

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Asian Neonatal Network Collaboration (AsianNeo): a study protocol for international collaborative comparisons of health services and outcomes to improve quality of care for sick newborn infants in Asia: Survey, cohort, and quality improvement studies
AUTHORS	Isayama, Tetsuya; Miyake, Fuyu; Rohsiswatmo, Rinawati; Dewi, Rizalya; Ozawa, Yuri; Tomotaki, Seiichi; Morisaki, N; Chee, Seok Chiong; Neoh, Siew Hong; Imperial, Ma. Lourdes S.; Velasco, Belen; Chang, Yun Sil; Cho, Sujin; Youn, YoungAh; Quek, Bin Huey; Poon, Woei Bing; Amin, Zubair; Jayaratne, Kapila; Kumara, L.P.C. Saman; Lin, Yuh-Jyh; Chang, Jui-Hsing; Lin, Hsiang Yu; Lin, Ming-Chih; Nuntnarumit, Pracha; Ngercham, Sopapan; Prempunpong, Chatchay; Prempraphan, Pathaporn; Supapannachart, Sarayut; Kusuda, Satoshi; AsianNeo, Asian Neonatal Network Collaboration

VERSION 1 – REVIEW

REVIEWER	Leweyehu Alemaw Mengstie Debre Berhan University
REVIEW RETURNED	15-Feb-2024

GENERAL COMMENTS	<p>Reviewer comment</p> <p>Comment 1= on title it is good if u include the study deign, based on journal guide line</p> <p>Comment 2=on heading of abstract please include sub heading of Registration details next to Ethics and dissemination section.read author guide for protocol</p> <p>Comment 3= potential implication sub heading are not in proper place</p> <p>Comment 4=heading –study aim, specific aim is not important,just delete it and for further read author guide for protocol</p> <p>Comment 5=the type of sampling tequinique, you used and sample size calculation are not clearly elaborate?</p> <p>Comment 6=what types of software used for analysis? Clearly elaborate it?</p> <p>Comment 7=what is your primary outcome?</p> <p>Comment 8=under heading ETHICS AND DISSEMINATION, writing the sub heading Ethics and dissemination is not important delete it and merge under the heading of “ETHICS AND DISSEMINATION”.in addition try to paraphrase and rewrite it.</p> <p>Comment 9= There is also a Discussion section but in my view that should be removed. Discussion is needed for the consideration of the results, but there are no results.</p> <p>Comment 10=summmry as asub heading on page 25 is not important</p> <p>Comment 11=for all of your papper cheack https://bmjopen.bmj.com/pages/authors#protocol author guide line</p>
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	from the following link and revise your manuscript.
REVIEWER	Kazumichi Fujioka Kobe University
REVIEW RETURNED	01-Apr-2024

GENERAL COMMENTS	<p>This is well designed international comparative collaborative project. The impact for including low and middle income country in terms of quality of intensive care for preterm babies is high, and this is necessary study.</p> <p>I would ask for authors several clarifications as below.</p> <ol style="list-style-type: none"> 1. The collaborative including 9 countries, however the study only include 5 of them in the project 2. I think it is due to the availability of the national database of respective countries, however it should be mentioned in the study introduction. It sounds like including all 9 countries in every projects. 2. Regarding the project 3, authors mentioned that databases of 4 other countries will be created, but is there a consensus that each country's database will be created using a system based in Japan? There is a risk that Japan will become dominantly involved in the medical information of the four countries. If possible, please mention about possibility of future transfer to each country's own data center. 3. It should be stated in the abstract that the number of included countries for projects 1-4 is different. 4. Please also describe the procedures if a country that is not currently included in the program newly participates.
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Mr. Leweyehu Alemaw Mengstie, Debre Berhan University

Reviewer 1's comment 1:

on title it is good if u include the study deign, based on journal guide line

Authors' reply to Reviewer 1's comment 1:

Thank you for the comment. Based on the suggestion of the reviewer1's suggestion, we added "Survey, cohort, and quality improvement studies" in the title.

Reviewer 1's comment 2:

Comment 2=on heading of abstract, please include sub heading of Registration details next to Ethics and dissemination section. Read author guide for protocol

Authors' reply to Reviewer 1's comment 2:

Thank you for the comment. The author guidelines mentioned that "Registration details should be included as a final section, if appropriate".

Because of the observational nature of the proposed studies, we do not plan to register them to trial registries. Therefore, we added the following sentences in the abstract.

"Registration details:

The registration of this study is not planned."

Reviewer 1's comment 3

Comment 3= potential implication sub heading are not in proper place

Authors' reply to Reviewer 1's comment 3:

Based on the reviewer's comment along with Editor's comment 1, we deleted the section 'potential implication' from the abstract.

Reviewer 1's comment 4:

Comment 4=heading –study aim, specific aim is not important, just delete it and for further read author guide for protocol

Authors' reply to Reviewer 1's comment 4:

Thank you for the suggestion. According to the reviewer's comment, we deleted the sections 'Study Aim' and 'Specific Aims'.

Then, we added the explanation of the AsianNeo in the 'INTRODUCTION' section as below.

Page 8, Lines 4-8

"In this context, the Asian Neonatal Network Collaboration (AsianNeo), comprising nine neonatal networks spanning low-, middle-, and high-income countries or regions (Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, and Thailand), was established with the aim of providing an international platform for pediatricians or neonatologists, researchers, and other healthcare providers.(17)"

In addition, we added the content of specific aims to the description of each project (Project 1 to 4) in the 'METHODS AND ANALYSES' section as below.

Page 11, Lines 9-10

Project 1: *“To understand differences in perinatal and neonatal healthcare systems, resources, and clinical management of sick newborns in Asian countries/regions, we plan to conduct _____”*

Page 12, Lines 11-12

Project 2: *“To describe and compare outcomes in sick newborns in Asian countries/regions, a retrospective cohort study of VLBW infants will be conducted _____”*

Page 18, Lines 5-7

Project 3: *“To establish a prospective patient registry of sick newborn infants (e.g., VLBW infants) among AsianNeo countries/regions through harmonizing database variable definitions, we will develop an AsianNeo registry _____”*

Page 20, Lines 7-9

Project 4: *“Based on the information obtained in Projects 1–3, we will develop and implement educational programs and quality improvement activities among AsianNeo country/regions and evaluate the effectiveness of their implementations.”*

Reviewer 1's comment 5:

Comment 5=the type of sampling technique, you used and sample size calculation are not clearly elaborate?

Authors' reply to Reviewer 1's comment 5:

Thank you for the comment. In fact, in the original manuscript, the explanation of the sampling method and sample size were described in the project 2 and 3 as below.

Original Page 14, Lines 1-3 (project 2) and Page 19, Lines 3-4 (project 3)

“The sample size of this study will be determined based on convenience sampling (data availability in each country/region).”

However, after receiving the reviewer's comment, we moved the sentences of the project 2 (Original Page 14, Lines 1-3) into the section 'analysis' as below to make them stand out.

Page 17, Lines 16-18

"Sample size and others

The sample size of this study will be determined based on convenience sampling (data availability in each country/region)."

Reviewer 1's comment 6:

Comment 6=what types of software used for analysis? Clearly elaborate it?

Authors' reply to Reviewer 1's comment 6:

We clarified the software as below.

Page 17, Lines 1 to Page 18, Lines 1-2

"All statistical analyses were performed using R Statistical Software (version 4.3.1; R Core Team 2021) with a 2-sided significance level of 0.05."

Reviewer 1's comment 7:

Comment 7=what is your primary outcome?

Authors' reply to Reviewer 1's comment 7:

The primary outcome was all-cause mortality prior to NICU discharge. It was described in the manuscript below.

Page 14, Lines 10-11

"The primary outcome for the comparison between countries and regions will be all-cause mortality prior to NICU discharge."

Reviewer 1's comment 8:

Comment 8=under heading ETHICS AND DISSEMINATION, writing the sub heading Ethics and dissemination is not important delete it and merge under the heading of "ETHICS AND DISSEMINATION".in addition try to paraphrase and rewrite it.

Authors' reply to Reviewer 1's comment 8:

According to the reviewer's comment, we deleted the sub-headings 'Ethics', and 'Dissemination' in the section of 'ETHICS AND DISSEMINATION'. Then, we moved the section 'Data ownership and intellectual properties' from the section to after the description of ethics and dissemination (Page 22, Lines13-19).

Reviewer 1's comment 9:

Comment 9= There is also a Discussion section but in my view that should be removed. Discussion is needed for the consideration of the results, but there are no results.

Authors' reply to Reviewer 1's comment 9:

We removed the 'DISCUSSION' section according to the reviewer's comment. However, we left the part of 'STRENGTH AND LIMITATIONS' without deleting because they were important information as a study protocol.

Reviewer 1's comment 10:

Comment 10=summry as asub heading on page 25 is not important

Authors' reply to Reviewer 1's comment 10:

Based on the Editor's comment, we deleted the 'Summary' section.

Reviewer 1's comment 11:

Comment 11=for all of your papper cheack <https://bmjopen.bmj.com/pages/authors#protocol> author guide line from the following link and revise your manuscript.

Authors' reply to Reviewer 1's comment 11:

We checked the Author Guide of BMJ Open and revised the manuscript accordingly.

Reviewer: 2

Dr. Kazumichi Fujioka, Kobe University

This is well designed international comparative collaborative project. The impact for including low and middle income country in terms of quality of intensive care for preterm babies is high, and this is necessary study. I would ask for authors several clarifications as below.

Reviewer 2's comment 1:

The collaborative including 9 countries, however the study only include 5 of them in the project 2. I think it is due to the availability of the national database of respective countries, however it should be mentioned in the study introduction. It sounds like including all 9 countries in every projects.

Authors' reply to Reviewer 2's comment 1:

Thank you for the important suggestion. We clarified the number of countries that will be included in each project (project 1-4) in the INTRODUCTION section as below.

Page 8, Lines 12-17

“For this purpose, in this study, we will perform four projects including (1) an institutional-level questionnaire survey (nine countries/regions), (2) a retrospective cohort study of VLBW infants (four countries/regions), (3) a prospective registry and cohort study of VLBW infants (six countries/regions), and (4) a quality improvement study (nine countries/regions). ”

Reviewer 2's comment 2:

Regarding the project 3, authors mentioned that databases of 4 other countries will be created, but is there a consensus that each country's database will be created using a system based in Japan? There is a risk that Japan will become dominantly involved in the medical information of the four countries. If possible, please mention about possibility of future transfer to each country's own data center.

Authors' reply to Reviewer 2's comment 2:

As an initial step, we will collect and transfer the data in these four countries to the database in the NCCHD, Tokyo, Japan, in this study. All the neonatal networks participating in this project agree with the data storage and analyses in Japan. However, as we mentioned in the manuscript, the data ownership belongs to each country or network that collect the data. So, any use of the data from each country should be approved by the steering committee members from each country where the data were collected. Japanese team will not use the data from each country without permission from each owner country as it was written as below.

Page 22, Lines 18 to Page 23, Lines 2

“All neonatal networks have the right to decline participation in certain projects or decline the use of data collected in their countries/regions for such projects.”

Reviewer 2's comment 3:

It should be stated in the abstract that the number of included countries for projects 1-4 is different.

Authors' reply to Reviewer 2's comment 3:

Thank you for the suggestion. We clarified that the number of participating countries in each project as below.

Page 3, Line 13 to Page 4, L1

“AsianNeo will undertake the following four studies: (1) institutional questionnaire surveys investigating neonatal intensive care unit (NICU) resources and the clinical management of sick newborn infants, with a focus on VLBW infants (nine countries/regions); (2) a retrospective cohort study to describe and compare the outcomes of VLBW infants among Asian countries and regions (four countries/regions); (3) a prospective cohort study to develop the AsianNeo registry of VLBW infants (six countries/regions); and (4) implementation and evaluation of educational and quality improvement projects in AsianNeo countries and regions (nine countries/regions).”

Reviewer 2's comment 4:

4. Please also describe the procedures if a country that is not currently included in the program newly participates.

Authors' reply to Reviewer 2's comment 4:

Thank you for your valuable suggestion. I added the following description in the manuscript.

Page 9, Lines 8-10

“New countries that are not currently members of the AsianNeo may apply for membership through the AsianNeo website (<https://asian-neo.org/index.html>), and upon approval by all the steering committee members, may join the AsianNeo.(17)”