



Public Health
England

INFORMATION LEAFLET for younger participants aged below 16 years

(Version 2, 7th June 2013)

(to accompany Information Leaflet sent to parents/guardians)

Study code: MULTIBOOST

Your doctor's surgery has agreed to help with a study that the Public Health England (PHE) is carrying out on vaccines that can help to prevent meningitis and whooping cough.

Meningitis and whooping cough are two very serious diseases that can be caused by germs called bacteria. Both of them can make people, especially children and young people, very ill.

As a young child, you were given injections (vaccines) to help protect you from serious illnesses including whooping cough and some types of meningitis. Those vaccines would have helped your immune system create antibodies to destroy those bacteria that cause these diseases.

However, we think that as young people grow, a time comes when they may not have enough antibodies left to fully protect them. So now that you are older, your antibodies may not be enough to protect you fully against these diseases. This doesn't mean that you will become ill but if we give you "booster" vaccines, they may help your body to produce more antibodies to help protect you in the future.

You can talk about this study with your family, and your Vaccine Research Nurse. You can also call Professor Liz Miller who is in charge of this study if you have questions.

If you want to take part in the study:

If you want to join the study, you have to sign a form (called assent form). Your parent or guardian will also sign another form (consent form) to say that you are all happy to do join this study.

What will happen during the study?

During the study, you will have two study appointments with your Vaccine Research Nurse.

Before the two study appointments, the nurse will discuss all the details with you and your parent or guardian, and they may speak with you on the telephone (or even visit your family at home if that is more convenient), to make sure that you understand everything and that you are ready for the study.

At your first study appointment, the nurse will check that you have signed the form and agreed to take part in the study. After this, the nurse will do two important things. First, she will take some blood from you. It will be no more than 10ml which is about 2 teaspoons. Then, she will give you two vaccine injections (one to protect against meningitis C, and the other to protect against whooping cough). The injections might hurt a bit – like a pin prick, but the blood samples shouldn't hurt at all as the nurse can give you some cream that will numb your skin so you can't feel the blood test.

Once the nurse has given you the injections, she will give you a diary and a personal digital thermometer. For the next one week after you get your injections, we would like you to write down what your temperature is, and also record how you are feeling. Your parent or guardian can help you with this.

The second time you see the nurse will be about a month after you have had the injections. At this time, she will take the second blood sample from you. Once this second appointment is completed, you will have finished the study.

What are we going to find out in this study?

In this study, there are different vaccines. A computer program will decide at random which two injections you will be given - it's a bit like tossing a coin. Other people taking part in the study may get different brands of vaccines.

We will need to test you to see if the vaccine has worked. The only way we can measure this is to take blood samples at your first and second appointments.

At the end of the study, we will look at all the results from everyone who has joined, and we can then see if any of the different vaccines are better than the others at protecting young people.

What if you don't want to take part in the study?

If you don't want to take part in this study, you don't have to.

Even after you have signed the form agreeing to take part in the study, you can change your mind at any time. You don't have to continue if you don't want to.

If you have questions:

If you have read all of this leaflet and have any questions you can speak to your family, or your study nurse. You can also read the leaflet that we have sent to your parent or guardian. That leaflet has some more details in it. If you still have questions you can ring Professor Liz Miller on 0208 327 7430 or email the Clinical Trials team at clinical.trials@phe.gov.uk. Don't be afraid to ask any questions, the nurse, Professor Miller and the Clinical Trials team are used to answering questions about the studies that they run.

Vaccine Research Nurse Contact Sticker.