BMJ Open Vaccine hesitancy from the parent perspectives: protocol for a qualitative study in Iran

Maziar Moradi-Lakeh,¹ Salime Goharinezhad ¹,² Soodabeh Hoveidamanesh,³ Ali Amirkafi,⁴ Seyed Mohsen Zahraei,⁵ Babak Eshrati⁶

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For numbered affiliations see end of article.

Correspondence to

Dr Salime Goharinezhad; goharinezhad@gmail.com

ABSTRACT

Introduction WHO declared vaccine hesitancy as a global public health threat in 2019. Since even a slight reduction in vaccine coverage rates can lead to a decrease in herd immunity, it is imperative to explore the underlying factors affecting vaccine hesitancy. This qualitative study protocol aims to explore determinant factors that influence vaccine hesitancy in Iran from the parent's perspective.

Methods and analysis Descriptive-Interpretive Qualitative research will be conducted to gain an insight into vaccine hesitancy in the west of Tehran province in Iran. Participants in the study will be recruited from vaccine-hesitant parents of children under 5 years' old who will be recognised as being hesitant to extract from the national health information system. The semistructured interviews and in-depth questions will be performed both face-to-face in an open space such as a park near their homes and via video call because of the COVID-19 pandemic and social distancing. Interviews will be conducted by a trained qualitative person. Transcribed data will be analysed through thematic analysis.

Ethics and dissemination Ethics approval was obtained from the research ethics committee at the Iran University of Medical Sciences (Approval ID #IR.IUMS.REC.1399.273). The results of the study are expected to be presented by the end of 2022 year. A variety of dissemination methods will be employed to communicate research findings, including presentations at conferences and peer-reviewed publications.

INTRODUCTION

Vaccination is considered as one the most successful health interventions of 20th century.¹ The effectiveness of this intervention is based on the number of the people who are immunised based on the direct effect of vaccine efficacy; and a second way of reaching 'herd immunisation'.² This type of immunity is achieved through decreasing the number of successful transmissions due to the reduced number of non-immunised population.³

However, during the past years, the concerns regarding the 'safety or effectiveness of immunization programs', 'questioning the need and benefit of vaccines', 'trust on

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Using personal stories of participants to probe more deeply into factors affecting vaccine hesitancy.
- ⇒ An expert in qualitative research, as well as public health experience, will conduct all study interviews.
- ⇒ In order to ensure maximum diversity, we will recruit participants from a wide range of socioeconomic backgrounds, education levels, living environments (rural, urban), age groups and ethnicities.
- ⇒ In this study, participants will come from the west of Tehran province, and their opinions may not be representative of other parents within the country or elsewhere

the health system/care providers and intentions' as reasons for vaccine hesitancy have increased, and caused spread of a term called 'Vaccine Hesitancy' more than before. This term is defined as delay in acceptance or refusal of vaccination. This definition consists of a broad range of beliefs from the ones who take all vaccines but are not completely sure about them, to the ones who refuse to take any vaccines because of their concerns whether against their efficacy or the possible side effects.⁴⁵

Vaccine hesitancy and refusal is not a problem limited only to some parts of the world, all countries are facing different levels of scepticism. Hesitancy and refusal rates vary from country to country mostly influencing the countries with higher income.⁴

More specific studies are conducted in different regions showing the people of all countries have some levels of doubt for vaccination. A study shows a refusal rate of 10.6% and hesitancy rate of 19.5% in Croatia; 12–13% refusal rate in North Carolina, USA and 12% of Italians vaccinate their children only because its mandatory.⁶ In Malaysia, this hesitancy rate in a sample of parents was measured 11.6% according to the studies criteria; although in the rest of the sample,

many parents did not totally agree with the immunisation routine and had concerns regarding vaccines' side-effects (40%), safety and efficacy (37.4%).⁷

Taking into account the prevalence and the increasing trend, it is important to find the roots of this international concern.⁸ Vaccine hesitancy and refusal is a multidimensional phenomenon, which is caused by different factors.⁹ It can be assessed in individual level in addition to sociocultural one. Lack of knowledge and information, previous unsatisfactory experience, risk perception, parental age and income in addition to cultural, moral and religious believes are among the causes of this upward trend.¹⁰ Notably with the daily expansion of internet and social media in our everyday lives, the information shared through them can play a vital role towards the decisions of individuals.¹¹ It is important to take note that the role of health professionals in giving correct information as most people consider them trustworthy and reliable. And finally the national policies can impact the perception of the people.¹²

Having roots in various personal and social factors, this situation can lead to some serious public health issues. For instance, the resurgence of Measles in Europe is an appropriate example. Currently, nearly all European countries are suffering from new cases of Measles, a disease that was supposed to be eliminated by the year 2020.¹³ This situation is emerged due to the increased number of people with hesitancy towards vaccination. This attitude comes from different reasons and is prevalent in nearly all countries but is more prominent in particular countries which led to a problem in the whole region due to international travels and contacts.¹⁴

WHO declared the vaccine hesitancy as a global public health threat in 2019.¹⁵ Since even a slight reduction in vaccine coverage rates can lead to decrease herd immunity, it is imperative to explore the underlying factors affecting vaccine hesitancy. In specific contexts, considering socioeconomic and cultural variation, to ensure interventions targeting hesitancy are well formulated and intervened.²

Qualitative data collection by focus on the participant's knowledge and attitude is common method to investigate complex sociocultural and behaviours factors related to vaccine refusal and hesitancy, in fact, it helps to capture various meaningful factors and a deep understanding that underlie vaccine hesitancy. It also leads to identify the contextualise factors toward tend to immunisation. Therefore, we aim to assess the vaccine hesitancy in Iran to explore themes related to the vaccination hesitancy.

The objectives of this study are:

- 1. Exploring parents' views, experiences and perceptions of routine vaccines.
- 2. Discovering the language parents use to express vaccine hesitancy.
- 3. Finding out factors that drive and force Iranian parents to refuse vaccinations.
- 4. Digging out how Iranian parents obtain information about vaccinations.

5. Developing a contextual framework that captures the Iranian parent's experiences and processes of planning to fulfil the routine immunisation of children.

METHODS AND ANALYSIS Study design

Studies have shown that parental vaccine refusal is a growing phenomenon worldwide. It is therefore vital to investigate the perceptions of those who declined some or all childhood vaccination. A qualitative study design with an interpretive descriptive methodology can answer the complex and contextual-based question. This design is applied when the aim of the study is to explore a phenomenon and consider its significance especially when a gap of knowledge exists on the topic.

'Interpretive Description' ID helps to develop evidencebased knowledge informed by exploring the perceptions and experiences of the targeted participants and provides deep insights to generate new information that can enhance future policies.¹⁶

This method also facilitates a highly adaptable qualitative approach that can clear phenomena that policymakers need to comprehend. In this approach unlike traditional qualitative studies, an experienced and knowledgeable researcher is the main source of insight. The researcher's engagement with the data can create an interpretation of the studied context.¹⁶

Study setting

Iran's Ministry of Health and Medical Education oversees 68 universities and faculties that implement its macropolicies and plans. Every medical university in Iran has a geographic catchment area that provides healthcare services to the areas within it. In the metropolis of Tehran, as the capital of the country with more than 13 million populations, all health service activities were provided by the three universities of medical sciences. One of them is the Iran University of Medical Sciences (IUMS), which covered the largest population among three medical universities in the Tehran Province. In fact, healthcare delivery in the West Regions of Tehran Province is under the supervision of the IUMS. This area consists of more than 5 million populations. The geographical situation of the areas covered by the University of Medical Sciences is displayed in figure 1.

In addition, in Iran, a comprehensive electronic health record (EHR) system has been provided to be used for all persons around the country. It includes a wide range of personal demographic information, health status, records of diseases, medical records, and all information affecting individual health. All Iranian people have to register in the EHR. One of the most important parts of this system is recording national immunisation and vaccination full range of people especially childhood immunisation. For detecting all children younger than 5 years of age who were either unvaccinated or undervaccinated, we will refer to data on EHR.

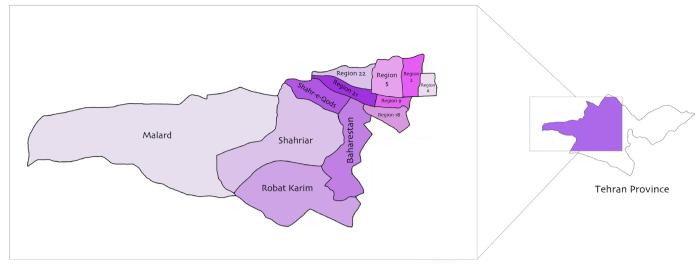


Figure 1 The catchment area of Iran University of Medical Sciences.

Sampling and recruitment of participants

The participants will be recruited of parents who have refused their child vaccination from the seven municipality regions and five cities (Shahriar, Malard, Robat-Karim, Shahre Ghods and, Baharestan) in the province of Tehran, Iran, using purposive maximum variation sampling (see figure 1). This selected area is diverse in terms of socioeconomics and demographical aspects and consists of more than 5 million people allow us to capture a broad range of attitudes and in-depth insight towards vaccine hesitancy among Iranian parents who have urban and rural localities. By referring to the EHR system, eligible parents who delayed or refused vaccines are listed based on their income status, level of education and place of residence, and an attempt is made to select a balanced combination from each of these different groups. Sampling will be continued until data saturation and no new themes or ideas are extracted. An estimated minimum number of 20 eligible parents will participate.¹⁷

The contact details of parents will be derived through the EHR system and then we will be contacted them via telephone and give them information about the study and ask them to ascertain their interest in participating.

Parents who are eligible and comfortable to participate in the study will be referred to a research staff member. After explaining the purpose of the study and providing adequate time to decision, written informed consent will then be obtained.

Data collection

Data collection consists of three instruments including semistructured interviews, sociodemographic and background information, and field notes. Using the interview guide, opinions, experiences and attitudes of vaccine-hesitant parents will be collected in order to develop a model for vaccine decision-making towards vaccine acceptance and mitigation of parental vaccine hesitancy (box 1). After the first three interviews, this interview guide will be modified based on research team consultation.

The sociodemographic questions will be age, level of education, source of information, number of children, occupation status and income status. We will also collect

Box 1 Interview guide

Demographic questions

Age, level of education, source of information for vaccination, number of children, occupation status, and income status. History of previous vaccination according to electronic health records

Main questions

Do you currently observe the recommended immunisation schedule for your child?

What are your reasons for doing this?

Have you ever delayed or declined your childhood vaccination? Why? How do you get the most common information about vaccines? Have you ever discussed your vaccination concerns with health professions or other parents? Why?

When you expose to negative reactions related to vaccinations, what do you do?

What problems do you experience when delivering vaccine? Is there adequate information about vaccinations?

What are your main source of information about vaccines? What are your main concerns regarding childhood vaccinations? Do you think immunisations are safe for children?

What are your worries about child vaccinations?

Do you have any concerns that the vaccines will not work? Do you ever postpone vaccination due to COVID-19?

What do you know about the role of vaccination in health communities? Have you ever delayed your baby vaccination for a specific reason? Do you have any concerns about the side-effects of vaccination? In your point of view, why do some parents delay or refuse to vaccinate their babies?

Do you have any negative experiences that would discourage your child's vaccination?

Do you trust the health system in vaccine programs and immunisation?

The field note related to the researcher's observation of the participants during the interview process such as nonverbal communication, body language, and expressions, facial modes, and reactions.

Before the appointment, one of the members of the research team will telephone parents to screen them for eligibility and get their consent.

Semistructured interviews will be performed by one of the research staff members who have experience in qualitative research. The interviews will be conducted via video call in the WhatsApp platform or face-to-face depending on their preference. Data will be collected between October and December 2022 and each interview will last 30–60 min.

With the participant's approval, each interview will be recorded by using an audio recorder. Before beginning the interviews, the participants will be ensured about the completely voluntary nature of participation in the study and their right to withdraw from it at any stage. An honorarium 1 000 000 Rails equivalent to US\$5 will be offered to the participating parents in appreciation for compensation for their time.

Since the virtual interview needs a quiet and appropriate place and time, we will ask the participants to express themselves when they will be able to participate in the interview. The questions of interview topic guide are provided in **box 1**. Second author will conduct pilot interviews and their deficiencies will be then resolved in the research staff. A research professional trained in qualitative methodology (Second author) will conduct all interviews. The interview audio files will be transcribed verbatim without considering identifiers such as names.

Data analysis approach

The analysis process will be guided by the interpretive description approach in the following four phases:

Phase 1: transcription the audio files.

Phase 2: familiarisation with the data and producing the initial codes.

Phase 3: comparing, contrasting, and searching the themes.

Phase 4: developing the patterns and reviewing the themes.

In the first phase, qualitative data will be transcribed verbatim, cleaned and saved by a moderator (AAK). Microsoft Word will be applied to support the analysis process. In the second phase, the two authors (SGN, SH) read the whole of transcriptions and will become familiar with the transcribed content and start initial coding. In the third phase, the two authors (SGN, SH) code and organise each interview according to the research question. Synchronously, the constant comparison analysis will be done for finding similar and different themes within and across interviews. The organisation of the data will be as broad as possible to refrain the premature closure. In the final phase, the patterns of data and themes emerge, and these were reviewed by all authors several times for clarification and consensus until a final depiction of the interpretive themes will be made. These four mentioned phases help us to achieve an overarching insight and provide a coherent and relevant description of the data. MAXQDA 2022 will be used for organising, analysing, visualising and managing the Interview data.

Patient and public involvement

Because this protocol is a public health initiative, there will be no patient recruitment. This study seeks to involve parents who have refused vaccinations for their children as participants. Participants will not be involved in the design of the study, the development of interview questions, or the conduct of the study. They will be interviewed to better understand for their attitudes and experiences regarding vaccine hesitancy. They will, also, be invited to comment on the transcripts and results of the analysis. A summary of the findings will be shared with those interested.

Ethics and dissemination

This study obtained ethics approval from the research committee of IUMS (ID#IR.IUMS.REC.1399.273). The written informed consent will be obtained before each interview. Participants will be informed about the study objective and voluntary participation.

The anonymity and confidentiality of the participants will be protected by eliminating their personal information and names in the data analysis and reporting. This study's findings will be presented in related conference presentations and peer-reviewed journals, as well as disseminated to all stakeholders.

DISCUSSION

As a result of the vaccines and vaccination programmes, many preventable diseases have been reduced drastically, and more than two million deaths have been prevented each year.¹⁸ Vaccination mainly targets children, and countries all over the world have taken several measures to enhance vaccination rates among children.¹⁹ Nevertheless, there is a significant rise among parents who refuse to vaccinate their children. An analysis of the UNICEF-WHO joint report shows that a majority of nations report parental vaccine hesitancy.⁴ The main reason parents hesitate or refuse to immunise their children with vaccines is their fear of their safety and side effects.²⁰ Furthermore, the WHO identified vaccine hesitancy as one of the 10 most serious threats against global health.²¹ Research on vaccine hesitancy to date has expanded our understanding of the global prevalence and found that there are individual and contextual factors to consider.²² According to some studies, the COVID-19 pandemic may have contributed to the rise of antivaccine movements.²⁰

However, addressing vaccine hesitancy is a complex problem that requires comprehensive, evidence-based strategies that are context sensitive.²³ To make these strategies effective, parents' insight and attitude towards routine vaccination are crucial in each setting.⁷

Since parents are the main decision makers for vaccinations, the purpose of this study is to identify factors that influence vaccine hesitancy from the perspective of parents in Tehran province. Understanding the root causes of vaccine hesitancy is essential for developing interventions intended to influence vaccine-hesitant views. The qualitative approach can help us understand why and how parents refuse childhood vaccinations. Therefore, this qualitative study will increase our insight and understanding of the child vaccination decisionmaking and vaccine hesitancy in Iran. Diversity in parent's opinions who participate in this study will enable us to elaborate what issues imputes successful implementation and large-scale up taking of routine vaccine.

As a consequence, the results of this study will contribute new perspectives on vaccine hesitancy and provide insight into the opinions of different types of socioeconomic and demographic households concerning vaccination. As mentioned previously, in order to effectively address vaccine hesitancy, comprehensive, context-specific interventions are needed. Currently, most of the interventions focus on improving vaccine information, while other interventions to promote vaccination are still necessary. In developing a customised vaccination programme, national immunisation committees should consider the cultural, political, economic and social context of different areas.

Author affiliations

¹Preventive Medicine and Public Health Research Center, Psychsocial Health Research Institute, Iran University of Medical Sciences, Tehran, Iran
²Department of Healthcare Services Management, School of Health Management & Information Sciences, Health Management and Economics Research Center, Health Management, Iran University of Medical Sciences, Tehran, Iran

³Burn Research Center, Iran University of Medical Sciences, Tehran, Iran
⁴Preventive Medicine and Public Health Research Center, Psychsocial Health Research Institute, Tehran, Iran

⁵Center for Communicable Disease Control, Ministry of Health and Medical Education, Tehran, Iran

⁶Department of Community Medicine, School of Medicine, Preventive Medicine and Public Health Research Center, Psychosocial Health Research Institute, Iran University of Medical Sciences, Tehran, Iran

Twitter Maziar Moradi-Lakeh @mmoradil

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ORCID iD

Salime Goharinezhad http://orcid.org/0000-0001-8565-3606

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