



## PARTICIPANT INFORMATION LEAFLET

For adult participants, aged 16 years and above

(Version 3, 19th July 2013)

### *Meningitis and whooping cough vaccination study (MULTIBOOST)*

**Short study title:** A STUDY OF THE EFFECTIVENESS AND SAFETY OF MENINGITIS AND WHOOPING COUGH BOOSTER VACCINES, GIVEN TOGETHER TO HEALTHY UK ADOLESCENTS

**Full (technical) title:** A phase III/IV randomised open-label study and comparison of the immunogenicity and safety of a single adolescent booster dose of a meningococcal group C conjugate booster vaccine (Meningitec™, OR NeisVac-C™, OR Menitorix™), when given concurrently with an acellular pertussis-containing booster vaccine (Repevax™ or IPV-Boostrix™)

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Your doctor's surgery is helping Public Health England (PHE) in a study of meningitis and whooping cough vaccines. Before you decide if you would like to join this study, you need to understand the reasons why the research is being done and what it would involve. Please take the time to read the following information carefully and talk to others about the study if you wish.

Part 1 tells you the purpose of the study and what it would involve.

Part 2 gives you more detailed information about the conduct of the study.

## PART 1

### **What is the purpose of the study?**

In the United Kingdom, teenagers are offered booster vaccines, which are extra doses of the vaccines they had as young children. These boosters are given to make sure that they stay protected against various serious illnesses into adulthood. Public Health England is carrying out this study, on behalf of the Department of Health, as it is important that the national immunisation schedule is updated so that young people are safely protected against as many serious diseases as possible.

It has been shown that antibody levels (the part of the blood that protects against infections) for meningitis and whooping cough become reduced over time, so booster vaccinations may be needed in teenage years. This study is looking at booster doses of meningitis C and whooping cough vaccines in young people aged 13.5 to 17 years who had received the appropriate doses of these vaccines in childhood (which can be checked in your General Practice records if you are not sure). This study will also help in planning vaccination programmes for the future.

### **Why have I been invited to take part?**

Young people aged 13.5 to 17 years, who received the appropriate doses of meningitis C and whooping cough vaccines in childhood (and who are also registered at the participating General Practitioners, GPs in Hertfordshire and Gloucestershire), are invited to take part.

We would like to invite you to join this study.

### **Do I have to take part?**

No. Participation in the study is entirely voluntary. If you would like to join the study after discussion with your Vaccine Research Nurse, you will be asked to sign a consent form. At the end of the study, we will inform you of your results and of any developments arising from the study.

You would be free to withdraw at any time without giving a reason. This will not affect your routine care. If you withdraw during the study, your Vaccine Research Nurse will be happy to discuss any further routine vaccinations that should be given by your GP surgery.

### **Will you do any safety checks before I take part?**

Yes. In order to protect the safety and well-being of everyone taking part in the study, there are strict eligibility and safety requirements for people who wish to join. So if you would like to take part, we will first check if you fit the criteria to participate, before you can join the study. The study nurse will ask you some questions and might also need to check your General Practice record to be sure that you are eligible.

### **Please tell the study nurse if you do not want them to check your medical record for eligibility for the study.**

If you are eligible, and do decide to participate, we will inform your General Practitioner that you are taking part in the study.

## **What will happen to me if I take part?**

If you would like to take part in the study, we will first check if you fit the criteria for taking part. This is to check for the safety and well-being of everyone taking part in the study. The study nurse will check these with you before you register (enrol) for the study. We will inform your General Practitioner (GP) that you are taking part in the study.

Once you enrol in the study, your involvement will last about a month and there will be two study visits.

During the first visit, you will receive two vaccines (one meningitis C vaccine; and one whooping cough vaccine) and you will also have a blood test. This first appointment will take about an hour.

The second (and last) visit will take place about 4 weeks later, and your child will have a blood test only. This visit will only take about 20 minutes.

The study visits will be conducted by your study nurse, and will take place at your General Practice surgery. It may be possible to arrange the second visit (for blood test only) at your home if it is more suitable for everyone.

An essential part of the study is checking whether the vaccines are able to stimulate natural body defences against diseases being vaccinated against. This can only be done by collecting blood samples. You will be offered some anaesthetic cream to numb the skin before the nurse takes a small blood sample (about 10ml, which is about two teaspoons) from you. This will be done on two occasions (once before vaccination, and once after 4 weeks).

At the end of this study, once we have completed the required tests, any samples left over may be valuable in other investigations to help improve our understanding of vaccines and how they work. You will be asked to consent to any samples left over from this study being kept for use in this way. You can still take part in this study if you do not wish any leftover samples from you to be kept for this use. No genetic tests will be carried out on your samples.

On each evening for seven days after the vaccination we will ask you to fill in a "Participant's Health Diary". This involves taking your temperature, looking at the injection site and answering some simple questions. We will provide a thermometer and a ruler for this purpose. Your Vaccine Research Nurse will show you how to take your temperature (oral) and how to complete the diary.

If you have an illness and see the General Practitioner or a hospital doctor, please inform the doctor that you are taking part in this study. If possible and at your convenience, please then

let us know by telephoning your Vaccine Research Nurse, that you have been unwell, even if this seems unrelated to vaccination. We may then contact your doctor for further information.

### **Which vaccines are involved in the study?**

There are a total of six vaccines being studied. You will receive **two** of these vaccines (one meningitis C vaccine; and one whooping cough vaccine).

(a) You will receive **one** out of the three study vaccines that protect against meningitis C. They are:

**Meningitec™** (made by the Nuron company)

or **NeisVac-C™** (made by Baxter)

or **Menitorix™** (made by GSK) - this vaccine also protects against the infection called Hib (*H. influenzae* type b).

(b) You will also receive **one** vaccine out of two that protect against whooping cough. They are:

**Repevax™** (made by Sanofi)

or **IPV-Boostrix™** (made by GSK)

Both of them are combination vaccines, which means that they each protect against more than one disease. They also protect against tetanus, diphtheria, and polio (in addition to whooping cough).

All the vaccines in this study are licensed for use in the United Kingdom. Although Menitorix is only licensed for use in children up to the age of two years, it has been well used in people above this age. Official United Kingdom immunisation guidelines recommend it for vaccinating older children and adults who require protection against either meningitis or *Haemophilus influenzae* type b (Hib) disease.

### **Which two vaccines will I receive?**

People who take part in the study will be divided into six groups, depending on which two vaccines are given. A computer programme will decide randomly (like tossing a coin) which

group you will be in. This is so that we can compare the different vaccines and make sure that we have similar numbers of people in each group. The different groups are shown in this table:

	Meningitec™ (Nuron)		NeisVac-C™ (Baxter)	Menitorix® (GSK)
Repevax™ (Sanofi)	Group 1		Group 2	Group 3
IPV-Boostrix™ (GSK)	Group 4		Group 5	Group 6

**Will this change my normal routine vaccination in any way?**

Yes. If you take part in this study, you will **not** need to receive your normal routine teenage booster vaccine dose against tetanus, whooping cough, and polio.

All young people aged between 13 and 18 years in the United Kingdom are routinely offered a single booster vaccine that protects against these three infections.

Since the vaccines in this study fully cover all of these infections, by participating in the study you would no longer need the routine vaccine.

Please note that for females, taking part in this study does not affect the routine vaccination against Human Papilloma Virus (HPV) that is offered to all girls aged between 12 and 13 years.

**What are the possible disadvantages as well as benefits of taking part?**

**Risks:** There are some possible side effects to any vaccination, including discomfort on injection as well as some swelling, redness, pain and/or heat to the touch at the injection site afterwards. Participants may also experience fever, headache, nausea (feeling sick), muscle pain, rash, joint pain and feeling generally unwell. These symptoms usually subside by themselves without treatment or affecting normal activities. Allergic reactions can occur with any vaccine but these are very rare, and the usual safety precautions as for any vaccination will be taken during this study.

To date, there has been no indication of any particular side effects with any of the study vaccines, other than those listed above and associated with any vaccine.

The blood sampling may cause slight discomfort and there may be some pain or bruising at

the site where the blood is taken.

**Benefits:** You will receive two vaccines which should boost your protection against meningitis C and whooping cough. These infections can be very serious and can cause death. One of the vaccines that you will receive may also offer a boost in protection against other difficult infections, namely diphtheria, polio, and tetanus; and also against *Haemophilus influenzae* type b (Hib) disease for some participants (depending on the study group that you are assigned to).

Information gained from this study will help to increase understanding of the how the vaccines work and will inform the national vaccination policy in the future.

**What are the side effects of any treatment when taking part?**

The section on “risks” (above) describes some side effects to vaccination. Severe allergic reactions can occur with any vaccine but these are very rare, all our research nurses are trained for this and the usual safety precautions for any vaccination will be taken here.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study, or any possible harm you might suffer, will be addressed. The detailed information on this is given in part 2.

**Will my participation in the study be kept confidential?**

Yes, we will follow ethical and legal practice and all information will be handled in confidence. The details are included in part 2.

**This completes part 1.**

**In summary:**

- **Participants will receive two vaccines in all (one dose of meningitis C vaccine, and one dose of a whooping cough combination vaccine).**
- **During the study, two blood samples will be taken; once at the first visit, and once 4 weeks later at the second visit.**

**If the information in part 1 has interested you and you are considering participation please read the additional information in part 2 before making any decision.**

## **PART 2**

### **What if relevant new information becomes available?**

Sometimes we get new information about vaccines which could include those being studied here. If this happens, we will let you know and discuss whether you should continue in the study. In some circumstances the study doctors may advise it best for you to withdraw from the study. If you decide to continue in light of the new information, we may ask you to sign an updated consent form.

If the study is stopped for any reason we will let you know, as well as give your General Practitioner information about your continuing care.

### **What will happen if I do not want to carry on in the study?**

You can withdraw from the study at any time without having to give a reason. If you withdraw, you would need to decide if you want samples collected from you to be destroyed (if any have already been collected). If you would like them to be destroyed, you would need to inform us in writing. We would retain any information collected to that point in case we needed to reach you at some time in the future based on the outcome of the study.

### **What if there is a problem?**

#### **Complaints**

If you have any concerns about any aspect of this study, you can contact the Vaccine Research Nurse or the study organisers (see details below), who will do their best to answer your questions. If you remain unhappy and wish to complain formally then you can do this through the National Health Service Complaints Procedure, details of which can be obtained at [www.nhs.uk](http://www.nhs.uk) or by phoning 0845 601 3012.

#### **Harm**

In the unlikely event that something does go wrong and you are harmed during the research, and this is due to someone's negligence, then you will have grounds for legal action for compensation against Public Health England but you may have to pay your legal costs. The National Health Service complaints mechanism will still be available to you. Where justified, an ex gratia payment for any non-negligent harm may be made.

### **What data and confidentiality safeguards are in place?**

Under the data protection laws, you have a right know how your personal data from this trial will be used, so that you understand exactly what information will be collected and who will have access to it. Personal data may include your name and address as well as results of the blood tests, and medical records so that we are able to analyse information and answer

the study objectives. The only people with access to this information will be employees or agents of Public Health England, the Department of Health or regulatory authorities who may wish to check the study is being properly carried out within the appropriate guidelines.

The data will only be used for the purposes of this study and any data released outside the above group will be anonymised. Data will be stored in secure Public Health England facilities and will be disposed of within clinical trial guidelines after the appropriate time period which may be a number of years. You have the right to obtain access to data relating to you. If you wish to obtain any information, please contact us on the numbers listed in this leaflet.

### **Involvement of my GP**

We will let your General Practitioner (GP) know that you are taking part in the study by writing them a letter. We will also give them a copy of the letter that we send to you with your antibody test results for their record.

### **What will happen to my blood samples?**

The two blood samples we take for this study would not be part of your routine medical care. The samples will be labelled with your study number but not your name. The samples will be tested in collaborating laboratories and results will be sent to Public Health England where they will be linked with information about you so that we can see whether things such as age or gender affect responses to vaccination.

Once we have completed these tests any blood left over from this trial may be used to help develop and refine the tests we have for measuring responses to vaccines. Any samples shared with other laboratories will be anonymised and will not be traceable to the person who gave them. You will be asked to consent to any blood left over from this study being used in this way (this is optional). You may still take part in the study if you do not wish to consent to this.

### **Will any genetic tests be done?**

No genetic tests will be carried out on your samples.

### **What will happen to the results of the research study?**

We plan to publish the results in a medical journal which will be accessible to the public (an access fee may apply with some journals). The results of the study will also be reported to the Department of Health to help planning national vaccination programmes in the future. In any report or publication arising from this study, it will not be feasible for readers to identify



any individual participant. No information that could allow identification of individuals will be included in any report or publication.

### **Who is organising and funding the research?**

The study is funded by the Department of Health and is being organised by the Immunisation Department of the Public Health England.

Public Health England is an independent body that protects the health and well-being of the population. Public Health England plays a critical role in protecting people from infectious diseases and in preventing harm when hazards involving chemicals, poisons or radiation occur.

### **Who reviewed the study?**

All research in the National Health Service is looked at by an independent group of people, called a Research Ethics Committee to protect the safety, rights, well-being and dignity of individuals. This study has been reviewed and given favourable approval by the London - Brent Research Ethics Committee - Reference 13/LO/0681.

### **Further information and contact details.**

Further information about our trials programme including links to the organisations reviewing research and the guidance we follow can be found at <http://www.hpa.org.uk> and typing *clinical trials* into the search bar.

Your contribution would be an important step towards the continual improvement of vaccine policy in the United Kingdom. You may be invited to take part in future studies with us by virtue of the surgery you attend. We reassure you that invitations for future studies will not be because of anything to be concerned about from results of this study.

If you have any further questions please ask your Vaccine Research Nurse, or contact the organiser Professor Liz Miller on 020 8327 7430.

You can also email your question to the Clinical Trials Team at [clinical.trials@phe.gov.uk](mailto:clinical.trials@phe.gov.uk)

**Thank you for your time.**

[Vaccine Research Nurse contact details sticker](#)