Report of Investigating Group appointed by Chief Executive Officer to carry out investigation into the mistake which resulted in 67 infant pupils in St. Conleth's Primary School, Newbridge, Co. Kildare, receiving the 3-1 Immunisation Booster instead of the intended 2-1 Immunisation Booster.

19th November 1996

18th November, 1996

Mr. P. J. Fitzpatrick,
Chief Executive Officer,
Eastern Health Board,
Dr. Steevens' Hospital,
Dublin 8.

Re: Investigation into the administration of '3 in 1' (Diptheria, Tetanus and Pertussis) vaccine at a routine school booster immunisation session in St. Conleth's School Newbridge, Co. Kildare on November 6th, 1996

Dear Mr. Fitzpatrick,

We the members of the investigation group established by you, hereby submit our report on above matter, in the context of the questions put to us in your letter of 11th November, 1996.

Yours sincerely,

Mr. John Kincaid,
Community Care Manager,
Midland Health Board.

Elizabeth Keane.

Dr. Elizabeth Keane,
M.B., B.ch., B.A.O., D.C.H., D.Obs.,
M.P.H., F.F.P.H.M.I.,
Director of Public Health
Southern Health Board.

Investigation into the administration of '3 in 1' (Diptheria, Tetanus and Pertussis) vaccine at a routine school booster immunisation session in St. Conleth's School, Newbridge, Co. Kildare on November 6th, 1996.

1. Establishment of the Investigation Group.

On November 8th, 1996, the Chief Executive Officer of the Eastern Health Board, established a two person group to carry out an investigation into the mistake which resulted in 67* senior infant pupils in St. Conleth's Infant School, Newbridge receiving the '3 in 1' i.e. diptheria, tetanus, pertussis immunisation, as a booster instead of the intended '2 in 1' i.e. diptheria, tetanus immunisation.

The members of the investigation group were :

- Dr. Elizabeth Keane, Director of Public Health, Southern Health Board
- Mr. John Kincaid, Manager, Community Care, Midland Health Board.

The terms of reference for the group set out by the Chief Executive Officer were:-

'To examine and report to the Chief Executive Officer of the Eastern Health Board in relation to :-

{1} All the circumstances leading up to and surrounding the mistake.

{2} The arrangements for storing vaccines.

{3} The system and protocols in place for drawing and checking vaccine for intended use.

{4} The procedures in place for the administration of vaccine in clinics/schools.

{5} Any other matters which the group considers should be included in the report'.

* The initial press statement, issued by the Eastern Health Board, referred to 66 senior infants. This appears to have arisen from the fact that the parent of twin children who were immunised on that day, completed one consent/vaccination record card only.

The Chief Executive Officer requested that the investigation be completed and a written report provided, as soon as possible.

2. Investigation.

(i) General.

The investigating group began its work on Monday, 11th November, 1996. The group met the following senior officials of the Eastern Health Board on that day:-

- Chief Executive Officer
- Acting Programme Manager Community Care
- Director of Public Health

At this meeting, a written statement, which had been submitted by the Area Medial Officer who administered the vaccine on November, 6th, 1996, was given to the investigating group.

The following Eastern Health Board staff were interviewed in the course of the investigations undertaken by the group :

- Acting Director of Community Care & Medical Officer of Health for Kildare Community Care Area;
- the Area Medical Officer who administered the vaccine to the children in St. Conleth's School on the 6th November;
- the Public Health Nurse who assisted the vaccination in St. Conleth's School;
- the Eastern Health Board Administrator who was conversant with arrangements for the supply of vaccines.

The group visited the Community Care headquarters in Naas, Co. Kildare, where the main facilities for the storage of vaccines were inspected. Newbridge Health Centre was also visited and the fridge there, in which vaccines were also stored, was inspected.

The group inspected the consent/vaccination record cards for the 67 children involved.

It also examined one of the ten dose vials which contained the '3 in 1' vaccine, used during the immunisation session on Wednesday, November 6th 1996, together with a selection of ten dose and single dose vials of '2 in 1' and other vaccines.

Each member of staff, who was interviewed or spoke with the group was fully co-operative and frank. The group was facilitated in every way in carrying out its work.

(ii) Operational Procedures and Practice.

On November 11th, 1996, the group met with the Acting Director of Community Care, Kildare, and established from her the current practice in relation to the organisation of the booster immunisation programme for children at school entry stage (5 - 6 years).

National policy and Eastern Health Board practice, is that a booster injection of Diphtheria and Tetanus ('2 in 1') and oral polio is offered, subject to the consent of parent/guardian. It is not national policy or local practice to offer Pertussis immunisation as part of this booster programme.

The National Immunisation Committee is preparing immunisation guidelines for Ireland. Pending the introduction of these guidelines, the current guidelines for good practice, used by those involved in immunisations, are contained in the book 'Immunisation against Infectious Disease', (known as 'the Green Book') produced by Department of Health (U.K.) and published by Her Majesty's Stationary Office, as updated from time to time. These guidelines cover the storage of vaccines and immunisation procedures. Both the Acting Director of Community Care, Kildare and the Area Medical Officer concerned in this investigation, confirmed that they are familiar with these guidelines.

The practice in the Kildare Community Care area for a number of years, is that a booster ('2 in 1') immunisation is delivered to children in Senior Infants classes on school premises. The main features of the delivery of the programme are as follows :-

Printed consent/vaccination record cards are distributed by the Public Health Nurse to the parents/guardians through the Principal of the school. If parents/guardians wish to have their children receive booster immunisation ('2 in 1'), they sign the consent card and return it to the school.

The date for the immunisation session is agreed by Health Board staff with the School Principal.

On the day of the immunisation session, the doctor checks the consent card for each child presenting for immunisation. This consent card contains answers by the parent/guardian in relation to contra-indications, if any.

The nurse assists with the organisation of children and with the preparation of needles and syringes.

The doctor checks the vaccine, draws up correct dose, then gives the injection to the child.

The doctor records the immunisation details on individual vaccination record cards.

The foregoing relates to custom and practice as established by the investigating group. No written protocols were available.

(iii) Storage and transport of vaccines.

Vaccines are stored in a special vaccines fridge in Community Care headquarters, Naas, Co. Kildare.

New stock is ordered by the clerical staff in accordance with national contracts for the purchase of vaccines. Vaccines are transported from this fridge to the site of the vaccine clinic/school in a cool box. On occasion, vaccines are stored in a domestic type fridge in peripheral health centres.

(iv) Events relating to the 6th November, 1996 - St. Conleth's School.

Prior to Wednesday, November 6th, 1996

On October 4th, 1996, the Area Medical Officer and the Public Health Nurse began the organisation of booster immunisation in St. Conleth's School, Newbridge. Consent/immunisation record cards were left to the school by the Public Health Nurse on October 11th, 1996, for circulation to parents. Signed consent forms which were returned, were collected from the school on October 21st and 25th, 1996.

During the interview with the Area Medical Officer, she said that the holding of immunisation sessions in St. Conleth's School on November 6th and 7th, 1996, was decided by her in consultation with the Public Health Nurse on Monday, November 4th, 1996. This decision was conveyed to the Principal of St. Conleth's on November 4th, 1996, by the Public Health Nurse.

On the afternoon of Tuesday November 5th, 1996 the Area Medical Officer went to the vaccine fridge in the Community Care Headquarters in Naas, to collect ten dose vials of '2 in 1' vaccine. She could find no ten dose vials of '2 in 1' vaccine in stock. She then took a supply of single dose '2 in 1' vials in a cool box for use in St. Conleths School, Newbridge, on the following day.

Wednesday, November 6th, 1996 (am)

On her way to St. Conleths on the morning of November 6th, 1996 the Area Medical Officer had reason to call to the local health centre in Newbridge. When there she looked in the fridge for ten dose vials of '2 in 1' vaccine.

In error, the Area Medical Officer took a supply of ten dose vials of '3 in 1' vaccine from the fridge in the Health Centre, Newbridge thinking it to be '2 in 1' vaccine, and brought it to St. Conleth's School.

This '3 in 1' contained whole-cell Pertussis vaccine, and had been in use for the primary childhood immunisation programme, administered by the Area Medical Officers up to early 1996, by which time the transfer of the administration of the immunisation programme to general practitioners, had been completed.

At St. Conleth's School, the Area Medical Officer checked the expiry date and batch number of the '3 in 1' vaccine. The Public Health Nurse assisted the Area Medical Officer in checking the batch number and expiry date for record purposes. The Area Medical Officer drew up this '3 in 1' vaccine in syringes and administered it to the 67 children, believing at all times that it was the '2 in 1' vaccine.

Wednesday 6th, November 1996 (pm)

The Area Medical Officer was scheduled to deputise that afternoon, for the Acting Director of Community Care, who was attending a meeting in Dublin.

The Area Medical Officer, alone, discovered her mistake during that afternoon, when she was completing the individual immunisation record cards for the children. On that afternoon the Area Medical Officer, in addition to writing up the immunisation cards, was involved in the management and medical examination of 3 children being taken into emergency care through an Order of the Court.

She reported her error to her Superior, the Acting Director of Community Care Kildare, at 7.30 p.m. that evening. The Acting Director of Community Care agreed with the Area Medical Officer that the Area Medical Officer would go back to St. Conleth's School on Thursday 7th November, 1996 to check on the 67 children who had been immunised on the previous day, complete the vaccination programme of '2 in 1' for the balance of 22 children and telephone a report to the Acting Director of Community Care in Dublin, at 11.30 a.m. (Thursday 7th, November).

Thursday November 7th, 1996

The Area Medical Officer in discussion with the teaching staff at St. Conleth's found that 9 of the 67 children immunised the previous day, were not at school. Of the 58 in school, one child was reported to her as having a sore arm.

The AMO administered '2 in 1' vaccine to 22 children using single dose vials.

The Area Medical Officer got in contact with the Acting Director of Community Care by telephone at approximately 11.45 a.m. and reported the foregoing to her. The Acting Director immediately travelled to Dr. Steevens' Hospital to advise the Acting Programme Manager, Community Care.

Admission of mistake

In the course of her statement and in the group's interview with her, the Area Medical Officer who administered the wrong vaccine, accepted her error. She submitted that the following contributed to this error:-

- '3 in 1' vaccine should have been withdrawn from the fridge in Newbridge when it was no longer required by Area Medical Officers.
- Colour coding, print size on vials of vaccines and the packaging of ten dose vials of vaccine in trays, rather than individual boxes led to confusion.
- Lack of support in the checking procedure.
- Lack of written protocols.

She expressed her regret for the upset caused to the children, to their parents, to her colleagues, and to the Eastern Health Board.

3. Main findings.

The key task of the group was to identify the cause of the mistake, which resulted in 67 pupils of St. Conleth's receiving '3 in 1' vaccines instead of '2 in 1' on Wednesday, November 6th, 1996.

The group's check of the consent cards confirmed that consent had been given for booster ('2 in 1') for the 67 children immunised on November 6th, 1996. As referred to at 2 (ii) above '2 in 1' immunisation only, was offered to parents and it was '2 in 1' immunisation, for which parents consent was sought.

Based on its investigations, the group found that this mistake occurred, because the Area Medical Officer giving the vaccine did not make adequate checks to ensure that the vials of vaccines to be used, contained the correct vaccine.

This mistake occurred during a routine in which diligence by all concerned in the carrying out of exact procedures is fundamental to the practice of medicine. Such a fundamental breach could, in the view of the group, result in a loss of the confidence of parents and the public in the childhood immunisation programme.

The group found no evidence whatever, which would suggest any reason for the giving of the '3 in 1' vaccine other than human error. There was no intent to deviate from national policy and Eastern Health Board practice which is to offer diptheria and tetanus ('2 in 1') as a booster immunisation. The error which occurred on this occasion was promptly notified by the Area Medical Officer to the Acting Director of Community Care and thereafter by the Acting Director of Community Care to the Acting Programme Manager, Community Care.

4. Recommendations arising from main findings.

Based on its investigations, the group recommend that there should be clear guidelines and procedures for both the organisation of vaccine clinics in schools and the administration of vaccines. Guidelines should include that at the start of every immunisation session, the attending doctor and nurse should ensure that:-

- The identity of the vaccine is checked and recorded, to ensure that the right product is used, in the appropriate way on every occasion.
- The expiry date is noted and recorded.
- The date of immunisation, title of vaccine and batch number is recorded on the recipient's immunisation record.

5. Other recommendations arising.

(i) Storage of vaccines.

The group found no systematic procedure in place for the storage and stock control of vaccines and the disposal of time-expired vaccines or vaccines no longer required.

The publication 'Immunisation against Infectious Diseases' referred to at 2. (ii) above, sets out guidelines for the storage and disposal of vaccines. Based on the group's investigations there is a need to review arrangements for the storage, distribution and disposal of vaccines.

Vaccines should be stored only at Community Care main offices, in special vaccine fridges with temperature control and an alarm. A pharmacist or other suitably trained person should be nominated to supervise the safe storage of vaccines and should work to a written procedure. The use of domestic type fridges in peripheral health centres e.g. Newbridge, for storage of vaccines is not ideal and needs to be examined.

(ii) Packaging and labelling.

The group in its investigations noted the similiarity in the colour of labels and packaging in a variety of vaccines.

The packaging and labelling of vaccines should be examined in conjunction with the vaccine manufacturers, with a view to introducing a system of colour coding. Such a system, the group believe, would lessen the possibility of vaccines being incorrectly identified and distinguished. This however does not take away from the obligations of the medical practitioner as recommended in section 4 above.

Ten dose vials of vaccine are preferred by doctors when doing large clinics. Difficulties in the supply and availability of ten dose vials of '2 in 1' vaccine were brought to the group's attention during its investigation.

(iii) Procedure for administration of vaccine in schools.

The current system for advising parents regarding the booster immunisation programme through the school's teaching staff should be examined, so that parents/guardians are given sufficient notice of the day and time when the immunisation session will take place.

(iv) Immunisation guidelines for Ireland.

As referred to under 2. (ii) above, the National Immunisation Committee is preparing immunisation guidelines for Ireland.

The recommendations of the group may need to be reviewed in the light of any report issued by the National Committee.

John Kincaid

Mr. John Kincaid,
Community Care Manager,
Midland Health Board.

Date: 18 November 1996

Elizabeth Keane

Dr. Elizabeth Keane,
M.B., B.ch., B.A.O., D.C.H., D.Obs.,
M.P.H., F.F.P.H.M.I.,
Director of Public Health
Southern Health Board.

Date: 18 November 1996.