# Development of processes allowing near real-time refinement and validation of triage tools during the early stage of an outbreak in readiness for surge: the FLU-CATs Study

Sudhir Venkatesan,[1†] Puja R Myles,[1†] Gerard McCann,[2] Antonis A Kousoulis,[2] Maimoona Hashmi,[2] Rabah Belatri,[2] Emma Boyle,[2] Alan Barcroft,[2] Tjeerd Pieter van Staa,[3] Jamie J Kirkham,[4] Jonathan S Nguyen Van Tam,[1] Timothy J Williams[2] and Malcolm G Semple[4*]

[1]Division of Epidemiology and Public Health, University of Nottingham, Nottingham, UK
[2]Clinical Practice Research Datalink, Medicines and Healthcare products Regulatory Agency, London, UK
[3]University of Manchester, Manchester, UK
[4]Institute of Translational Medicine, University of Liverpool, Liverpool, UK

*Corresponding author
†Joint first authors

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# Scientific summary

## The FLU-CATs Study

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# Scientific summary

## Background

During pandemics of novel influenza and outbreaks of other emerging infections, surge in health-care demand can exceed capacity to provide normal standards of care. During surge, workload pressures may limit the time available for clinical decision-making and health-care worker absence because of personal sickness, or caring for dependants, may limit the skill mix. Imaging and laboratory services may also be limited. Health-care workers who are unfamiliar with clinical assessment and admission decision-making may be asked to fulfil 'gatekeeper' roles. In such exceptional circumstances, triage tools may aid decisions in identifying people who are most likely to benefit from higher levels of care.

Provisional UK Emergency Planning Guidance published in 2007 suggested the use of the CURB-65 pneumonia score and the Pandemic Medical Early Warning Score (PMEWS) for hospital triage of adults, but did not address the needs of children. Recognising this gap, a 'toolkit' of national guidance was developed in 2008 by the Department of Health for the UK, which included the newly developed Community Assessment Tools (CATs) for both children and adults in primary and secondary care, and matched hospital care pathways. The validity and utility of using triage tools in the community to aid management decisions during a pandemic remains untested. Both PMEWS and CATs were developed specifically with this purpose in mind and so we aimed to capture the criteria that would allow validation of these tools in this study.

The validity and utility of triage tools needs to be assessed in a large community-based prospective study of patients presenting with influenza-like illness (ILI), to give confidence to general practitioners (GPs) who may be asked to use such tools in the event of surge, and policy-makers who may need to recommend their use to GPs. Validation of a triage tool for use in an outbreak of a novel disease requires rapid research during the early phase of that outbreak. Rapid research should allow refinement and validation of triage tools so that in the event of surge a valid tool is available.

## Objectives

1. *In preparation for conducting rapid research in the early phase of a future outbreak* To develop information technology (IT) infrastructure and processes that allow near real-time analysis of GP assessments of people presenting with ILI, and GP management decisions and patient outcomes.
2. *As proof of concept and to test processes* To conduct a pilot study evaluating the performance of the triage tools 'CATs' and 'PMEWS' in predicting hospital admission and death in patients presenting with ILIs to GPs during inter-pandemic winter seasons.
3. To conduct a prospective near real-time analysis of structured clinical assessments for ILI using primary care electronic health records (EHRs) during a pandemic.

This report addresses only the first two objectives, involving preparatory work that would make the third objective feasible in the event of a pandemic.

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## Methods

### *Aim*

The overarching study aim is to conduct a prospective near real-time analysis of structured clinical assessments of ILI using primary care EHRs during a pandemic. This report covers the preparatory work, that is, IT infrastructure development, user testing and pilot study as 'proof of concept'.

### *Design*

The proof-of-concept study involved setting up and piloting a prospective near real-time analysis of structured clinical assessments and anonymised linkage to data from EHRs. User (GP) experience was evaluated by semistructured interviews. Processes were also developed for retrospective validation of outcome events using Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality data.

### *Setting*

Thirty GPs in England, Wales and Scotland participating in the Clinical Practice Research Datalink (CPRD) using the Vision® version 3.01 (In Practice Systems Ltd, London, UK) EHR.

### *Participants*

All people presenting with ILIs to participating GPs.

### *Interventions*

None.

### *Main outcome measures*

Study outcome is proof of concept through demonstration of data capture, appropriateness of data definitions and near real-time analysis. Primary patient outcomes are hospital admission within 24 hours and death (all causes) within 30 days of GP assessment. Secondary patient outcomes included GP decision to prescribe antibiotics and/or influenza-specific antivirals and/or refer to hospital, need for higher levels of care if admitted, and length of hospital stay.

### *Data sources*

Linked anonymised data from a study-specific web-based structured clinical assessment and primary care patient EHRs. Retrospective validation of hospital admission was planned using HES, and mortality data validation was planned using ONS data.

## Results

In the 24 months prior to April 2015, data from 704 adult and 159 child consultations to 30 GPs were captured. Influenza activity during these two winter seasons was low. GPs decided to refer 11 (1.6%) adults and 6 (3.8%) children to hospital. There were 13 (1.8%) deaths among adults and 2 (1.3%) among children. There were too few outcome events from which to draw any conclusions regarding the performance of the triage tools; however, the data captured allowed testing of almost all analytical algorithms and demonstrated proof of concept.

Data relating to each GP consultation were uploaded on to the CPRD database every night. The CPRD team then collated these data and sent weekly data to researchers based at the Universities of Nottingham and Liverpool. Additionally, on a monthly basis, the CPRD team sent background data (comorbidities, prescriptions, death, etc.) sourced from the EHRs for all patients with captured consultations. Each subsequent data instalment comprised the cumulative data acquired since the initiation of the study. Validation of outcome events with HES and ONS data was not possible for inclusion in this interim report because of a moratorium on provision of this data by the Health and Social Care Information Centre.

Six participating GPs agreed to be interviewed about their user experience. The main finding that emerged from these interviews was that the Local Eligibility Patient Identification Software (LEPIS) and web-based electronic Case Report Forms (eCRFs) were easy to use. The simplicity of the eCRFs encouraged GPs to participate in the study despite there not being any financial incentive for participation.

The GPs reported that the triage process of the consultation was quite easy to conduct and did not interfere with the routine GP consultation. Several GPs felt that a monetary incentive, even if small, would be necessary to increase GP participation in the study unless there was a statutory requirement to systematically collect data on all possible influenza cases during a pandemic. All interviewed GPs agreed that the FLU-CATs eCRF, with a few modifications, was ready to be used in a pandemic scenario. However, the setting up of the LEPIS system to enable data collection for the study was fraught with technical difficulties and not compatible with other EHR systems in use in the UK. Both these points are important limitations that would prevent a rapid national level rollout beyond the 650 plus practices currently using the Vision® EHR platform. Any decision aid based on the validated criteria could better be delivered separately on an open web-based platform or mobile phone 'app'.

Lessons learnt from the data analysis included that up to 74% of some clinical measurements (blood pressure in adults in this instance) were not recorded as part of GP's routine assessment of an adult person presenting with ILI. We would question the utility and adoption of triage tools that depend upon a clinical measurement that is not used in the routine assessment of ILI for use in a time-pressured pandemic situation.

## Conclusions

The use of EHRs linked to study-specific data capture forms increased the comprehensiveness, validity and usability of data; pre-prepared analytical processes allowed near real-time analysis of GP assessments, management decisions and patient outcomes on a weekly basis. The processes are dynamic and should allow refinement of triage criteria in the early stages of a future outbreak.

### *Future work*

We will test the effect of minimal remuneration on recruitment in future seasons, develop processes to include other EHR systems, attempt linkage to data on influenza surveillance and maintain processes in readiness for a future outbreak.

## Study registration

This study is registered as ISRCTN87130712 and UK Clinical Research Network 12827.

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