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Evaluation of current emergency department triage methods during a flu pandemic

Submission date
16/07/2012

Recruitment status
Stopped

Registration date
19/07/2012

Overall study status
Stopped

Last Edited
22/07/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to identify which patients presenting with influenza are at the greatest risk of a severe outcome. This is needed to accurately prioritise (triage) patients during a pandemic to target resources in the emergency department to those who need it. This research is of particular importance as there are currently no triage methods specifically for influenza.

Who can participate?
People involved in this study will be everyone turning up at the emergency department with suspected influenza; participants will be excluded if they request.

What does the study involve?
Data will be collected by the attending doctor, who will record results from the patient examination onto a standardised assessment form. This form will then make up part of the patient notes within the hospital. This information along with the 30-day outcome of what happened to the patient will be anonymously entered into a database within the hospital. This anonymous data will then be sent to researchers at The University of Sheffield for analysis.

What are the possible benefits and risks of participating?
Possible benefits to being in this research are that doctors are given a standardised clinical assessment form that highlights the sort of questions they need to be asking. This ensures that all bases are covered for the patient. Data collected from the initial phases of a pandemic will help to create new triage tools that could potentially be used during the later stages of the pandemic or in a subsequent pandemic influenza break out. There are no risks involved with participants whose data is included in this study as there is no intervention. This study does not in any way change the treatment of a patient within the emergency department.

Where is the study run from?
This study is being run from The University of Sheffield. The six pilot sites for this study are Sheffield Teaching Hospital (which is also acting as the sponsor), Sheffield Children's Hospital, York Teaching Hospital, The Royal London, University Hospital South Manchester and Salford Royal. During the pandemic phase data will be collected across 40 UK sites.

When is the study starting and how long is it expected to run for?
The pilot phase will run from the beginning of October 2012 to the end of March 2013. Unfortunately we cannot give dates for the pandemic phase as we don't know when a pandemic might occur but in this event the study would run for long enough to gather 20,000 cases.

Who is funding the study?
The study is funded by the Health Technology Assessment (HTA).

Who is the main contact?
Prof. Steve Goodacre
s.goodacre@sheffield.ac.uk

Study website
http://www.sheffield.ac.uk/scharr/sections/hsr/emergency/painted

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/46/07

Study information

Scientific Title
PAndemic INfluenza Triage in the Emergency Department (PAINTED)

Acronym
PAINTED

Study objectives
We will evaluate triage methods used to determine whether a patient with suspected pandemic influenza should be admitted to hospital or not, and whether they should be admitted to intensive or high dependency care. These will include the CURB-65 score (a risk prediction score for pneumonia, based on confusion, urea level, respiratory rate, blood pressure and age over 65 years), Pandemic Medical Early Warning Score (PMEWS), the swine flu hospital pathway, SMART-COP, the SwiFT score and any new methods developed before the next pandemic. We will also develop two new triage methods based upon
1. Presenting clinical characteristics alone and
2. Presenting clinical characteristics, electrocardiogram (ECG), chest X-ray and routine blood test results

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Haydock Ethics Committee, 25/06/2012, REC ref: 12/NW/0303

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Patient information sheets can be found at http://www.sheffield.ac.uk/polopoly_fs/1.196298!/file/PAINTEDAdultInfoLeaflet2012Version2.pdf (Adult)http://www.sheffield.ac.uk/polopoly_fs/1.196296!/file/PAINTEDChildInfoLeaflet2012Version2.pdf (Child)

Health condition(s) or problem(s) studied
Pandemic influenza

Interventions
Emergency department staff will be provided with a standardised assessment form. This form acts not only as a data collection form, for the purposes of the research, but also as a clinical record stored within the hospital and forming part of the patients' notes. The form will include information needed for the evaluation of triage methods. These data items should be routinely recorded by hospital staff on admission regardless of the research. The form will not request additional tests to be made purely for the purposes of the research. If, for example, the doctor

decided that an X-ray is not necessary for a patient then that decision is recorded and no X-ray performed.

CLRN research nurses will track patients until 30 days after initial emergency department attendance through a hospital record review to identify any adverse outcomes that have occurred.

In this study adverse outcome is defined as patients who die or require respiratory, cardiovascular, or renal support. In addition to this the length and location of hospital stay will be recorded, as will the use if any antiviral agents or antibiotics.

Respiratory support is defined as any intervention to protect the patient's airway or assist their ventilation, including non-invasive ventilation or acute administration of continuous positive airway pressure. It does not include supplemental oxygen alone or nebulised bronchodilators.

Cardiovascular support is defined as any intervention to maintain organ perfusion, such as inotropic drugs, or invasively monitor cardiovascular status, such as central venous pressure or pulmonary artery pressure monitoring, or peripheral arterial cannulation. It does not include peripheral intravenous cannulation and/or fluid administration.

Renal support is defined as any intervention to assist renal function, such as haemoperfusion, haemodialysis or peritoneal dialysis. It does not include intravenous fluid administration.

Intervention Type
Behavioural

Primary outcome measure
Patients will be followed-up until 30 days after attendance by hospital record review..

1. Patients who die or require respiratory, cardiovascular or renal support they will be defined as having an adverse outcome.
2. If they survive to 30 days without requiring respiratory, cardiovascular or renal support they will be defined as having no adverse outcome.
3. If a severe pandemic leads to hospital resources being overwhelmed we 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.

At day 30 the anonymous data will be entered into the database.

Secondary outcome measures
1. Record whether patients are treated with antiviral agents or antibiotics
2. The length and location of any hospital stay

Overall study start date
01/10/2012

Completion date
01/01/2025

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
We will include all adults and children presenting the emergency department of the participating hospitals with suspected pandemic influenza during the peak of the pandemic. Patients will be eligible for inclusion if they meet the current clinical diagnostic criteria of
1. Fever (pyrexia ≥38°C) or a history of fever and
2. Influenza-like illness (two or more of cough, sore throat, rhinorrhoea, limb or joint pain, headache, vomiting or diarrhoea) or
3. Severe and/or life-threatening illness suggestive of an infectious process or
4. If they meet any future clinical diagnostic criteria recommended by the Department of Health.
The assessing clinician will determine eligibility and complete the data collection form if the patient is considered to have suspected pandemic influenza.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500 for pilot phase 20,000 for the pandemic phase

Total final enrolment
165

Key exclusion criteria
We will not attempt to retrospectively apply the clinical diagnostic criteria and exclude patients who appear to have been inappropriately included. Patients will only be excluded if they request exclusion from the study.

Date of first enrolment
01/10/2012

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Sheffield Teaching Hospital
Sheffield
United Kingdom
S10 2SE

Study participating centre
Sheffield Children's Hospital
Sheffield
United Kingdom
S10 2TH

Study participating centre
York Teaching Hospital
York
United Kingdom
YO31 8HE

Study participating centre
The Royal London Hospital
London
United Kingdom
E1 1BB

Study participating centre
University Hospital South Manchester
Manchester
United Kingdom
M23 9LT

Study participating centre
Salford Royal Hospital
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Sheffield Teaching Hospital (UK)

Sponsor details
Sheffield Teaching Hospital NHS Foundation Trust
1st Floor
11 Broomfield Road
Sheffield
England
United Kingdom
S10 2SE

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) 11/46/07

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
Anonymised individual participant data are available from Professor Steve Goodacre (s.goodacre@sheffield.ac.uk) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2015		Yes	No
HRA research summary			28/06/2023	No	No