This is the first in a series of two articles on Adverse Events Following Immunization (AEFI). This article is on the types of AEFI and the next article will focus on prevention of AEFI.

Background

Vaccines used in national immunization programmes are extremely safe and effective. But, no vaccine is perfectly safe and adverse events can occur following immunization. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events. Surveillance of AEFIs is an effective means of monitoring immunization safety and contributes to the credibility of the immunization programme. It allows for proper management of AEFIs and avoids inappropriate responses to reports of AEFIs that can create a sense of crisis in the absence of immunization safety surveillance.

Irrespective of the cause, when AEFI occur, confusion is created among people to the extent that they may refuse further immunizations for their children leaving them susceptible to vaccine preventable diseases which are more disabling and life threatening. Therefore, surveillance of AEFI provides information to help plan on regaining public confidence on immunization. Timely response to public concerns about safety of vaccines as well as prompt communication will protect the public and preserve the integrity of the immunization programme as well.

Adverse Events Following Immunization

The goal of immunization is to protect the individual and the public from vaccine preventable diseases. Although modern vaccines are safe, no vaccine is entirely without risk. Some people experience adverse events following immunization (AEFI) ranging from mild side effects to life-threatening but rare, illnesses. In the majority of cases these events are mere coincidences. In others, they are caused by the vaccine or due an error in the administration of vaccine or sometimes, there is no causal relationship at all.

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunization process or coincidental events that are not due to the vaccine or immunization process, but are associated with immunization by chance. Earlier AEFIs were classified into five categories. In 2012, Council for International Organizations of Medical Sciences (CIOMS) / WHO revised this classification concerning particularly cause-specific categorization of AEFIs and a new categorization has been introduced. (Table 1)

Vaccine Reaction

A vaccine reaction is an individual’s response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. The new cause-specific categorization is important for decision making on a vaccine product, as it clearly differentiates the two types of possible vaccine reactions.

(i) Vaccine product related reaction; a vaccine reaction is an individual’s response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly and

(ii) Vaccine quality defect-related reaction; which is important to note that vaccine quality defect during manufacturing process has an impact on individuals response and there by increased risk of adverse vaccine reactions. (Details are available on the "Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance, 2012).
Common, minor vaccine reactions

The purpose of a vaccine is to induce immunity by causing the recipient’s immune system to react to the vaccine. A quality and safe vaccine reduces these reactions to a minimum while producing the best possible immunity. The proportion of reaction occurrences likely to be expected and observed with the most commonly used vaccines. (Refer Table 2) In addition, some of the vaccine components, excipients (e.g. aluminium adjuvant, stabilizers or preservatives) can also lead to the vaccine reactions.

Fever can result as part of the immune response. Fever shall be anticipated in nearly 10% of vaccinees, except with DPT which produces fever in nearly 50% of those vaccinated. Fever is a systemic reaction that usually occur within 24-48 hours of immunization except for those produced by measles, mumps and rubella vaccines which may occurs 6 to 12 days after immunization. However, it continues only for 24 – 48 hours.

Local reactions include pain, swelling and/or redness at the injection site and can be expected in about 10% of vaccinees. BCG causes a specific local reaction which starts as a papule (lump) 2-4 weeks after immunization and may get ulcerated and healed after several months, leaving a scar. Keloid (thickened scar tissue) from the BCG after immunization may get ulcerated and healed after several months, leaving a scar. Keloid (thickened scar tissue) from the BCG may occur within 24-48 hours of immunization except with DPT which produces fever in nearly 50% of those vaccinated. Fever is a systemic reaction that usually occurs within 24-48 hours of immunization except for those produced by measles, mumps and rubella vaccines which may occur 6 to 12 days after immunization. However, it continues only for 24 – 48 hours.

Table 1: Cause-specific categorization of adverse events following immunization (CIOMS/WHO, 2012)

<table>
<thead>
<tr>
<th>Cause specific Type of AEFI</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine product-related reaction</td>
<td>An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.</td>
</tr>
<tr>
<td>Vaccine quality defect-related reaction</td>
<td>An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer.</td>
</tr>
<tr>
<td>Immunization error-related reaction</td>
<td>An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.</td>
</tr>
<tr>
<td>Coincidental event</td>
<td>An AEFI caused by something other than the vaccine product, immunization error or immunization anxiety</td>
</tr>
<tr>
<td>Immunization anxiety-related reaction</td>
<td>An AEFI arising from anxiety about the immunization.</td>
</tr>
</tbody>
</table>

Note: “Immunization” as used in these definitions means the usage of a vaccine for the purpose of immunizing individuals. “Usage” includes all processes that occur after a vaccine product has left the manufacturing/packaging site, i.e. handling, prescribing and administration of the vaccine

Table 2: Frequency of common minor adverse reaction

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Local Effects(pain, swelling, redness)</th>
<th>Fever (&gt; 38°C)</th>
<th>Irritability, malaise and systemic symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Common 90%-95%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Hepatitis B | Adults up to 30%  
Children up to 5% | 1 – 6% |                                          |
| Hib     | 5%-15%  
5%-10%                         |                |                                          |
| Pertussis (DTP–whole cell) | up to 50%  
up to 50% | up to 55%  
up to 55% |                                          |
| Measles/MMR | ~ 10%  
5%-15% | 5% (Rash) |                                          |
| Tetanus/DT/aTd* | ~10%  
~10% | ~25%  
~25% |                                          |
| OPV     | None  
None | Less than 1%  
Less than 1% |                                          |

*Rate of local reactions is likely to increase with booster doses, up to 50 -85%.

Systemic reactions: Common systemic reactions are irritability, malaise and loss of appetite. These systemic reactions are relatively common following DPwT vaccination. For measles/MMR and OPV vaccines, systemic reactions arise from vaccine virus infection. Measles vaccine may cause fever, rash, and/or conjunctivitis. It is very mild compared to “wild” measles virus, but for severely immunocompromised individuals, it can be severe, and may be even fatal. Vaccine reactions for Mumps (parotitis ; swollen parotid gland) and Rubella (joint pains and swollen cervical lymph nodes) minimally affect the vaccinnees.

Rare serious vaccine reactions

It is important to note that there is a difference between the terms "serious" and "severe" adverse events or reactions."Serious" and ‘severe’ are often used as interch–angeable terms but they are not. A serious adverse event or reaction is a regulatory term. "Severe" is used to describe the intensity of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance. (e.g Fever is a common relatively minor medical event, but according to its severity it can be graded as mild fever or moderate fever. Anaphylaxis is always serious event and life threatening.)

As defined by the Uppsala Monitoring Centre (UMC), a serious adverse event or reaction is any untoward medical occurrence following any dose of vaccine that

- Results in death
- Requires hospitalization or prolongation of hospital stay
- Results in persistent or significant disability/ incapacity is life-threatening

Most of the rare and more serious vaccine reactions (e.g. seizures, thrombocytopenia, hypotonic hypersensitive episodes, persistent inconsolable screaming) do not lead to long term problems. Anaphylaxis, while potentially fatal, is treatable without having any long term effects. Although encephalopathy is included as a rare reaction to measles or DPT vaccine, it is not certain whether these vaccines infect cause encephalopathy

Source
### Table 1: Vaccine-preventable Diseases & AFP

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. of Cases by Province</th>
<th>Number of cases during current week in 2012</th>
<th>Number of cases during same week in 2011</th>
<th>Total number of cases to date in 2012</th>
<th>Total number of cases to date in 2011</th>
<th>Difference between the number of cases to date in 2012 &amp; 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Flaccid Paralysis</td>
<td>W: 01  C: 00  S: 00  N: 00  E: 00  NW: 00  NC: 00  U: 01  Sab: 01</td>
<td>02</td>
<td>00</td>
<td>67</td>
<td>75</td>
<td>- 10.7 %</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>W: 00  C: 00  S: 00  N: 00  E: 00  NW: 00  NC: 00  U: 00  Sab: 00</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Measles</td>
<td>W: 00  C: 02  S: 00  N: 00  E: 00  NW: 00  NC: 00  U: 04  Sab: 01</td>
<td>04</td>
<td>01</td>
<td>57</td>
<td>114</td>
<td>- 50.0 %</td>
</tr>
<tr>
<td>Tetanus</td>
<td>W: 00  C: 00  S: 00  N: 00  E: 00  NW: 00  NC: 00  U: 00  Sab: 00</td>
<td>00</td>
<td>00</td>
<td>11</td>
<td>24</td>
<td>- 54.2 %</td>
</tr>
<tr>
<td>Whooping Cough</td>
<td>W: 00  C: 00  S: 00  N: 00  E: 00  NW: 00  NC: 00  U: 00  Sab: 00</td>
<td>00</td>
<td>00</td>
<td>89</td>
<td>48</td>
<td>+ 85.4 %</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>W: 17  C: 25  S: 07  N: 16  E: 08  NW: 05  NC: 09  U: 01  Sab: 08</td>
<td>249</td>
<td>268</td>
<td>7399</td>
<td>7795</td>
<td>- 05.1 %</td>
</tr>
</tbody>
</table>

#### Key to Table 1 & 2

**Provinces:**
- W: Western
- C: Central
- S: Southern
- N: North
- E: East
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- 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
- PU: Puttalam
- AP: Anuradhapura
- PO: Polonnaruwa
- BD: Badulla
- MO: Moneragala
- RP: Ratnapura
- KG: Kegalle

**Data Sources:**
- Special Surveillance: Acute Flaccid Paralysis.

### Table 2: Newly Introduced Notifiable Disease

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. of Cases by Province</th>
<th>Number of cases during current week in 2012</th>
<th>Number of cases during same week in 2011</th>
<th>Total number of cases to date in 2012</th>
<th>Total number of cases to date in 2011</th>
<th>Difference between the number of cases to date in 2012 &amp; 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chickenpox</td>
<td>W: 07  C: 07  S: 29  N: 00  E: 01  NW: 04  NC: 08  U: 02  Sab: 06</td>
<td>64</td>
<td>75</td>
<td>3811</td>
<td>3628</td>
<td>+ 05.0 %</td>
</tr>
<tr>
<td>Meningitis</td>
<td>W: 07  C: 03  S: 00  N: 00  E: 01  NW: 00  NC: 00  U: 01  Sab: 00</td>
<td>12</td>
<td>08</td>
<td>698</td>
<td>734</td>
<td>- 04.9 %</td>
</tr>
<tr>
<td>Mumps</td>
<td>W: 06  C: 06  S: 02  N: 04  E: 02  NW: 01  NC: 00  U: 00  Sab: 00</td>
<td>27</td>
<td>76</td>
<td>3941</td>
<td>2719</td>
<td>+ 44.9 %</td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>W: 00  C: 04  S: 00  N: 00  E: 00  NW: 04  NC: 00  U: 09  Sab: 00</td>
<td>09</td>
<td>14</td>
<td>949</td>
<td>689</td>
<td>+ 37.7 %</td>
</tr>
</tbody>
</table>

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**Data Sources:**
- Special Surveillance: Acute Flaccid Paralysis.

### Dengue Prevention and Control Health Messages

You have a duty and a responsibility in preventing dengue fever. Make sure that your environment is free from water collections where the dengue mosquito could breed.
Table 4: Selected notifiable diseases reported by Medical Officers of Health

<table>
<thead>
<tr>
<th>Division</th>
<th>Dengue Fever / DHF</th>
<th>Dysentery</th>
<th>Encephalitis</th>
<th>Enteric Fever</th>
<th>Food Poisoning</th>
<th>Leptospirosis</th>
<th>Typhus Fever</th>
<th>Viral Hepatitis</th>
<th>Human Rabies</th>
<th>Returns Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colombo</td>
<td>55 8351 2 133 0 8 2 196 0 46 1 174 1 6 2 105 0 5</td>
<td>31</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gampaha</td>
<td>139 6719 2 76 0 15 0 56 1 42 11 237 0 21 8 287 0 0</td>
<td>80</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kalutara</td>
<td>8 2375 0 94 0 4 1 45 0 28 0 232 0 4 0 32 0 2</td>
<td>54</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kandy</td>
<td>36 2136 3 110 0 2 1 23 0 56 2 66 0 106 4 101 0 0</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matale</td>
<td>2 473 1 81 0 5 0 12 2 34 1 40 0 3 0 33 0 0</td>
<td>67</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuwara</td>
<td>2 298 1 166 0 3 0 26 0 8 0 32 0 60 0 18 0 1</td>
<td>54</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Galle</td>
<td>9 1370 1 115 0 6 0 15 0 17 0 110 0 64 0 3 0 0</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Hambantota</td>
<td>6 513 2 41 0 3 0 7 0 30 0 67 0 52 0 21 0 0</td>
<td>67</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Matara</td>
<td>56 1577 3 78 0 8 0 19 0 28 2 163 3 73 1 126 0 0</td>
<td>100</td>
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</tr>
<tr>
<td>Jaffna</td>
<td>17 486 7 181 0 14 1 319 0 82 0 2 0 257 0 18 0 1</td>
<td>42</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kilinochchi</td>
<td>0 78 1 28 0 2 0 32 0 43 0 4 0 30 0 4 0 1</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mannar</td>
<td>1 128 0 69 0 4 4 46 0 17 0 23 0 42 0 2 0 0</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vavuniya</td>
<td>3 84 3 38 0 21 0 12 0 20 0 18 0 3 0 1 0 0</td>
<td>75</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mullaitivu</td>
<td>0 22 1 21 0 1 0 12 0 3 0 3 0 5 0 1 0 0</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batticaloa</td>
<td>4 631 4 238 0 3 0 16 0 307 0 8 0 0 0 8 0 4</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampara</td>
<td>0 130 0 80 0 3 0 6 0 12 0 27 0 0 0 3 0 0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trincomalee</td>
<td>1 135 5 186 0 2 0 16 0 13 1 38 0 18 0 4 0 0</td>
<td>75</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kurunegala</td>
<td>37 2422 4 182 0 16 1 90 0 38 2 135 0 31 0 128 0 4</td>
<td>73</td>
<td></td>
<td></td>
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<tr>
<td>Puttalam</td>
<td>36 1282 1 88 0 8 0 12 2 12 1 39 0 16 0 6 0 2</td>
<td>58</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Anuradhapu</td>
<td>4 337 3 78 0 7 0 13 0 21 0 78 0 23 0 57 0 1</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polonnaruw</td>
<td>1 221 0 67 0 2 0 4 0 121 0 49 0 3 0 40 0 1</td>
<td>43</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Badulla</td>
<td>3 325 2 110 0 4 0 50 0 3 0 36 1 110 1 43 0 0</td>
<td>71</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Monaragala</td>
<td>4 237 0 58 0 6 0 24 0 7 2 64 0 76 0 169 0 2</td>
<td>36</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ratnapura</td>
<td>12 3474 10 224 0 25 0 48 0 12 2 275 0 39 0 113 0 2</td>
<td>39</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kegalle</td>
<td>33 2384 1 55 0 9 1 25 1 11 2 158 2 61 7 533 0 0</td>
<td>91</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Kalmune</td>
<td>0 187 1 250 0 2 0 7 0 87 0 9 0 1 0 10 0 3</td>
<td>23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

| SRI LANKA | 469 | 36375 | 58 | 2847 | 00 | 183 | 11 | 1131 | 06 | 1098 | 27 | 2087 | 07 | 1104 | 23 | 1866 | 00 | 29 | 59 |

*A Dengue Fever / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.
**Timely refers to returns received on or before 26th October , 2012 Total number of reporting units 329. Number of reporting units data provided for the current week: 267
A = Cases reported during the current week. B = Cumulative cases for the year.

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ON STATE SERVICE

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