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Countermeasures for mpox (formerly known as monkeypox), primarily vaccines, have been in limited supply in many countries during outbreaks. Equitable allocation of scarce resources during public health emergencies is a complex challenge. Identifying the objectives and core values for the allocation of mpox countermeasures, using those values to provide guidance for priority groups and prioritisation tiers, and optimising allocation implementation are important. The fundamental values for the allocation of mpox countermeasures are: preventing death and illness; reducing the association between death or illness and unjust disparities; prioritising those who prevent harm or mitigate disparities; recognising contributions to combating an outbreak; and treating similar individuals similarly. Ethically and equitably marshalling available countermeasures requires articulating these fundamental objectives, identifying priority tiers, and recognising trade-offs between prioritising the people at the highest risk of infection and the people at the highest risk of harm if infected. These five values can provide guidance on preferable priority categories for a more ethically sound response and suggest methods for optimising allocation of countermeasures for mpox and other diseases for which countermeasures are in short supply. Properly marshalling available countermeasures will be crucial for future effective and equitable national responses to outbreaks.

Introduction

Medical countermeasures, most prominently vaccines, have been proposed to quell the monkeypox virus outbreak, but have been in limited supply in areas with severe outbreaks. During the scarcity, jurisdictions worldwide adopted different approaches to allocating supply without ethically justifying them. Some of these approaches are well justified, but others are not. We put forward an ethical framework for allocating scarce countermeasures for mpox (formerly known as monkeypox) within countries in which it has historically not been endemic. This framework progresses from core values to delineating priority tiers for the ethical distribution of countermeasures.

Fundamental ethical values

Allocating any scarce countermeasure against infectious disease involves balancing ethical values. Sustained attention to allocative principles, particularly in light of the COVID-19 pandemic, has revealed a degree of overlapping consensus in which ethical values are the most relevant factor to consider during public health emergencies.[1–4] Building on this previous work, we have identified five widely shared ethical values of particular relevance to allocating mpox countermeasures. First, preventing harm includes preventing death and illness as well as indirect harms, such as curtailed education, employment, and caregiving. Second, mitigating inequities involves preventing disadvantages from generating worse infectious-disease outcomes. Third, instrumental value involves protecting health workers and others who can prevent harm or mitigate inequities in the future. Fourth, reciprocity involves prioritising those individuals whose past choices have mitigated, or avoided exacerbating, previous outbreaks. Finally, equal concern involves similar treatment of people who are similar in other respects and excludes arbitrarily treating people differently. Governance values, such as transparency, should be recognised as constraints rather than substantive values to guide prioritisation.

Priority groups

Preventing medical harm and mitigating inequities in an outbreak of an infectious disease requires understanding three groups: people at greatest risk of infection, of infecting others, and of suffering the most harm if infected (panel). Mpox infection in non-endemic countries, such as the USA, has disproportionately been concentrated among men who have sex with men (MSM), particularly those with multiple sexual partners.[5] Conversely, factors associated with a heightened risk of developing severe disease from mpox include pregnancy, young age (ie, up to approximately 10 years), being immunocompromised, and some skin conditions.[6,7] Factors expected to lessen vulnerability to infection, complications, and the likelihood of spreading disease include, most prominently, vaccination and previous infection. Additionally, previous smallpox vaccination probably provides some protection, but with less certainty.[6]

People might also have indirect harm from mpox outbreaks, such as income loss from inability to work or loss of access to needed caregiving. Policy interventions, such as paid sick leave, can mitigate many indirect harms, thereby preserving a limited vaccine supply for people facing direct medical harm.

One compelling way of mitigating harm is to prioritise groups who are at high risk of becoming infected and of poorer outcomes if infected, such as MSM who are living with uncontrolled HIV.[1,8–10] Beyond these groups, policy makers face trade-offs: to prevent the spread of infection, which would support prioritising MSM with multiple partners, or to focus on groups at a greater risk of complications if infected, such as immunocompromised

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***Panel*: Ethical values and priority factors**

Ethical value: prevent harm

Objective: to prevent death and illness directly caused by mpox and indirectly attributable to spread of the infection

Priority factors:

Risk of infection

- Direct exposure to the monkeypox virus via any route
- Having multiple sexual partners, particularly with communities with a high prevalence of the monkeypox virus (eg, men who have sex with men)
- Working with the mpox virus in a laboratory or clinic

Risk of infecting others

- Having multiple sexual partners, particularly when engaging in sexual acts that have a high risk of viral transmission
- Working in close bodily contact with others, such as patients, without adequate personal protective equipment
- Live or learn in congregate setting

Risk of death or complications if infected

- Being immunocompromised
- Being pregnant
- Being a young child (up to approximately 10 years of age)
- Being immune-naive (ie, no prior smallpox vaccine, mpox vaccine, or mpox infection)

Ethical value: mitigate inequity

Objective: to reduce the association between death or illness and unjust disadvantages

Priority factors:

Being subject to unjust disadvantages

- Stigmatised medical condition (eg, HIV)
- Poverty
- Racism, homophobia, or transphobia

Ethical value: instrumental value

Objective: to prioritise those who can prevent harm or mitigate disparities

Priority factors:

- Maintaining the ability to protect others in the future (ie, assuring the availability of medical or laboratory expertise)
- Risk of losing ability to help others if infected (ie, caregiving)

Ethical value: reciprocity

Objective: to recognise contributions to combating, or not exacerbating, an outbreak

Priority factors:

Having previously contributed to an outbreak response

- Provision of health services
- Participation in clinical trials
- Reduction of, or non-engagement in, high-risk sexual activity

Ethical value: equal concern

Objective: to treat similar individuals similarly

Priority factors:

Applies to all individuals

individuals. So far, most countries have tacitly emphasised preventing spread, but this goal should be explicitly weighed against protecting those less exposed but at a higher risk if infected. Priority might be warranted for groups who fall into both categories: people who have a greater risk of being infected and also have a greater risk of harm if infected.

In the mpox outbreak, mitigating inequities will typically align with preventing harm. People facing the greatest harm from mpox, such as people living with uncontrolled HIV, are typically also unjustly disadvantaged. Recognising instrumental value requires considering which individuals would be most likely to subject others to indirect harm or worsened inequities if infected with mpox. During the COVID-19 pandemic, instrumental value was invoked to prioritise health workers. However, during the mpox outbreak, health workers have been able to adequately mitigate mpox risk through non-pharmaceutical interventions, such as personal protective equipment. Conversely, difficulties with replacing or protecting caregivers of children or people who are immunocompromised might give them a stronger claim of instrumental value.

Reciprocity assigns higher priority to those who have mitigated pandemic harms, especially at substantial sacrifice, and lower priority to those who have exacerbated harms. In other outbreaks, reciprocity has been invoked to prioritise health workers and participants in clinical trials. During the mpox outbreak, reciprocity could, in theory, be invoked to prioritise MSM who have seriously reduced their sexual interactions to quell the outbreak. However, in doing so, they have lowered their harm-prevention priority by reducing their own exposure. More generally, invoking reciprocity for any given group could invite unnecessary controversy over whose sacrifices are sufficient to merit countermeasure prioritisation. Where the harm of an infectious disease is serious, harm prevention (eg, through postexposure prophylaxis) should typically take priority over reciprocity. If reciprocity is invoked, it should only have a subordinate role to resolve ties among individuals otherwise designated for similar priority.

Prioritisation tiers

These ethical values of preventing harm, mitigating inequity, instrumental value, reciprocity, and equal concern help to identify the five core elements of appropriate mpox-vaccine prioritisation within jurisdictions (table). Details of how to apply these values will vary by jurisdiction and differences in disease burden, risk profiles, practical constraints in distribution, cultural norms, and other factors. For instance, high-quality data of clinical efficacy for mpox vaccination in humans remain scarce.[7,11,12] Our proposed allocative framework is based on currently available information in countries that have been particularly hard-hit by the current mpox outbreak.

When defining the order of groups, policy makers should prioritise groups with the strongest overall claims, often people whose protection effectively realises multiple values. When prioritising within large groups, such as MSM, decision makers should prioritise those

	Gradient	Rationale	Implementation challenges
Priority tier 1			
People with a confirmed exposure to mpox (previously known as monkeypox)	When vaccine supply is insufficient for universal postexposure prophylaxis, prioritise people who would also be included in other tiers (eg, MSM with multiple sexual partners)	High risk of infection	Intervention needs to be delivered quickly to realise benefit; for healthy people who are exposed, infection is likely to be self-limiting and the net benefit might be smaller than the use of scarce resources for other people
MSM living with HIV or are immunocompromised	People with multiple sexual partners should be prioritised within this group	High risk of infection; high risk of severe outcomes; socially disadvantaged group	People who are severely immunocompromised might gain less protection from vaccines, although intensive schedules could be used
MSM who are not immunocompromised with multiple sexual partners	People who have more sexual partners should have a higher priority than people who do not	Socially disadvantaged group; high risk of infection and transmission to others	Establishing eligibility without self-attestation is difficult, although eligibility has been assessed with data on recent sexually transmitted infections as a proxy for the risk of exposure
Sex workers	..	High risk of infection and transmission to others; socially disadvantaged group	..
Priority tier 2			
Non-MSM living with HIV or who are immunocompromised	People who are severely immunocompromised should have a high priority	High risk of infection; high risk of severe outcomes; socially disadvantaged group	People who are severely immunocompromised might not gain much protection from vaccines; establishing eligibility on the basis of illness is easier than establishing eligibility on the basis of sexual partners
MSM generally	..	High risk of infection	Establishing eligibility is difficult without self-attestation
Primary caregivers of children or people who are immunocompromised	..	Ability to protect others from harm; contribution to mitigating pandemic harms	..
Priority tier 3			
Pregnant women	..	High risk of severe outcomes	Little data on vaccine safety and efficacy in this population
Children under 10 years of age	..	High risk of severe outcomes	Little data on vaccine safety and efficacy in this population
People with some skin conditions	..	High risk of severe outcomes	..
Priority tier 4			
Others	Less priority to people who have had a previous smallpox vaccine	..	..

MSM=men who have sex with men.

Table: **Groups within each priority tier**

whose access fulfils multiple ethical values rather than creating queues for vaccines. For example, they might prioritise immunocompromised MSM with multiple partners. Further, because protecting many more people will typically better prevent harm and mitigate inequities, fractional dosing could be used within all tiers if it achieves greater population protection per unit of vaccine, even if individual recipients might prefer full doses. Importantly, priority tiers should not be rigidly implemented. For example, to accelerate delivery and reduce waste, a small portion of vaccine supply could initially be open to all interested MSM, whereas the bulk is reserved for people at a higher risk, such as MSM who are immunocompromised or have multiple partners. Notably, not all people living with HIV have severe immunosuppression that worsens mpox outcomes: although advanced immunosuppression worsens outcomes, outcomes in people with high CD4 counts (ie, >500 cells per mm^3) are similar to those in people without HIV.[13] More severe immunosuppression is often linked to other forms of disadvantage, such as not having reliable access to antiretroviral therapies for HIV.

Because harm prevention depends on observed transmission, priority groups should change over time if prevalence shifts. For instance, MSM are currently most exposed, but this exposure could change if spread within congregate living settings increases. If pre-exposure vaccination for some groups, such as the general public or all children, has a low expected benefit, they should be a low priority.

Although the same ethical values and priority factors remain relevant regardless of available vaccine supply, limitations to a supply might change how the values are operationalised. For instance, countries with a limited

supply might be restricted to allocating postexposure prophylaxis, whereas countries with a greater supply might be able to provide postexposure prophylaxis to all exposed individuals as well as some primary preventive vaccination. Our focus on allocation within countries, not among countries, does not endorse hoarding vaccines for local use, but only explains how priority groups should be ordered given a limited local vaccine supply.

Optimising implementation

Optimally implementing the priority tiers is also important to realising ethical values. During the COVID-19 pandemic and the mpox outbreak, the USA often distributed vaccines via publicly visible queues in which recipients self-attested eligibility. Both visible queues and self-attestation unethically exacerbate inequities. Queues involve burdensome waits that can discourage uptake and publicly identify an individual as MSM or as having multiple partners. Self-attestation incentivises lying to obtain vaccines. Several high-income countries use active outreach, an ethically preferable approach in which clinics invite patients known to have a high risk of infection or complications to make vaccination appointments.

Vaccine dosing schedules should also seek to realise ethical values and should be implemented by taking a public health rather than a physician–patient perspective. In many countries, most eligible patients have been designated to receive a one-fifth dose intradermally on the basis of preliminary evidence that fractional dosing delivered intradermally is adequately effective,[14] but a few groups (eg, children and people with keloid scars) still receive subcutaneous full doses. When vaccines are scarce, giving one person a subcutaneous dose means foregoing three to five intradermal doses. For postexposure prophylaxis, the elevated risk of mpox complications in young children could justify foregoing five adult vaccinations to provide subcutaneous doses. But foregoing five adult vaccinations to vaccinate teenagers or people with keloid scars, who are not at the same elevated risk of complications, is difficult to justify.

To effectively realise ethical values, prioritisation plans should avoid grouping people at disparate amounts of risk together into one priority tier. Neglecting the importance of limiting tier size, some jurisdictions made all people who had more than one recent sex partner eligible for mpox vaccines, regardless of how many partners or whether those partners were MSM.[15] Ignoring substantially different risks, this approach does not realise equal concern and is poor at preventing harm and mitigating inequities. Such a broad grouping might be motivated by a desire to avoid stigma, but doing so exacerbates health inequities by requiring MSM and sex workers to compete for scarce vaccines with heterosexual adults who are far less exposed and often more socially advantaged.

Although current allocation policies have focused on inactivated-virus vaccines, other countermeasures, such as antivirals and live-virus vaccines, also require coordinated allocation. Most notably, a live-virus vaccine, LC16m8, is stockpiled in Japan where it has been authorised and successfully used for the vaccination of non-immunocompromised individuals, including children. Meanwhile, antivirals might present an alternative to vaccines for individuals who have been exposed or infected, allowing the scarce supply to be directed to people at a higher risk if infected.

Prioritisation decisions should acknowledge the uncertainty that exists around the comparative effectiveness of fractional and full doses and evolving evidence. New information about exposure and risk of infection can and should change policy. Gaps in current evidence also highlight the need for rigorous data collection and analysis as well as clinical trials. Determining real-world vaccine efficacy against transmission and factors that increase post-infection risk is crucial to optimising prioritisation.

Conclusion

Properly marshalling available countermeasures is crucial for effective and equitable mpox responses at a national level. Many jurisdictions have identified prioritised groups for limited vaccine supply. Yet, few have articulated fundamental objectives for allocation, recognised trade-offs between prioritising people at the highest risk of infection and people at the highest risk of harm if infected, or justified their prioritisation decisions. We have explained how these gaps can be filled and have provided guidance on preferable priority categories for a more ethically sound response. Although each disease and context are different, these principles could also be considered and adapted to other diseases in which risk is variable and availability of medical countermeasures limited.

Contributors

All authors were involved in drafting and critically revising the manuscript for important intellectual content.

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