

HAEMOPHILUS *INFLUENZA* type b CONJUGATE VACCINE (Hib)

GENERAL INFORMATION

Contraindications and Precautions include the following:

- Anaphylactic reaction to a vaccine component or following a prior dose of that vaccine
- Moderate or severe acute illness
- Children younger than 6 weeks of age

Adverse events include the following:

- Swelling, redness and/or pain
- Systemic reactions infrequent, serious adverse reactions rare

ACIP Recommended Population

*All infants, including those born premature should receive a primary series conjugate Hib vaccine (separate or in combination), beginning at 2 months of age. The number of doses in the primary series depends on the type of vaccine used. A primary series of PRP-OMP (PedvaxHIB) vaccine is two doses; PRP-T (ActHIB) requires a three-dose primary series (see table). A booster is recommended at 12-15 months regardless of which vaccine is used for the primary series. "PRP-T (Hiberix) may only be used for the booster (or final) dose in a patient aged 12 months through 59 months. Note that the ACIP specifically approves the use of this vaccine at ages 12-14 months, even though the package insert says it is licensed from 15-59 months."

*For persons older than age 5 years (including adults) who have a medical indication for the vaccine (e.g., bone marrow transplant or spleen removed), a single dose of Hib vaccine is indicated. These indications are rare. Administer with MD or APN order.

***Federally funded vaccine may be used for these groups.**

Administration of Vaccine:

- Appropriate age for Hib: at least 2 months old, but less than 5 years
- Appropriate time interval since last Hib

Children who have started the 3 dose primary series of vaccinations with ActHib vaccine may complete the primary series with Pedvax HIB but will still need a total of 3 doses in the primary series. The dose administered routinely after age 12 months is a booster dose.

PLAN

Have accompanying adult read "Vaccine Information Statement"/ "Vaccine Information Materials"

Counsel regarding benefits, side effects, and management

NOTE: This vaccine is lyophilized and must be reconstituted with the diluent that is provided with the vaccine; NO OTHER DILUENT CAN BE USED; reconstitute with entire content of diluent vial and inject the entire amount of the reconstituted vial; this is a single unit dose and must be administered within 24 hours of reconstitution

HAEMOPHILUS INFLUENZAE type b CONJUGATE VACCINE (Hib)

Administer IM 0.5 cc of vaccine as follows:

VACCINE	AGE BEGINNING PRIMARY SERIES	PRIMARY SERIES	BOOSTER
PRP-T (ActHIB for any dose; Hiberix for final/booster dose only)	2-6 months	3 doses, 2 months apart	12-15 months**
	7-11 months	2 doses, 2 months apart	12-15 months**
	12-14 months	1 dose	2 months later
	15-59 months	1 dose	---
PRP-OMP (PedvaxHIB)	2-6 months	2 doses, 2 months apart	12-15 months**
	7-11 months	2 doses, 2 months apart	12-15 months**
	12-14 months	1 dose	2 months later
	15-59 months	1 dose	---

**At least 2 months after previous dose

NOTE:

- If child is greater than 59 months of age, HIB Vaccine is not routinely indicated
- Ideally, the same brand of vaccine should be used throughout the entire vaccination series; however, where it is necessary to change the types of vaccine, a child 2-6 months of age seen for the primary series should receive three doses of Hib vaccine (i.e., child receives 1 dose ActHIB should then receive 2 doses of Pedvax HIB or if child receives 2 doses of ActHIB should then receive 1 dose of Pedvax HIB for primary series; child would then get booster at 12-15 months)
- Hib vaccines may be given simultaneously at different injection sites with all other vaccines.

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date, name, address and title of person administering vaccine

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

HAEMOPHILUS *INFLUENZAE* type b CONJUGATE VACCINE (Hib)

Follow-up:

If severe reaction is reported as occurring within 30 days following vaccine administered by health department personnel, VAERS Report form must be completed
Return at appropriate interval according to schedule

REFERENCES

“Epidemiology and Prevention of Vaccine - Preventable Diseases”, 10th Edition, Centers for Disease Control and Prevention, Department of Health and Human Services, February 2008
ACIP Adult Immunization Schedule footnote, 2009
“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis
July 8, 2009
"CDC. Licensure of a Haemophilus influenzae type B (Hib) vaccine (Hiberix) and Updated Recommendations for Use of Hib Vaccine. MMWR. 2009;58(36);1008-1009."

2009 H1N1 LIVE ATTENUATED INFLUENZA VACCINE (LAIV) (FluMist® by MedImmune)

GENERAL INFORMATION

The 2009 H1N1 (“pandemic” or “swine” flu) influenza vaccine comes in two forms: inactivated vaccine administered by injection (the “flu shot”) and live attenuated, intranasally-administered vaccine (LAIV). Both vaccines are FDA-licensed and manufactured in the same way as seasonal influenza vaccine; only the strain of virus in the vaccine is different.

In the absence of an influenza vaccine shortage, the Tennessee Immunization Program recommends vaccination of persons in all CDC-recommended groups.

Any changes in eligibility for vaccination during influenza season will be announced through Tennessee Immunization Program policy updates.

The 2009 H1N1 LAIV is available through a special federal program for all persons eligible to receive it. There is no charge for the vaccine or administration in any public health vaccination setting; federal policy permits billing of insurance for administration in public health operated clinics (state/regional public health policies address this elsewhere).

No preference between inactivated injected vaccine and LAIV is expressed for persons who are eligible to receive either. See the 2009 H1N1 inactivated vaccine protocol for influenza vaccination of persons who are not eligible for LAIV

A separate protocol covers 2009-2010 seasonal influenza vaccine.

2009 H1N1 LAIV indication:

2009 H1N1 LAIV is approved by the Food and Drug Administration (FDA) for use in healthy persons aged 24 months through 49 years who are not pregnant.

Persons medically eligible for LAIV who are among CDC target populations for 2009 H1N1 influenza vaccination include some healthcare workers, household contacts of infants <6 months of age, and all healthy children and young adults ages 2 years through 24 years.

If supply is sufficient to meet demand among target populations, persons eligible for LAIV outside those target populations (i.e., healthy persons 25 through 49 years) may receive it.

Special situations:

2009 H1N1 LAIV may be co-administered with any other vaccine at the same visit except with the 2009-2010 seasonal LAIV. Live vaccines that are not given on the same day (e.g., varicella, MMR) should be administered at least 4 weeks apart. NOTE: The interval recommended at this writing is subject to change (to a shorter interval) – the protocol will be updated when changed.

Patients who require both seasonal and 2009 H1N1 influenza vaccines at the same visit may have 1 in the form of LAIV and 1 inactivated (shot), or both inactivated vaccines.

Patients **<10 years of age require 2 doses** of 2009 H1N1 vaccine, about 1 month apart, for adequate protection. They do not have to use the same type of vaccine (TIV or LAIV)

for both doses. The protocol will be updated with a more specific minimum interval, when known.

Breastfeeding or living in a household with a pregnant woman or immunocompromised person (who is able to live outside a special hospital isolation ward, such as a bone marrow transplant unit) is not a contraindication to vaccination.

Contraindications and precautions:

People less than 2 years of age or age 50 years or older
People with a medical condition that places them at high risk for complications from influenza [e.g., chronic heart or lung disease, asthma, diabetes, kidney disease, hemoglobinopathies, any condition that compromises the ability to handle respiratory secretions, pregnant women, or persons with a weakened immune system]
Children less than 5 years old with a history of recurrent (more than 1 episode) wheezing
Children or adolescents receiving aspirin therapy
People with a history of Guillain-Barré syndrome
People who have taken oseltamivir (Tamiflu) or zanamivir (Relenza) antiviral medication within the previous 48 hours

Common Adverse Reactions ($\geq 10\%$ of patients)

Nasal congestion
Sore throat in adults
Fever $>100^{\circ}\text{F}$ in children ages 2-6 years

PLAN

Have recipient, parent, or guardian read Vaccine Information Statement (VIS)
Verify that the patient has not taken oseltamivir or zanamivir antiviral medication within the past 48 hours
Verify that the patient has not received seasonal LAIV within the past 4 weeks
Counsel regarding benefits, side effects, and management
Administer vaccine intranasal spray (0.1ml in each nostril) according to manufacturer's recommendation
Remind about the need for seasonal influenza vaccine for protection against seasonal influenza viruses this season. Advise parent or guardian of recipients less than 10 years of age to return for a second dose in 1 month if the child is receiving 2009 H1N1 influenza vaccine for the first time.
Advise them not to take oseltamivir or zanamivir antiviral medication, unless medically necessary, within 2 weeks of receiving LAIV (whether seasonal or 2009 H1N1). These medications can interfere with the effectiveness of LAIV.
Advise to wait in clinic 20 minutes after intranasal administration
Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine
Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate VAERS form: <http://vaers.hhs.gov>)

Recommended Schedule and Dosage of 2009 H1N1 LAIV (FluMist®):

Age Group	Dosage Schedule
Children 24 months through 9 years	2 doses (each dose 0.1ml per nostril) given about 1 month apart
Other persons aged 10-49 years	1 dose (0.1 ml per nostril)

Referral Indicators:

Persons with severe allergy to eggs or other components of vaccine (gelatin, gentamicin, arginine)

Persons with history of Guillain-Barré syndrome

Persons having moderate to severe acute febrile illness or illnesses with significant nasal congestion (until illness resolves)

REFERENCES

Use of Influenza A (H1N1) 2009 Monovalent Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, August 28, 2009. Available at <http://www.cdc.gov/mmwr/pdf/rr/rr58e0821.pdf> Last accessed October 2, 2009.

Influenza A (H1N1) 2009 Monovalent Vaccine, Live Intranasal, Package Insert (MedImmune). Revised September 2009.

2009 H1N1 INACTIVATED INFLUENZA VACCINE (various manufacturers)

GENERAL INFORMATION

General Recommendations for 2009 H1N1 Influenza Vaccination:

The 2009 H1N1 (“pandemic” or “swine” flu) influenza vaccine comes in two forms: inactivated vaccine administered by injection (the “flu shot”) and live attenuated, intranasally-administered vaccine (LAIV). Both vaccines are FDA-licensed and manufactured in the same way as seasonal influenza vaccine: only the strain of virus in the vaccine is different.

In the absence of an influenza vaccine shortage, the Tennessee Immunization Program recommends vaccination of persons in all CDC-recommended groups.

Any changes in eligibility for vaccination during influenza season will be announced through Tennessee Immunization Program policy updates.

The 2009 H1N1 inactivated vaccine is available through a special federal program for all persons eligible to receive it. There is no charge for the vaccine or administration in any public health vaccination setting; federal policy permits billing of insurance for administration in public health operated clinics (state/regional public health policies address this elsewhere).

No preference between inactivated injected vaccine and LAIV is expressed for persons who are eligible to receive either. See the 2009 H1N1 live attenuated vaccine protocol for influenza vaccination of persons who are not eligible for LAIV

A separate protocol covers 2009-2010 seasonal influenza vaccine.

Special Clinical Notes:

Seasonal influenza vaccine (either LAIV or inactivated injected vaccine) may be co-administered with 2009 H1N1 inactivated vaccine, if indicated.

All children 6 months through 9 years are recommended to receive 2 doses of 2009 H1N1 influenza vaccine, about 1 month apart, for adequate protection.

Licensed inactivated vaccine formulations by manufacturer:

Manufacturer	Product Formulation	FDA-licensed ages
Sanofi Pasteur (Fluzone®)	0.25 ml preservative-free, pre-filled syringe (PFS)	6-35 months only
	0.5 ml PFS	≥36 months
	5 ml multidose vial	≥ 6 months
Novartis (Fluvirin®)	5 ml multidose vial	≥4 years
CSL Biotherapies (Afluria®)	0.5 ml PFS or 5 ml multidose vial	≥18 years
GSK TIV (Flulaval®)	5 ml multidose vial	≥18 years

Centers for Disease Control and Prevention (CDC) recommendations:

The CDC has recommended 2009 H1N1 influenza vaccine for the following:

Initial target groups (in no particular order):

Pregnant women

Persons who live with or care for infants aged <6 months (e.g., parents, siblings and daycare providers)

Health-care and emergency medical services personnel

ALL persons aged 6 months through 24 years (especially <5 years, chronically ill)

Persons aged 25 through 64 years with certain chronic medical conditions¹

CDC-recommended subset of target groups: For consideration only if local demand temporarily greatly exceeds supply (follow local/regional public health guidance)

Pregnant women

Persons who live with or care for infants aged <6 months (e.g., parents, siblings and daycare providers)

Health-care and emergency medical services personnel who have direct contact with patients or infectious material

Children aged 6 months through 4 years

Children aged 5 years through 18 years who have medical conditions that put them at higher risk for influenza-related complications¹

As supplies permit (follow local/regional public health guidance):

CDC Second Level Group

Other healthy adults 25 through 64 years wishing to be vaccinated.

CDC Lowest Level Group (lowest rates of infection with 2009 H1N1 influenza)

Adults 65 years of age and older wishing to be vaccinated.

Persons who should not receive the influenza vaccine include the following:

(See Referral Indicators)

Persons with a severe allergy (i.e., anaphylactic allergic reaction) to a previous dose of any influenza vaccine or its components

Children less than 6 months of age

PLAN

Have recipient, parent, or guardian read Vaccine Information Statement (VIS)

Counsel regarding benefits, side effects, and management

Administer vaccine injection according to manufacturer's recommendation

Remind about the need for seasonal influenza vaccine to protect against seasonal influenza viruses (co-administration permitted). Advise parent or guardian of recipients less than 10

¹ Those with chronic medical conditions at increased risk for complications include: Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders (including diabetes mellitus); persons who have immunosuppression (including immunosuppression caused by medication or HIV); children (aged 6 months--18 years) on long-term aspirin therapy.

years of age to return for a second dose of 2009 H1N1 influenza vaccine in about 1 month (protocol will be updated with a more specific interval, if one is published)

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate VAERS form)

Recommended Schedule and Dosage of 2009 H1N1 Inactivated Vaccine:

Age Group	Dosage	No. Doses	Route
6 through 35 months	0.25 ml	2	Intramuscular
3 through 9 years	0.50 ml	2	Intramuscular
Age 10 years and older	0.50 ml	1	Intramuscular

* Two doses of 2009 H1N1 influenza vaccine administered about 1 month apart are recommended for **all** children 6 months through 9 years of age. TIV or LAIV may be used interchangeably for either dose, if appropriate.

Referral Indicators:

Persons allergic to eggs or components of vaccine (see package insert)

Persons with history of Guillain-Barré syndrome

Persons having moderate to severe acute febrile illness (until illness resolves)

REFERENCES

Use of Influenza A (H1N1) 2009 Monovalent Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, August 28, 2009. Available at <http://www.cdc.gov/mmwr/pdf/rr/rr58e0821.pdf> Last accessed October 2, 2009.

POLIO VACCINE, INACTIVATED ALL-IPV SCHEDULE

GENERAL INFORMATION

IPV is the only poliovirus vaccine recommended for all persons

The all-IPV routine schedule requires 4 doses of vaccine to be given at ages 2 months, 4 months, 6-18 months, and 4-6 years

IPV can be administered simultaneously with all other vaccines recommended for the same visit

Contraindications and precautions to IPV include:

Anaphylactic hypersensitivity

Severe febrile illness (a precaution; delay until resolved)

Allergic to streptomycin, neomycin, or polymixin B

Pregnancy (a precaution; however, if required because immediate protection needed for traveling outside of country, obtain a physician order)

Adverse Reactions to IPV include:

Possibility of hypersensitivity reactions in individuals sensitive to streptomycin, polymixin B, or neomycin

PLAN

Have accompanying adult read Vaccine Information Statement/Vaccine Information Material

Counsel regarding benefits, side effects, and management

Administer appropriate vaccine, as specified by manufacturer, in accordance with schedule

Recommended Vaccine Schedule:

2 months, 4 months, 6-18 months, and 4-6 years

The minimum age for dose 1 is 6 weeks.

A minimum interval of 4 weeks is required from dose 1 to dose 2 and from dose 2 to dose 3. A minimum interval of 6 months is required between doses 3 and 4.

Use of minimum intervals during the first 6 months of life is recommended only if the recipient is at risk for exposure (during an outbreak or for travel to a polio-endemic area). History shots administered using minimum intervals do not need to be repeated.

The final dose of IPV is recommended routinely at 4-6 years of age, regardless of the number of previous doses.

Children immunized with the DTaP/IPV-Hib combination vaccine (Pentacel) will receive 4 doses of IPV by 18 months of age and are recommended to receive a

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POLIO VACCINE, INACTIVATED ALL-IPV SCHEDULE (Continued)

5th dose at 4-6 years. If a 5-dose schedule is used, a minimum interval of 6 months is recommended between doses 4 and 5.

The 4th dose is not needed if the 3rd dose is given on or after the 4th birthday

See table below for details of approved use for various IPV-containing vaccines.

TABLE. Currently licensed vaccines containing inactivated poliovirus vaccine (IPV) — United States, 2009*

Vaccine composition	Trade name	Manufacturer	Approved use in ACIP [†] routine schedule	Comments
IPV	Ipol (Poliovax [§])	Sanofi Pasteur	2, 4, 6–18 mos, and 4–6 yrs	Approved for use in infants, children, and adults [¶]
DTaP-HepB-IPV**	Pediarix	GlaxoSmithKline	2, 4, and 6 mos	Approved for first 3 doses of IPV through age 6 yrs ^{††}
DTaP-IPV/Hib ^{§§}	Pentacel	Sanofi Pasteur	2, 4, 6, and 15–18 mos	Approved for 4 doses of IPV through age 4 yrs ^{¶¶}
DTaP-IPV***	Kinrix	GlaxoSmithKline	4–6 yrs	Approved for booster dose at age 4–6 yrs ^{†††}

* As of August 5, 2009.

[†] Advisory Committee on Immunization Practices. Full schedule available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a5.htm>.

[§] Not currently distributed in the United States.

[¶] Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf>.

** Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B (recombinant), and inactivated poliovirus vaccine combined.

^{††} Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm168055.pdf>.

^{§§} Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, and *Haemophilus b* conjugate (tetanus toxoid conjugate) vaccine.

^{¶¶} Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109810.pdf>.

^{***} Diphtheria and tetanus toxoids and acellular pertussis adsorbed, and inactivated poliovirus vaccine.

^{†††} Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm107220.pdf>.

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date, name, address and title of person administering vaccine (National Childhood Vaccine Injury Act)

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate form)

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

History of severe reaction to previous dose

Follow-up:

Return at appropriate interval according to schedule

References

MMWR, August 7, 2009/58 (30): 829. Updated Recommendations of the Advisory Committee on Immunization Practices Regarding Routine Poliovirus Vaccination.

MMWR, July 16, 1999/48(27);590. Recommendations of the Advisory Committee on Immunization Practices; Revised Recommendations for Routine Poliomyelitis Vaccination

Epidemiology and Prevention of Vaccine-Preventable Diseases, Centers for Disease Control and Prevention, latest edition

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Anaphylactic hypersensitivity

Severe febrile illness (a precaution; delay until resolved)

Allergic to streptomycin, neomycin, or polymixin B

Pregnancy (a precaution; however, if required because immediate protection needed for traveling outside of country, obtain a physician order)

Adverse Reactions to IPV include:

Possibility of hypersensitivity reactions in individuals sensitive to streptomycin, polymixin B, or neomycin

PLAN

Have accompanying adult read Vaccine Information Statement/Vaccine Information Material

Counsel regarding benefits, side effects, and management

Administer appropriate vaccine, as specified by manufacturer, in accordance with schedule

Recommended Vaccine Schedule:

2 months, 4 months, 6-18 months, and 4-6 years

The minimum age for dose 1 is 6 weeks.

A minimum interval of 4 weeks is required from dose 1 to dose 2 and from dose 2 to dose 3. A minimum interval of 6 months is required between doses 3 and 4.

Use of minimum intervals during the first 6 months of life is recommended only if the recipient is at risk for exposure (during an outbreak or for travel to a polio-endemic area). History shots administered using minimum intervals do not need to be repeated.

The final dose of IPV is recommended routinely at 4-6 years of age, regardless of the number of previous doses.

Children immunized with the DTaP/IPV-Hib combination vaccine (Pentacel) will receive 4 doses of IPV by 18 months of age and are recommended to receive a

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POLIO VACCINE, INACTIVATED ALL-IPV SCHEDULE (Continued)

5th dose at 4-6 years. If a 5-dose schedule is used, a minimum interval of 6 months is recommended between doses 4 and 5.

The 4th dose is not needed if the 3rd dose is given on or after the 4th birthday

See table below for details of approved use for various IPV-containing vaccines.

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DTaP-HepB-IPV**	Pediarix	GlaxoSmithKline	2, 4, and 6 mos	Approved for first 3 doses of IPV through age 6 yrs ^{††}
DTaP-IPV/Hib ^{§§}	Pentacel	Sanofi Pasteur	2, 4, 6, and 15–18 mos	Approved for 4 doses of IPV through age 4 yrs ^{¶¶}
DTaP-IPV***	Kinrix	GlaxoSmithKline	4–6 yrs	Approved for booster dose at age 4–6 yrs ^{†††}

* As of August 5, 2009.

[†] Advisory Committee on Immunization Practices. Full schedule available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a5.htm>.

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[¶] Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf>.

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^{†††} Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm107220.pdf>.

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date, name, address and title of person administering vaccine (National Childhood Vaccine Injury Act)

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate form)

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

History of severe reaction to previous dose

Follow-up:

Return at appropriate interval according to schedule

References

MMWR, August 7, 2009/58 (30): 829. Updated Recommendations of the Advisory Committee on Immunization Practices Regarding Routine Poliovirus Vaccination.

MMWR, July 16, 1999/48(27);590. Recommendations of the Advisory Committee on Immunization Practices; Revised Recommendations for Routine Poliomyelitis Vaccination

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