

Study Protocol: The Policy Analysis of Reducing Neonatal Mortality in Iran



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ABSTRACT

Context: Publishing study protocols have been recently growing due to their substantial benefits. Such advantages include increasing the research transparency, reducing the selective reporting of outcomes, and preventing the unnecessary duplications of research. This paper explained the rationale and methods of a policy analysis study on newborn mortality in Iran. The study objectives are identifying the risk factors of neonatal mortality in Iran, identifying the experiences of successful countries in this area, analyzing the policies of reducing neonatal mortality in Iran, analyzing the policies of reducing neonatal mortality in the high-burden provinces of neonatal mortality in Iran.

Methods: This study consists of four steps; each corresponds to one aim of the study. The steps are as follows: A systematic review of the risk factors of neonatal mortality in Iran, a comparative study of policymaking to reduce neonatal mortality in successful countries, the analysis of policies of reducing neonatal mortality in Iran using policy models, and developing policy options for reducing the neonatal mortality in the high-burden provinces.

Conclusions: This study is designed for analyzing the policies of reducing neonatal mortality in Iran. The results may provide recommendations for the provinces with high rates of neonatal mortality. The study will identify the advantages, disadvantages, and defects of the existing policies. As a result, we would be able to develop proper plans to further reduce neonatal mortality. Moreover, the findings and methods of this study can help other countries, especially the developing ones, in reducing their neonatal mortality. The data could also be beneficial in other healthcare areas, including under-five mortality and maternal mortality.

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1. Context

The mortality rate of children aged ≤ 5 years is an essential health indicator of countries; thus, it is significant in evaluating the health systems performance (1). This indicator is emphasized in the Millennium Development Goals (MDGs) and the Sustainable Development Goals (SDGs) (2).

Evidence suggests considerable declines in Infant Mortality Rate (IMR) and the under-five mortality rate in recent decades; however, the Neonatal Mortality Rate (NMR) experienced minor and slow reduction (3). As a result, a significant proportion (nearly half) of the under-five mortality occurs in the neonatal period, defined as the first 28 days of life (4). Therefore, the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) suggested that to reduce the under-five children's mortality, countries should focus on reducing the NMR (4).

Figure 1 shows the trend of NMR in Iran. Despite the fast and significant decline of the NMR in the past decades, such decline rate has been slowed in recent years. As a result, many neighbor and region countries have an NMR less than Iran (4). In this regard, we aimed to analyze the policies of reducing the NMR in Iran and to provide recommendations that benefit from the experiences of successful countries in this area. The neonatal mortality is not equally distributed in Iran; some provinces have higher rates of newborn mortality (almost two times higher than the country's average rate) (5). Therefore, the designed study will provide specific recommendations for these provinces. (Data are obtained from the annual reports of WHO and UNICEF)

The domestic studies mostly described the rate, causes, and risk factors of the neonatal mortality in a cross-sectional manner (6-11). There was no policy analysis study

on neonatal mortality in Iran. The available international data on the policies of reducing the neonatal mortality were limited and only considered a particular aspect of the policy process, like agenda-setting or stakeholder analysis (12-15). Thus, no comprehensive policy analysis was found on reducing neonatal mortality considering all policy process dimensions. Moreover, the available studies were all retrospective and only investigated the past/present policies. Therefore, this study will perform a prospective policy analysis of the provinces with a high burden of neonatal mortality.

According to the WHO and UNICEF, some countries have had significant achievements in reducing neonatal mortality in the 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). China had implemented several policies for this purpose. Their most essential measures were as follows: establishing the Department of Maternal and Child Health Services in the Ministry of Health in 1990s (16); passing the Law on Maternal and Infant Healthcare in 1994 to make the maternal and neonatal health an essential part of the development programs (16); running the Two Reductions Program to decrease the rates of maternal and neonatal mortality in 2000 (16); implementing and expanding the New Rural Cooperative Medical Scheme in 2003 and increase the rate of births in health facilities (17), and adopting the Every Newborn Action Plan (ENAP) in 2015 (18).

According to the issues mentioned above, this study is designed with the following aims: 1. Identifying the risk factors of neonatal mortality in Iran; 2. Identifying the experiences of successful countries; 3. Analyzing the policies of reducing neonatal mortality in Iran; 4. Analyzing the policies of reducing neonatal mortality in the high-burden provinces of neonatal mortality in Iran.

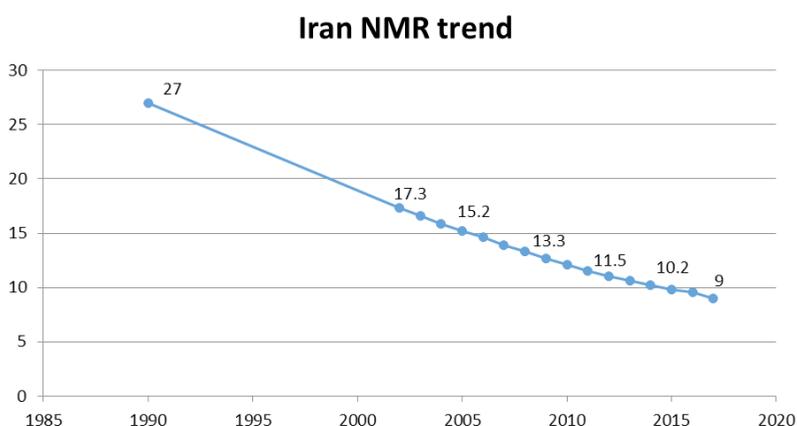


Figure 1. The trend of NMR in Iran (deaths per 1000 live births)

2. Methods

This study has four steps; each step corresponds to one aim of the study. The steps are described below.

2.1. Step one: The 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. The inclusion criteria are assessing at least one risk factor for neonatal mortality in Iran/one or more cities, provinces, hospitals, the existence of a control group (case-control or cohort study designs), performing multivariate regression analysis, and reporting Odds Ratio (OR). The exclusion criteria are studying a specific population of newborns (e.g. preterm newborns or low birth weight), conducting interventions, studying perinatal mortality and the lack of distinguishing stillbirth and maternal mortality from neonatal mortality, studying the causes of death instead of its risk factors, case reports, and studies with no full-text available, like conference abstracts. The intended Patient, Intervention, Comparison, Outcome (PICO) items are as follows: the study participants/population: Iranian dead newborns; intervention status: No intervention; comparator: Iranian live newborns, and outcomes: the risk factors of neonatal mortality. The primary outcome of interest is the list of risk factors of neonatal mortality. The additional outcome is the ORs of each risk factor.

The literature review will be conducted using the keywords of “newborn, neonate, mortality, death, and Iran” in Science Direct, Scopus, ISI web of science, EM-BASE, Cochrane, and PubMed databases with no time limitation. The search will be repeated with the Persian equivalents of the keywords in the national databases of SID, Magiran, IranMedex, and IranDoc along with Google Scholar search engine. 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 follows: (mortality [Title/Abstract]) AND (Iran[Title/Abstract]) and (newborn[Title/Abstract]) OR (neonat*[Title/Abstract]).

The article search will be performed by a research team member, 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 the uniform handling of the data, an extraction form will be developed, including 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 independently be extracted by two members of the research team. Furthermore, any disagreements will be resolved by discussion. Data analysis will include two qualitative and quantitative parts. 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, neonatal, hospital, and socioeconomic risk factors.

Moreover, in the quantitative part, the ORs reported for each risk factor will be synthesized by meta-analysis to measure the effect size of each risk factor. The meta-analysis will be performed 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 considering the design and population of studies and by the I2 statistics. Funnel plot will be applied for detecting the risk of bias in the included studies in the meta-analysis. This step of the protocol is developed according to the PRISMA-P checklist. Moreover, the report of this step will be prepared according to the PRISMA checklist.

2.2. Step two: The comparative study of policymaking of reducing neonatal mortality in successful countries

In this step, a comparative approach will be used to study the policymaking of reducing neonatal mortality in successful countries. The aim of this step is to identify the successful policies of other countries and use their experiences of developing, implementing and evaluating policies in the last step of study; i.e. proposing policy options for high burden provinces. To select the countries, the UNICEF 2017 report entitled “levels and trends in child mortality” will be used; as a result, countries that reduced their NMR more than 60% between 1990 and 2015 will be selected (3). Then, the country with the most reduction in each regional office of the WHO will be selected. In the case of data scarcity about that particular country, the next identified country will replace it. The primary list of these countries includes China, Cuba, Lebanon, Thailand, and Turkey.

The required data in this step will be gathered from the international reports, the international agencies’ websites, like WHO and UNICEF, web search, and research

papers. To extract the data, a table will be used developed based on the conceptual framework of Green et al. which includes policymaking process, context, evidence, the policies' content, the policies' outcomes, action takers, and the nature of the policy problem (20).

In the "context", the general information of country and its health system will be gathered. Such data will include healthcare financing, health workforce, and service delivery. The "evidence" will include both the existence and use of evidence. In the "action takers" part, all individuals and organizations with a 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" part, the nature of neonatal death will be studied from the viewpoints of people and authorities. The "policymaking process" will include agenda setting, policy development, and policy implementation. In the "policy", all the executed programs for reducing the NMR will be reviewed. Finally, in the "policy outcome", the trend and changes of NMR in one particular country will be studied.

2.3. Step three: The analysis of policies of reducing neonatal mortality in Iran using policy models

This step will be conducted by a 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 using the content analysis method. The PICO of this step are as follows: population: an expert on neonatal health and related fields; intervention: deployed policies, and 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 Policymaking 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, the Health Network of country, professionals from the fields of midwifery, nursing, pediatrics, and key researchers who published several research papers on neonatal mortality would be interviewed. The inclusion criterion in this step is to have ≥5 years of working experiences in the fields related to

newborn health. The purposive sampling method will be applied to select the study participants; thus, those with the most information would include in the study. The sampling would be heterogeneous to achieve the maximum possible sample variety. They will be selected from various classes of policymaking and implementation and different organizations and interest groups. No sample size is calculated in this step. Additionally, the number of participants is estimated to be 30 to 35 individuals. The data collection will be continued until the data saturation; thus, we may exceed this number.

A topic guide with open-ended questions for a semi-structured interview will be applied in this step. The topic guide will be developed based on the conceptual framework of study, the Green model (20). The interview questions will be general to encourage the participants to provide their opinions. Some examples of the questions include the following: "Please describe the process of making policies on newborn health (i.e. developing, implementing and evaluating the policies)"; "Which micro- and macro-level sociocultural, legal, institutional, and economic factors affect the policymaking of neonatal health?"; and "Which people and organizations influence the neonatal health policies and which of them are involved in that?" The applicability and clarity of the questions will be assessed after conducting three pilot interviews and the necessary revisions will be made. The topic guide will include questions on all items of the Green model, as discussed earlier. Furthermore, some demographic characteristics of the study participants will be recorded. Those will include working history in the field of newborn health and care, the duration of working experiences on newborn health, and the academic field of study.

After obtaining the participants' consent, the interviews will be voice-recorded. In addition, the important points will be noted 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 the participants' states will be noted during the interview. A digital voice recorder will be used for recording the interviews, and another one will be used as a backup for the first one. The interviewers will avoid calling the participants by name during the interview to protect their identity confidentiality. The interviews will be conducted by a research team member, educated on qualitative studies and interview techniques. He is also familiar with the specific terminology of neonatal health.

To improve data validity, the respondent validation will be applied; therefore, at the end of each interview session, the participant will be provided with a summary of his/her statements. This is to assure that the statements are correctly understood by the researcher. The participant will also be requested to add other statements to the previous ones, if desired.

The date, time, and place of interviews will be assigned by the agreement of the participants and preferably at their workplace 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 as well as the applied measures for protecting the identities' confidentiality. Then, a written informed consent form will be signed by the participant. The participants will be assured that they can quit the study at any stage. Finally, the contact information of the participant will be obtained for possible future connections. Each interview is estimated to last 45 minutes.

The data collection and analysis will be performed simultaneously; thus, after each interview, their transcripts will be analyzed before conducting the next interview. After conducting each interview, the recorded voice will be transcribed, and the relevant notes and non-verbal observations will be considered. Moreover, the subject's characteristics and the time and place of interview will be added to accelerate future works of analysis and interpretation. The analysis will be conducted independently by two research team members. In addition, any conflicts will be solved by discussion.

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

Framework analysis method will be applied to analyze the interviews' data. It is a qualitative content analysis that categorizes and summarizes data in a thematic manner to facilitate the analysis. The analysis will begin with reading the transcribed text of interviews several times for familiarization. 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 themes, a part of the text will be analyzed by another researcher; then, their agreement will be assessed.

Three conceptual frameworks will be applied in this step of the study. Generally, the framework developed by Green et al. (20) will be used for analyzing the policies of reducing neonatal mortality in Iran. The framework is described in step two. The other framework is the Stages Model of policymaking process (21). The Green model includes agenda setting, policy development, and policy implementation parts. However, the Stages model covers the evaluation of policies in addition to the aforementioned parts. Therefore, we will use the stages model for the policymaking process within the Green model.

In the Stages model, the first stage is agenda setting, which comprises separate models like Kingdon's Three Stream model (21). Thus, we will use a separate model for agenda-setting in 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 affecting the agenda (22). The Shiffman and Smith model of agenda-setting will be applied in this step of the study. It consists of power of the action takers, political environment, ideas, and the issue characteristics items. Framework analysis is a 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 framework. In this study, the mentioned three frameworks will be applied within each other to assure more detailed work on the data. This also provides a more comprehensive picture of the study subject.

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

This step will be conducted using a qualitative approach. As a result, some recommendations will be made for the high-burden provinces in terms of reducing neonatal mortality. The recommendations will be provided in the form of the policy brief. The high-burden provinces are defined as those with the highest NMR in the country. They include Sistan and Baluchestan, Kermanshah, and Hormozgan provinces.

The solutions derived from the literature review at step two will be compared with the findings of this step. Such comparison enables the researchers to provide better policy options. The policy options will consider the context of provinces in terms of socioeconomic and cultural characteristics.

This step has no documented analysis; however, the stakeholder analysis will be performed with more details than the previous step. Sampling will be similar to step three, and the participants will be critical informants from national and local involved organizations. The data collection tool and

method, as well as data analysis, will be similar to step three. The findings of steps one, two, and three will also be used to develop the policy options. The conceptual framework for this step will be the Green model, described in step two. The methodological difference of this step with the 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 the analysis of policy. However, they will be applied in a prospective manner to develop new policies in step 4, which is called the analysis for policy.

3. Discussion

The results of the designed study will determine the successes, failures, and defects of the policies of reducing NMR in Iran. Therefore, the findings of this study may be beneficial for the authorities of the newborns' health 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 and Medical Education to specially concentrate on such provinces. The reduction of NMR in these provinces would highly reduce the average NMR of the country.

The possible reduction in the NMR will reduce under-five children mortality (4) and increase the life expectancy of the country population (23). Then, the health status of the country and its worldwide ranking will be improved (24). In addition, reducing the NMR in high-burden provinces would improve the health equity in the provinces of country (25).

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

In addition to the application of the study results, each step of it has its 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 the identification of the major risk factors of neonatal mortality in Iran. Accordingly, based on these findings, proper strategies would be proposed in the final steps of study. At the step two, the policies of successful countries will be reviewed. The findings of this step would help us as benchmarks in developing the policies for the provinces. The benchmarking would consider the context, action takers, and other elements of the target provinces (21). The third step will clarify the advantages and disadvantages of the

current and past policies. As a result, we will be able to develop new policies with higher odds of success. Eventually, the fourth step will help the provinces to decline their NMR.

4. Conclusion

The study is designed to analyze the policies of reducing neonatal mortality in Iran. We also aim to analyze the policies of reducing neonatal mortality in the provinces with the highest NMR. The study outputs will be recommendations for the neonatal health policies of the country along with specific suggestions for the provinces with the highest NMR.

Ethical Considerations

Compliance with ethical guidelines

The protocol has been reviewed and approved by the Institutional Review Board as well as the Ethics Committee of IUMS. The study protocol was registered in 2017 in IUMS and is currently running.

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Authors contributions

Conception of the study and approving: All author; Collect the data and drafting this manuscript: Amin Daemi; Analyze the data: Amin Daemi and Hamid Ravaghi; Revising this manuscript: Hamid Ravaghi and Mehdi Jafari; Supervising the study: Hamid Ravaghi.

Conflicts of interest

The authors declared no conflict of interest.

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