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BCG immunization and scar formation

Tuberculosis (TB) has been declared a global emergency by the World Health Organization (WHO) and *Mycobacterium tuberculosis* is now considered to be responsible for more adult deaths than any other pathogen. It is expected to cause 30 million deaths in the coming decade.

Control of this disease relies upon prevention through Bacillus Calmette-Guérin (BCG) vaccination or "preventive therapy", and the ascertainment and treatment of cases.

Although investigations pertaining to TB vaccines are resurging, immunization against TB is limited to the bacillus Calmette-Guérin (BCG) vaccine. The WHO recommends a single BCG vaccine at birth in countries with a high prevalence of active TB disease. Though BCG vaccines are among the most widely used vaccines in the world, policies for their use differ between countries, and there is a history of controversy concerning their efficacy and impact.

There is an increased concern among parents and some treating practitioners regarding the absence of BCG scar following BCG inoculation and management of such children.

A correct intradermal injection of a potent vaccines rise to a local superficial ulcer after about 6 weeks and after heeling it leaves a permanent round scar, typically 2-8 mm in diameter. According to the findings of the EPI survey 2006 in the Colombo Municipality area and OPV Coverage Assessment survey in Badulla, 2006 showed that the majority of children [90%] developed scar after BCG vaccination. In other words BCG scar failure rate is around 10%. A similar pattern has been observed in other studies conducted in other countries as well. A failure rate of 10% is equal to success rate of 90%, which is quite respectable and acceptable. These rates indirectly tell us that the potency and inoculation technique of BCG vaccine in our national EPI programme is satisfactory. Still the absence of a scar at the site of vaccination in the remaining 10% children is a cause for concern.

The presence or absence of a BCG scar is often used as an indicator of previous vaccination in clinical settings as well as surveys performed by health institutions such as the Expanded Program on Immunization to assess vaccine uptake. However, the sensitivity of the BCG scar as an index of vaccination status is still a subject of controversy. Failure to form a scar may be related to factors such as lack of maturation of the immune system, faulty technique, or use of a nonpotent vaccine.

The probability that BCG vaccination leaves a lasting scar is lower after vaccination in early infancy than at older ages. This is due in part to the low doses of vaccine recommended in infancy, but may be influenced by the difficulty of injecting the full amount into infants, and by relatively weak local immunological response in the very young. Conversely, the comparatively higher incidence of scar formation in children vaccinated at a later age may be due to higher post vaccination allergy. Keloid formation on the scar site appears to be more common in

Contents **Page**

1. *Leading Article - BCG immunization and scar formation* 1
2. *Surveillance of vaccine preventable diseases & AFP (28th July– 3rd August 2007)* 3
3. *Summary of diseases under special surveillance (28th July– 3rd August 2007)* 3
4. *Summary of newly introduced notifiable diseases (28th July– 3rd August 2007)* 3
5. *Laboratory surveillance of dengue fever (28th July– 3rd August 2007)* 3
6. *Summary of selected notifiable diseases reported (28th July– 3rd August 2007)* 4

There is increasing evidence that several genes which control cellular immune mechanisms influence susceptibility to tuberculosis and other mycobacterial infections, and thus it has been conjectured that population genetic differences might explain the behavior of BCG.

By considering the above facts it is clear that merely the absence of the BCG scar does not mean the child is not benefited from previous vaccination. There are two possibilities, namely no immune response or no scar formation inspite of immune response. Our National EPI programme addresses this issue as follows.

According to the national EPI programme, all children under 5 years of age without a visible BCG scar after 6 months of vaccination are revaccinated. It is not mandatory to do mantoux test before reinoculation of BCG in preschoolers with a history of BCG inoculation, but no scar. There would be no harm in giving them BCG again and you would see "take" in some, accelerated response in others and no response in a few. Scientifically speaking, it would be ideal to test them with mantox test and to classify them as those with nonresponce [meaning no prior immune response], with positive response but induration of 5-10mm [most propably immune response due to earlier BCG] or induration of 15mm or more [most probably infected with myco-acterium tuberculosis].

According to the available evidence ,our current BCG policy is more rational, appropriate and feasible to address the issue of absence of BCG scar following BCG inoculation.

Health workers who are involved in the EPI programe has to take optimum measures to ensure the potency of the vaccine and the correct intradermel technique of administration.

Source:

Issues relating to the use of BCG in immunization programmes - WHO Geneva 1999.

The editor wishes to acknowledge Dr Manori Mallawarachchi for the assistance in the preparation of this article.

Bacillus Calmette-Guérin (BCG) vaccine

BCG is generally considered to be a tuberculosis vaccine, and its policies have historically been determined with tuberculosis control in mind. However, it has been known since the 1970s that BCG vaccines are also effective against other mycobacterial diseases, in particular leprosy. Although the WHO has noted that the widespread application of BCG is likely to have been a factor in the decline of leprosy incidence observed in certain populations, it has not recommended repeated doses of BCG to this end.

Aside from small quantities of liquid BCG produced for local use, all of today's BCG vaccines are provided in freeze-dried form. The freeze-drying process, in addition to the particular culture methods employed by different manufacturers, leads to considerable differences in the numbers and proportions of viable and dead organisms per dose of vaccine. It is recognized that this has implications both for reactogenicity (measured in terms of the size of the local lesion) and the induction of delayed type hypersensitivity. Each is correlated with the number of viable organisms in the vaccine dose; but the relationship differs between vaccine strains, reflecting different qualitative as well as quantitative reactogenicities. The association.is complicated further by a synergistic effect, attributable to the presence of non-viable organisms.

WHO guidelines for BCG use within the EPI, which mentions only "symptomatic HIV infection (i.e.AIDS)" as a contraindication for BCG. Importantly, HIV positivity in the absence of clinical signs of impaired immunity is not considered a contraindication by the EPI.

The (clinical) efficacy of a vaccine is measured in terms of the percentage reduction in disease among vaccinated individuals that is attributable to vaccination. BCG vaccines are generally given to protect against tuberculosis. Though the WHO now emphasizes BCG's utility in prevention of severe childhood disease (e.g. tuberculous meningitis), the main public health burden of tuberculosis is associated with adult pulmonary disease. It is therefore important to consider BCG vaccine efficacy against childhood tuberculosis, separately from that against adult tuberculosis.

There is evidence that BCG provides consistent and appreciable protection against tuberculous meningitis and miliary disease. A meta-analysis of five randomized controlled trials and eight case control studies indicated no significant heterogeneity, and an average protection on the order of 80% (86%, with 95% CI: 65% to 95% for controlled trials and 75%, with 95% CI: 61% to 84% for case control studies). This was confirmed by a meta-analysis of protection associated with vaccination in infancy.

Adult pulmonary tuberculosis has attracted most attention, as it is responsible for the major public health burden of tuberculosis, but it is also associated with the greatest controversy relating to BCG. A wide range of efficacy estimates (0 to approximately 80%) have been provided, both by trials and observational case control and contact studies

In addition to the continued uncertainty over BCG efficacy, there is uncertainty about the duration of protection. A recent analysis was unable to identify convincing evidence of a consistent pattern of protection over time, or for any evidence of protection against pulmonary disease lasting more than 15 years. It is important to note that this absence of evidence for protection after 15 years does not mean absence of effect, as there are in fact very few relevant data on this issue.

Table 1: Vaccine-preventable Diseases & AFP

28th July - 3rd August 2007 (31st Week)

Disease	No. of Cases by Province								Number of cases during current week in 2007	Number of cases during same week in 2006	Total number of cases to date in 2007	Total number of cases to date in 2006	Difference between the number of cases to date between 2007 & 2006
	W	C	S	NE	NW	NC	U	Sab					
Acute Flaccid Paralysis	00	00	00	00	01 PU=1	00	00	00	01	00	57	75	-24.0%
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00.0%
Measles	00	01 ML=1	01 HB=1	02 TR=2	00	00	00	00	04	01	48	24	+100.0%
Tetanus	00	00	00	00	00	00	00	00	00	00	21	31	-32.1%
Whooping Cough	01 CO=1	00	00	00	00	00	00	01 RP=1	02	00	27	60	-55.0%
Tuberculosis	130	02	18	23	01	04	00	18	203	301	6124	6322	-3.1%

Table 2: Diseases under Special Surveillance

28th July - 3rd August 2007 (31st Week)

Disease	No. of Cases by Province								Number of cases during current week in 2007	Number of cases during same week in 2006	Total number of cases to date in 2007	Total number of cases to date in 2006	Difference between the number of cases to date between 2007 & 2006
	W	C	S	NE	NW	NC	U	Sab					
DF/DHF*	31	12	06	01	20	05	03	19	97	180	3049	5890	-48.2%
Encephalitis	00	00	00	00	00	00	00	00	00	00	132	84	+57.i%
Human Rabies	00	00	00	00	01 KR=1	00	00	00	01	01	29	27	+7.4%

Table 3: Newly Introduced Notifiable Diseases

28th July - 3rd August 2007 (31st Week)

Disease	No. of Cases by Province								Number of cases during current week in 2007	Total number of cases to date in 2007
	W	C	S	NE	NW	NC	U	Sab		
Chickenpox	12	07	07	01	08	01	03	10	49	2138
Meningitis	03 CB=1 GM=1 KL=1	00	04 GL=4	00	00	01 PO=1	02 BD=1 MO=1	00	10	257
Mumps	10	04	03	01	06	05	02	02	77	1002

*DF / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.
NA= Not Available.

Sources:
Weekly Return of Communicable Diseases:
Diphtheria, Measles, Tetanus, Whooping Cough, Human Rabies, Dengue Haemorrhagic Fever, Japanese Encephalitis, Chickenpox, Meningitis, Mumps.
Special Surveillance:
Acute Flaccid Paralysis.
National Control Program for Tuberculosis and Chest Diseases:
Tuberculosis.
Details by districts are given in Table 5.

Provinces: W=Western, C=Central, S=Southern, NE=North & 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.

Table 4: Laboratory Surveillance of Dengue Fever

28th July - 3rd August 2007 (31st Week)

Samples	Number tested	Number positive *	Serotypes				
			D_1	D_2	D_3	D_4	Negative
Number for current week	09	02	00	02	00	00	00
Total number to date in 2007	368	35	01	18	09	00	06

Source: Genetech Molecular Diagnostics & School of Gene Technology, Colombo. * Not all positives are subjected to serotyping.

Table 5: Selected notifiable diseases reported by Medical Officers of Health
28th July - 3rd August 2007 (31st Week)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptos-pirosis		Typhus Fever		Viral Hepatitis		Returns Re-ceived Timely**
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	23	813	05	248	00	07	01	42	00	51	00	78	00	02	07	91	**92**
Gampaha	04	329	07	252	00	18	00	46	00	35	00	149	02	13	04	91	**79**
Kalutara	04	203	06	334	00	02	00	35	03	25	04	76	00	01	00	43	**100**
Kandy	08	273	04	185	00	03	01	42	00	07	02	51	00	49	55	1622	**91**
Matale	03	69	03	130	00	06	01	13	00	11	01	35	00	05	04	96	**75**
Nuwara Eliya	01	31	01	183	00	02	02	92	00	366	00	08	01	29	19	377	**100**
Galle	02	59	02	102	00	09	01	13	03	36	00	34	02	21	00	14	**94**
Hambantota	01	35	07	85	00	05	01	19	00	17	00	33	00	34	00	13	**100**
Matara	03	101	07	209	00	08	00	25	01	13	00	116	01	139	00	24	**94**
Jaffna	00	28	00	95	00	02	00	322	00	05	00	00	00	81	00	16	**00**
Kilinochchi	00	01	00	00	00	00	00	04	00	00	00	00	00	02	00	02	**25**
Mannar	00	07	00	14	00	00	01	58	00	00	00	01	00	00	00	07	**50**
Vavuniya	00	12	00	33	00	04	00	11	00	40	00	02	00	00	00	06	**100**
Mullaitivu	00	03	00	15	00	08	00	16	00	01	00	00	00	00	00	04	**60**
Batticaloa	00	67	06	425	00	08	00	14	00	10	00	00	00	22	15	667	**55**
Ampara	00	03	00	67	00	00	00	03	00	00	00	00	00	00	01	18	**14**
Trincomalee	01	52	07	173	00	03	01	20	00	23	00	07	00	10	04	91	**89**
Kurunegala	18	335	03	294	00	03	02	50	00	19	00	20	00	32	05	44	**83**
Puttalam	02	84	02	85	00	10	01	56	00	03	01	16	00	04	01	64	**100**
Anuradhapura	05	119	04	67	00	08	00	17	00	14	00	18	00	18	01	34	**79**
Polonnaruwa	00	43	00	59	00	02	01	09	00	04	00	19	00	00	02	21	**100**
Badulla	01	28	03	397	00	02	03	68	00	08	00	34	00	104	12	206	**80**
Monaragala	02	18	05	243	00	02	01	39	00	10	00	37	01	45	02	27	**100**
Ratnapura	14	188	12	390	00	12	00	45	07	15	01	28	02	18	04	67	**81**
Kegalle	05	148	02	188	01	07	02	36	00	04	01	70	02	19	06	125	**91**
Kalmunai	0	03	04	114	00	01	01	08	00	04	00	00	00	02	00	92	**77**
SRI LANKA	**97**	**3049**	**90**	**4387**	**00**	**132**	**20**	**1103**	**14**	**721**	**10**	**842**	**11**	**650**	**142**	**3862**	**85**

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 11 August 2007. Total number of reporting units =290. Number of reporting units data provided for the current week: 237
A = Cases reported during the current week. **B** = Cumulative cases for the year.

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