Author’s response to reviews

Title: INA-RESPOND: A Multi-center Clinical Research Network in Indonesia

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Author’s response to reviews: see over
Point by point response to Reviewer comments

We thank the Reviewers for their helpful comments. We have tried to address the comments, questions, and corrections in our revised manuscript. A point-by-point response is listed below.

Reviewer 1:

General comments

The paper describes a new network to support infectious disease research in Indonesia in collaboration with the NIAID in the US. While this is clearly a laudable effort for the country, the paper presents only the most general aspects of the collaboration. The paper does not address the challenges faced by the network to fulfill its mission in the context of health research policy in the country. It would be important to identify those features of the collaboration that were designed specifically to meet the challenges.

Response: We thank the reviewer for this comment. We have added the following as the challenges that faced by the network to fulfill the mission and how the network address these challenges. All is added in a new section on page 11, line 256

CHALLENGES:

INA-RESPOND presented a unique approach to research in Indonesia. As a first step it was very important to engage stakeholders, researchers, national health programs and policy makers. Given that the more common paradigm was of externally sponsored research, it was important to encourage clinicians and health policy makers to identify research priorities in Indonesia and to enhance the understanding that the sustainability of the network depended on their own active and continued participation. Engaging busy clinicians in all research processes, from the preparation of study protocols to publication, and recruiting full time research assistants at the sites that were interested in a research career were also priorities.

To respond to these, INA-RESPOND engaged in meetings with stakeholders and developed an Advisory committee (as described above). On an ongoing basis the network holds regular trainings, workshops and seminars to build trust by involving and regularly updating all parties on the network activities. The network also provides opportunities for members to travel to national and international research conferences in areas of interest and holds regular Steering Committee meetings and issues a newsletter to review network progress. Researchers, stakeholders and research assistants are engaged in development of research concepts and protocols. Future plans include supporting researchers to complete master and doctorate degrees.

Specific comments

1. The introduction could make reference to the health research policy in the country, including its governance and administration and current funding. What is the importance of INA-Respond in financial and human resource terms?
Response: We agree with the reviewer. An explanation regarding health research policy, current funding, and the importance of INA-RESPOND in terms of finance and human resources are added in the background section, page 4 line 76, and page 5 line 105, as follows:

Indonesia is also working on incorporating research into its national agenda where health research is governed by several regulations. These include regulations about shipment of clinical specimens, biological materials and data sharing, intellectual property rights, health research as a part of national health system, transfer of technology, research results and publication, and community involvement and more recently the requirement to register clinical research. Infectious disease research and surveillance in Indonesia is managed by the Ministry of Health (MoH), Ministry of Research and Technology (MoRT), and Ministry of Education (MoE). Research and surveillance under the MoH are conducted by three government agencies: (1) the National Institute of Health Research and Development (NIHRD), (2) the Directorate General of Disease Control and Health Environment and (3) the Directorate General of Medical Services. Research at the MoRT is mostly conducted by the Eijkman Institute for Molecular Biology; and at the MoE by the medical and public health faculties.

Since the MoH budget for research is limited (44 million US dollars in 2014) and the priority is not for conducting clinical research, this partnership is advantageous as it can attract additional research funding by providing potential collaborators a well-developed infrastructure and facilities.

2. p. 4. The authors could also mention the threat of chronic diseases as a valid justification for internal and international networking.

Response: We agree with the reviewer. The interest of this network to collaborate in non-infectious and chronic diseases threat of chronic diseases, has been added on page 12 line 298, as follows:

Once research facilities exist they can be leveraged for non-infectious disease research as well. While research on infectious diseases is the current research focus of the network, INA-RESPOND is also interested to collaborate in non-infectious and chronic diseases since the threat of these diseases is also emerging. A soon to commence study will include a collaboration with the US National Cancer Institute of the NIH to evaluate smoking as a risk factor in diseases.


Response: We agree with the reviewer. We have added the references above
1) in the background (page 5, line 102):
Recognizing this, the National Institute of Health Research and Development (NIHRD) engaged in a partnership with the United States National Institutes of Allergy and Infectious Disease (NIAID) within the National Institutes of Health (NIH) to develop a network that could potentially become a leading scientific collaboration in the country to address questions of national and global impact, and to enhance the capacity for implementation research[7].

2) in the goals and values of the network (page 7, line 158):
Anticipating centrality towards the most established members, that is commonly found[7], INA-RESPOND is enhancing the research and laboratory capacities in all the sites so that site take turns as the principal investigators and they are able to perform standard laboratory assays.

3) in the organizational structure (page 8, line 193):
Financial and technical support for the network comes from the NIHRD under the MoH and the US NIAID under the Department of Health and Human Services (DHHS). Additionally, all partners contribute resources at their sites so that research is integrated within the hospitals. Unlike other collaborations or networks, which are often donor driven[7], all the strategic decisions are made by the steering committee and governing board, in which the donors have equal vote with other members.

4) in the future network vision and collaborations (page 13, line 298), as has also been described above:
While research on infectious diseases is the current research focus of the network, INA-RESPOND is also interested to collaborate in non-infectious and chronic diseases since the threat of these diseases is also emerging[9]. A soon to commence study will include a collaboration with the US National Cancer Institute of the NIH to evaluate smoking as a risk factor in diseases.

4. p. 8. It would be of interest to describe in greater detail the priority setting methods used by INA-Respond, and how they are addressing the challenges faced in the allocation of scarce research and health resources. Furthermore, the guidelines to assess relevance to priorities within research proposals could be described.

Response: We agree with the reviewer. The priority setting methods that are used by INA-RESPOND in addressing the scarce research and health resources are added in “Research implementation and Current Studies” section, page 10 line 227, as follows:
Research priorities identified and proposals received are evaluated by the steering committee based on country priorities as outlined by the MoH, potential impact, capacity building elements, current capabilities and resource allocation expected from the network. Selected ideas are forwarded to the Governing Board for prior to protocol development. INA-RESPOND is preparing guidelines that describe these procedures for potential collaborators as well as network members.

Reviewer: 2

Minor Essential Revisions:

1. Background, towards end of 2nd par.: ... NIH to develop a network that could potentially BECOME (not: becoming) a leading scientific collaboration ....

   Response: It has been corrected (page 5, line 105)

2. Authors information: MHG is an infectious diseases specialist .... Universitas Diponegoro, SEMARANG (NOT: Bandung).

   Response: It has been corrected (page 16, line 375)

3. Figure 2: Within the Box "Disease Control for Environmental Health", the first item probably is meant to be: Directorate of SEXUALLY Transmitted Disease Control.

   Response: It has been corrected to read: “Directorate of direct transmitted infectious disease control”.

Discretionary Revisions:

Research Implementation and Current Studies, 2nd par.: Protocols are reviewed......, followed by the Institutional Review Board (IRB) of record. Suggestions: I would suggest here to be mentioned explicitly: ...., including Research Ethics Committee review.

Response: We agree with the reviewer. Research Ethics Committee has been included (page 10, line 236) to read:

Protocols are reviewed by a scientific review committee at the NIHRD, followed by the Research Ethics Committee/Institutional Review Board (IRB) of record. To facilitate regulatory approvals, INA-RESPOND has developed reliance agreements between multiple IRBs to circumvent the need for multiple approvals.