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Combining Vaccines against Meningitis:

an infant immunisation study

Study title: A Phase II, randomised, partially blinded study to assess the safety, tolerability and immunogenicity of meningococcal combined ABCWY vaccine when administered to healthy infants.

Participant information sheet

We are inviting infants aged approximately 2 months to take part in a study to at improving vaccine protection against meningitis in babies.

Before you decide whether to take part, it is important for you to understand what the study is about and what the participation would involve. Please take your time to read the information carefully and discuss with others if you wish. If anything is unclear or you would like further information, please contact the study team.

Your child is invited to take part in this research study for a meningitis vaccine.

Why has my child been invited to take part?

You have been approached because your child will shortly be due their routine immunisations and you live in an area where the study is being carried out. **Taking part in this study is voluntary.**

Who is doing this study?

This study is being conducted by the Oxford Vaccine Group and is sponsored and funded by GlaxoSmithKline, a company that discovers and makes vaccines, medicines and other healthcare products. GlaxoSmithKline are paying the University of Oxford and study sites to do this study. The Oxford Vaccine Group is an independent research team at the University of Oxford that includes scientists, doctors, nurses and play assistants. We perform research studies on topics related to infectious diseases and vaccines for children and adults.

Who reviewed the study?

An independent group of people called a Research Ethics Committee protect the safety, rights, well-being and dignity of individuals who take part in research studies. This study has been reviewed and given favourable opinion by the South Central - Berkshire Research Ethics Committee. Details of the study can also be found on the following website https://trials.ovg.ox.ac.uk/trials/menabcwy-study

Does my child have to take part?

No, taking part in this study is voluntary. It is up to you to decide whether or not to allow your child to take part. You may choose not to allow your child to take part or you can choose to enrol them and withdraw from the study later if you change your mind. If you decide your child can take part, you will be given this information booklet and time to review the information. You can have as much time as you need to read and think about this information and discuss it with others (eg family, friends, GP) if you wish, before deciding whether or not to allow your child to take part in this study. Please ask us if there is anything that is not clear or if you would like more information.

If you decide not to allow your child to take part, you do not have to give a reason, If you decide to allow your child to take part, you are still free to withdraw your consent at any time and without giving a reason. A decision to withdraw your child at any time, or a decision not to allow your child to take part will not affect the standard of care they receive.

What is the purpose of this study?

This study is evaluating two potential new vaccines against meningitis. Before a new vaccine can be marketed and given to many people, it needs to be tested and then approved by national health agencies. Several studies are done to test the vaccine when given to people. National health agencies such as (in the UK) the Medicines and Healthcare products Regulatory Agency (MHRA) look at the results of these studies and approve the vaccine for use. All routine vaccines that you and your child receive have been through this same process.

The testing is done in 2 parts:

1. Testing in a laboratory.
2. Testing how well the vaccine works in people. This is called a 'research study'.

National health agencies look at the results of these studies to approve the vaccine for use. All vaccines recommended for use in the UK have been through this process.

Several different germs can cause serious infections of the blood and nervous system. A germ (bacterium) called Meningococcus, also called *Neisseria meningitidis*, can cause several serious diseases, including meningitis and blood infection (sepsis). Meningitis affects the brain and spinal cord. It can cause hearing loss, seizures, learning and behaviour problems, severe brain damage and even death. Death can occur in about half of untreated meningitis cases. Meningitis can happen to anyone but is more common in teenagers, and young children, including babies. This research study will help us learn about vaccines that protect against diseases caused by different types of meningococcus: types A, B, C, W, Y.

This research study will test two versions of vaccines against types A, B, C, W and Y meningococcus. One is referred to as 'MenABCWY' vaccine and the other is MenACWY-7B' which will be tested at 2 different doses, this study will to help us learn if those are safe and increase protection against types A, B, C, W, and Y meningococcus in babies.

An investigational vaccine means it is still experimental. The vaccine has not yet been approved for routine use by the MHRA, but the MHRA has approved its use in this study. This study is the first time that these vaccines will be given to babies.

What vaccines are being studied?

MenABCWY vaccine

The MenABCWY vaccine has been developed by combining 2 of GSK's already approved vaccines, *Menveo* (MenACWY vaccine) and *Bexsero* (MenB vaccine). So far, the MenABCWY vaccine has been given to approximately 1500 people aged 10 years and older in other studies.

Bexsero is a vaccine that helps to protect against the meningococcus B germ. *Menveo* is a vaccine that helps protect against types A, C, W and Y of the meningococcus. The use of *Bexsero* and *Menveo* have already been approved in many countries as separate vaccines. In the UK, *Bexsero* is approved for people from the age of 2 months. *Menveo* is approved for use for people from the age of 2 years.

MenACWY-7B vaccine

The MenACWY-7B vaccine is based on the *Bexsero* and *Menveo* vaccines mentioned above, along with an extra protein designed to further broaden protection.

Another vaccine used in this study is called *Nimenrix.* This is used as a comparison (control) vaccine and is approved in the UK from 2 months of age to protect against types A, C, W and Y of the meningococcus.

This study will be conducted in a step-wise manner, in 2 parts. You have been invited to participate in Part 2 of the study. This informed consent applies only to Part 2. Approximately 688 babies from several countries who are around 2 months of age will take part in the whole study 40 babies in Part 1 and 648 in Part 2 and study participants will be involved with the study for 16 months. Overall, approximately 110 babies are expected to be included from the UK

Which vaccine will your child get?

Your child would be participating in Part 2 of the research study. Your child will be placed in 1 of 4 groups by chance, like rolling dice. A computer will be used to assign your child to a group. This process is called randomisation. Neither you nor the study doctor can choose a group.

The table and figure below show you what will happen in the study based on the group to which your child is assigned, and more details about this are provided in the next section, 'What does your child need to do in this study?',

	Approximate number of participants	Visit 1 (Day 1)	Visit 2 (Day 61)	Visit 4 (Day 301)
Group 1	162	**MenABCWY** Routine vaccines	**MenABCWY** Routine vaccines	**MenABCWY** Routine vaccines
Group 2	162	**MenACWY-7B (lower dosage)** Routine vaccines	**MenACWY-7B (lower dosage)** Routine vaccines	**MenACWY-7B (lower dosage)** Routine vaccines
Group 3	162	**MenACWY-7B (higher dosage)** Routine vaccines	**MenACWY-7B (higher dosage)** Routine vaccines	**MenACWY-7B (higher dosage)** Routine vaccines
Group 4	162	***Bexsero*** ***Nimenrix*** Routine vaccines	***Bexsero*** ***Nimenrix*** Routine vaccines	***Bexsero*** ***Nimenrix*** Routine vaccines

At the vaccination visits, your child will also receive the routine vaccines, that he/she is recommended to receive even without participating in this study:

- *Infanrix-Hexa* (protecting against diphtheria, pertussis (whopping cough), tetanus, polio, Hemophilus influenza type b (Hib, a cause of meningitis) and Hepatitis B. In the UK this would normally be administered at 2, 3 and 4 months of age, while in this study it will be administered at 2, 4 and 12 months of age
- *Prevanr13* (protecting against 13 types of pneumococcus, a cause of meningitis, sepsis and pneumonia). In the UK this is now administered at 3 and 12 months of age, while in this study it will be administered at 2, 4 and 12 months of age (as was routine in the UK up until January 2020).
- *Rotarix* (protecting against rotavirus, a common cause of vomiting and diarrhoeal disease). In the UK this is normally administered at 2 and 3 months of age, and in this study would be administered at 4 months of age.
- *MMR* (protecting against measles, mumps and rubella). This will be administered at 13 months of age, wheras in the UK this would normally be administered at 12 months of age

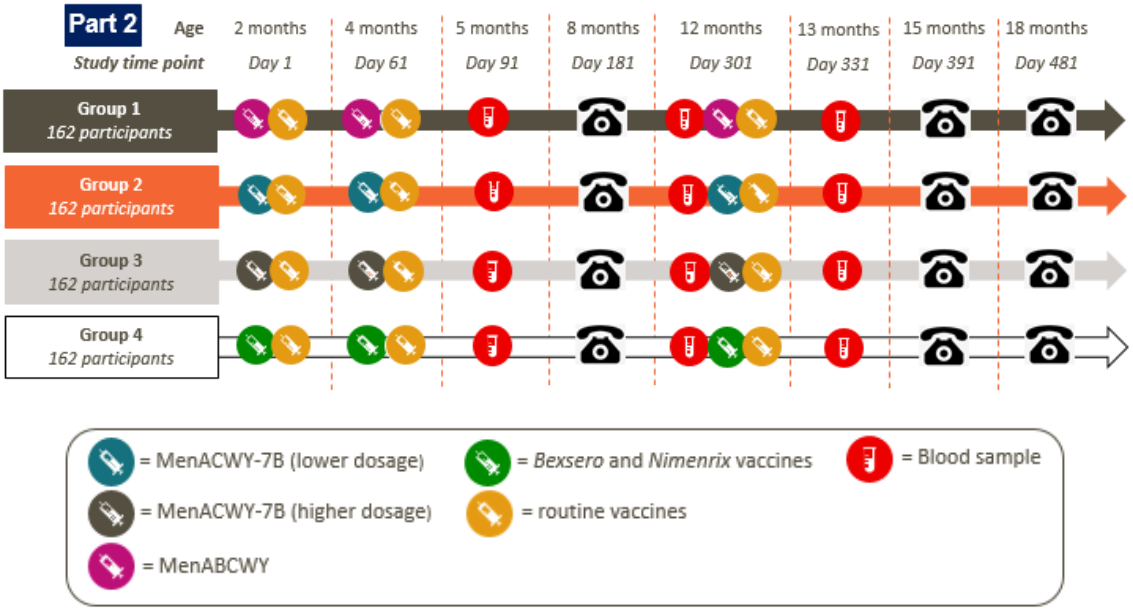
Routine vaccination	Child's age when vaccine is usually administered in UK	Child's age when vaccine will be administered in this study
Infanrix Hexa (1st dose)	2 months of age	2 months of age
Infanrix Hexa (2nd dose)	3 months of age	4 months of age
Infanrix Hexa (3rd dose)	4 months of age	12 months of age
Prevenar 1st dose	3 months of age	2 months of age
Prevenar 2nd dose	Not applicable	4 months of age
Prevenar 3rd dose	12 months of age	12 months of age
Rotarix 1st dose	2 months of age	2 months of age
Rotarix 2nd dose	3 months of age	4 months of age

MMR	12 months of age	13 months of age

A group of external experts have looked at the side effects that may be reported in the babies taking part in Part 1 of the study. These experts are independent from GSK. These experts have decided that it was safe to continue the study vaccination, Part 2 has started, and the babies can be enrolled in the 4 groups.

If your child will be included in Group 4 of the study, both you and the study doctor will know which study vaccines your child will get.

If your child will be included in Group 1, or Group 2 or Group 3, neither you nor the study doctor will know which study vaccine your child will get. Other people involved in the study, such as the person giving the vaccine, will know which vaccine is being given. This is done to be sure the results of the study are not affected by the power of suggestion. You and the study doctor will be told what vaccines were given to your child only after the study has been completed or in case of a medical emergency.



What does your child need to do in this study?

Informed Consent: At the screening visit, the study doctor will explain the study to you in detail and to answer any questions you may have. If you are interested in your child

participating in the study, you will be asked to sign the Consent Form. **You will receive a copy of the complete and fully signed consent form.**

You would have to follow the study doctor's and study staff's instructions. Please tell them about any changes to your child health during the study.

The study doctor will ask you some questions, to check that the study is right for your child. This includes the number of weeks of pregnancy when your child was born, date of birth, your child's vaccination history and collecting information about your child's health status.

If your child joins the study, your child would be in the study for about 16 months (1 year and 4 months). Please note that your child would not be able to join other research studies until the completion of this one.

If you agree to your child joining this study, you agree to:

 Follow the study doctor's and study staff's instructions.

 Be available for the planned study visits and telephone calls: about 5 clinic visits and 3 telephone calls. Study visits will be performed at your home or the study site.

 Let your child receive injections 3 times throughout the study and 2 oral vaccinations.

 Let your child give a 5mL (about 1 teaspoon) blood sample 3 times throughout the study for tests.

 Complete the electronic diary (it is like an application installed on your cell phone, if you agree, or on a device provided by the site) after the injections/vaccination. An automatic alarm will alert you to complete the diary during the period after vaccination.

Tell the study team about any medicines and other vaccines or treatments your child takes during the study. With your permission, your study doctor will contact your child's GP to inform him/her that your child is participating in the study.

Health checks by the study team-staff.

Your child's vaccination may be moved to a later date if your child has an acute illness and/or fever (body temperature equal or greater than 38.0°C) at the time of vaccination. It may also be moved if your child had a significant acute illness in the 7 days before the vaccination.

If a study visit includes a blood sample and your child took antibiotics within 3 days of the visit, that visit, including the blood draw, will be moved to a later date. If this happens, the study team will tell you when to come back. Your study doctor will explain any other conditions, including those related to COVID-19, that may delay vaccination or blood sampling.

You will receive a subject card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if your child needs emergency care during the study. The medical staff can then contact your study team if needed to ask about the vaccine your child received

Once your child completes the study visits, or if they are withdrawn from the study vaccination schedule or if the study is terminated by GSK, they will not receive any additional vaccinations from GSK and the study Doctor will discuss further immunisation for your child with you.

Figure 1 shows the schedule of study visits and contacts and the study activities are described below.

General Information and Medical History: At Visit 1, you will be asked to provide general information about your child, your child's medical history and vaccination history. Your child will have height and weight measured.

At Visit 1 and at all visits and telephone calls, the study staff will ask about all medications including prescription medicines, over the counter medications, dietary

supplements, vitamins and herbal medications your child is currently taking and may have taken recently in the past. If necessary, you may be requested to get medical records from other doctors.

Physical Exam: Your child will have a physical exam. Measurement of blood pressure, heart rate and temperature will be done. Depending on your child's medical history the doctor or nurse may also perform a more detailed assessment of different body parts *(head, neck, thyroid, ears, eyes, nose, throat, chest, lungs, heart, lymph nodes, abdomen, skin, muscles and skeleton, nervous system and other if needed)*. This is done to ensure your child is eligible to participate in this study. At the first visit this will be done for all. For the next visits: Visit 2, 3, 4 and 5, the physical exam will be only done if the study doctor thinks it is necessary.

Blood samples: At different study visits (Visits 3, 4 and 5) a blood sample will be taken from your child. All together we will draw about 3 teaspoons of blood (15 mL) from your child during study. Here's how: about 1 teaspoon (5 mL) each at Visit 3, Visit 4 and Visit 5.

Vaccination: Your child will get the study vaccines that were assigned to your child by chance at Visit 1, Visit 2 and Visit 4. At the vaccination visits, your child will also receive the routine vaccines. A member of the site staff will inject the vaccines into the muscle of both thighs (except Rotarix which is an oral vaccine).

After Vaccination: After each study vaccines administration, your child will be observed for about 30 minutes so that the study doctor or his/her staff can see whether your child has any side effects from the study vaccine. During this time, the staff will ask questions, check your child, and may examine your child. The site will also give you instructions for what to do after your child's visit and provide details for his/her next visit. The study staff will train you on how to use and enter information in the eDiary during this time.

Individual electronic diary: You will be asked to report certain information after your child has got the vaccine on an individual electronic diary (called eDiary). This diary reminds you to report specific types of side effects that are looked for after vaccine

administration.

A software application will be installed in your smartphone, if you have one and give permission. Otherwise, the study team will provide you with a device, preinstalled with the software application.

The site staff will explain how to use the device or the application on your smartphone

and make entries for up to 30 days after the vaccine is given. You will also be asked to:

- Look at the place where your child got the study vaccine and measure specific reactions you may see.
- Indicate if your child experiences other kinds of reactions that are sometimes seen after study vaccine administration, such as fever, irritability/fussiness, loss of appetite, drowsiness, vomiting and diarrhoea.
- Measure your child's body temperature, preferably by underarm.
- Call the site staff if your child experiences symptoms that concern you or the child needs to visit a doctor or medical professional.
- Bring the eDiary device/your smartphone with you at the clinic visit, as indicated by the site staff.

The electronic diary device's in-built audio-visual alarms will also alert you to complete the diary during the period after vaccination.

Safety Telephone Call: You will receive a total of 3 telephone calls during the course of the study. The study staff will call you to review with you your child's general health status, such as any visits to the doctor for any new and/or serious health problems since the last vaccination/ last visit to the study centre/ last phone call. The phone calls can be expected at the following time points:

- Telephone call (T)1: Around 4 months after your child's second vaccines administration at Visit 2.
- T2: Around 3 months after your child's third vaccines administration at Visit 4.
- T3: Around 6 months after your child's third vaccines administration at Visit 4.

Figure 1 Calendar for your child

Approximately 16 months

	Visit 1 Day 1	**Visit 2** Day 61	**Visit 3** Day 91	**Phone call 1** Day 181	**Visit 4** Day 301	**Visit 5** Day 331	**Phone call 2** Day 391	**Phone call 3** Day 481
Physical exam^								
Blood draw#								
Vaccination								
Complete the eDiary								
Review of eDiary			 *			 *		
Health questions								

^ On day 1, a general physical examination will be done. On other days, it will be done if the study doctor decides it's necessary.
# Refer to "Additional information for study participants" for the volume of blood sample to be taken at each visit
* eDiary device will be collected back by the site staff (if applicable)

What potential benefits can your child expect?

There may or may not be a direct medical benefit to your child if he/she takes part in this study.

- If your child receives *Bexsero* and *Nimenrix, Bexsero* might protect against diseases caused by the meningitis germ type B and *Nimenrix* might protect against diseases caused by the meningitis germ types A, C, W and Y.
- If your child receives MenABCWY vaccine, the MenABCWY vaccine might protect against the diseases caused by all 5 types of meningitis germ (A, B, C, W, Y) as a single combined vaccine.

This study may also help us learn more about meningococcal disease and the effects of the investigational vaccine MenACWY-7B and how well it works. By taking part, your child may help make new vaccine(s) to protect people from diseases caused by meningitis germ.

During this study, your child will also have regular health check-ups.

What potential risks can your child expect?

Like all medicines and vaccines, the study vaccines may cause side effects – although not everyone gets them. A side effect is an unwanted medical event that may have been caused by the study vaccine. Doctors do not know all the side effects that may happen after the study vaccine. Everyone taking part in the study will be observed carefully for any side effects. Call the study doctor if there are any changes to your child's health that concern you.

We have listed the side effects and risks that we know about below. Others could also happen. Ask the study doctor if you have any questions about the possible risks or side effects.

With any vaccine an allergic reaction with itching and a rash is possible. Rarely, allergic reactions may be severe, with sudden onset of symptoms such as redness, fast heart rate, swelling of the face, trouble breathing and swallowing or sudden drop in blood pressure. These usually happen shortly after receiving a vaccine. These allergic reactions can be life threatening; therefore, the study staff will watch your child for about 30 minutes after each vaccination.

Fever may occur following administration of the study vaccines. To prevent/treat it you can give your child medicines which are used to reduce pain/fever (such as paracetamol) at the time or closely after vaccination. You can discuss and get advice from your study doctor.

This is the first time that the study vaccines MenACWY-7B and MenABCWY will be given in babies, so no side effect can be listed here for these investigational vaccines for this age group. However, as described earlier in this form, these vaccines are based upon 2 established vaccines, *Menveo* and *Bexsero* which have been tested in other studies and are marketed vaccines.

Possible side effects with *Bexsero*

As noted below, short lived fever and irritability are commonly seen after Bexsero, and the NHS recommends that all children receiving this vaccine at 2 and 4 months of age also receive a dose of paracetamol shortly after immunisation, and 3 further doses over the next 24 hours.

Infants and children (up to 10 years of age)

Very common (may happen in more than 1 in 10 people): fever greater than or equal to (38ºC), loss of appetite, swelling at the injection site, hardness at the injection site, redness at the injection site, tenderness at the injection site (including severe injection site tenderness resulting in crying when injected limb is moved), painful joints, sleepiness, feeling irritable, unusual crying, vomiting (uncommon after booster), diarrhoea, headache.

Common (may happen in up to 1 in 10 people): skin rash.

Uncommon (may happen in up to 1 in 100 people): high fever, (40°C) or greater, seizures (including febrile seizures), dry skin, paleness (rare after booster).

Rare (may happen in up to 1 in 1000 people): Kawasaki disease (which can have symptoms such as fever that lasts for more than five days, associated with a skin rash on the trunk of the body, and sometimes followed by a peeling of the skin on the hands and fingers, swollen glands in the neck, red eyes, lips, throat and tongue), skin rash that can be itchy.

Other side effects (all age groups)

Side effects that have been reported during marketed use include:

- enlarged lymph nodes;
- allergic reactions that may include severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing), difficulty breathing with wheezing or coughing, rash, loss of consciousness and very low blood pressure;
- fainting or collapsing, less responsive than usual or lack of awareness, and paleness or bluish skin discoloration in young children; feeling faint or fainting;
- skin rash (adolescents from 11 years of age and adults);
- fever (adolescents from 11 years of age and adults); injection site reactions like extensive swelling of the vaccinated limb, blisters at or around the injection site and hard lump at the injection site (which may last for more than one month).

If you would like more information about this vaccine, you can request a copy of the prescribing information from the study team.

Possible side effects with *Infanrix hexa*

See your doctor straight away if your child has any of the following serious side effects: collapse, times when they lose consciousness or have a lack of awareness, fits – with or without fever.

These side effects have happened very rarely with other vaccines against whooping cough. They usually happen within 2 to 3 days after vaccination.

Other side effects include:

Very common (these may occur with more than 1 in 10 doses of the vaccine): loss of appetite, unusual crying, feeling irritable or restless, pain, redness and swelling where the injection was given, fever of 38°C or higher, sleepiness.

Common (these may occur with up to 1 in 10 doses of the vaccine): feeling nervous, being sick (vomiting), diarrhoea, fever higher than 39.5°C, swelling larger than 5 cm where the injection was given, hard lump where the injection was given, itching.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine): upper respiratory tract infection, tiredness, cough, large swelling of the vaccinated limb

Rare (these may occur with up to 1 in 1,000 doses of the vaccine): bronchitis, rash

Very Rare (these may occur with up to 1 in 10,000 doses of the vaccine): swollen glands in the neck, armpit or groin (lymphadenopathy), Bleeding or bruising more easily than normal (thrombocytopenia), temporarily stopping breathing (apnoea), in babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioneurotic oedema), swelling of the whole injected limb, blister where the injection was given, hives (urticaria), skin rash (dermatitis).

If you would like more information about this vaccine, you can request a copy of the prescribing information from the study team.

Possible side effects with *Rotarix*

Common (these may occur with up to 1 in 10 doses of the vaccine): diarrhoea, irritability.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine): pain in the stomach (see also below for signs of very rare side effects of intussusception), flatulence, dermatitis.

Side effects that occurred during routine use of Rotarix include:

Rare (these may occur with up to 1 in 1,000 doses of the vaccine): blood in stools, children with a rare inherited illness called Severe Combined Immunodeficiency (SCID) may have an inflamed stomach or gut (gastroenteritis) and pass the vaccine virus in their stools. The signs of gastroenteritis may include feeling sick, being sick, stomach cramps or diarrhoea.

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine): intussusception (part of the intestine gets blocked or twisted). The signs may include severe stomach pain, persistent vomiting, blood in stools, a swollen belly and/or high fever. **Contact a doctor/health care professional right away if your child experiences these symptoms.**

- **Large safety studies conducted since the vaccine is on the market have shown that intussusception occurs more frequently in the first week after the first dose, and to a lesser extent after the second dose.**
- **Pieces from a virus that is commonly seen in animals (called "PCV-1") were found in Rotarix vaccine. This virus does not make animals or people sick.**

  If you would like more information about this vaccine, you can request a copy of the prescribing information from the study team.

Possible side effects with *Nimenrix*

Very common (these may occur with more than 1 in 10 doses of the vaccine):

• fever

• tiredness (fatigue)

• headache

• feeling drowsy

• loss of appetite

• feeling irritable

• swelling, pain and redness where the injection is given.

Common (these may occur with up to 1 in 10 doses of the vaccine):

• bruising (haematoma) where the injection is given

• stomach and digestion problems such as diarrhoea, vomiting and nausea

• rash (infants).

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

• rash

• crying

• itching

• feeling dizzy

• aching muscles

• pain in the arms or legs

• generally feeling unwell

• difficulty sleeping

• decreased feeling or sensitivity, especially in the skin

• reactions where the injection is given such as itching, a feeling of warmth or numbness or a hard lump.

Not known: frequency cannot be estimated from the available data

• injection site swelling and redness; this may affect a large area of the vaccinated limb

• enlarged lymph nodes.

If you would like more information about this vaccine, you can request a copy of the prescribing information from the study team.

Possible side effects with *Prevenar13*

The following side effects include those reported for Prevenar 13 in infants and children

(6 weeks to 5 years of age):

The most common side effects (these may occur with more than 1 in 10 doses of the vaccine) are:

• Decreased appetite

• Fever; irritability; pain, tenderness, redness, swelling or hardness at the vaccination-site;

drowsiness; restless sleep

• Redness, hardness, swelling at the vaccination-site of 2.5 cm -7.0 cm (after the booster dose and in

older children [aged 2 to 5 years])

Common side effects (these may occur with up to 1 in 10 doses of the vaccine) are:

• Vomiting; diarrhoea

• Fever of more than 39°C; tenderness at the vaccination-site interfering with movement, redness,

hardness, swelling at the vaccination-site of 2.5 cm -7.0 cm (after the initial course of injections)

• Rash

Uncommon side effects (these may occur with up to 1 in 100 doses of the vaccine) are:

• Seizures (or fits), including those caused by a high temperature

• Hives (urticaria or urticaria-like rash)

• Redness, swelling, or hardness at the vaccination-site of more than 7 cm; crying

Rare side effects (these may occur with up to 1 in 1,000 doses of the vaccine) are:

• Collapse or shock-like state (hypotonic-hyporesponsive episode)

• Allergic (hypersensitivity) reaction, including swelling of the face and/or lips, difficulty in breathing

The following additional side effects have been seen with Prevenar 13 in postmarketing experience

• Severe allergic reaction including shock (cardiovascular collapse); angioedema (swelling of lips,

face or throat)

• Hives (urticaria), redness and irritation (dermatitis) and itching (pruritus) at the vaccination-site;

flushing

• Enlarged lymph nodes or glands (lymphadenopathy) near the vaccination-site, such as under the

arm or in the groin

• A rash causing itchy red blotches (erythema multiforme)

If you would like more information about this vaccine, you can request a copy of the prescribing information from the study team.

Other risks in the study:

- **Possible risks from injections**: Pain, redness, soreness, itchiness, swelling, or bruising. There is a very small chance of infection.
- **Possible risks from giving blood**: Your child may feel faint, have mild local pain, bruising, irritation or redness from the needle.
- **Latex**: Your child should not receive the vaccine if he/she allergic to latex.
- **Allergy:** Your child should not receive the study vaccine if he/she have had an allergic reaction (hypersensitivity) to any of the ingredients of the study vaccine.

Are there other vaccines or treatments available?

There is no combined meningitis vaccine available in the market that may help protect against all 5 meningococcus germ types A, B, C, W and Y in one injection. However in the UK schedule infants do receive Bexsero at 2, 4 and 12 months of age, and MenACWY as a teenager.

Age	Current UK schedule	Study schedule (variable according to study group)
2 months	Bexsero Infanrix-Hexa Rotarix (oral)	**MenACWY-7B or Men ACWY + Men B (control)** DTaP/Hib/HepB/IPV PCV13 Rotarix (oral)

3 months	Prevenar13 Infanrix-Hexa Rotarix (oral)	
4 months	Bexsero Infanrix-Hexa	**MenACWY-7B or Men ACWY + Men B (control)** DTaP/Hib/HepB/IPV PCV13 Rotarix (oral)
12 months	Bexsero Prevanar13 Hib-MenC* MMR	**MenACWY-7B or Men ACWY + Men B (control)** DTaP/Hib/HepB/IPV PCV13
13 month		**MMR**

Hib-MenC is administered as a booster dose against Haemophilus influenza type b (Hib) and type C meningococcus (MenC). In this study this would be replaced by the vaccines containing MenACWY (for MenC) and Infanrix-hexa (for Hib).

What will happen to your child's samples?

As part of the study, your child's blood samples will be taken. Your child's samples will be given a unique code number. The code number will not identify your child directly and will not have your child's personal information (data).

Your child's samples may be sent to GSK laboratories, other laboratories working on behalf of GSK or institutions working with GSK. These institutions and/or laboratories may be outside the country where you live.

Your child's samples will be tested to look at how his/her body reacts to the study vaccine(s).

Your child's samples will also be used to perform additional tests, during and after the study to:

- **Ensure the quality of the tests used for the study vaccine(s) or disease(s) is maintained over time,**
- **Develop and improve tests related to the study vaccine(s) or disease(s).**

These additional tests will never include genetic testing. Genetic testing means tests to look at your family traits (the things passed down in your family).

Your child's samples will be kept for a maximum of 20 years from the end of the entire study.

What will happen to your child's personal information (data)?

The study doctor and other study staff will collect data that can identify your child. This may include your child's name, address, phone number and treatment history. Personal health information will be collected as part of the study. Once collected, either on site or at your home**, data that directly identifies your child will not leave the study site (except for home study visits) or be sent to GSK.**

During this study, your child will be assigned a unique code number. Your child's data will be collected and shared only in relation to this code number. Data that directly identifies you will not leave the study site (except for home study visits) or be sent to GSK.

The data collected about your child will be held by Oxford Vaccine Group and GSK and/or third parties working on behalf of GSK and/or institutions working with GSK. GSK will protect all data collected about your child and will only share it as described in this consent form.

The coded data may be:

- **Shared by GSK with health agencies.**
- **Used to test and improve computer software used by GSK.**
- **Combined with results from other studies to better understand the effects of** vaccine(s) **on higher number of people.**

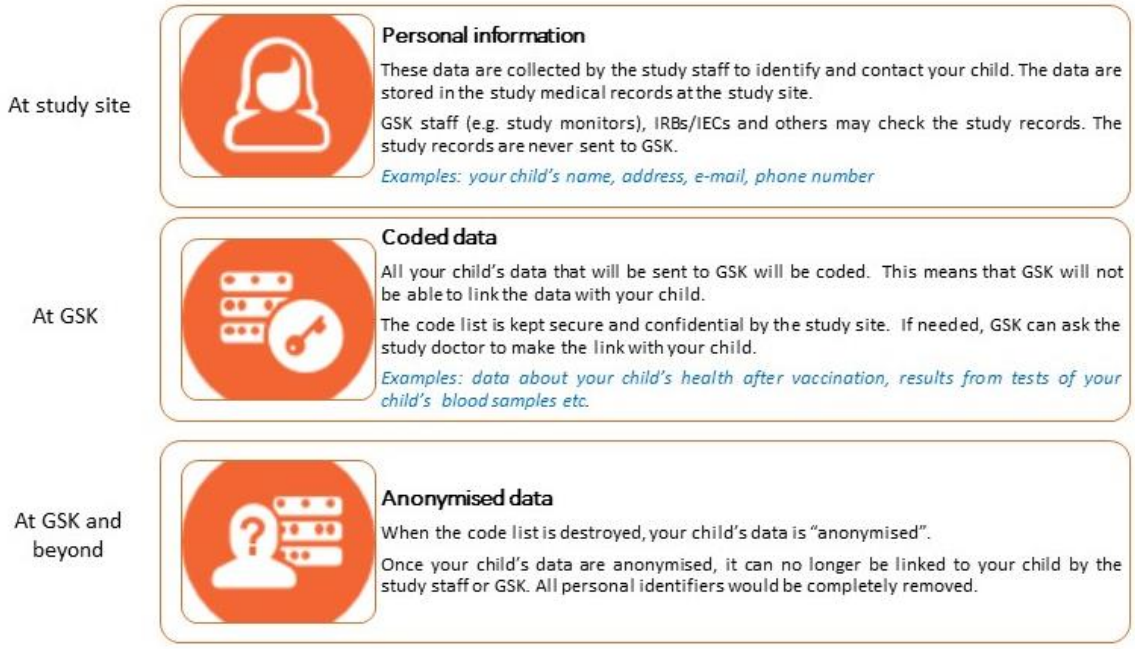
In addition, GSK may need to anonymise your child's data. This means your child's code number can no longer be linked to you him/her. GSK, other scientists and organisations use anonymised data to learn about diseases and medicines. Anonymised data may be used for this study or other purposes, including further research.

Your child may be offered an opportunity to have study visits performed at your home. If you and your doctor agree to utilise home care services, a licensed nurse will contact you to schedule the visits.

If you do not agree with the use of your child's data as described in this form, your child cannot join this study.

Go to Figure 2 and Annex 1 to learn more about how your data will be used.

Figure 2 What happens to your child's data



OPTIONAL USE OF SAMPLES AND CODED DATA

If you agree, your child's samples that are left over after the end of the study and his/her coded data may be used for:

- **Further research related to the study vaccines and/or disease. This means additional studies conducted to understand the study vaccines and/or diseases better.**
- **Further research NOT related to the study vaccine(s) and/or disease(s). This means additional studies conducted to understand other vaccines(s) and/or diseases or for the development of new treatments or research methods. In this case, this research will always be approved by an IEC.**

The results of these further research studies will not be shared with you.

Even if you disagree to the optional use of samples and coded data, your child can still join the study. You will be asked to indicate your choice on the signature page.

Who has access to your child's personal information?

All your child's personal information collected for this study will be stored in the study medical records at the study site. GSK staff, people working on behalf of GSK, review boards , and regulatory authorities may check the study records. This is done to make sure that the study is carried out in compliance with legal and quality requirements. For this purpose, personnel acting on behalf of the sponsor may view your child's data at study site or by using protected multimedia tools (e.g. secure email and/or fax, video or uploading your documents to a computer system). Appropriate measures will be taken to protect your child's personal information. No information directly identifying your child (e.g. name, address, phone number) will be retained by GSK staff or others acting on behalf of GSK.

Communication of information related to this study

The study doctor will tell you if a new vaccine or treatment for meningococcal disease becomes available in your country during this study. You can then decide if you wish that your child leaves the study to receive this new vaccine or treatment or to continue in this study. Any other new information that might change your choice to let your child stay in the study will be shared and discussed with you as soon as possible.

After the study has ended, the study results will be shared with the study doctor. You may ask the study doctor for the results and he/she will explain the results to you.

GSK will develop an easy to read summary of the study results. This result summary will be made available on https://www.trialsummaries.com. You may sign up now for an email notification when the summary becomes available.

Can your child leave the study?

Your child can leave the study at any time. You do not have to give a reason if you choose to withdraw your child. Tell the study doctor if you no longer want your child to take part. Your choice will not change the quality of care your child would receive outside of this study. If you decide to remove your child from the study, you and the study doctor will discuss the best way to do this and will arrange appropriate care for your child.

If you decide to withdraw your child from this study, all the data and samples collected while your child was in the study will remain as part of the study. These data and samples will be used as described in this form.

The study doctor may find out information about your child's health after he/she has left the study. If this information relates to the safety of the vaccine your child received during the study, the study doctor will send it to GSK.

Can your child be asked to leave the study?

Your child may be asked to leave the study if:

- **Test results show that this study is no longer right for your child.**
- **You do not follow the study instructions.**
- **The study doctor thinks it is best for your child to leave, for example if your child develops specific health problems.**
- **The entire study needs to be stopped for everyone.**

If this happens, the study doctor will explain the reason to you and ensure proper follow-up.

What happens if your child is harmed or injured during this study?

- **If it is an emergency, call the emergency number for help or go to the A & E department of your local hospital**.
- **If it is not an emergency, contact the study doctor immediately. He/she will take care of your child or will contact another doctor, if needed.**
- **If your child is injured by the study vaccine or a study procedure, he/she may be entitled to compensation, including payment or reimbursement for the cost of reasonable and necessary medical care. The study doctor can give you information about how to obtain compensation in case of injury.**

Signing this form will not change your child's right to take legal action if you believe your child was injured because of taking part in this study.

What happens during special circumstances like COVID-19 pandemic?

Some study procedures may be adapted to ensure your child's safety during special situations like the ongoing Coronavirus disease 2019 (COVID-19) pandemic.

Government and health authorities have issued advice and imposed certain restrictions to control the COVID-19 pandemic. It is important that you follow all official advice.

What should you do if you suspect your child has COVID-19 infection?

The most common symptoms of COVID-19 include fever, cough and difficulty in breathing or shortness of breath. If you/your child feel unwell or have any of the above symptoms, you should call your usual doctor or contact NHS 111. If you/your child are diagnosed with COVID-19 or test positive for SARS CoV02 please let the study doctor know

Will your child be paid for taking part in the study?

You will not be paid for taking part in this study. As part of the study, you will receive the vaccine and all the study tests and procedures at no cost to you.

Insurance coverage

Before taking part, you should consider if this will affect any insurance your child currently has or may purchase in the future. If you have a health insurance policy then seek advice if necessary from your insurance company.

Whom should you contact if you have questions?

If you have a complaint about any aspect of this study, first please talk with or call the study doctor or site staff member. If you would still like to raise a complaint, you may contact Oxford Vaccine Group on 01865 611400 or the local Patient Advice and Liaison Service (PALS)

Person to contact for any questions: Dr Genevieve Haddock, Oxford Vaccine Group, CCVTM, Churchill Hospital, Headington, Oxford. OX3 7LE. Tel: 01865 611400

Person to contact about your rights: Oxford Vaccine Group, CCVTM, Churchill Hospital, Headington, Oxford. OX3 7LE. Tel: 01865 611400, or the local Patient Advice and Liaison Service (PALS)

Person to contact in case of injury: Dr Genevieve Haddock, Oxford Vaccine Group, CCVTM, Churchill Hospital, Headington, Oxford. OX3 7LE. Tel: 01865 611400

Annex 1 How will your child's data be used?

Why will your child's data be collected?

Various data related to your child's participation in this study will be collected. GSK will use this data to address the purpose of the study, as well as for scientific and medical publications. Your child's data will be coded and handled as described earlier in this form.

Who will be able to see your child's data?

Your child's data may be shared with:

- **GSK, third parties working on behalf of GSK or institutions working with GSK. This is done to make sure that the study is being run properly.**
- **The researchers at this study site.**
- **Regulatory agencies, such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) or others, who review and approve new vaccines or medicines. These agencies will be granted direct access to your data. This is so that they can verify clinical trial procedures and/or data**.
- **The General Data Protection Regulation (GDPR) states that GSK must have a legal basis in law in order to process your sensitive personal data. The legal bases for processing your sensitive personal data in this study, including the collection of adverse event information are legitimate interest and scientific research, and for the collection of adverse events, public interest. The legal basis for processing your sensitive personal data for sharing and processing your data outside the United Kingdom and to process your data to undertake further research is your consent.**

Although the study results may be published in medical journals, on the internet and discussed in meetings, data that identifies your child will not appear in any publication or in any meetings.

What happens if your child's data is transferred?

Your child's coded data may be transferred to trusted persons in other countries. Data protection and privacy laws may not be as strong in these countries as the laws in your home country. However, when data is transferred, GSK makes sure that appropriate and suitable safeguards are used.

More information about these safeguards used is found at:

- **Standard Contractual Clauses page of European Commission website:** https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en

- GSK's Binding Corporate Rules webpage: https://www.gsk.com/en-gb/about-us/policies-codes-and-standards/binding-corporate-rules/

What are your rights to access your child's data?

At any time, you may ask the study doctor to look at your child's data. In certain circumstances, you may request:

- **To learn more about what is done with your child's data.**
- **A copy of your child's data.**
- **To correct and/or delete your child's data.**
- **To transfer your child's data to a third party (such as your personal doctor), in a format suitable for re-use. However, depending on when you request it, these rights to access, change or move your information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate**

You may also:

- **Object to what is done to your child's data by contacting the study doctor, the site's data privacy officer [insert details] or GSK's data privacy officer. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113)**
- **Claim compensation for damages caused due to unlawful use of your child's data, through the courts.**

How long will your child's data be used?

Your child's data will be used only for as long as it is needed for the study and further research, with your consent. It may be kept for longer, where required by law. GSK must keep the coded data from research studies for a minimum of 30 years.

WHERE ELSE CAN YOU FIND INFORMATION ABOUT THIS STUDY?

There will be a description of this study on the GSK Study Register http://www.gsk-clinicalstudyregister.com and/or other clinical trial registries. It may also appear in clinical trial registries in countries where the study is conducted.

A description of this study will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include data that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who will collect and process your child's data?

A data controller collects and processes data. It determines why and how it is processed. GlaxoSmithKline Biologicals SA is the data controller for this study.

Who owns the study results?

GSK will own the study results. GSK plans to use the results, and may get patents, or sell the vaccine in the future, or make profits in other ways. You will not be paid any part of this.

Whom should you contact if you have any questions?

For questions or requests regarding what is done to your child's data, please first contact the study doctor or site's data privacy officer. You can also contact the GSK's Data Privacy Officer at EU-DPO@gsk.com.

Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Telephone: 01865 611400 info@ovg.ox.ac.uk www.ovg.ox.ac.uk

Study Number:	
Centre Name:	
Study Participant Number:	

Name of Principal Researcher:……

A Phase II, randomised, partially blinded study to assess the safety, tolerability and immunogenicity of meningococcal combined ABCWY vaccine when administered to healthy infants.

Combining vaccines against meningitis: An infant immunisation study.

Consent Form

If you agree with each section below, please INITIAL the box:

NB. <*All*> boxes below need to be initialled in order for the participant to be enrolled in to the study.

		INITIAL
1)	I have read and understood the participant information sheet UK part 2 version 03 dated 01 Apr 2022 for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2)	I have been given time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to allow my child to take part in the study. I understand that participation in this study is voluntary and that I am free to withdraw my child from the study at any time, without giving any reason, without medical care or legal rights being affected, the study doctor may ask my child to leave the study at any time and my	

	child cannot be in another study while taking part in this study.	
3)	I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by responsible individuals from GlaxoSmithKline Biologicals S.A, companies acting on their behalf, NHS Trust/Health Board or regulatory authorities where it is relevant to my child taking part in research. I give permission for these individuals to have access to my child's records.	
4)	I have been given the names of study staff whom I can call.	
5)	I agree to my child's GP being informed about their participation in this study.	
6)	I agree that my child's personal and medical information can be used as described in the participant information sheet *(UK part 2 version 03 dated 01 Apr 2022).*	
7)	I agree that my child's samples are used as described in the participant information sheet *(UK part 2 version 03 dated 01 Apr 2022).*	
8)	I freely agree to my child taking part in this study.	

Please indicate if your child's samples and coded data can be used for further research <u>related</u> to this study vaccine/disease once the study is complete:

	Yes, I agree			**No, I do not agree**

Please indicate if your child's samples and coded data can be used for further research <u>NOT related</u> to this study vaccine or disease, once the study is complete:

	Yes, I agree			**No, I do not agree**

Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Telephone: 01865 611400 info@ovg.ox.ac.uk www.ovg.ox.ac.uk

Please indicate if your child's left over samples and coded data can be used for further research related to this study vaccine or disease, once the study is complete:

	Yes, I agree			**No, I do not agree**

indicate if your child's left over samples and coded data can be used for further research NOT related to this study vaccine or disease, once the study is complete:

	Yes, I agree			**No, I do not agree**

Please print and sign your name below and add today's date:

Name of study participant (infant): _____

_____	_____	_____
Name of parent/legal guardian	Signature	Date

Relationship with study participant: _____

_____	_____	_____
Name of person taking consent	Signature	Date

N.B. The parent/legal guardian must date his/her own signature

1 copy for parent/legal guardian study participant; 1 copy for study file; 1 copy to be kept with hospital/clinic notes.