

The Swine Flu Triage (SwiFT) study: 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

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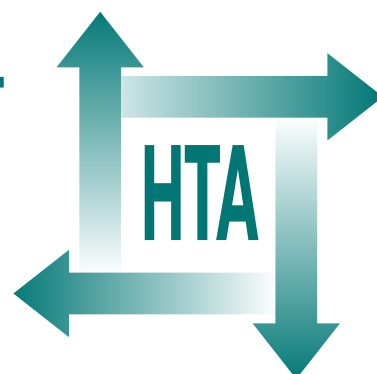
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Executive summary

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Executive summary

Background

In April 2009, the World Health Organization (WHO) announced confirmed human cases of pandemic influenza A 2009 (H1N1) in Mexico and the USA and raised the pandemic alert level to Phase 4 and subsequently to Phase 5. In May 2009, the first case of human-to-human transmission in the UK was confirmed. In June 2009, the WHO raised the pandemic alert level to Phase 6, the highest level, and the total number of UK cases reached 1000 with the first UK death attributed to H1N1. This advent of a new strain of influenza A, known as swine 'flu, presented an opportunity for research to be commissioned both to inform patient management during the pandemic and, possibly, to inform future pandemics.

Early in the pandemic, it was clear that H1N1 had the potential to cause life-threatening illness. However, the likely impact of the pandemic on the critical care capacity in the UK was unknown. Estimates of the attack, hospitalisation and case fatality rates were extremely uncertain. Based on data to 14 June 2009, the peak requirement for critical care was estimated to be between 0% and 250% of current capacity. These estimates suggested that existing critical care resources, including any surge capacity gained through expansion into Level 2 beds and theatre/recovery settings, could be vastly exceeded.

Excessive demand, where resources are finite, creates an ethical dilemma and triage is required to guide equitable and efficient resource allocation. The rationale for triage should be fair, transparent and meet the principles of distributive justice. Approaches based specifically on models for patients with respiratory infections may be inappropriate as triage decisions need to be made for all patients, not only those with influenza, as a single pool of resources will have to be shared.

Objectives

The aim of the Swine Flu Triage study (SwiFT) was to provide information, early in the pandemic, to

guide critical care clinicians and policy-makers. The objectives were:

1. To initiate and co-ordinate an essential research study efficiently, within the NHS, in a pandemic situation.
2. To use both existing critical care and early pandemic data to inform care during the pandemic (potentially to inform triage – if the situation arose where demand for critical care seriously exceeded capacity).
3. To monitor the impact of the H1N1 pandemic on critical care services, in real time, with regular feedback to critical care clinicians and others to inform ongoing policy and practice.

Methods

Objective 1

From late July 2009, in parallel with study design, development and set-up, central and local research governance approvals were required, rapidly, for approximately 220 organisations in five countries – England, Wales, Northern Ireland, Scotland and the Republic of Ireland (ROI).

Objective 2

For the modelling on existing data, consecutive admissions in the Case Mix Programme Database (CMPD), from 1 January 2007 to 31 March 2009, were extracted. The Case Mix Programme (CMP) is the national, comparative outcome audit ongoing in approximately 90% of adult, critical care units in England, Wales and Northern Ireland, co-ordinated by the Intensive Care National Audit & Research Centre (ICNARC). The CMPD has been evaluated as high quality by the Directory of Clinical Databases.

Two approaches were taken to modelling. First, the impact of cancellation/postponement of elective/scheduled surgery, in terms of the percentage of admissions avoided/postponed and the percentage of calendar days of critical care, Level 3 and advanced respiratory support saved, respectively, both overall and across units, was explored. Second, models on two patient

cohorts (all admissions and admissions for acute exacerbations of respiratory illness) were developed using a primary outcome of potentially avoidable admission, critical care required or death. Only routine physiological variables, measured and recorded during the first 24 hours following admission to the critical care unit, were included in the modelling: lowest systolic blood pressure; highest temperature; highest heart rate; highest respiratory rate; and neurological status. The effect of adding lowest partial pressure of oxygen (PaO_2), associated fraction of inspired oxygen (FiO_2) or PaO_2 : FiO_2 ratio; base excess; highest blood lactate; and highest serum urea was explored. Finally, the effect of adding severe comorbidity and/or age was also explored.

Models were fitted using ordered logistic regression, with the primary performance measure being the ability of the model to discriminate between the three outcome categories, assessed by Harrell's concordance statistic. Efron's optimism bootstrap was used to shrink estimates to adjust for overfitting. The effect of using a model to triage patients with low or high scores was explored by modelling potential outcomes for triaged patients.

Objective 3

To monitor the H1N1 pandemic, all acute hospitals in England, Scotland, Wales, Northern Ireland and the ROI were encouraged to participate in SwiFT. All patients, adult or paediatric, were included if they had either confirmed or suspected H1N1 and were referred and assessed as requiring critical care or they were non-H1N1 patients referred and assessed as requiring critical care (under usual/non-pandemic circumstances), but not admitted to a critical care unit in the hospital where referred and assessed. Selected clinical data were collected both from the point of referral and assessment for critical care and daily (by calendar day 00:00–23:59) while receiving critical care. Data were collected on consecutive patients, meeting the inclusion criteria, until SwiFT closed to recruitment on 31 January 2010.

SwiFT data were entered onto a secure, web-based data entry system developed and hosted by the ICNARC. Data collection manuals and forms, definitions and error checking were available for download from or built into the web portal. Weekly reports were submitted to the Department of Health and published on the SwiFT web portal to provide regular reporting to clinicians on the

evolving pandemic. The impact of the pandemic on critical care system capacity was assessed through the numbers of patients reported as: transferred to receive critical care in another acute hospital; managed in an extended critical care or non-critical care area; and refused critical care. The impact of the pandemic was also assessed by reviewing data from the CMPD relative to previous years.

Risk factors for death while receiving critical care and for duration of critical care among survivors were assessed by Cox proportional hazards regression models.

Confirmed H1N1 cases in SwiFT were compared with confirmed H1N1 patients from wave 1 of the pandemic and pre-pandemic cohorts of critical care unit admissions with pneumonia from the CMPD, and with published cohorts of critically ill patients with H1N1, internationally.

Results

Objective 1

With respect to SwiFT, the ability to initiate essential research efficiently, within the NHS in a pandemic situation, appeared to be successful. Of the 221 organisations identified across the five countries, submission for local research and development (R&D) approval was achieved for 192 (87%) and approved for 180 (81%). Local R&D approval was both quick and timely for the 150 NHS Trusts in England, with 91 achieving approval within 1 day of central R&D approval. Local R&D approval was similarly quick in Northern Ireland and the ROI, but not as timely. Scotland was slower, but timely relative to Scottish Research Ethics Committee (REC) review. Wales was neither quick nor timely. SwiFT commenced in 192 of 301 (64%) acute hospitals in 158 of 221 organisations. Participation varied across countries: 76% (19 of 25 acute hospitals in Scotland), 72% (154 of 214 acute hospitals in England), 44% (four of nine acute hospitals in Northern Ireland), 38% (6 of 16 acute hospitals in Wales) and 19% (7 of 37 acute hospitals in ROI).

Objective 2

Data were extracted from the CMPD for 105,397 admissions to 148 adult, general critical care units in England, Wales and Northern Ireland from 1 January 2007 to 31 March 2009. Excluding

admissions with missing data, 105,380 admissions to 148 units (99.98%) were included in the modelling.

Overall, 25,828 (25%) admissions were associated with elective/scheduled surgery. Cancellation/postponement of these admissions resulted in calendar day savings of 17% for critical care, 11% for Level 3 care, and 10% for advanced respiratory support. There was considerable variation across the 148 units.

After exclusion of admissions associated with elective/scheduled surgery, readmissions and missing data, 74,510 admissions to 148 units were used for the triage modelling, with 15,996 (21%) identified as admissions for acute exacerbations of respiratory illness.

Of all admissions, 19,557 (26%) were classified as 'potentially avoidable', 31,074 (42%) as 'critical care required', and 23,879 (32%) died before discharge from acute hospital. Of admissions with acute exacerbations of respiratory illness, 4098 (26%) were 'potentially avoidable', 5800 (36%) 'critical care required' and 6098 (38%) died before discharge from acute hospital.

The model based on core variables alone produced a concordance of 0.75 (considered 'satisfactory'). Incorporating all additional variables raised this to a maximum of 0.79. The discrimination of the models among admissions with acute exacerbations of respiratory illness was worse, with concordance statistics from 0.71 to 0.75. Among all admissions, the single additional variables that added most discriminatory ability to the core variables were FiO_2 and urea (each raising the concordance to 0.77). Adding severe comorbidity to the model had a negligible effect on concordance; adding age produced a small improvement in concordance, but raises ethical issues.

Using the model based on core variables plus FiO_2 and combining categories from the original fine categorisation to produce a score from 0 to 12 points, the effect of triaging patients with low and high scores was investigated. Triaging patients with scores of 0–3 to temporary critical care areas would result in 57% of critical care unit admissions being diverted, but 58% may subsequently require transfer to the critical care unit, resulting in an overall saving of 11% of critical care unit bed days. Triaging patients with scores of ≥ 6 to no critical care would divert 14% of critical care unit

admissions, saving 15% of bed days; however, 99% of these patients would die, with 30% of the deaths being potentially avoidable if critical care had been provided.

Objective 3

Overall, 1725 confirmed or suspected H1N1 cases and three non-H1N1 cases were reported. Of the 1725 H1N1 cases, 562 (33%) were confirmed to have H1N1, either on initial assessment or during critical care, 899 (52%) tested negative having initially been suspected, and 264 (15%) were neither confirmed nor tested negative. Of the three non-H1N1 cases, one was reported to have been refused critical care owing to lack of available staff and beds, and two received critical care in an extended critical care area. Of the suspected and confirmed H1N1 cases, one was reported to have been refused critical care owing to perceived futility and one owing to lack of available staff and beds, two died while under assessment before transfer to a critical care unit could be arranged, 42 received critical care in an extended critical care area and two in a non-critical care area, and 11 were transferred to receive critical care in another acute hospital. Little impact of the pandemic could be observed by comparing data from the CMPD with previous years.

Confirmed H1N1 cases were younger than those suspected or tested negative (92% aged < 65 years vs 75% and 73%, respectively), more likely to be pregnant (13% of female patients vs 2% and 3%) and more likely to be obese/morbidly obese (25% vs 20% and 13%). Acute severity of illness on initial assessment, as measured by CURB-65 (confusion, urea, respiratory rate, blood pressure, age over 65 years), was low with 61% of confirmed H1N1 cases scoring 0 or 1 points (vs 59% and 46%). Confirmed cases required a median of 8.5 days of critical care (vs 1.3 and 5.4 days) and 79% survived to the end of critical care (vs 69% and 85%).

Risk factors for death while receiving critical care were increasing age, increasing Sequential Organ Failure Assessment (SOFA) score, severe chronic organ dysfunction and being immunocompromised. Pregnancy was associated with a lower risk of death. Increasing duration of critical care among survivors was associated with increasing age up to 50 years, increasing SOFA score, overweight/obesity, pregnancy, confirmed H1N1 on initial assessment, severe chronic organ dysfunction and respiratory presentation.

The age distribution for confirmed H1N1 cases in SwiFT was similar to wave 1 of the pandemic, and considerably younger than pre-pandemic cohorts with viral or bacterial pneumonia. Seventy-seven per cent of confirmed H1N1 cases in SwiFT received advanced respiratory support for a median of 9 calendar days, similar to wave 1 and pre-pandemic viral pneumonia, but higher than pre-pandemic bacterial pneumonia. Overall duration of critical care was longer for confirmed H1N1 cases in SwiFT than in wave 1 or for pre-pandemic cohorts. Mortality before the end of critical care was lower for confirmed H1N1 cases in SwiFT (21%) than in wave 1 (27%) or pre-pandemic cohorts (26% and 31%, respectively).

The demographics of confirmed H1N1 cases in SwiFT were broadly comparable with cohorts of critically ill H1N1 patients from Australia and New Zealand, Canada, Mexico and Spain. All countries reported a very high proportion of cases aged < 65 years. All except Mexico reported a high proportion of pregnant cases. Mean daily SOFA scores showed a decreasing trend that very closely matched that reported in Canada and was parallel to, but lower than, that reported in Mexico. When split by survival status, the SOFA score increased and then remained high for non-survivors, but decreased in survivors. Mortality at the latest reported follow-up in each country varied from 17% in Australia and New Zealand and Canada to 41% in Mexico. All countries reported long durations of critical care and high requirements for mechanical ventilation.

Conclusions

To everyone's relief, H1N1 did not overwhelm critical care services in the NHS. SwiFT did, however, highlight a number of issues for discussion, some with future implications for health care and priorities for research.

SwiFT indicated that, in some acute hospitals in some of the countries, research could be set up rapidly to provide information, early on in a pandemic, to guide critical care clinicians and policy-makers. However, a number of factors played an important role.

First, the ICNARC's existing capacity, expertise and networks should not be underestimated, even with accelerated procedures for central research and information governance. The experienced staff and established processes and expertise at

the ICNARC allowed for the rapid institution of SwiFT and without this 'rolling start' the results of SwiFT may well not have been achieved. If similar capacity, expertise and networks do not exist in other areas, where acute and emergency care will be delivered in a pandemic, the results of SwiFT cannot be considered to be generalisable and there is no room for complacency.

Second, for SwiFT, each of the five countries responded with varying degrees of success in achieving research and information governance approvals. It was clear that the current research governance systems vary among countries and some appeared much better able to react to the need for a rapid study of an evolving health-care issue. Research governance systems appeared more effective in those countries with centralised systems, namely England and Scotland. However, even in the light of recent advances, research governance is often a major barrier to the conduct of research for researchers and the best examples achieved in SwiFT should be the norm, and not the exception, if research that matters to patients is going to be delivered. All should strive to become more able to rapidly process research, especially research that is time-sensitive.

Third, securing local resources appeared to be the main key to participation. It should be noted that it took almost 2 months (following the secure, web-based data entry system going 'live' on 17 September 2009) for comprehensive coverage – SwiFT figures did not equal weekly prevalence figures published by the Health Protection Agency (HPA) (for England) until the week commencing 9 December 2009. It appeared that, even in England where local resources were supposedly available, individuals at the local level did not appear to know how to access them. This may be because the Comprehensive Local Research Network (CLRN) system is new, but anecdotal experience suggests that process and provision are not standard across CLRNs. Improved access to local resources for supporting research (particularly outside England) should be a high priority.

In conclusion, even with the ICNARC's existing capacity, expertise and networks, a Herculean effort and accelerated procedures for governance, the effort and time scale involved in obtaining approvals was unacceptable during a pandemic. There was considerable variation in procedures (including inconsistency in ethics advice between England and Scotland) and in local resources available across the five countries which added to

the complexity of the process and inhibited this collaborative research.

Implication for health care 1: Efforts should be continued to further streamline the current research and information governance procedures and access to local resources required for establishing a research study of benefit to patients, both within and across countries, whether during a pandemic or not.

More generally, a review of the utility and value of information provided (both during and after the pandemic) to clinicians and policy-makers from the commissioned/funded H1N1 research should be conducted. More specifically to SwiFT, whether the balance was achieved correctly, in terms of required data for SwiFT, should be revisited. It is clear from the amount of data that were subsequently entered onto the SwiFT database after the end of the study, that the data requested, specifically the daily data, may have overwhelmed the available resources. In addition, were the reports useful to both clinicians and policy-makers, interaction with the latter indicated such, but clinical feedback should be elicited.

Implication for health care 2: A review of the utility and value of information provided (both during and after the pandemic) to clinicians and policy-makers from the commissioned/funded H1N1 research should be conducted (to include SwiFT) to learn both the generic and specific lessons prior to future pandemics.

SwiFT proposed longer-term follow-up using linkage to national death registration. Unfortunately, such linkage is not currently available using NHS Number. Algorithms for linkage to the NHS Central Register using NHS Number, without the need for patient names, are currently being developed by the NHS Information Centre and planned to be in operation by the end of 2010, recently extended to the end of 2011.

Implication for health care 3: The availability of a system to link using NHS Number should remain a high priority to inform health-care outcomes.

Triage could be required at several steps in the care pathway for patients in a pandemic: first, in primary care, to determine which patients required hospital assessment; second, in the emergency department, to determine which patients needed hospital admission; and third, in hospital, to determine which patients needed critical care. These three triage steps require different triage thresholds and, most probably, different triage

models. SwiFT considered only the third step in the care pathway for H1N1 patients – the decision to admit to critical care only and, more specifically, on identifying which patients not to admit when resources are scarce – from among those who would be admitted under usual (non-pandemic) circumstances.

A simple, physiology-based triage model was developed that had only ‘satisfactory’ concordance. This simple model outperformed CURB-65 among admissions with acute exacerbations of respiratory illness, and seemed to support similar findings from an emergency department cohort. Severity of illness of H1N1 cases, on initial presentation (as assessed by the CURB-65 score), was remarkably low, with 61% of confirmed H1N1 cases scoring 0 or 1 point. According to the Department of Health guidelines drawn up by the British Thoracic Society, British Infection Society and HPA (well in advance of the current pandemic), such patients would be triaged for management at home and not even be admitted to hospital.

Implications for health care 4: CURB-65 appeared an unreliable triage tool.

The utility of a score, derived from the simple, physiology-based triage model, to triage patients for critical care in a pandemic seemed to be minimal. While there may be some scope for using triage models during a pandemic, it seemed clear that these scores/models are not sufficiently discriminatory to be relied upon in isolation, and the resultant savings in terms of critical care unit bed days would not be substantial.

Implication for health care 5: At this time, pandemic planning should not be based on assumptions that a reliable triage tool is available for critical care and the mild nature of the H1N1 pandemic should not induce complacency.

The development of the simple, physiology-based triage model was limited by the available data. In particular, the most extreme physiological measurements from the first 24 hours following admission to a critical care unit, available from the CMPD, were assumed to be representative of pre-admission values that would be used to make a triage decision. Routinely available data on all acute hospital admissions potentially requiring critical care are required to enable a fuller exploration of decision-making around critical care admission. In addition, data on the duration and trajectory of critical illness would enable

exploration of triage models to consider earlier discontinuation of critical care for patients initially admitted to critical care.

Implication for health care 6: There is a lack of accurate data to inform usual, non-pandemic, decision-making both around critical care admission and around continuation of critical care treatment, once commenced.

SwiFT successfully collected data on > 1700 critically ill patients who were affected by the H1N1 pandemic, either directly (as a confirmed or suspected H1N1 case) or indirectly through not being admitted to a critical care unit as a result of the pandemic ($n = 3$). The substantial discordance, between the 'reasonable worst-case scenario' and that experienced, underlines the caution that needs to be exercised in accepting modelled data for any new pathogen or for a known pathogen in a new context. To this end, the existing critical care capacity coped – with only a minority of patients experiencing a level of critical care provision lower than in normal, non-pandemic circumstances.

Caution should also be applied in using SwiFT data to model future outbreaks. While SwiFT data would provide reasonably robust estimates for modelling critical care requirements in a subsequent outbreak of an unchanged virus in the UK, it is important to recognise several caveats. First, changes in population immunity (either natural or due to immunisation) may modify disease load, both across the UK and within local communities. Second, these estimates could suffer from substantial inaccuracy if there is a significant change in the antigenicity of the virus. Third, the estimates could be erroneous if applied to a new virus [e.g. H5N1 (avian influenza)]. These considerations make a strong case for even earlier accumulation of data than that achieved by SwiFT in the course of any future epidemic.

Implication for health care 7: Caution needs to be exercised in accepting modelled data for any new pathogen or for a known pathogen in a new context.

The markedly different distribution of ethnicity in confirmed wave 1 H1N1 cases, identified through the CMP, with the distribution of ethnicity in confirmed wave 2 H1N1 cases from SwiFT likely represented early hot spots in the West Midlands and London. The distribution of ethnicity for the latter was similar to that typically observed among critical care admissions more generally.

Implications for health care 8: Caution needs to be exercised in interpretation of data early on in an emerging pandemic and it is important to keep policies and messages up to date.

Research recommendations

Clearly, further research into triage modelling, at each step in the care pathway, is a high priority and specifically important for critical care decision-making. Such research should have two main themes: first, the development and validation of triage models; and second, the potential use of such models for critical care decision-making.

With respect to the first theme, given that triage decisions in a pandemic situation should be made for all patients considered for critical care (and not just those afflicted by the pandemic), data for, and research on, developing and testing the utility of triage models for critical care does not require a pandemic situation. However, to develop such triage models requires the collection of accurate data on all acute hospital admissions potentially requiring critical care to enable a fuller exploration of decision-making around critical care admission and data on the duration and trajectory of critical illness to enable exploration of triage models to consider earlier discontinuation of critical care for patients initially admitted to critical care. In addition to conventional validation of such triage models, validation could also encompass a comparison with subjective clinical decision-making and an assessment of the potential impact of any triage model on future pandemic situations.

Research recommendation 1: Development and validation of triage models to address the research question – what are the best triage models for critical care decision-making?

With respect to the second theme, the use of triage models, there is a need for a much wider public involvement and debate on this issue. This was highlighted in SwiFT, where the North West REC showed considerable disquiet about the potential use of such models without public involvement and debate. It is far better to have public debate on the role of triage modelling in a situation where critical care services become overwhelmed, sooner rather than later, and a pandemic situation is not the best time to be addressing the utility and ethics of triage models in critical care decision-making.

Research recommendation 2: Public involvement and debate around the role of triage modelling in a situation where critical care services become overwhelmed to address the research question – what are the utility and ethics of triage models in critical care decision-making?

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Publication

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This themed issue of the *Health Technology Assessment* journal series contains a collection of research commissioned by the NIHR as part of the Department of Health's (DH) response to the H1N1 swine flu pandemic. The NIHR through the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) commissioned a number of research projects looking into the treatment and management of H1N1 influenza.

NETSCC managed the pandemic flu research over a very short timescale in two ways. Firstly, it responded to urgent national research priority areas identified by the Scientific Advisory Group in Emergencies (SAGE). Secondly, a call for research proposals to inform policy and patient care in the current influenza pandemic was issued in June 2009. All research proposals went through a process of academic peer review by clinicians and methodologists as well as being reviewed by a specially convened NIHR Flu Commissioning Board.

The final reports from these projects have been peer reviewed by a number of independent expert referees before publication in this journal series.

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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.

The research reports in this themed issue were funded through the Cochrane Collaboration; the Health Services Research programme (HSR); the Health Technology Assessment programme (HTA); the Policy Research Programme (PRP); the Public Health Research programme (PHR); and the Service Delivery and Organisation Programme (SDO).

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The PRP provides the evidence base for policy development on public health and social care issues. It funds research in three main ways: 5-year programmes of research in 16 research units, a primary-care research centre, a public health research consortium, and a surveillance unit; programmes of interlinked studies on key policy initiatives; and single projects and literature reviews.

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The SDO programme commissions research evidence that improves practice in relation to the organisation and delivery of health care. It also builds research capability and capacity amongst those who manage, organise and deliver services – improving their understanding of the research literature and how to use research evidence.

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