Executive Summary: Polio

Background

In 2019, the polio eradication program has experienced an increase in detections of paralytic cases caused by Wild Poliovirus Type 1 (WPV1) as well as an unexpected increase in number of outbreaks and cases of circulating vaccine derived polioviruses (cVDPVs). Despite these setbacks, the program has been able to keep Africa free of WPV1 for >3 years; and WPV type 3 is now considered eradicated globally.

As of 21 August 2019, there have been 66 wild poliovirus (WPV) cases, compared with a total of 33 in the whole of 2018. WPV cases have been located in Afghanistan: 13 cases in 2019 (compared with 11 for the same period in 2018), and Pakistan: 53 cases in 2019 (compared with 3 for the same period in 2018). Additionally, there is wide-spread detection of WPV in environmental surveillance in both Pakistan and Afghanistan; and repeated environmental detections of WPV1 in Iran, most likely a result of importations from Pakistan. Further, there have been 53 cases of circulating vaccine-derived poliovirus (cVDPV), vast majority of them detected in sub-Saharan Africa. Most of these new cVDPV2 outbreaks were seeded by monovalent OPV2 (mOPV2) which had been used to respond to preceding cVDPV2 outbreaks. Thus, there is an urgent need for a new type 2 vaccine.

Because of the ever-expanding outbreaks of cVDPV2 in Africa, the world is running out of mOPV2. While sufficient supplies of mOPV2 are absolutely critical in the next 12-18 months, the best approach to deal with cVDPV2, is the development and regulatory approval of a novel OPV2 (nOPV2) that is currently in phase II clinical trials. Clinical data demonstrated that nOPV2 provides equal or better immunogenicity compared with mOPV2, and a substantially lower risk of seeding new VDPV2 due to higher genetic stability. The results of these trials will be used to apply for WHO's Emergency Use Listing (EUL) in early 2020. Any delay in EUL approval will seriously delay addressing the cVDPV2 problem and could undermine donor confidence.

To overcome an acute shortage of mOPV2, we explored strategies to stretch current mOPV2 supply, including using one instead of two drops as an immunizing dose. A clinical trial was conducted in Mozambique to assess immunogenicity of one drop of mOPV2.

Purpose of the session and summary

This session will consist of three presentations: (1) global epidemiological overview including presentation of the main areas of concern and new strategies for outbreak control, (2) brief summary of preliminary clinical results from nOPV2 trials; and (3) report from deliberations of SAGE Polio Working Group which will include brief presentation of results from mOPV2 one-drop trial.

For this SAGE meeting, there are two items for decision/endorsement: endorse call for acceleration of clinical development and licensing of nOPV2 vaccine; and endorsement of one-drop mOPV2 strategy if mOPV2 supply should further deteriorate.

In addition, SAGE members will be invited to comment on the progress of polio eradication and on challenges and strategies to overcome the remaining obstacles to achieving final eradication.

Background documents in the yellow book

- Report from meeting of SAGE WG on polio (held on August 21-22, 2019)
    - This report provides summary of the deliberations of the SAGE Working Group

- Summary of preliminary results from clinical trials on safety and immunogenicity of novel OPV2 (nOPV2) [SAGE will be asked to deliberate and endorse acceleration of nOPV2 clinical development and licensing]
    - This summary will provide information on the clinical data from nOPV2 trials that show its immunogenicity, safety, and genetic stability

- Summary of preliminary results from clinical trial on safety and immunogenicity of one-drop mOPV2 administration [SAGE will be asked to deliberate on and endorse use of one-drop mOPV2 in times of supply scarcity]
    - This summary will provide information from a trial in Mozambique

Background documents on the web

- None