Policy analysis of reducing neonatal mortality in Iran and suggesting policy options for high-burden provinces: Study protocol

Running title: Study protocol for neonatal mortality policy analysis, Iran

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Abstract

Background: Publishing study protocols have been growing recently due to its substantial benefits such as increasing the research transparency, reducing the selective reporting of the outcomes, and preventing unnecessary duplications of the research.

Objectives: This paper explains the rationale and methods of a policy analysis study on newborn mortality in Iran. Study objectives are: identifying the risk factors of neonatal mortality in Iran, identifying the experiences of successful countries, analysis of policies of reducing neonatal mortality in Iran, analysis for policies of reducing neonatal mortality in high-burden provinces of neonatal mortality in Iran.

Methods: This study has four steps each of which is corresponding to one aim of the study. The steps are: systematic review of the risk factors of neonatal mortality in Iran, comparative study of policy making of reducing neonatal mortality in successful countries, analysis of policies of reducing neonatal mortality in Iran by using policy models, and developing policy options for reducing the neonatal mortality in the high-burden provinces.

Conclusion: This study is designed for analysis of the policies of reducing neonatal mortality in Iran and then providing recommendations for the provinces that rank higher in terms of neonatal mortality. The study will identify the successes, failures, and defects of the policies. So, using them, we would be able to develop proper plans for more reductions of the neonatal mortality. Moreover, the findings and methods of this study can help other countries, especially the developing countries, in reducing their neonatal mortality and also in other areas of health such as under-five mortality and maternal mortality.

Keywords: Newborn, Mortality, Policy, Iran

1. Background

Mortality of the children under five years old is an important indicator of health of the countries and thus a major outcome for evaluating the health systems performance (1). This indicator is emphasized in Millennium Development Goals (MDGs) and then the Sustainable Development Goals (SDGs) (2). Evidence and statistics show that despite considerable declines in infant mortality rate (IMR) and in under-five mortality rate in recent decades, the neonatal mortality rate (NMR) experienced lesser and slower reduction (3). As a result, a significant proportion (nearly half) of the under-five mortality occurs in neonatal period which is defined to be the first 28 days of life (4). So the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) suggest that with the aim of reducing the under-five children's mortality, countries should focus on reducing the NMR (4).

Figure1 shows the trend of the NMR in Iran. In spite of the fast and significant decline of the NMR in past decades, the rate of decline has been slowed in recent years. So that, many neighbor and region countries have an NMR less than Iran (4). These factors caused us to want to analyze the policies of reducing the NMR in Iran and to provide recommendations that benefit from the experiences of successful countries. The evidence also shows that the distribution of the neonatal mortality within the country is not fair and some provinces have higher rate of newborn mortality- almost two times the average of the country (5). So this study will provide specific recommendations for these provinces.

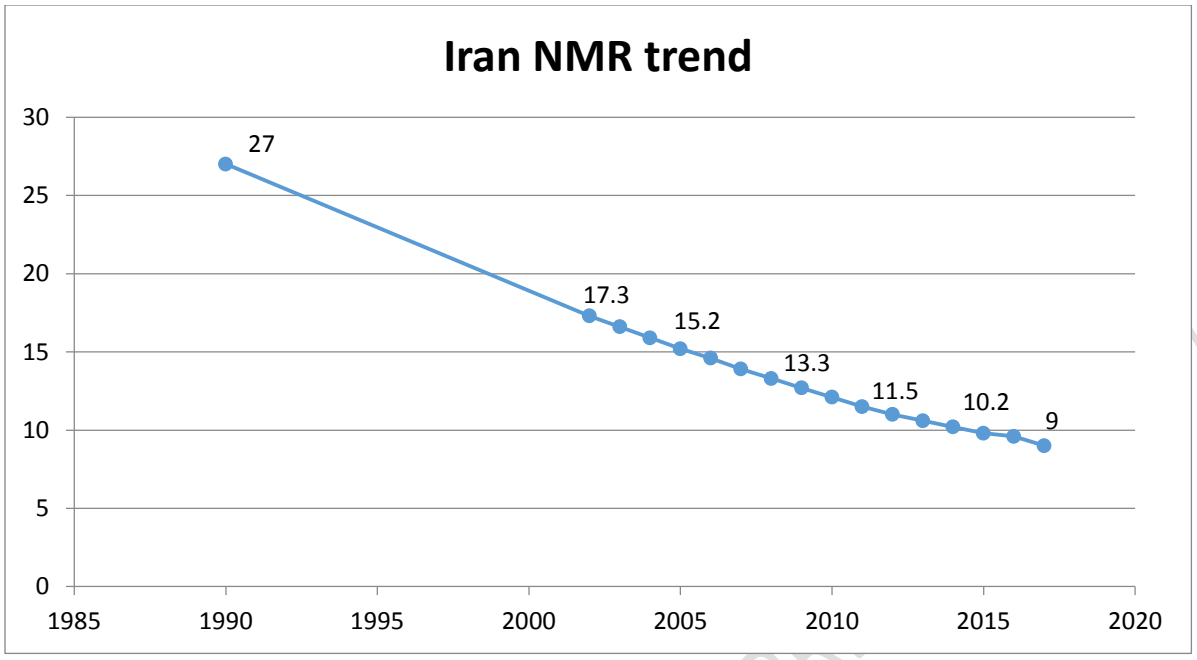

Figure1: Trend of neonatal mortality rate (NMR) in Iran (deaths per 1000 live births)
(Data from annual reports of the WHO and UNICEF)

Review of the domestic literature showed that the published studies mostly describe the rate, causes and risk factors of the neonatal mortality in a cross-sectional manner (6-11) and no study was available as policy analysis of neonatal mortality in Iran. The search of the international literature resulted in some papers on policies of reducing the neonatal mortality in some countries but they were limited in number and also limited to a particular aspect of the policy process such as agenda setting or stakeholder analysis (12-15). Thus no comprehensive study was found that had performed a policy analysis on reducing neonatal mortality considering all areas and steps of policy process. Moreover, the available studies were all retrospective and had investigated the past/present policies. But this study will perform an analysis for policy in a prospective manner for the provinces of high burden of neonatal mortality.

According to the reports of the WHO and UNICEF, some countries have had significant achievements in reducing neonatal mortality in last decades. An example of these countries is China which had reduced the NMR from 30 to 5 deaths in every 1000 live births between 1990 and 2017 (3). It had implemented several policies to do so. The most important ones are: establishing the Department of Maternal and Child Health Service in the Ministry of Health in 1990s (16), passing the Law on Maternal and Infant Health Care in 1994 to make the maternal

and neonatal health an essential part of development programs (16), running the Two Reductions Program to decrease the rates of both maternal and neonatal mortality in 2000 (16), implementing and expanding the New Rural Cooperative Medical Scheme in 2003 and then to increase the rate of births in health facilities (17), and adopting the Every Newborn Action Plan (ENAP) in 2015 (18).

2. Objectives

According to the above mentioned issues, this study is designed with the following aims:

- Identifying the risk factors of neonatal mortality in Iran
- Identifying the experiences of successful countries
- Analysis of policies of reducing neonatal mortality in Iran
- Analysis for policies of reducing neonatal mortality in high-burden provinces of neonatal mortality in Iran

3. Methods

This study has four steps each of which is corresponding to one aim of the study. The steps are described here.

Step one: Systematic review of the risk factors of neonatal mortality in Iran

In this step the risk factors of neonatal mortality in Iran will be identified. Inclusion criteria are: assessing at least one risk factor for neonatal mortality in Iran/one or more city, province, hospital, having control group (case-control or cohort study designs), and performing multivariate regression analysis and reporting odds ratio (OR). Exclusion criteria are: studying a specific population of newborns such as preterm newborns or low birth weight, having intervention, studying perinatal mortality and not separating still birth and maternal mortality with neonatal mortality, studying the causes of death instead of risk factors of death, case reports, and studies with no full-text available such as conference abstracts. The intended PICO items: Participants/Population: Iranian dead newborns, Intervention: no intervention, Comparator: Iranian alive newborns, Outcomes: risk factors of the neonatal mortality. The main outcome of

interest is the list of the risk factors of the neonatal mortality. The additional outcome is the ORs of each risk factor.

The literature search will be conducted using the keywords of "newborn, neonate, mortality, death, Iran" in Science Direct, Scopus, ISI web of science, EMBASE, Cochrane, and PubMed with no time limit. The search will repeat with Persian equivalents of the keywords in national databases of SID, Magiran, IranMedex, and IranDoc along with Google Scholar. The retrieved records will be pooled in EndNote X4 software and the duplicates will be removed. All included studies will be reference checked and citation checked. The Google Scholar Citation will be used for the citation check. Moreover, the key journals of the study subject will be hand searched for additional studies. An example of search strategy for PubMed is as: (((mortality [Title/Abstract]) AND iran[Title/Abstract])) AND ((newborn[Title/Abstract]) OR neonat*[Title/Abstract]).

The search for the papers will be performed by one of the research team and the quality appraisal will be performed by two of them. To select the proper tool for quality appraisal of the included studies, the recommendations of Zeng et al will be considered according to the study designs (19). To assure uniform handling of the data, an extraction form will be developed which will include language, year, journal name, authors, title, study design, study period, study place and population, sample size, data collection method, applied statistical test, and the findings of the risk factors of the neonatal mortality. The data will be extracted independently by two members of the research team and any disagreement will be resolved by discussion. Data analysis will have two parts of qualitative and quantitative. At the qualitative part the content analysis method will be used to identify and categorize the risk factors. The identified risk factors will be classified as maternal risk factors, neonatal risk factors, hospital risk factors, and socio-economic risk factors. And in the quantitative part, the odds ratios (ORs) reported for each risk factor will be synthesized by meta-analysis to get the effect size of each risk factor. The meta-analysis will be done by the CMA2 software and the forest plot will be drawn. Then regarding the prevalence of that particular risk factor, the number of the attributable deaths to each risk factor will be calculated. The heterogeneity of the studies will be assessed by considering the design and population of the studies and also by the I^2 statistics. Funnel plot will be applied for risk of bias for the included studies in the meta-analysis. This step of the protocol is written according to the

PRISMA-P checklist and the report of this step will be prepared according to the PRISMA checklist.

Step two: Comparative study of policy making of reducing neonatal mortality in successful countries

In this step, the policy making of reducing neonatal mortality in successful countries will be studied with a comparative approach. The aim of this step is to identify the successful policies of other countries and using their experiences of developing, implementing and evaluation of policies in the last step of the study which is proposing policy options for the high burden provinces. To select the countries the report 2017 of the UNICEF entitled "Levels and trends in child mortality" will be used so that those countries that reduced their NMR more than 60% between 1990 and 2015 will be selected (3). Then the country that had the most reduction in each regional office of the WHO will be selected. If the available data and evidence was limited about that particular country, the next country will be replaced. The primary list of these countries includes China, Cuba, Lebanon, Thailand, and Turkey.

Required data in this step will be gathered from the international reports, web sites of the international agencies such as WHO and UNICEF, web search, and research papers. To extract the data, a table will be used that is developed based on the conceptual framework of Green et al. and includes policy making process, context, evidence, content of the policies, outcomes of the policies, actors, and the nature of the policy problem (20).

At the "context" the general information of the country and its health system will be gathered including: healthcare financing, health work force, and service delivery. The "evidence" will include both the existence and use of the evidence. In the "actors" all individuals and organizations that have role in reducing the NMR will be identified and their type (public, private, NGO) and level of activity (local, regional, national) will be determined. In the "nature of the problem", the nature of neonatal death will be studied from the viewpoints of the people and authorities. The "policy making process" will include agenda setting, policy development, and policy implementation. In the "policy" all the executed programs for reducing the NMR will be reviewed. And finally, in the "policy outcome", the trend and changes of the NMR in that particular country will be studied.

Step three: Analysis of policies of reducing neonatal mortality in Iran by using policy models

This step will be conducted with qualitative approach and the required data will be gathered by in-depth interviews with experts and key informants. Moreover, a document review and analysis will be performed to complete the data and assure its accuracy. For the document analysis, all the related documents will be reviewed including the plans, programs, instructions, and national regulations. The Green model (20), as described in step two, will be applied for document analysis and by using the content analysis method. The PICO of this step are: Population: expert on neonatal health and related fields; Intervention: deployed policies; Context: Iran.

To conduct the interviews, the key informant people would be the current and previous authorities and experts from the Division of Newborn Health, Division of Children's Health, Division of Maternal Health, and Health Policy Making Council in the Ministry of Health and Medical Education. Moreover, some experts from the Association of Iranian Neonatologists, Association of Iranian Pediatricians, Association of Promotion of Breast Feeding, medical universities, hospitals with labor departments, Health Network of the county, professionals from the field of midwifery, nursing, pediatrics, and key researchers that had published several research papers on neonatal mortality would be interviewed. The inclusion criteria in this step is to have at least five years of working experiences in the fields related to newborn health. Purposive sampling method will be applied to select the participants so that those who have most information would include in the study. The sampling would be heterogeneous so that the participants would have maximum variety. They will be from various levels of policy making and implementation and from various organizations and interest groups. No sample size is calculated in this step and it is estimated that the number of participants will be 30 to 35 individuals. Yet, the data collection will be continued until the data saturation and thus may exceed this number.

Data collection tool in this step is a topic guide with open-ended questions for semi-structured interview. The topic guide will be developed based on the conceptual framework of the study, the Green model (20). The questions of the interview will be general so that the participant is encouraged to provide his/her opinions. Examples of the questions are: Please describe the process of making policies on newborn health (i.e. developing, implementing and evaluating the

policies); Which micro- and macro- level factors of social, cultural, legal, institutional and economic affect the policy making of the neonatal health?; What people and organizations influence the policies of the neonatal health and which of them are involved in? Applicability and understandability of the questions will be assessed after three pilot interviews and the required revisions will be made. The topic guide will include questions on all items of the Green model as discussed earlier. Furthermore, a few demographic characteristics of the participants will be recorded including: working history in the field of newborn health and care, the length of working experiences on newborn health, and the academic field of study.

After getting the permission of the participants, the interviews will be recorded as voice. In addition, the important points will be note taken during the interviews. The interviewers will avoid any expression on whether the opinion of the participant is true or false. Moreover, the tone of speech and non-verbal expressions and states of the participants during the interview will be noted. A digital voice recorder will be used for recording the interviews and another one will be kept for possible problems of the first one. The interviewers will avoid calling the participants by name during the interview to help keeping their identity confidential. The interviews will be conducted by one member of research team who is educated on qualitative studies and interview techniques. He is also familiar with the specific terminology of neonatal health.

To increase the validity of the data, the respondent validation will be applied so that at the end of each interview session, the participant will be provided with a summary of his/her statements. This is because of making sure that the statements are correctly understood by the researcher. The participant will also be asked that if he/she want to add any other statement to the previous ones.

Date, time and place of the interviews will be assigned by the agreement of the participants and preferably at their work place to help them feel comfortable. At the beginning of each interview session the interviewer will provide a brief description of the study and its aims and also the applied measures for keeping the confidentiality of the identities. Then the written informed consent form will be signed by the participant. The participants will be assured that they can quit the study at any stage of the study. Finally, the contact information of the participant will gathered for possible future connections. The time of each interview is estimated to be 45 minutes.

The data collection and analysis will be performed simultaneously so that after each interview, its text will be analyzed and then the next interview will be conducted. After conducting each interview the recorded voice will be transcribed and the notes of the interview and the non-verbal observations will be added to it. Moreover, the characteristics of the participant and time and place of the interview will be added to it to accelerate future works of analysis and interpretation. The analysis will be done independently by two members of the research team and any conflicts will be solved by discussion.

The deployed policies to reduce the NMR in Iran will be extracted from the interviews and, in more details, from the document review which will include major programs and instructions is past years. Moreover, the trend of the NMR will be derived from the national data on the neonatal mortality (the IMAN network) and the reports of the WHO and UNICEF.

Framework analysis method will be applied for the analysis of the data of the interviews. It is a kind of qualitative content analysis that categorizes and summarizes the data in a thematic manner to facilitate the analysis. The analysis will begin with reading the transcribed text of the interviews several times to get familiarized. Then the codes, sub-themes and themes will be derived from the text. The themes will be organized according to the conceptual framework of the study which is described in the next paragraph. To assure the reliability of the coding and the themes, a part of the text will be analyzed by another researcher and then their agreement will be assessed.

Three conceptual frameworks will be applied in the step of the study. Generally the framework developed by Green et al (20) will be used for the analysis of the policies of the reducing neonatal mortality in Iran. The framework is described in step two. The other framework is the Stages Model of policy making process (21). The Green model has the parts of Agenda setting, Policy development, and Policy implementation. But the Stages model has the Evaluation of the policies in addition to them. So we will use the stages model for the Policy Making Process within the Green model. Within the Stages model, the first stage is the Agenda Setting which has separate models such as Kingdon's Three Stream model (21). So we will use a separate model for agenda setting within the Stages model to be able to work on more details. The model developed by Shiffman and Smith has more details than the Kingdon's model and explicitly considers the factors that affect the agenda (22). The Shiffman and Smith model of agenda

setting will be applied in this step of the study and it has the items of: power of the actors, political environment, ideas, and the characteristics of the issue. Framework analysis is a method of qualitative data analysis in which a framework is used to categorize the themes and sub-themes identified in the data. It helps the researchers to put the codes of the qualitative data into the pre-defined items of the framework. In this study the mentioned three frameworks will be applied within each other to assure more detailed work on the data and to provide more comprehensive picture of the study subject.

Step four: Developing policy options for reducing the neonatal mortality in the high-burden provinces

This step will be conducted with qualitative approach and some recommendations will be made for the high-burden provinces to assist them in reducing the neonatal mortality. The recommendations will be in the form of policy brief. The high-burden provinces are defined as the provinces that have the highest rate of neonatal mortality (NMR) in the country. They include Sistan and Baluchestan, Kermanshah, and Hormozgan provinces.

The solutions derived from the literature review at the Step Two will be compared with the findings of this step to make the researchers able to provide better policy options. Yet, the policy options will consider the context of the provinces in terms of social, economic, and cultural characteristics.

This step has no document analysis but stakeholder analysis will be performed with more details than the previous step. Sampling will be similar to step three and the participants will be key informants from national and local involved organizations. Data collection tool and method and also data analysis will be similar to step three. The findings of the steps one, two and three will also be used to develop the policy options. The conceptual framework for this step the Green model which is described in step two. The methodological difference of this step with step three is that the frameworks and data were used to analyze the past and current policies of reducing neonatal mortality in step three which is called analysis of policy. But they will be applied in a prospective manner to develop new policies in step four which is called analysis for policy.

The study is of a Ph.D. thesis in the field of Health Policy in Iran University of Medical Sciences (IUMS). The protocol has been reviewed and approved by the Institutional Review Board as well

as the Ethics Committee of the pertaining university. The study protocol is registered at 2017 in IUMS and currently is running.

4. Discussion

The results of the study will determine the successes, failures, and defects of the policies of reducing NMR in Iran. So, using the findings of this study, the authorities of the newborns' health would be able to develop proper strategies to accelerate the reduction of newborns' deaths. In addition, focusing on the high-burden provinces and recommending separate policy options for them might help the Ministry of Health to specially concentrate on those provinces. The reduction of the NMR in these provinces would highly reduce the average NMR of the country.

The possible reduction in the NMR will result in reduced under-five children mortality (4) and also increased life expectancy of the country (23). Then health situation of the country and its rank worldwide will be improved (24). On the other hand, reducing the NMR in high-burden provinces would improve the equity in health among the provinces of the country (25).

The methods applied in this study can be a benchmark for other countries, especially the developing ones so that they can analyze their policies of reducing neonatal mortality and then adopt proper strategies according to their context. Furthermore, these methods can be applied for other important health indicators such as under-five mortality and maternal mortality.

In addition to the application of the results of the study, each step of it has its own application at the next step of the study which is mentioned here. The findings of the first step – the systematic review of the risk factors of neonatal mortality- would lead to identification of the major risk factors of neonatal mortality in Iran and then based on these findings, proper strategies would be proposed in the final steps of the study. At the step two, the policies of the successful countries will be reviewed. Findings of this step would help us as benchmarks in developing the policies for the provinces. Yet, the benchmarking would consider the context, actors, and other elements of the target provinces (21). The third step will shed light on the strengths and weaknesses of the current and past policies and then we will be able to develop new policies with higher probability of success. Finally, the fourth step will help the provinces to decline their NMR.

5. Conclusion

This study is designed with the aim of analysis of policies of reducing neonatal mortality in Iran and analysis for policies of reducing neonatal mortality in the provinces that have highest NMR. The study outputs will be recommendations for the neonatal health policies of the country along with specific recommendations for the provinces that have highest rate of the NMR.

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Author contribution

AD, HR, and MJ contributed in conception of the study; AD will collect the data; AD and HR will analyze the data; AD drafted this manuscript and will draft the next ones; HR and MJ critically revised this manuscript and will do the next ones; HR supervises the study; AD, HR and MJ approved this manuscript.

Conflict of interest

The authors declare no conflict of interest.