



Developing Countries Vaccine Manufacturers Network

17th Annual Meeting
Buenos Aires, Argentina, 26 October 2016

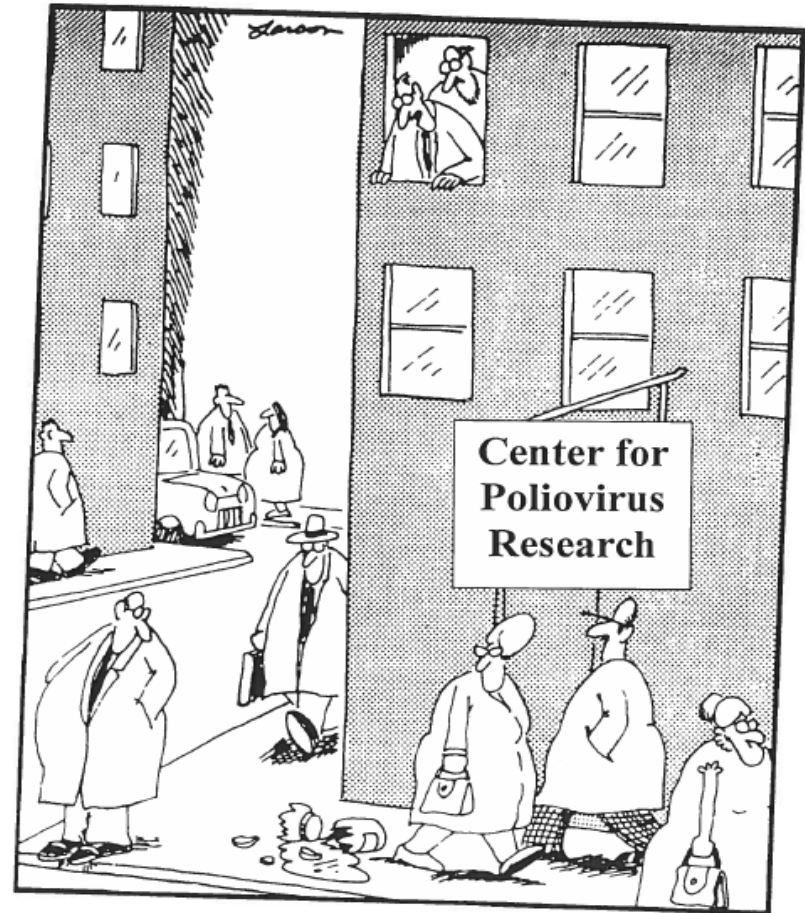
Update on WHO Global Action Plan for containment of polioviruses (GAPIII/ CCS)

Jackie Fournier-Caruana

Containment:

"The other half of eradication"

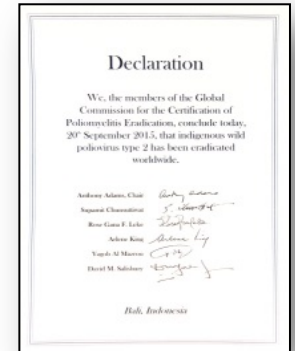
Cochi S. Challenge of the post-eradication era: Poliovirus containment and stopping polio immunization. Presented at "Global Consultation on Progress towards Eradication of Poliomyelitis", Geneva, 2 June – 3 June 1999



"Uh-oh."

PV containment. Where are we now?

- WPV2: declared eradicated in Sep 2015
- Global tOPV-bOPV switch: Apr 2016
- We are now in the 'PV2 containment period' (Phase II of GAPIII)



What does this mean?

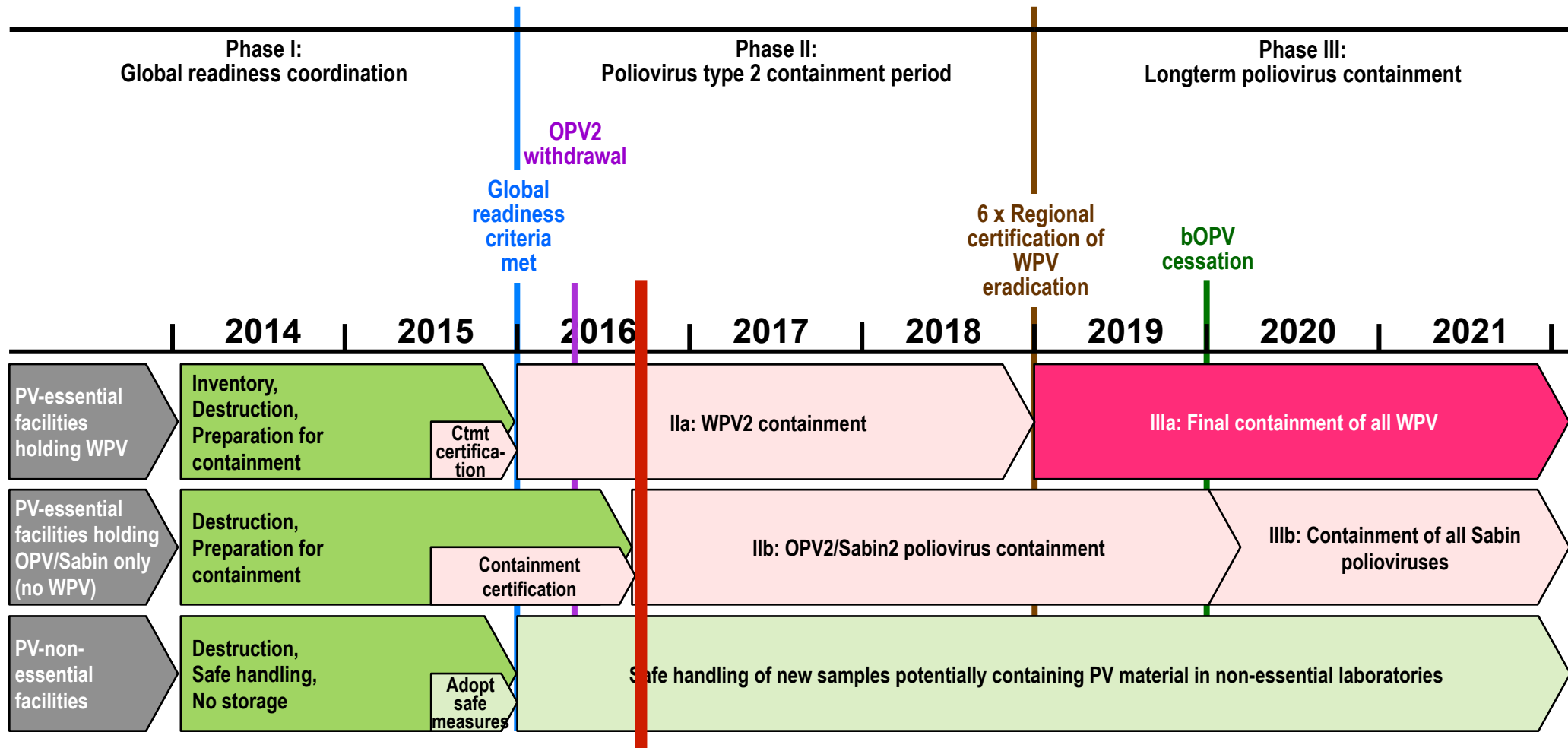


PV containment. What does this mean?

- According to GAPIII, PV2 should by now be in containment
 - WPV2/VDPV2 since 1 Jan 2016
 - OPV2/Sabin2 since 1 Aug 2016
- GAPIII was first drafted in 2009, then endorsed by
 - SAGE in 2014
 - WHA in 2015
- Containment certification scheme endorsed by SAGE in October 2016



Phase II timelines



Phase II: Where should we be now?

Phase II:

According to GAPIII:

- ☢ PEFs should have demonstrated implementation of GAPIII
- ☢ NACs should have certified PEFs against GAPIII

PEFs: Poliovirus-essential facilities

- ☢ Poliovirus vaccine production facilities
- ☢ Research facilities
- ☢ Repositories

NACs: National Authorities for Containment

Are we where we should be?
If not, why not?



Phase II:

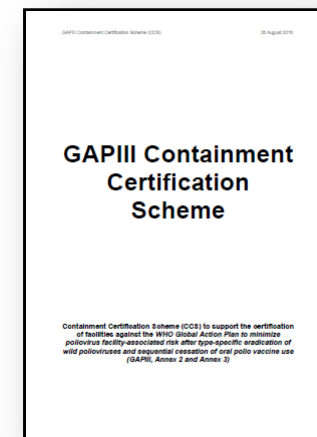
Why are we not where we should be?

- ❖ Containment implementation timelines short
- ❖ Lack of national regulatory framework to implement containment
- ❖ Lack of expertise to implement GAPIII
- ❖ National Authority for Containment (NAC) just being identified
- ❖ Lack of certification expertise

Phase II: The need for CCS

A containment certification scheme to ensure:

1. A robust, transparent and equitable mechanism is applied for containment certification across sectors and geographies
2. GAPIII is appropriately and timely implemented in all PV-essential facilities
3. Gradual implementation of GAPIII requirements
 1. Certificate of participation CP
 2. Interim certificate of containment ICC
 3. Certificate of containment CC



Containment Certification Scheme (CCS): Objectives

- ☣ Identify and define **roles and responsibilities for stakeholders (PEFs, NACs, GCC, WHO)** ensuring transparency and consistency of approach
- ☣ Specify the mechanisms required for oversight at international and national levels to ensure **robust, transparent and equitable certification mechanisms** across sectors and geographies
- ☣ Describe the relevant **oversight mechanism** to assure that GAPIII controls have been appropriately identified, implemented and monitored
- ☣ Define adequate reporting and recording mechanisms to ensure confidence in the scheme and its ability to **provide the required level of assurance** to global eradication stakeholders

WHO's support for the implementation of **Phase II**

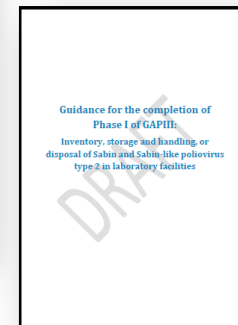
Support to stakeholders

- ☢ Containment Certification Scheme (CCS)
- ☢ Interim containment certification options available in preparation for full implementation of GAPIII requirements in Phase III (CP, ICC, CC)
- ☢ International oversight mechanism proposed to ensure globally harmonized containment certification procedures
- ☢ Regional GAPIII Implementation and certification trainings for NACs and PEFs
- ☢ Development of pool of GAPIII containment auditors to support countries' containment certification efforts

Next steps

- Publish CCS
- Promote CCS and engage countries in CCS implementation
 - Ensure dPEFs request 'Certificate of Participation' and engage in ICC/CC process
 - Ensure appropriate biorisk management in agreement with NAC and GCC
 - Allow to maintain stocks for a defined period without full GAPIII implementation
 - Minimize risk of interruption of IPV production and supply
- GAPIII Implementation and Certification Training for late-comers
 - 24-28 Oct, Bangkok
- GAPIII Training for Auditors: develop a pool of auditors to support NACs
 - 5 sessions planned Q 1/2 , 2017
- Align TRS 926 Annex 2 with GAPIII

Conclusions



polio

- ❖ Poliovirus containment is a major **global endeavour**, engaging and non-polio stakeholders
- ❖ **Only destruction** of polioviruses **eliminates** risk of release from facilities
- ❖ Global **oversight** of containment is necessary
- ❖ Countries and facilities are key to poliovirus containment



**For any questions or suggestions on poliovirus
containment, GAPIII and CCS**

please contact: previsanin@who.int

**[http://www.polioeradication.org/Portals/0/Document/
Resources/PostEradication/GAPIII_2014.pdf](http://www.polioeradication.org/Portals/0/Document/Resources/PostEradication/GAPIII_2014.pdf)**



Thank you