PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Primary healthcare system readiness to prevent and manage non-communicable diseases in Bangladesh: A mixed-method study protocol
AUTHORS	Kabir, Ashraful; Karim, Md; Billah, Baki

VERSION 1 – REVIEW

REVIEWER	Wesonga, R chool of Statistics and Planning, Makerere University, School of Statistics and Planning
REVIEW RETURNED	11-May-2021

GENERAL COMMENTS	May 11, 2021

1 TITLE: PRIMARY HEALTHCARE SYSTEM READINESS TO PREVENT AND MANAGE NON-COMMUNICABLE DISEASES IN BANGLADESH: A STUDY PROTOCOL
INTRODUCTION In this study protocol, the authors intend to recognize and assess the
Bangladeshi health system's readiness to prevent and manage NCDs at the primary level.
They prefer to use a mixed-method design. Numerical data will be collected using households
and health facilities surveys,while textual data will be collected by interviewing healthcare
providers, policy planners, health administrators, and community members. Two independent
samples t-test, ANOVA and chi-square test methods will be used for univariate
analysis, and multiple regression analysis will be used formultivariable analysis, while thematic
analysis approach will be used to analyze textual data.

2 COMMENTS
1. Generally, the authors have articulated the the study protocol well in its desired format.
However, does status necessarily imply readiness?
2. The authors' intention to assess readiness is short of a number of indicators, such as;
firstly, compromise between WHO and Bangladesh definition of NCD, target population
served by each healthcare, NCD prevalence rates, NCD incidence rates, time
trend factor, including mortality rates, etc...

	3. They should adopt uniform terminology, eg textual data is better referred to as qualitative data
	4. The two independent samples t-test, ANOVA and chi-square test methods are used for where two variables are involved, hence, bivariate rather than univariate analysis should be used
	5. At this protocol level, the authors should have known the nature of the outcome variable, thus rather than just say they will use Regression for multivariate analysis, it suffices to specify the regression model to be fitted, and at least why and for what objective to serve.
	6. What is the nature of the composite score, what are its exact constituents and measurement scale?
	7. Describe the nature of the mixed methods approach in some detail, for example, is it sequential, etc...
	8. Authors need to revisit national representativeness of the sample size as well accounting for non-response rate. Also remember to type correctly Z® 2 Æ 1.96

| **REVIEWER** | Duong, David
Harvard Medical School, Center for Primary Care |
| **REVIEW RETURNED** | 14-May-2021 |

GENERAL COMMENTS	1. I would do a more detailed literature review of to cite/reference other research that has been done on this very topic (assessing NCD readiness using SARA and WHO PEN (i.e. 10.15171/ijhpm.2018.104, 10.1186/s12889-020-09279-z, etc...), and provide discussion on how the authors' approach is similar or different.
	2. For the IRB, given that the research is mainly conducted in Bangladesh, would it necessary to obtain IRB approval from an organization in Bangladesh, or mention that this study has undergone review in Bangladesh as well?
	3. Authors indicate that Bangladesh's definition of NCDs incorporates more diseases than what the WHO covers; in your discussion section, please address if the tool will be modified to include this, and if not, then provide a sentence indicating this and why, and its implications.
	4. Given that there are facility surveys, would it be reasonable to add in a component of randomly going to select facilities to validate what the staff have filled out to see if it matches?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. R Wesonga, chool of Statistics and Planning, Makerere University, Sultan Qaboos University, College of Science

Reviewer: 1

Comment 4: Generally, the authors have articulated the study protocol well in its desired for-mat. However, does status necessarily imply readiness?

Response: We find this comment very insightful for greater clarity and relevance of the study protocol. We viewed the health system from a holistic perspective and designed this study for a comprehensive investigation of health system readiness at the primary healthcare level of Bangladesh. This study will examine the health system readiness from both the supply-side and demand-side perspectives by using modified standardized tools adapted from relevant literature. In addition, we elaborately described the methods and procedures for evaluating the readiness of specific health system components. Therefore, we believe this study protocol will be useful to appropriately investigate the readiness of the primary healthcare system for the major NCDs (diabetes mellitus, chronic respiratory diseases, cardiovascular disease, and cancer) in Bangladesh.

Comment 5: The authors' intention to assess readiness is short of a number of indicators, such as; firstly, compromise between WHO and Bangladesh definition of NCD, target population served by each healthcare, NCD prevalence rates, NCD incidence rates, time trend factor, including mortality rates, etc...

Response: Thank you for raising it. The indicators for readiness will be measured according to the WHO SARA reference manual and PEN interventions, which have been used in many countries and contexts, and they have been cited in this protocol. Our study will use these well-defined and agreed indicators for examining the health system readiness at the primary healthcare level for four major NCDs identified by the WHO (diabetes mellitus (DM), chronic respiratory diseases (CRD), cardiovascular disease (CVD), and cancer). Although NCDs lists in Bangladesh includes some more diseases or conditions, considering the high prevalence of NCDs, the scope of service available at the primary health care level, and the current strategic and programmatic priority, the above 4 categories of NCDs have been included in this study.

We have addressed this in the limitation and discussion section of the revised version (Lines: 51-64, Pages: 3-4; and 548-552, Page: 30).

Comment 6: They should adopt uniform terminology, eg textual data is better referred to as qualitative data

Response: We agree that unique terminology should be used throughout the paper. We have replaced 'textual data' with 'qualitative data' in the revised version.

Comment 7: The two independent samples t-test, ANOVA and chi-square test methods are used for where two variables are involved, hence, bivariate rather than univariate analysis should be used

Response: The comment has been addressed by replacing 'univariate' with 'bivariate.' This text was added in the revised version (line:34, Page: 2).

Comment 8: At this protocol level, the authors should have known the nature of the outcome variable, thus rather than just say they will use Regression for multivariate analysis, it suffices to specify the regression model to be fitted, and at least why and for what objective to serve.

Response: The comment has been addressed, and this section has been supplemented with the following texts: Lines: 458-470, Pages: 26

'In the facility survey, the primary outcome variable is 'readiness' of the primary healthcare system in Bangladesh, where it is measured in binary scale (has two categories: 'ready' and 'not-ready'). The readiness variable will be rated as an index grouped into following three domains as proposed in the WHO SARA methodology: (i) staff and guidelines, (ii) diagnostic equipment, and (iii) medicines and essential commodities. Each of these domains has multiple indicators, which will be measured in nominal scales: 'Yes' and 'No'. An index for each domain will be calculated as the mean availability of indicators, which ranges from 0.00 to 100%. The facility readiness index (composite score) will then be calculated as the mean of all these three domains and a facility will be considered as 'ready' if its index is above 50% (54). The binary multiple logistic regression analysis will be performed to evaluate the relationship between the outcome 'readiness' and several potential explanatory variables such as facility type (e.g., inpatients, outpatient), facility location (e.g., rural, urban), and managing authority (e.g. public, private) of the facility.'

Lines: 440-448, Pages: 25
In the household survey, 'the outcome variable will be the 'care-seeking for NCDs', which will be recorded in the following 3 categories: no care or self-care, semi-qualified professional care, and qualified professional care. The potential explanatory variables will be the individual characteristics (i.e., age, sex, education, comorbidity, occupation), household characteristics (i.e., socio-economic status, household size), and contextual characteristics (i.e., the distance of the facility from the household, type of residence). The relationship of these variables with 'care-seeking for NCDs' will be assessed by employing multiple multinomial logistic regression analyses, as the outcome variable has more than 2 categories.'

Comment 9: What is the nature of the composite score, what are its exact constituents and measurement scale?

Response: The composite score for facility readiness will be measured based on the three domains: (i) essential medicine and commodities, (ii) diagnostic equipment, and (iii) staff & guidelines as proposed in the WHO SARA methodology. The score for each domain will be measured on the nominal scale as 'ready' and 'not-ready.' The composite score will be calculated as the mean score of items in each domain, which gives scores between 0.00 to 100%. A facility with a score of above 50% will be considered as 'ready' (54); please see response to Comment 8 for more details.

Comment 10: Describe the nature of the mixed methods approach in some detail, for example, is it sequential, etc...

Response: We have addressed the comment by adding the following text in the revised version (Lines: 236-243, Pages: 15).

'A mixed-method design implies combining quantitative and qualitative approaches to evaluate research questions (51). Mixed-method design is viewed as appropriate to get a comprehensive understanding as it examines the observed phenomena from multiple perspectives and to validate findings through triangulation of methods, participants, and sources (51, 52). The mixed-method study includes various designs: convergent design, explanatory sequential design, and exploratory sequential design. This study will use convergent design by collecting qualitative and quantitative data in parallel, then analyzing them separately, and finally merging qualitative and quantitative data.

Comment 11: Authors need to revisit national representativeness of the sample size as well accounting for non-response rate. Also remember to type correctly Za-2= 1.96

Response: The national representation of our sample size (n=1386) has been ensured by using multi-stage cluster random sampling method (randomly selecting multiple clusters and choosing subjects randomly from each cluster to form the final sample) as well as maintaining urban-rural, age, and sex proportion distribution reported by the latest Bangladesh population census conducted in 2011 (61). The nationally representative 'Bangladesh Demographic and Health Survey' reported a non-response rate of less than 10% in household surveys (61, 62). We have revised our sample size by applying 10% non-response rate in the revised version. We have fixed the typo as $Z\alpha/2=1.96$.

Comment 12: I would do a more detailed literature review of to cite/reference other research that has been done on this very topic (assessing NCD readiness using SARA and WHO PEN (i.e. 10.15171/ijhpm.2018.104, 10.1186/s12889-020-09279-z, etc...), and provide discussion on how the authors' approach is similar or different.

Response: We have cited more relevant literature in the discussion section, including the recommended articles. The following text has been added in the revised manuscript

Lines: 98-103, Page: 5 in the introduction section:
Several studies in South Asia, Southeast Asia, and sub-Sharan Africa investigated the primary healthcare system readiness for NCDs from the supply-side perspective, mainly the facility-level readiness using the WHO SARA reference manual and/or WHO PEN intervention package. However, the demand-side aspect of primary healthcare system readiness, such as the community characteristics and associated determinants, remains largely under-explored.

Lines: 553-561, Page: 30 in the discussion section
'The existing studies mainly investigated supply-side factors to assess the healthcare system readiness for NCDs (i.e., medicine, basic amenities, medical products, and technologies) as devised in the WHO SARA methodology and/or WHO PEN interventions. However, the demand-side factors, which is an essential consideration in addressing NCDs, remain largely under-explored. The proposed study will examine healthcare system readiness by adopting a mixed-method approach and applying the relevant health system framework (57). In this present study, use of a conceptual framework and combining various methods/tools will offer a deeper and comprehensive understanding of the healthcare system's readiness from both supply-side and demand-side perspectives.'

Comment 13: For the IRB, given that the research is mainly conducted in Bangladesh, would it necessary to obtain IRB approval from an organization in Bangladesh, or mention that this study has undergone review in Bangladesh as well?

Response: This study also received ethical approval from 'Bangladesh Medical Research Council,' a national research body under the Ministry of Health and Family Welfare (MoHFW) in Bangladesh. We have added the following text in the revised version (Line: 39-40, Page: 3; and 528-529, Page: 29)

'The project also obtained ethical approval from the Bangladesh Medical Research Council (Ref: BMRC/NREC/2019-2022/270).'

Comment 14: Authors indicate that Bangladesh's definition of NCDs incorporates more diseases than what the WHO covers; in your discussion section, please address if the tool will be modified to include this, and if not, then provide a sentence indicating this and why, and its implications.

Response: We have addressed this comment by supplementing the following text in the manuscript. (Lines: 548-552, Page: 30)

Although NCDs lists in Bangladesh include some more diseases or conditions (including arsenicosis, mental health disorders, hearing disabilities, birth defects, and road injuries), our study will include the major NCDs (diabetes mellitus, chronic respiratory diseases, cardiovascular disease, and cancer) prioritised by the WHO. Therefore, we did not require to modify any tool to include these locally defined NCDs.

Comment 15: Given that there are facility surveys, would it be reasonable to add in a component of randomly going to select facilities to validate what the staff have filled out to see if it matches?

Response: The facility-level data will be collected through face-to-face interviews. A random selection of a few healthcare facilities to validate the response of the interviewers (facility heads/designated personnel) may not be possible in a separate arrangement because of access restrictions to the healthcare facilities' information records. We have addressed this comment by adding the following text in the revised version (Lines: 418-424, Page: 24).

'Healthcare facilities will be randomly selected for facility survey. We will prepare the list of healthcare facilities at the primary care level by collecting basic information (facility type, location, service availability, operating hours, etc.) from the 'Directorate General of Health Services' database. From this list, we will randomly select healthcare facilities located at various levels with the variation of size and patient load (e.g., UHC, UHC/Union sub-centre CC, private clinic/hospital, NGO clinic/hospital). Facility-level data will be gathered by face-to-face interviewing facility heads/designated personnel.'

Reviewer: 1
Competing interests of Reviewer: None to declare

Reviewer: 2
Competing interests of Reviewer: None