

## Ethical Considerations of Age De-escalation in Adult Vaccine Trials

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### DESCRIPTION

The emergence of new vaccines, particularly in response to the COVID-19 pandemic, has brought to the forefront the ethical debate surrounding age de-escalation in adult vaccine trials. Age de-escalation refers to the deliberate inclusion of older adults, who are typically excluded from initial phases of vaccine trials, to assess vaccine safety and efficacy across age groups.

#### Equity and inclusivity

**Age as a consideration:** Equity in healthcare research necessitates that clinical trials reflect the population's diversity. Age de-escalation seeks to address a long-standing inequity in vaccine development, where older adults were often excluded from early-stage trials. This practice has historically resulted in insufficient data on vaccine safety and efficacy in this age group.

**Protecting vulnerable populations:** Older adults are a potentially vulnerable population in the context of vaccine trials, and their inclusion is essential for their protection. The age de-escalation approach helps ensure that vaccines are safe and effective for this group, reducing their vulnerability to infectious diseases.

**Addressing health disparities:** Health disparities among older adults, particularly in underserved communities, highlight the ethical obligation to include them in vaccine trials. Age de-escalation is a step toward addressing these disparities by ensuring that research benefits are accessible to all, regardless of age.

#### Ethical challenges and considerations

**Informed consent:** Obtaining informed consent from older adults can be complex due to cognitive decline or health-related challenges. Researchers must adopt appropriate consent procedures that consider these limitations while respecting participants' autonomy.

**Safety and tolerance:** Vaccine trials in older adults must be closely monitored, given their increased vulnerability to adverse

events. Ethical considerations dictate that researchers have a robust safety monitoring system in place to promptly detect and address any potential side effects.

**Health status variability:** Older adults exhibit a wide range of health statuses and comorbidities. Vaccine trials should account for this variability, ensuring that the results are relevant to older adults with diverse health conditions.

**Inclusion of frail and care-dependent elderly:** Ethical considerations extend to the inclusion of frail and care-dependent older adults, who may not have the capacity to provide informed consent. Researchers must navigate these challenges, ensuring that their inclusion is ethically sound and protective of their rights.

**Equitable resource allocation:** Ethical concerns related to resource allocation must be addressed. Including older adults may require additional resources, such as specialized healthcare services or extended trial durations. Researchers should allocate these resources fairly, without disproportionately burdening other groups or delaying vaccine development.

The ethical considerations surrounding age de-escalation in adult vaccine trials are rooted in principles of equity, inclusivity, and protection of vulnerable populations. By intentionally including older adults in vaccine research, we strive to address historical gaps in knowledge and disparities in healthcare.

However, this approach comes with unique challenges related to informed consent, safety, health status variability, and resource allocation. Ethical vaccine research should prioritize equitable participation while carefully addressing these challenges. It is our ethical duty to ensure that older adults, regardless of their health or cognitive status, have the opportunity to contribute to and benefit from scientific advancements in vaccine development. Age de-escalation is not just a scientific strategy; it is a moral imperative that reflects our commitment to ethical research and the well-being of all age groups in our society.

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