

From The Chief Medical Officer:
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To: Directors of Public Health for onward cascade to all General Practitioners (General Practitioners - please ensure this message is seen by all practice nurses, health visitors, non-principals and locums working in your practice)
Trust Medical Directors for onward cascade to consultant paediatricians, consultant microbiologists)
Consultants in Communicable Disease Control
Trust Nursing Directors
Board pharmaceutical advisers
Community pharmacists
Regional Epidemiologist

Dear Colleague

URGENT COMMUNICATION

PRIVATE IMMUNISATION CLINICS AT ELSTREE AND SHEFFIELD, ENGLAND

1. The purpose of this urgent communication is to alert you to a problem associated with a number of private immunisation clinics in England who have been offering single vaccines for measles, mumps and rubella. Aberrant practices at these clinics may have resulted in children having inadequate protection against measles, mumps and rubella and, also, a potentially higher risk of bacterial infections.
2. The information obtained from these clinics does not allow us to discount the possibility that children from Northern Ireland may have been immunised at these clinics.

BACKGROUND

3. Earlier this year a problem was identified at immunisation clinics held by Lifeline Care Limited at Elstree Aerodrome and Hillsborough Arena, Sheffield. These clinics have now closed as they were not registered with the National Care Standards Commission. The clinics had been offering measles and/or mumps and/or rubella vaccines on a private basis to children from a large catchment area in the south and also the north of England. At the time the understanding was that just over 1000 children among those immunised during the period 3 June-22 December 2002 had received vaccines which had not been reconstituted and administered in accordance with the data sheets of the manufacturers. This included a method of making up multiple doses of vaccine in advance. Department of

Health, London, therefore recommended that this group of just over 1000 children should be given MMR vaccine.

THE UPDATED SITUATION

4. Further information has become available that aberrant reconstitution and administration practices were undertaken at these clinics before June 2002. Also anyone who was immunised at these clinics could have been immunised by a non standard procedure. The advice now is that all previous patients who received measles and/or mumps and/or rubella vaccine/s at these clinics should be immunised with MMR vaccine. This should be given according to current national recommendations. The present estimate is that this could involve up to 40,000 immunisations going back over a 10 year period.

ONGOING SITUATION

5. From July 9th Department of Health in London will be using regional advertising and the media to announce the advice to parents about getting MMR. Parents of children who may have been immunised at this clinic will be advised to contact their GP.

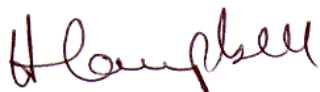
6. We are asking GPs, if they are aware a patient registered with them has attended immunisation clinics at Elstree Aerodrome or the Hillsborough Arena, to advise the parents of these patients about our concerns and to offer MMR vaccine.

7. A Q & A brief is attached and should be read in conjunction with this message.

8. DHSSPS continues to recommend MMR as the safest and most effective way to protect all children against measles, mumps and rubella.

If you require further information on the national situation please contact: Dr David Salisbury (Tel: 020 7972 1519, Fax: 020 7972 5758) or Dorian Kennedy (Tel: 020 7972 1523, Fax: 020 7972 5758 Immunisation and Communicable Disease Team, Department of Health, 606A Skipton House, 80 London Road, SE1 6LH.

Yours Sincerely



Dr Henrietta Campbell
Chief Medical Officer

8 July 2003.

Questions and answers. Elstree and Hillsborough advice line.

Q1. What exactly has happened?

A. The private vaccine clinics that had been offering single antigen vaccines had not been following the correct procedures recommended by the manufacturer for making up and administering the vaccines. Also the clinic made up batches of vaccines in advance for an unknown number of its vaccination clinics. This is not normal practice and might have led to the vaccines being less effective than normal (and therefore not offering the child proper protection) as well as producing contamination and risking bacterial infection from the injection.

The clinics in question have been reported to the National Care Standards Commission. See also answer to Q14.

Q.2 Over what period of time was there problems at the clinics?

A. It was thought originally that the problem occurred only during 3 June – 22 December 2002. However new information has come to light that problems with the vaccine had been occurring over a longer period. Unfortunately we have been unable to find out exactly when these problems started. Thus anyone who was vaccinated at either of these clinics could be at risk.

Q3. Which clinics have been affected?

A. As far as we are aware, only the single antigen vaccine clinics run by Lifeline Care Ltd at Elstree Aeromedical Centre and Hillsborough Arena Sheffield. All sessions at these clinics could have been affected.

Q4. What does this mean for my child? Could my child have been harmed?

A. Our two greatest concerns are that:

1) The clinics had not followed the correct procedure recommended by the manufacturer for making up and administering the vaccines. Also the clinic made up batches of vaccines in advance for an unknown number of its vaccination clinics. This is not normal practice and might have led to the vaccines being less effective than normal. This means that some children who have been vaccinated may not be adequately protected against one or more of the diseases for which they received the vaccine.

2) Due to the way in which the vaccines were prepared, they may have become contaminated. This could have increased the risk of children suffering bacterial infections from the immunisation or greater side effects to the vaccines.

If your child has been well since the immunisation, it is very unlikely that any problems will now occur directly as a result of the injection.

If you are concerned about your child's health please see your GP. If your child did experience infection or adverse reactions after receiving the vaccine, you should inform your GP so that the reaction can be reported to the Committee on Safety of Medicines in the usual way.

Q5. How will I know if my child was affected?

A. Any child vaccinated in the single antigen vaccine clinics held at Elstree Aeromedical Centre and Hillsborough Arena, Sheffield could have been affected.

Q6. Can I have my child tested to see if they have responded to the vaccine?

A. Although blood (and, in some cases, saliva) tests are available to detect antibodies to the *illnesses*, it is very difficult to interpret the results of antibody tests to the *vaccines*. Even if we did an antibody test, we would not be able to reassure you confidently that your child has been protected. It is much better to be sure by vaccinating them. The safest and most effective way to do this is with the MMR vaccine. (See Questions 8, 9 and 10).

Q7. What should I do now?

A. We are recommending that all children who were vaccinated with single antigen vaccine for measles or mumps or rubella should be properly vaccinated, with MMR. This applies whatever age your previously vaccinated child is now. You should see your GP about arranging this.

Q8. What if my child has, in fact, been given an effective vaccine?

A. There is no harm from having a second or even a third dose of vaccine if you are already immune. The body would recognise that it had met the vaccine virus before, and respond by eliminating it promptly. This is exactly what would happen if your body encountered the virus naturally.

If you require further information, please see your GP or the websites below.

Q9. If my child did respond to the vaccine, surely revaccination will overload their immune system?

A. The immune system is designed to deal with repeated exposure to many different antigens, from birth. Recent studies have also shown that the immune system of young children can deal with thousands of different antigens at the same time. Repeating a vaccination will boost any existing immunity. It will not damage the immune system. In fact, the immune system is designed to work this way.

If you require further information, please see your GP or the websites below.

Q10. If my child is revaccinated, will they be more likely to get side effects?

A. No. In fact, research has shown that side effects are LESS likely to occur and are less pronounced after a second or further dose of vaccine, than they are after the first dose.

If you require further information, please see your GP.

Q11. I would like my child to be revaccinated with single antigen vaccine instead of MMR. What should I do now?

A. We cannot recommend single antigen vaccine be used. MMR is the safest and most effective way to protect children against all three diseases. Some of the single antigen vaccines are not readily available.

If you choose to take your child to a private clinic, either for single vaccines or for a blood test, you should exercise caution. You should ensure that the clinic is registered with the National Care Standards Commission. The clinic should be able to demonstrate that they follow the manufacturer's requirements exactly on transport, storage, reconstitution and administration of the vaccine. The clinic should provide support in the weeks following each vaccination in case of any adverse events.

Q12. What if I do not get my child revaccinated?

A. Your child may have responded to the vaccine and may be protected. We cannot guarantee this so we recommend that your child be revaccinated with MMR. This will give them protection against all three diseases.

Q13. Where can I get more information?

A. For more information about what has happened, for information about MMR vaccine, or information about immunisation in general, you should speak to your GP or health visitor.

For detailed information about MMR you may visit the following websites:

<http://www.immunisation.nhs.uk>

<http://www.mmrthefacts.nhs.uk>

<http://www.HPA.org.uk>

<http://www.nhsdirect.nhs.uk>

Q14. I have heard the clinics at Elstree and Sheffield have been shut down. What is the situation there?

A. The National Care Standards Commission registers and inspects private health care services. The NCSC ordered that the clinics operated by Lifeline Care Limited at Elstree and at Sheffield stop practising from 5pm on 20 February 2003. The clinics were not registered with the NCSC and as such were operating outside the law.

Q15. Should my child have blood tests?

A. We are not recommending that blood tests be done which are often unreliable. We recommend revaccination.

Q16. Can you not tell which vaccines were contaminated from the batch numbers?

A. This would only be useful if a particular batch of vaccine was responsible for a problem. In this case, because our concerns are related to the way vaccine doses were handled, any batch number could be affected. The vaccines themselves were not contaminated when they arrived at the clinics. The problem was that they might have become contaminated because of the way they were prepared in the clinics.

Q17. I want to have my child revaccinated. How long should I wait?

A. As it is now more than six weeks since the last child was vaccinated using the non-standard procedure, children may be revaccinated now.

Q18. Can I get my money back from the clinic?

A. Your child is a private patient of Lifeline Care Limited. Patients must approach the clinics directly about this.

Q19. I would like to make a formal complaint against the clinic . Who do I complain to?

A. The National Care Standards Commission on 0191 233 3556.

Q20. I have more questions. Who can I contact?

A. You can phone the dedicated helpline number telephone 0845 850 9850. Also you can contact your GP or health visitor in the usual way.

Q21. My child had vaccines at the clinic but not vaccines for measles or mumps or rubella. What shall I do?

A. Contact your GP for advice.
[Ends]