WEEKLY EPIDEMIOLOGICAL REPORT

A publication of the Epidemiology Unit
Ministry of Healthcare and Nutrition

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Vol. 37 No.05 30th January- 05th February 2010

WEER SRI LANKA - 2010

Impact of fear of Adverse Events Following Immunization on pertussis control: the untold story

During the past few months, the Expanded Programme on Immunization of Sri Lanka has gone through one of the turbulent periods of its history due to the recently experienced Adverse Events Following Immunization (AEFI), consequent to administration of pentavalent and rubella vaccines. As a result, programme managers have to work hard to maintain the confidence of the public on immunization and thereby keep the vaccine preventable diseases under control. The following description is based on a study, published in *The Lancet* a leading medical journal. It gives the experiences of United Kingdom, Hungary, Australia and a few other countries on the fear of AEFI following pertussis vaccination and how it affected their pertussis vaccination programme. The author has taken pertussis vaccination and control of pertussis for his study because pertussis vaccine had many perceived side effects mainly the encephalopathy.

Pertussis whole-cell vaccines, whether monovalent or trivalent as in diphtheria-tetanus-pertussis (DTP), have been important in the control of pertussis. The decrease of pertussis incidence in these countries resulting from vaccination may have created the impression that pertussis was becoming milder and more scarce owing to medical and social development. As pertussis became rarer, attention shifted from the disease to the adverse events following vaccination which are often unrelated. In countries like UK, Australia and Japan, publicity surrounding such adverse events gave rise to fear of AEFI after whole-cell pertussis vaccination.

The author has taken two groups of countries for the comparison purpose. These two groups are described below.

Group I:

includes countries in which use of whole-cell pertussis vaccine (in DTP) has lasted decades, Hungary, the former East Germany, Poland, and the USA. These countries provided comprehensive DTP coverage with little or no interruption by fear of AEFI.

Group II:

includes countries in which fear of AEFI affected pertussis control programmes. Within this group two subgroups were demarcated. They were defined as opposition to whole-cell pertussis vaccines by groups that were actively (subgroup 01) and passively (subgroup 02) opposed the use of vaccines. Sweden, Japan, the UK, and the Russian Federation had active opposition to whole-cell vaccines, that is, well organized groups that sought to stop their use by means of news stories, television interviews, lectures, popular articles, books, and other writings. Distraught parents whose children suffered adverse events blaming on whole-cell pertussis vaccination featured prominently. Some outspoken medical authorities became leaders in these movements.

Italy, the former West Germany, Ireland, and Australia had less organized, passive movements against whole-cell pertussis vaccines, in which health-care providers withheld vaccines because of safety concerns, based on published data especially in the United Kingdom.

Group I:

As regards countries with sustained use of whole-cell pertussis vaccines, Hungary's pertussis control programme has been exemplary. Surveillance, including mandatory reporting, also began in 1931. Immunization with whole-cell pertussis vaccine has continued without interruption since 1955. Vaccine coverage with three primary and two booster doses has been nearly 100%. Reported incidences fell from more than 100 per 100 000 in the prevaccine era to less than one per 100 000 post vaccination, where they have remained for almost 30 years (figure 1).

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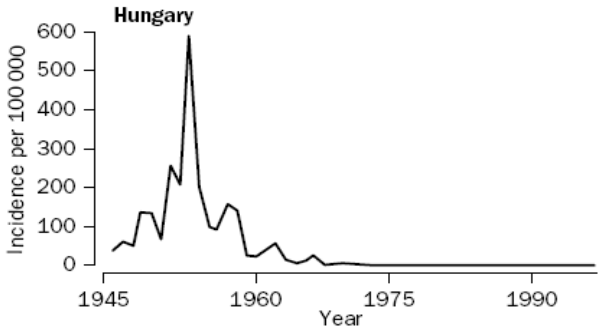

Figure 01. Incidences of pertussis in Hungary (Source: The Lancet, 1998)

Group II: includes the countries with pertussis-control programmes affected by active and passive movements against whole-cell vaccines. This group initially had varying success in controlling pertussis, first with monovalent whole-cell vaccine, and subsequently with DTP. Reported incidence exceeded 100 per 100,000 in the late 1940s and early 1950s, when vaccination programmes began. Coverage accelerated during the 1960s, reaching roughly 80% during the 1970s. The consequent fall in reported incidence, ranging from ten-fold to 100-fold, set the stage for movements against whole-cell pertussis vaccines due to occurrence of AEFI.

For example United Kingdom (UK) after a 1974 report, ascribing 36 neurological reactions to whole-cell pertussis vaccine, persistent television and press coverage interrupted a successful vaccination programme (figure 2). A prominent public health academic, claimed that the protective effect of the vaccine was marginal and did not outweigh its danger. Others reached opposite conclusions based on the fall in pertussis incidence after introduction of the vaccine in the 1950s. Although health authorities resisted pressure to withdraw the vaccine, loss of confidence in it led to a sharp reduction in coverage from 81% to 31% in merely about a 5 year period. Pertussis epidemics followed (figure 2). Confidence was restored after publication of a national reassessment of vaccine efficacy that showed "outstanding value in preventing serious disease". Provision of financial incentives for general practitioners who achieved the target of vaccine coverage contributed to the recovery reaching the vaccine coverage up to 93%. With the regaining of confidence and the vaccine coverage disease incidence declined dramatically, and has since been low (figure 2).

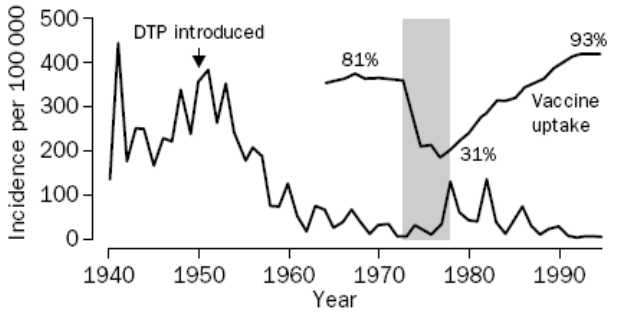

Figure 02. Incidences of pertussis in United Kingdom (Source: The Lancet, 1998)

Australia, had a very good controlled over pertussis during the 1970s, with an incidence rate as low as one per 100 000 in the latter part of the 1970s (figure 3). However, confidence in the vaccine waned when news was received from the UK about alleged neurological reactions associated with the vaccine. In a postal survey from the early 1990s, McIntryre and Nolan found that up to 58% of randomly selected vaccine providers would give DT when DTP was indicated. In 1993, Lester and Nolan warned that "geographically clustered populations of children who have inadequate pertussis protection could promote epidemic outbreaks". A large outbreak with more than 5000 cases occurred in 1994 (figure 3).

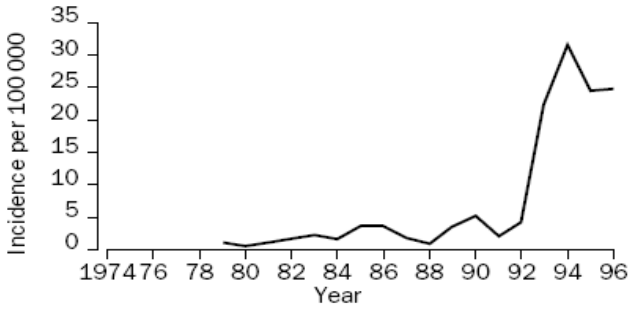

Figure 03. Incidences of pertussis in Australia.(Source: The Lancet, 1998)

These facts show the importance of vaccines against pertussis which can be extrapolated to other vaccine preventable diseases also.

Importantly, anti-vaccine advocates do not mention minimize or deny the consequences of compromised immunization programmes. Cases among children deprived of vaccine may have exceeded hundreds of thousands and disease related clinical complications (eg, pneumonia, encephalopathy, and seizures) may have numbered tens of thousands.

Severe side-effects of whole-cell pertussis vaccines are so rare that they defy measurement. The American Academy of Paediatrics, the USA's National Vaccine Advisory Committee and the Advisory Committee on Immunization Practices concur that whole-cell pertussis vaccine is not a proven cause of brain damage, sudden infant death syndrome (SIDS), infantile spasms or Reye's syndrome. Anaphylactic reactions to DTP components are exceedingly rare.

Mild local and systemic reactions (fever, fussiness, drowsiness, and brief loss of appetite) are fairly common with the vaccine, whereas moderate reactions (long periods of crying, sometimes at an unusually high pitch, limpness, and pallor) are also rare.

Since acellular vaccines cause fewer side-effects, some developed countries (eg, the USA) plan to switch to such vaccines. The choice between whole-cell and acellular pertussis vaccines involves trade-offs between safety, efficacy, practicality and cost. In addition to fewer mild or moderate reactions, acellular vaccine could interrupt disease transmission by means of its potential use in adolescents and adults. However, the best acellular vaccines may not provide protection equal to that of the best whole-cell vaccines. Replacement of whole-cell pertussis vaccines with acellular vaccines might conceivably lead to less effective control at substantially higher costs. Despite the advantages of acellular vaccines, lower costs and better protection are compelling reasons for use of whole-cell pertussis vaccines to continue in many countries, particularly those with limited resources. **Physicians who choose acellular vaccine for their clients have a special responsibility to strengthen their surveillance to monitor disease impact, costs, and rare adverse events information that will guide others in the future.**

Therefore, it is evident that we need to carry forward the immunization programme to control vaccine preventable diseases. At the same time necessary steps should be taken to reduce the incidences of AEFI and provide adequate care for those who get AEFI because it is not completely avoidable. It is also fruitful to develop a mechanism to counteract the fear of AEFI.

Reference: Gangarosa E J etal. Impact of anti-vaccine movements on pertussis control: the untold story. The Lancet, 1998, 351, 356-361.

Table 1: Vaccine-preventable Diseases & AFP

23rd – 29th January - 2010(04th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	01	00	00	00	00	00	00	00	00	01	02	04	05	- 20 .0 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	-
Measles	00	01	00	00	01	00	00	00	00	02	02	18	12	+50.0 %
Tetanus	00	00	00	00	00	00	00	00	00	00	00	03	04	- 25.0 %
Whooping Cough	00	00	00	00	00	00	00	00	00	00	01	01	09	- 88.9 %
Tuberculosis	05	11	03	12	02	03	00	05	26	67	153	698	630	+10.8 %

Table 2: Newly Introduced Notifiable Disease

23rd – 29th January - 2010(04th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	06	03	04	01	01	07	02	02	04	32	170	222	490	- 54.7 %
Meningitis	01 KT=1	00	00	00	00	02 KR=1 PU=1	01 PO=1	00	05 KG=2 RP=3	09	16	172	79	+117.7 %
Mumps	00	00	02	00	01	01	00	00	00	04	30	62	159	- 61.0 %
Leishmaniasis	00	00	02 MT=2	00	00	00	05 AP=5	00	00	07	06	24	28	- 14.3 %

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.

DPDHS 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, Whooping Cough, Chickenpox, Meningitis, Mumps.

Special Surveillance: Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008.

Table 4: Selected notifiable diseases reported by Medical Officers of Health

23rd – 29th January - 2010(04th Week)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	97	552	1	17	0	0	0	7	0	5	3	36	0	1	4	6	0	0	**69**
Gampaha	71	547	0	3	0	1	0	2	0	0	2	11	0	0	0	9	1	1	**60**
Kalutara	24	111	5	16	0	2	1	3	0	6	3	19	0	0	4	5	0	0	**92**
Kandy	25	200	3	43	0	0	0	2	0	0	0	9	3	19	1	9	0	1	**87**
Matale	5	65	0	10	0	0	0	1	0	0	1	12	0	0	0	6	0	0	**42**
Nuwara	3	27	0	9	0	0	0	17	0	0	0	3	0	8	0	3	0	0	**85**
Galle	2	31	0	11	0	1	0	0	0	0	0	1	1	1	0	1	0	1	**68**
Hambant	9	41	1	4	1	1	0	0	0	0	0	9	2	17	0	0	0	0	**82**
Matara	4	36	3	13	0	0	0	0	0	32	2	10	4	23	1	5	0	0	**94**
Jaffna	47	654	0	13	0	0	10	83	0	3	0	0	8	46	1	7	0	0	**50**
Kili-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Mannar	0	25	0	8	0	0	0	7	0	0	0	0	0	0	0	3	0	0	**60**
Vavuniya	2	313	0	5	0	1	0	10	0	0	0	0	0	0	0	3	0	0	**50**
Mullaitivu	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Batticaloa	50	259	0	9	0	0	1	4	0	2	0	0	0	1	0	0	0	0	**62**
Ampara	0	6	2	10	0	0	0	2	0	2	1	10	0	0	1	4	0	0	**71**
Trincomal	25	211	6	20	0	0	2	2	0	1	0	6	0	2	0	4	0	0	**60**
Kurunega	23	183	1	28	0	2	0	5	0	0	0	9	2	5	0	6	0	0	**65**
Puttalam	11	173	0	16	0	1	0	7	0	0	1	6	0	0	0	0	0	0	**67**
Anuradha	36	237	0	11	0	0	0	2	0	0	0	3	0	3	1	5	0	1	**53**
Polonnar	10	32	0	11	0	0	0	0	0	0	3	16	0	0	0	5	0	0	**71**
Badulla	4	61	3	14	0	0	0	5	0	6	0	7	0	3	1	6	0	0	**67**
Monaraga	5	40	2	29	0	0	0	5	0	0	0	6	0	2	0	0	0	0	**64**
Ratnapur	15	74	0	26	0	2	0	3	0	6	3	31	0	8	4	20	0	1	**67**
Kegalle	16	67	2	5	0	3	0	3	2	2	0	16	1	2	1	11	0	0	**55**
Kalmunai	14	136	0	15	0	1	0	1	0	0	0	0	0	0	0	1	0	0	**23**
SRI LANKA	**488**	**4081**	**29**	**346**	**01**	**13**	**14**	**171**	**02**	**65**	**19**	**220**	**21**	**141**	**19**	**119**	**01**	**05**	**64**

Source: Weekly Returns of Communicable Diseases WRCD).
*Dengue Fever / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.
**Timely refers to returns received on or before 29th January, 2010 Total number of reporting units =311. Number of reporting units data provided for the current week: 205
A = Cases reported during the current week. B = Cumulative cases for the year.

PRINTING OF THIS PUBLICATION IS FUNDED BY THE UNITED NATIONS CHILDREN'S FUND (UNICEF).

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