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Evaluation of COVID-19 assessment in emergency departments and ambulance services

Submission date
27/03/2020

Recruitment status
No longer recruiting

Registration date
04/05/2020

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Respiratory (lung) infections, such as influenza or the coronavirus, affect the lungs and airways, typically causing symptoms such as fever, sore throat, coughing and breathing difficulties. They have the potential to cause a pandemic if a new strain of the virus becomes widespread across many countries. This can result in increased numbers of patients attending hospital and needing investigation or admission, and can place a huge strain on the NHS.
Patients contacting NHS 111, calling for a 999 ambulance or attending a hospital emergency department with suspected pandemic respiratory infection need to be rapidly assessed to identify who has severe illness and needs hospital admission. This process is known as "triage" and often uses methods, such as scores or decision rules, which have been developed to assess the severity of illness and predict which patients are at risk of life-threatening complications. Triage methods have been developed and are ready for use in a pandemic, but it is not known how well they perform in terms of correctly predicting who needs hospital admission and who does not. The researchers plan to use patient data from the early phases of a pandemic to test how well existing triage methods predict serious complications, identify cases where the triage methods did not predict serious complications or recommended unnecessary hospital admission, and modify triage methods or develop new triage methods that predict serious complications better than existing methods. This will involve recording medical details in a standardised way from patients with a suspected respiratory infection and then using hospital records to follow patients up to find out if they die or suffer a life-threatening complication.

Who can participate?
All adults and children with suspected respiratory infection during a pandemic who present at the emergency department of a participating hospital, call 111 or 999 services or are attended by a 999 ambulance from a participating ambulance trust

What does the study involve?
The researchers plan to use routine electronic data collected from people using the emergency care system (via 111 and 999 calls, ambulance conveyance, or hospital emergency department) with suspected respiratory infections during a pandemic. Participating emergency departments

will be provided with electronic and/or paper forms that can be integrated into the patient record and used to collect standardised triage assessment data. The form can be used at triage or at full patient assessment and will form part of the clinical record. It can also be used by the emergency department to guide triage assessment. For example, the data recorded can be used to recommend diversion away from the hospital if criteria are not met or admission to hospital if criteria are met. The form will include key variables used in recommended triage methods, such as PMEWS and the swine flu hospital pathway, and other variables considered to be potentially useful predictors of adverse outcome. The researchers will allow participating sites to adapt the form to their local circumstances, for example omitting variables that are already routinely collected. The electronic and/or paper forms can also be used by paramedics in participating ambulance services. The electronic form will be used to collect data as part on the electronic case report form (eCRF) and can be used to support decisions, such as a decision not to transport the patient to hospital if triage criteria are not met. Alternatively, for 111 and 999 triage calls ambulance services could provide the University of Sheffield with the routinely collected triage question of patients with suspected respiratory infection pandemic. Though this routine data would not match data collected from participating hospitals it would closer reflect the data ambulances are collecting with patients and lessen the workload placed on frontline staff. The researchers will work with participating ambulance trusts to choose a data collection approach that best fits their capacity. Participating emergency departments and ambulances could also provide regular datasets to the University of Sheffield. Sites' business intelligence units or equivalent would be handle file transfers through a secure file transfer system, such as a FTP server.

What are the possible benefits and risks of participating?
There are no direct benefits to a patient but there are potential benefits to the ability of emergency departments to prioritise pandemic cases appropriately, so those that most require care receive it in a timely manner. The results of the study could be used in subsequent phases of a pandemic to produce a guideline or rule to decide which patients require hospital admission. The findings can also be used by doctors and nurses to identify which individual patients are at risk of serious complications. The researchers may also be able to identify which patient characteristics are associated with an increased risk of serious complications in a particular pandemic. For example, in 2009 it was found that pregnant patients and those suffering from obesity were at higher risk. The risks to patients involved in the study are very low. The study will not involve any change to the way patients are investigated or treated. Data collection has been designed to assist medical staff so that it does not interfere with patient care, and has been tested during a winter flu season. Most personal details will be removed from information that leaves a hospital, the researchers are only recording NHS numbers and ambulance incident numbers so they can track how patients move through health services. More identifiable information, such as patient’s names, will only be available to local trained nurses who work alongside the care teams. The researchers do not plan to ask patients for written consent to use their data in the study because this would incur delays that could be harmful in a pandemic. However, they will inform patients of the study and ensure that they are able to remove their data from the study if they wish. This approach worked well in the 2009 study and was approved by an independent Research Ethics Committee and the National Information Governance Board.

Where is the study run from?
The study will be undertaken by experienced researchers in Sheffield, Manchester and London who will involve around 40 hospitals across the country. They include experts in emergency medicine, intensive care, public health, and statistics. The Clinical Trials Unit in Sheffield is registered to provide research support and will be responsible for collecting and analysing the data.

When is the study starting and how long is it expected to run for?
October 2012 to October 2021

Who is funding the study?
Health Research Health Technology Assessment (NIHR HTA) Programme (UK)

Who is the main contact?
Dr Ben Thomas, priest-study@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Steve Goodacre

ORCID ID
http://orcid.org/0000-0003-0803-8444

Contact details
3023 Regent Court
211 Portobello Street
Sheffield
United Kingdom
S1 4DP
+44 (0)114 222 0842
priest-study@sheffield.ac.uk

Type(s)
Scientific

Contact name
Dr Ben Thomas

Contact details
Clinical Trials Research Unit
ScHARR
University of Sheffield
Innovation Centr
217 Portobello
Sheffield
United Kingdom
S1 4DP

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
101138

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 12725, IRAS 101138

Study information

Scientific Title
The PRIEST study: Pandemic Respiratory Infection Emergency System Triage

Acronym
PRIEST

Study objectives
The aim of this study is to optimise the triage of people using the emergency care system (111 and 999 calls, ambulance conveyance, or hospital emergency department) with suspected respiratory infections during a pandemic and identify the most accurate triage method for predicting severe illness among patients attending the emergency department with a suspected respiratory infection.

The specific objectives during the pandemic are:
1. To undertake continuous monitoring of the performance of the emergency care triage method (or methods) used for suspected respiratory infections during a pandemic.
2. To identify clinical characteristics and routine tests associated with under-triage (false negative assessent) or over-triage (false positive assessment) during a pandemic.
3. To determine the discriminant value of alternative triage methods for predicting severe illness in patients presenting with suspected respiratory infection during a pandemic.
4. To inform policymakers and practitioners during a pandemic of the study's emerging findings.

The specific objectives after the pandemic are:
1. To determine the discriminant value of emergency department triage methods for predicting severe illness in patients presenting with suspected pandemic respiratory infection.
2. To determine the discriminant value of presenting clinical characteristics and routine tests for identifying severe illness.
3. To determine the independent predictive value of presenting clinical characteristics and routine tests for severe illness.
4. To develop new triage methods based upon presenting clinical characteristics alone or presenting clinical characteristics, electrocardiogram (ECG), chest X-ray and routine blood test results, depending upon the data available and the predictive value of variables evaluated in objective 3.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 25/06/2012, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048165; haydock.rec@hra.nhs.uk), REC ref: 12/NW/0303

Study design
Both; Design type: Other, Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Participant information sheets can be found at: https://www.sheffield.ac.uk/scharr/sections/hsr/cure/priestpages/priest

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The researchers plan to undertake an observational cohort study using routine electronic data capture from people using the emergency care system (via 111 and 999 calls, ambulance conveyance, or hospital emergency department) with suspected respiratory infections during a pandemic.

Participating emergency departments will be provided with electronic and/or paper forms that can be integrated into the patient record and used to collect standardised triage assessment data. The form can be used at triage or at full patient assessment, and will form part of the clinical record. It can also be used by the emergency department to guide triage assessment. For example, the data recorded can be used to recommend diversion away from the hospital if criteria are not met or admission to hospital if criteria are met. The form will include key variables used in recommended triage methods, such as PMEWS and the swine flu hospital pathway, and other variables considered to be potentially useful predictors of adverse outcome. We will allow participating sites to adapt the form to their local circumstances, for example omitting variables that are already routinely collected.

The electronic and/or paper forms can also be used by paramedics in participating ambulance services. The electronic form will be used to collect data as part on the electronic case report form (eCRF) and can be used to support decisions, such as a decision not to transport the patient to hospital if triage criteria are not met. Alternatively, for 111 and 999 triage calls ambulance services could provide the University of Sheffield with the routinely collected triage question of patients with suspected respiratory infection pandemic. Though this routine data would not match data collected from participating hospitals it would a) closer reflect the data ambulances

are collecting with patients and b) lesson the work load placed on front line staff. The researchers will work with participating Ambulance trusts to choose a data collection approach that best fits their capacity.

Participating emergency departments and ambulances could also provide regular datasets of the study's predictor variables to the University of Sheffield. Sites business intelligence units or equivalent would be handle file transfers through a secure file transfer system, such as a FTP server.

Intervention Type
Other

Primary outcome measure
Patients who die or require respiratory, cardiovascular or renal support will be defined as having an adverse outcome. If patients survive to 30 days without requiring respiratory, cardiovascular or renal support they will be defined as having no adverse outcome. If a severe pandemic leads to hospital resources being overwhelmed the researchers will categorise patients as having an adverse outcome if they were deemed to have needed respiratory, cardiovascular or renal support but were denied this due to lack of resources; Timepoint(s): 30 days

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2012

Completion date
31/10/2021

Eligibility

Key inclusion criteria
All adults and children with suspected respiratory infection during a pandemic who present at the emergency department of a participating hospital, call 111 or 999 services or are attended by a 999 ambulance from a participating ambulance trust.

Patients will be eligible for inclusion if they meet the current clinical diagnostic criteria;
1. Fever (pyrexia ≥38°C) or a history of a fever
2. Influenza-like illness (two or more of cough, sore throat, rhinorrhoea, limb or joint pain, headache, vomiting or diarrhoea or severe and/or life-threatening illness suggestive of an infectious process. (Or if they meet any future clinical diagnostic criteria recommended by the Department of Health).

Participant type(s)
Patient

Age group
Mixed

Sex

Both

Target number of participants
Planned Sample Size: 20,000; UK Sample Size: 20,000

Total final enrolment
22445

Key exclusion criteria
Participants will only be excluded from the study if they request to be.

Date of first enrolment
26/03/2020

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Rd
Sheffield
United Kingdom
S5 7AU

Study participating centre
Sheffield Children’s NHS Foundation Trust
Sheffield Children's Hospital
Clarkson St
Broomhall
Sheffield
United Kingdom
S10 2TH

Study participating centre
Salford Royal NHS Foundation Trust
Salford Royal Hospital
Stott Ln
Salford
United Kingdom
M6 8HD

Study participating centre
York Teaching Hospital
Wigginton Rd
Clifton
York
United Kingdom
YO31 8HE

Study participating centre
Scarborough General Hospital
Woodlands Dr
Scarborough
United Kingdom
YO12 6QL

Study participating centre
Barts Health NHS Trust
St Bartholomew's Hospital
W Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Rd
Hull
United Kingdom
HU3 2JZ

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Rd
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Rd
Reading
United Kingdom
RG1 5AN

Study participating centre
Dorset County Hospital NHS Foundation Trust
Dorset County Hospital
Williams Ave
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire Royal Hospital
Great Western Rd
Gloucester
United Kingdom
GL1 3NN

Study participating centre

The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Rd
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
The Shrewsbury & Telford Hospital NHS Trust
Princess Royal Hospital
Apley Castle
Telford
United Kingdom
TF1 6TF

Study participating centre
The Shrewsbury & Telford Hospital NHS Trust
Royal Shrewsbury Hospital
Mytton Oak Rd
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
University Hospital North Midlands NHS Trust
Royal Stoke Hospital
Newcastle Rd
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre

Southend University Hospital NHS Foundation Trust
Southend Hospital
Prittlewell Chase
Westcliff-on-Sea
Southend-on-Sea
United Kingdom
SS0 0RY

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Harrogate District Hospital
Harrogate District Hospital
Lancaster Park Rd
Harrogate
United Kingdom
HG2 7SX

Study participating centre
NHS Lothian
Royal Infirmary of Edinburgh
51 Little France Cres
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Royal Hospital for Sick Children
9 Sciennes Rd
Edinburgh
United Kingdom
EH9 1LF

Study participating centre

St John's Hospital
Howden W Rd
Howden
Livingston
United Kingdom
EH54 6PP

Study participating centre
Western General Hospital
Crewe Rd S
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Mid and South Essex NHS Foundation Trust
Broomfield Hospital
Court Rd
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Newcastle Upon Tyne Hospitals NHS Trust
Royal Victoria Infirmary
Queen Victoria Rd
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Manchester University NHS Foundation Trust
Manchester Royal Infirmary
Oxford Rd
Manchester
United Kingdom
M13 9WL

Study participating centre

Royal Manchester Children’s Hospital
Oxford Rd
Manchester
United Kingdom
M13 9WL

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Aintree University Hospital
Lower Ln
Liverpool
United Kingdom
L9 7AL

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital
Hills Rd
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Rd
Lenton
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Craigavon Area Hospital
68 Lurgan Rd
Portadown
Craigavon
United Kingdom
BT63 5QQ

Study participating centre

Wexham Park Hospital
Wexham St
Slough
United Kingdom
SL2 4HL

Study participating centre
The Queen Elizabeth Hospital King’s Lynn NHS Foundation Trust
Queen Elizabeth Hospital
Gayton Rd
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Aneurin Bevan University Health Board
Royal Gwent Hospital
Cardiff Rd
Newport
United Kingdom
NP20 2UB

Study participating centre
Aneurin Bevan University Health Board
Nevill Hall Hospital
Brecon Rd
Abergavenny
United Kingdom
NP7 7EG

Study participating centre
Great Western Hospitals NHS Foundation Trust
Great Western Hospital
Marlborough Rd
Swindon
United Kingdom
SN3 6BB

Study participating centre
King's College Hospital NHS Foundation Trust
King’s College Hospital

Denmark Hill
Brixton
London
United Kingdom
SE5 9RS

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
Ashford Hospital
London Rd
Stanwell
Ashford
United Kingdom
TW15 3AA

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
St Peter’s Hospital
Guildford Rd
Lyne
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Lancashire Teaching Hospitals NHS Trust
Royal Preston Hospital
Sharoe Green Ln
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
Epsom Hospital
Dorking Rd
Epsom
United Kingdom
KT18 7EG

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Ln
Sutton
Carshalton
United Kingdom
SM5 1AA

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of North Tees
Hardwick Road
Stockton on Tees
Cleveland
United Kingdom
TS19 8PE

Study participating centre
Guys and St Thomas' NHS Foundation Trust
Evelina London Children’s Hospital
Westminster Bridge Rd
Bishop's
London
United Kingdom
SE1 7EH

Study participating centre
Barnsley Hospital NHS Foundation Trust
Barnsley Hospital
Gawber Rd
Barnsley
United Kingdom
S75 2EP

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds General Infirmary
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James' University Hospital
Beckett St
Harehills
Leeds
United Kingdom
LS9 7TF

Study participating centre
County Durham and Darlington NHS Foundation Trust
Hollyhurst Rd
Darlington
United Kingdom
DL3 6HX

Study participating centre
County Durham and Darlington NHS Foundation Trust
University Hospital of North Durham
North Rd
Durham
United Kingdom
DH1 5TW

Study participating centre
St George’s University Hospital NHS Foundation Trust
St. James Wing
St George's Hospital
Blackshaw Rd
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
South Tees Hospitals NHS Foundation Trust
The James Cook University Hospital
Marton Rd
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Alder Hey Children's Hospital
E Prescot Rd
Liverpool
United Kingdom
L12 2AP

Study participating centre
Stockport NHS Foundation Trust
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool Hospital
Prescot St
Liverpool
United Kingdom
L7 8XP

Study participating centre
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Royal Bournemouth Hospital
Castle Ln E
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Sherwood Forest Hospital NHS Foundation Trust
Sutton Rd
Stockwell Gate
Mansfield
United Kingdom
NG18 5QE

Study participating centre
East Sussex Healthcare NHS Trust
Conquest Hospital
The Ridge
Hastings
Saint Leonards-on-Sea
United Kingdom
TN37 7RD

Study participating centre
East Sussex Healthcare NHS Trust
Eastbourne District General Hospital
Kings Dr
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Bolton NHS Foundation Trust
Royal Bolton Hospital
Minerva Rd
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Surrey and Sussex Healthcare Foundation Trust
East Surrey Hospital
Canada Ave
Redhill
United Kingdom
RH1 5RH

Study participating centre
East Lancashire Hospital NHS Trust
Royal Blackburn Teaching Hospital
Haslingden Rd
Blackburn
United Kingdom
BB2 3HH

Study participating centre
East Lancashire Hospital NHS Trust
Burnley General Teaching Hospital
Casterton Ave
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Lewisham and Greenwich NHS Trust
Queen Elizabeth Hospital
Stadium Rd
Woolwich
London
United Kingdom
SE18 4QH

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
Royal Hallamshire Hospital
Glossop Road
Broomhall
Sheffield
England
United Kingdom
S10 2JF
+44 (0)114 226 5935
getinvolved@sth.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 11/46/07

Results and Publications

Publication and dissemination plan
Additional study documents including the study protocol can be found and downloaded at the study website: https://www.sheffield.ac.uk/scharr/sections/hsr/cure/priestpages/priest

Publication and dissemination plan to be confirmed at a later date

Intention to publish date
31/07/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		01/06/2020	22/07/2020	No	No
Results article	post-exertion oxygen saturation sub-study results	03/12/2020	07/12/2020	Yes	No
Results article	results	25/11/2020	15/01/2021	Yes	No
Preprint results	non-peer-reviewed analysis of DNAR status in preprint	27/01/2021	19/03/2021	No	No
Results article	triage tool development results	22/01/2021	19/03/2021	Yes	No
Results article	secondary analysis results	01/07/2021	10/05/2021	Yes	No
Results article		03/06/2021	07/06/2021	Yes	No
Preprint results	Prognostic accuracy study results	29/07/2021	30/07/2021	No	No
Preprint results	Observational cohort study results	19/10/2021	21/10/2021	No	No
Preprint results	Accuracy of telephone triage	29/06/2021	03/12/2021	No	No
Preprint results	Prognostic accuracy results for children	10/09/2021	03/12/2021	No	No
Dataset		25/11/2020	14/06/2023	No	No
HRA research summary			28/06/2023	No	No