The Independent SAGE Report 25

Issues and recommendations concerning COVID-19 vaccine rollout

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Summary and recommendations

Preliminary results from clinical trials indicate that there are at least three vaccines that could play an important part in addressing the COVID-19 pandemic. This is a very major advance in our fight against the virus. The following report identifies some of the key determinants of the most effective use of these vaccines in the future and presents some preliminary recommendations.

The following recommendations have been developed from consideration of factors likely to influence how far vaccine roll out meets the goal of combating COVID-19.

Accountability

1. Ensure transparent, publicly accountable, independent assessment of vaccine trial data to guide UK regulatory approval.
2. Beyond the issue of regulatory approval, set up a fully independent evaluation programme that has full access to trial data and a direct route to dissemination of findings to the public without censorship.
3. Build problem detection and troubleshooting into the implementation programme from the start.

Communication

4. Use honest, clear, and targeted communication about the vaccine and its effectiveness and side effects to inform and build trust in the general population and key stakeholders.
5. Anticipate, monitor, and address disinformation campaigns, and avoid fuelling these campaigns by exaggerated or questionable reporting in press releases, and academic papers.
6. Anticipate and address concerns arising from the inevitable health issues that will arise that may or may not be related to the vaccine.
7. Avoid overstating the potential of the vaccines and acknowledge their limitations from the start.
8. Accept that doubts and questions about vaccines are reasonable and should be fully addressed, treating those who express legitimate doubts with respect.

Implementation

9. Use co-production and stakeholder engagement at all stages in the roll out.
10. Use the vaccine as a part of the overall strategy to eliminate COVID 19 from the UK

Background

The recent announcements by university/drug company collaborations (Pfizer/BioNTech, Moderna, University of Oxford/AstraZeneca and the Sputnik 5 team) of preliminary results from Phase 3 (final stage) vaccine trials have been greeted with enthusiasm around the world. The promise of effective vaccines is particularly welcome for the populations of countries whose governments have failed to protect them from the burden of disease generated by COVID-19. These results also demonstrate that the immune responses elicted by other COVID-19 vaccines in Phase 2 trials may lead to protection. We can expect more detailed results from these trials over the next few weeks.

For a vaccine programme to be effective it needs to be widely implemented and accepted by the population. This requires trust. Trust is not built by issuing interim results of a study through press releases without making clear distinctions between planned and post-hoc analyses and transparent reporting of way in which the study has deviated from its original design. Neither is it built by failing to highlight the huge commercial conflicts of interest that exist.

A vaccine programme has to be part of a wider strategy for combating COVID-19, including public health measures to control spread of the virus and medium and long-term plans that may include repeated vaccination over an extended period.

Considerations to address in vaccine rollout

With this in mind, a set of specific considerations have been identified by members of Independent SAGE, including its behavioural sub-group, drawing on experience development and implementation of other pharmacological treatments, and in line with a broad criteria for evaluation interventions of this kind. These considerations were used to derive the preliminary recommendations listed at the start of this report.

Efficacy and Safety

1. Basing plans for vaccine purchasing and mass rollout on sketchy press releases is unsatisfactory. It is essential that trial data of sufficient granularity are made available to the public as well as the UK independent regulatory structures responsible for assessing efficacy and safety. Further, those regulatory processes must be allowed to proceed without external pressure, implicit or explicit.
2. It is rare for results from efficacy trials to be matched in routine clinical settings and in the case of COVID-19 there are major implementation issues that may reduce both effectiveness and impact. These involve behavioural factors related to complexities in processes involved in manufacture, quality control, transport, storage and other logistics (e.g., need for very low temperature containment for some vaccines) and application.
3. Whilst many hundreds of thousands of trial participants have received one of the vaccines to date, only short-term efficacy and safety data are available. Most adverse effects of vaccines will indeed be apparent from such short term follow up. Nevertheless, there is always a possibility of longer-term adverse reactions, including neurological effects, and also what is termed "enhancement" of future infection.
4. Stringent "Phase 4" (post licencing) safety monitoring systems must be in place, including through the "Yellow Card" reporting of adverse events, and vaccine recipients should be well versed in these requirements and processes.
5. It remains unclear how long vaccine-induced protection will last. Such data will emerge through long-term follow-up of vaccine recipients.
6. There is such a lot at stake financially that there will be a strong pressure to ignore or downplay problems on the part of commercial providers and to exaggerate benefits. It will be crucial to involve a fully independent watchdog to oversee evaluation.

Acceptability

7. Polling evidence shows that between 30% and 40% of the UK population currently have doubts about taking a COVID-19 vaccine. However, it is important to distinguish between those who are 'anti-vaxxers' (and have an unconditional opposition to the vaccine) and a considerably larger group of those who have been labelled 'vaccine hesitant' (have concerns about safety that they want answered before being willing to take the vaccine). On the one hand, anti-vaxxers will seek to mobilise distrust in Government and the health authorities in order to turn hesitancy into opposition to vaccination. On the other hand, the success of any vaccination programme depends on gaining the trust of those who are hesitant. This starts with recognising and addressing legitimate concerns.
8. Building trust around the vaccine cannot be separated from general questions of trust and confidence in the Government. In addition, however, there are a number of specific measures that need to be taken:
    - *Accuracy*: The potential of the vaccine should not be over-stated, nor should potential limitations be hidden. The public should be informed in advance that there will be some side effects and that, in addition, many people will experience naturally occurring adverse events (symptoms which arise soon after receiving the vaccine) unrelated to the vaccine. It should be noted that there is generally lower tolerance for the negative effects of drugs

that are preventative rather than curative, and the danger of a backlash will be much greater if these effects are only acknowledged later.

- *Transparency*: Trust depends upon full information both about the process by which the vaccine is approved (what steps are involved and the independence of those involved) and what is in the vaccine.
- *Dialogue*: as shown by the procedural justice literature, trust in authority depends upon the extent to which authorities treat people with respect. In particular it is important to listen to people and be seen to heed their concerns – especially in health contexts. It is important to establish a two-way dialogue with those who are vaccine hesitant.

Prioritisation

9. In September, the UK's Joint Committee on Vaccination and Immunisation (JCVI) produced interim priority guidance on how administration of the vaccine should be targeted in the early phases of its availability. This was based on the risk factors identified to date for serious disease and death. It is entirely appropriate that the vaccine should be made available initially for the vaccination of people in older age groups, particularly those in residential care settings, health and social care workers and to NHS frontline staff. This is supported by research modelling the effects of different approaches to population vaccination against COVID-19.

10. The overall risk from a disease is a function of a) risk of exposure to infection, and b) risk of disease once infected. We now know that some occupational groups (those which are public facing), overcrowding, and social deprivation are associated with higher seroprevalence of COVID-19, reflecting greater exposure risk. This is in addition to potential co-morbidities and other risk factors for severe disease. The JCVI and other policy makers need to consider such exposure data in prioritising groups for vaccination.

11. In order to gain public acceptance for the legitimacy of any prioritisation scheme, it is important that it is not simply imposed from above. As noted in point 7 above, it is important to develop a dialogue between government, scientists and the widest possible range of groups amongst the general public.

12. Decisions about who to prioritise to receive the vaccine will need to take account of the likely uptake of the offer in the priority groups and here again, communication and dialogue are critical.

13. Extreme caution is needed before providing an "immune passport" to vaccinated individuals. This risks producing a further stratification and inequity for the population, and make protection of those who have not yet been vaccinated more difficult.

14. When deciding who to prioritise, it will be important to anticipate and address perceived unfairness. This is another area in which co-production and extensive stakeholder engagement will be required.

Practicability

15. The need for multiple doses, travel to vaccine centres and the nature of who is giving the vaccine and where, can be expected to influence uptake and adherence. The more accessible, familiar and trusted, the higher the uptake is likely to be. Some population groups can be expected to have greater difficulties accessing the vaccine than others – in particular those ethnic groups that have less overall take up of NHS services.

16. Extensive and co-ordinated consultation with key stakeholders will be required when developing the human and physical infrastructure required for vaccine roll-out representing localities, settings, professional groups, cultural and ethnic groups, and logistic expertise.

17. NHS oversight of vaccine rollout will be crucial, including involvement of public and primary care. This is not only important for rebuilding of Trust, but also ensuring optimal data flows and clinical follow up of those vaccinated.
18. The programme must have the capacity to detect problems and to instigate troubleshooting built in from the start and not as an afterthought.
19. The potential need for regular vaccine boosters (for instance, annually) should be considered in developing infrastructure.

Spill-over effects

20. The prospect of the vaccine becoming available may cause the population to show reduced adherence to protective behaviours in advance of it being disseminated because of reduced concern about the virus.

21. Having been vaccinated may lead to overconfidence in the degree of protection or infectiousness. This may be exacerbated by lack of clarity about the effectiveness of the vaccine for disease protection versus infectiousness.

22. Having the vaccine available may lead authorities in government and organisations to fail to address key weaknesses in key protective measures such as the Find-Test-Trace-Isolate-Support programme.

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Following the science