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| **PRIEST Study: P**andemic **R**espiratory **I**nfection **E**mergency **S**ystem **T**riage**ISRCTN:** 56149622**Portfolio** 12725 |

**Frequently Asked Questions**

This information and FAQs document is intended for sites participating in the PRIEST study. It contains important information about the anticipated operation of the study and the patient pathway in a pandemic situation.

**What is the aim of the PRIEST study?**

The PRIEST study aims to optimise the triage of people using the emergency care system (999 ambulance or hospital emergency department) with suspected respiratory infections, namely coronavirus, and identify the most accurate triage method for predicting severe illness among patients attending the emergency department with suspected coronavirus.

**What are the changes from the PAINTED to PRIEST study?**

In preparation for COVID-19, we submitted an amendment to change from the PAINTED to PRIEST study. The amendment changes the study in several ways. The changes most relevant to sites are:

1) The study can now look at all respiratory infection pandemics, not only influenza. This means that currently, we are looking at coronavirus

2) The PRIEST study has the additional objective of feeding back emerging evidence to health services during the pandemic

3) The PREST study allows for additional follow up of patients that require further information, e.g. false negatives i.e. patients that have been sent home but later have an adverse outcome

**Is this a DHSC priority study?**

Yes. PRIEST is an **urgent public health study**. While PRIEST is an observational study, the information we collect is recognised as of great importance to helping clinicians prioritise resources at this crucial time.

**We are participating in another pandemic study or trial; can we still participate in the PRIEST study?**

There are no barriers to running more than one of the pandemic studies within your department. In fact, the chief investigators from all pandemic portfolio studies have agreed mutual support in principle. Patients identified in one study may also be suitable for PRIEST and visa versa. Co-enrolment to both studies is actively encouraged.

**What is the study method?**

PRIEST is an observational cohort study of coronavirus during the current pandemic. We will be recording medical details from patients with suspected coronavirus, who arrive at emergency departments or are triaged through ambulance services. We will then use hospital records to follow these patients up to 30 days on to find out if they die or suffer a life-threatening complication.

**What are the outputs of this study?**

We will evaluate triage methods used to determine whether a patient with suspected coronavirus should be admitted to hospital or not, and whether they should be admitted to intensive or high dependency care. In the following stages of the pandemic, this evidence could be used to produce guidelines to help decide which patients would benefit from being admitted to hospital.

**What information should we give patients?**

Child, adolescent, and adult leaflets should be given to patients (or parents/ guardians of patients) when they have been assessed as eligible at triage, subject to any infection control requirements. The leaflet offers the patient the opportunity to withdraw their data from the study. You should also display study posters around your emergency department. We suggest that these posters are laminated, for infection control reasons. Due to infection control, if you are unable to give patients leaflets we suggest you direct them to posters so they find out about the study and make a decision on opting out.

**Should we print the study material?**

We ask that you print the study material and laminate posters. As a central team we are working from home. If this is an issue please let us know and we will make arrangements to print and send documents to you.

**How do we identify patients with coronavirus?**

Any patients suspected of having coronavirus can be included in the study. Patients can be identified through usual clinical screening. If patient details are being extracted from patient notes, you may find it useful for those in triage to make a note of the patient's NHS number so you can identify them later. Additionally, consider asking your local information team to provide a list of patients being reported to have suspected COVID-19, if your local electronic system is recording this information. We are aiming to make this study pragmatic and limit impact on front line care. Please work with your assigned Research Assistant if you are having any issues.

**Who is eligible to join the PRIEST study?**

We will include all adults and children presenting with suspected coronavirus during the pandemic.

**Do patients need to be diagnosed with COVID-19/Coronavirus?**

No, patients do not have to have a formal diagnosis of COVID-19. A suspected case is enough when including patents and filling out the initial data collection tool at triage/adding them to the study database.

**We are triaging patients outside of the ED in the pandemic, can we include these patients?**

Yes. We consider these triage hubs, or similar, to be an extension of the hospital ED system and therefore should be included in the study where possible. We consider patients to be eligible if they are booked in as hospital patients, which we assume would be within the ED system. If you are unsure whether your hub classifies, please get in touch right away for clarification, via the study email address (PRIEST-study@sheffield.ac.uk).

**Do we need to seek consent from the patients?**

No, but they can opt-out of the research. We have approval from the Confidentiality Advisory Group (CAG – formally the NIGB) Section 251, to record patient identifiers, namely the NHS number, without seeking patient consent. Section 251 enables the common law duty of confidentiality to be overridden to enable disclosure of confidential patient information for medical purposes. Please see <https://www.hra.nhs.uk/documents/223/cag-frequently-asked-questions-1.pdf> for more information.

**What if a participant doesn’t want us to use their data in the study?**

Posters will be put up in the ED, and leaflets will be available for patients, informing them of the study, and how to withdraw their data. Patients can opt-out of the study by telling the care/research staff in the ED, or emailing/calling at a later date. There is an option on the database to select ‘withdrawn’. If this is selected, the database will not allow you to enter any data for this patient.

**What data are we collecting on patients?**

All of the data we need on Pandemic Respiratory Infection form v5.0 and Follow-up form v3.0. The Pandemic Respiratory Infection form includes patient information such as patient vital signs, presenting features, current medicine, lifestyle, and medical history. The follow-up form asks for information on whether patients have had an adverse outcome such as requiring organ support, admitted to HDU/ICU, or died. Once collected this information should be entered onto the study databases. Please be aware that there are some fields on the Pandemic Respiratory Infection Form that we do not require on the study database, these are there for your use if you wish to use the form for triage purposes.

**When should we collect data?**

Please collect data on the Pandemic Respiratory Infection form as soon as you are able in your department. This can be done by the clinician or research nurse who sees that patient. The form has been designed to help you triage patients if required. If this is not possible you can retrospectively extract patient details from patient notes and input them straight on to the study database, without completing the Pandemic Respiratory Infection Form. Please work with the Research Assistant assigned to your site so we can provide support where necessary and also share good practice between sites.

**Who fills in the Pandemic Respiratory Infection Form?**

Anyone within the emergency department who may routinely fill in clinical assessment forms as part of their work can use the form to assess patients. However, we are taking a pragmatic approach considering the time we are in. It does not have to be a member of the direct care team that enters the patient information into the Prospect database. If a member of staff has capacity and local approval to access patient information then they can add patient details to the study database as long as they have local clinical and/or research support, e.g. local PI and research nurse.

**Does a clinician have to sign the Pandemic Respiratory Information Form?**

No. There is a space for clinician name and signature, but completing this is not strictly required if using the form for data collection only. If you are using the form for triage purposes, you must decide locally whether you mandate that someone signs the form.

**How do we return the patient information?**

We are asking that you send the study information back to the University of Sheffield through entering it on to the study database (named Prospect). We will forward information/training to help you access and use the database. Please contact your assigned Research Assistant via the study email address (priest-study@sheffield.ac.uk) if you have any issues.

**What do we do with the completed Pandemic Respiratory Infection forms?**

As the form doubles up as clinical notes, we advise that they are kept in the ED patient records, when used in this way. A photocopy may then be taken by the research staff member and removed to a safe and secure place. We advise that this is done on a frequent and routine basis during the pandemic to ensure that forms are not lost, misplaced, moved onto other wards, or are scanned into other formats prior to retrieval. Data from the form must be input in the Prospect database.

A screencast demonstration, available on the PRIEST website, shows how to access the database from a computer terminal and how to upload data from the forms online, link: <https://www.sheffield.ac.uk/scharr/sections/hsr/cure/priestpages/priest>

**Should we send the paper form back to the University of Sheffield?**

No. This form can be used to help with triage of patients as required locally.

**How do we report ‘recruitment’ of patients into PRIEST?**

As patients are not strictly ‘recruited’ to PRIEST, (Recruitment is defined as a patient freely giving consent to partake in a study) there are no accruals to record as there are for trials. CRN research staff are advised to complete an ‘exception report’ to record the patients collected as a means of evidencing the work done. We are currently liaising with the NIHR to see whether it is possible for sites to get accruals. This is not yet guaranteed, but we will keep you updated.

**How do I get access to the study database?**

Your assigned Research Assistant will ask you to provide the name, study role and email address of all members of staff who need access to the database, to allow them to enter data at your site. Those members of staff will then be sent individual login details.

**Can we enter information straight from patient notes into the study database?**

Yes. If you find it easier to enter patient information from patient notes and not use the paper form that is fine.

**Will we need to follow-up with patients and when?**

Yes. Patients should be followed-up until 30 day after attendance by hospital record review. However, to achieve the new objective of PRIEST of feeding back emerging evidence during a pandemic we ask sites to provide follow-up data **as early as possible** about patients into the study database. If we identify emerging patterns of adverse outcomes we may ask you to capture additional information about these patients, we will let you know if this is required.

**Who can be a site Principal Investigator (PI)?**

Anyone within the emergency department who routinely assesses patients as part of their work, has relevant experience, and is available to act as PI at this time can take on that role. This may include clinicians, nurses or allied health professionals.

**Is any staff training required?**

To reduce burden on sites, we will not be keeping a formal record of training. However, site staff will be expected to watch the training videos available on the PRIEST website,and read the study materials provided, for guidance. You can also talk to your assigned Research assistant for more guidance and arrange a training call if necessary.

**What additional work is involved for clinical and research staff?**

The triage tool is designed in such a way that it can be used as a triage form, meaning no additional work is required in terms of patient assessment. Identifying completed Pandemic Respiratory Infection Forms, retrieving them, and uploading the data to the Prospect online database will be additional to standard practice but we can provide assistance in developing a streamlined process for this.

**Do we get paid for participation in PRIEST?**

Yes, in the recent variation to contract, sites will now be paid for 15 min per patient included at triage, at the rate of band 6.5 afc. This variation to contract was arranged before the activation for COVID-19. It is going through the final approval steps now, so will not be with your contracts department yet, but should be soon. In the COVID-19 pandemic, it is possible that we will exceed our financial allocation to pay sites. We are in discussions with the NIHR for how we can continue to provide financial support to sites at this point and will keep you updated.

**How long will the study run for?**

The study does not have an official endpoint. It will run for the length of the pandemic. For an influenza pandemic, this was envisaged to be around 3 months of data collection. However, for COVID-19 the length is unknown. We will reassess this on an ongoing basis and will seek additional funding as required. We will of course work with sites to assess ongoing capacity and capability as the situation evolves, and will provide appropriate support where possible.

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| **Who should I contact if I have any further questions?**In the first instance, please contact your assigned Research Assistant via the PRIEST email address (PRIEST-study@sheffield.ac.uk) and we will do our best to get back to you as soon as possible. Alternatively, you may contact the Chief Investigator, Professor Steve Goodacre (steve.goodacre@sth.nhs.uk, s.goodacre@sheffield.ac.uk or study manager Dr Ben Thomas (b.d.thomas@sheffield.ac.uk)  |