statistical methods are inadequately described. A description on how qualitative themes were derived could be helpful.

**Response:** The statistical methods used to carry out the quantitative data have been mentioned. The socio-cultural, socio-economic barriers and stigmas to access healthcare services, participants' factors as barriers to accessing the healthcare services were expressed in bar diagrams. For the IDIs and KIIs, interview sessions were scheduled and conducted with each participant. The interview session continued up to the last theoretical saturation and until enough data was collected. Empathetic neutrality was maintained throughout the procedures. Interviews were audio recorded. After recording, immediate transcription of recorded interview was done. Coding of transcribed data was done and themes were developed. Finally data interpretations were done and concepts were developed by thematic analysis procedure. Line no.191-204

**2. Comment**    Quality, clarity and appropriateness of the Table(s). The chi-square tests in Table 1 are largely unnecessary as they test for differences between treated and untreated groups which were never used to interpret results. Grouping "student" and "unemployed" together in the occupation category is inappropriate as these.

**Response:** Chi squared test has been removed. The number and percentage of categorical variables have been shown in the Table 1. Line no.489-491

**3. Comment**    Quality, clarity and appropriateness of the Figure(s), if any. Figures contain grammatical errors.

**Response:** Figures have been changed. Line no.525-532

**5. Comment**    Pertinence of the Discussion section whether it justify the main message of the manuscript without repeating the results: The discussion section partially summarizes findings and cites relevant literature, but it primarily repeats results rather than interpreting their meaning, explaining contradictions, or deriving specific, actionable implications tailored to the Bangladeshi context.

**Response:** The discussion section has been changed substantially focusing the study objectives and findings. Repeated results have been removed. Actionable implications of findings have been given. Line no.312-355

**6. Comment**    Whether the Conclusion of the manuscript is supported by the data. The conclusion is partially supported by the data but overreaches by recommending psychological interventions without evidence of their effectiveness and fails to derive specific, actionable recommendations directly from the study's key findings.

**Response:** The conclusion has been changed on the basis of study findings. Now it reads, "The socio-cultural barriers involving cleft lip and palate (CL/P) are creating profound challenges for affected individuals and their families, require a public health care providers' intervention to educate society about the natural causes and ease of management for addressing these issue,` thereby increasing opportunities for patients substantially." Line no.356-360

**7. Comment**    Whether the manuscript is supported by appropriate and up-to-date References. The references are not consistently formatted: serial numbering is not maintained, author names have inconsistency, upper/lower case usage, and citations lack publication years. A thorough revision following journal style guidelines is required.

**Response:** The references have been have been thoroughly reviewed and formatted following the journal guidelines. Line no.373-481

**8. Comment**    Straightforward, clear, and logical Storytelling. The storytelling is fragmented, with poor integration between quantitative and qualitative findings.

**Response:** Integration between quantitative and qualitative findings has been made by linking the similar findings from both studies. Line no.338-345

**Reviewer I: Hridi, ORCID: 0000-0002-7708-0614, COI: None, AI disclosure:** I have used grammarly to see the fluency of english and grammatical coherence across the paper

**7. Comment**    Appropriateness of the Title. "Barriers and Stigmas" overlaps conceptually (stigma is a type of barrier). The title does not signal that this is a mixed-methods approach or a facility-based study

**Response:** The title has been changed. Now it reads, "Barriers in accessing treatments for cleft lip and cleft palate in Bangladesh" Line no.2

**8. Comment**    It does not clearly specify the sampling strategy (facility-based purposive sampling) or that the participants were adults only.

**Response:** The study purposively selected 105 treated and untreated adult patients with a craniofacial anomaly. Line no.46-47

**8. Comment**    The timeframe of data collection is missing, and the measurement approach is insufficiently described.

**Response:** Data were collected from September 2019 to June 2023. Line no.47-48

**9. Comment**    Although SAGE is mentioned, the specific instruments or scales used to assess stigma and barriers are not identified.

**Response:** The Socio-demographic data were collected utilizing the WHO's World Health Study on global Ageing and adult health (SAGE) survey, self-administered questionnaires assessed socio-cultural, economic, and healthcare barriers and stigmas. The qualitative parts included the in-depth interviews of 16 patients and 7 key informants' interviews of the cleft services. Line no.48-50

**10. Comment**    The type of quantitative analysis is not stated, and the qualitative analysis method is also omitted. There is a sample size inconsistency between sections, and the conclusion makes claims about quality of life and self-esteem that were not directly measured.

**Response:** The methods section has been changed. Proper explanations of quantitative and qualitative methods have been given. Line no.124-140. The conclusion of the study has been changed. Now it reads, "The barriers involving cleft lip and palate (CL/P) are creating profound challenges for affected individuals and their families, require a public health care providers' intervention to educate society about the natural causes and ease of management for addressing these issue,` thereby increasing opportunities for patients substantially. Line no.356-360

**11. Comment**    Clarity and appropriateness of the Objective(s). It is expressed in broad terms and does not specify the target population (adult, facility-attending patients), the domains of barriers (social, economic, health-system), or the mixed-methods intent. In several later sections, the manuscript extends into self-esteem, psychological well-being, and quality of life, which are not explicitly included in the objective and not directly measured.

**Response:** This study examined the barriers to treatment for CL/P in Bangladesh, utilizing a mixed-methods approach. Line no.116-117

**12. Comment**    Clarity of the rationale for conducting the study is given in the Introduction section: The rationale for conducting the study is not fully developed in the Introduction. The section successfully establishes that cleft lip and palate are prevalent, associated with stigma, and linked to access challenges in low- and middle-income settings. It notes a relative lack of country-specific evidence. However, the justification remains mostly descriptive and does not build a strong logical argument for why this particular study is necessary now and in this setting. The Introduction does not clearly show what is unknown, what is inconsistent in existing evidence, or how this mixed-methods approach will uniquely address that gap.

**Response:** The introduction has been changed. Rationale and objectives has been given focusing the contexts in the low- and middle-income settings. Line no.99-117

**13. Comment**
- In the methods section, some key elements are missing, such as the:
- Exact sampling procedure.
- Operational definitions of barriers and stigma.
- The structure and validation of the quantitative questionnaire.
- The coding and analytical process for qualitative data.
- Mixed-methods integration procedures are not specified, making it unclear how the two datasets inform each other.

**Response:**
- Total of 105 adult cleft lip and/or palate patients were recruited using purposive sampling based on specific characteristics or criteria relevant to the study's objectives. The selection was intentional and strategic. The researcher used their expertise and knowledge to identify and choose individuals who are most likely to contribute valuable data. Line no.142-145
- Barrier: Our participants experienced various levels of socio cultural and socio economic, certain personal factors and different self-perceived obstacles and challenges while seeking for health cares. Barriers to health care access are any physical, financial, social, or structural obstacles that restrict, delay, or prevent individuals from obtaining necessary medical services, evidence-based care, or health information. Line no.155-160
- Stigma : The negative attitudes or false beliefs associated with these specific traits, circumstances, or health symptoms were assessed among the participants. Stigma refers to a negative view, belief, or attitude towards an individual or group due to specific traits or characteristics, resulting in discrimination and social disapproval. Line no.161-165
  WHO's World Health Study on global Ageing and adult health (SAGE) survey were used to collect socio-demographic data.
  Self-administered questionnaire was used to assess the perceived barriers reported by the patients in accessing health care services. This section included seven questions employing 5 point Likert scale from "No" (1) to "Most"(5).
  Both interviewer-administered questionnaire and a semi-structured interview were carried out to assess the socio cultural, socio economic barriers and personal factors related to access of the healthcare services. Line no.130-138
- The interview session was continued up to the last theoretical saturation and until enough data was collected. Empathetic neutrality was maintained throughout the procedures. Interviews were audio recorded. After recording, immediate transcription of recorded interview was done. Coding of transcribed data was done and themes were developed. Finally data interpretations were done and concepts were developed by thematic analysis procedure. Line no.198-204
- Integration between quantitative and qualitative findings has been made by linking the similar findings from both studies. Line no.338-345

**14. Comment** Clarity and appropriateness of the Design to achieve the objective(s).

The design is not clearly aligned with the stated objectives. The manuscript does not specify the type of mixed-methods design (e.g., convergent, explanatory sequential), nor does it describe how the qualitative and quantitative components are integrated to address the research question. Additionally, because the sample is facility-based and adult-only, the design limits generalizability, which is not acknowledged in framing the objectives. While a mixed-methods approach is conceptually suitable, the lack of clarity on integration, sampling strategy, and analytic framework reduces confidence that the design fully supports the stated aim of exploring societal stigmas and barriers in Bangladesh.

**Response:** The statistical methods used to carry out the quantitative data have been mentioned. The socio-cultural, socio-economic barriers and stigmas to access healthcare services, participants' factors as barriers to accessing the healthcare services were expressed in bar diagrams. For the IDIs and KIIs, interview sessions were scheduled and conducted with each participant. The interview session continued up to the last theoretical saturation and until enough data was collected. Empathetic neutrality was maintained throughout the procedures. Interviews were audio recorded. After recording, immediate transcription of recorded interview was done. Coding of transcribed data was done and themes were developed. Finally data interpretations were done and concepts were developed by thematic analysis procedure.
Line no.195-204

**15. Comment** Appropriate and thorough description of the Statistical methods.

The manuscript does not specify the type of mixed-methods design (e.g., convergent, explanatory sequential), nor does it describe how the qualitative and quantitative components are integrated to address the research question. Additionally, because the sample is facility-based and adult-only, the design limits generalizability. While a mixed-methods approach is conceptually suitable, the lack of clarity on integration, sampling strategy, and analytic framework reduces confidence that the design fully supports the stated aim of exploring societal stigmas and barriers in Bangladesh.

**Response:** We have updated the analysis as per suggestion. Line no. 191-205

**16. Comment** Pertinence of the Discussion section whether it justify the main message of the manuscript without repeating the results.

While some comparisons with studies from India, Africa, and other LMICs are made, the discussion does not critically analyze the findings in light of theory, health policy, or broader implications for Bangladesh. Claims about quality of life, self-esteem, and gender vulnerabilities are discussed despite these outcomes not being measured, which weakens conceptual justification.

**Response:** The discussion section has been changed substantially focusing the study objectives and findings. Repeated results have been removed. Actionable implications of findings have been given. Line no.312-355

**17. Comment** Whether Strength(s) and Limitation(s) are well described. Not described

**Response:** Strength(s) and Limitation(s) have been mentioned at the end of the discussion section. Now they read, "Certain barriers faced at different levels and the treatment-related obstacles that adult CL/P patients experience have not been the subject of any prior research in our nation. The selection of study participants using purposive sampling enabled the inclusion of cleft patients based on specific characteristics or criteria relevant to the study's objectives. As it was a cross sectional study the causal relationships cannot be proven but this study may help to address the multifactorial challenges that cause significant delays in timely treatments, and can lead to lifelong consequences for the patients in low- and middle-income countries (LMICs). This will also allow researchers to identify, analyze, and mitigate these obstacles—ranging from lack of awareness to economic constraints—thereby improving access to care and enabling comprehensive treatment planning."
Line no.345-355

**18. Comment** Whether the Conclusion of the manuscript is supported by the data.

The manuscript talks about impacts on self-esteem, quality of life, and long-term psychosocial burden, which were not directly measured in the study. Similarly, recommendations for counseling and social skills interventions, while reasonable, are suggestive rather than empirically tested, and the study design (cross-sectional, descriptive) does not allow causal inference.

**Response:** The conclusion has been changed on the basis of study findings. now it reads, "The barriers involving cleft lip and palate (CL/P) are creating profound challenges for affected individuals and their families, require a public health care providers' intervention to educate society about the natural causes and ease of management for addressing these issue,` thereby increasing opportunities for patients substantially." Line no.356-360

**19. Comment** Whether the manuscript is supported by appropriate and up-to-date References.

a. Duplicates: Refs 15 and 16 are identical.

b. Some DOI/PMID entries are incomplete or inconsistent.

**Response:**

a. Duplicated references have been removed.

b. DOI/PMID entries have reviewed and corrected.

**20. Comment** I do not see the justification for including the third author in the author list. I would like to alert the corresponding author about possible authorship violation. I believe this paper partially encompasses the thesis work of the lead author. If this is correct, the authors should exercise more caution about any direct or indirect ethical violations.

**Response:** The third author was working as a research Co-coordinator in the Dept. of Public Health & Informatics of BMU, at the time when the study was conducted. She has contributed in the conception and design of the study; acquisition, analysis, and interpretation of data; manuscript drafting and revising it critically; approval of the final version of the manuscript and guarantor of accuracy and integrity of the work. Line no.16-20

**21. Comment** We need a declaration that "The manuscript encompasses the x/y thesis of PQ."

**Response:** Declaration has been given as- This article partially encompasses PhD thesis of Dr. Tanzila Rafique. Line no. 37

**22. Comment** Stigma itself is a barrier. Therefore, the manuscript revisions must address this redundancy.

**Response:** The word "stigma" has been used as a type of barrier instead of considering it a separate word from barrier

**23. Comment** Line 110: What adaptations to the WHO Questionnaire were made?

**Response:** WHO's World Health Study on global Ageing and adult health (SAGE) survey were used to collect socio-demographic data. Line no.48-49 & Line no.130-131

**8. Comment** Cross-sectional design appeared twice in the Methods section (lines 103 and 115);

**Response:** Repeated information has been removed.

**24. Comment** Please justify the choice of purposive sampling. What was the purpose behind it, and how were they recruited?

**Response:** Total of 105 adult cleft lip and/or palate patients were recruited using purposive sampling based on specific characteristics or criteria relevant to the study's objectives. The selection was intentional and strategic. The researcher used their expertise and knowledge to identify and choose individuals who are most likely to contribute valuable data. Patients with medically handicapped conditions or those unwilling to participate in the study were excluded. Line no. 142-146
The selection of study participants using purposive sampling enabled the inclusion of cleft patients based on specific characteristics or criteria relevant to the study's objectives. Line no. 347-349

**25. Comment** Operational definitions given in the key variables ascertainment contain bookish definitions of stigma, social stigma, self-esteem and psychological well-being (references 10-14).

**Response:** The operational definitions have been changed. Line no.149-179

**26. Comment** Statistical methods hardly have anything beyond numbers (%) for the quantitative data, which showcases the study's position at the elementary level.

**Response:** The statistical methods have been changed as per suggestions. The socio-cultural, socio-economic barriers and stigmas to access healthcare services, participants' factors as barriers to accessing the healthcare services were expressed in bar diagrams. For the IDIs and KIIs, interview sessions were scheduled and conducted with each participant. The interview session continued up to the last theoretical saturation and until enough data was collected. Empathetic neutrality was maintained throughout the procedures. Interviews were audio recorded. After recording, immediate transcription of recorded interview was done. Coding of transcribed data was done and themes were developed. Finally data interpretations were done and concepts were developed by thematic analysis procedure. Line no.189-202

**27. Comment** The conclusion is too lengthy! One paragraph would suffice.

**Response:** The conclusion has been changed. Now it reads, "The barriers involving cleft lip and palate (CL/P) are creating profound challenges for affected individuals and their families, require a public health care providers' intervention to educate society about the natural causes and ease of management for addressing these issue,` thereby increasing opportunities for patients substantially. Line no.

**28. Comment** Funding and IRB memos should be supplemented by their dates.

**Response:** Date has been added in the funding and IRB memos. Line no.151-155

**29. Comment** Reference 20 includes authors' academic degrees.

**Response:** References have been corrected and replaced as needed.

**30. Comment** Table 1: Why should the treated and untreated groups is compared with statistical tests? Is there any objective for this analysis? As presented, the results suggest people with CLP should remain unmarried (P=0.03).

**Response:** We have updated the analysis as per suggestion. Descriptive statistics of the categorical variables have been expressed in the Table 1 as the number and percentage. Line no.485-487

**31. Comment** Table 2: I do not understand the meaning of this table; can the study clearly present the proportion of people who suffer from stigma or any other barriers? The Figure could present only the "Yes" values (with "No" implied).

**Response:** Table 2. The number and percentage of perceived barriers related to the treatment and healthcare provider has been given. Meaningful barrier were defined as response of Moderate, Much, or Most. Line no. 496-498. Figure 1 & 2 has been changed. The total number of barriers according to age category and sex of the participants have been given in figure no. 1 and 2. Line no. 521-530

**Reviewer F:** **Ahsan Aziz Sarkar,** **ORCID:** **0000-0002-8800-8669,** **COI:** **None,** **AI disclosure:** ChatGPT was used to assist in correcting the grammar and improving the clarity of the written feedback

**32. Comment** In the "Key variable ascertainments" section of the Methods, the authors provide definitions for "self-esteem," "low self-esteem," and "psychological well-being." While these are relevant concepts in the broader context of cleft lip and palate (CL/P) research, they were not measured as primary variables in this study. It is strongly recommended to remove the definitions for "self-esteem," "low self-esteem "and" psychological well-being" from this section.

**Response:** The definition for "self-esteem," "low self-esteem "and" psychological well-being" has been removed from the "Key variable ascertainments" section. Line No.150-171

**33. Comment** In the "Statistical analysis" section, the authors state, "As the key outcome variables were categorical, we conducted multivariate logistic regression analysis to understand the factors associated with the treatment status." However, the results of this regression analysis are not presented anywhere in the Results section, nor are they discussed in the manuscript. The authors must address this discrepancy.

**Response:** Multivariate logistic regression analysis was not considered in the final manuscript. This part has been removed from the "Statistical analysis" section. Line no. 179-193

**34. Comment** The axis scales on the figures requires revision. For instance, the percentage values exceed 100 (e.g., reaching 120), which is not appropriate for a graph representing proportions of a whole.

**Response:** Axis scale on the figures (1&2) has been changed. Line no. 504-522

**Reviewer I:** **Hridi,** **ORCID:** **0000-0002-7708-0614,** **COI:** **None,** **AI disclosure:** I have used grammarly to see the fluency of english and grammatical coherence across the paper

**35. Comment** Line 510: There are several methodological and reporting problems in this table from a qualitative research perspective. The issues relate to conceptual hierarchy, labeling, analytical consistency, and reporting standards.

**Response:** Table 3 has been reformatted. The qualitative themes and sub themes developed from the IDIs of study participants has been reported. Line no. 485-486

**36. Comment** Line 534: Figure 3: The figure may be resized for better readability of the barriers on the left-hand side

**Response:** Figure 3 has been resized. On the left hand side, the barriers name has been written clearly.

Line no. 532-535

**37. Comment** References: 10 and 18 are identical

**Response:** Reference no.18 has been removed as it was identical with reference no.10.

**38. Comment** Reference: 5
Hunt OT et al. The psychosocial effects of cleft lip and palate: A systematic review. European Journal of Orthodontics 2025; 27(3):274–85
This is incorrect because: Volume 27 belongs to 2005, not 2025.

**Response:** This was a typo and we have corrected it. Now the reference reads as- Hunt O T, Burden D, Hepper p, Johnston T. The psychosocial effects of cleft lip and palate: A systematic review. The European Journal of Orthodontics. 2005; 27(3):274-85, doi: 10.1093/ejo/cji004. Line no. 387-389

**39. Comment** The manuscript addresses an important topic, but the clarity and readability of the English need improvement. Although the main ideas can be understood, there are several grammatical mistakes, repetitive sentences, and some awkward or unclear wording. In some places, the sentences are too long and the flow of the text becomes difficult to follow. There are also small issues with punctuation, verb tense, and consistency in terminology.

**Response:** These issues have been checked thoroughly throughout the text. The grammatical mistakes, repetitive or too long sentences, punctuation, verb tense, and consistency in terminology have been properly checked and corrections have been done where necessary.