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COMMITTEE ON SAFETY OF MEDICINES

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

JOINT SUB-COMMITTEE ON ADVERSE REACTIONS TO VACCINES AND IMMUNOLOGICAL PRODUCTS

Summary of suspected adverse reactions to vaccines report on Yellow Cards registered during the period 19 September 1985 to 10 January 1986

1. Suspected adverse reactions to diphtheria, tetanus and pertussis vaccines (DPT) and to diphtheria, tetanus and pertussis vaccine given with oral poliovaccine (OPV)

Ninety suspected adverse reactions were registered during this period.

Adverse Reaction	Current Period	Previous Period
Deaths	[redacted]	7
Encephalitis	-	-
Convulsions	6	11
Infantile spasms	-	[redacted]
Myoclonus/twitching	-	-
Collapse	-	-
Anaphylactoid reaction	-	-
Fever	18	14
Injection site disorder	37	22
Screaming or abnormal crying	12	12
Screaming and arthralgia	[redacted]	[redacted]
White attacks	[redacted]	-
Cyanosis	[redacted]	[redacted]
Cerebral irritability	[redacted]	-
Rash	[redacted]	-
Angio-oedema and rash	[redacted]	-
Vomiting	[redacted]	-
Other reactions	[redacted]	8
	90	68

(a) Abnormal fever

[redacted] A [redacted] who following a dose of Trivax developed initially a high fever, then screaming, drowsiness, irritability and was off feeds for an extended six day period. No evidence of intercurrent infection was found.

(b) Cot deaths

(i) [redacted] A [redacted] who after a first dose of Trivax AD (Batch Number [redacted] and oral poliovaccine on [redacted] was found dead [redacted] after immunisation. [redacted] was known to be alive [redacted] after vaccination. The results of a post-mortem are awaited.

(ii) [redacted] A [redacted] who received a first dose of Trivax (Batch Number [redacted] and oral poliovaccine on [redacted] and was found dead on [redacted] No initial adverse reaction was noted to the vaccine in particular, there were no screaming attacks nor was there any irritability. Cause of death - Sudden Infant Death Syndrome.

(c) Cerebral irritability

[redacted] An [redacted] after a third dose of DPT vaccine, within two hours developed neck stiffness and crying followed by lethargy and reduced appetite. [redacted] recovered after five days. Three weeks before immunisation [redacted] had an upper respiratory tract infection and still had a slight cough and snuffles at the time of vaccination.

(d) Convulsions

Six patients with convulsions or possible convulsions were reported. Details are given in Table I.

2. Suspected adverse reaction to monovalent pertussis vaccine

[redacted] reports have been received. These comprise:

(i) [redacted] A [redacted] who after a first dose of pertussis vaccine became restless and hyperactive for 12-14 hours.

(ii) [redacted] reports of injection site reactions.

3. Suspected adverse reactions to oral poliovaccine

[redacted] suspected adverse reactions were registered.

(i) [redacted] A [redacted] who after a dose of OPV had an influenza-like illness from which [redacted] recovered in 24 hours followed 10 days later by severe stiffness of the neck lasting two days. There was no photophobia. [redacted] was seen at that time by the general practitioner but he felt that the story suggested possible meningism due to the oral poliovaccine [redacted] had received. The [redacted] had also been immunised against typhoid and cholera at the same time.

(ii) [redacted] A baby who became irritable, off [redacted] food and not [redacted] three days after a third dose of oral poliovaccine. These symptoms persisted for six days.

(iii) [redacted] A child who after a first and second dose of oral poliovaccine became sleepy for three days and had diarrhoea for four-six weeks. The third dose of OPV is to be given separately from the triple vaccine.

4. Suspected adverse reactions to diphtheria/tetanus and diphtheria/tetanus given with OPV

During this period 26 reports were registered. They are analysed in the following table.

Adverse Reaction	Primary Course	Booster	Total
Cot death	-	-	-
Convulsions	[redacted]	[redacted]	[redacted]
Injection site reaction	[redacted]	13	[redacted]
Injection site reaction and fever	-	[redacted]	[redacted]
Fever	-	[redacted]	
Rash	[redacted]	-	[redacted]
Vomiting	[redacted]	-	[redacted]
Irritability and pallor	[redacted]		[redacted]
Other	-	[redacted]	[redacted]
Totals	8	19	27

(a) Convulsions

Details of [redacted] patients who had suspected convulsions are given in Table II.

(b) Other

[redacted] A [redacted] who six to eight hours after a booster dose of diphtheria/tetanus vaccine developed severe vomiting and collapse with abdominal pain.

5. Suspected adverse reactions to tetanus vaccine

Seventy-two suspected adverse reports were registered. These include:

(i) A report of 13 injection site reactions occurring in a school following the use of tetanus vaccine (Batch Number [redacted]). No other adverse reaction reports received by the CSM have been associated with this batch. There was also a report of 29 adverse reactions associated with tetanus vaccine (Batch Number [redacted] and OPV (Batch Number [redacted], in two adjoining schools. Eight amongst 81 children in one school had adverse reactions; six had injection site reactions, one accompanied by fever, one with lymphadenopathy and one child had nausea and dizziness: two had headaches. In the nearby school, 21 of 82 children were suspected of having adverse reactions. Fifteen children had injection site reactions which in four was accompanied by malaise and one by a rash, four had influenza-like illnesses and two had upper respiratory infections.

The CSM had not received any other suspected adverse reactions reports associated with this particular batch.

(ii) [redacted] A [redacted] who on the day following an injection of tetanus toxoid and dose of oral poliovaccine developed diarrhoea with streaks of blood which ended some 11 days later. On the 12th day after immunisation [redacted] developed arthralgia, and flitting joint swelling redness which was treated with cortico-steroids. [redacted] was also receiving Tegretol, Anafranil, Nardil and Temazepam.

6. Suspected adverse reactions to measles vaccines

Eighteen reports were received during this period.

(a) Reports of suspected convulsions are given in Table III.

(b) The more important reports are described below:-

[redacted] A [redacted] who after a dose of Rimevax (Batch Number [redacted], developed urticaria and an erythematous rash which appeared 30 minutes after injection and faded after about two hours with full recovery.

[redacted] A [redacted] who nine days after immunisation with Mevilin developed a widespread macular rash, anorexia and fractiousness which persisted for five days. A day before onset of these symptoms [redacted] was found to have a right otitis media and was given Penbritin syrup 600mg daily for two days.

[redacted] A [redacted] who two minutes after receiving a dose of Rimevax (Batch Number [redacted] developed anaphylaxis from which [redacted] recovered when resuscitation was undertaken. There was a history of allergy to eggs when taken by mouth.

[redacted] A [redacted] who received Rimevax (Batch Number [redacted]) vaccine and on the late evening of the following day [redacted] became grizzely, pyrexial and developed an erythematous rash over the abdomen and back. [redacted] fever continued overnight despite sponging and paracetamol. These clinical features continued through the following day and [redacted] temperature rose to 104°F (40°C) when measured rectally at about 3.00pm; this was accompanied by strange jitters, not like those of pyrexia, but described by a paediatric registrar as ataxic. The temperature came under control later that day. On the following day [redacted] the rash cleared and the involuntary movements had ceased. General examination was normal and the child was well.

7. Suspected adverse reactions to rubella vaccine

[redacted] reports have been received and registered:-

(i) A report of a [redacted] who 10-15 minutes after receiving Cendevax vaccine complained of feeling sick and faint. [redacted] became pale and [redacted] pulse was very feeble. 0.5ml of 1:1,000 adrenaline was given intramuscularly. In view of continued complaints of uneasiness, and faintness [redacted] was admitted to hospital where [redacted] blood pressure was noted to be 90/50. [redacted] was later discharged. [redacted].

(ii) A report of a [redacted] who 10 minutes after receiving a dose of rubella vaccine in the left arm lost consciousness for 20 minutes and on recovery of consciousness had a transient left hemiparesis which lasted half a day. [redacted] had had a previous febrile fit when aged three and an episode of loss of consciousness more briefly after BCG vaccination. [redacted].

8. Suspected adverse reaction to BCG vaccine

[redacted] report has been received of a macular cutaneous rash on both arms.

9. Suspected adverse reactions to influenza vaccines

Fourteen suspected adverse reactions were registered. These comprise:

(i) [redacted] A [redacted] who four days after being immunised against influenza suddenly died in the street. [redacted] was also receiving Warfrain, Neonaclex K, Temazepam and Distalgesic following a mitral valve replacement, mild congestive cardiac failure, insomnia and pain respectively. The patient was apparently perfectly well on the day of immunisation but this vaccination had been postponed two days previously because [redacted] was then recovering from a cold.

(ii) [redacted] A report of a sudden grand mal seizure, nine hours after immunisation against influenza in a [redacted] who had had no seizures in the previous 19 months sine sodium valproate treatment had been commenced.

(iii) A report of a [redacted] who two to three minutes after being immunised against influenza lost consciousness and subsequently had twitching around the mouth. Over the next two hours there was periodic drowsiness and twitching followed by full recovery. The episode was not typical of a vasovasal attack, the patient had tachycardia. There was no history of previous fits, TIA's etc. Quite well before immunisation No history of egg allergy.

(iv) [redacted] A [redacted] who on the same day that [redacted] was vaccinated against influenza had a grand mal fit.

(v) [redacted] A report of a [redacted] who one hour after receiving immunisation against influenza developed an exascerbation of [redacted] mild chronic bronchitis with increasing pyrexia and dyspnoea and then a cough and sputum which developed into a lobar pneumonia.

(vi) [redacted] A report of a [redacted] who after being immunised against influenza collapsed with right sided chest pain. [redacted] pulse was feeble, [redacted] was cold and clammy with a blood pressure of 130/80. [redacted] was admitted to hospital.

(vii) [redacted] reports of influenzal like illness. [redacted] occurred about two hours after immunisation and the [redacted] on the following day.

(viii) [redacted] A report of a [redacted] who four to five hours after immunisation against influenza had a generalised flare-up of osteoarthrosis which ended 72 hours later. [redacted] also had an injection site reaction.

(ix) [redacted] of urticaria and viral upper respitatory infection, (12 days later) and [redacted] reports of injection site reaction.

10. Suspected adverse reactions to monovalent typhoid vaccine

[redacted] reports have been registered.

[redacted] A [redacted] who on the same day after receiving 0.25ml of monovalent typhoid vaccine developed a severe headache, neck pain, pyrexia, lethargy and apparently was not able to walk. [redacted] recovered the following day.

The other report was of an injection site reaction.

11. Suspected adverse reactions to monovalent typhoid and cholera vaccines withoor without the simultaneous administration of OPV

[redacted] reports have been registered. These comprise:

(i) [redacted] One to two hours after receiving subcutaneous doses of typhoid and cholera vaccines developed back and chest pain followed by a syncopal episode and the confusion during recovery. Subsequently [redacted] had a severe local reaction with swelling and redness. The patient has a history of mild allergy but not to these preparations. No adverse reactions were reported in people vaccinated with doses of the same containers of these vaccines.

(ii) [redacted] A [redacted] who four days after a second dose of typhoid and cholera vaccines developed florid erythema multiforme but remained well in [redacted]

(iii) [redacted] A [redacted] who within one hour of receiving a first dose of cholera, typhoid and OPV developed severe muscle pain, occipital headache, bronchospasm and cyanosis. [redacted] recovered after being treated with intravenous hydrocortisone and diazepam.

(iv) [redacted] A [redacted] who, one and a half hours after receiving a dose of typhoid and cholera vaccines had severe rigors lasting about one hour. [redacted] temperature rose to 38°C. [redacted] recovered after 24 hours.

12. Suspected adverse reactions to cholera, typhoid and tetanus vaccines

[redacted] A [redacted] who 20 minutes after receiving cholera, typhoid and tetanus vaccine developed rigors and a temperature (39.5°C) which ended some 12 hours later. Sixty minutes after vaccination [redacted] was found to have a transient but profound neutropenia which ended several hours later.

13. Suspected adverse reactions to cholera vaccine

[redacted] reports have been received of injection site reactions which were followed by severe malaise.

14. Suspected adverse reactions to house dust mite desensitising agents

Nine reports have been received, [redacted] of bronchospasm, [redacted] of urticaria and [redacted] of bronchospasm and urticaria, [redacted] of purpura, [redacted] of injection site reaction and [redacted] of anaphylaxis.

15. Suspected adverse reactions to grass pollen vaccines

Nine reports have been received,

(i) [redacted] A report of a fatal acute anaphylaxis following the last of three injections for hay fever (pollinex) referred to HM Coroner.

(ii) [redacted] A report of possible attack of petit mal following first monthly maintenance dose of alavac-S.

[redacted] episodes occurred in a [redacted] (six and 18 hours after immunisation) of blankness, in which

(a) Spilled a plate of food with no recollection shown of this happening.

(b) Drove [redacted] car up a bank when others in the car said [redacted] appeared not to know what [redacted] was doing.

(iii) [redacted] reports of injection site reactions, [redacted] of bronchospasm, [redacted] of urticaria, [redacted] of palpitations, dizziness and sweating and [redacted] of apnoea, rash, parathesiae and paresis two hours after receiving a ninth injection of an intial course. The last patient recovered afer receiving adrenaline following by Prednisolone.

16. Suspected adverse reaction to tuberculin PPD

A [redacted] three to four hours after an intradermal injection of one in 10,000 tuberculin PPD, developed malaise, anorexia, vomiting and diarrhoea plus fever. [redacted] was admitted to hospital, ill, dehydrated, hypotensive and febrile. [redacted] had a delayed skin reaction which was several centimeters in diameter some 72 hours later, which persisted for several weeks but without necrosis. [redacted] also had reversible renal failure and liver damage. [redacted] recovered after treatment with hydrocortisone and rehydration and was subsequently with RIFINAH. The suspected tuberculous cervical lymphadenopathy was later confirmed positive for tubercle bacculle.

17. Suspected adverse reactions to hepatitis vaccine

Three reports have been received. These comprise:

(i) [redacted] A [redacted] who four to five days after a second dose of H-B-Vax developed the symptoms and signs of a right brachial neuritis (confirmed by neuro-physiological studies) which persisted for four to five weeks. [redacted] had suffered from a similar episode of right sided brachial neuritis in [redacted] for which no cause was found. The reporting physician did not think that the hepatitis B vaccine was a causative factor for the present episode but it may have been a precipitating factor.

(ii) [redacted] reports of injection site reactions.

Table 1 Convulsions or possible convulsions associated with DPT/OPV immunisation

Yellow Card Number	Age in months	Vaccine (Dose No.)	Interval Immunisation/ Convulsion	Associated Pyrexia reported	Additional Information
[redacted]	[redacted]	DPT & OPV (2)	3-4 hours	Yes	Possible convulsion or rigor lasting 2-3 minutes. Admitted to hospital. Full investigation screen including LP negative.
[redacted]	[redacted]	DPT (2)	40 hours	Yes	Fever for 48 hours with convulsion at 40th hour. No fits before or during the subsequent seven months.
[redacted]	[redacted]	DPT (3)	Same day	Yes	Localised induration. Recovered. No evidence of neurological damage
[redacted]	[redacted]	DPT (2)	?	?	Under treatment for "corneal clouding".
[redacted]	[redacted]	DPT + OPV (1)	7 hours	Yes	Fever, convulsions and left hemiplegia occurred approximately 7 hours after immunisation. Much improved following day when large local reaction and rash on chest noted. Discharged next day from hospital
[redacted]	[redacted]	Trivax AD + OPV(3)	Same day	Yes	Admitted to hospital for 72 hours. Recovered.

Table II Convulsions or possible convulsions associated with DT + OPV immunisation

Yellow Card Number	Age	Vaccine (Dose)	Interval Immunisation/ Convulsion	Associated pyrexia	Additional Information
[redacted]	[redacted]		2 days	?	Two fits - admitted to hospital. Known diabetic on Insulin.
[redacted]	[redacted]	DT + OPV (1)	10 days	?	No permanent neurological damage.
	[redacted]	DT + OPV (2)	2 days	?	The possibility of an allergic reaction suggested

Table III Convulsions associated with Measles Immunisation (19.9.85 - 15.1.86.)

Yellow Card Number	Age in Months	Sex	Immunisation/ convulsion interval	Duration	Associated pyrexia reported	Additional Information
[redacted]	[redacted]	[redacted]	7 days	½ minute	Yes	No previous febrile fits. No FH of febrile fits
[redacted]	[redacted]	[redacted]	7 days	2 minutes x 2	Yes	Admitted to hospital. See Appendix.
[redacted]	[redacted]	[redacted]	Within 48 hours	?	No	Admitted to hospital. Discharged on anticonvulants
[redacted]	[redacted]	[redacted]	5½ hours	2 minutes		One febrile convulsion prior to this which was right sided and focal. EEG normal. Since immunisation in May 1984 (without immunoglobulin) has had one further fit. No sequelae (October 1985). Three triple immunisations before first febrile fit.
[redacted]		[redacted]				
[redacted]		[redacted]	10 days	-	Yes	Recovered