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Reports

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Abstract

Background: Priority-setting for early access to vaccines during a pandemic optimizes the impact of vaccine rollout, however, low- and middle-income countries (LMICs) have little experience in policymaking on this. In the Islamic Republic of Iran, the national clinical ethics committee developed a policy for early access to COVID-19 vaccines with support from the national committee on COVID-19 vaccine.

Aims: This paper reports the process and results of a national COVID-19 vaccine priority-setting in the Islamic Republic of Iran and discusses its ethical and cultural aspects.

Methods: A multidisciplinary team of experts planned and developed a national guideline following an extensive literature review and face-to-face consultations.

Results: We present the list of priority groups and subgroups, tiered through a 4-phase process, as well as the ethical values and sociocultural issues underpinning COVID-19 vaccine prioritization in the Islamic Republic of Iran.

Conclusions: Our experience shows that a transparent and well-reasoned policymaking process can inform fair priority-setting for pandemic vaccines, especially in LMICs.

Keywords: priority-setting, vaccine, vaccination, COVID-19, prioritization, health policy, ethics, Iran

Citation: Bahmani F, Parsapour A, Abbasi N, Zahraei S, Tavakoli N, Shamsi-Gooshki E. Priority-setting for early access to COVID-19 vaccines in Islamic Republic of Iran. East Mediterr Health J. 2023;29(7):587–598. https://doi.org/10.26719/emhj.23.040
Received: 22/07/22; Accepted: 08/12/22

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Introduction

The COVID-19 pandemic has negatively changed the world and caused great harm, including direct damage to global health, with 534 439 577 confirmed cases and 6 307 218 confirmed deaths worldwide as of 10 June 2022 (1). The pandemic has caused indirect harm by diminishing healthcare delivery to patients with noncommunicable diseases (2); negative consequences for the mental health of the world population (3); and devastating economic losses in low-, middle- and even high-income countries (4,5). The Islamic Republic of Iran documented a surge of COVID-19 cases shortly after the official announcement of the first deaths due to SARS-CoV-2 on 19 February, and as of 10 June 2022, 7 233 472 confirmed COVID-19 cases and 141 343 deaths had been reported (1).

Vaccination is essential to mitigate the harms caused by infectious disease outbreaks, and priority-setting for access to vaccines optimizes the impact of vaccine rollout (6). Inequitable access to safe and effective vaccinaton demands fairness and justice-driven debate around priority-setting for access (7). Prioritization of access to the SARS-CoV-2 vaccine was essential and challenging because supplies were predicted to be critically low in the early phase of vaccine release.

Priority-setting involves processes to decide on the allocation of resources among competing programmes or groups of people (8). There is an increasing demand for explicit, evidence-based prioritization (8) as this can help policymakers better accept their responsibility by increasing public awareness vis-à-vis healthcare decision-making (9).

Hence, in the middle of the COVID-19 pandemic, when the vaccine manufacturers were fighting hard to deliver their first batches, the Strategic Advisory Group of Experts on Immunization of the World Health Organization (WHO) guided countries toward vaccination programmes based on transparent and fair prioritization plans. The WHO provided ethical guidance by publishing a values framework for prioritizing access to the COVID-19 vaccine (10), followed by a prioritization roadmap (6). Health ethics experts and policymakers also made efforts to guide vaccine allocation policies ethically. For example, in the United States of America, in August 2020, the Center for Health Security at Johns Hopkins University published an interim framework for COVID-19 vaccine allocation (11). In September 2020, the Advisory Committee on Immunization Practices proposed 5 ethical principles for distributing the vaccine (12). In October 2020, the final report of a robust study on COVID-19 vaccine allocation by The National Academies of Sciences, Engineering, and Medicine was published (13).

These documents exemplified a rich body of bioethical academic reflection on pandemic vaccine priority-setting in developed countries. Less attention has been paid to addressing the practical application of the proposed frameworks across low- and middle-income countries (LMICs) (14). Although LMICs have little experience in policymaking on priority-setting in general, and for pandemic vaccines in particular (15), research shows that in these countries, priority-setting is commonly based on disorganized reasoning, which arises through ad hoc or implicit processes and lacks reliable evidence, leading to poor health policymaking (15). Indeed, countries in the Middle East are vulnerable to pandemics because of their specific cultural, political and economic context (16).

The Iranian National Clinical Ethics Committee has been established as a policymaking, supervisory and decision-making body in the Ministry of Health and Medical Education since 2018. It is responsible for developing national guidelines on clinical and public health ethics.

With support from the national committee on the COVID-19 vaccine, the National Clinical Ethics Committee developed a guideline for early access to COVID-19 vaccines. This study reports the process and results of the collaborative efforts of the National Clinical Ethics Committee and the National Immunization Technical Advisory Group, known as the COVID-19 Vaccine Technical Committee, in determining priority groups for access to the COVID-19 vaccine, and discusses the cultural aspects of policymaking on vaccine prioritization in the Islamic Republic of Iran.

Methods

Planning

The secretariat of the National Clinical Ethics Committee developed and approved a planning proposal, which defined the scope of the guideline, including its overall purposes, target users, necessary implementation activities, main outcomes, resources and timing

(Figure 1). Accordingly, in November 2020 a working group was formed, comprising experts in public health, epidemiology, patient rights and medical ethics along with medical professionals involved in managing the response to the COVID-19 pandemic (Table 1). All invited experts declared that they had no conflict of interest regarding the subject of the guideline and its publication.

Guideline development process

Review of existing guidelines and country priority lists

We conducted 2 nonsystematic literature reviews in November and December 2020 to answer the review questions below.

Which ethical principles and values play a role in early pandemic vaccine allocation and how do they manifest this?

What are the priorities for access to COVID-19 vaccine in different countries?

The key search terms were “vaccine prioritization”, “vaccine allocation” and “vaccination ethics”. We searched the MEDLINE database via PubMed and Google Scholar for articles published between January 2019 and 31 December 2020. Key bioethics databases and recently developed guidelines for COVID-19 vaccine allocation were also searched. We manually included COVID-19 vaccine priority lists of countries and institutes from national and

international websites. No geographical limitations were applied, however, we limited the search languages to English and French.

Articles were included if they contained the primary search terms “vaccine”, “allocation” and “prioritization”. A total of 217 records were identified, and after removing duplicates, editorials and commentary articles, and articles discussing global vaccine allocation or mathematical and computer simulation models, 14 papers and 10 guidelines were included for review.

Generation of a comparative list of priority groups and subgroups

We generated a comparative list of priority groups and subgroups by organizing the data extracted from the literature review into a table in which the rows represented the priority population groups and subgroups, the columns represented each country or guideline, and the cell entries specified the rank of that population group or subgroup in the priority list for different countries or guidelines (Table 2).

Development of value framework, identification of prioritization objectives and drafting the guideline

By conducting review sessions and through reflection and prudent debate about the existing literature on ethics and vaccine allocation during pandemics, we sketched a value framework for prioritizing the COVID-19 vaccine (Table 3). We proposed a preliminary priority list according to the average ranking of each population group on the comparative list (Table 2) and the value framework. The value framework and the priority list were sent electronically to 2 qualified external experts for peer review and impartial evaluation and revised accordingly, which yielded a first draft of the guideline.

Developing consensus

Given the time-sensitive nature of the guideline, we employed a face-to-face consensus meeting. The panel included expert members of the National Immunization Technical Advisory Group (Table 1) and the lead author, an expert in medical ethics.

To shorten consensus-making timeframes, the lead author circulated the draft to all members, gathered and qualitatively analysed the comments, and prepared a summary report. After that, all priority groups were openly discussed in several meetings at the Ministry of Health and

Medical Education and a consensus of > 70% was achieved for all priorities.

Review and approval

The National Vaccine Committee approved the prioritization list. Subsequently, a joint meeting of the Supreme Council of Medical Ethics (the highest bioethics body in the country, a part of the policy approval framework in the Ministry of Health and Medical Education) and the National Clinical Ethics Committee recognized the guideline in line with the Iranian constitution and upstream laws, and issued the final approval for the Ministry of Health and Medical Education.

National endorsement and dissemination

On 10 January 2021, the National Headquarters for COVID-19 Control, the first body established in the Presidential Institution to manage the response to COVID-19, endorsed the guideline officially and released it to local media as Chapter 4 of the “COVID-19 National Deployment and Vaccination Plan”.

Results

The expert groups involved in the various decision-making stages represented a diverse range of expertise, age, sex and academic roles. For details of the groups, see Table 1 .

The 2 fundamental values of maximizing benefit and justice and the 2 operational concepts of utility and equity were recognized as culturally appropriate to ethically guide the prioritization of access to the COVID-19 vaccine (Table 3). The guideline recommended a 4-phase process for vaccine allocation; each phase was split into subphases, including tiered population groups (Table 4).

Discussion

Overview

This study describes the consultative process that resulted in the urgent development of an ethical guideline for prioritizing access to COVID-19 vaccines in the Islamic Republic of Iran between November 2020 and January 2021. Here we discuss the cultural aspects which informed our decision-making.

Starting vaccine rollout with healthcare workers: truthful risk communication and maintaining public trust

The value “maximizing benefits and minimizing harms” is central to public health policymaking. The objective is to determine which policy is the best to protect people from hospitalization and death because of COVID-19, and implies that older adults, who bear the highest rate of hospitalization and death (17), have priority access to vaccine. However, we recommended prioritizing front-line healthcare workers over those individuals at a very high risk of getting sick and dying from COVID-19 in the first phase. This decision is in agreement with the recommendations of WHO (6) and National Academies of Sciences, Engineering, and Medicine guidelines (13), but is at variance with the Advisory Committee on Immunization Practices report, which places healthcare workers and elderly residents in long-time care facilities in the first phase, without specifying the priority group (18).

Besides the ethical justification commonly buoying the placing of healthcare workers as the top priority for vaccination, our decision was based on trust and the imperative to increase public confidence in the COVID-19 vaccine.

Trustworthiness is a virtue, and building a climate of trust is vital for the healthcare setting (19). People demand trust through the honest and transparent communication from governments in response to the COVID-19 pandemic (20). Vaccine confidence has been a challenging issue for a long time, and is closely related to public trust in the broader healthcare system (21). Although the COVID-19 vaccines have been proved safe and efficient by scientific evidence, the issue of building trust constitutes an essential aspect of COVID-19 vaccine uptake due to the expediency of the vaccine development and the emergency use authorization by the food and drug regulatory systems around the world (22).

However, there are specific issues that may impinge on public trust regarding COVID-19 vaccines in the Islamic Republic of Iran. First, the younger and healthier population of healthcare workers was given priority because there was great uncertainty about which vaccines would be available in the early stages and the side-effects and safety of the available vaccines. Second, COVID-19 mortality rates are typically higher among frail elderly persons and those with severe underlying conditions than among healthcare workers. For example, in the first month of the COVID-19 vaccine rollout, 113 deaths were reported after vaccination, of which 78 (65%) occurred among residents of long-term care facilities without any detected causal relationship (23).

Given that vaccine confidence depends on the perceived risk of the vaccine causing harm rather than benefit (24), the risk of people attributing nonrelated deaths to vaccines in the early

stages of vaccine rollout is serious. It was more feasible to follow-up and monitor adverse vaccine events among the healthcare workers group.

Prioritizing individuals above 65 years over those with high-risk comorbidities: utility and fairness considerations

Deciding between prioritizing individuals aged over 65 years and those with high-risk comorbidities was challenging as both population groups have been shown to be at higher risk for COVID-19 hospitalization and death in Iran than in other countries (25,26). However, the current guideline assigned vaccine priority to individuals over 65 years. This agrees with the recommendations of the Advisory Committee on Immunization Practices and the WHO guideline. However, in the National Academies of Sciences, Engineering, and Medicine guideline, population groups with underlying problems take precedence over age groups.

The first justification was the higher case fatality and hospitalization rates resulting from the SARS-CoV-2-virus among populations aged 65–70 years or over than among any other population (27–29). According to official reports, 70% of Iranian COVID-19-related deaths occurred among people over 60 years (30). Epidemiological studies show that those aged 65+ years had the highest cumulative risk of death among hospitalized patients with confirmed COVID-19 and that among patients with comorbidities or a high body mass index, there was a greater risk of mortality and hospitalization than among the normal population (31,32).

Second, aging is associated with a higher prevalence of comorbidities. Comorbid conditions are more common (33,34) and more severe (35) among adults over 65 years. Therefore, prioritizing the older age groups also addresses several COVID-19 risk factors, including hypertension, diabetes and cardiovascular disease (35,36).

Third, there is the greater feasibility of providing fair access to all members of an eligible group. Although the Iranian healthcare infrastructure is adequate considering the nature of the risk factors and the vast geographical area of the country, the government cannot afford equal recalling of all eligible individuals in all the aforementioned COVID-19 risk groups.

There is a normative justification to avoid encouraging people to commit fraud, such as faking medical record indicating their comorbid condition.

Including marginalized populations and those who may experience discrimination due to unequal power relationships in the priority list: equity considerations

To avoid discrimination, we explicitly included all eligible population subgroups, and addressed individuals at higher risk of inequitable distribution of vaccines due to unequal power relationships such as medical students and funeral staff in cemeteries, and marginalized populations like prisoners and immigrants. The Islamic Republic of Iran has been host to nearly 3 million Afghan refugees for over 4 decades (37). Afghans are more prone to social inequalities, leading to a higher risk of infectious diseases (38). Unregistered migrant populations are also assigned priority despite the logistic difficulties.

Responsiveness for silent guideline situations: accountability considerations

There are instances when the guideline is silent about which subpopulation in a priority group has priority to access the vaccines and how to fairly distribute vaccines in a subpopulation. Accountable policymaking for pandemic vaccine rollout should include clearly defined roles and responsibilities for these situations.

We recommended involving regional (or university) and local (or hospital) clinical ethics committees to further prioritize vaccine access at the centres within their regions or among the staff at their centres by using the ethical framework of our guideline. It may be regarded as an innovation in that our study predicted the severe shortages that occurred during the early months of the vaccine rollout due to the low pace of the vaccine supply chain in the Islamic Republic of Iran. The experts decided not to wait for enough vaccines to completely immunize all eligible individuals within a hospital or a healthcare centre, and distributed the available doses as early and evenly as possible among a population tier. Therefore, it was predicted that a few doses of vaccines would be delivered to hospitals at each stage; for example, less than 10 shots may be delivered to the staff of a small hospital located in areas far from the provincial capitals. Hence, it suggested that hospital ethics committee prioritize between members of an eligible population group in such situations.

Feasibility considerations

The primary healthcare facility network in the Islamic Republic of Iran has become highly organized (39) and accessible, especially among rural populations (40). An online registration system established for COVID-19 vaccination by the Ministry of Health and Medical Education may increase the feasibility of the guideline. Also, the registration of all patients suffering from chronic disease (e.g. chronic renal failure, diabetes) in a nongovernmental foundation that organizes and promotes care delivery facilitates the implementation of Phase 2 of the recommended vaccination programme.

Study limitations

The most important limitation of this study was the lack of sufficient public engagement in the decision-making process due to time pressures. However, the director of a national nongovernmental organization, Patients' Rights Watch, was present for the approval process as a National Clinical Ethics Committee member. He also supported efforts to informally seek public opinion by providing feedback and comments from the board of trustees of their organization. Besides, the comments of the clergy, lawyers, and nonmedical experts in the various decision-making stages made possible indirect, timely and informed communication with people from diverse backgrounds.

Despite low public participation in the guideline development, the feedback obtained from lay and society professionals after its publication and dissemination is proof of its acceptability and legitimacy. The guideline developed and disseminated as the "National Document" usually appears to be the reference document for resolving conflicts about the priority population, and deviations from it are addressed. In one example, the Medical Council suggested prioritizing artists for access to vaccines, a suggestion which faced solid public reaction citing the national prioritization plan. However, to promote fairness and participation in the same guidelines in future pandemic planning, much more effort must be made to seek public opinion and involve stakeholders.

Conclusions

The need for public health decision-making based on scientific evidence, ethical principles (13) and sociocultural issues (41) is widely acknowledged. Our experience

shows the administrative possibility and public acceptability of implementing explicit and value-based priority-setting in a developing country. Further evaluation of the reported process and its outcome may improve decision-making practices on resource

allocation. In conclusion, we can recommend further research aimed at assessing the application of this guideline, including qualitative research for documentating the experiences of stakeholders and quantitative analysis exploring the compatibility of the allocation of vaccines with the proposed allocation guideline.

Another conclusion of this work was the successful approach to ethics experts as the "ethicist as an insider". Cooperation between a professional ethicist and experts from the National Immunization Technical Advisory Group could inform constructive integration of the National Clinical Ethics Committee with the policymaking bodies of the healthcare system.

The most critical shortcomings of the proposed priority-setting policy were the failure to include medical risks and the low participation of the public. Our experience showed that striving to ensure greater communication with and involvement of people in health governance processes increases the legitimacy of public health interventions.

Funding: None.

Competing interests: At the time of the study, Fatemeh Bahmani was a member of the National Clinical Ethics Committee; Alireza Parsapour was secretary of the Supreme Council of Medical Ethics and the National Clinical Ethics Committee; Nasrin Abbasi was the technical officer at the National Clinical Ethics Committee secretariat; Seyyed Mohsen Zahraee was the director of the vaccine-preventable diseases department in the Center for Communicable Disease Control, and a member of the National Committee on the COVID-19 Vaccine and the National Immunization Technical Advisory Group; Nader Tavakkoli was deputy clinical head of the Tehran Coronavirus Taskforce; Ehsan Shamsi-Gooshki was secretary of the National Committee for Ethics in Biomedical Research, Member of the National Clinical Ethics Committee, National Immunization Technical Advisory Group and National Committee on the COVID-19 vaccine.

Définition des priorités pour l'accès rapide aux vaccins contre la COVID-19 en République islamique d’Iran

Résumé

Contexte : La définition des priorités pour l'accès rapide aux vaccins pendant une pandémie optimise l'impact du déploiement des vaccins, mais les pays à revenu faible ou intermédiaire ont peu d'expérience dans l'élaboration de politiques à ce sujet. En République islamique d'Iran, le comité national d'éthique clinique a mis au point une politique pour l'accès rapide aux vaccins contre la COVID-19 avec l'appui du comité national sur le vaccin contre cette maladie.

Objectif : Le présent article rend compte du processus et des résultats de l'établissement des priorités nationales en matière de vaccination contre la COVID-19 en République islamique d'Iran et aborde ses aspects éthiques et culturels.

Méthodes : Une équipe multidisciplinaire d'experts a planifié et élaboré des lignes directrices

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nationales à la suite d'une analyse documentaire approfondie et de consultations en personne.

Résultats : Nous présentons la liste des groupes et sous-groupes prioritaires, hiérarchisés selon un processus en quatre phases, ainsi que les valeurs éthiques et les questions socioculturelles qui sous-tendent la priorisation du vaccin contre la COVID-19 en République islamique d'Iran.

Conclusion : Notre expérience montre qu'un processus d'élaboration de politiques transparent et bien raisonné permet d'éclairer la définition de priorités équitables pour les vaccins pandémiques, en particulier dans les pays à revenu faible et intermédiaire.

تحديد أولويات الحصول المبكر على لقاحات كوفيد **-19** في جمهورية إيران الإسلامية

فاطمة بهماني، علي رضا بارسابور، نسرين عباسي، سيد زهرائي، نادر توكلى، إحسان شمسي - جوشكي

الخلاصة

: إن تحديد أولويات الحصول المبكر على اللقاحات أثناء الجائحة يُحسِّن من أثرالخلفية
نشر اللقاحات، غير أن البلدان ذات الدخل المنخفض والمتوسط ليس لديها سوى قدر ضئيل من
الخبرة في رسم السياسات المتعلقة بهذا الشأن . وفي جمهورية إيران الإسلامية، وضعت
اللجنة الوطنية المعنية بالأخلاقيات السريرية سياسة بشأن الإتاحة المبكرة للقاحات
كوفيد -19 بدعم من اللجنة الوطنية المعنية بلقاحات كوفيد -19.

: هدفت هذه الدراسة إلى تحديد الأولويات الوطنية للقاحات كوفيد -19 ونتائجها فيالأهداف
جمهورية إيران الإسلامية، ويناقش جوانبها الأخلاقية والثقافية .

: اضطلع فريق من الخبراء المتعددي التخصصات بالتخطيط لوضع مبادئ توجيهيةطرق البحث
وطنية، وأعدَّ هذه المبادئ التوجيهية عقب إجراء استعراض موسَّع للمصنفات، وعقد
مشاورات وجهًا لوجه .

: عُرْضت قائمة الفئات والفئات الفرعية ذات الأولوية في صورة متدرجة، وذلك عبرالنتائ **ج**

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عملية تتألف من 4 مراحل، بالإضافة إلى القيم الأخلاقية والقضايا الاجتماعية الثقافية
التي يستند إليها تحديد أولويات لقاحات كوفيد -19 في جمهورية إيران الإسلامية .

: أظهرت التجربة أن عملية رسم السياسات الشفافة والمنطقية يمكن الاسترشادالاستنتاجات
بها في تحديد أولويات اللقاحات بإنصاف أثناء الجائحة، لا سيَّما في البلدان ذات الدخل
المنخفض والمتوسط .

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