World Health Organization

Ebola vaccines

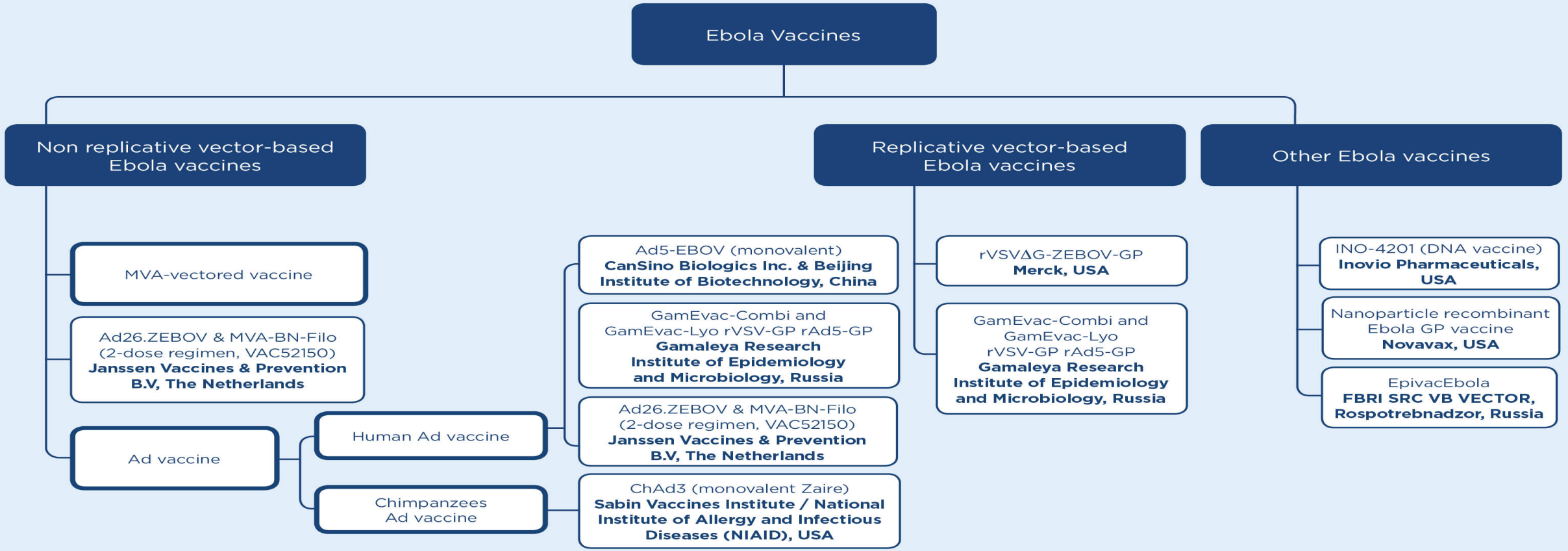
Towards global vaccine security

October 4, 2019

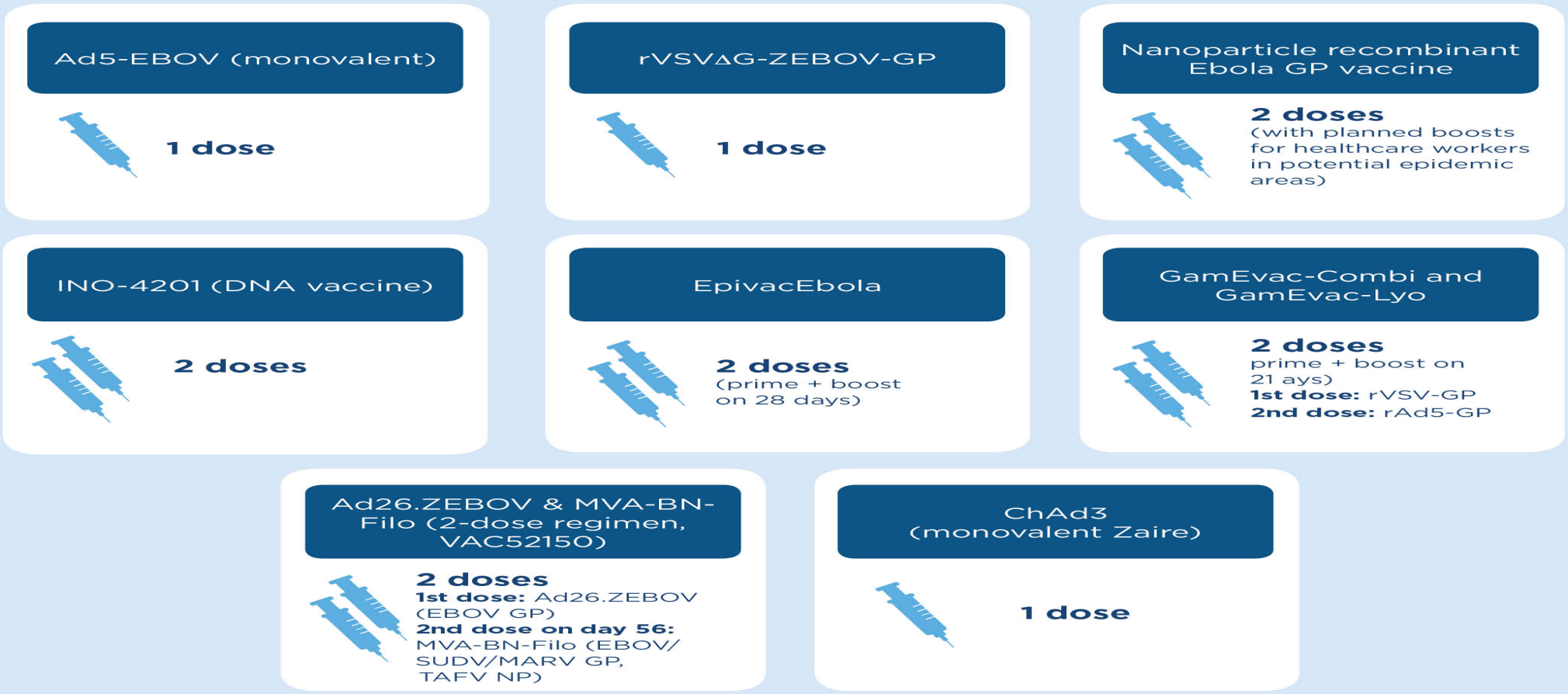
R&DBlueprint

Powering research
to prevent epidemics

TYPES OF CANDIDATE EBOLA VACCINES



Ebola vaccines
Number of doses needed /vaccination schedule



EBOLA VACCINES

According to the number of people who have received the vaccine in clinical trials or as part of expanded access and compassionate use protocols

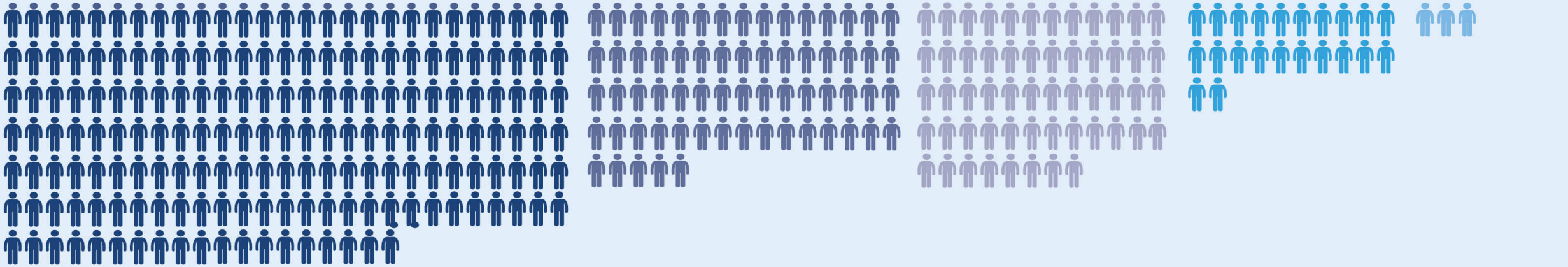
rVSVΔG-ZEBOV-GP
>18,000 people in clinical trials

Ad26.ZEBOV & MVA-BN-Filo
(2-dose regimen, VAC52150)
>6,500 people in clinical trials

ChAd3
(monovalent Zaire)
>5,600 people in clinical trials

GamEvac-Combi
and GamEvac-Lyo
2,200 people in clinical trials

EpivacEbola
300 people in clinical trials



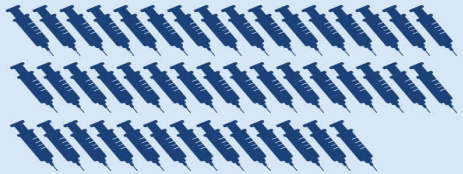
>200,000 people
compassionate use/expanded access protocols

• Infographic represents total figures divided by 100

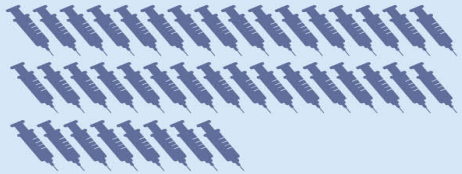
EBOLA VACCINES

According to doses currently available as of 30 August 2019

ChAd3 (monovalent Zaire)
Sabin Vaccines Institute / National Institute of Allergy and Infectious
450,000 doses



rVSVΔG-ZEBOV-GP
Merck, USA
400,000 doses



Ad26.ZEBOV & MVA-BN-Filo
(2-dose regimen, VAC52150)
Janssen Vaccines & Prevention B.V, The Netherlands
45,000 labelled regimens

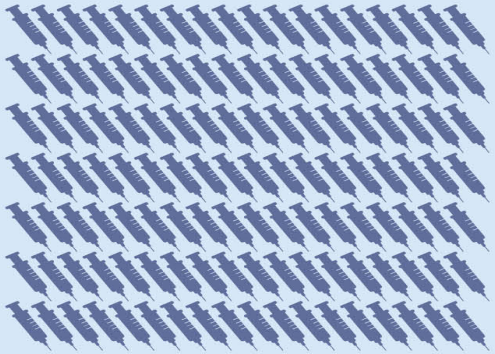
EpivacEbola
FBRI SRC VB VECTOR, Rospotrebnadzor, Russia
20,000 doses

Ad5-EBOV
(monovalent)
CanSino Biologics Inc. & Beijing Institute of Biotechnology, China
20,000 doses

According to doses potentially available in 2020

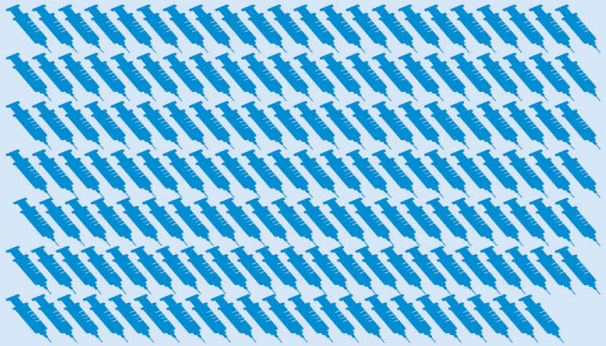
ChAd3 (monovalent Zaire)
Sabin Vaccines Institute / National Institute of Allergy and Infectious
No data

rVSVΔG-ZEBOV-GP
Merck, USA
1.3 million

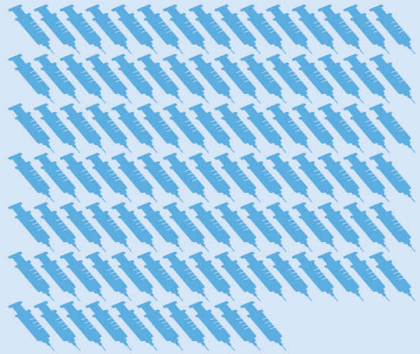


(Guinea dose = 2x107 pfu/mL)

Ad26.ZEBOV & MVA-BN-Filo
(2-dose regimen, VAC52150)
Janssen Vaccines & Prevention B.V, The Netherlands
Up to 1.5 million



EpivacEbola
FBRI SRC VB VECTOR, Rospotrebnadzor, Russia
1 million



Ad5-EBOV
(monovalent)
CanSino Biologics Inc. & Beijing Institute of Biotechnology, China
150,000 doses

• Infographic represents total figures divided by 10,000

Goal

"Ensure ethically timely access to Ebola vaccines."

Objectives

Guided by robust scientific and policy recommendations

1. Ensure **access** to vaccines as part of **outbreak response** actions

2. Ensure **access** to vaccine for **preventive vaccination** activities **between outbreaks**

3. Facilitate ethical and scientifically sound research including clinical regulatory oversight to evaluate candidate Ebola vaccines

Objectives

1. **Ensure access to vaccines as part of outbreak response actions**
   a) Sufficient and affordable vaccine supply, and ethical distribution (Stockpile for emergencies)
   b) Build regulatory country capacity to deploy (unlicensed and licensed) vaccines and implement reactive vaccination

2. **Ensure access to vaccine for preventive vaccination activities between outbreaks**
   a) Sufficient and affordable vaccine supply to prevent further expansion of the outbreak
   b) Build country capacity to implement vaccination of HCWs and FLWs in high risk areas following a carefully documented risk-benefit evaluation that prioritizes at risk HCWs on ethical grounds
   c) Build regulatory country capacity to deploy (unlicensed and licensed) vaccines and implement preventive vaccination in HCWs and FLWs

3. **Facilitate ethically and scientifically sound research including clinical regulatory oversight to evaluate candidate Ebola vaccines**
   a) Provide support for efficacy evaluation for all candidate vaccines in clinical development phase
   b) Provide regulatory support to member states to review clinical trials of Ebola vaccines through AVAREF and collaboration with relevant NRAs and ethics committees.
   c) Build research, GPP and GCP capacity in countries at risk of EVD
   d) Ensure the availability of innovative generic scientifically and ethically sound protocols to evaluate efficacy in the context of epidemics or public health emergencies and include specific target groups (children, pregnant women)

Principles (see https://www.who.int/bulletin/volumes/91/4/12-113480.pdf)

- **Distributive justice**: fair distribution
- **Evidence based decision making**

  (guided by SAGE recommendations, independent expert advice and regulatory reviews/approvals)
- **Procedural justice**: Transparent decision-making process
- **Timely deployment**: rapid response process
- **Sustainable access**: affordable pricing, adequate production capacity and secured funding

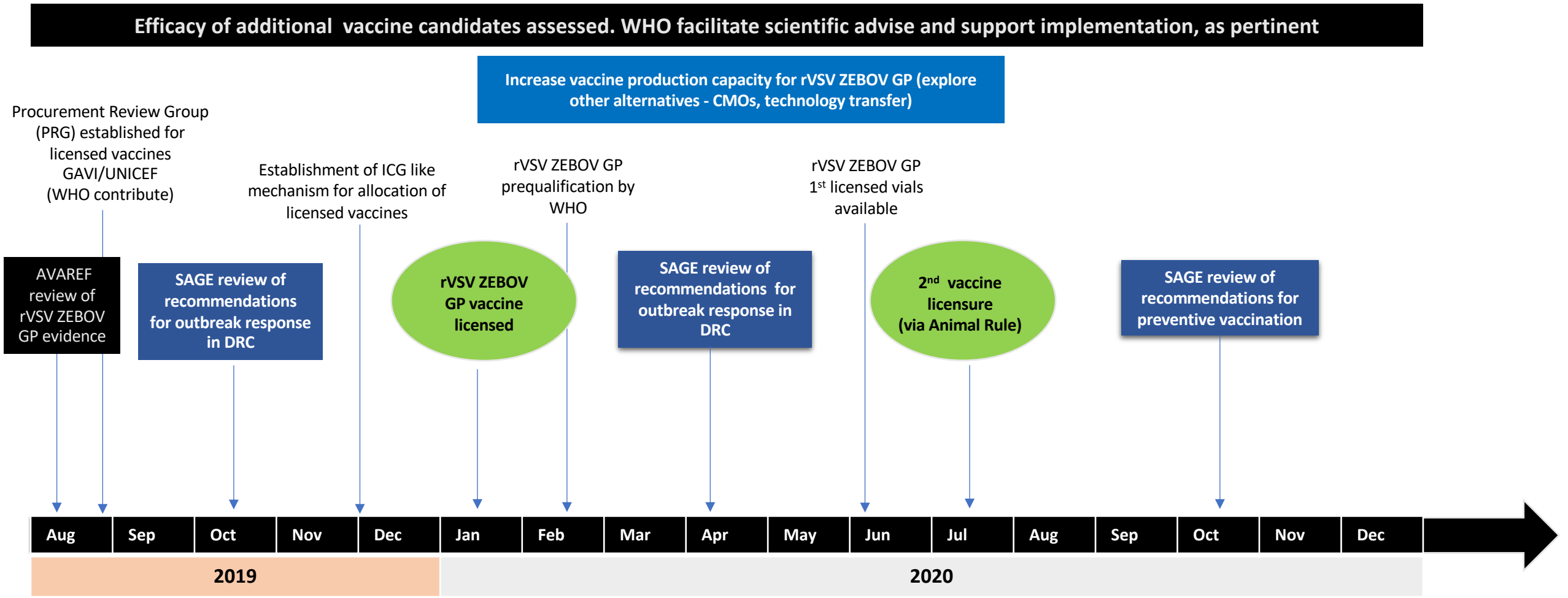
Objectives/ Expected outcomes

		2019		2020				Key Stakeholders*	
		Q3	Q4	Q1	Q2	Q3	Q4	WHO	Partners*
1-a	Ensure **access** to sufficient vaccine doses							WHE	GAVI/UNICEF
1-b	Continue building regulatory **country capacity (13 countries)** to deploy unlicensed/licensed vaccines and implement reactive vaccination							MVP/RHT R&D Blueprint	AFRO/MOHs
2-a	Ensure **country capacity** to implement vaccination of HCWs and FLWs in high risk areas during outbreaks							WHE	AFRO/CO/MOH
2-b	Ensure **country capacity** to make a risk-benefit evaluation to prioritize HCFs and HCWs during outbreaks							WHE	AFRO/CO/MOH
2-c	Continue building country capacity to deploy (unlicensed and licensed) vaccines and implement preventive vaccination in HCWs and FLWs							R&D Blueprint	AFRO/MOH
3-a	Provide support **efficacy evaluation** for all candidate vaccines in clinical development phase							R&D Blueprint	AFRO/MOH
3-b	Provide regulatory support to 13 member states on the review of Clinical trials of Ebola vaccines through AVAREF and collaboration from relevant Regulatory agencies and ethics committees (VSV Vaccine licensure in the 13 countries)							MVP/RHT	AFRO/AVAREF
3-c	Built **research, GPP and GCP capacity** at country level							R&D Blueprint	Research institutions
3-d	Ensure the **availability of innovative generic protocols** to evaluate vaccine efficacy in the context of epidemics or public health emergencies							R&D Blue print	Research institutions, Academy

Strategies to achieve the proposed objectives

Type	Objective 1	Objective 2	Objective 3
Use models to forecast **potential vaccine demand** in the short- mid and long term	☑	☑	
Implement mechanisms for **monitoring performance** of the vaccine following deployment	☑	☑	
Document existing and future **vaccine capacity production** for all candidate vaccines	☑		
Define and agree on **vaccine procurement strategies** and mechanisms that incorporate current TPPs and SAGE recommendations	☑	☑	
Maintain up to date **Target Product Profiles** (TPP)	☑	☑	
Maintain up to date **vaccine immunization policy** (SAGE)	☑	☑	
Build country **readiness capacity** (risk/benefit evaluation and decision)	☑	☑	☑
Propose and agree a **vaccine allocation mechanism** (ICG-like)	☑	☑	
Continued strengthening **regulatory capacity** (Quality safety and efficacy) and regulatory preparedness for emergencies (emergency authorization and licensure/market authorization)	☑	☑	☑
Strengthen and expand research capacity			☑
Define and agree on sustainable mechanisms for financing	☑	☑	☑

Selected milestones (examples)



WHO, Gavi and UNICEF will continue to consult widely, and fostering interactions with the international scientific, ethics, regulatory, vaccine development, public health partners, industry and funders' communities to facilitate Ebola vaccine(s) assessments and availability.

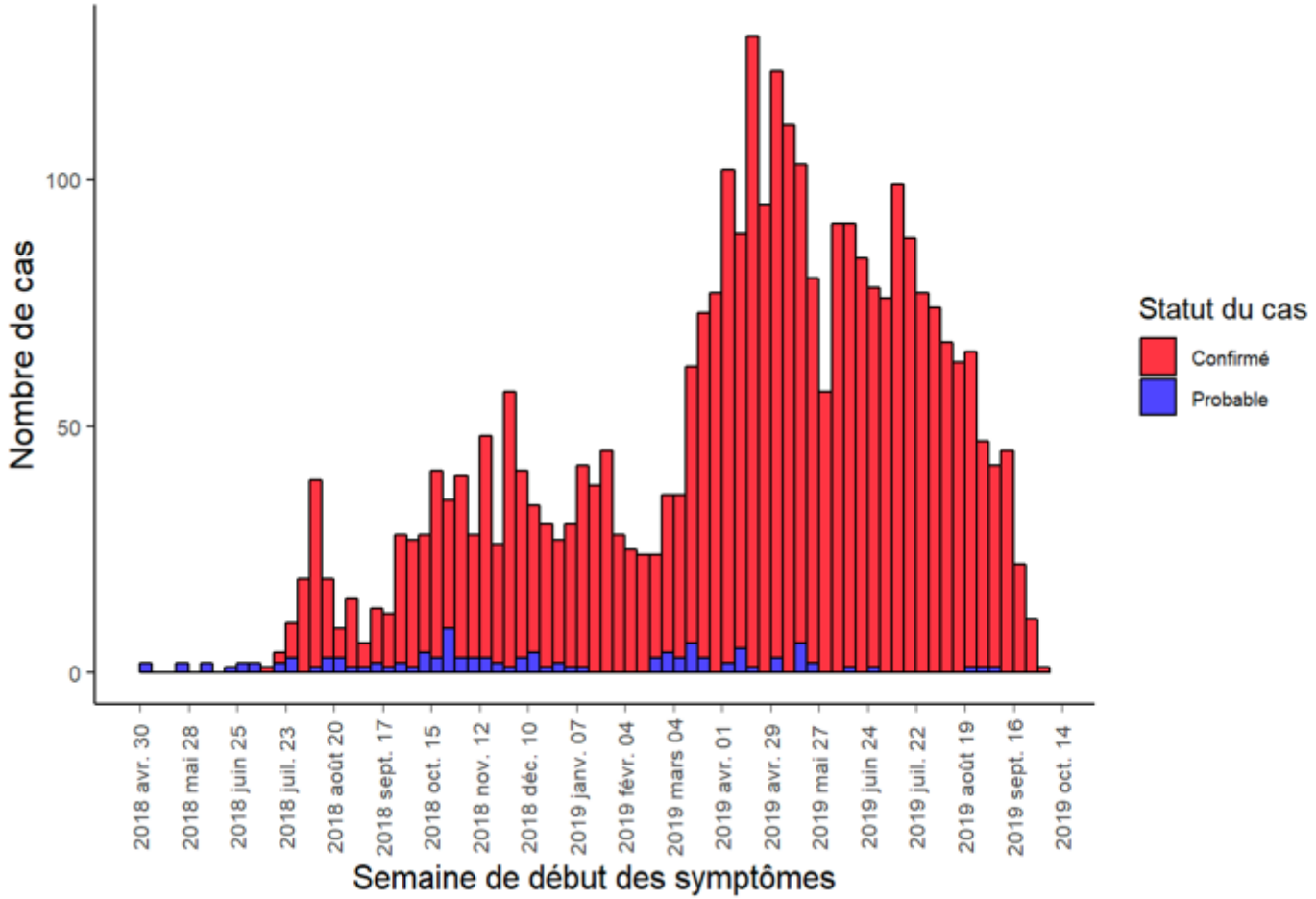
WHO and partners will also foster key activities to ensure accelerated R&D, the optimal policy and deployment of Ebola vaccines if licensed in order to avert full-blown epidemics.

Conclusions and proposed next steps

Helen Rees
Co-Chair of SAGE Working Group
on Ebola Vaccines

On the current outlook of the outbreak

- Transmission intensity substantial but encouraging trends over last weeks
- Shifts in hotspots from Katwa/Butembo to Beni, and Mandima, Kalunguta and Mambasa
  - Shift from mostly urban to mostly rural context
- Risk of further spread in DRC and to neighbouring countries remains very high



On the implementation of the SAGE recommendations

Most recommendations have been implemented in DRC and neighboring countries.

- There is a need to continue to monitor vaccine effect and safety
- The steps to soon initiate the studies with the J&J vaccine – once approved by national ERC and NRA -are welcomed as they address a previous SAGE recommendation.

On the potential for further adjustments of the dose

The Ebola vaccines Working Group has considered the evidence on further reduction of dose of rVSV ZEBOV GP.

The proposed next steps are to:

- monitor outbreak evolution,
- define criteria to trigger a risk benefit analysis,
- review once more the evidence
- conduct a risk benefit analysis

On the effect of rVSV ZEBOV GP on the outbreak control

The Ebola vaccines Working Group has considered the data on ring vaccination in DRC, the estimated effect of ring vaccination and the forecasted impact on the outbreak evolution

The next steps are to:

- DSMB to complete review of efficacy, effectiveness and safety.
- GACVS to update the review on safety profile of rVSV ZEBOV GP.
- SAGE WG to consider the outcomes of the above reviews and any implications for policy recommendations.

On the plans for global Ebola vaccines security

The Ebola vaccines Working Group has considered a draft proposal to develop a plan.

The next steps are to:

- WHO Secretariat to complete the plan and to seek inputs from all key stakeholders.
- SAGE WG to review the revised version of the plan and consider any implications for policy recommendations.

On the plans for global Ebola vaccines security

It is anticipated that the global demand for vaccines may increase and therefore increased supply capacity and multiple manufacturers will be needed in the short- to medium-term to meet this demand and ensure vaccine security.

a. **the impact of the ongoing Ebola outbreak in Eastern DRC and the potential to implement strategies complementary to ring vaccination** in particular more aggressive vaccination of people at risk (e.g. health care workers in affected areas and border areas and other at risk populations),

b. **the demonstrated effect and safety of rVSV ZEBOV GP during a large outbreak** and therefore the expanded demand from neighboring countries and others with perceived risk of EVD importations

c. **once a licensed vaccines become available**, **it is likely the vaccine demand will increase**

d. **If the outbreak continues in Eastern DRC, other countries**, including industrialized non-Gavi supported countries, may want to stockpile or procure vaccines for preventive vaccination in HCWs.

Further policy deliberations should ensue at SAGE, including considerations for use of vaccines for preventive vaccination.

Current recommendations

No additional modifications to the current recommendations are proposed at this time point