

Swine Flu Triage (SwiFT)

Development and ongoing refinement of a triage tool to provide regular information to guide immediate policy and practice for the use of critical care services during the H1N1 swine influenza pandemic.

STUDY PROTOCOL

Version 1.3

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1. Project summary

Estimates of the requirement for critical care during the current H1N1 swine influenza pandemic indicate that current critical care resources, including any possible surge capacity, could be vastly exceeded. Excessive demand, where resources are finite, creates an ethical dilemma. In this situation, the principles of biomedical ethics and international law dictate that triage be used to guide equitable and efficient resource allocation and that the rationale for triage should be fair and transparent and meet the principles of distributive justice.

Existing, proposed tools for triage of patients considered for critical care have been based on expert opinion, existing severity scores for either general critical care or pneumonia, or developed and/or validated using small, single-centre populations. Consequently, all have limitations regarding their application in the UK NHS.

The SwiFT study has two major components: development and ongoing refinement of triage tools; and ongoing H1N1 swine influenza pandemic-related data collection.

Triage tools will be developed using existing, available data, predominantly the ICNARC Case Mix Programme Database of admissions to adult, general critical care units in England, Wales and Northern Ireland. The primary focus will be on a model to triage all referrals, in order to maintain the principles of distributive justice. All models developed will regularly updated with any relevant data both on H1N1 cases admitted to Case Mix Programme units and emerging from the ongoing H1N1 swine influenza pandemic-related data collection outlined below.

The SwiFT study will establish ongoing H1N1 swine influenza pandemic-related data collection for all patients (adult or paediatric) with confirmed or suspected H1N1 swine influenza referred for critical care, and for patients without confirmed or suspected H1N1 swine influenza that are refused critical care as a direct or indirect result of the pandemic. The dataset will include those variables that are considered able to be rapidly, routinely and accurately collected, even at the peak of the pandemic, and will be informed by all other relevant ongoing activities, both nationally and internationally. Data will be entered locally onto a secure web portal.

The primary purpose of the ongoing H1N1 swine influenza pandemic-related data collection is to allow policy makers within the NHS to assess, in real-time, the burden on critical care services of severe H1N1 swine influenza throughout the NHS and to rapidly respond to escalation in the number of severe cases.

2. Research objectives

- (i) To develop triage tools to guide use of critical care services in the UK during the H1N1 swine influenza pandemic using existing, available data, from within and outside ICNARC.
- (ii) To establish ongoing H1N1 swine influenza pandemic-related data collection for all patients with confirmed or suspected H1N1 swine influenza referred for critical care, and for patients without confirmed or suspected H1N1 swine influenza that are refused critical care as a direct or indirect result of the pandemic.
- (iii) To refine the triage tools, on a regular basis, using emerging data from objective (ii).
- (iv) To identify all relevant jurisdictions and establish the content required, and timelines for, regular reporting to guide immediate policy and practice on the use of critical care services during the H1N1 swine influenza pandemic.
- (v) To deliver regular reports, plus any ad hoc analyses requested, and participate in H1N1 swine influenza pandemic meetings, as required, and to interact with other pandemic-related activities to maximise use of collected data.
- (vi) To publish a final report describing the impact of the H1N1 swine influenza pandemic on critical care services, use and patients' care and outcomes.

3. Background

Potential impact of H1N1 pandemic

On 11 June 2009, the World Health Organization raised the level of influenza pandemic alert from phase 5 to phase 6 indicating the start of an influenza pandemic.¹ H1N1 swine influenza has the potential to cause life threatening illness. However, the likely impact of the pandemic on current critical care capacity is unknown. Estimates of the attack rate, hospitalisation rate and case fatality rate are extremely uncertain.

In the light of these uncertainties, Ercole *et al.*,² have attempted to model the likely impact of an H1N1 swine influenza pandemic, lasting twelve weeks, on critical care in England.

Based on disease severity data from the USA³ and from Mexico,⁴ attack rates of 61% for age less than 15 years and 29% for age 15 years or greater (early experience suggests that the attack rate is particularly high in the young) with a hospital admission rate from 0 to 2.0%, were used. The latter exceeded the then current hospital admission rate (0%) for the first 752 cases in England (as of 14 June 2009) and yet, the US hospital admission rate at this time was 9% (95%CI 7 to 12%). Latest estimates from the Health Protection Agency (as of 23 July 2009) indicate the current hospitalisation rate to be 1.7%.⁵ Of 840 currently hospitalised patients, 7.5% (n=63) are in critical care. Current estimated attack rate assumptions are for a 20% (10-30%) attack rate over six months, with 50% of those in an eight week period (D Menon, personal communication).

The assumed impact was that 36% of hospital admissions would require critical care and that 50% of these would require ventilatory support (early experience suggests that the H1N1 virus has the potential to elicit an immunologically severe host response). Using age-stratified data for the English population, the peak requirement for critical care for H1N1 swine influenza cases was estimated to be between 0% and 250% of current capacity (current capacity was the sum of total adult Level 3 beds and total paediatric intensive care beds). Peak ventilator usage was estimated to be between 0% and 120% of current capacity (current capacity was assumed to be equal to the number of beds).

Focussing solely on H1N1 swine influenza cases, these estimates suggest that current critical care resources, including any possible surge capacity gained through expansion into Level 2 beds and theatre/recovery settings (addressing only beds and equipment and not availability of trained critical care staff – a likely limitation due to unavailability of trained staff through pandemic-induced illness), could be vastly exceeded.

All projected modelling estimates suggest that current critical care resources may be overwhelmed. Excessive demand, where resources are finite, creates an ethical dilemma and many emergency plans apply a utilitarian approach. In this situation, the principles of biomedical ethics and international law dictate that triage be used to guide equitable and efficient resource allocation and that the rationale for triage should be fair and transparent and meet the principles of distributive justice.

Previous critical care-related triage modelling

For obvious reasons, no H1N1 swine influenza critical care-related triage models exist. However, H5N1 avian influenza did initiate the development of triage models.⁶⁻¹¹

Existing, proposed tools for triage of patients considered for critical care have been based on expert opinion,⁶ existing severity scores for either general critical care (e.g. SOFA)^{7,8} or pneumonia (e.g. CURB-65),⁹ or developed and/or validated using small, single-centre populations of patients presenting to emergency departments with either community-acquired pneumonias¹⁰ or suspected infection.¹¹ Current guidance from the Department of Health recognises that there are currently no universally accepted systems available for triage in this context.¹² The guidance focus on the use of a SOFA-based system, but acknowledges that further research in this area is required, and that, in the event a more robust tool is developed, the guidance will be updated.

Many models rely on data relating to chronic health conditions,⁶⁻¹⁰ which may be difficult to assess reliably during the peak of the pandemic. In addition, many models use laboratory parameters,⁶⁻⁹ the measurement of which will be resource-intensive and may delay a triage decision.

Approaches based specifically on models for patients with respiratory infections may be inappropriate, as triage decisions will need to be made for all patients considered for critical care, and not only those with influenza, as a single pool of resources will have to be shared among all patients.^{7,13} While the triage tool needs to be simple enough to be applied quickly and consistently during the peak of the pandemic (which may not be the case for SOFA-based tools)⁸ it should also be complex enough to be 'scaleable', i.e. able to adjust the decision criteria in order to match demand against capacity.¹³ It also needs to be able to match inevitable staff shortages (from staff sickness as well as increased demand) and suboptimal staff expertise (arising from the need to redeploy staff to critical care), against the actual clinical demands posed by patients. For example, the high reported incidence of renal failure in H1N1 infection to date means that staff resource allocation models need to take account of the need to provide renal replacement therapy.

Ongoing national and international efforts

Under the auspices of the Department of Health and the Scientific Advisory Group for Emergencies, the aim of the Flu Clinical Information Network (FLU-CIN), co-ordinated by the University of Nottingham, is to deliver an information collection system that will gather hospital data on H1N1 swine influenza from a network of sentinel hospitals (Imperial, Leicester, Liverpool, Nottingham & Sheffield – with the possibility of expansion). Although the data emerging from the sentinel hospitals will be important, to ensure that sufficient, accurate data on those referred for critical care are available early in the pandemic, there is the need for more widespread data collection if we are to maximise the impact of the early phase of the pandemic to guide ongoing policy and practice on the use of critical care resources during the H1N1 swine influenza pandemic.

At this stage, we are aware of three other major international H1N1 swine influenza pandemic-based data collection projects directly related to the potential demand on critical care resources (in Canada, Australia/New Zealand, and Europe-wide, coordinated by the European Society of Intensive Care Medicine). Regular email and teleconference communication channels have been established and shared learning, experience and documentation has commenced. Established close links between existing national critical care research groups (e.g. in Canada, in Australia/New Zealand, in France, etc.) provide an unrivalled opportunity for coordination of efforts. Standardised data collection and a commitment to rapid accumulation, integration, and analysis of early pandemic data from many countries are planned. One key collaboration is with the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group. The likely acceleration of the pandemic in the antipodean winter will mean that the information from critical care units in the ANZICS collaboration will be available well in advance of our peak pandemic rates, and could be used to inform and explore our plans for the coming UK winter.

Within these international collaborations, there are many advantages to maintaining a UK-specific data collection. These include: the ability to rapidly disseminate real-time results, both to the Department of Health and other relevant jurisdictions (to inform policy) and to participating hospitals (to inform practice); the ability to rapidly update the dataset to address new knowledge or treatment practices; combining the data collection portal with other UK-specific sources of advice and information; and to do all of this in a framework that adheres to all appropriate UK research governance and data protection arrangements.

4. Study design

Development and ongoing refinement of triage tools

Existing available data within ICNARC

Since 1996, ICNARC has co-ordinated the standardised collection of case mix and outcome data for consecutive admissions to adult, general critical care units in England, Wales and Northern Ireland through the Case Mix Programme. The Case Mix Programme Database (CMPD) currently holds over 800,000 admissions to 209 units (82% coverage). Data completeness and accuracy are promoted by a precise dataset specification with rules and definitions for all variables, regular data collection training courses and extensive local and central data validation. The CMPD will be available for the proposed modelling.

Case mix data in the CMPD include age, acute severity of illness and severe comorbidities. Acute severity of illness is assessed based on the most extreme physiological measurements from the first 24 hours following admission to the critical care unit (see: below). Patients are followed up to ultimate discharge from an acute hospital. Resource use data include the duration of stay in critical care and in hospital, and the duration of support of specific organ systems.

Physiology data in the CMPD include (all values recorded as lowest and highest in the first 24 hours (except where indicated):

- Temperature
- Blood pressure
- Heart rate
- Respiratory rate (ventilated and non-ventilated)
- PaO₂ (lowest) and associated FiO₂, PaCO₂, pH
- pH (lowest) and associated PaCO₂
- Serum bicarbonate
- Serum sodium
- Serum potassium
- Blood lactate (highest)
- Serum urea (highest)
- Serum creatinine
- Urine output (total)
- Haemoglobin
- White blood cell count

- Platelet count
- Glasgow Coma Score (lowest) and eye, motor and verbal components.

These case mix and outcome data are available for both Level 2 and Level 3 admissions to critical care units. Participating units include both standalone intensive care units and combined intensive care and high dependency units.

Other relevant data held by ICNARC include those accumulated from a small number of NHS hospitals for the evaluation of physiological “track and trigger” systems (e.g. early warning scores)¹⁴ as part of our NIHR SDO funded mixed methods evaluation of the complex intervention termed critical care outreach services.¹⁵ These latter data contain vital signs for patients being assessed for need for critical care, collected pre-critical care and include whether admission to critical care occurred or not. These, too, will inform our models.

Existing available data outside ICNARC

Using our existing national and international links, we will seek any additional relevant data to inform the proposed modelling.

As the Case Mix Programme focuses on the 24-hour period immediately following admission to a critical care unit, the CMPD is suited to answering questions related to the decision to admit the patient to critical care. A second important point on the care pathway, the decision to discharge a patient from critical care (and, in particular, when bed numbers are inadequate who should be discharged to make way for another patient) is beyond the scope of this dataset. We will therefore endeavour to identify other sources of data, external to ICNARC, with serial/daily recording of physiological status and outcome.

Identifying relevant cohorts

It is intended that our models will provide the ability to triage all referrals, or those solely pandemic-related, for critical care; therefore identification of relevant cohorts will reflect this. The primary focus will be on a model to triage all referrals, in order to maintain the principles of distributive justice. Using the CMPD, cohorts can be identified in many ways e.g. by reason for admission to critical care, by source of admission, by prior duration of hospital stay, etc. or using a combination of these. In addition, seasonal data – with particular reference to previous influenza outbreaks – will be investigated.

Initial cohorts will include:

- all referrals model – all admissions to units excluding those following elective surgery and those admitted for pre-surgical physiological optimisation (our rationale is that these activities would be curtailed as part of surge capacity expansion);

- pandemic-related referrals model – admissions to units with a reason for admission representing a community acquired complication of respiratory disease (specified by emerging, international pandemic data on presentation characteristics).

In addition, all units participating in the Case Mix Programme have been requested to submit early data related to any admission with suspected or confirmed H1N1 swine influenza. These data will form another initial cohort for modelling and for comparison with non-H1N1 influenza cases to inform the choice of relevant cohorts for modelling.

These, and other cohorts, may be further refined. Due to the large size of the CMPD, cohorts selected will be based on recent critical care case mix and outcome data to reflect current practice.

Developing the triage tools

Selection of variables to include in the triage models will focus on information we anticipate will be readily available at the peak of the H1N1 swine influenza pandemic. Additional, less readily available variables will be tested for importance and only included if there is the potential for rapid, inexpensive, point-of-care testing e.g. blood lactate.

Selection of outcomes will reflect not only survival but duration of survival and use of critical care resources. Models will reflect both those admissions whose prognostic risk is too low to justify admission to critical care (in particular, those that receive minimal organ support that could be delivered in a non-critical care setting) and also those whose prognosis is too poor. The primary outcome for the development of the triage models will therefore be an ordinal (3-level) outcome on the following scale:

1. Minimal requirement for critical care (acute hospital survivors receiving no advanced respiratory support, advanced cardiovascular support, renal support, liver support or neurological support)
2. Hospital survivors requiring critical care (all other acute hospital survivors)
3. Death before ultimate discharge from an acute hospital.

First 24 hour physiology data will be used to identify factors that discriminate among these three categories in each relevant cohort. Using ordered logistic regression, simple prognostic models will be developed that may be used to underpin triage tools for critical care with a sliding scale depending on the level of alert and pressure on critical care resources.

The ability of the models to discriminate among the three categories will be assessed using the concordance (c index), a natural extension of the area under the receiver operating

characteristic (ROC) curve from binary logistic regression. At each cut-off, the sensitivity, specificity, and positive and negative predictive value will be evaluated and the potential capacity gained (in terms of proportion of critical care bed days saved) resulting from applying the triage model will be estimated using datasets re-sampled from the CMPD, with increased weighting toward admissions with acute exacerbations of respiratory disease (at varying levels to represent different stages and/or severities of the pandemic).

All models developed will be informed by previous work in this area, and performance will be compared, where appropriate, to that of existing models.

All models developed will be regularly updated with any relevant data both on H1N1 cases admitted to Case Mix Programme units and emerging from the ongoing H1N1 swine influenza pandemic-related data collection outlined below.

Ongoing H1N1 swine influenza pandemic-related data collection

Inclusion criteria

All patients (adult or paediatric) referred for critical care, who would be admitted in “usual” circumstances, and either:

- A. have confirmed or suspected H1N1 swine influenza and are either refused critical care or receive critical care within or outside a critical care unit; or
- B. are refused critical care or receive critical care outside a critical care unit, as a direct or indirect result of the pandemic.

Dataset

The dataset will include those variables that are considered able to be rapidly, routinely and accurately collected, even at the peak of the pandemic, and available at the point of potential referral for critical care. The dataset will be informed by all other relevant ongoing activities, both nationally and internationally. Every effort will be made to ensure that data collected are standardised with, but do not duplicate, these other national activities. Where possible, variables will be compatible with current, ongoing, non-pandemic-related data collection activities within NHS hospitals, both outside and within critical care (e.g. NHS Critical Care Minimum Data Set – CCMDs, Case Mix Programme, Scottish Intensive Care Society Audit Group – SIGSAG, Paediatric Intensive Care Audit Network – PICANet etc.). Relevant and sufficient identifiers (e.g. NHS Number, Case Mix Programme Admission number, SICSAG Admission number, PICANet Admission number, hospital number, etc.) will be collected to allow for data linkage, longer-term follow-up using the NHS Central Register (hopefully

expedited) and subsequent re-retrieval of the admission record at a later date. Patient-based data will be supplemented by data on the outcome of the triage decision, reason for the decision and the location of subsequent care. Patients receiving critical care will have a small dataset of organ support, treatment and organ failure (SOFA) data collected daily for the duration of critical care. Follow-up of patients not receiving critical care and longer-term follow-up of patients receiving critical care will be undertaken centrally using NHS Number.

Data entry

Data will be entered locally onto a secure web portal. Participating hospitals will be expected and encouraged to provide daily updates with respect to patient data entry. The SwiFT portal will include daily entry of patient data but also weekly entry of hospital pandemic response data related to issues involving staff, beds and equipment required for delivering critical care. In this way, hospitals' response to the pandemic will be monitored. The SwiFT portal will also provide a route to feed back weekly summary reports on the data to participating hospitals. In addition, regular reports on the epidemiology, risk factors and treatment of H1N1 swine influenza from data emerging, nationally and internationally will be made available. Finally, the SwiFT portal will support a forum to promote exchange of information between clinicians.

Data security

ICNARC meets all NHS data security requirements and is regularly reviewed, both for the Case Mix Programme and for its ongoing research programme, by the National Information Governance Board for Health and Social Care. ICNARC is registered with the Information Commissioner's Office under the Data Protection Act. Full details of system security are available in the SwiFT Systems Level Security Policy.

Reporting

The primary purpose of the ongoing H1N1 swine influenza pandemic-related data collection is to allow policy makers within the NHS to assess, in real-time, the burden on critical care services of severe H1N1 swine influenza throughout the NHS and to rapidly respond to escalation in the number of severe cases.

To facilitate this, all relevant jurisdictions will be contacted (Department of Health, Health Protection Agency, devolved administrations, etc.) and the required content of regular reporting will be established. In addition, timelines for regular reporting, to guide immediate policy and practice on the use of critical care services, will be agreed. Ad hoc reporting will also be available.

It is hoped that ongoing communication and real-time data linkage can occur between all relevant national H1N1 swine influenza pandemic-related data collection activities to increase the information available to inform NHS policy and practice.

The secondary purpose of the ongoing H1N1 swine influenza pandemic-related data collection is, at the end of pandemic, to publish a final report of its impact to inform policy and practice for future pandemics. This will involve both national and international collaboration.

5. Organisation

Study Steering Group

The Study Steering Group (SSG) responsibilities are to approve the study protocol and any amendments, to monitor and supervise the study towards its research objectives, to review relevant information from external sources, and to resolve problems identified by the Study Management Group. Face-to-face meetings will be held at regular intervals determined by need and not less than once a year, with routine business conducted by telephone, email and post. The SSG membership is shown below. Representatives of the funder (NIHR HTA Programme) and the sponsor (ICNARC) will be invited to observe at SSG meetings.

Membership

Professor Kathy Rowan (Chair)	Director, ICNARC
Dr David Harrison	Senior Statistician, ICNARC
Dr Danny McAuley	Senior Lecturer in Intensive Care Medicine, The Queen's University, Belfast
Professor David Menon	Professor of Anaesthesia, University of Cambridge
Dr Gavin Perkins	Associate Professor in Critical Care and Resuscitation, University of Warwick
Dr Bruce Taylor	Consultant in Critical Care Medicine & Anaesthesia, Portsmouth Hospitals NHS Trust

Study Management Group

The day-to-day running of the SwiFT study will be overseen by a Study Management Group (SMG) consisting of the ICNARC staff directly involved in the study. The SMG membership is shown below.

Membership

Professor Kathy Rowan	Director
Dr David Harrison	Senior Statistician
Ms Lucy Lloyd-Scott	Case Mix Programme Manager
Mr Phil Restarick	Research Coordinator

Data monitoring

As the study does not involve any change to usual care for patients, an independent Data Monitoring Committee (DMC) will not be required. The SSG will oversee those responsibilities usually delegated to a DMC.

Service users

The two service user representatives and charity trustees on ICNARC's Board of Management, as ex-critical care patients, will provide this perspective. All involvement of service users in SwiFT will follow the guidelines and recommendations for good practice from INVOLVE (<http://www.invo.org.uk>).

Ethical arrangements

ICNARC holds approval from the National Information Governance Board for Health and Social Care (NIGB) under Section 251 of the NHS Act 2006 to hold limited patient identifiable data for the Case Mix Programme without consent (approval number: PIAG2-10(f)/2005). NIGB have approved an extension of this existing approval to cover the SwiFT study.

An application to an NHS Research Ethics Committee is pending.

Research governance

The study will be managed according to the Medical Research Council's Guidelines for Good Research Practice (http://www.mrc.ac.uk/pdf-good_research_practice.pdf), Guidelines for Good Clinical Practice in Clinical Trials (<http://www.mrc.ac.uk/pdf-ctg.pdf>) and Procedure for Inquiring into Allegations of Scientific Misconduct (http://www.mrc.ac.uk/pdf-mis_con.pdf). ICNARC has developed its own policies and procedures based on these MRC guidelines, which are adhered to for all research activities at ICNARC. In addition, ICNARC has contractual confidentiality agreements with all members of staff. Policies regarding alleged scientific misconduct and breach of confidentiality are reinforced by disciplinary procedures. The ICNARC research staff undergoes regular training in Good Clinical Practice (GCP).

Funding

Research costs for this study have been met by a grant from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (project reference 09/86/01). NHS Support Costs for data collection will be met through the Comprehensive Local Research Networks (CLRN) from NIHR contingency funds.

Indemnity

ICNARC holds professional liability insurance (certificate number A05305/0808, Market International Insurance Co Ltd) to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research. This policy also covers the potential legal liability of ICNARC as both sponsor and employer for harm to participants arising from the design of the research. Indemnity to meet the potential legal liability of investigators/collaborators for harm to participants arising from the conduct of the research is provided by the NHS indemnity scheme or through professional indemnity.

6. References

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