The case for discontinuing use of oral polio vaccine
DA Henderson
European Study Group on the Molecular Biology of Picornaviruses (EUROPIC)
North Falmouth MA
16 May 2002

F-18

Polio - eradicate.

(over) The vaccines - IPV
(over) - OPV

Contrast & Comp

Hx of program -

Americas - 1990 goal
Strategy
NIDs

Global eradicatn - 1988 & years 2000 goal. (possible in Americas; possible anywhere.
Rotary / UNICEF / U.S.

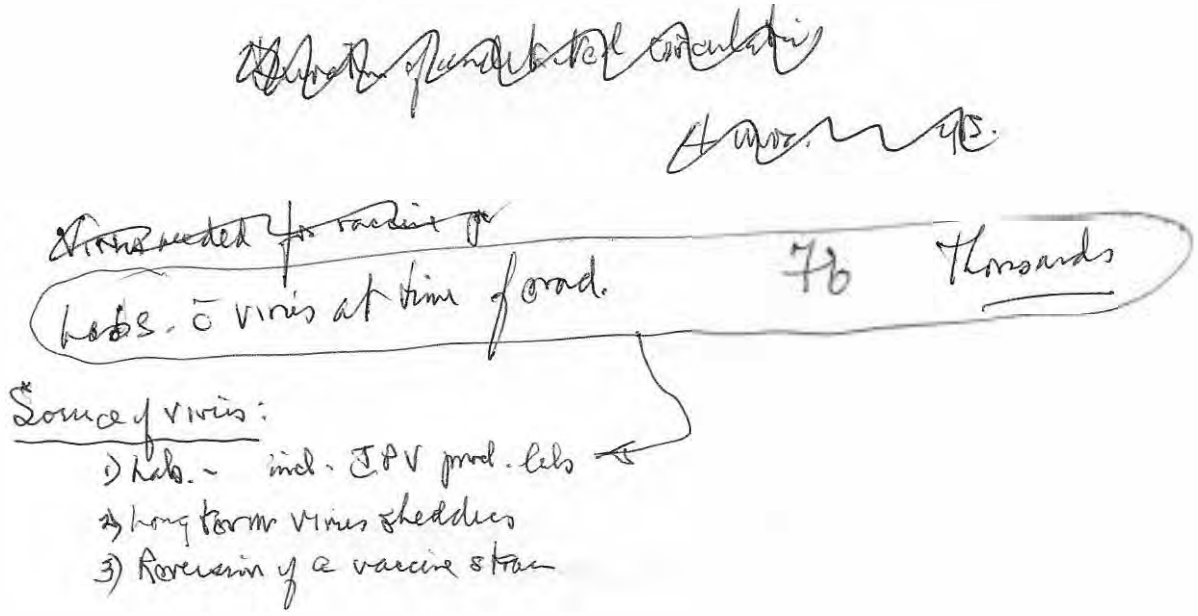
Progress made.

Comparisons
Smallpox and Polio Vaccines

	Smallpox	OPV
Number of doses to protect	**1**	**5+**
Potent at ambient temperature for:	**30+ days**	**1-2 days**
Reversion to virulence	**No**	**Yes**
Vaccine storage	**40+years**	**5 years**

Comparisons
Smallpox and Polio Infections

	Smallpox	Polio
Possible duration of infection	**2-3 weeks**	**9+years**
Asymptomatic transmitters	**0**	**99/100**
Surveillance-containment possible	**Yes**	**No**
Longest duration -- undetected	**4 months**	**? years**
Lab diagnosis needed	**Marginal/0**	**Critical**



Policies for the Future

- **Eradication = Interruption of continuing transmission of polio virus**

  Probabilities of success

- **Vaccination = Continuation or non-continuation -- a different issue**

  Costs vs. savings arguments

- **Rationale for continuing use of OPV in developing countries**

  1) **Intestinal immunity**
  2) **Cost**
  3) **Facility of administration**
  4) **Need for a reserve epidemic vaccine supply** — ~~[illegible]~~ the only vaccine should an outbreak occur.
  5) **Questionable immunity of IPV in developing countries**

  Does the present demand that a reserve of smallpox vaccine be created tell us anything???

A Reprise

- **1982 -- Fogarty International Center -- What next to eradicate?**
- **1985 -- PAHO -- the decision to eradicate polio in the Americas**
- **1988 -- Talloires, France --the decision for global eradication**

  A dissent
- **2002 -- Reality and logical options**

  Continue OPV for the developing countries ✓ other vaccines

  Use IPV when desired in the industrialized countries

  Develop a new OPV

    More antigenic

    Heat stable

    Non-paralytogenic

Comparisons
Containing wild viruses

	Smallpox	Polio
Possible duration of infection	3-4 weeks	? years
Duration of undetected circulation	4 months	? years
Laboratories with virus at eradication	<100	1000+
Virus needed for vaccine production	No	Yes (IPV)

NEW PROBLEMS

OPV strains can become more virulent and cause outbreaks

- **Dominican Republic-Haiti (2000) -- Type I**

  19+ cases of flaccid paralysis – 8 confirmed

  Origin: 2 years before first detected cases

- **Egypt (1988-93) Type II**

  32 cases in 8 of 27 governorates

- **China (early 90s) Type II**

OPV strains in immune-deficient persons may be excreted for 5+ years

Comparison of Salk (IPV) and Sabin (OPV) Vaccines

	Salk (IPV)	Sabin (IPV)
Virus	Wild strains Virus from fetal cells.	Attenuated
Formalin killed	Yes	No
Administration	Injection	Oral
Protection (3 doses)	>95 %	> 95 % but…
Pharyngeal immun.	Yes	Yes
Intestinal immunity	Little	Yes
Household Spread	No	Yes
Cost	$.45-2.00	$.08
Vaccine caused cases	No	Yes

IPV increasingly used in industrialized countries

OPV is preferred in developing and middle income countries

ONE ADDITIONAL PIECE OF INFORMATION

Alternative vaccination strategies post polio eradication

(eradication - 31 Dec. 2002: confirmation - 31 Dec. 2005)

- **IPV -- Extend to all countries by 2005**

  Continue: **+ For "x" years**
  + Indefinitely

- **OPV**
  Stop use beginning in 2005

  Phased approach by region or country

  All countries stop at one time

  After global mass vaccination day(s)
  No special preparation

  Continue: **+ For "x" years**
  + Indefinitely

- **Introduce new vaccine**

piece of information

? Stop Vaccination
? Who will believe?

Problems:
IPV - quantity - two A cont.
where to produce? BSH-4
cost,
international mission.
coverage.

Vaccination strategies

o National Immunization Days

+ twice each year

+ children under 5 years

+ during low point in season (cool period)_

o House to House Vaccination in High Risk Areas

+ slum areas and areas reporting 1+ cases in prior 3 years

o Routine Vaccination in Health Centers

o Vaccination in Outbreak Areas

Strategies for polio eradication

- Surveillance for acute flaccid paralysis
  - + Weekly reports from hospitals, rehab centers, later, all health units
  - + All reported cases investigated within 48 hours by clinician and epidemiologist
  - + Stool specimens collected within 14 days from all suspected cases
  - + Vaccination of all children under 5 years in a defined area, usually 2000 persons

Questions that no one really wants to answer

1. Can eradication be achieved by 2005 or 2020?

2. How much of a priority is polio eradication in the developing countries?

3. What does one do if polio reemerges?

    + From a silently circulating revertant
    + From an IPV production facility or lab

4. Can IPV substitute for OPV in the developing world?

5. Why is so important to stop OPV use?

6. Are the formulation of present policies free of commercial pressures?

CHARACTERISTICS OF IPV AND OPV

	IPV	OPV
Administration	Needle	Oral
Cost (2000)	$1 to 2	.08
>95% protection - doses needed*	2 [redacted] (3+)	3 [redacted] (4-6)
Oropharyngeal immunity	++++	++++
Intestinal immunity	+	++++
Spread to HH contacts	0	++++
Effective in epidemic	No	Yes
Vaccine-induced cases	No	1 / 1,000,000

* industrialized country (developing country)

CONTAINING THE VIRUS

(Reference: WHO)

1. 2001-2002

Inventory of all labs for potentially infectious virus

- **Diagnostic labs**
- **Environmental labs**
- **Research labs in all departments**
- **Vaccine production labs**

Note: includes fecal, throat, environmental samples
: includes specs possibly containing OPV
: excludes specs held for 3+months without refrigeration

2. 2002 (last case of polio)

Transfer all material to BSL-3 laboratory facility

3. 2005 (eradication confirmed)

All potentially infectious materials with wild virus to be moved to BSL-4 lab

STRATEGY OPTIONS FOR STOPPING POLIO VACCINATION

(PER CDC POLIO STAFF)

1. Replace OPV with a new vaccine

2. Replace OPV with IPV everywhere

Continue IPV for "x" years until OPV strains stop circulating.

3. Continue OPV until eradication is certified and then stop vaccination more or less simultaneously everywhere

Assumption eradication will be achieved by 2005
OPV use must be stopped