

EEPRIS Study

Evaluation of Enhanced Paediatric Respiratory Infection Surveillance

EEPRIS is a single site community-based feasibility cohort study of paediatric respiratory infection surveillance. It is run by the University of Bristol together with Public Health England and is funded by the NIHR Health Protection Research Unit (HPRU).

The team are looking to recruit twelve GP practices within a ten mile radius of Bristol city centre to help run the study.

Aim: To assess the feasibility of collecting and using real time paediatric RTI microbiological surveillance data. EEPRIS will inform the design of a future full scale RTI surveillance cohort study with a nested randomised controlled trial of a real-time microbiology and illness profile intervention. EEPRIS will also provide evidence of the duration of community paediatric RTI and consultation rates.

What is involved:

- Practices will be required to run database searches and send letters of invitation to potential participants (via the research team's Docmail account).
- The research team will require a computer for medical notes review for approximately two full days per practice after April 2016 when the active participation phase is complete.
- Practices are asked to nominate two or more clinicians (GPs and/or Nurse Prescribers) to take part in a 30 minute one to one interview (in person or via telephone) about the wider aims of the study.

Reimbursement:

- SSCs are: £486 per practice (tbc)
- Research costs are approximately £500 per practice

These cover the costs of initial meetings, administrative tasks around study set up and patient mailout, occasional communication, two thirty minute clinician interviews, and providing facilities for a member of our research team to review medical notes of participants.

If you are interested in taking part or would like further information please contact the EEPRIS team:

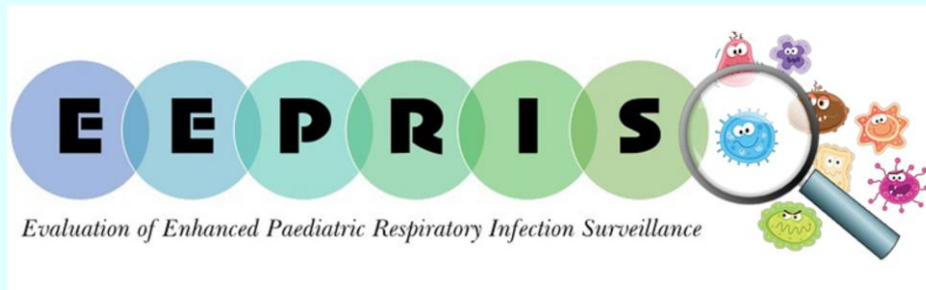
Emma Anderson (Study Manager) and Abhi Vora (Study Administrator)

Email: eepris-study@bristol.ac.uk

Tel: **0117 3314598**

Website: www.bristol.ac.uk/eepris (tbc)

Or please send expressions of interest to [*insert CRN contact details*]



Research Information Sheet for Practices

Study title: The EEPRIS Study. Evaluation of Enhanced Paediatric Respiratory Infection Surveillance: Community and primary care-based feasibility cohort study.

Location: Twelve GP surgeries within a ten mile radius of Bristol city centre. CCGs: Bristol, South Gloucestershire and North Somerset.

Research design: The University of Bristol (together with Public Health England) is conducting an enhanced paediatric respiratory tract infection (RTI) microbiology surveillance feasibility cohort study, with nested qualitative research. A prospectively recruited, representative cohort of children will be invited to contribute data regarding the incidence and symptom profile of RTIs, and the use of primary care services over one winter period (October 2015 to May/June 2016). Parents, children and clinicians will also contribute interview data.

Context:

There is a growing burden on primary care clinicians, as well as a growing public health threat of increasing antimicrobial resistance (AMR). Respiratory tract infections (RTIs) are the most common problem managed by primary care with the majority occurring in children and around 50% of patients given antibiotics. It is not clear precisely what proportion of children with RTIs are brought to the attention of primary care, but it is clear that even small changes in consultation rates could have a significant impact on primary care resources .

We are planning a future intervention to help parents make better consultation decisions and we think real-time information regarding the community circulation of paediatric RTI illness profiles with associated microbiology, could be useful for parents and clinicians. The purpose of EEPRIS is to establish the feasibility of the data collection methods, including microbiological data.

Recruitment

We would like 12 GP surgeries to help us recruit approximately 40 families each (or 65 children) in Bristol via Docmail mailout in winter of 2015 (/ early 2016). Interested families will be invited to contact the research team who will organise all subsequent data collection and follow up.

The Study Aim:

EEPRIS aims to assess the feasibility of collecting and using real time paediatric RTI symptom and microbiological data – the purpose of such data being to develop a clinician and/or parent-based intervention to improve primary care utilisation for paediatric RTI.

EEPRIS will inform the design of a future full scale RTI surveillance cohort study with a nested randomised controlled trial (RCT) of a real-time microbiology and illness profile intervention. EEPRIS will also provide evidence of the duration of community paediatric RTI and rates of consultation.

What is involved for the practice?

Once you have confirmed you would like to participate, we would like to visit your practice to meet with your practice manager/ data manager. This will be to complete the sign-up process, explain the study in more detail and provide all the information needed for the practice to send the Docmail study invitation .

Further tasks for participating practices will be to:

1. Nominate a management lead and a GP lead, for occasionally contact about the study
2. Run a database search to identify eligible children (exclusion codes provided), and provide anonymous demographics of search results to the research team
3. Run a sub-list for GP to review as possible exclusions
4. Send an invitation pack via the study Docmail prepaid account (instructions will be supplied) to parents of eligible children inviting them to take part in the research
5. Liaise with the research team to maintain a list of patients who opt in or out of the study
6. Send a second standard letter to any non-responders via Docmail
7. Send a SMS text to non-responders (if your surgery subscribes to a patient text service)
8. Report any Adverse Events (AE) and Serious Adverse Events (SAE) to the study team.
9. Provide a computer (for approximately two full days) for a member of the EEPRIS research team (who has appropriate data control clearances) to review participating children's medical notes for evidence of primary care RTI consultations (after May/June 2016)
10. Invite a sample of (two or more) GPs and/or nurse prescribers to each take part in a 30 minute audio-recorded interview about the wider aims of the study – i.e. the design, delivery and perceived impact of a future online intervention based on real-time community RTI surveillance data.

Optional: We would like to take notes of freely given comments about the wider aims of the study (i.e. the future intervention) in surgery meetings and other contacts about EEPRIS and potentially use them to supplement our clinician interview data for our nested qualitative research.

Maximum time and GP Practice staffing required:

- GP: 1.5 hours for main study; (plus 30 mins for each clinician interview)
- Practice manager: 3 hours for study set up and liaison
- Administrator: 6 hours for mailout administration, communication and support

Are practice costs reimbursed?

YES. We reimburse costs of staff time in setting up the study at a rate of **£236.64** per practice.

There are also Service Support Costs payable at **£486** (tbc) for the letter mailout tasks.

We additionally reimburse £40 per 30 minute clinician interview (average = 2 per practice = £80), and £12.50 per hour for computer and desk hire for notes reviewing (average = 2 days per practice = £200)

Practice feedback

Feedback of main study results will be offered to practices by a written report around the end of 2016. Feedback about the progress of the study will be provided via contacts with the research team.

NB: Results of individual patients' microbiological analysis will NOT be fed back to GPs. These are for research (not clinical/diagnostic) purposes only.

Ethical considerations

- The study will be conducted in accordance with the Research Governance Framework, NHS Research Ethics Committee and HRA approvals and University of Bristol guidance.
- Practice staff will send letters (via Docmail) to parents of children registered at the practice. The letter invites interested parents to contact the study team. The research team will not have access to any patient details unless they contact the research team directly.
- Patients are informed about risks and benefits of taking part before consenting to participate, and older children will not take part if they do not sign their assent.
- All information provided by research participants will be treated confidentially and stored on an encrypted database and in locked cabinets only accessible by the research team. This includes patient data and clinician interview data and any notes taken at meetings.
- Participating parents will be offered a £15 shopping voucher to thank them for contributing RTI data for any child within the study; and £5 for participating in an (optional) interview.

Study Team:

Dr Abhi Vora, Study Administrator

Ms Emma Anderson, Study Manager

Professor Alastair Hay, Chief Investigator

If you are interested, please contact Dr Abhi Vora as soon as possible:

Tel: **0117 3314598**

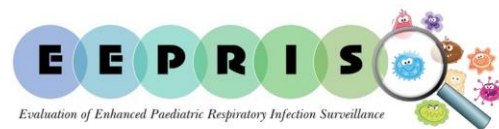
Email: **eepris-kids@bristol.ac.uk**

Address:

School of Social and Community Medicine,
University of Bristol,
Canynges Hall,
39 Whatley Road,
Bristol BS8 2PS

Website: **bristol.ac.uk/eepris**

For the parent/carer of
[Child's Name]
[Child's Address]



[Date]

For the parent/carer of [child's name],

You are invited to take part in a research study on children's coughs, colds and ear infections

We are helping the University of Bristol recruit parents and children into the EEPRIS study.

The EEPRIS study is interested in the symptoms of normal coughs, colds and ear infections that children develop over the winter. Your participation could help doctors better manage these common illnesses in children, and could in future help target antibiotic prescribing to the children that really need it. It can help parents to better understand how to manage their children's illnesses too.

The study is set up to collect information on the symptoms of these common infections and identify the viruses that cause them. Previous research tells us a good deal about respiratory infections when seen by doctors, but not so much about how they develop in the community.

Taking part in the study involves replying to a weekly email (or text) over the winter. Then if your child picks up a cough, cold, sore throat, ear infection or chest infection, we will ask you to provide some information online and have a research nurse visit your child to collect clinical information for the study.

Please read the information leaflet provided for more detail about what is involved. Then if you would like to take part, please send your completed consent form to the study team in the envelope provided. We want to enrol children as soon as possible at the beginning of winter to collect all the information we need, so please reply as soon as possible (within two weeks would be great). Please be aware that once we receive your consent form, we will need to ask a few questions to check that you and your child are eligible to take part.

You may receive more than one letter about this study if you have more than one child who is suitable to invite. The main information is the same, but each child has an individual consent form for you to return if you wish to enrol them in the study. There is no obligation to take part, and also, once you are enrolled, you remain free to opt out of the study at any time.

If you would like to ask questions before you sign up, please contact Emma (study manager) and Abhi (study administrator) on: **eepris-kids@bristol.ac.uk** or **0117 3314598**. If you know other parents who may be interested in taking part, please pass on the study web address for them to find out more information about getting involved: <http://www.bristol.ac.uk/eepris>.

Yours sincerely,

[Name of Doctor]

...helping to understand children's coughs, colds and ear infections

This leaflet provides information for parents and carers

We would like to invite you and your child to take part in our research study.

Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read the following information carefully and feel free to talk to others about the study if you wish.

Please don't hesitate to ask us if anything is unclear or if you would like more information, and take your time deciding whether or not you wish to take part.

What is the purpose of the study?

We are interested in the normal coughs, colds, sore throats, chest infections and ear infections that most children develop over the winter. These are collectively called **respiratory tract infections**. We know a good deal from previous research into these infections in children who are taken to the doctor. We know far less about how these symptoms develop out in the community (especially in children who do not go to the doctor with their symptoms).

We want to collect information about the symptoms of these illnesses going round in the local community and how long they last. We also want to try to find out what the actual bugs are by looking at nasal and saliva swabs taken from the children when they are ill and comparing these with swabs taken when they are well.

One main point of doing this work is to see if it would be possible to roll this out on a bigger scale to feed the information on illnesses going around in the community into an online resource. This type of 'real-time' illness information could help parents and GPs know what common bugs are going round in the area and how best to manage them – with a special interest in:

- helping parents know whether to take their child to the doctor, and
- helping GPs give antibiotics only to children who really need them

Study Contact Details

Abhi Vora Study Administrator	Tel: 0117 3314598 Email: eepris-kids@bristol.ac.uk Website: http://www.bristol.ac.uk/eepris
Emma Anderson Study Manager	Address: School of Social and Community Medicine, University of Bristol, Canyng Hall, 39 Whatley Road, Bristol BS8 2PS
Professor Alastair Hay Principal Investigator	

Why have my child and I been invited to take part?

You have been invited to take part in this study because your child is aged between 3 months and 15 years (and has no known condition affecting the immune system). This invitation to take part in our research has come from your GP surgery because it is one of several surgeries in Bristol who have agreed to invite their patients into our study. We at the University of Bristol have no access to your contact details or anything about you until you contact us directly yourself.

We are hoping to recruit nearly 500 parents (or about 800 children) to take part in our study to track normal respiratory infections (coughs, colds, sore throats, chest and ear infections) over the winter.

How long will we be involved if we take part?

If you decide to take part, you will be in the study for just a few weeks (minimum) or up to a whole winter period (maximum), depending on when (or if) your child develops a respiratory infection – and whether you carry on in the study after they get better. In other words:

- Minimum duration is from your enrolment in winter (2015/2016) until your child has one episode of illness (cough, cold, sore throat, chest or ear infection) through to recovery.
- Maximum duration is from your enrolment at the beginning of winter (2015) until we finish collecting data in May/June 2016.

Most children are expected to pick up at least one respiratory infection over this period. You can opt out of the study at any time.

What are the advantages of taking part?

You will be making a valuable contribution to research on the illnesses that affect most children in our country. The wider aims of this research are to improve the understanding, diagnosis and management of respiratory illnesses which could benefit your child and many other children in future. Ultimately we would like to set up a website that provides real-time information on the illnesses circulating in the community. This could help doctors make decisions about treatment, and help parents feel more confident in managing their children's health.

Will I be compensated for taking part in the study?

If your child develops a respiratory illness during the study (and it is likely that they will), and you complete our surveys and research nurse visit, we will give you a £15 high street voucher as a thank you gift for your time. If you also take part in the interview study, you will receive an extra £5 shopping voucher.

Are there any disadvantages in taking part?

The only disadvantage in taking part is the time taken – to answer research questions and to have a research nurse visit. There are no real risks in taking part, as we are simply collecting information about naturally occurring illnesses. Taking nasal and saliva swabs are simple procedures and are not uncomfortable for the child.

Will my taking part in this study be kept confidential?

Yes, all information collected about you and your child in this study will be kept strictly confidential in accordance with the Data Protection Act. Even your GP will not see your answers to the survey. Your name will not appear on any papers or reports. To keep your information confidential all survey answers will be identified by a code only, and stored on password protected computers in locked buildings which are alarmed when staff are not there. The computer based systems have secure encryption to ensure confidentiality for any data collected or sent over the internet.

Only staff on the research team or from regulatory authorities (University of Bristol, NHS R&D offices, and regulatory inspectors), who check the quality of the research, will be given access to the data, and only on an as-needed basis. A monitoring authority may also want to cross check the research data we collect with NHS medical notes for a small sample of our participants. Your identifiable details will only be available to the immediate study team who need it. Data records which cannot be linked to you or your child in any way will be kept securely for twenty years in line with University of Bristol policies.

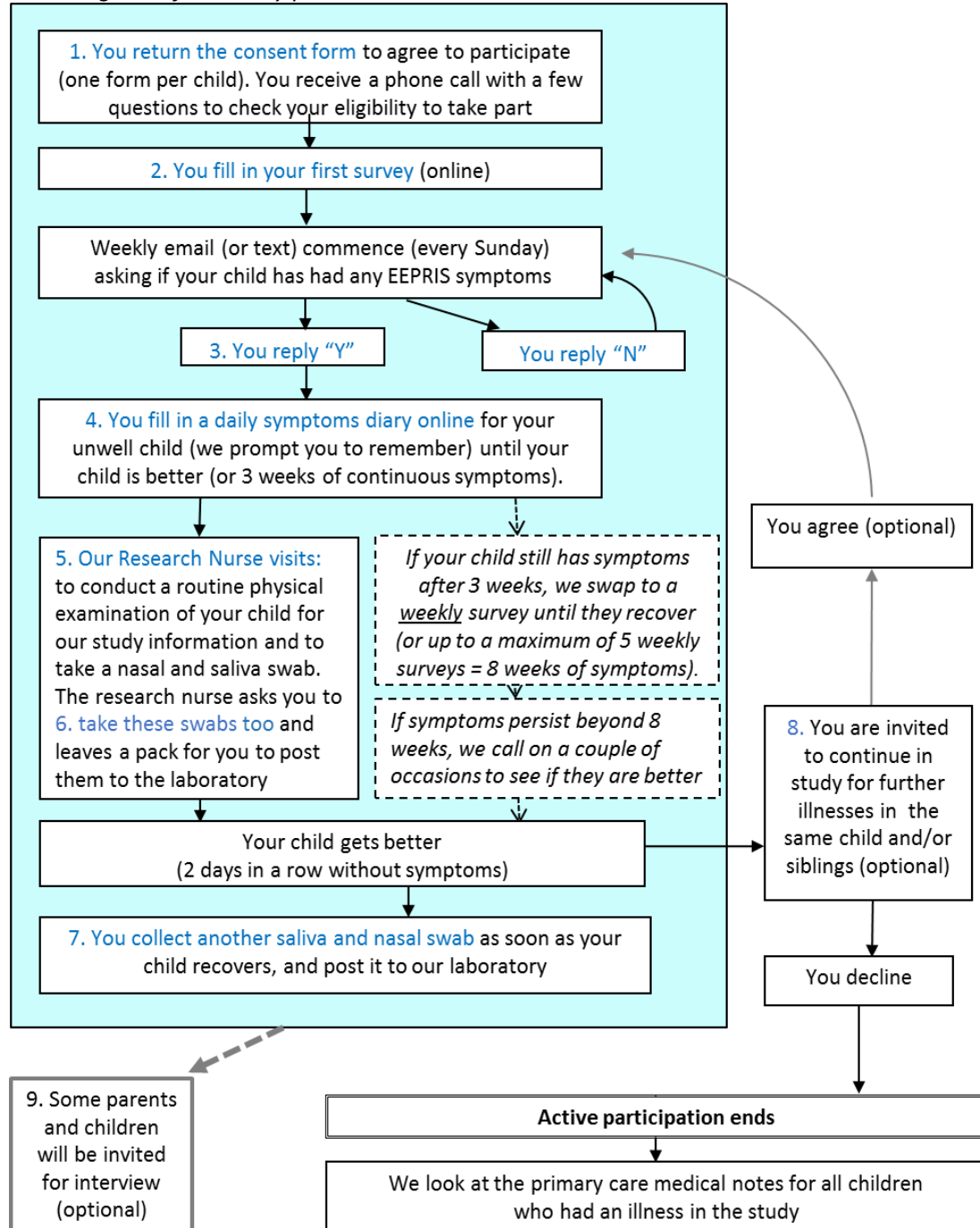
If we take part, what does it involve for me and my child?

1. Once you send back your complete consent form – one for each child – we will call you to check that you understand everything about the study and that you and your child are eligible to take part. If you are, we will welcome you to the study and send you an email with a link to fill in a brief online survey to start you in the study. Please note – there is a separate starter survey to complete for each child you enrol, but you will have just the one welcome phone call even if you have more than one child in the study.
2. Once you have filled in the survey, you will start to receive a weekly email (or text) every Sunday to ask if your child has developed any EEPRIS symptoms (cough, cold, sore throat, chesty symptoms or ear ache/discharge) in the last week. We ask that you respond (simple Yes/No) to each one. Please note – you will receive a separate email (/text) for each child you enrol.
3. When you reply Y (to tell us your child has developed any of the EEPRIS symptoms) we will email a link to complete a daily symptoms survey online (via phone, tablet or desktop).
4. We ask you to complete the daily survey (prompted by email or text reminders every two days) until your child feels better. We will call you if you forget to fill these in for a few days.
5. A research nurse will arrange to visit while your child is ill to take a record information on their physical symptoms for the study and collect a swab of saliva and a swab from just inside the child's nostril.
6. During the visit you will be asked to collect the same samples yourself which the research nurse will ask you to put in a post box to send to the laboratory (pre-paid postal packaging provided). This is because we want to compare swabs taken by a nurse with the swabs that parents can use and put in the post, to see if the posted ones will be good enough to use on a wider scale in future.
7. We ask you to collect one more set of saliva and nasal swabs (on your own at home using a kit provided by the research nurse) as soon as your child is better and post these to our laboratory.
8. Once you have provided information and swabs for one complete infection, you can opt to carry on in the study with the same child (and/or any other children in your household) or finish. If you opt to carry on, the weekly emails (or texts) will resume for any children you consent to carry on with. No weekly emails (or texts) checking for new symptoms will be sent after the end of our data collection phase (May/June 2016)

OPTIONAL:

9. We will invite a selection of parents and children to take part in one audio-recorded interview, of about 45 minutes, at your home (or location of choice). This is to find out parents' and children's experiences of taking part in the study, and to gather opinions on a possible future online resource of 'real-time' illness information. You do not have to agree to be interviewed to take part in the study.

Flow diagram of the study process:



Additional information

At the end of the winter period we will collect some information from the medical records of each child who had a respiratory infection in the study. We will check to see if they saw the GP or another healthcare professional when they were ill, and if antibiotics or other medications were prescribed.

We will also collect information from your child's medical records about any vaccines they have had and any major long-term conditions, as these can make a difference to how likely a child is to become ill. We will check for antibiotics prescribed in the 12 months before they were recruited to the study, and for any consultations in that time to do with respiratory infections. Only staff on the research team or clinical staff will be allowed to collect this information.

What will happen if we don't want to carry on with the study?

You and your child can leave the study at any time, without giving a reason. This will not affect the care your family receives now or in the future. If you do decide to leave the study, we will use the information we have collected up to that time, unless you tell us otherwise.

What will happen to my samples?

The samples will be sent to a laboratory to test what bugs (viruses and bacteria) they contain. Neither parents nor GPs will receive feedback on the findings from individual children's swabs.

We would also like to ask your permission to keep any left-over material from samples at the end of the study, rather than throw them away. This will allow us and/or other researchers to do further work on them in the future. Some of this could include genetic analysis (like DNA mapping) of the bacteria and viruses in the samples to gain more detailed information about them, with a potential for genetic analysis of your child's cells also (only to look for genes relating to risk factors for infection). You can separately decline for genetic analysis of samples. No information that could be used to identify you will be given to anyone using the samples. Neither the samples nor anything in them or any information related to them will be sold or used to make money. You will be able to say on the consent form whether you would be happy for your samples to be kept and used in this way or not, and you do not need to agree to any of this in order to take part in this study.

Who can take part?

You and your child (aged over 3 months and under 15 years) can take part if you:

- have legal responsibility for the child
- have access to the internet (preferably daily)
- are happy to give a brief (Y/N) response to a weekly email (or text) while in the study
- are willing to provide information online (via phone, tablet or desktop) if/when your child develops symptoms of a respiratory infection over the winter
- are willing to have a research nurse visit to do a basic physical examination to collect information for our study (e.g. listen to your child's chest, check oxygen levels, like doctor or nurse would in the NHS) collect saliva and nasal swabs from your child, and to take these swabs yourself as well.

Do we have to take part?

No, it is up to you whether or not you want your child to take part. Deciding not to take part will not affect the care you or your child receive from your doctor or nurse now or in the future. You have been given this information to read now, and the study team can discuss it with you in more detail if you would like to get in touch (contact details are at the beginning of this leaflet). A child-friendly copy of this information sheet is provided for your child to read, or for you to read to your child so that he or she can understand what is being asked and why.

For children in year 3 (aged 7/8 and over): If they are happy to be included then they will need to sign to say they agree to take part – on the child assent form (found on the back of the main consent form). This is as well as your consent. We have to make sure that any child who is unhappy about taking part knows they don't have to and it is OK for them to refuse. This form means that if your child can understand what is being explained but doesn't want to take part or sign the form, we will not include them.

What will happen to the results of the research study?

A report of the study results will be completed for the funding body. Results will also be published in scientific journals and presented at scientific conferences. You or your child will not be identified in any report, publication or presentation; all results will be completely anonymous.

We will send you a newsletter with a summary of the main results of the study, and we will update our website with links to study publications when they become available. It is a fairly lengthy process to publish results, so the final results of this study will not be available for at least a year.

What if relevant new information becomes available?

Sometimes we get new information about the illness being studied but this is unlikely to happen during the time you are involved in this study. If the study is stopped for any other reason, we will tell you and the care of your child by your doctor or nurse will continue as normal.

What if something goes wrong?

If you have complaints or concerns about the study, please get in touch with the study team in the first instance. Taking part in this study will not affect your normal rights to pursue any complaint about your medical treatment within the NHS in the normal way.

Remember, this is a research study, not medical care. If you have any concerns about your child's health or your own, please seek advice from your doctor (not the study team) as usual.

Who is organising and funding the study?

The research is run by the University of Bristol working with NHS GP surgeries in the Bristol area. Our research team is based in the School of Social and Community Medicine, which has a reputation for high quality research and experience with working with NHS patients, GPs and the public.

The study is funded by the National Institute for Health Research (NIHR), Health Protection Research Unit (HPRU). The HPRU is a partnership between universities across England and Public Health England (PHE) which supports high quality research to protect our health.

Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee to protect your child's safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the South West Frenchay Bristol Research Ethics Committee (reference: 15/SW/0264).

How do I enrol in the study?

If you have decided that you would like to take part, please:

- **Fill in the consent form (and ask your child to sign assent if in school year 3 or older)**
- **Post it back to the research team in the Freepost envelope provided.**

Once we receive this we will call you to check that you understand everything about the study and that you and your child are eligible to take part.

If you are, we will welcome you into the study, email you a copy of your consent information and the link to a survey to start you in the study, and send you a welcome pack in the post.

Thank you for reading this and considering taking part in this study

What is the EEPRIS team trying to find out?

Everyone gets a cough, cold or ear infection now and then. These are the most common illnesses that children get, yet there are some things we still don't know about them.

We want to find out how long these illnesses last, and what symptoms children have each day (for example, runny nose, sore throat, feeling tired). We also want to find out what germs might be making children ill.



Doctors and nurses want to be able to give the right advice and treatment. The more we know about illnesses, the better we can treat them.

Your parents or carers know about the study. If they are happy for you to join, it is still your choice if you do or not.

If you are in school year 3 or above, you will need to sign a form to show that you agree to help with this study.



Thank you for taking the time to read this or listening to someone read it to you

Who will know about me being in the study?

Your parent/carer, your doctor or nurse and the study team, and anyone you choose to tell.

What if I want to know more or have a problem with the study?

Your parent/carer will probably be able to help, and they will know how to contact the study team. You can also email us at: **eepris-kids@bristol.ac.uk**

But please make sure your parent/carer knows first as we are likely to get in touch with them if there is a problem

Thank you again for reading this

Professor Alastair Hay (Principal Investigator)
and the EEPRIS Team.

Any questions? Please contact:

Emma Anderson, Study Manager
Abhi Vora, Administrator

Tel: 0117 3314598

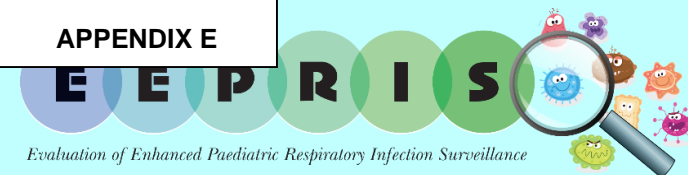
Email: eepris-kids@bristol.ac.uk

Or check out our website:

www.bristol.ac.uk/eepris



APPENDIX E



...helping to understand children's
coughs, colds and ear infections

Young person's leaflet

Do you want to be a
Health Research Hero?



How can I help?

You can be a health research hero by signing up to our study!

We want to find out about any cough, cold, sore throat or ear infection you catch this winter.



What do you want me to do?

You don't need to do anything at first. We will send a message to your parent/carer each week to see if you pick up a cough, cold, sore throat or ear infection over the winter.

If you do pick one up, we will ask your parent/carer to keep a diary of your symptoms each day and we will arrange for a nurse to come and visit you.



* Help keep a diary until you are better:

Your parent will fill in a diary, which asks about your symptoms (like runny nose, sore throat, feeling tired).

It will take a few minutes each day and you can help them make sure they get it right!

* Have a research nurse come and visit:

- The research nurse will ask you some questions about your illness and take a look at you to see how you are. The research nurse will take your temperature and pulse and check your throat and your breathing

- The research nurse will also take a swab from your nose, and another one of your saliva (spit) and ask your parent to do this too



* When you are better:

We will ask your parent to take **one more set of swabs** to see if the germs we thought were causing the illness have gone.

Nose and saliva (spit) swabs

We want to take swabs because we would like to try to find out exactly which germs might be making you ill. The nurse will gently wipe a cotton bud just inside your nose to "catch" some of the germs that may be making you ill. This won't hurt. The nurse will ask you to suck on another cotton bud to take some of your saliva (spit).

We want your parent/carer to take these swabs too to see if we find the same germs on them all.

Having the swabs taken is quick and easy.

We will send the swabs to a lab where they will look closely at the germs (like under a microscope) to see what is in there.



Then what happens?

Once you are better, you can finish if you like. Otherwise you can carry on in the study in case you catch something else before the end of April (if you and your parent/carer are happy to).

We will invite some parents and children in the study to tell us about their experiences of taking part. This would be by a researcher coming to your house and asking some questions and recording your answers. You don't have to agree to this to take part in the study.

When I have finished, then what?

We will look at the notes kept by your doctor to understand your medical history and check which vaccines you have had since you were a baby. We will also check if you saw a doctor or nurse for your illness when you were in the study.

We will keep the nose and saliva swabs so that we can look at the germs again in future.



We need to keep just enough information about your illness and about you so that researchers can learn more about these illnesses in the future. They won't be able to find out who each of the swabs or information came from.

At the end of the study, we will write a report which explains what we found. We will share this with doctors and people who help treat you and we will send a letter to your parents to explain what we find.

What if I want to leave the study? You can leave the study at any time and you don't need to tell us why.



EEPRIS STUDY CONSENT FORM

If you have any questions you wish to ask before you sign this consent form, contact the study team on: Tel: **0117 331 4598** or eepris-kids@bristol.ac.uk

IRAS Project ID: 180097

[child's first name] <small>All fields pre-filled in by GP</small>	[child's surname]	[child's DOB]	[M/F]	[child's NHS no.]	[Child's GP surgery]
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Please write your INITIALS in these boxes to confirm that you agree with each statement

1. I have read and understand the study information sheet (version 1, 2015-08-13). I have considered the information and had the opportunity to contact the team with questions (answered satisfactorily if applicable).	<input type="checkbox"/>	<input type="checkbox"/>
2. I understand that the participation of my child (named above) and me is voluntary and we are free to withdraw at any time, without giving reason, without our medical care or legal rights being affected.	<input type="checkbox"/>	<input type="checkbox"/>
3. I agree to receive, check and reply to weekly contact from the study team via mobile phone or email to confirm my child's respiratory illness status (cough, cold, or ear infection) over the winter.	<input type="checkbox"/>	<input type="checkbox"/>
4. I agree to provide information online for the study (via phone, tablet or desktop).	<input type="checkbox"/>	<input type="checkbox"/>
5. I agree to my GP being informed of my child's participation in this study.	<input type="checkbox"/>	<input type="checkbox"/>
6. If my child (named above) develops respiratory symptoms during the study, I agree to a nurse visit to conduct a routine physical examination of my child and collect saliva and nasal swabs from my child, and for me to collect saliva and nasal swabs at the same time, and again when my child is better.	<input type="checkbox"/>	<input type="checkbox"/>
7. If my child (named above) develops respiratory symptoms in the study, I agree to answer online questions while s/he is ill, and receive reminders (by text/email/telephone) from the study team to do this.	<input type="checkbox"/>	<input type="checkbox"/>
8. I give permission for the medical notes of my child (named above) to be accessed by members of the EEPRIS Study team for data collection relevant to taking part in this research. I understand that this may also include regulatory authorities (for study monitoring purposes only).	<input type="checkbox"/>	<input type="checkbox"/>
9. I understand that information collected for this study will be held securely under provisions of the 1998 Data Protection Act; electronic files in encoded format; paper files stored securely at the University.	<input type="checkbox"/>	<input type="checkbox"/>
10. I agree to the use of my child's and my anonymised data in reports and publications of the study.	<input type="checkbox"/>	<input type="checkbox"/>
11. I understand that this is research, not medical care. I will see my GP for health concerns about me or my child as normal.	<input type="checkbox"/>	<input type="checkbox"/>
12. I agree for me and my child (named above) to take part in the EEPRIS study.	<input type="checkbox"/>	<input type="checkbox"/>

Please note that you can still participate whether or not you agree to the following four statements:

1. Our anonymised information can be stored for possible use in future projects by other researchers.	<input type="checkbox"/>	<input type="checkbox"/>
2. My child's left-over study samples may be stored anonymously (any identification linking me and my child to the sample is destroyed) and may be analysed in future genetic research.	<input type="checkbox"/>	<input type="checkbox"/>
3. My child's left-over samples may be stored anonymously (any identification linking me and my child to the sample is destroyed) and may be analysed in future non-genetic research.	<input type="checkbox"/>	<input type="checkbox"/>
4. I agree to take part in one audio-recorded interview (of up to forty five minute duration) if I am selected for interview after participating - about my experiences of the study and the wider aims of this research.	<input type="checkbox"/>	<input type="checkbox"/>

PARENT/ CARER DETAILS (Please use block capitals to fill in):

Title:	First name:	Surname:	Preferred name (if applicable):	Gender: M / F
Postal address:				Post code:
Mobile number:		Landline number:	Email address:	
Can we leave answer messages (e.g. to remind you to complete questionnaires)?			On your mobile: Y / N	On your landline: Y / N

I confirm that I have legal responsibility for the child named above and s/he is registered as a full (not temporary) patient at: [GP practice name – updated by practice].

Signature of parent/carer:	Date: / / 20 DD MM YY YY YY
----------------------------	--

EEPRIS STUDY CONSENT FORM

If you have any questions you wish to ask before you sign this consent form, contact the study team on: Tel: **0117 331 4598** or eepris-kids@bristol.ac.uk

IRAS Project ID: 180097

[child's first name] <small>All fields pre-filled in by GP</small>	[child's surname]	[child's DOB]	[M/F]	[child's NHS no.]	[Child's GP surgery]
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Please write your INITIALS in these boxes to confirm that you agree with each statement

1. I have read and understand the study information sheet (version 1, 2015-08-13). I have considered the information and had the opportunity to contact the team with questions (answered satisfactorily if applicable).	<input type="checkbox"/>	<input type="checkbox"/>
2. I understand that the participation of my child (named above) and me is voluntary and we are free to withdraw at any time, without giving reason, without our medical care or legal rights being affected.	<input type="checkbox"/>	<input type="checkbox"/>
3. I agree to receive, check and reply to weekly contact from the study team via mobile phone or email to confirm my child's respiratory illness status (cough, cold, or ear infection) over the winter.	<input type="checkbox"/>	<input type="checkbox"/>
4. I agree to provide information online for the study (via phone, tablet or desktop).	<input type="checkbox"/>	<input type="checkbox"/>
5. I agree to my GP being informed of my child's participation in this study.	<input type="checkbox"/>	<input type="checkbox"/>
6. If my child (named above) develops respiratory symptoms during the study, I agree to a nurse visit to conduct a routine physical examination of my child and collect saliva and nasal swabs from my child, and for me to collect saliva and nasal swabs at the same time, and again when my child is better.	<input type="checkbox"/>	<input type="checkbox"/>
7. If my child (named above) develops respiratory symptoms in the study, I agree to answer online questions while s/he is ill, and receive reminders (by text/email/telephone) from the study team to do this.	<input type="checkbox"/>	<input type="checkbox"/>
8. I give permission for the medical notes of my child (named above) to be accessed by members of the EEPRIS Study team for data collection relevant to taking part in this research. I understand that this may also include regulatory authorities (for study monitoring purposes only).	<input type="checkbox"/>	<input type="checkbox"/>
9. I understand that information collected for this study will be held securely under provisions of the 1998 Data Protection Act; electronic files in encoded format; paper files stored securely at the University.	<input type="checkbox"/>	<input type="checkbox"/>
10. I agree to the use of my child's and my anonymised data in reports and publications of the study.	<input type="checkbox"/>	<input type="checkbox"/>
11. I understand that this is research, not medical care. I will see my GP for health concerns about me or my child as normal.	<input type="checkbox"/>	<input type="checkbox"/>
12. I agree for me and my child (named above) to take part in the EEPRIS study.	<input type="checkbox"/>	<input type="checkbox"/>

Please note that you can still participate whether or not you agree to the following four statements:

1. Our anonymised information can be stored for possible use in future projects by other researchers.	<input type="checkbox"/>	<input type="checkbox"/>
2. My child's left-over study samples may be stored anonymously (any identification linking me and my child to the sample is destroyed) and may be analysed in future genetic research.	<input type="checkbox"/>	<input type="checkbox"/>
3. My child's left-over samples may be stored anonymously (any identification linking me and my child to the sample is destroyed) and may be analysed in future non-genetic research.	<input type="checkbox"/>	<input type="checkbox"/>
4. I agree to take part in one audio-recorded interview (of up to forty five minute duration) if I am selected for interview after participating - about my experiences of the study and the wider aims of this research.	<input type="checkbox"/>	<input type="checkbox"/>

PARENT/ CARER DETAILS (Please use block capitals to fill in):

Title:	First name:	Surname:	Preferred name (if applicable):	Gender: M / F
Postal address:				Post code:
Mobile number:	Landline number:	Email address:		
Can we leave answer messages (e.g. to remind you to complete questionnaires)?		On your mobile: Y / N	On your landline: Y / N	

I confirm that I have legal responsibility for the child named above and s/he is registered as a full (not temporary) patient at: **[GP practice name – updated by practice]**.

Signature of parent/carer:	Date: <u> </u> / <u> </u> / 20 <u> </u> D D M M Y Y Y Y
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PLEASE ALSO ASK YOUR CHILD TO SIGN ASSENT OVERLEAF

EEPRIS STUDY CONSENT FORM

If you have any questions you wish to ask before you sign this consent form, contact the study team on: Tel: **0117 331 4598** or eepris-kids@bristol.ac.uk

For young people in school year 3 (7-8 years old) and above



EEPRIS STUDY ASSENT FORM

(Assent means you are agreeing to help with this study)



Please circle Yes or No for each question:

1. I have read or had read to me the study booklet and this form about agreeing to take part	YES NO
2. If I have any questions I know I can ask my parents or the people running the study	YES NO
3. I understand that this study is about coughs and colds and ear infections	YES NO
4. I know that if I get a cough or cold or an ear infection this winter, my parent will be filling in a survey about it	YES NO
5. I understand that if I get a cough or a cold this winter, a nurse will visit me	YES NO
6. I understand that when the nurse visits, my parent and the nurse will take swabs from me: one from just inside my nose, and one of my saliva (spit) to be tested for germs	YES NO
7. I understand that the germs will be kept and may be used for research in the future	YES NO
8. I understand that I will have one more swab taken when I'm feeling better	YES NO
9. I understand that a researcher may come round to talk with me and my parent about what it was like to take part in the study. I know I don't have to take part in this if I don't want to.	YES NO
10. I know I can stop taking part in the study at any time without having to give a reason why.	YES NO

I am happy to take part in the study (please circle):	YES NO
My first name is:	My surname is:
My signature:	Today's date is: _____ / _____ / 20____ D D M M Y Y Y Y

If you don't want to take part, don't sign your name!

[GP Practice headed paper with logo]

For the parent/carer of
[Child's Name]
[Child's Address]



[Date]

For the parent/carer of [child's name],

Follow-up on invitation to take part in the EEPRIS research study

You may remember our writing to you about taking part in the EEPRIS study – this is a research project aimed at helping us to better understand children's coughs, colds and ear infections. Your participation could help doctors better manage these common illnesses in children.

The EEPRIS study team have not received your completed form and so we would like to remind you that if you would like to take part in the study, please send in your consent form as soon as possible (please ignore this letter if you have recently done this). This is the first step in the process. Once the study team receive your form, they will call you and send you a link to fill in a survey to get you started.

If you would like to ask anything about the study before signing up, please contact the EEPRIS study team either by email: eepris-kids@bristol.ac.uk or you can talk to Emma (study manager) or Abhi (study administrator) on **0117 3314598**. More information is also available on their website <http://www.bristol.ac.uk/eepris/>.

You are not under any obligation to take part in this study and the study team do not have your contact details. If you do not contact the study team yourself, we will assume you would rather not take part in this research.

Thank you for reading about the EEPRIS study.

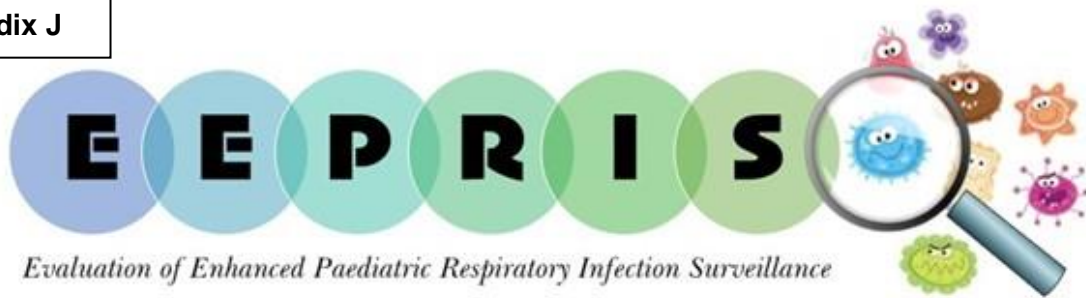
Yours sincerely,

[Name of Doctor]



“If you wish to take part in the EEPRIS study of children’s coughs, colds and ear infections, please return your form. For info: <http://www.bristol.ac.uk/eepris/> (tbc)”

[160 characters]



...helping to understand children's coughs, colds and ear infections

The first step to developing better ways to treat the most common infections in children is to understand more about them. We want to find out how coughs, colds and ear infections develop at home, and what those infections actually are.



- **Would you like to help with this new research?**
- **Do you have a child aged between 3 months and 15 years?**
- **Could you fill in questionnaires online (on your smart phone, tablet or computer)?**

If you are interested in taking part or want to find out more:

Call: (0117) 33 14598

e-mail: eepris-kids@bristol.ac.uk

Website: <http://www.bristol.ac.uk/eepris> (tbc)

Or you can pick up a card from reception.

Emma Anderson (Study Manager), Abhi Vora (Study Administrator), Alastair Hay (Professor of Primary Care and General Practitioner)
Centre for Academic Primary Care, School of Social and Community Medicine, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS



Contact card for recruitment

Recommend a friend! Please pass this card to other Bristol parents

EEPRIS 

Evaluation of Enhanced Paediatric Respiratory Infection Surveillance

...helping to understand children's coughs, colds and ear infections

For information about our study and how to take part please visit:
<http://www.bristol.ac.uk/eepris>

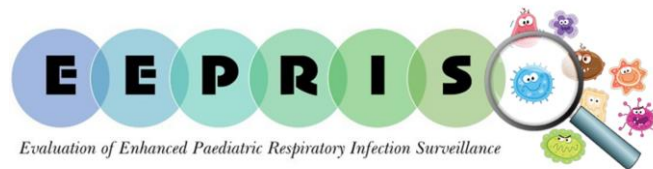
Or contact the EEPRIS Study team direct:
Email: eepris-kids@bristol.ac.uk Tel: (0117) 331 4598

 University of
BRISTOL





 Public Health
England



Centre for Academic Primary Care, School of Social and Community Medicine
University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS

telephone: (0117) 331 4598
email: eepris-study@bristol.ac.uk
website: <http://www.bristol.ac.uk/eepris/> (tbc)

[Parent's Name]
[Address]

Parent ID code:
[insert code]

[Date]

Dear [parentstitle] [parentssurname]

Welcome to EEPRIS!

Thank you very much for enrolling [child/ren's name(s)] into the EEPRIS Study; we are delighted that you want to take part in this important study that will help us to better understand children's coughs, colds and ear infections.

You will by now have received a web link (on your phone or by email) to your first online survey – one for each child you have enrolled – to start you in the study. Thank you if you have already filled in this survey. Filling it in is an important step in the process because it gives us “baseline information”. Once it is filled in you will receive the weekly emails (or texts) asking about your child's health. These will come every Sunday early evening, and ask you to click on a link to respond (simple “yes” or “no”) to whether your child has developed any of the EEPRIS symptoms over the last week.

We have included with this letter a fridge magnet that will help you remember the symptoms to look out for (remember, this is over and above what is normal for your child), and a poster guide to taking part. (You might like to use the magnet to keep the poster in view!).

We have also included some contact cards that you are welcome to hand to other parents who you think might be interested in the EEPRIS study.

You have more detail about the study in the information sheet that you received from your GP. A copy of this can be found on our website: <http://www.bristol.ac.uk/eepris>.

If at any time there is something you would like to ask about the study, you can contact Emma (study manager) or Abhi (study administrator) either by email: eepris-kids@bristol.ac.uk or you can talk to one of us on 0117 3314598. More information is also available on our website <http://www.bristol.ac.uk/eepris>.

Thank you again for agreeing to take part in the EEPRIS study.

With our best wishes,

Yours sincerely,

On behalf of the EEPRIS study team:

Abhi Vora (Study Administrator) Emma Anderson (Study Manager) Alastair Hay (Professor of Primary Care and General Practitioner)

Fridge magnet for parents



A Step by Step Guide for parents/carers taking part in



If you have any questions about your participation in the study we would be happy to hear from you!

Please email: eepris-kids@bristol.ac.uk
or Call: 01173314598



Remember:

This is a research study, not medical care.
If you are worried about your child's health, please seek medical advice from your GP as usual.



STEP 4 - Once your child is better (no symptoms for two days), please take another **set of swabs** and pop them in the post (make sure to log this online in your final brief survey)

We may also invite you to be interviewed if you agreed to this.

STEP 3 - Please keep us updated by filling in the **daily diary** (online).

We hope that your child will be starting to feel better soon.

STEP 2 - Once your child has EEPRIS symptoms and you respond 'Y' to that Sunday's email/text link, we will call you to arrange your **Research Nurse visit**.

See 'take a closer look'

STEP 1 - Once you have filled in your first survey, we will send an email (or text) every Sunday to check if your child has had any **EEPRIS symptoms**.

(the fridge magnet will remind you what these are!)

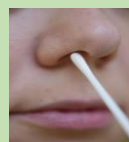
Take a closer look at the Research Nurse Visit



A Research Nurse will visit to collect information for the study by taking some routine observations.

The observations include temperature, pulse, oxygen levels and how fast your child is breathing. The Research Nurse will also listen for any noisy breathing sounds and will ask if your child can open wide to look at their throat.

They will also swab your child's nose and mouth and ask you take some samples too- it is quick & easy, it might tickle a bit but won't hurt!



See sample collection instructions for more details on taking swabs!

Visible to parent at top of screen on each page:

**EEPRIS Study [logo] [UoB logo]
Baseline Questionnaire**

Child initials; Child year of birth (already entered from consent)

Database auto-input: Date baseline questionnaire completed

SCREEN PAGE 1

Welcome to EEPRIS!

Evaluation of **E**nhanced **P**aediatric **R**espiratory **I**nfection **S**urveillance Study

**This is a study about normal coughs, colds, ear and chest infections in children.
We want to track children's symptoms as they develop in the home.**

The symptoms we are interested in are:

Runny/blocked nose, earache or ear discharge, cough, sore throat and chesty symptoms (wheezing/whistling; breathing faster than normal) - over and above what is normal for [child's initials].

QUESTION: Is [child's initials] experiencing any of these symptoms TODAY? Yes / No

[-> If yes, auto text then reads:]

We are interested in collecting information on any new respiratory illnesses that [child's initials] develops after they have recovered from this one. This is because we want to gather information from the very beginning of symptoms. We will contact you once a week to see if [child's initials] is better. Once these symptoms have gone away, [child's initials] will start in the main study process and you will then start receiving weekly contact to check for any new respiratory illness.

SCREEN PAGE 2**ABOUT YOU (CHILD'S PARENT/GUARDIAN):**

We would like to find out a little bit about you and [child's initials] so that at the end of the study we have a better picture of the people that helped us with our study and how our results can be applied to national programmes

1. How did you first find out about the EEPRIS study? (tick one option)

- Letter from your doctor
- Text from your doctor
- Poster or card in doctor's surgery
- Word of mouth (someone told me about it)
- Other (please specify) [free text]

2. What is your date of birth? DD/MM/YYYY**3. How would you describe your ethnicity?****4. Please describe your current employment status:**

- Working full time
- Working part-time
- Full time parent/care-giver
- In education
- Not currently employed

5. What is your highest level of education?

- No official qualification
- Up to GCSEs / GCEs / 'O' Levels or equivalent
- 'A' levels / NVQs / GNVQs or equivalent
- First degree/ diploma/ HNC/ HND or equivalent
- Higher degree (e.g. MSc, PhD) or equivalent

6. Do you have any medical/ nursing training? Yes/ No**7. Has a relative or friend of yours ever been hospitalised for complications from a cough, cold, sore throat, ear infection or chest infection?**

Yes/ No/ Not sure

→ If yes: **Was it a child of yours?** Yes/ No

ETHNICITY DROP DOWN LIST:

- White
- 1 British
- 2 Irish
- 3 Any Other White background
- Mixed
- 4 White and Black Caribbean
- 5 White and Black African
- 6 White and Asian
- 7 Any Other Mixed background
- Asian or Asian British
- 8 Indian
- 9 Pakistani
- 10 Bangladeshi
- 11 Chinese
- 12 Any Other Asian background
- Black or Black British
- 13 Caribbean
- 14 African
- 15 Any Other Black background
16. Other ethnic group
- 17 I would rather not answer

SCREEN PAGE 3:**ABOUT [CHILD'S INITIALS]:**

8. How would you describe [child's initials]'s ethnicity?
9. Does [child's initials] regularly spend time at another address (e.g. separated parent)? Yes / No
10. If so, on average how many nights per week? # btw 1 – 7 (0.5 allowed in answer field)
11. Has [child's initials] ever had:
- a) Asthma Yes/ No
 - b) Eczema Yes/ No
 - c) Hayfever Yes/ No
12. Was [child's initials] still receiving any breast milk at 3 months old? Yes/ No
13. Does your child attend school? Yes/ No
- If no:
14. Does [child's initials] attend day-care regularly?
- Yes – on average 3-5 days per week
 - Yes – on average 1-2 days per week
 - No

ETHNICITY DROP DOWN LIST:

- White
- 1 British
 - 2 Irish
 - 3 Any Other White background
- Mixed
- 4 White and Black Caribbean
 - 5 White and Black African
 - 6 White and Asian
 - 7 Any Other Mixed background
- Asian or Asian British
- 8 Indian
 - 9 Pakistani
 - 10 Bangladeshi
 - 11 Chinese
 - 12 Any Other Asian background
- Black or Black British
- 13 Caribbean
 - 14 African
 - 15 Any Other Black background
16. Other ethnic group
- 17 I would rather not answer

[Info box to click on]: Day-care includes nurseries and childminders (usually looking after three children or more at a time).

SCREEN PAGE 4**ABOUT THE HOUSEHOLD:**

15. How many adults (aged 16+) in total live in [child's initials]'s main home (including you)? #

[Info box to click on]: This is where the child lives regularly – i.e. more than half the time.

16. Age of each adult (on last birthday)

(double digit field - one per each adult - number of fields = dependent on answer to Q8)

17. How many other children (aged under 16) in total live regularly in your child's main home (NOT including [child's initials])? #

[Info box to click on]: Living regularly means usually resident in the house - i.e. more than half the time

18. Date of birth of each other child (month and year only) – NOT including [child's initials]

DD/MM/YYYY (one per each child - number of fields = dependent on answer to Q10)

19. Number of bedrooms in child's main home #

[Info box to click on]: A smoker is anyone who uses tobacco products (cigarettes/ roll-ups/ pipe, but not e-cigarettes) at least once a week

20. Does a smoker live in the main home? Yes/ No

21. Is there a pet cat or dog living in the main home? Yes/ No

SCREEN PAGE 5

HEALTH QUESTIONNAIRES

Please indicate how much you agree with each of the following statements

(We understand that questionnaires like these do not capture everyone's experiences accurately. Please select the answer that most applies to you most of the time)

My child's infections worry me a lot.

1. Every time my child is ill, I am afraid it is something serious.
2. My child becomes ill more frequently than other children of the same age.
3. I am often afraid that my child may become seriously ill.
4. When my child is ill I feel confident about:
 - a) looking after my child at home
 - b) knowing when my child can go back to school or nursery.
5. When my child has been ill, I have known when to seek help and advice from:
 - a) family and friends
 - b) healthcare professionals
6. When my child has been ill I have:
 - a) taken part in decisions about their care with healthcare professionals
 - b) been provided with copies of any letters or reports

DROP DOWN LIST FOR EACH STATEMENT (Qs 1 – 8)

- 1 Fully agree
- 2 Partly agree
- 3 Neither agree nor disagree
- 4 Partly disagree
- 5 Totally disagree

7. When my child is ill I generally feel confident about:
 - a) looking after them
 - b) seeking advice or help from family and friends
 - c) seeking advice or help from healthcare professionals
8. When doctors or nurses have given me information, I have been able to understand the meaning of information about:
 - a) my child's treatment
 - b) preventing further illness
 - c) result of tests

DROP DOWN LIST FOR Q 9

- 1 Fully agree
- 2 Partly agree
- 3 Neither agree nor disagree
- 4 Partly disagree
- 5 Totally disagree
- 6 N/A – no information given

9. When my child has been ill, I have tried the following sources of information or advice:
 - a) My local doctor's surgery Y/N
 - b) 111 phone line Y/N
 - c) Local pharmacy Y/N
 - d) Health visitor Y/N
 - e) Other parents Y/N
 - f) My parents/ other people in my family who have had children Y/N
 - g) NHS internet sites (e.g. NHS Choices) Y/N
 - h) Other internet sites you choose to visit directly (e.g. Mumsnet, Netmums): Y/N If yes: please specify [free text]
 - i) Generic search engine (e.g. Google, Ask) search term results Y/N
 - j) Social Media (e.g. Facebook, Twitter) Y/N

Reveal the following question for each yes answer:

I have found/ I generally find this a good source of information or advice:

DROP DOWN LIST

- Fully agree
- Partly agree
- Neither agree nor disagree
- Partly disagree
- Totally disagree

k) Other: please specify Y/N [free text]

SCREEN PAGE 6

1. Once we have analysed all the information that we have collected, we are planning to send out a newsletter to give you a summary of our results. This is likely to be in late 2016. Would you like to receive this newsletter by email or post?
- Email
 - Post
 - Both email and post
 - I do not wish to receive a newsletter, thank you

SCREEN PAGE 7

Thank you very much for completing this questionnaire.
[*child's initials*] is now fully enrolled in the EEPRIS Study.

What happens next?

- The research team will call you to welcome you into the study (unless you have already received your welcome call), and you will receive a welcome pack in the post.
- You will start to receive a weekly email (or text) each Sunday to ask if [*child's initials*] has developed any of the EEPRIS symptoms in the previous week. Please could you reply straight away each week (just a “yes” or “no” tick box response via the online link) .
- If you have another child to enrol in the study, please check the other email (or text) to follow the separate link to complete their enrolment questionnaire.
- You can always contact us if you have any questions: 0117 3314598; email: eepris-kids@bristol.ac.uk

**TEXT (AND EMAIL) PROMPTS COMMENCE ONCE BASELINE QUESTIONNAIRE IS COMPLETE *
(unless parent ticked 'Yes' for Q1, screen page 1 (see box above):*

EVERY SUNDAY AT 18:30 (6.30pm) - WEEKLY EMAIL (or TEXT):

Hi, has [child's first initials], (born: [insert year of birth]) developed any EEPRIS symptoms in the last 7 days? Please click to reply: [\[insert survey link\]](#)



Survey page:

EEPRIS symptoms:

- Blocked/runny nose
- Earache/ ear discharge
- Sore throat
- Cough
- Chesty symptoms (breathing faster than normal; wheeze or whistling chest)
 - over and above what is normal for your child

Has your child with the initials [child's initials] (year of birth: 20XX) developed any of these symptoms in the last 7 days?

Yes / No

→ A "Yes" response automatically generates the following text:

Please fill in the symptoms and recovery questionnaire which will be automatically sent to you within a few minutes.

We will also call you within a few days to arrange for a research nurse to visit you to carry out a simple physical examination on [child's initials] (e.g. listen to their chest, check their oxygen levels as a doctor or nurse would normally do) and to collect a saliva sample and nasal swab.

→ A "Yes" response automatically then forwards to the first 'symptoms and recovery' survey.

→ A "No" response automatically generates:

"Thank you for responding, we really value your contribution. We will check again next week. Best wishes, the EEPRIS team"

Visible to parent at top of screen on each page:

[EEPRIS logo] [UoB logo]

EEPRIS Study

Symptoms and Recovery Questionnaire

Child initials; Child year of birth (*already entered from consent*)

Database auto-input: **Date baseline questionnaire completed**

SYMPTOMS:

We are interested in scoring your child's respiratory symptoms over and above what is normal for them. Please choose a score that represents how bad each of the symptoms were on average over the 24 hours - for each day listed.

(We know questionnaire boxes don't accurately represent all people's experiences, but please make your best estimate out of the options).

How were your child's symptoms over each day?

1. Earache
2. Sore throat
3. Runny/ blocked nose
4. Ear discharge
5. Dry cough
6. Wet/productive cough
7. Barking/ croupy cough
8. Breathing faster/ shortness of breath
9. Wheeze/ whistling chest
10. Fever/ chills
11. Fatigue
12. Disruption to sleep
13. Disruption to other usual activities

DROP DOWN LIST A:

- 0 = normal/ not affected
- 1 = very little problem
- 2 = slight problem
- 3 = moderately bad
- 4 = bad
- 5 = very bad
- 6 = as bad as it could be
- 7 - Child is unable to communicate this information (because too young/ learning difficulties)

DROP DOWN LIST B:

- 0 = normal/ not affected
- 1 = very little problem
- 2 = slight problem
- 3 = moderately bad
- 4 = bad
- 5 = very bad
- 6 = as bad as it could be

14. How unwell do you feel your child has been overall on this day?

Well 0 1 2 3 4 5 6 7 8 9 Very unwell
10

Scale to complete for each day of symptoms

15. How worried have you been overall about your child's illness on this day?

Not at all worried
0 1 2 3 4 5 6 7 8 9 Very worried
10

16. How confident have you felt about looking after your child yourself on this day?

Not confident at all
0 1 2 3 4 5 6 7 8 9 Very confident
10

WHAT ARE THE EFFECTS OF YOUR CHILD'S RESPIRATORY ILLNESS? (cough, cold, sore throat, ear infection or chest infection):

Please complete for each day:

1. Did your child stay off school/ daycare on this day because of this illness?

→ If yes, what triggered this decision?

2. Did you or another carer take time off work on this day because of your child's respiratory illness?

→ If yes, how many hours?

3. Did you seek NHS medical advice on this day for your child's respiratory illness?

If yes: what triggered this decision?

If yes: Please indicate which of the following sources of NHS medical advice you used on this day (for this respiratory illness):

- Calling 111
- Taking your child to see the doctor (GP)
- Hospital visit (or continued stay)
- Other (please specify)

4. Did you use the internet for advice about your child's respiratory illness on this day?

→ If yes, what did you use?

5. Did your child take any medications for this respiratory illness on this day?

If yes:

Please indicate which of the following your child took (for this respiratory illness):

- a) antibiotics
- b) any other prescribed medications
→ If yes, what did they take? [Free text]
- c) any other (non prescribed) medications (including over the counter medications, or alternative/complementary therapies) for this respiratory illness?
→ If yes, what did they take? [Free text]

[Database auto-input days with dates from beginning of symptoms (answer to Q1, screen page 1)]

Yes: full day Yes: half day No Not applicable (child not in school/ daycare)
If Y: [free text]
Yes/ No/ Not applicable (not usually working on this day) If Y: # hrs
Yes / No If Y: [free text] Yes / No Yes/ No Yes/ No Yes/ No (if yes): [free text]
Yes / No If Y: drop down list*
Yes / No Yes/ No Yes/ No If Y: [free text]
Yes/ No If Y: [free text]

[Info box]: We know your child may be given antibiotics for other infections (e.g. skin or urinary), but please answer "No" if it was not for the respiratory infection we are interested in.

6. How much did you spend on any medicine for your child's respiratory illness on this day (whether your child took it or not)?	£ #
7. Did your child take antibiotics on this day for any other illness?	Yes / No
8. Did any other members of your household have any of the EEPRIS symptoms on this day?	Yes / No
If yes: → How many adults (aged 16+) have any symptoms? → How many other children (aged 15 and below) have any symptoms?	# #

[Info box]: EEPRIS Symptoms are:
Runny/blocked nose, earache or ear discharge, cough, sore throat and chesty symptoms (wheezing/whistling; breathing faster than normal) - over and above what is normal

*Internet drop down list (tick as many as apply):

- NHS internet sites (e.g. NHS Choices)
- Other internet sites you choose to visit directly (e.g. Mumsnet, Netmums)
if ticked, please specify: [free text]
- Generic search engine (e.g. Google, Ask) search term results
- Social Media (e.g. Facebook, Twitter)

To display every time the survey is completed:

Thank you very much for answering these questions. We value your contribution to our study.

**Please fill in your answers to these questions for each day that your child is unwell.
We will send you reminders every two days with the survey link to help you remember.**

This survey is for the full week. When you choose 'Save & Return Later', your re-entry code will flash up in a message. This is the same code we will send with your reminders to fill in the survey for future days until it is complete.

(If your child is ill for more than 21 days, we will then only ask for a weekly update)

Remember, this is a research study, not medical care.

If you are worried about your child's health, please seek medical advice from your GP as usual.

After completion of the first symptoms questionnaire above:

Each further day (with its date) will be released to the survey at 6pm each day. The parent will be able to fill in the symptoms and impact questions at the end of each day – accessible via the initial link – which is the same as the link texted and emailed every two days

Text and email prompt sent to parent every 2 days with a survey link:

This is a reminder to please fill in the EEPRIS questionnaires for [child's initials] for the last two days (if you haven't done so already). *[Insert survey link]*. Thank you so much. - The EEPRIS team.

This process continues up to:

*2 consecutive symptom-free days OR maximum 21 days from date of symptoms onset
(whichever comes sooner)*

SECTION 2: AFTER 2 CONSECUTIVE SYMPTOM-FREE DAYS:

(as entered on symptoms questionnaire)

➔ Automatically trigger different screen page 4:

END: SCREEN PAGE 4

Great news, your child has recovered! Just a few more quick questions:

1. Would you have preferred paper questionnaires rather than filling in questionnaires online? Y / N

2. How user-friendly did you find the online questionnaire in our study?

Comment: *[free text]*

DROP DOWN LIST:

Very
quite
fairly
not really
not at all

3. Do you think that taking part in the study had an impact on how you dealt with your child's illness in any way?

Yes / No

➔ *If yes:* Please tell us here: *[free text]*

4. Would you like to carry on in the study with [child's initials] in case they develop another infection?

Yes / No thank you

➔ ***If Yes:***

If "No thank you" selected to either Q4 or 5, database stops ongoing tasks for relevant child/ren

Thank you so much for continuing to help us with our study! We will carry on with the weekly prompts as before.

Weekly symptoms trigger prompts resume for the current child from the following Sunday evening

5. Are you happy to carry on in the study for any other children in your family you have enrolled in the study?

Yes / No thank you/

Not applicable – no other children enrolled in study

➔ ***If yes add:***

Thank you for agreeing to continue in the study with your other child/ren. We will continue to send you weekly prompts for them.

['Not applicable' option automatically populated for parents with no other children in study]

[OR whole question deleted for parents with no other children in study]

NEW QUESTIONNAIRE TO SEND:

****SAMPLES FROM RECOVERED CHILD QUESTIONNAIRE ****

Please take a saliva and nasal swab from [child's initials] as soon as possible and post the samples to our laboratory in the pre-addressed pack that the nurse provided at your home visit. (This is so that we can have samples when your child is well for comparison).

We are sending you a link to one more quick questionnaire. Please fill this in when you have taken the samples. Once you have filled it in, we will make a record that you are due your shopping voucher for completing all the study surveys.

Please fill in the following quick questions on the day that you take the sample:

1. Did you take a nasal sample from [child's initials] after they recovered? Yes/ No
 - If yes: On what date did you take the nasal sample? DD/MM/YYYY
 - If yes: Did [child's initials] have a runny nose at the time of taking the sample? Yes/ No
 - If no: What stopped you taking this sample? [free text]

2. Did you take a saliva sample from [child's initials] after they recovered? Yes/ No
 - If yes: On what date did you take the saliva sample? DD/MM/YYYY
 - If no: What stopped you taking this sample? [free text]

How were your child's symptoms on the date you took the samples?

Runny/ blocked nose	DROP DOWN LIST A
Ear discharge	LIST A
Earache	LIST B
Sore throat	LIST B
Dry cough	LIST A
Wet/productive cough	LIST A
Barking/ croupy cough	LIST A
Breathing faster/ shortness of breath	LIST A
Wheeze/ whistling chest	LIST A
Fever/ chills	LIST A
Fatigue	LIST A
Disruption to sleep	LIST A
Disruption to other usual activities	LIST A

DROP DOWN LIST A:

0 = normal/ not affected
 1 = very little problem
 2 = slight problem
 3 = moderately bad
 4 = bad
 5 = very bad
 6 = as bad as it could be

DROP DOWN LIST B:

0 = normal/ not affected
 1 = very little problem
 2 = slight problem
 3 = moderately bad
 4 = bad
 5 = very bad
 6 = as bad as it could be
 7 - Child is unable to communicate this information (because too young/ learning difficulties)

Once samples questionnaire complete:

Thank you so much for filling in these surveys. We really value your contribution to our research study. It couldn't happen without you.

THANK YOU VOUCHER:

We have made a record that you are eligible to receive your shopping voucher as a thank you for completing all the surveys.

We will send it to you at the end of the active data collection phase (May/June 2016) to the address we have recorded for you.

If you would like us to send your voucher to a different address, please contact us to let us know:
email: eepris-kids@bristol.ac.uk
tel: (0117) 331 4598

For all parents who consented to qualitative interview:

When you enrolled in the study, you said you would be happy to be invited to be interviewed about taking part. We are not interviewing everyone who takes part, but if you are selected you may receive a phone call to see if you are willing to meet our interviewer.

Visible to parent at top of screen on each page:

[EEPRIS logo] [UoB logo]

EEPRIS Study

Symptoms and Recovery Questionnaire – weekly questions

Child initials; Child year of birth (*already entered from consent*)

Database auto-input: **Date baseline questionnaire completed**

Screen page 1

SYMPTOMS:

We are interested in scoring your child's symptoms over and above what is normal for them.

Did your child suffer from the following symptoms in the last week (day 22 – day/date to day 28 – day/date)?

- | | |
|--|--|
| 1. Earache | Yes/ No / Child unable to communicate this information |
| 2. Sore Throat | Yes/ No / Child unable to communicate this information |
| 3. Runny/ blocked nose | Yes/ No |
| 4. Ear discharge | Yes/ No |
| 5. Dry cough | Yes/ No |
| 6. Wet/ productive cough | Yes/ No |
| 7. Barking/ croupy cough | Yes/ No |
| 8. Breathing faster/ shortness of breath | Yes/ No |
| 9. Wheeze/ whistling chest | Yes/ No |
| 10. Fever/ chills | Yes/ No |
| 11. Fatigue | Yes/ No |
| 12. Disruption to sleep | Yes/ No |
| 13. Disruption to other usual activities | Yes/ No |

14. How unwell do you feel your child has been overall over the last 7 days?

Well												Very unwell
0	1	2	3	4	5	6	7	8	9	10		

15. How worried have you been overall about your child's illness over the last 7 days?

Not at all worried												Very worried
0	1	2	3	4	5	6	7	8	9	10		

15. How confident have you felt about looking after your child yourself over the last 7 days?

Not confident at all												Very confident
0	1	2	3	4	5	6	7	8	9	10		

Data Collection Forms - 3 Weekly questionnaire for ongoing RTIs EEPRIS Study Version 2 2015-10-13

Screen page 2

WHAT ARE THE EFFECTS OF YOUR CHILD'S RESPIRATORY ILLNESS? (cough, cold, sore throat, ear infection or chest infection):

1. **Did your child stay off school/ daycare over the last seven days because of this respiratory illness?**
 Yes/ No/ Not applicable (child not in school/ daycare)
 → If yes: **How many days (you can specify half days)?** [# between 1 – 7 (– allow .5)]
 → If yes, what triggered this decision? [free text]
2. **Did you or another carer take time of work over the last seven days because of your child's respiratory illness?**
 Yes/ No/ Not applicable
 → If yes: **How many HOURS?**
3. **Did you seek NHS medical advice over the last 7 days for your child's respiratory illness (e.g. by calling 111, or visiting a GP (or hospital)**
 → If yes, what triggered this decision? [free text]
 → If yes, Please indicate which of the following sources of NHS medical advice you used (for this respiratory illness):

a) Calling 111	Yes/ No
b) Taking your child to see the doctor (GP)	Yes/ No
c) Hospital visit (or continued stay)	Yes/ No
d) Other (please specify)	Yes/ No [free text if yes]
4. **Did you use the internet for advice about your child's respiratory illness today? Yes/ No**
 → If yes, what did you use? (tick as many as apply)
 - NHS internet sites (e.g. NHS Choices)
 - Other internet sites you choose to visit directly (e.g. Mumsnet, Netmums) (if ticked), please specify: [free text]
 - Generic search engine (e.g. Google, Ask) search term results
 - Social Media (e.g. Facebook, Twitter)
5. **Did your child take any medications for this respiratory illness over the last 7 days? Y/N**
 → If yes, please indicate which of the following your child took (for this respiratory illness):
 - a) **antibiotics** Yes/ No
 → If yes: **On how many days?** [# between 1 – 7]

[Info box]: We know your child may be given antibiotics for other infections (e.g. skin or urinary), but please answer "No" if it was not for the respiratory infection we are interested in.
 - b) **any other prescribed medications**
 → If yes: **What did they take?** [free text]
 - c) **Any other non-prescribed medications (including over the counter medications, or alternative/ complementary therapies)** Yes/ No
 → If yes: **What did they take?** [free text]

6. How much did you spend on any medicine for your child's respiratory illness over the last 7 days?

£ # (2 decimal places)

7. Did your child take antibiotics over the last 7 days for any other illness?

Yes/ No

➔ If yes: On how many days? [# between 1 – 7]

8. Did any other members of your household have any of the EEPRIS symptoms over the last seven days?

Yes/ No

➔ If yes: How many adults (aged 16+) had any symptoms? [#]

➔ If yes: How many other children (aged 15 and below) had any symptoms? [#]

[Info box]: EEPRIS Symptoms are:
Runny/blocked nose, earache or ear discharge, cough, sore throat and chesty symptoms (wheezing/whistling; breathing faster than normal) - over and above what is normal

9. Has your child now recovered from this respiratory illness (at least the last two days without any symptoms)?

Yes/ No

➔ If yes: go to "Symptoms and recovery Questionnaire" - SECTION 2: AFTER 2 CONSECUTIVE SYMPTOM-FREE DAYS

➔ If no: **We are sorry to hear that. We will contact you next week for an update. Best wishes.**
Until max 5 weekly questionnaires (= 8 weeks of symptoms data collection).

Remember, this is a research study, not medical care.

If you are worried about your child's health, please seek medical advice from your GP as usual.

If max time point (8 weeks) is reached and symptoms are ongoing, generate automatic page (on completion of 5th weekly symptoms questionnaire):

We are very sorry that your child is not better yet.

Thank you kindly for filling in questionnaires for the last eight weeks. Here are just four more questions:

1. Would you have preferred paper questionnaires rather than filling in questionnaires online? Y / N

2. How user-friendly did you find the online questionnaire in our study?

Comment: *[free text]*

DROP DOWN LIST:

Very
quite
fairly
not really
not at all

3. Do you think that taking part in the study had an impact on how you dealt with your child's illness in any way?

Yes / No

→ If yes: Please tell us here: *[free text]*

If "No thank you" selected to Q4,
database stops ongoing tasks for
relevant child/ren

4. Are you happy to carry on in the study for any other children you have enrolled in the study?

- Yes
- No thank you
- Not applicable – no other children enrolled in study

['Not applicable' option automatically
populated for parents with no other children
in study]

[OR whole question deleted for parents with
no other children in study]

[If yes to question 4 add: Thank you for agreeing to continue in the study with your other child/ren. We will continue to send you weekly prompts for them.]

Thank you so much for keeping in touch and providing information for our study. We really value your support. We hope [child's initials] gets better soon.

We would like to take samples when they are better if it's possible. Please could you let us know if [child's initials] has at least two days without symptoms before June [email: eepris-kids@bristol.ac.uk; tel (0117) 3314598], If we do not hear from you, we will call you a few times in the next few weeks to check.

THANK YOU VOUCHER:

Once we have collected those samples, or, if your child does not recover before June (whichever comes first), we will post you a shopping voucher as a thank you for taking part. We will send it to the address we have recorded for you. If you would like us to send your voucher to a different address, please contact us to let us know: email: eepris-kids@bristol.ac.uk; tel: (0117) 3314598

With very best wishes, the EEPRIS Team.

Remember, this is a research study, not medical care.

If you are worried about your child's health, please seek medical advice from your GP as usual.

Visible to nurse at top of screen on each page:

EEPRIS Study [logo] [UoB logo]

Clinical Examination

Child initials; Child year of birth (already entered from consent)

[SCREEN PAGE 1]

Clinical examination

1. **Date:** DD/MM/YYYY

2. **Temperature** [#] °C OR: Unable to take (e.g. child uncooperative) [tick box]
3. **Pulse** [#] bpm OR: Unable to take (e.g. child uncooperative) [tick box]
4. **Respiratory rate** [#] bpm OR: Unable to take (e.g. child uncooperative) [tick box]
5. **O2 sat** [#] % OR: Unable to take O2 sat/no equipment [tick box]

6. Is the throat normal? Y/ N/ not possible to examine (e.g. child will not open mouth)
 → If N - please tick as many of the following if present:
 - inflamed;
 - enlarged tonsils;
 - pus/exudate on tonsils/pharynx;
 - enlarged tonsillar/cervical lymph nodes

7. **Consciousness level** normal / irritable / drowsy
8. **Capillary refill time** 2 seconds or less / 3 seconds or more

9. **Pallor** absent / present
10. **Grunting** absent / present
11. **Nasal flaring** absent / present
12. **Stridor** absent / present
13. **Inter/subcostal recession** absent / present
14. **Wheeze or whistling in the chest** absent / unilateral / bilateral
15. **Crackles/crepitations** absent / unilateral / bilateral
16. **Bronchial breathing** absent / unilateral / bilateral

[SCREEN PAGE 2]

General Assessment

17. How unwell do you consider the child to be?

Well 0 1 2 3 4 5 6 7 8 9 10 Very unwell

18. Main working respiratory tract diagnosis

Drop down list

19. My gut feeling is "something is wrong"

No / Yes

20. Advised to seek GP care

No / Yes

→ If yes, nurse comments [free text]

WORKING DIAGNOSIS DROP DOWN LIST:

- Upper respiratory tract infection (URTI) / Cold
- Otitis media / ear infection
- Sinusitis
- Tonsillitis / pharyngitis / quinsy / throat abscess / peritonsillar cellulitis
- Croup
- Whooping cough
- Tracheitis
- Chest infection/Bronchitis/ Lower respiratory tract infection (LRTI)
- Bronchiolitis
- Pneumonia
- Exacerbation of asthma / viral wheeze
- Viral illness
- Influenza / influenza type illness / flu
- Other - please specify [free text]

[SCREEN PAGE 3]

SWABS:

1. (To ask the parent): Has the child had an influenza vaccination within the last 7 days?

No/ Yes/ unsure

2. Did the child have a runny nose at the time of taking the sample? Yes/ No

3. Parent-taken nasal swab Yes/ No

→ If no, reason: [free text]

- parent required nurse advice for taking nasal swab? Yes/ No

-> If yes: why? [free text]

4. Parent-taken saliva swab Yes/ No

→ If no, reason: [free text]

- parent required nurse advice for taking saliva swab? Yes/ No

-> If yes: why? [free text]

5. Nurse-taken nasal swab Yes/ No

→ If no, reason: [free text]

6. Nurse-taken saliva swab Yes/ No

→ If no, reason: [free text]

NB: we want AdminDb to have a barcode linked to each sample.
Plus prompts for administrator to populate the barcode fields once
any samples collection information is filled in.

Please record reason(s) for any missing data from clinical examination (and/or any issues with taking swabs):

[Free text]

REVIEW DETAILS for each child who contributed RTI data to study

1. Participant identifiable details	
1.1. Child's Participant ID Number	Pre-populated
1.2. Child's NHS number	Pre-populated (unless not recruited via mailout)
1.3. Child's date of birth	Pre-populated
1.4. Child's gender	Pre-populated
1.5. Recruiting primary care site name	Pre-populated
1.6. Do the above pre-populated fields match information in the child's medical notes exactly?	Yes/No. If no, contact study team

2. EEPRIS relevant dates	[All fields to be pre-populated]
2.1 EEPRIS Study baseline questionnaire date (date baseline completed)	DD/MM/YYYY
2.2 Date of first RTI initial symptoms	DD/MM/YYYY
2.3 Did symptoms resolve within EEPRIS?	Yes/ No/ missing data
2.3.1 If yes, date of RTI symptom resolution	DD/MM/YYYY
2.3.2 If no or missing data, date stopped collecting data on this RTI	DD/MM/YYYY
2.4 Any other EEPRIS RTIs in same child?	Yes/ No
2.4.1 If yes, how many further RTIs?	[#]
2.4.2 Date of second RTI initial symptoms	DD/MM/YYYY
2.4.3 Did symptoms resolve within EEPRIS?	Yes/ No/ missing data
2.4.4 If yes, date of RTI symptom resolution	DD/MM/YYYY
2.4.5 If no or missing data, date stopped collecting data on this RTI	DD/MM/YYYY
2.4.6 Date of third RTI initial symptoms	DD/MM/YYYY
2.4.7 Did symptoms resolve within EEPRIS?	Yes/ No/ missing data
2.4.8 If yes, date of RTI symptom resolution	DD/MM/YYYY
2.4.9 If no or missing data, date stopped collecting data on this RTI	DD/MM/YYYY

3. Notes review details	
3.1. Initials of reviewer	[Free text]
3.2. Date review completed	DD/MM/YYYY
3.3. Are notes available for review?	Yes/ No
3.3.1. If no, reason that notes are not available	[Free text]
3.4. Notes available to be reviewed at this practice	Paper / electronic / both
3.5. Are notes available from 12 months prior to baseline?	Yes/ No
3.5.1 If no, date they are available from	DD/MM/YYYY
3.6. Most recent date child registered at the practice	DD/MM/YYYY
3.7. Child has left the surgery	No/Yes
3.7.1. If yes, date that the child left the surgery	DD/MM/YYYY
3.7.2. If yes, contact the Health Records Authority to locate the notes.	Contact attempts and outcomes: [Free text for notes]
3.7.3. New notes location:	[Free text name of GP surgery]

If yes, AdminDb to flag up that we need to contact Health Records Authority to locate the notes. Then re-start form 3.

HISTORY OF CHRONIC AND RELEVANT CONDITIONS

History of chronic conditions (from birth)	
Time period relevant to this question:	[insert dates: from child's date of birth, to the date of baseline questionnaire]
4 Is there a history of chronic illness or significant co-morbidities?	No/Yes <i>If yes complete details below.</i>
4.1 Cystic fibrosis	No/Yes
4.2 chronic lung disease of prematurity	No/Yes
4.3 previous aspiration pneumonia	No/Yes
4.4 HIV	No/Yes
4.5 splenectomy	No/Yes
4.6 sickle cell anaemia	No/Yes
4.7 IgA deficiency	No/Yes
4.8 hypoplasia of the lung	No/Yes
4.9 systemic lupus erythematosus	No/Yes
4.10 Alpha-1-antitrypsin deficiency	No/Yes
4.11 neutropenia	No/Yes
4.12 Hunter's syndrome	No/Yes
4.13 CHARGE syndrome	No/Yes
4.14 heart failure requiring ongoing medication	No/Yes
4.15 congenital heart disease requiring ongoing medication – i.e. still under treatment	No/Yes
4.16 hepatic disease	No/Yes
4.17 renal disease	No/Yes
4.18 severe developmental delay and tracheostomy.	No/Yes
4.19 cancer patient (solid tumours and haematological malignancies)	No/Yes
4.20 Immunodeficiency states:	
4.20.1 transplant recipients	No/Yes
4.20.2 autoimmune disease (such as Systemic lupus erythematosus)	No/Yes
4.20.3 respiratory patients treated with immunosuppressant medications	No/Yes
4.21 Current asthma (defined as a current active problem, or asthma medication prescribed within the last 12 months)	No/Yes
4.22 Previous asthma (defined as asthma medication prescribed prior to the last 12 months)	No/Yes
4.23 Diabetes	No/Yes
4.24 Epilepsy	No/Yes
4.25 Bronchiectasis	No/Yes
4.26 Down's Syndrome	No/Yes
4.27 Cerebral Palsy	No/Yes
4.28 Other	No/Yes
4.28.1 If yes to other, specify	Free text

NB: grey shaded cells = eligibility check questions

5. Low birth weight (<2.5 kg)?

Yes / No / unclear (or data not available)

6. Pre-term birth (before 37 weeks gestation)?

Yes / No / unclear (or data not available)

REPEAT MEDICATIONS

AdminDb to
prepopulate dates

Repeat medications for chronic conditions	
Time period relevant to this question:	[insert dates: from 3 months before study baseline to end of study participation]
7. Are any repeat medications for chronic conditions being used at the time of this notes review?	No / Yes <i>If yes complete details below</i>
a) Med 1: Name	
b) Med 1: Strength (mg – or mg/ml if suspension)	
c) Med 1: Dose (e.g. 2.5ml OR 1 tablet)	
d) Med 1: Frequency	
a) Med 2: Name	
b) Med 2: Strength (mg – or mg/ml if suspension)	
c) Med 1: Dose (e.g. 2.5ml OR 1 tablet)	
d) Med 1: Frequency	
a) Med 3: Name	
b) Med 3: Strength (mg – or mg/ml if suspension)	
c) Med 3: Dose (e.g. 2.5ml OR 1 tablet)	
d) Med 3: Frequency	

→ Database to allow more to be added

Drop down list for frequency:

OD – once daily
BD – twice daily
TDS – three times daily
QDS – four times daily
Other (please specify)

VACCINATION HISTORY

AdminDb to
prepopulate dates

8. Vaccination history (from birth)

Time period relevant to this question: [insert dates: from child's date of birth, to end of study participation]

8.1 DTaP/IPV/Hib – Diphtheria, tetanus, acellular pertussis, polio, Hib 5-in-1 vaccine

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.5 Hib/MenC – Haemophilus influenzae type b and meningitis C combined vaccine

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.2 PCV 7 - Pneumococcal conjugate vaccine (7 valent)

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.6 MMR – Measles, Mumps and Rubella combined vaccine

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.3 PCV 13: Pneumococcal conjugate vaccine (13 valent)

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.7 DtaP/IPV – 4-in-1 pre-school booster. Diphtheria, tetanus, pertussis and polio

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.4 MenC – Meningococcal serogroup C conjugate vaccine MCC

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

8.8 MR – Measles and Rubella combined vaccine

- None recorded ☐
- Dose 1: DD/MM/YYYY
- Dose 2: DD/MM/YYYY
- Dose 3: DD/MM/YYYY
- Dose 4: DD/MM/YYYY
- Dose 5: DD/MM/YYYY

AdminDb to
prepopulate dates

9. Vaccination history (from 12 months pre study entry to end of child's active participation phase)

Time period relevant to this question: [insert dates: from the date 12 months before study baseline to end of study participation]

9.1 Seasonal flu

None recorded ☐
 Dose 1: DD/MM/YYYY
 Dose 2: DD/MM/YYYY
 Dose 3: DD/MM/YYYY
 Dose 4: DD/MM/YYYY
 Dose 5: DD/MM/YYYY

9.2 Other flu

None recorded ☐
 Dose 1: DD/MM/YYYY
 Dose 2: DD/MM/YYYY
 Dose 3: DD/MM/YYYY
 Dose 4: DD/MM/YYYY
 Dose 5: DD/MM/YYYY

CONSULTATIONS PRE STUDY ENTRY

Please give details of every occasion on which the child saw a doctor or nurse (face-to-face appointment) for all cases of RTI, within the 12 months prior to study baseline data completed.

AdminDb to
prepopulate dates

10. Consultation details for all RTIs in 12 months pre EEPRIS baseline

Time period relevant to this question: [insert dates: from 12 months before study baseline date to study baseline date]: DD/MM/YYYY – DD/MM/YYYY

Date of face-to-face consultation for RTI	Symptoms identified	Antibiotics prescribed?	Evidence of hospital admission?	Date admitted to hospital	Date discharged from hospital	Discharge diagnosis
DD/MM/YYYY	Symptoms & diagnoses drop down list	Yes/ No	Yes/ No	DD/MM/YYYY	DD/MM/YYYY	[free text]
DD/MM/YYYY	Symptoms & diagnoses drop down list	Yes/ No	Yes/ No	DD/MM/YYYY	DD/MM/YYYY	[free text]
DD/MM/YYYY	Symptoms & diagnoses drop down list	Yes/ No	Yes/ No	DD/MM/YYYY	DD/MM/YYYY	[free text]

PTO

SYMPTOMS AND DIAGNOSES DROP DOWN LIST – Select all that apply

- Upper respiratory tract infection (URTI) / Cold
- Otitis media / ear infection
- Sinusitis
- Tonsillitis / pharyngitis / quinsy / throat abscess / peritonsillar cellulitis
- Croup
- Whooping cough
- Tracheitis
- Chest infection/Bronchitis/ Lower respiratory tract infection (LRTI)
- Bronchiolitis
- Pneumonia
- Exacerbation of asthma / viral wheeze
- Viral illness
- Influenza / influenza type illness / flu
- Runny nose/ blocked nose / rhinorrhoea/ coryza/ nasal congestion
- Sore throat / difficult or painful swallowing / inflamed pharynx or tonsils
- Ear ache / ear pain / otalgia / difficulty hearing / ear discharge/ red ear
- Sinus pain / tenderness / face pain
- Stridor
- Lymphadenopathy / swollen or tender glands in head or neck
- Cough (unspecified as to dry or productive)
- Dry cough
- Productive cough / sputum
- Chest / shoulder pain
- Wheeze / whistling in chest
- Crackles / crepitations / ronchi / rales / bronchial breathing / pleural rub
- Grunting / nasal flaring / intercostal recession / subcostal recession
- Dyspnoea / short of breath / breathing faster than normal
- Low oxygen saturation / Low O2 sats / oxygen saturation <92%
- Chills / shivering / rigor
- Fever / high temperature / temperature recorded at >38°C
- Malaise / tired / tiredness / fatigue / listless
- Myalgia / muscle aches all over / achy all over
- Headache
- Other (please specify)

RTI Primary Care Consultations – complete for each complete RTI period (from symptoms onset to symptoms resolution)

For any EEPRIS RTI for which we have no confirmation of symptoms resolution – either due to illness ongoing beyond 8 weeks, or data collection phase ending before symptoms resolution, or missing data, the RTI period for notes data collection will be 8 weeks (56 days) from symptoms onset.

Exclude unrelated routine appointments (e.g. immunisations) and trauma related appointments.

AdminDb to prepopulate from date of symptom onset to symptoms resolution (final date of symptoms – i.e. before the final 2 symptom-free days), or default to add 56 days

11. Consultation details for EEPRIS RTIS	
Time period relevant to this question:	[insert dates: from date of symptoms onset to symptoms resolution – OR 56 days from onset] DD/MM/YYYY – DD/MM/YYYY
11.1 Relevant consultations during this period?	No/Yes If yes, fill in further Qs:
11.1.1 If yes, how many relevant consultations during this period?	#

REDCap to create a set of the following questions x answer to Q5.2

[NB: Make it easy to return to Q5.2 and change the number]

11.1.2 Consultation date	DD/MM/YYYY
11.1.3 Professional seen:	Doctor/ nurse/ other <i>Specify role if other:</i> [free text]
11.1.4 Consultation type	<u>DROP DOWN LIST</u> <ul style="list-style-type: none"> - GP practice - face to face - GP practice - tel consultation - Walk in clinic - face to face - OOH - face to face - OOH - tel consultation
11.1.5 Symptoms/ diagnoses mentioned in consultation notes:	Symptoms & diagnoses drop down list - as above [multiple selections possible]
11.1.6 Was the child prescribed an antibiotic at this consultation for the EEPRIS RTI?	Yes/ No
11.1.6.1 If yes, (generic) name of antibiotic	<u>Select one from drop down list:</u> <ul style="list-style-type: none"> - Amoxicillin - Clarithromycin - Erythromycin - Erythromycin Ethyl Succinate - Phenoxymethylpenicillin (Penicillin V) - Flucloxacillin - Co-amoxiclav (Augmentin) - Azithromycin - Other (please specify) [free text]

11.1.6.2 If yes, is it recorded as a delayed (or deferred) prescription?	Yes/ No
11.1.7 Was the child prescribed any other medication at this consultation for the EEPRIS RTI?	Yes/ No
11.1.7.1 If yes, what was prescribed?	Free text
11.1.8 Child referred to secondary care (for tests or admission)?	Yes/ No

HOSPITAL ADMISSIONS, OUTPATIENT APPOINTMENTS AND TESTS FOR EEPRIS RTIs

Please complete this section for every each hospital visit (admission, outpatients appointment or test) within each EEPRIS RTI period. Include only visits which fall within the RTI duration timeframe, not tests which have been booked but will be carried out after the period indicated.

AdminDb to prepopulate from date of symptom onset to symptoms resolution (final date of symptoms – i.e. before the final 2 symptom-free days), or default to add 56 days

12 Hospital admissions, outpatient appointments and tests within EEPRIS RTI duration	
Time period relevant to this question:	[insert dates: from date of symptoms onset to symptoms resolution – OR 56 days from onset] DD/MM/YYYY – DD/MM/YYYY
12.1 Secondary care contacts in this period? (A and E contact, outpatient appointments, tests or hospital admissions)	No/Yes If yes complete below for each visit:
12.2 Possibility that this is a serious adverse event related to participation in the EEPRIS study?	No/ Yes If yes, fill in standard study SAE form

12.1.1 Date of visit	DD/MM/YYYY
12.1.2 Location (name of hospital)	[Free text]
12.1.3 Type of visit	DROP DOWN LIST: ▪ A & E/ ▪ Outpatients/Test ▪ Hospital admission
12.1.3.1 If admitted, date of discharge	DD/MM/YYYY
12.1.4 Type of specialist referred to	[Free text] or tick 'none'
12.1.5 Tests/ procedures carried out (include OPCS code if available)	[Free text] or tick 'none'
12.1.6 Main diagnosis (include ICD10 code if available)	[Free text] or tick 'none'
12.1.7 Other diagnosis (include ICD10 code if available)	[Free text] or tick 'none'

12.1.8 Is there another secondary care contact to add within this RTI period?	Yes/ No (if yes add repeat of fields from 12.1.1 onwards)
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List of microbial targets for PCR studies

Taqman Array Community surveillance panel

	Assay Name
1	RSV A
2	RSV B
3	HPIV 1
4	HPIV 2
5	HPIV 3
6	HPIV 4
7	Enterovirus
8	Rhinovirus
9	<i>B. pertussis</i> ptxS1
10	Coronavirus GP2 OC43/HKU1
11	Coronavirus NL63
12	Coronavirus 229E
13	HMPV
14	MS2 (Exogenous RNA control)
15	Adenovirus
16	Bocavirus
17	Adenovirus #2
18	H3 seasonal
19	<i>M. pneumoniae</i>
20	<i>C. pneumoniae</i>
21	H1N1 2009
22	H1N1 2009 Tamiflu sensitive
23	H1N1 2009 Tamiflu resistant
24	Flu B Quad

	Assay Name
25	Flu B B
26	<i>S. aureus</i> PVL
27	Flu A CDC DC
28	Flu A Q AM2
29	<i>S. pneumoniae</i>
30	<i>S. pyogenes</i>
31	<i>S. aureus</i> Nuc (aureus specific)
32	EVD68
33	<i>Staphylococcus</i> tuf (staph species)
34	Mec A (antimicrobial resistance marker)
35	<i>N. meningitidis</i>
36	<i>H. influenzae</i> (all types)
37	<i>Fusobacterium necrophorum</i>
38	<i>M. pneumoniae</i> b
39	<i>B. pertussis</i> IS481
40	Parechovirus
41	<i>M. catarrhalis</i>
42	<i>B. parapertussis</i>
43	OC43 specific
44	Rnase P
45	HPIV 1 #2
46	HPIV 3 #2
47	Rhinovirus #2
48	Lambda (Exogenous DNA control)

The Taqman Array Card Assay (above) detects the following bacteria and viruses:

Viruses

Respiratory syncytial virus types A and B
Parainfluenzaviruses types 1-4
Enteroviruses
Enterovirus D68
Rhinoviruses
Coronavirus types OC43, HKU1, NL63 and 229E
Human metapneumovirus
Adenoviruses
Bocaviruses
Influenza A
Influenza A H1N1 pdm 2009
Influenza A H3N2
Influenza B
Influenza A H1N1 pdm 2009 oseltamivir resistant variants
Influenza A H1N1 pdm 2009 oseltamivir sensitive variants

Bacteria (red writing in assay card above)

Bordetella species
Bordetella pertussis
Bordetella parapertussis
Mycoplasma pneumoniae
Chlamydia pneumonia
Staphylococcal species
Staphylococcus aureus
Staphylococcus aureus PVL
Streptococcus pneumonia
Streptococcus pyogenes
Haemophilus influenza
Fusobacterium necrophorum
Moraxella catarrhalis
Methicillin A resistance gene

Controls (blue writing in assay card above)

MS2 (exogenous RNA control)
Lambda (exogenous DNA control)
RNase P (endogenous DNA/RNA control)



EEPRIS Study Clinician Interviews Information Sheet

Your Practice is involved in the Evaluation of Enhanced Paediatric Respiratory Infection Surveillance: Feasibility cohort study – the EEPRIS Study.

We are inviting you to be interviewed as a part of this study.

Before you decide if you want to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

This study aims to explore your perceptions as a GP or nurse prescriber regarding on how the microbiology and real-time illness symptoms data could be used as part of a future online intervention that informs parents and clinicians about circulating microbes and illness profiles in the community. We will use the information collected in the interview study to feed into the design of this online resource.

Why have I been chosen?

You have been selected as you are a GP or nurse prescriber, and your practice has nominated you to be approached for interview as a part of collaborating with the EEPRIS Study.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You will still be free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

If you agree to take part we will arrange a face-to-face (at your practice, or convenient location) or telephone interview at a time convenient to you. This study is a qualitative study, and as such you will be asked to take part in a semi-structured interview during which you will be provided with an outline of a microbiology and symptoms profile intervention and asked questions around the areas as outlined above. The interview will take about 30 minutes and your interview will be audio-recorded. This recording will be labelled anonymously. The interview will then be transcribed and will then be deleted. All data will be anonymised and will remain confidential.

Will I have to do anything differently?

No, this study is exploring your views only and will not impact on your professional practice.

Are there any side effects, disadvantages and risks of taking part?

We are not aware of any side effects, disadvantages or risks to you of taking part in this interview.

What are the possible benefits of taking part?

We hope that the information gained from this study will benefit future management of paediatric respiratory tract infections in primary care. It will also contribute towards the emerging body of evidence looking at infection surveillance and online resources for clinicians.

What if something goes wrong?

We do not expect any harm coming to you from being in this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

**Will my taking part in this study be kept confidential?**

All information collected about you during the course of the research will be kept strictly confidential. Any information about you that is collected from the interview will have your name and address and any other reference to place or peoples' names removed so that you cannot be recognised from it.

What will happen to the results of the research study?

We will submit the results of this (and the main EEPRIS research study) for publishing in a peer-reviewed academic journal. Participating GP practices will be informed of all publications arising from this research via newsletter at the end of the study at the end of 2016. Further publications/ news from the study will be reported on our study website which practices can access.

Who is organising and funding the research?

The National Institute for Health Research (NIHR) Health Protection Research Unit (HPRU) - Evaluation of Interventions has funded this research study.

Who has reviewed the study?

This research study has been reviewed and approved by South West Frenchay Bristol Research Ethics Committee (reference: 15/SW/0264).

Contact and further information

If you need further information to help you decide, please contact **Emma Anderson** at the University of Bristol on **0117 3314573**. Or email: **eepris-study@bristol.ac.uk**

Thank you for reading this and for considering taking part in this study.

EEPRIS Clinician Interview Study

Clinician CONSENT FORM

	Please initial box
1. I confirm that I have read and understand the information sheet [version 1, 2015-08-03] for the above study and have had the opportunity to ask questions.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree to the interview to be audio-recorded.	
4. I understand that information gathered in this research study may be published or presented in public forums; however all data will be anonymised and will remain confidential. I understand that the audio recording will be labelled anonymously. The interview will be transcribed and will then be deleted.	
5. I agree to take part in the above study.	

When you have initialled all the boxes above, please complete below, including the date:

Name of participant _____

Signature _____ Date _____

Name of researcher taking consent _____

Signature _____ Date _____

Clinician interview topic guide

Present the RTI illness vignettes to the clinician (e.g. [Virus/ bacteria name plus some data/info] “This is/ these are bugs known to be circulating in the area at the moment. The typical symptoms are [x, y and z]. NB: This bug and/or symptom profile may not be true for your patient”).

Explain that it is an illustration of the type of information that would be presented online as real-time data on circulating microbes and associated symptom presentation in the community.

Elicit initial reactions to the information.

Topic prompts:

i) Coherence – the perceived meaning of the intervention

‘What do you think of the intervention?’ prompt for the following:

- overall coherence
- usefulness/ value
- appropriateness of content
- alignment with professional goals

ii) Cognitive participation – the commitment participants are willing to make

- What would stop you from using it? (barriers)
- What would help you to use it? (facilitators)
- What would you need from a website and informational content of this kind for it to be useful?
- How feasible do you think such an intervention is for you to use in practice?
- How acceptable do you think it might be to parents? And how would you perceive their use of such a resource? (possible additional question)

iii) Collective action – the effort that participants will make in response to an intervention

- What impact would the availability of this information have on your consultation style?
- ...or antibiotic prescribing? (confidence, targeting etc) or acute referral patterns
- How does it fit with your existing practices
 - e.g. for sourcing community illness information (e.g. other informational websites/ resources used within or to inform consultation and practice)

Any further comments on the intervention:

- design
- delivery
- perceived impact in practice?

...helping to understand children's coughs, colds and ear infections

This leaflet provides information for parents and carers about the EEPRIS interview study

We would like to invite you and your child to take part in an interview to discuss your experiences of EEPRIS.

When you joined the EEPRIS study you kindly agreed to be interviewed as part of the research. We are interviewing a selection of the people taking part in the main study, and we would like to meet with you for one interview. If you have a child in year group 3 (aged 7/8) or above we would like to include them in the interview if they would like to be a part of it. Neither you nor your child have to take part, and before you decide whether to go ahead, we would like you to understand why we are doing this interview study and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please read the following information carefully and feel free to talk to others about the interview study if you wish.

What is the purpose of the interview study?

There are two purposes of the interview study. First we want to find out parents' and children's (aged 7/8 and over) experiences of taking part in the EEPRIS study. We are particularly interested in your experiences of the different parts of EEPRIS such as the email (/text) messages, research nurse visit and daily symptom reporting and whether you think these components could be improved. Second we want to gather opinions on a possible future online resource of 'real-time' illnesses circulating in the community. This type of 'real-time' illness information could help parents and GPs know what common bugs are going round in the area and how best to manage them. We will use the information collected in the interview study to feed into the design of this online resource.

Why have I (and my child) been invited to take part?

You have been invited to take part in this additional interview study because you and your child/children have participated in EEPRIS. We are inviting a selection of parents who consented to take part in an interview. Any participating children in year 3 (aged 7/8) or over are also welcome to participate in the interview with you as we would also like to know their experiences of participating in EEPRIS.

If we take part, what does it involve for me and my child?

If you agree to take part, a researcher from the University of Bristol will visit you to discuss your views on the EEPRIS study and a possible future online resource of 'real-time' illnesses circulating in the community. If your child is year group 3 (aged 7/8) or above, we would like to include them in the discussion too. We expect it will take about 45 minutes, and can take place at a time and place convenient to you (either at your home or another location of your choice).

With your permission we would like to make an audio recording of the interview which will be typed up (transcribed) by a third party so that we can remember what was said. The third party will sign a confidentiality agreement. After it is transcribed, the audio recording will be deleted and the transcript will be anonymised (any identifiable information about who you are will be deleted).

Will I be compensated for taking part in the study?

We will give you a £5 high street voucher as a thank you gift for your time.

What are the advantages of taking part?

You will be making a valuable contribution to research on the illnesses that affect most children in our country. The wider aims of this research are to improve the understanding, diagnosis and management of respiratory illnesses which could benefit your child and many children in future.

Are there any disadvantages in taking part?

There are no real risks in taking part in this interview study. The only disadvantage in taking part is the time taken.

What will my information be used for?

The information we record will only be used for the purposes of the research study as described above. The transcripts will be downloaded to the university server and will be stored securely and in accordance with the requirements of the Data Protection Act for up to 3 years. A report of the study results will be completed for the funding body. Results will also be published in scientific journals and presented at scientific conferences. Anonymous quotes from the interview may be published as part of this research project.

We will send you a newsletter with a summary of the main results of the study, and we will update our website with links to study publications when they become available. It is a fairly lengthy process to publish results, so the final results of this study will not be available for at least a year.

Do we have to take part?

No, it is up to you whether or not you want to take part. If you do decide to take part in the interview study you are free to stop taking part without giving a reason at any time. If you change your mind about being part of this interview study you have two weeks after the interview in which to inform the study team and we can delete any information relating to you if you like.

What if something goes wrong?

If you have complaints or concerns about the study, please get in touch with the study team in the first instance. Taking part in this study will not affect your normal rights to pursue any complaint about your medical treatment within the NHS in the normal way.

Remember, this is a research study, not medical care. If you have any concerns about your child's health or your own, please seek advice from your doctor (not the study team) as usual.

What should I do now?

If you are willing to take part in this research, your contact is **Jo Kesten** who is conducting interviews within the EEPRIS study. Jo will contact you shortly to see if you want to arrange to meet her. Please contact Jo if you have any further questions or to arrange a date and time to meet:

Email: jo.kesten@bristol.ac.uk or telephone: (0117) 3421245

Thank you for reading this and considering taking part in this study

You can also contact the main EEPRIS study team on the usual contact details:

Email: eepris-kids@bristol.ac.uk; telephone: (0117) 3314598; website: <http://www.bristol.ac.uk/eepris>
Parent Information Leaflet Interview EEPRIS Study. Version 2 (2015-10-14)

Page 2 of 2

Parent (and children) interview topic guide

Main topic	Subthemes within topics	Prompts to be used if necessary
1. Experiences and acceptability of the feasibility study components	Overall experience of study	
	Study participation	Barriers to recruitment
		Facilitators to recruitment
		Suggestions for approaches to recruitment in a future project
	Positive and negative aspects of the study / incentives and barriers to data completion	Acceptability of text messages and/or follow up telephone calls (e.g. frequency, timing, content)
		Time burden (especially if reported more than one RTI)
		Convenience/acceptability of research nurse visits
		Convenience/acceptability of daily symptom records
		Ability to take nasal swabs
	Impact of completing symptom diary on perceptions of illness	E.g. did completing the diary influence level of concern regarding RTI symptoms
	Potential improvements to study elements	

**PARENTS ONLY
(NOT CHILDREN)**

2. Perceived value, acceptability and likely impact of online intervention.

Feedback on value of intervention proposal

Provide description of intervention and present example of vignette to be used in the online intervention (e.g. “Microbiological bug name (and some data/info) with some text to say: “This is/ these are bugs known to be circulating in the area at the moment. The typical symptoms are [x, y and z]. NB: This bug and/or symptom profile may not be true for your child (or patient).”)

Feedback on vignettes

E.g. *What do you think of these stories?*

Perceived influence of vignettes

Anticipated influence on:

- *Perceived need to consult*
- *Perceived confidence about when to consult*
- *Concern for child health*

How might vignettes be used?

Checked when child becomes unwell
To determine when to consult

Feedback on information in vignettes

Level of detail
User-friendly
Perceptions of credibility Symptoms (including severity and length)
Number of children with similar symptoms in local area
Area level specific information
Advice about when to consult for various symptoms

How do these vignettes compare to information obtained elsewhere?

NHS choices website
Social media
Family and friends

Optimum design of intervention

Information platform (PC, tablet, smartphone, website, social media)

Alerting system (e.g. sign-up to receive text messages)

Receipt of information via GPs vs online.

Adverse and Serious Adverse Event Reporting Form

Secure Fax: 0117 928 7311

Please complete this form using black ink and BLOCK capitals. Options should be selected by placing a cross(X) in the appropriate box.

Once complete, please fax to **Emma Anderson (Study Manager)** as soon as possible, ideally within 24 hours, of the event taking place. If you have any questions relating to this form or reporting please ring the study team on **0117 331 4598**.

A serious adverse event is any medical occurrence that results in death, is life-threatening, requires or prolongs hospitalisation, causes persistent or significant disability, results in congenital abnormalities or represents potentially serious harm to research patients and others.

Section 1 – Participant & Site Details

1. Study ID: -
2. Date of Birth:
3. Site ID:
4. Site Name:

Section 2 – Adverse Event Details

5. Please provide a description of the serious adverse event:

Use BLOCK capitals (continue on separate sheet if necessary):

6. Date of onset:
7. Has the event resolved: Yes ☐
No ☐
Ongoing ☐
8. Date resolved:

Section 3 – Type of Event

9. Which serious category did the event match?

(tick one box)

Resulted in death ☐

Life-threatening ☐

Required hospitalisation, or prolongation of existing hospitalisation ☐

Persistent or significant disability /incapacity ☐

Other important medical condition ☐

10. Was the event related to study participation?

Unrelated ☐

Unlikely to be related ☐

Possibly related ☐

Probably related ☐

Definitely related ☐

11. Was the event expected?

Expected ☐

Unexpected ☐

Section 4 – Form Details

12. Date SAE form completed:

--	--	--	--	--	--	--	--

13. Signature of person responsible for notification :

--

14. Please Print Name:

--

15. Please Print Position:

--

For [CENTRE] use ONLY

1. Date received:

--	--	--	--	--	--	--	--

2. Date entered on database:

--	--	--	--	--	--	--	--

3. Entered by:

--	--

4. Name of reviewer:

--

5. Date of review:

--	--	--	--	--	--	--	--

6. Type of event:

SAE ☐

SAR ☐

7. Comments:

--