TABLE 2[12] PERCENTAGE OF INFANTS PRESENTING WITH LOCAL OR SYSTEMIC REACTIONS AT 6, 24, AND 48 HOURS OF IMMUNIZATION WITH IPOL VACCINE ADMINISTERED INTRAMUSCULARLY CONCOMITANTLY AT SEPARATE SITES WITH SANOFI[¶] WHOLE-CELL DTP VACCINE AT 2 AND 4 MONTHS OF AGE AND WITH SANOFI ACELLULAR PERTUSSIS VACCINE (TRIPEDIA®) AT 18 MONTHS OF AGE

REACTION	AGE AT IMMUNIZATION								
	2 Months (n=211)			4 Months (n=206)			18 Months† (n=74)		
	6 Hrs.	24 Hrs.	48 Hrs.	6 Hrs.	24 Hrs.	48 Hrs.	6 Hrs.	24 Hrs.	48 Hrs.
Local, IPOL vaccine alone[§]									
Erythema >1"	0.5%	0.5%	0.5%	1.0%	0.0%	0.0%	1.4%	0.0%	0.0%
Swelling	11.4%	5.7%	0.9%	11.2%	4.9%	1.9%	2.7%	0.0%	0.0%
Tenderness	29.4%	8.5%	2.8%	22.8%	4.4%	1.0%	13.5%	4.1%	0.0%
Systemic*									
Fever >102.2°F	1.0%	0.5%	0.5%	2.0%	0.5%	0.0%	0.0%	0.0%	4.2%
Irritability	64.5%	24.6%	17.5%	49.5%	25.7%	11.7%	14.7%	6.7%	8.0%
Tiredness	60.7%	31.8%	7.1%	38.8%	18.4%	6.3%	9.3%	5.3%	4.0%
Anorexia	16.6%	8.1%	4.3%	6.3%	4.4%	2.4%	2.7%	1.3%	2.7%
Vomiting	1.9%	2.8%	2.8%	1.9%	1.5%	1.0%	1.3%	1.3%	0.0%
Persistent Crying	Percentage of infants within 72 hours after immunization was 0.0% after dose one, 1.4% after dose two, and 0.0% after dose three.								

¶ Sanofi Pasteur Inc. formerly known as Aventis Pasteur Inc.
§ Data are from the IPOL vaccine administration site, given intramuscularly.
* The adverse reaction profile includes the concomitant use of Sanofi whole-cell DTP vaccine or Tripedia vaccine with IPOL vaccine. Rates are comparable in frequency and severity to that reported for whole-cell DTP given alone.
† Children who have been vaccinated with Tripedia vaccine.

DIGESTIVE SYSTEM
Anorexia and vomiting occurred with frequencies not significantly different as reported when DTP was given alone without IPV or OPV.[12]

NERVOUS SYSTEM
Although no causal relationship between IPOL vaccine and GBS has been established,[28] GBS has been temporally related to administration of another inactivated poliovirus vaccine.

Reporting of Adverse Events
The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires physicians and other health-care providers who administer vaccines to maintain permanent vaccination records and to report occurrences of certain adverse events to the US Department of Health and Human Services. Reportable events include those listed in the Act for each vaccine and events specified in the package insert as contraindications to further doses of that vaccine.[38,39,40]

Reporting by parents or guardians of all adverse events after vaccine administration should be encouraged. Adverse events following immunization with vaccine should be reported by health-care providers to the US Department of Health and Human Services (DHHS) Vaccine Adverse Event Reporting System (VAERS). Reporting forms and information about reporting requirements or completion of the form can be obtained from VAERS through a toll-free number 1-800-822-7967.[38,39,40]

Health-care providers also should report these events to the Pharmacovigilance Department, Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 or call 1-800-822-2463.

DOSAGE AND ADMINISTRATION
Before administration, parenteral drug products should be checked visually for any deviation from normal appearance including container integrity. The syringe or vial and its packaging should be inspected prior to use for evidence of leakage, premature activation of the plunger, or a faulty tip seal. If evidence of such defects are observed, the syringe should not be used.

After preparation of the injection site, immediately administer IPOL vaccine intramuscularly or subcutaneously. In infants and small children, the mid-lateral aspect of the thigh is the preferred site. In older children and adults IPOL vaccine should be administered intramuscularly or subcutaneously in the deltoid area.

The syringe is intended for single use only, must not be reused, and must be disposed of properly and promptly following its use.

To help avoid HIV (AIDS), HBV (Hepatitis), and other infectious diseases due to accidental needlesticks, contaminated needles should not be recapped or removed, unless there is no alternative or that such action is required by a specific medical procedure.

Care should be taken to avoid administering the injection into or near blood vessels and nerves. If blood or any suspicious discoloration appears in the syringe, do not inject but discard contents and repeat procedures using a new dose of vaccine administered at a different site.

DO NOT ADMINISTER VACCINE INTRAVENOUSLY.

Children
The primary series of IPOL vaccine consists of three 0.5 mL doses administered intramuscularly or subcutaneously, preferably eight or more weeks apart and usually at ages 2, 4, and 6 to 18 months. Under no circumstances should the vaccine be given more frequently than four weeks apart. The first immunization may be administered as early as six weeks of age. For this series, a booster dose of IPOL vaccine is administered at 4 to 6 years of age.[41]

Use with Other Vaccines
From historical data on the antibody responses to diphtheria, tetanus, whole-cell or acellular pertussis, Hib, or hepatitis B vaccines used concomitantly with IPOL vaccine, no interferences have been observed on the immunological end points accepted for clinical protection.[11,16,36] (See DRUG INTERACTIONS section.)

If the third dose of IPOL vaccine is given between 12 to 18 months of age, it may be desirable to administer this dose with Measles, Mumps, and Rubella (MMR) vaccine and/or other vaccines using separate syringes at separate sites,[28] but no data on the immunological interference between IPOL vaccine and these vaccines exist.

Use in Previously Vaccinated Children
Children and adolescents with a previously incomplete series of polio vaccine should receive sufficient additional doses of IPOL vaccine to complete the series. OPV is no longer recommended for routine immunization and is recommended only in special circumstances[7] (see **General Recommendations** section).

Interruption of the recommended schedule with a delay between doses does not interfere with the final immunity. There is no need to start the series over again, regardless of the time elapsed between doses.

The need to routinely administer additional doses is unknown at this time.[28]

Adults
Unvaccinated Adults
A primary series of IPOL vaccine is recommended for unvaccinated adults at increased risk of exposure to poliovirus. While the responses of adults to primary series have not been studied, the recommended schedule for adults is two doses given at a 1 to 2 month interval and a third dose given 6 to 12 months later. If less than 3 months but more than 2 months are available before protection is needed, three doses of IPOL vaccine should be given at least 1 month apart. Likewise, if only 1 or 2 months are available, two doses of IPOL vaccine should be given at least 1 month apart. If less than 1 month is available, a single dose of IPOL vaccine is recommended.[28]

Incompletely Vaccinated Adults
Adults who are at an increased risk of exposure to poliovirus and who have had at least one dose of OPV, fewer than three doses of conventional IPV or a combination of conventional IPV or OPV totaling fewer than three doses should receive at least one dose of IPOL vaccine. Additional doses needed to complete a primary series should be given if time permits.[28]

Completely Vaccinated Adults
Adults who are at an increased risk of exposure to poliovirus and who have previously completed a primary series with one or a combination of polio vaccines can be given a dose of IPOL vaccine.

The preferred injection site of IPOL vaccine for adults is in the deltoid area.

HOW SUPPLIED
Syringe, without needle, 0.5 mL (10 per package).
Product No. 49281-860-55

Vial, 10 Dose – Product No. 49281-860-10

CPT® Code: 90713

CPT is a registered trademark of the American Medical Association.

STORAGE
The vaccine is stable if stored in the refrigerator at 2°C to 8°C (35°F to 46°F). The vaccine must not be frozen.

REFERENCES

1. van Wezel AL, et al. Inactivated poliovirus vaccine: Current production methods and new developments. Rev Infect Dis 6 (Suppl 2): S335-S340, 1984
2. Montagnon BJ, et al. Industrial scale production of inactivated poliovirus vaccine prepared by culture of Vero cells on microcarrier. Rev Infect Dis 6 (Suppl 2): S341-S344, 1984
3. McBean AM, et al. Serologic response to oral polio vaccine and enhanced-potency inactivated polio vaccines. Am J Epidemiol 128: 615-628, 1988
4. Murdin AD, et al. Inactivated poliovirus vaccine: past and present experience. Vaccine 8: 735-746, 1996
5. Sabin AB. Poliomyelitis. In Brande AI, Davis CE, Fierer J (eds) International Textbook of Medicine, Vol II. Infectious Diseases and Medical Microbiology. 2nd ed. Philadelphia, WBSaunders, 1986
6. Prevots DR, et al. Vaccine-associated paralytic poliomyelitis in the United States, 1980-1994: current risk and potential impact of a proposed sequential schedule of IPV followed by OPV (Abstract #H90). In: Abstracts of the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, DC. American Society for Microbiology, 179, 1996
7. ACIP. Updated Recommendations of the Advisory Committee on Immunization Practices. Poliomyelitis Prevention in the United States. MMWR 49: No. RR-5, 2000

8. Salk J, et al. Antigen content of inactivated poliovirus vaccine for use in a one- or two-dose regimen. Ann Clin Res 14: 204-212, 1982
9. Salk J, et al. Killed poliovirus antigen titration in humans. Develop Biol Standard 41: 119-132, 1978
10. Salk J, et al. Theoretical and practical considerations in the application of killed poliovirus vaccine for the control of paralytic poliomyelitis. Develop Biol Standard 47: 181-198, 1981
11. Unpublished data available from Sanofi Pasteur SA
12. Unpublished data available from Sanofi Pasteur Inc.
13. Faden H, et al. Comparative evaluation of immunization with live attenuated and enhanced potency inactivated trivalent poliovirus vaccines in childhood: Systemic and local immune responses. J Infect Dis 162: 1291-1297, 1990
14. Vidor E, et al. The place of DTP/eIPV vaccine in routine pædiatric vaccination. Rev Med Virol 4: 261-277, 1994
15. Bottiger M. Long-term immunity following vaccination with killed poliovirus vaccine in Sweden, a country with no circulating poliovirus. Rev Infect Dis 6 (Suppl 2): S548-S551, 1984
16. Plotkin SA, et al. Inactivated polio vaccine for the United States: a missed vaccination opportunity. Pediatr Infect Dis J 14: 835-839, 1995
17. Marine WM, et al. Limitation of fecal and pharyngeal poliovirus excretion in Salk-vaccinated children. A family study during a Type 1 poliomyelitis epidemic. Amer J Hyg 76: 173-195, 1962
18. Bottiger M, et al. Vaccination with attenuated Type 1 poliovirus, the Chat strain. II. Transmission of virus in relation to age. Acta Paed Scand 55: 416-421, 1966
19. Dick GWA, et al. Vaccination against poliomyelitis with live virus vaccines. Effect of previous Salk vaccination on virus excretion. Brit Med J 2: 266-269, 1961
20. Wehrle PF, et al. Transmission of poliovirus; III. Prevalence of polioviruses in pharyngeal secretions of infected household contacts of patients with clinical disease. Pediatrics 27: 762-764, 1961
21. Adenyi-Jones SC, et al. Systemic and local immune responses to enhanced-potency inactivated poliovirus vaccine in premature and term infants. J Pediatr 120: No 5, 686-689, 1992
22. Chin TDY. Immunity induced by inactivated poliovirus vaccine and excretion of virus. Rev Infect Dis 6 (Suppl 2): S369-S370, 1984
23. Salk D. Herd effect and virus eradication with use of killed poliovirus vaccine. Develop Biol Standard 47: 247-255, 1981
24. Bijerk H. Surveillance and control of poliomyelitis in the Netherlands. Rev Infect Dis 6 (Suppl 2): S451-S456, 1984
25. Lapinleimu K. Elimination of poliomyelitis in Finland. Rev Infect Dis 6 (Suppl 2): S457-S460, 1984
26. Conyn van Spaendonck M, et al. Circulation of Poliovirus during the poliomyelitis outbreak in the Netherlands in 1992-1993. Amer J Epidemiology 143: 929-935, 1996
27. Strebel PM, et al. Epidemiology of poliomyelitis in the United States one decade after the last reported case of indigenous wild virus associated disease. Clin Infect Dis 14: 568-579, 1992
28. ACIP. Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of Inactivated Poliovirus Vaccine followed by Oral Poliovirus Vaccine. MMWR 46: No. RR-3, 1997
29. WHO. Weekly Epidemiology Record 54: 82-83, 1979
30. Certification of poliomyelitis eradication – the Americas, 1994. MMWR 43: 720-722, 1994
31. Institute of Medicine. An evaluation of poliomyelitis vaccine poliomyelitis vaccine policy options. Washington, DC. National Academy of Sciences, 1988
32. ACIP. Immunization of children infected with human T-lymphotropic virus type III/lymphadenopathy-associated virus. MMWR 35: 595-606, 1986
33. ACIP. General recommendations on immunization. MMWR 43: No. RR-1, 1994
34. Barbi M, et al. Antibody response to inactivated polio vaccine (eIPV) in children born to HIV positive mothers. Eur J Epidemiol 8: 211-216, 1992
35. Varon D, et al. Response to hemophilic patients to poliovirus vaccination: Correlation with HIV serology and with immunological parameters. J Med Virol 40: 91-95, 1993
36. Vidor E, et al. Fifteen-years experience with vero-produced enhanced potency inactivated poliovirus vaccine (eIPV). Ped Infect Dis J, 312-322, 1997
37. Stratton, R. et al. Adverse Events Associated with Childhood Vaccines. Polio Vaccines. National Academy Press, 295-299, 1994
38. CDC. Vaccine Adverse Event Reporting System – United States. MMWR 39: 730-733, 1990
39. CDC. National Childhood Vaccine Injury Act. Requirements for permanent vaccination records and for reporting of selected events after vaccination. MMWR 37: 197-200, 1988
40. Food & Drug Administration. New Reporting Requirements for Vaccine Adverse Events. FDA Drug Bull 18 (2), 16-18, 1988
41. Recommended childhood immunization schedule – United States, 1999. MMWR 48: 12-16, 1999

Product information
as of December 2005

Manufactured by:
Sanofi Pasteur SA
Lyon France
US Govt License #1724

Distributed by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA
1-800-VACCINE (1-800-822-2463)

sanofi pasteur

平成２３(２０１１)年3月　発行

厚生労働科学研究費補助金

創薬基盤推進研究事業：政策創薬総合研究事業

厚生労働省　エイズ治療薬研究班

国内未承認エイズ治療薬等を用いたＨＩＶ感染症治療薬及びＨＩＶ感染症至適治療法の開発に係る応用研究

平成２２年度　総括・分担研究報告書

研究代表者　福武　勝幸

事務局
〒160-0023　東京都新宿区西新宿　6-7-1
東京医科大学病院　臨床検査医学講座
電話　03-3342-6111