The PAndemic INfluenza Triage in the Emergency Department (PAINTED) pilot cohort study

Steve Goodacre,* Andy Irving, Richard Wilson, Daniel Beever and Kirsty Challen

School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK

*Corresponding author

Declared competing interests of authors: Steve Goodacre is deputy chairperson of the Health Technology Assessment Programme Clinical Evaluation and Trials Board, and was chairperson of the Pandemic Influenza Themed Call Board.

Published January 2015
DOI: 10.3310/hta19030

Scientific summary

The PAINTED pilot cohort study

Health Technology Assessment 2015; Vol. 19: No. 3
DOI: 10.3310/hta19030

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

An influenza pandemic could place huge demands upon emergency departments and acute hospital services. Triage methods are required to identify patients who are at high risk of adverse outcome for hospital admission and critical care, and patients who are at low risk of adverse outcome, who can be discharged home with self-care advice. In this situation, triage refers to the whole process of emergency department assessment, including diagnostic tests, if appropriate, to determine referral and treatment decisions rather than a brief initial assessment to determine priority for medical assessment.

Existing triage methods for suspected pandemic influenza have limited accuracy and have not been fully evaluated in a pandemic. Research is therefore required to determine the diagnostic accuracy of existing triage methods in a pandemic; refine existing methods; and explore whether or not new methods with improved accuracy can be developed. To undertake research in a pandemic we need to prepare research processes, secure regulatory processes in advance and identify potential barriers to successful completion.

Objectives

We aimed to prepare and pilot a study to be undertaken in an influenza pandemic to identify the most accurate triage method for predicting severe illness among patients attending the emergency department with suspected pandemic influenza. The objectives of the main pandemic study will be to:

1. determine the discriminant value of emergency department triage methods for predicting severe illness in patients presenting with suspected pandemic influenza
2. determine the discriminant value of presenting clinical characteristics and routine tests for identifying severe illness
3. determine the independent predictive value of presenting clinical characteristics and routine tests for severe illness
4. develop two new triage methods based upon (1) presenting clinical characteristics alone and (2) presenting clinical characteristics, electrocardiogram (ECG), chest X-ray (CXR) and routine blood test results.

The objectives of the pilot phase were to:

1. develop and test the use of a standardised clinical assessment form (CAF) that could be used for both clinical record documentation and research data collection during a pandemic
2. develop and test a secure online database to allow efficient data management in a pandemic
3. analyse pilot data from patients with seasonal influenza to ensure that data are reasonably complete and within expected ranges
4. seek clinician views on the usability of the standardised CAF
5. obtain all regulatory approvals required for the main study so that it can be activated rapidly in the event of a pandemic.

Methods

The main pandemic study

This will be a prospective observational cohort study of patients attending the emergency department with suspected pandemic influenza. Adults and children presenting to the emergency departments of the participating hospitals with suspected influenza will be included if they meet the clinical diagnostic criteria in operation at the time of the pandemic. The assessing clinician will determine eligibility and complete a standardised CAF if the patient is considered to have suspected influenza. The standardised CAF will record potential predictors of adverse outcome, including known predictors and variables used in existing triage methods.

Patients will be followed up until 30 days after attendance by hospital record review to identify adverse outcomes. Patients who die or require respiratory, cardiovascular or renal support will be defined as having an adverse outcome. If they survive to 30 days without requiring respiratory, cardiovascular or renal support they will be defined as having no adverse outcome. We will also record whether they are treated with antiviral agents or antibiotics, and the length and location of any hospital stay.

Analysis will estimate the discriminant value of existing triage methods (CURB-65, the Pandemic Modified Early Warning Score, the swine flu hospital pathway, the SMART-COP score and the SwiFT score), clinical predictors and diagnostic tests for predicting adverse events up to 30 days. We will also use multivariate analysis to develop two new triage methods based on presenting (1) clinical characteristics alone (age, gender, pregnancy, obesity, comorbidities, physiological variables) and (2) characteristics, routine blood tests and CXR), if data allow. The sample size will ultimately depend upon the size and severity of the pandemic. We have planned for a sample size of 20,000 cases, including 200 (1%) with an adverse outcome, recruited across 40 hospitals. A sample of 150 with an adverse outcome will allow us to estimate a *c*-statistic of a triage method, clinical variable or test with a standard error of 0.03 (assuming the true *c*-statistic was 0.8).

The pilot study

We developed a standardised CAF and online database to collect data from patients presenting to the emergency department with suspected pandemic influenza. We then tested the form, database and other study processes in a pilot study of patients presenting to six hospitals with suspected seasonal influenza in winter 2012–13. Patient selection, data collection, follow-up and outcome definitions were as planned for the pandemic study. Analysis was limited to descriptive reporting of patient flow, data completeness and patient characteristics.

Face-to-face, semistructured interviews were undertaken with 12 clinicians, who were likely to be undertaking patient assessment in a pandemic, to determine their views towards the standardised CAF and identify any improvements that could make the form more usable. Data from the interviews were analysed using the framework approach.

Results

The standardised CAF and secure online database were successfully developed and used to collect data in winter 2012–13. Some 165 patients with suspected influenza were identified across the six participating hospitals and had CAFs completed. Ten patients subsequently withdrew their data from the study leaving 155 (94%) available for analysis. Follow-up data were available from 129 of 155 patients at 30 days (83%). Of these, 50 of 129 (39%) were admitted to hospital, with a mean length of stay of 3.9 days (median 2 days, range 0–22 days). Three cases (2%) were recorded as having suffered an adverse outcome. All three died; two also received respiratory, cardiovascular and/or renal support.

There appeared to be variation between the hospitals, allowing for small numbers. Three of the hospitals identified 150 of 165 (91%) of the patients and all 10 withdrawing patients were at the same hospital. The proportion with missing follow-up data varied from 8% to 31% and the proportion admitted varied from 4% to 85% across the three hospitals with meaningful numbers of cases. All of the deaths were at one hospital. There was less variation between hospitals in rates of missing data, and for most key variables, missing rates were between 5% and 30%. Higher missing rates were recorded for blood pressure (BP) (39%), inspired oxygen (43%), capillary refill (36%) and Glasgow Coma Scale score (43%).

The mean age of the cohort was 31 years (median 26.5 years, range 1–92 years) with 49 of 127 (39%) aged 0–16 years. There were 72 males and 71 females. Influenza was thought by the clinician to be the most likely diagnosis in 34 of 155 cases (22%). Mean symptom duration was 5.6 days (median 3 days, range 1–56 days). Performance status among those with usable data for this variable was unrestricted/normal in 78 (67%), limited by strenuous activity in 7 (6%), limited by non-strenuous activity in 25 (21%), limited by self-care in five (4%) and bed-/chair-bound in two (2%). Social isolation (defined as living alone or having no fixed abode) was reported by 27 patients (16%). Chronic diseases were recorded with the following frequencies: heart disease,18; renal impairment, six; steroid therapy, one; asthma, 17; other chronic lung disease, 14; diabetes, nine; active malignancy, one; and immunosuppression, one.

Mean [standard deviation (SD)] physiological measures were temperature 37.8 °C (SD 1.0°C), pulse rate 108 beats/minute (SD 28 beats/minute), respiratory rate 25 breaths/minute (SD 10 breaths/minute), systolic BP 124 mmHg (SD 23 mmHg), diastolic BP 71 mmHg (SD 13 mmHg) and oxygen saturation 96% (SD 3%). CXR was normal in 28, abnormal in 23 and not done in 67 of the 118 cases with details recorded. ECG was normal in 26, abnormal in 14 and not done in 71 of the 111 cases with electrocardiography details recorded. Blood test results were available for 32 of 155 cases.

The qualitative interviews revealed generally positive views towards the standardised CAF. Most clinicians felt that the content was appropriate and usable. The structure was felt to be clear, simple, concise and logical, with some participants commenting that it mirrored their own practice of taking notes. Concerns about lack of space for free text were raised but counterbalanced by appreciation that it fitted on to one A4 page. A number of amendments were suggested, but only three of these were suggested by more than one participant and no suggestions were made by more than two participants. We therefore did not make any substantial amendments to the form.

Research Ethics Committee approval was secured in advance for the main study. Personal data were not collected during the pilot study but the protocol was amended to state that the NHS number would be used in the pandemic study to allow linkage with data from the Office for National Statistics and the Intensive Care National Audit and Research Centre. The Confidentiality Advisory Group of the Health Research Authority granted approval for use of the NHS number in the pandemic study under Section 251 of the NHS Act 2006. Separate arrangements were made in Scotland and Northern Ireland. We secured approvals from 41 separate English trusts (49 separate sites), one Welsh site, one Northern Irish site and two Scottish sites.

Conclusions

An observational cohort study to identify the most accurate triage method for predicting severe illness in emergency department attendees with suspected pandemic influenza has been set up and is ready to activate in a pandemic. Clinician views of the standardised CAF were generally positive. We were able to collect usable data using the standardised CAF, although problems of missing data may limit analysis and the paucity of seasonal influenza cases limited our ability to fully test how case identification and data collection will proceed in pandemic.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the Health Technology Assessment programme as project number 11/46/07. The contractual start date was in August 2012. The report detailing the set up phase and initial outcomes began editorial review in October 2014 and was accepted for publication in December 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report. Should the study progress further, the full report will be published in the *Health Technology Assessment* journal.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).