Author’s response to reviews

Title: Analysis and exploration of infertility policies in Iran: A study protocol

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Author’s response to reviews:

Rosanna Gonzalez-Mcquire
Health Research Policy and Systems

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Dear Rosanna,

HRPS-D-19-00037
Analysis and exploration of infertility policies in Iran: A study protocol

Thank you for your e-mail and sending the reviewer’s comments for us. We found the comments very constructive and helpful. Please find the following point-by-point responses as requested. I hope you find the revisions satisfactory.

Wish you all the best.

Yours sincerely
Minoor Lamyian

Reviewer #1:

Thank you for the opportunity to review this protocol, which concerns an area of importance. I have few comments which require a substantial revision of the article, and therefore I did not read the entire article with an intention to provide detailed feedback, as the paper could change significantly.

Major comments
Objective 1: Review of infertility policies in selected countries and Iran: What type of a review are the authors reviewing? This objective needs to be a proper systematic literature review of infertility policies. As it is currently, it is unsystematic and prone to bias. Which countries will be included?
Clear criteria for geographic countries that will be involved, services (is it IVF, ART, ICSI or all of these?) outcomes of interest, search strategy (a bit of this is presented), data that you will extract, measurable indicators that you will compare, methods of synthesis and comparison (narrative or quantitative) etc should be strengthened. I suggest that 1) the authors look at the review recently conducted by researchers at Oxford such as Hirsch and James Duffy to see an example of policy review, and 2) to refer to appropriate guidelines for reviewing literature - e.g. PRISMA guidelines.

Thank you. We have now revised this section as follows:

Stage I: Review of infertility services policy in selected countries and Iran

At this stage a systematic literature review on infertility policies guided by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) will be performed [26].

a. Definition: The policy documents will be defined as all formal records and reports that were written by national governments, national scientific communities and academic societies, national authorities and international organizations' decisions, reports, plans and actions such as World Health Organization, World Bank, world health statistics, world development indicators and demographic and health survey. The type of evidence will include: provincial annual reports, core public health function/standards documents, health human resources (HHR), human resource planning (HRP) annual reports, business plan, commissioning policy documents, clinical guidelines, health profession legislation, and other public health (PH) reports such as competency development and leadership frameworks.

b. Search engines and time period: Documents will be selected from 1994 (since the Cairo Conference) until the end of 2018. The Cairo Conference recommended countries to plan and implement action to prevent and treat infertility [27]. The search engines will include PubMed, ISI, Google Scholar, all public websites, websites of health ministries, and websites of infertility clinics searching for review articles, gray papers, government records and guidelines, protocols, and clinical guidelines.

c. Search strategy: The search strategy will include a combination of keywords infertility, policy-making, affordability, availability, acceptability, awareness, responsibilities, insurance, health policy, prevention, financial management, childlessness, equity, utilization and cost.

d. Inclusion and exclusion criteria: Documents in English language that address the operational model of infertility programs, rules and policies will be included. The main focus at this stage will be on infertility policies, executive processes and prevention or implementation of policies in providing fair services in three levels (prevention, early treatment and supportive care). Irrelevant documents will be excluded. For instance, discussion papers, advertisements, video clips, newspapers, online advertising sites, movie content, and marketing channels will not be included.

e. Selection of countries: The selection of countries will be based on availability of appropriate documents and existence of comprehensive infertility policy from all five continents and from all income groups (high, middle and low) with the help of the expert panel and the research team.

f. Data extraction and synthesis: First a datasheet for each country will be prepared including the following information: name and aim of the policy, author(s) or organization name, and actors involved. These will be tabulated and made ready for further analysis (Table 1). Then, we will identify three components for each policy document as defined by universal health coverage (UHC). These are: 1) financial protection 2) population coverage 3) and service package including services for prevention, treatment and supportive care [28]. The indicators and practical definition of policy components were provided and was finalized in two sessions by an expert panel consisting of two specialists in health policy, two public health scientists, a gynecologist and a reproductive health specialist. These explanatory variables and indicators are described in Table 2. Then the findings will be scored. For each component if the policy satisfies the condition a score of 3 will be assigned, otherwise a score of 2 (intermediate) or 1 (low) will be considered (Table 3). Finally, a scoring sheet containing scores for all countries including Iran will be provided and compared. A hypothetical scoring sheet is provided in Table 4.
Stage II: Infertility policy analysis of Iran: After conducting the above literature review and synthesis, authors propose to use Walt and Gilson framework, by contacting and interviewing people and actors. So the authors will compare epistemologically different sets of research results. Given the parameters that the authors want to measure in Objective 1 above (e.g. equity, proportions covered by insurance, availability, affordability etc), how will the authors compare those parameters with qualitative themes --- which are essentially people's opinions and perspectives regarding fertility policies? This is a significant methodological mismatch which needs to be addressed. In my view the second objective should be a review of the actual published policies and guidelines documents in Iran to identify their context, contexts and actors (including institutions) that are prominent / have a role in these policies. Then, and only then could the authors then decide to conduct interviews etc, to respond to the PERCEIVED reasons as to why Iranian fertility policies are as they are. and that perhaps needs to be the third objective of this doctoral study. I hope that the authors find this suggestion useful.

This now was revised and the following changes were made as recommended:

A:
Stage II: Documentary analysis of Iranian infertility policies
At this stage, a review of the actual published policies and guidelines documents in Iran will be carried out [29,30]. As such we will use the content analysis. It is suitable for exploring rationales, strengths, and weaknesses of the infertility policies [31,32]. This will help us to identify content, context, process, and actors that are prominent or have a role in these policies. We will code all the data that extracted at stage I, and the rest of the documents related to the infertility care policies in Persian language. Thematic analysis then will be conducted, and categorized based on the Walt and Gilson (1994) framework.

B:
Exploration
In this stage, the policies resulted from the first stage will be integrated with the findings from qualitative content analysis in the second and third stages to synthesize a comprehensive proposed model for infertility prevention and care in Iran by the expert panel. The probable integration model of stages and hypothetical conditions are shown in Table 5[36].