


# Time for action: towards an intersectional gender approach to COVID-19 vaccine development and deployment that leaves no one behind

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**To cite:** Heidari S, Durrheim DN, Faden R, *et al.* Time for action: towards an intersectional gender approach to COVID-19 vaccine development and deployment that leaves no one behind. *BMJ Global Health* 2021;**6**:e006854. doi:10.1136/bmjgh-2021-006854

Received 8 July 2021  
Accepted 23 July 2021

## INTRODUCTION

The COVID-19 pandemic has exposed once again how gender and other inequalities are inter-related with and worsen health disparities. Gender shapes risk of infection, vulnerability to disease and experience of ill health, and socioeconomic disparities.<sup>1</sup> Important interplays between biological sex and gender, as a social construct, and other variables such as age, race and ethnicity, and other health conditions, have demonstrated differential risks of COVID-19 exposure, acquisition and outcomes.<sup>2,3</sup> Sex-based differences in vaccine-induced immune response and adverse events are well documented, and may influence vaccine acceptance, access and uptake, which are also highly gendered.<sup>4</sup> Hence, it is imperative that sex and gender be meaningfully considered alongside other intersecting dimensions when developing and deploying COVID-19 vaccines.<sup>5</sup> Inherent in this is the need for meaningful engagement of the expertise and leadership of women in all scientific research, policymaking and programmatic decision-making processes at global, national and local levels.

This article provides a critical review of the role of sex and gender dimensions from vaccine development to delivery (figure 1). It offers six recommended actions for incorporating an intersectional gender lens in COVID-19 vaccine development and deployment efforts to fast-track and end the pandemic in an equitable way<sup>4</sup> (table 1). The proposed actions are also applicable and necessary for future vaccine research and programmes.

## Summary box

- ▶ The COVID-19 pandemic has revealed persistent gender inequalities that exacerbate health inequities.
- ▶ Sex and gender intersect with other variables such as age, race and ethnicity, and other health conditions, resulting in differential risks and outcomes of COVID-19.
- ▶ Importantly, well-documented sex differences in vaccine-induced immune response and adverse events, alongside gendered factors related to vaccination programmes, may influence vaccine acceptance, access and uptake, further worsening inequities.
- ▶ It is thus imperative that an intersectional gender lens be systematically applied to development and deployment of COVID-19 vaccines.
- ▶ Integral to this approach is meaningful engagement of women at all levels to ensure that scientific, policymaking and programmatic decision-making processes benefit from their leadership, expertise and perspectives.
- ▶ This article presents a rationale and recommended actions for incorporating sex and gender dimensions in current and future COVID-19 vaccine development and deployment efforts to fast-track an end to the pandemic in an equitable way.

## ACTION 1: EPIDEMIOLOGICAL DATA BY SEX AND AGE, AS A MINIMUM, MUST BE ROUTINELY COLLECTED, ANALYSED AND REPORTED TO INFORM VACCINATION STRATEGIES

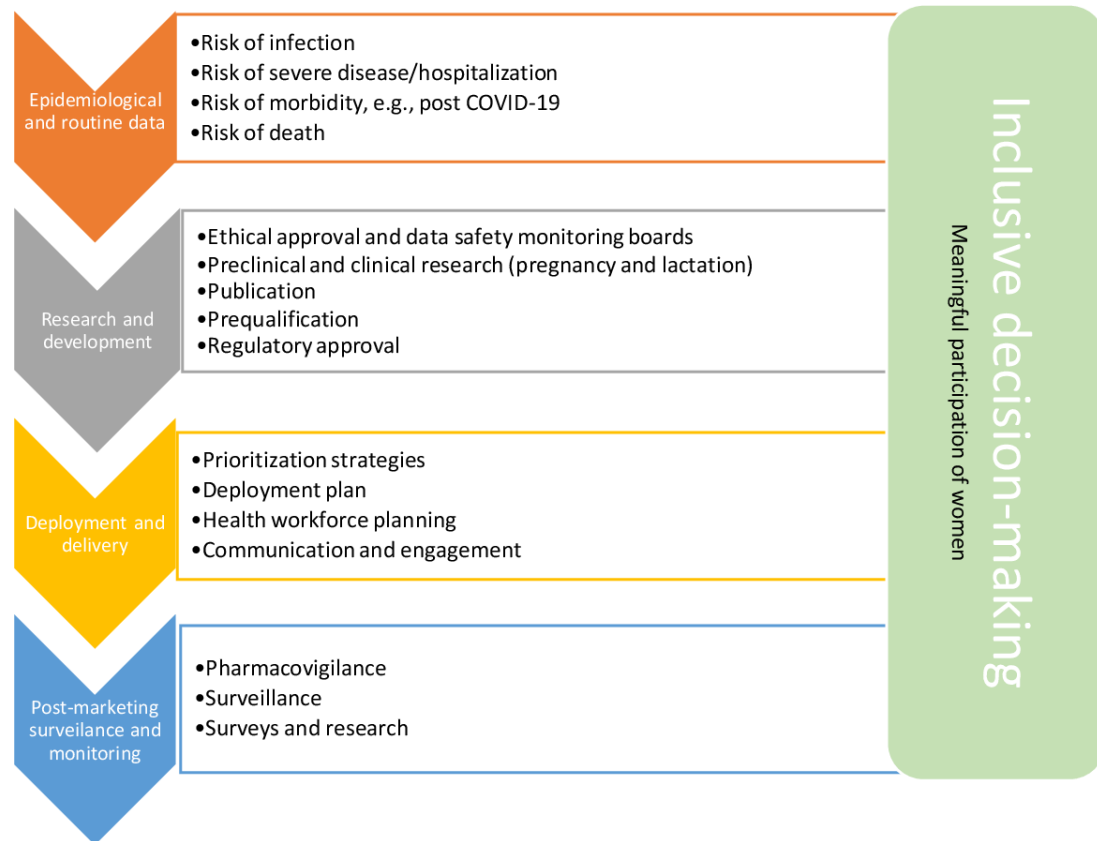
To better understand who is at greater risk of SARS-CoV-2 infection, morbidity and mortality, we need granular data. Global aggregate data indicate an equal distribution of cases between women and men, but a higher case fatality rate in men.<sup>6</sup> Partial data on hospitalisation and intensive care



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**Figure 1** Overview of key areas of COVID-19 vaccine development and deployment where intersectional gender dimensions should be considered, provided in the proposed actions.

unit (ICU) admission from a handful of countries indicate greater severity of disease in men, explained by a combination of higher biological susceptibility and gender-related behavioural risk factors. The higher prevalence of comorbidities in men may be a result of both sex-related and gender-related risk factors, influenced by higher rates of tobacco and alcohol consumption. Poorer compliance with non-pharmaceutical interventions and delay in seeking healthcare may further increase men's COVID-19 risk. Other factors related to differences in testing, hospital access and ICU admission policies cannot be excluded.<sup>7</sup> The incidence and case fatality rates depend on the extent of testing among different population groups, which may vary across countries and over time.<sup>8</sup> Unfortunately, data on testing, hospitalisation, ICU admission and the post-COVID-19 condition are rarely available by sex and other indicators, leaving us in the dark with respect to which groups are at greater risk and why.

Notably, transmission patterns and SARS-CoV-2 incidence and mortality vary between women and men across age groups in different countries as well as within countries.<sup>8-11</sup> The age-specific female to male ratios and patterns of morbidity and mortality can further change over time, shaped by evolving exposure and transmission patterns in the society or extent of testing or diagnosis.<sup>8</sup> While data continue to point to higher mortality among men, emerging data reveal that mid-adult women are more likely to suffer

from post-COVID-19 condition.<sup>12 13</sup> Gender differences can further vary within populations, with greater impact on those affected by structural disadvantages, such as racial or ethnic minorities, people of diverse sexual orientation and gender identity, and other underserved groups. Reports point to higher mortality rates among racial and ethnic minorities, explained by structural vulnerabilities.<sup>14 15</sup> These groups may have greater exposure due to working in the service sectors, living in congregant housing or facilities, or having limited access to accurate information, prevention measures or health services. Unfortunately, data on minority groups are rarely available and gender differences within groups are rarely examined, while these indeed exist. A report from England and Wales points to a differential male to female mortality ratio for different ethnic minority groups, ranging from 1.3 to 3.5.<sup>16</sup> Hence, routine collection of disaggregated data and regular intersectional gender analysis will be invaluable in informing targeted interventions in light of limited capacity and resources (table 1).

#### **ACTION 2: COVID-19 VACCINE STUDIES MUST BE DESIGNED TO ADEQUATELY CAPTURE SEX AND GENDER DIFFERENCES IN SAFETY, EFFICACY AND EFFECTIVENESS OF VACCINES**

Sex differences in the immune response to self-antigens, pathogens and vaccines across the life course are well documented.<sup>10 17 18</sup> Females generally exhibit greater humoral and cell-mediated immune responses to antigens than males as well as upregulated expression of

**Table 1** Recommended actions for integrating sex and gender considerations in COVID-19 vaccine development and deployment

|                          | Who?   | What?  |
|--------------------------|--|--|
| Data collection          | Member states  | Collect, analyse and report data disaggregated by sex and age, at a minimum on: <ul style="list-style-type: none"> <li>▶ Symptomatic and asymptomatic infection</li> <li>▶ Testing</li> <li>▶ Hospitalisation</li> <li>▶ Post-COVID-19 condition</li> <li>▶ Death</li> </ul> Disaggregated data should be collected to enable analysis for different occupation groups.  |
|                          | WHO  | <ul style="list-style-type: none"> <li>▶ Encourage and support member states to strengthen collection of disaggregated data.</li> <li>▶ Make disaggregated data publicly available.</li> <li>▶ Conduct regular intersectional gender analysis to inform policy and guideline development.</li> </ul>   |
| Research and development | Researchers (academia and pharmaceutical companies)                                      | <ul style="list-style-type: none"> <li>▶ Design preclinical and clinical studies that allow sex and gender analyses and examine the rationale for alternative vaccine dosage, frequency and interval for women and men.</li> <li>▶ Plan DART studies at an early stage and appropriately design trials for inclusion of pregnant and lactating women.</li> <li>▶ Consider intersectional gender dimensions in clinical trials to facilitate balanced representation and trial participation.</li> <li>▶ Collect data by sex and age, at a minimum, and other gender-related variables.</li> <li>▶ Ensure follow-up and collection of data on participants who inadvertently become pregnant during trials.</li> <li>▶ Ensure meaningful sex- and gender-based analysis.</li> <li>▶ Make raw disaggregated data publicly available (such as supplementary material in peer-reviewed journals).</li> <li>▶ Report data by sex and age, including data on discontinuation and dropouts, adverse events and primary and secondary outcomes.</li> </ul>   |
|                          | Research ethics committees and data and safety monitoring boards                         | <ul style="list-style-type: none"> <li>▶ Review the gendered risk and benefit of studies.</li> <li>▶ Ensure that studies adequately consider sex and gender dimensions in the study protocol, and monitor adherence to protocols.</li> <li>▶ Ensure protocols include mandatory follow-up on the outcome of participants who become pregnant during study.</li> <li>▶ Review by data and safety monitoring board to consider sex and gender implications.</li> </ul>   |
|                          | Editors, peer reviewers and publishers   | <ul style="list-style-type: none"> <li>▶ Evaluate whether sex and gender dimensions are adequately addressed in the reporting of the study and its findings (see SAGER guidelines<sup>37</sup>).</li> <li>▶ Require that all baseline and outcome data, including data on discontinuation and adverse events, be provided by sex, at a minimum.</li> <li>▶ Request subgroup analysis, if appropriate.</li> </ul>   |
|                          | Regulatory agencies and WHO prequalification mechanism                                   | <ul style="list-style-type: none"> <li>▶ Require that all data, including data on discontinuation and adverse events, be provided by sex, at a minimum.</li> <li>▶ Request subgroup analysis, if appropriate.</li> <li>▶ Evaluate sex and gender dimensions.</li> <li>▶ Require complete data by sex, and sex- and gender-based analysis.</li> <li>▶ Conduct a thorough review of equal safety and efficacy in women and men and whether different dosing strategies may be justified.</li> </ul>  |
|                          | WHO, ministries of health and other international, regional or national technical bodies | <ul style="list-style-type: none"> <li>▶ Adequately incorporate gender considerations in policy recommendations and technical guidelines, and be transparent about the underlying evidence.</li> </ul>   |
| Deployment and delivery  | WHO (SAGE)   | <ul style="list-style-type: none"> <li>▶ Ensure that intersectional gender dimensions are considered in guidance on prioritisations, allocation and deployment.</li> </ul>   |
|                          | Member states  | <ul style="list-style-type: none"> <li>▶ Be mindful about gender gaps and biases in data when developing prioritisation strategies and deployment plans.</li> <li>▶ Conduct baseline gender assessment to identify needs and barriers to immunisation.</li> <li>▶ Be transparent about the rationale and the evidence on which groups are prioritised.</li> <li>▶ Invest to improve data collection capacity and monitoring to ensure reliable gender data.</li> <li>▶ Develop gender transformative national policies to minimise gender and other inequities.</li> <li>▶ Ensure vaccine campaigns and information are gender sensitive and do not stereotype certain groups.</li> <li>▶ Provide training to health workers to sensitise them about gender dimensions and minimise discriminatory provider attitudes.</li> <li>▶ Invest in the well-being and resilience of the health workforce by ensuring a respectful and enabling working environment, zero tolerance for sexual harassment and gender-based discrimination, measures to prevent burnout, provision of psychosocial support, sick leave, insurance and prompt payment of salaries, guarantee of equal pay, access to suitable personal protective equipment, essential hygiene and sanitation products, as well as essential sexual and reproductive health services.</li> </ul> |
|                          | Civil society  | <ul style="list-style-type: none"> <li>▶ Advocate for transparent decision-making about prioritisation and deployment plans.</li> <li>▶ Involve community-based organisations in vaccine delivery to collect and analyse disaggregated data and monitor and address gender and other inequities in access to vaccines.</li> </ul>  |

Continued

Table 1 Continued

|                             | Who?          | What?  |
|-----------------------------|---------------|--|
| Monitoring and surveillance | Member states | <ul style="list-style-type: none"> <li>▶ Ensure that postmarketing surveillance and pharmacovigilance systems adequately collect data by sex and other important variables.</li> <li>▶ Monitor potential gender differences in access and uptake.</li> <li>▶ Invest in qualitative research to understand gender differences in vaccine hesitancy, acceptability, accessibility and uptake.</li> </ul> |
| Inclusive decision-making   | WHO           | Ensure that international COVID-19 vaccine governance structures and policymaking are inclusive, gender balanced, transparent and evidence based.  |
|                             | Member states | ▶ Ensure that national and subnational decision-making processes on distribution of resources, equipment, policies and practices meaningfully involve women.   |

DART, development and reproductive toxicology; SAGE, Strategic Advisory Group of Experts on Immunization; SAGER, Sex and Gender Equity in Research.

antiviral and proinflammatory genes, many of which are regulated by oestrogen.<sup>18 19</sup> Similar patterns are observed in patients with COVID-19, where women with mild to moderate COVID-19 infection show more robust cellular responses and higher antibody levels than men, while men show higher levels of inflammatory cytokines and chemokines than women.<sup>20</sup>

Sex-based differences in vaccine-induced immune responses have been observed following administration of several vaccines, such as influenza, yellow fever and hepatitis A and B, with female adults showing protective antibody responses twice as high as males.<sup>19 21</sup> The observed sex differences likely shrink following reproductive senescence due to a drop in circulating oestradiol in women.<sup>22</sup> Sex steroids have immunoregulatory functions and influence B-cell activity, antibody production and vaccine efficacy.<sup>21 22</sup>

Differential adverse reactions have also been reported in studies of trivalent inactivated influenza vaccine (TIV), inactivated monovalent 2009 H1N1 vaccines and yellow fever vaccines, with women experiencing greater local and systemic adverse reactions, including higher allergic reactions, than men.<sup>2 5 22 23</sup> Early data following administration of 1 893 360 first doses of the Pfizer-BioNTech COVID-19 vaccine in the USA reported 21 cases of anaphylaxis, 90% of which occurred in women.<sup>24</sup> The majority (90%) of non-anaphylaxis allergic reactions were also in women.<sup>24</sup> Similar data were reported following administration of 4 041 396 first doses of the Moderna COVID-19 vaccines (100% and 91% of anaphylaxis and non-anaphylaxis allergic reactions, respectively, occurred in women).<sup>25</sup> The authors suggested that the female predominance may be attributed to women receiving two-thirds of the vaccines (64% of the Pfizer vaccine doses and 61% of Moderna), but other reasons cannot be ruled out. More recently, a very rare yet severe blood clotting condition—thrombosis with thrombocytopenia syndrome—was observed following administration of the AstraZeneca vaccine (24 reported cases, 18 of which were fatal, out of 25 million people who received the vaccine in the European Union and UK as of 22 March 2021<sup>26</sup>) as well as the Janssen COVID-19 vaccine (22 out of a total of 28 cases in women following administration of more than 8.7 million doses in the USA as of 7 May 2021<sup>27</sup>) mainly in women under the age of 60 years.<sup>28</sup> At the same time, there

has been an increase in the reported cases of myocarditis and pericarditis in the USA following mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), predominantly in adolescent and young men, which are being further investigated.<sup>29 30</sup> It is important to emphasise that these adverse events are very rare, and all events have been reported in both women and men. Nevertheless, additional research is warranted to understand the potential underlying mechanism for sex-related and age-related risks.<sup>28</sup>

Despite well-established evidence about the sex difference in immune response and adverse reactions following vaccinations, most vaccine studies do not systematically analyse either outcome data by sex or the clinical implications of differential immune responses in terms of efficacy, dosing or time interval optimisation.<sup>21 31</sup> To our knowledge, one study has explored alternative dosing strategies and reported that women receiving a half dose of TIV exhibit similar or greater antibody response than men receiving a full dose.<sup>32</sup> While the clinical implications of differential immune responses to vaccines remain to be investigated, sex- and gender-based analysis may provide important insights. Additional research is also needed to examine vaccine safety and efficacy among intersex and transgender populations.

While the gender balance in vaccine trials has substantially improved over the years, studies are rarely designed to capture sex or gender differences, seldom report outcome data by sex and inadequately examine implications in terms of gender.<sup>31 33 34</sup> Some of the recent COVID-19 vaccine studies report the overall efficacy by sex. However, data on discontinuation after the first and second doses, or adverse reactions are not reported by sex, and studies do not examine possible sex differences across age groups or arms with differential dosing or interval.<sup>35 36</sup> In the context of vaccine shortages, sex- and gender-based analysis of efficacy and adverse event profiles, or consideration of alternative dosage, frequency of administration or timing interval, could provide useful insights, suggest ways to enhance efficacy, reduce adverse reactions and improve overall acceptability and uptake.<sup>22</sup> Evidence of an equal safety and efficacy profile of a potential alternative dosage for women (as may be expected based on preliminary immunogenicity data and indications from



previous studies of influenza vaccines) could influence the availability, cost and affordability of COVID-19 vaccines. Although the programmatic and logistical implications of such 'sex-specific' vaccine dosing are unknown, experiences from differential dosing of medications may be informative.

Bringing about change requires gatekeepers in the health research system to ensure a systematic integration of these dimensions at all stages of vaccine research and development. Researchers must incorporate sex and gender dimensions at the time of design of studies (including preclinical and animal studies). To successfully enrol and retain sufficient numbers of women and men in vaccine trials, a gender lens must be applied to every aspect of trial design, including how information and invitation for recruitment are formulated and distributed; how trials are planned to facilitate participation in terms of timing, location and consideration of childcare issues; financial implications in terms of income loss or indirect costs related to participation; and whether accurate information about the potential experience of adverse effects is provided.

Ethics committees and data safety and monitoring boards must require consideration of sex and gender in study protocols and review these dimensions in interim analyses and monitoring. Editors and peer reviewers of scientific journals need to remind investigators and pharmaceutical companies to report baseline and outcome data (including data on adverse events and discontinuation) by sex, as a minimum, as recommended by the Sex and Gender Equity in Research (SAGER) guidelines.<sup>37</sup> National regulatory agencies and WHO prequalification mechanisms should require complete data by sex (and, ideally, concurrently by sex and age) as well as sex- and gender-based analysis, to conduct a thorough review of equal safety and efficacy in both women and men and whether different dosing strategies may be justified. WHO, ministries of health and other international, regional or national bodies must adequately incorporate gender considerations in their recommendations in technical guidelines and be transparent about the underlying evidence (table 1).

### **ACTION 3: DATA ON SAFETY, EFFICACY AND EFFECTIVENESS OF VACCINES IN PREGNANT WOMEN AND LACTATING WOMEN MUST BE GENERATED AT AN EARLY STAGE**

A growing body of data show an increased risk of severe disease and death in pregnant women with symptomatic COVID-19 infection compared with non-pregnant women.<sup>38</sup> A living systematic review and meta-analysis of clinical manifestations, risk factors and maternal and perinatal outcomes of COVID-19 in pregnancy confirm that while pregnant women with COVID-19 are less likely to have symptoms, they are at greater risk of ICU admission, invasive ventilation and extracorporeal membrane oxygenation treatment, and are more likely to die than are non-pregnant women.<sup>38–43</sup> Pregnant women of colour

and underserved groups appear to experience a disproportionately higher prevalence of COVID-19 infection and a greater risk of ICU admission and death.<sup>38 39 44</sup>

These disparities are due to a range of social and structural factors that include socioeconomic disparities, access barriers, occupational exposure and prevalence of chronic conditions. Pregnant women with comorbidities such as obesity, chronic hypertension and diabetes may be at an even higher risk of severe illness (consistent with the general population with similar comorbidities), which can result in an elevated risk of adverse pregnancy and birth outcomes.<sup>38–40 42 43 45 46</sup>

Yet, data on the safety and efficacy of COVID-19 vaccines during pregnancy and lactation are very limited. Pregnant women have historically been excluded from clinical trials, even from trials for vaccines whose primary target was pregnant women, such as Zika.<sup>47</sup> Recent efforts, such as the US Task Force on Research Specific to Pregnant Women and Lactating Women or the Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies Working Group, provide ethical guidance for preparedness, research and response for pregnant women and vaccines against emerging epidemic threats.<sup>47 48</sup> Despite these recommendations, initial clinical trials with COVID-19 vaccine candidates excluded pregnant women, and development and reproductive toxicology (DART) animal data have been lagging. Data from DART studies of COVID-19 vaccines are now available, indicating no reproductive toxicity.<sup>49–53</sup> Clinical studies with pregnant women commenced in 2021, but most will only be completed in 2022.<sup>54 55</sup> The failure to collect timely pregnancy-specific data denies pregnant women vaccines that could protect them and their infants from severe disease and death.<sup>47</sup> In some countries, pregnant women have been excluded from vaccine programmes due to insufficient evidence. In the interim, WHO recommends the use of COVID-19 vaccines in pregnant women when the benefits outweigh the potential risks. In the absence of evidence, the burden of decision-making lies with women and their clinicians. To support pregnant women in making this assessment, the WHO guidance states that pregnant women should be informed about the risks of COVID-19 in pregnancy, the likely benefits of vaccination and the current limitations of safety data.<sup>56–58</sup>

It is critical that DART studies be initiated at an early stage, and pregnant and lactating women be included in appropriately designed vaccine trials to generate sufficient and timely evidence about the safety of vaccines on pregnancy outcomes as well as to assess immune responses to vaccination in pregnant women, which are different from those of non-pregnant women.<sup>48</sup> Furthermore, participants who become pregnant during clinical trials must be followed up, and data on pregnancy outcomes collected and reported.<sup>48 59</sup> Dedicated pregnancy registries, such as those being developed by the US Food and Drug Administration and the European Medicines Agency, are also needed to ensure adequate

postmarketing surveillance. An international pregnancy registry is also being implemented<sup>60–62</sup> (table 1).

#### **ACTION 4: COVID-19 PRIORITISATION STRATEGIES AND DEPLOYMENT PLANS MUST BE GENDER RESPONSIVE AND MINDFUL OF GENDER-RELATED BARRIERS TO IMMUNISATION**

The supply constraints and limited availability of COVID-19 vaccines call for prioritisation strategies to identify target populations, taking into account transmission, morbidity and mortality risk. The *WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply* (version 1.1, 13 November 2020), anchored in a values framework,<sup>63</sup> encourages prioritisation decisions to also consider maintenance of essential services and ‘reciprocity towards groups that have been placed at disproportionate risks to mitigate consequences of this pandemic’.<sup>45</sup> The roadmap includes a section on gender and adheres to an equal respect principle of reaching both men and women in every priority group. The disproportionate burden of paid and unpaid care on women, and their frequent contact with children and the elderly (either as caregivers or in occupations that are predominantly female, such as nurseries and schools, nursing homes and homes for elderly care) put them at greater risk of contact with others who may have symptomatic or asymptomatic infection, yet many may not be categorised as high risk. The notion of reciprocity is also important to bear in mind in relation to front-line health workers and the overall greater contribution of women to sustaining the well-being, education and immunisation of children during the pandemic. Furthermore, the intersectional challenges affecting people of diverse sexual orientation and gender identity, and other minorities also need to be appropriately considered.

The WHO SAGE roadmap provides guidance; however, prioritisation decisions are the responsibility of countries, why it is critical that national prioritisation decisions and policy recommendations are based on national data on vaccine performance and safety, and evolving evidence on transmission patterns, disease and death. However, such decisions will be constrained by the availability of disaggregated data. Failing to collect, analyse and report data by sex and age on a range of indicators will hamper gender-responsive guidance. Often, in the absence of sufficient data, decisions are informed by mathematical models, the reliability and precision of which are highly dependent on the accuracy and completeness of data and the assumptions that underpin them. Studies already point to ‘biased prediction models due to unrepresentative datasets and other limitations during model development’, and how decisions based on these models risk reproducing and reinforcing inequalities.<sup>64</sup> In light of the gender gaps and biases in available data, national prioritisation decisions must be transparent about the rationale and the evidence on which groups are prioritised. At the same time, data collection capacity and monitoring must be strengthened to ensure that reliable gender-sensitive data underpin national policymaking.<sup>65</sup>

Similarly, deployment plans need to be designed with gender and other equity concerns in mind.<sup>66</sup> Quality of services, provider attitudes, communication, education and health literacy, autonomy and agency, access and control over resources, mobility, gender-based violence and other harmful practices come into play during COVID-19 vaccine deployment. These issues may create gender-related barriers to immunisation—particularly for specific groups such as people of diverse sexual orientation and gender identity, ethnic minorities, and migrants and refugees—and must be accounted for to ensure equitable vaccination.<sup>67</sup>

Importantly, the well-being and resilience of health and social workers, most of whom are women, is paramount during the pandemic and vaccination roll-out. The scale and pace of COVID-19 vaccine roll-out will create an additional workload on already stretched and, in many places, weak health systems. Governments must ensure respectful and enabling working environments with zero tolerance for sexual harassment and gender-based discrimination. Working hours and shift assignments must aim to prevent burnout, and resources should be made available for mental health and psychosocial support, sick leave, health insurance and prompt payment of salaries, and guaranteeing equal pay. Provision of continuous training on infection prevention and control measures, suitable personal protective equipment, essential hygiene and sanitation products, as well as access to sexual and reproductive health service are equally essential. Particular attention must be paid to prevent and combat gender-based and intimate partner violence, as data point to a sharp increase during the pandemic<sup>68</sup> (table 1).

#### **ACTION 5: POSTMARKETING SURVEILLANCE AND MONITORING MUST COLLECT DISAGGREGATED DATA TO CAPTURE POTENTIAL DIFFERENTIAL EFFECTS AND UPTAKE**

The effectiveness of the COVID-19 vaccine strategy in ending the pandemic will depend on high immunisation coverage to produce community immunity and minimise transmission. Thus, key to successful COVID-19 vaccination programmes is addressing vaccine hesitancy, enhancing confidence in and acceptability of COVID-19 vaccines and facilitating access. All of these factors are gendered and can be negatively influenced by harmful gender norms, beliefs and expectations.

In turn, factors affecting vaccine acceptance and resistance include concerns or misperceptions about vaccine safety, effectiveness and adverse effects. Lower formal educational levels are also correlated with not getting vaccinated.<sup>69</sup> Vaccine uptake, on the other hand, is positively associated with the perception that infectious diseases are ‘likely, serious, and regrettable’.<sup>70</sup> Differences in vaccine uptake and vaccine confidence, that is, ‘believing that vaccines are important, save lives, and have few side effects’, have been observed between women and men.<sup>70</sup> For example, studies of seasonal influenza vaccines have shown lower acceptability and uptake of vaccines among women compared with men.<sup>22</sup> A systematic review

on uptake of vaccination against pandemic influenza concluded that men were more likely to intend to be vaccinated and to be vaccinated than women.<sup>71</sup> In some countries, more women expressed fears about the efficacy and safety of the pandemic influenza vaccine, which may explain their lower uptake.<sup>71</sup> Uptake can further be influenced by accessibility, such as feasibility in terms of timing and location of vaccination programmes.

Data from various countries point to gender differences in vaccine acceptance.<sup>72</sup> In early 2021, an online survey in the USA reported male respondents being more sceptical about COVID-19 vaccines than women.<sup>73</sup> The findings further found that men who asserted they were 'completely masculine' were more likely than other men to be COVID-19 vaccine resistant (21% vs 17%).<sup>73</sup> In contrast, another survey among nearly 1800 health-care workers in the USA showed that women were twice as likely to be vaccine resistant (27% vs 13%), defined as unwillingness to be vaccinated.<sup>74</sup> Although reasons for the gender differences in vaccine resistance were not captured by the survey, the highly publicised greater occurrence of the rare COVID-19 vaccine adverse reactions among women described earlier may influence perception of vaccine safety and vaccine confidence.<sup>24 26 75</sup> While these events remain rare, the differences between women and men underscore the necessity for pharmacovigilance, surveillance and monitoring systems to collect, analyse and report data by sex and other indicators to identify or rule out any notable discrepancies in vaccine safety and experience of adverse events. Qualitative studies (including ethnographic research) may shed further light on contextual gender dimensions and increase understanding of underlying causes for and consequences of vaccine hesitancy.

Correct and nuanced information about the differential risks and frequency of adverse events to alleviate vaccine safety concerns and other factors that influence acceptability of vaccines must be developed and designed with gender in mind.<sup>76</sup> Gender and equity dimensions are important when developing communication and advocacy materials: how information on vaccination and vaccine safety is communicated and by whom, the languages used, who is portrayed in the material and how, whom the materials reach and how they are perceived, and the way information is distributed and disseminated (as well as the choice and use of social media and the messaging). All these factors are influenced by gender, and a gender transformative approach has the potential to optimise programmes and ensure equitable access to COVID-19 vaccines (table 1).

### **ACTION 6: EQUAL PARTICIPATION OF WOMEN IN DECISION-MAKING AT ALL LEVELS CAN SUPPORT SUCCESSFUL VACCINE IMPLEMENTATION**

Women constitute up to 70% of the health workforce, yet only 25% are represented in senior positions.<sup>77</sup> The recent Global Health 50/50 report shows that among 201

global health organisations reviewed, only 36% reached parity in senior management and 29% reached parity in governing bodies. Of these, the majority had male chief executive officers and board chairs (71% and 69%, respectively).<sup>78</sup> Gender imbalances in the management and decision-making positions of the health sector must be addressed, and flexible workplace policies and plans must be implemented in a way that does not undermine the safety and resilience of the predominantly female health workforce. In the context of COVID-19 vaccines, decision-making processes at national, subnational or international levels must ensure women, especially women health workers, are engaged and involved in decisions about allocation and distribution of resources and equipment, and in the development of policies and programmes, given that these have an impact on their health and well-being.<sup>79</sup> International COVID-19 vaccine governance structures, as well as regional and national committees related to vaccination, need to be gender balanced and inclusive (table 1).

### **CONCLUSIONS**

As several COVID-19 vaccines are being rolled out at unparalleled pace and scale, and other vaccine candidates are in clinical trials, it is imperative that gender considerations be central throughout the continuum of vaccine development throughout deployment. The lessons learnt from COVID-19 vaccines are relevant for future research and development of other vaccines. Applying an intersectional gender lens at each step of the process will help identify potential sex differences, and gender-related inequities, and support tailored vaccination programmes that can effectively respond to the diverse needs and experiences of women, men and non-binary persons, thereby ensuring vaccination of 'everyone, everywhere'.

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**Contributors** SH wrote the initial draft of the manuscript. TSG, SK, FO, RF, DND and NM provided comments to subsequent revisions. All authors read and approved the manuscript.

**Funding** The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Disclaimer** The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views, decisions or policies of their respective organisations.



**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; internally peer reviewed.

**Data availability statement** No primary data have been used in this article. All data relevant to the study are included in the article or uploaded as supplementary information.

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