

WEEKLY EPIDEMIOLOGICAL REPORT

A publication of the Epidemiology Unit Ministry of Health, Nutrition & Indigenous Medicine 231, de Saram Place, Colombo 01000, Sri Lanka

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Efficacy of Fractional Inactivated Polio Vaccine

Introduction

The Polio Eradication and Endgame Strategic Plan 2013– 2018 is a comprehensive long term plan which was developed by the Global Polio Eradication Initiative in consultation with national health authorities, global health initiatives, scientific experts, donors and other stakeholders. It addresses what is needed to be done in order to have a polio free world by 2018. Strengthening immunization systems and withdrawing oral polio vaccine is one of the four objectives of this strategic plan.

Oral Polio Vaccine (OPV) has the unique ability to interrupt person to person spread of polio virus. However, it also carries the risk of giving rise to vaccine associated polio. Poliomyelitis cases due to wild polio virus type 2 were last detected in 1999. In the recent years, more than 90% of circulating Vaccine Derived Polio Virus cases (cVDPV) were caused by vaccine derived type 2 strain. Therefore, polio type 2 withdrawal has been identified as an important step in the Polio Eradication Endgame strategies.

Inactivated Polio Vaccine (IPV) introduction has been done in 2015 as an initial step in the polio type 2 withdrawal procedure. This measure has been taken to ensure maintenance of polio type 2 immunity before the plan of switching over from tOPV to bOPV.

However, due to the scarcity of IPV worldwide, polio low risk countries like Sri Lanka will receive the next stock of IPV at the latter part of 2017. Consequently, the Advisory Committee on Communicable diseases (ACCD) has decided to start giving fractional dose IPV (fIPV) instead of full dose IPV.

Fractional dose IPV

Fractional dose IPV is administration of 0.1 ml of IPV, which is one fifth of the full dose, via intradermal route as 2 doses. This is recommended to be given at the ages of 2 and 4 months.

Basis and impact of intradermal route for administration of vaccines

Intramuscular route, subcutaneous route and intradermal route are the available routes for administration of vaccines. Among them, most commonly used are intramuscular and subcutaneous routes where intradermal route is only used to administer few vaccines like BCG and rabies vaccine. However, in the recent past, intradermal route has gained much popularity due to the fact that dermis and epidermis of the human skin contain abundant antigen presenting cells thus inducing a larger scale immune response when a vaccine is delivered to the dermis. Apart from that, there is a possibility of producing mucosal immunity by cross communication between the skin and mucosal surfaces once the antigen is presented to the skin. Therefore, the dose needed to obtain a particular amount of immune response will be reduceddose sparing. In fact for some vaccines, dose

Contents	Page
 Leading Article – Efficacy of fractional inactivated Polio Vaccine Summary of selected notifiable diseases reported -(02th – 08th July 2016) Surveillance of vaccine preventable diseases & AFP -(02th – 08th July 2016) 	1 3 4

WER Sri Lanka - Vol. 43 No. 29

sparing effect through intradermal administration is clearly demonstrated.

Resultant dose sparing through intradermal administration of vaccines is beneficial for immunization programmes in several aspects. As more doses can be obtained from existing vaccine vials, this will reduce per injection cost, especially in resource poor settings. Vaccine availability will also be increased in situations where vaccine supply is limited.

Along with the benefits, some constraints are also associated with intradermal administration of vaccines. In certain situations, vaccines may needed to be reformulated where vaccine is required to be concentrated as more antigen per dose is required. Sometimes dose sparing effect may allow to obtain multiple doses per vial thus necessitating the need to add a preservative or changing the vaccine presentation into small volume single doses. Intradermal administration of vaccines itself is a technique where a lot of training and expertise are required. This also highlights the need to develop novel devices for this task.

Considerable number of clinical trials have been conducted for intradermal administration of vaccines against 11 diseases including IPV, where several of them have demonstrated promising evidence on dose sparing. One clinical trial conducted in Oman has showed similar rates of seroconversion but lower antibody titres when reduced intradermal IPV doses are administered at 2,4 and 6 months of age.

Factors affecting immunogenicity of IPV

As in the case of several infant vaccines, presence of maternally derived antibodies affect the immunogenicity of IPV. Several mechanisms are hypothesized to be responsible for producing this effect. Neutralization of live viral vaccines by maternal antibodies, inhibition of infant B cell activation by maternal antibodies, epitope masking by maternal antibodies are some of the proposed mechanisms.

However, it has been observed that, when Rabies vaccine is administered intradermally, with co-administration of Rabies immunoglobulin, the immunogenicity of Rabies vaccine was not affected. So, it is thought that, in a similar manner, inhibitory effect of maternal antibodies to IPV can be reduced by intradermal administration of IPV.

Evidence on effectiveness of fractional dose IPV

Considerable number of clinical trials have been conducted to assess the effectiveness of fIPV, comparing the seroconversion and antibody titre after fIPV with full dose IPV and oral polio vaccine. Results generated through these trials are variable though many points towards more or less similar efficacy to full dose IPV.

Most of these researches were done with the objective of comparing humoral antibody response after full dose IPV and fIPV, evaluating dose specific immune response and determining Adverse Events Following Immunization (AEFI).

A recent research in 2010, which was conducted to assess fractional doses of IPV in Oman demonstrated seroconversion rates of 97.3%, 95.7% and 97.95% for polio virus types 1,2 and 3 respectively, after the 3 dose schedule of fIPV. The same study has demonstrated 100% efficacy for all three virus types after full dose IPV. However, median antibody titres after fIPV is less than that after full dose IPV. The researchers have arrived at the conclusion that fIPV can achieve similar seroconversion rates for full dose IPV and the difference in median antibody titres is unlikely to have practical implications.

Another research titled "Priming after a fractional dose of IPV" which was conducted in Cuba has arrived at several conclusions after analyzing the results. First, the study has showed that after a first dose IPV, seroconversion and priming resulted in an immune response in at least 90% of infants. The study has also showed that the administration of IPV in infants at 4 months and 8 months resulted in seroconversion in more than 90% of infants with correspondingly high antibody titre, regardless of whether fractional or full dose were used. Most of the researches have demonstrated the relative safety of fIPV as well.

Sources

- Polio Eradication and Endgame Strategic Plan 2013-2018 available at <u>http://www.polioeradication.org/</u> resourcelibrary/strategyandwork.aspx
- Intradermal delivery of vaccines: potential benefits and current challenges available at <u>http://www.who.int/bulletin/</u> volumes/89/3/10-079426/en/
- Randomized controlled clinical trial of fractional doses of inactivated poliovirus vaccine administered intradermally by needle-free device in Cuba available at <u>http://</u> <u>www.ncbi.nlm.nih.gov/pubmed/20350164</u>
- Fractional doses of Inactivated Poliovirus Vaccine in Oman available <u>at http://www.nejm.org/doi/full/10.1056/</u> <u>NEJMoa0909383#t=article</u>
- Priming after a Fractional Dose of Inactivated Poliovirus Vaccine available at <u>http://www.nejm.org/doi/full/10.1056/</u> <u>NEJMoa1202541#t=article</u>

Compiled by Dr. S.A.I.K. Sudasinghe of the Epidemiology Unit

WER Sri Lanka - Vol. 43 No. 29	WER	Sri Lanka -	Vol.	43	No. 2	9
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\$	*–	44	7	43	87	54	100	50	92	100	100	25	80	100	80	50	14	75	76	62	47	86	82	91	67	91	62	68
Leishmani- asis	В	0	3	0	٢	15	0	З	192	132	-	0	0	4	4	-	£	с	53	2	131	80	3	28		0	0	668
Leist asis	A	0	0	0	0	0	0	0	-		0	0	0	0	0	0	0	0	0	0	-	-	-	0	0	0	0	വ
Meningitis	B	28	21	42	30	47	29	27	1	17	34	6	-	8	9	5	-	6	38	27	25	12	116	18	92	31	14	698
Men	A	0	0	2	-	0	ę	0	0	4	2	0	0	-	0	0	0	0	-	2	-	-	3	-		0		24
Chickenpox	ш	228	207	161	109	22	84	183	150	113	114	10	7	23	11	64	80	114	192	51	151	74	118	43	116	203	55	2683
Chick	4	-	-	9	-	0	-	З	2	ß	6	0	0	0	-	0	0	-	З	с	-	-	-	0	7	6	0	46
Human Rabies	Ξ	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	-	2	0	0	0	0	2	0	0	4	10
	A	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Viral Hepatitis	В	20	16	15	39	13	26	6	22	19	8	0	0	9	-	6	7	32	18	0	12	2	83	103	87	16	с	563
T	A		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	-	-		0	0	4
Typhus Fever	В	2	6	9	59	14	48	57	38	28	547	21	37	6	5	2	0	20	21	58	22	-	60	82	22	20	0	1194
	A	0	0	-	0	0	-	0	0	0	8	-	0	-	0	-	0	0	-	0	0	0	£	m	-	2	0	25
Leptospirosis	Β	122	138	266	85	57	30	180	81	119	8	12	8	12	23	32	23	22	110	33	212	76	89	145	344	130	1	2368
Lep	A	2	-	0	2	0	-	2	-	2	0	0	0	0		0	0	0	3	0	3	0	3	2	9	-	0	30
Food Poisoning	ш	24	7	18	29	2	15	с	50	35	42	2	5	28	36	88	20	24	11	0	22	12	22	10	22	46	40	616
Poi	A	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	7
Enteric Fever	в	37	13	19	11	11	35	3	2	9	52	30	17	55	17	24	0	10	٦	4	5	6	9	2	22	20	4	415
Enteri	A	0	0	0	0	0	2	0	0	-	1	0	0	7	٦	0	0	0	0	0	0	0	1	0	0	-	0	14
Encephaliti s	в	3	5	4	13		-	8	-	11	3	0	4	ε	2	0	-	2	8	3	1	2	10		20	16	с	126
Enc	A	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	-	0	0	0	0	0	-	0	4
Dysentery	в	91	39	51	107	36	59	71	35	77	137	28	13	œ	19	117	25	40	184	41	48	19	76	39	226	56	51	1753
Dyse	A	ε	0	0	-	2	ς	9	-	2	4		0	0	0	З	0	2	7	5	0	2	-	-	4	ε	4	55
e Fever	в	7892	2185	1675	1770	353	210	941	458	591	1389	52	97	169	124	330	124	295	1373	667	336	250	425	199	1527	825	367	24624
Dengue Fever	A	293	30	102	139	31	18	31	30	48	52	0	-	9	4	2	-	-	87	13	4	19	34	12	72	35	-	1066
RDHS Division		Colombo	Gampaha	Kalutara	Kandy	Matale	NuwaraEliya	Galle	Hambantota	Matara	Jaffna	Kilinochchi	Mannar	Vavuniya	Mullaitivu	Batticaloa	Ampara	Trincomalee	Kurunegala	Puttalam	Anuradhapura	Polonnaruwa	Badulla	Monaragala	Ratnapura	Kegalle	Kalmune	SRILANKA

WER Sri Lanka - Vol. 43 No. 29

Table 2: Vaccine-Preventable Diseases & AFP

02th - 08th July 2016 (28th Week)

09th-15th July 2016

Disease				No. of Ca	ses by F	Province	e			Number of cases during current	Number of cases during same	Total number of cases to	Total num- ber of cases to date in	Difference between the number of
	W	С	S	N	E	NW	NC	U	Sab	week in 2016	week in 2015	date in 2016	2015	cases to date in 2016 & 2015
AFP*	00	01	00	01	00	00	00	00	00	02	01	35	40	-12.5%
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	0%
Mumps	00	00	02	00	00	00	00	00	01	03	07	227	218	+4.1%
Measles	00	00	00	00	00	00	00	00	00	00	82	288	1423	-80.1%
Rubella	00	00	00	00	00	00	00	00	00	00	00	06	06	0%
CRS**	00	00	00	00	00	00	00	00	00	00	00	00	00	0%
Tetanus	00	00	00	00	00	00	00	00	00	00	01	04	11	-63.6%
Neonatal Teta- nus	00	00	00	00	00	00	00	00	00	00	00	00	00	0%
Japanese En- cephalitis	01	00	00	00	00	00	00	00	00	01	00	08	07	+14.2%
Whooping Cough	00	00	00	00	00	00	00	00	00	00	03	31	47	+34.0%
Tuberculosis	89	12	04	11	12	16	04	06	28	182	122	5114	5179	+1.2%

Key to Table 1 & 2

Provinces: W: Western, C: Central, S: Southern, N: North, E: East, NC: North Central, NW: North Western, U: Uva, Sab: Sabaragamuwa.

RDHS Divisions: CB: Colombo, GM: Gampaha, KL: Kalutara, KD: Kandy, ML: Matale, NE: Nuwara Eliya, GL: Galle, HB: Hambantota, MT: Matara, JF: Jaffna,

KN: Killinochchi, MN: Mannar, VA: Vavuniya, MU: Mullaitivu, BT: Batticaloa, AM: Ampara, TR: Trincomalee, KM: Kalmunai, KR: Kurunegala, PU: Puttalam, AP: Anuradhapura, PO: Polonnaruwa, BD: Badulla, MO: Moneragala, RP: Ratnapura, KG: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Neonatal Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps., Rubella, CRS, Special Surveillance: AFP* (Acute Flaccid Paralysis), Japanese Encephalitis

CRS** =Congenital Rubella Syndrome

AFP and all clinically confirmed Vaccine Preventable Diseases except Tuberculosis and Mumps should be investigated by the MOH

Dengue Prevention and Control Health Messages

Look for plants such as bamboo, bohemia, rampe and banana in your surroundings and maintain them

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Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to chepid@sltnet.lk. **Prior approval should be obtained from the Epidemiology Unit before publishing data in this publication**

ON STATE SERVICE

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