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Evaluation and refinement of pandemic inFLUenza Community Assessment Tools

Submission date	**Recruitment status**	[X] Prospectively registered
07/12/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/12/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2015	Respiratory	

Plain English summary of protocol

Background and study aims

Flu pandemics occurs when a new flu virus emerges, rapidly spreads and causes widespread disease in many communities in many continents. Fortunately severe pandemics are rare events. When they occur health care capacity both in the community and hospitals can be overwhelmed. When this happens doctors need to make difficult decisions about who should be admitted to hospital and who can safely be allowed to stay at home. To do this fairly, most doctors feel that the same types of patient assessments and questions should be used across the wider community. This process is called triage. The ethical principle of "triage" is to do most for most in a fair way. This does not mean treating everybody equally. It means using scarce resources for those people most likely to benefit from treatment. Triage tools should help doctors identify which people are most likely to benefit from treatments only available in hospital and which people can safely be managed at home.The difficulty in designing triage tools for a future flu pandemic is that the exact nature of disease caused by a pandemic virus is generally unknown until that pandemic occurs. A further difficulty is that flu can affect children and adults quite differently. A one-size-fits-all tool is unlikely to work. This study will develop processes that will test how parts of a general practitioner's questions and assessment of children and adults with flu like illness can predict who: can safely be kept at home; need hospital admission; need high dependency or intensive care; are most at-risk of dying. The study uses the General Practitioner's (GP's) routine electronic record to capture most of the information and links to the hospital record if the patient is admitted to hospital. These records are be accessed by researchers without revealing people's identities at the Clinical Practice Research Datalink, which is part of the Medicines and Healthcare products Regulatory Authority (MHRA). We will develop technology that allows records from about 600 GP surgeries across the UK to be studied automatically every week. This is quite complicated and needs to be set up in advance by working closely with the GPs that will ultimately use these tools. This first part of the study is called feasibility and pilot work. In the event of a pandemic, the processes that have been developed will "go-live" and allow us to refine triage tools and check that they are "fit-for-purpose" in readiness for use should a pandemic become severe.

Who can participate?

People of all ages presenting to General Practitioners with Influenza Like Illness.

What does the study involve?
The study will be invisible to patients. GPs will be asked to record their routine consultations in a structured manner.

What are the possible benefits and risks of participating?
There are no immediate benefits or risks to patients. It would be reasonable to expect that participating GPs will develop a more structured approach to the assessment of patients presenting with Influenza Like Illness, and this may benefit patients. The knowledge and tools that evolve from this study will allow GPs and others to make better decisions about managing people with influenza like illness, particularly if the event of a severe influenza pandemic.

Where is the study run from?
This is a collaboration between researchers working at The University of Liverpool, The University of Nottingham, and the Clinical Practice Research Datalink, MHRA, London.

When is the study starting and how long is it expected to run for?
We anticipate that the study will start in January 2013 and run for a total of 30 months.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme.

Who is the main contact?
Dr MG (Calum) Semple
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Study website
http://www.nottingham.ac.uk/research/groups/healthprotection/projects/flu-cats.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/46/22

Study information

Scientific Title
Real time refinement and validation of criteria and tools used in primary care to aid hospital referral decisions for patients of all ages in the event of surge during an influenza pandemic

Acronym
FLU-CATs

Study objectives
Assessment, refinement and validation of triage tools to guide GP referral of patients with influenza like illness during a pandemic in readiness for use should widespread illness exceed health care capacity (surge).

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=12827 and http://www.nets.nihr.ac.uk/projects/hta/114622
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/81777/PRO-11-46-22.pdf

On 13/07/2015 the overall trial end date was changed from 01/07/2015 to 01/01/2018.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Scientific Advisory Committee for MHRA database research (ISAC), 29/05/2012, ref: 12_043R

Study design
Prospective observational analysis

Primary study design
Observational

Secondary study design
Non-randomised controlled trial

Study setting(s)
Other

Study type(s)

Screening

Participant information sheet
There is no patient information leaflet. There is no requirement for consent on recruitment. The study uses anonymised data harvested from routine consultations recorded by GPs in electronic health care records.

Health condition(s) or problem(s) studied
Influenza like illness, influenza, seasonal influenza, pandemic influenza

Interventions
This is an observational study using anonymised data harvested from the electronic records of routine general practice consultations.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Hospital admission within 24 hours of GP assessment
2. Death within 30 days of GP assessment (all causes)

Secondary outcome measures
1. GP's decision to refer for hospital admission
2. Any need for augmented level of care during hospital admission i.e. level 2 - High Dependency and level 3 - Intensive/Critical Care, accepting that there are minor differences between paediatric and adult definitions of levels of care
3. Length of hospital stay (stratified >48 hours, ≥6 days & ≥12 days)

Overall study start date
01/01/2013

Completion date
01/01/2018

Eligibility

Key inclusion criteria
All people of all ages presenting to primary care general practitioners with influenza like illness

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2013

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Child Health
Liverpool
United Kingdom
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Sponsor information

Organisation
University of Liverpool (UK)

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Sponsor type
University/education

Website
http://www.liv.ac.uk/translational-medicine/departmentsandgroups/womens-and-childrens-health/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment - HTA (UK) ref:11/46/22

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015		Yes	No