

SAGE Polio Working Group

***Policy directions for discussion at
SAGE April 2012 meeting***

E. Miller, Chair

16-17 February 2012

Context: SAGE Polio Working Group ToRs

- WHO Position Paper on Polio Immunization in the pre-eradication period: *published June 2010*
- Policy guidance on routine IPV use in low-income settings in post-eradication era: *Nov 2012/Apr 2013*
- Assess utility & feasibility of type 2 OPV cessation (tOPV-bOPV 'switch'): *target April 2012 for recommendations.*

OPV2 cessation: rationale & context

High & increasing type 2 cVDPV burden

- cVDPV2 accounts for 83% of all 495 cVDPV cases since 2000
- cVDPV2 found in 8 of 9 countries reporting any cVDPV in 2008-10
- 38% of the estimated 250-500 annual VAPP cases globally are P2

No re-introduction of wild PV2 since 2004, despite limited PV containment measures.

Surveillance & response nearly optimal in most countries, with work ongoing to identify & address gaps.

bOPV licensed & scaled up, sufficient quantities could be available within 24 months (but, some countries rely on non-PQ'd national OPV).

Low-cost IPV options, suggest <US\$0.5/dose is currently feasible.

Nov 2011: SAGE decisions

- stated that phased rather than simultaneous removal of SABIN serotypes is desirable,
- agreed that a pre-eradication switch from tOPV to bOPV for routine immunization is advantageous,
- requested more work on costs, vaccine availability, programmatic implications & communications.

Jan 2012: WHO Executive Board

'Requests...a comprehensive eradication & endgame strategy....inform Member States of the potential timing of a switch from tOPV to bOPV for all routine immunization programmes.

EB Resolution 130/19

Feb 2012: WG meeting on tOPV-bOPV switch

Key questions:

- 1. should routine IPV use be selective or universal ?*
- 2. if universal, should minimum schedule be 1 or 2 doses?*
- 3. can intramuscular & intradermal dosing (1/5th) with IPV be considered equivalent in context of a tOPV-bOPV switch?*
- 4. optimal timing for a tOPV-bOPV switch? as part of the 'emergency plan' (e.g. late 2013/early 2014) or after?*

Feb 2012: evidence base & policy directions

Timing: *the frequency & consequences of cVDPV2s are increasing (e.g. Nigeria re-established type 2), suggesting earliest possible OPV2 cessation is desirable.*

Universal vs. selective IPV use:

- *all countries are at risk of cVDPV2 exposure;*
- *all OPV using countries are at risk of cVDPV emergence;*
- *IPV can reduce the consequences of a cVDPV;*
- *however, risk varies significantly by area suggesting 'universal' use but schedule adapted to the level of risk.*

Evidence Base: 1 vs. 2 IPV doses

- *1 dose of IPV significantly boosts humoral immunity in previously OPV-vaccinated children;*
- *1 dose of IPV could also boost mucosal immunity, thereby maximizing type 2 protection prior to a tOPV-bOPV switch;*
- *1 IPV dose appears to prime 95% of naïve children against PV2 (and, based on VAPP data, may provide protection);*
- *a 2nd IPV dose may not further reduce the risk of cVDPV2 emergence, but would consolidate type 2 immunity and potentially reduce the consequences of a cVDPV2 emergence in cVDPV high-risk & bordering areas.*

Intramuscular vs. intradermal (1/5th dose) use:

- *in naïve infants, IM dosing typically results in somewhat higher seroconversion rates & substantially higher titres.*
- *in naïve infants, ID dosing appears to be equivalent to IM for priming against type 2 if given at 4 months of age.*
- *in previously OPV-vaccinated infants, ID dosing is likely to be equivalent to IM dosing for immunity boosting, although there are insufficient data to confirm this.*
- *ID study results still quite variable due to differences in vaccines, delivery device, etc.*

Next Steps: polio policy recommendations

Immediate: *SAGE to highlight (a) int'l public health emergency due to re-established type 2 polio in Nigeria; (b) important to rapidly seek regulatory approval for ID IPV.*

Apr 2012: *SAGE to consider specific recommendations on timing for a tOPV-bOPV switch and the role of IPV therein.*

Jun 2012: *WG to consider additional outbreak response, surveillance & containment policies for tOPV-bOPV switch.*

by Apr 2013: *WG consideration of additional role/need for IPV in post-eradication (post-bOPV) era.*