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Working paper:

ASPHER Third COVID-19 Vaccines Statement

Towards 'Vaccine internationalism':

Equitable global vaccine goals are fundamental to combatting COVID-19

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Summary points:

Chaos or cohesion? ASPHER is concerned about the potential for chaotic differences in vaccination policies between countries which threaten our collective ability to control and suppress the virus worldwide and allow the potential for further virus mutations which may be vaccine resistant. Until we are all free of the virus, no-one will be free of the virus. We need to see global consensus on vaccine policy and governments ceding leadership on vaccination policy and oversight to the World Health Organisation.

Equity or exclusion? Current vaccine nationalism adds to division, and creates a climate in which public trust in governments and health authorities is diminished and an effective response to the pandemic is jeopardized. Loss of trust in vaccine policies creates a climate in which there are deserving and undeserving recipients of vaccine and conditions are created in which vaccine hesitancy can be allowed to grow.

1. Introduction

ASPHER considers that the core aim of the COVID-19 vaccination programmes should be to achieve (vaccine derived) herd immunity worldwide as soon as possible, thereby minimizing the spread of the virus between countries and within countries. The avoidance of inequalities in acquisition and delivery of vaccinations is a fundamental ethical and moral issue, of fairness, between and within all countries. There is also a strategic imperative with pragmatic consequences to ensure other vital goals of comprehensive global vaccination, such as to support sustainable economic development, allow international travel and movement, and by restoring and further building accessible health and social care systems for all our populations.

COVID-19 has disproportionately affected sub-populations such as the elderly who tend to suffer from more severe disease and minorities and workers in selected occupations who are at an increased risk of exposure to the virus. In addition, owners of small businesses, children of school-going age and their parents have suffered significantly from the consequences of lockdown measures. Vaccine policy, carefully and sensitively implemented, provides an overarching opportunity to help redress and alleviate the inequalities due to the COVID-19 pandemic.

Moreover, beyond the profound ethical dimension, no region or nation can be free of the pandemic, until all nations are free of it. This should be a practical and pragmatic concern for everybody. Until there is an international consensus and operational strategy, the virus will find new vulnerable populations and continue to spread. It won't respect international boundaries and will not be limited or eradicated by uneven coverage of vaccination across different populations and countries. It will continue to replicate and mutate to new and as yet unpredictable forms of the virus, which potentially limit the effectiveness of vaccines and further threaten the world's health and economic prosperity. This will result in a continuing need for restrictions on international travel, variably and inadequately implemented by individual countries. For this reason, ASPHER believes that we urgently need to address a number of critical issues. These include international strategy and government commitment, implementation issues (including priority setting and rollout phasing plans); concerns about departure from standard practices during vaccine shortages and delays, assessment and intervention to minimise vaccine hesitancy and identification of priorities in research.

2. International strategy and governmental commitment

1. Greater international effort should be made to deliver comprehensive vaccination programmes across the globe.
2. National governments should commit to international leadership of the vaccination effort through the World Health Organisation, supported by other international key agencies. The ugly face of 'vaccine nationalism' must be overcome (ref- Tedros Reuters 18/1/21) and be replaced by 'vaccine internationalism.'
3. A clear strategy needs to be adopted of how to move towards reducing the spread of the virus. This is not simply a question of finding funding, to support poorer countries access to vaccines. It requires an international consensus of governments and an explicit strategy that national governments will follow. Such a strategy requires recognition of the need to deploy vaccines appropriately, in accordance with local circumstances in the health system e.g. cold chain context, or in relation to a country's health budget and economic circumstances.
4. We would encourage WHO and public health agencies to urgently revise and agree on global evaluation frameworks for the COVID-19 vaccines. This should build upon historical (and recent pandemic related) communicable disease control, elimination, and eradication approaches. The rapid reporting dashboard must ensure global surveillance and disease epidemiology, rapid reporting of vaccine delivery and uptake (with planned seroprevalence studies), and support for alerting and mobilizing outbreak control for emergent diseases.
5. There is growing concern that Africa is suffering a COVID-19 pandemic crisis that has led to the loss of thousands of lives and disrupted millions more and that the pandemic is under-reported and under recognised in African states. There are also particular considerations for the suitable deployment of vaccines. For example, the Pfizer vaccine is unsuitable without expensive refridgeration below -70 Celsius for transportation. International efforts are need to ensure vaccination programmes are effective and appropriate for administration in the differing circumstances within countries.
6. We need to anticipate significant mutations in the SARS-COV-2 virus in order to maintain and develop vaccine responses to the virus. There is a need for a global collaboration in immunology, virology, public health and vaccinology which takes a One Health approach

with ecologists and veterinary scientists. A good example is the international collaboration on anticipating the antigenic drift of influenza viruses, which is advanced and sophisticated and. (Ref). It will be essential to secure global collaboration and capacity to anticipate the antigenic drift or shift in the SARS-COV-2 and to predict and adapt vaccines to combat these new strains when necessary. Without this, there may be the possibility of a perpetual COVID-19 pandemic. We believe that the World Health Organisation should to lead our efforts on this.

3. National government considerations

1. There are should be meaningful timescales to achieve maximal population coverage in all countries.
2. There should be transparency in publication of the results of monitoring programmes and the consideration of variation in dosage schedules.
3. There should be formulation of detailed vaccination programmes, including quality and field effectiveness aspects such as:
    - Highly developed logistics and deployment of vaccine and staff.
    - Rational prioritisation and greater clarity about population sub-groups such as increased vulnerability to severe disease, pregnant and breastfeeding women and children. Other priority groups should include those performing essential duties, health-care workers and caregivers and other key workers.
    - Reminding and training vaccinators on the correct technique of intramuscular administration of the vaccine (injection technique skills) and the basic qualifications required to give the injections.
    - Making public the time distribution of vaccinations (including weekends and holidays), verifying that there are sufficient personnel within the health system to administer the vaccines, and in case it is not enough, assessing the recruitment of contingency personnel.
    - Identifying vaccine precautions and contraindications in extraordinary cases
    - Ensuring pharmacovigilance and impact assessment plan for COVID-19 vaccines.
    - Strong communication to counteract fake news and vaccine hesitancy

4. Priority setting and rollout phasing plans.

1. We advocate that each country, from the beginning, should have a transparent and auditable (socio-ecological) policy for addressing vaccine inequalities challenges.
2. We recognize the current broad priority setting adopted by most countries, covers accepted vulnerable groups and health and social care workers.
3. However, there is a judgment to be made about who is at highest risk of exposure, and who is at highest risk of severe consequences of the disease. For this reason, we believe health and care workers should be placed in first priority in view of the high level of occupational exposure to the virus they face, the need for resilience in this workforce to continue to care for others, and uncertainties about the severity, particularly from the new variants of SARS-COV-2. The other high priority group is the elderly (particularly those in care homes), who are at a substantially higher risk of severe disease. Care-givers for the elderly should also be prioritized.
4. We recognise there are sound grounds for vaccinating school teachers and pre-school facility child carers if we wish schools and nurseries to continue to be open and their staff resilient to infection, when other sectors of society are closed.
5. Other key services workers or those occupationally highly exposed could be in phasing plans.
6. Countries should consider vaccinating key workers who are essential for maintaining overall economic and social resilience, for example, police, power and water workers, nuclear and chemical plant operators.
7. We encourage collaborative work with disadvantaged communities to engage, gain trust and maximise inclusion*. (reference)*Consider communal or crowded settings that are prone to outbreaks, such as prisons, migrant camps and detention centres, and those supporting homeless people could be considered.
8. Recognising that some of the elderly and other high risk groups will still be at risk of disease due to a less than 100% efficacy of the vaccine, there is a need to outline a policy for immunizing children to reduce the community spread of the virus
9. Varying schedules or doses should be carried out with caution since they have not been formally tested in clinical trials. However, extrapolations are possible if they are

evaluated carefully with accompanying scientific data. We recognised these variations are based on interpretations of available data, but that this may be small numbers and sub-set analysis. It has also been based on scientific judgements with some justification on past experience with vaccines. Some of these variations to vaccine dosage or schedule are shown in the table. All alternative options that go beyond the technical data sheet of each vaccine (which specifies its characteristics and practical aspects) derived from the clinical trials whose results have generated its approval, must be carefully researched to assess whether or not they affect the impact of the administered vaccine itself.

10. We believe other models of targeted implementation of vaccination should be carefully evaluated. This would be particularly the case if more formal disease eradication strategies were to be adopted, e.g. pursuit of localised foci of infection to help achieve full elimination in any remote areas or outlying community. ('Ring vaccination' as applied in smallpox eradication)

Current live or proposed changes to does and schedules of COVID-19 vaccines

1. Delaying second dose (UK decision)
   Advantages
   Greater population coverage
   Disadvantages
   Less individual immunity
   Loss of immunity over time
   Failure to come for the second dose
2. Giving half doses (USA suggestion)
   Advantages
   Greater population coverage
   Disadvantages
   Untested in trials
   Less individual immunity
   Loss of immunity over time
   Not sure whether second dose should be full or half
3. Mixing vaccines from different manufacturers
   Advantages
   More flexibility in purchasing and distributing vaccines
   Disadvantages
   Not usually recommended
   Should not be using vaccines produced by different technologies

5. Assessment and intervention to minimise vaccine hesitancy

Vaccine hesitancy is likely to remain a problem. Despite the high compliance in the initial vaccination campaigns, this may be due to vaccinating the "easy to reach" population first. Later in the campaigns we may encounter more resistance. First, we must identify misinformation and disinformation that will gradually emerge around vaccines, to know where the problems are and to counteract them. Also, interventions should be designed taking into account behavioural aspects for acceptance and uptake of COVID-19 vaccines. Moreover, it is important to identify the possible resistant groups and the reasons for their resistance to the vaccine. In this way, tailored information programs can be developed and shared internationally.

It is also necessary for appropriate public information campaigns communicate realistic expectations of what mass vaccination will achieve and when. Social distancing and non-pharmaceutical interventions will remain necessary for a considerable time before substantial suppression of viral transmission will be achieved. Side effects and complications of vaccination need to be understood and acknowledged. We cannot be reliant on pharmaceutical industry public information nor can there be collusion with pharmaceutical companies on post marketing surveillance issues. Unless public information and surveillance are clearly authoritative and independent, vaccination programmes may attract distrust and disillusionment from the general public and vaccine hesitancy may grow.

6. Research questions

1. Immunisation may produce immunity but it is not clear whether it reduces excretion of viable virus at infectious dose levels. It may therefore prevent illness but not prevent spread. Non pharmaceutical protections including masks and social distancing would continue to be needed.
2. Herd immunity – the percent of the population that needs to be immunized in order to achieve herd immunity is still not clear. Some commentators have suggested it is 70%; however in Manaus 76% of the population has been infected and there is still no herd immunity.

3. We are still awaiting trial results on the safety of the vaccine in children under the age of 16.
4. Effective methods of monitoring the impact of the vaccine on disease rates are in development.
5. The role of antibody surveys is also being assessed. The length of time immunity is maintained is a very important question.
6. Concerns about departure from standard practices during vaccine shortages and delays as highlighted above in section 4 also require continuing research. Varying schedules or doses should be carried out with caution since they have not been formally tested in clinical trials. However, extrapolations are possible if they are evaluated carefully with accompanying scientific data.

7. Conclusion

ASPHER believes the creation of a range of vaccines to combat SARS-COV-2 is a major scientific achievement brought about through genuinely international efforts. The willingness of scientists to collaborate must now be matched by politicians from all nations. There is a need for global capacity and collaboration to anticipate new strains of the virus and new modifications of vaccines. Without it, we may be faced with a perpetual COVD pandemic. There must be no continuation of the 'vaccine nationalism' we have seen.

Politicians of all nations must commit to a global strategy for the control and eventual elimination of the SARs-COV-2 virus, cause of the COVID-19 pandemic. There must be a genuine commitment to equality of access to vaccines between and within countries. This is a fundamental question of fairness and the right of all global citizens to health. But it is more: the virus will not be eliminated anywhere, if it is not eliminated everywhere. Restoration of the pursuit of health and the pursuit of a better economic and social future or our global citizens requires a global commitment to the biggest vaccination programme ever undertaken. Nations should pool their sovereignty and put their weight behind the World Health Organisation to make this happen.

References

1. Polack FP, Thomas SJ, Kitchin N, Absalon J, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med 2020.
2. L.R. Baden, H.M. El Sahly, B. Essink, K. Kotloff, S. Frey, R. Novak, D. Diemert, Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med 2020
3. The WHO communication e-module covers this to some extent https://vaccine-safety-training.org/overview-and-outcomes-6.html
4. https://blogs.bmj.com/bmj/2020/12/11/the-covid-vaccination-programme-is-an-achievement-but-must-not-lead-to-more-health-inequalities/
5. The UK had adopted a socioecological model as per PHE recommendations to prevent and mitigate likely inequalities. https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020/annex-a-covid-19-vaccine-and-health-inequalities-considerations-for-prioritisation-and-implementation
6. Perhaps mention examples of country level training models and prior assessment e.g. uk. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool
7. The broad WHO glossary and vaccinator training e-modules are there and could be tailored? https://vaccine-safety-training.org/glossary.html
8. WHO Technical Advisory Group on Behavioural Insights and Sciences for Health. Behavioural considerations for acceptance and uptake of COVID-19 vaccines. Geneva: World Health Organization; 2020. https://apps.who.int/iris/bitstream/handle/10665/337335/9789240016927-eng.pdf

Appendix

Table. The efficacy of the Pfizer and Moderna vaccines

Vaccine	**Overall efficacy**	**95% CI**	**Cases Placebo vs Vaccine**	
All ages				
Pfizer	95.0	90.3-97.6		
Moderna	94.1	89.3-97.6		
Over age 65				
Pfizer	94.7	66.7-99.9	19 to 1	
Moderna	86.4	61.4-95.2	29 vs 4	
After first dose				
Pfizer				
All cases after first dose	52.4	29.5-68.4	82 vs 39	
2-7 days after second dose	90.5	61.0-98.9	21 vs 2	