SAGE recommendations regarding evaluation of other Ebola vaccines and ongoing plans

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R&DBlueprint
Powering research to prevent epidemics

World Health Organization

HEALTH EMERGENCIES programme

Meeting of the Strategic Advisory Group of Experts on immunization, April 2015: conclusions and recommendations

SAGE stressed the importance of applying rigour and science in implementation programme design and evaluation of delivery of vaccines, in order to maximize the impact of current and future vaccines and delivery technologies.

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SAGE supported WHO's plan to expand guidance beyond the current framework on the use of vaccines in humanitarian emergencies to include guidance on how to re-establish routine vaccination in those settings.

At the January 2015 WHO Executive Board meeting, Member States endorsed a resolution for pre-emptive development of vaccines against emerging infectious diseases such as Ebola virus disease.

Meeting of the Strategic Advisory Group of Experts on immunization, October 2015: conclusions and recommendations

Efforts to develop vaccines against filoviruses other than ZEBOV, such as Sudan, Bundibugyo and Marburg should be pursued. Multivalent filovirus vaccines are desirable.

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All trials should carefully document adverse events using standard definitions, including duration, severity and sequelae

Meeting of the Strategic Advisory Group of Experts on immunization, April 2017: conclusions and recommendations

SAGE encouraged manufacturers of candidate Ebola vaccines to proactively engage with relevant national regulatory authorities in Africa and regional regulatory structures (e.g. African Vaccine Regulatory Forum, AVAREF) regarding licensure requirements.

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As different Ebola candidate vaccines may have characteristics suited to different scenarios and populations, SAGE supported the ongoing development of all candidate vaccines and recommends that vaccine developers submit data as they become available to the WHO Secretariat to inform policies.

Meeting of the Strategic Advisory Group of Experts on immunization, October 2018: conclusions and recommendations

If an outbreak is caused by an Ebola virus strain other than Zaire, consideration should be given to using candidate vaccines that target the respective viral strain. Currently, 1 multivalent vaccine (Ad26.ZEBOV/MVA-BNFilo) is in phase 2 of clinical development.

SAGE noted that opportunities should be sought to assess the efficacy of other candidate EVD vaccines, such as in health care and front-line workers in areas that are not at high risk for EVD and are thus not eligible to receive the rVSV-ZEBOV vaccine in current study protocols and SAGE recommendations.

Particular consideration should be given to the inclusion of pregnant and lactating women into vaccine research. Data on use of the vaccine in paediatric populations in such trials should be recorded.

immunization,

Feb 2019: conclusions and interim

As SAGE noted previously, it is important to advance the clinical evaluation of other vaccines against EVD and to accrue additional information on their immunogenicity, safety and efficacy if possible.

Noting the available data, SAGE recommends that consideration is given to the use of any of these three new vaccines to vaccinate HCWs and FLWs in the neighboring areas where there is a possibility of spread.

Such vaccination should be implemented as part of a randomised clinical trial and in compliance with GCP and informed consent.

Since these three new candidate vaccines are non-replicating or replication deficient, pregnant and lactating women should be included into the clinical trial protocols.

The protocols must include provisions for safety monitoring and for documentation of EVD cases among vaccinees, including follow-up of pregnant women and their offspring.

Choice of vaccine should be undertaken by national authorities based on a transparent and evidence-based process. The WHO R&D Blueprint expert group on vaccine trials is asked to provide guidance on the design of such trials.

immunization,

Feb 2019: conclusions and interim

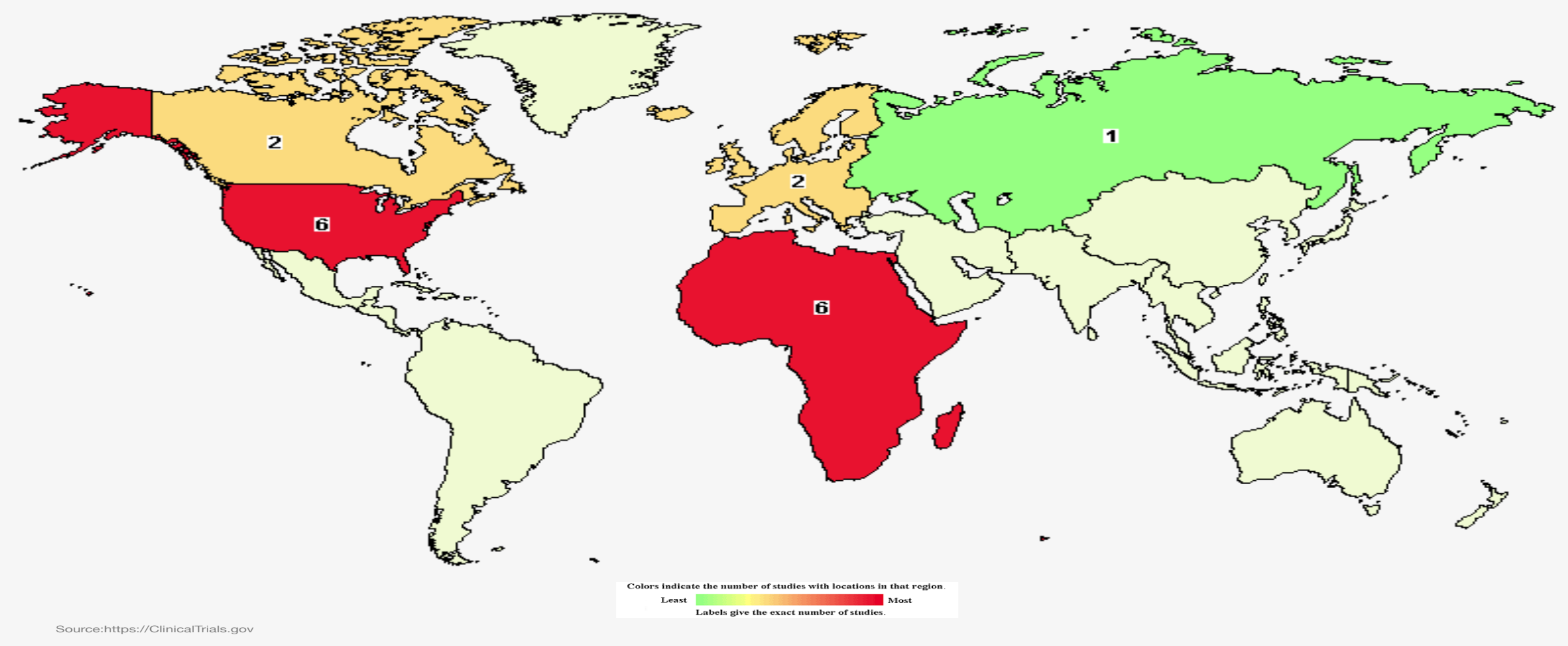
If a confirmed case of Ebola (Zaire strain) is observed among the HCWs or FLWs vaccinated with one of these three candidate vaccine regimens,

SAGE reiterated that the control of such an outbreak must include the use of rVSV-ZEBOV-GP using the ring vaccination, or the geographic targeted approach if necessary, as previously recommended by SAGE, **in preference to these new candidate vaccines.**

SAGE stressed that in outbreak affected areas, HCWs and FLWs should continue to be offered the rVSV-ZEBOV-GP vaccine.

Current efforts to assess Ebola vaccines in Africa

5 April 2019



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Current WHO recommendations on the basis of previous SAGE deliberations

- There is a need and it is important to test additional Ebola vaccines
- **Such vaccination should be implemented as part of a randomised clinical trial and in compliance with GCP and with informed consent.**
- Protocols must be designed in a way that their outcomes help inform policy and advance the regulatory evaluation of vaccines.
- **Choice of vaccine should be undertaken by national authorities based on a transparent and evidence-based process.**
- An AVAREF assisted review of the protocols could contribute to support this process.

Ongoing opportunities to test additional vaccines in the context of the current outbreak

- ✓ Jan 23, 2019 – WHO R&D Blueprint follow up expert consultation to discuss potential trial designs
- ✓ Feb 2019 - WHO supported independent review of evidence on 3 candidate vaccines
- ✓ March – INRB – MOH –CEPI - LSHTM and other stakeholders held a protocol discussion meeting in Kinshasa

Throughout this process, WHO has provided technical support, shared experiences with similar trials and have provided inputs to draft protocol.