NIGB

Ethics and Confidentiality Committee

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Keryn Vella
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keryn.vella@icnarc.org

30 July 2009

Dear Keryn

Re: Application for extension of Case Mix Programme (PIAG2-10(f)/2005) for data collection for SwiFT (Swine Flu Triage) Study

Thank you for applying for support under section 251 of the NHS Act 2006 to process patient identifiable information without consent. This application for extension of section 251 support was considered by the Chair of the Ethics and Confidentiality Committee on 29 July 2009.

The Committee accepted that this was undoubtedly an extension of the current work undertaken by ICNARC and the proposed study used the same methodology adopted by other studies in the Case Mix Programme. The Committee was pleased to note that the proposal for the extension was well developed and clear and appreciated the urgent nature of this work.

As such, I am pleased to inform you that this extension request of PIAG2-10(f)/2005) for data collection by ICNARC for the SwiFT study was approved, subject to confirmation of satisfactory REC approval to the NIGB office.

Conditions of Approval

1. Confirmation of satisfactory REC approval to be submitted to the NIGB Office.
2. This extension has been approved until the official end of the pandemic.

I will arrange for the Register of approved activities to be shortly updated on our website http://www.nigb.nhs.uk/ecc/register-1/register-of-approved-applications to include this extension.

Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the above conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any

changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements.

If you have any queries please get in touch. I would be grateful if you could quote the above reference number, in full, in all future correspondence.

Yours Sincerely

Claire Edgeworth
Approvals Officer

NIHR CRN
NIHR Clinical Research Network
Coordinating Centre

NHS
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21st August 2009

Professor Kathryn M Rowan
ICNARC
Tavistock House
Tavistock Square
London
WC1H 9HR

Dear Professor Rowan

Re: 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
(IRAS Ref: 29928)

The study detailed above has now proceeded through National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) successfully and I am pleased to confirm that it is eligible for inclusion on the National Institute for Health Research Clinical Research Network (NIHR CRN) Portfolio.

Please note that recruitment/accrual study data must be uploaded every month as a condition to be on the NIHR CRN Portfolio. Please be aware that accrual data is monitored and the CLRNs are notified if the study is not uploading accrual data.

It is your responsibility to:

- identify and forward (by return post and/or email) the name and contact details of the person who will be responsible for uploading the accrual data for your study. The named person is referred to as the 'accrual contact'
- ensure that the accrual contact uploads recruitment/accrual data regularly on a monthly basis. Reported accrual activity ultimately informs the allocation of funding for NHS support
- confirm whether the study is open to new sites. This information is extremely important to the successful development of studies.

We will then:

- enter the study on the NIHR CRN Portfolio upon the receipt of accrual contact's details
- forward an accrual data package with detailed instructions on how to upload the data to the accrual contact.

Thank you for your support in this process which will be critical to the successful development of NIHR CRN Portfolio. Our aim is to ensure the provision of high

quality infrastructure to support clinical research in the NHS and support the delivery of your study.

Please do not hesitate to contact me should you require further information

Best Wishes

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18 August 2009

Professor K M Rowan
Director
ICNARC
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Dear Professor Rowan

Full title of study: **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**
REC reference number: **09/H1010/58**

The North West Research Ethics Committee reviewed the above application at the meeting held on 11 August 2009. Thank you for attending to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	***Version***	***Date***
Covering Letter - from Professor Kathy Rowan		07 August 2009
Application	IRAS Version 2.3	07 August 2009
Investigator CV - for Professor Kathryn M Rowan		04 August 2009
Protocol	1.3	03 August 2009
Patient Information Leaflet	1	07 August 2009
Patient Information Poster	1	07 August 2009
Compensation Arrangements: Professional Liability Insurance Certificate - No: A05305/0808		27 August 2008
Letter from Sponsor - from Keryn Vella, Operations Director, ICNARC		04 August 2009
Letter from funder - NIHR Health Technology Assessment programme		27 July 2009
Referees' Reports		
Letter confirming approval from the National Information Governance Board for Health and Social Care (NIGB)		30 July 2009
Spreadsheet of Research Sites		

Provisional opinion

Estimates of the likely impact of the H1N1 swine influenza pandemic on critical care suggest that current critical care resources could be overwhelmed. Latest figures have shown that hospital admissions for H1N1 swine influenza have been rising and, of these, an increasing proportion of patients are being admitted to critical care. It is estimated that there will be a surge in critical care admissions as a result of H1N1 swine influenza during autumn 2009.

In the event that demand for critical care services outstrips provision, triage of patients referred for critical care will become essential.

Existing, proposed tools for triage of patients considered for critical care may not be appropriate for use in the current pandemic due to several factors, as follows: -

1. Many triage tools rely on data relating to chronic health conditions, which may be difficult to assess reliably during the peak of the pandemic.
2. Many triage tools use laboratory parameters, the measurement of which will be resource−intensive and may delay a triage decision.
3. Some triage tools are based around existing risk models for respiratory illness such as pneumonia; however, triage decisions will need to be made for all patients considered for critical care (not only those with influenza) since all patients must share a single pool of resources.
4. Finally, none of the existing triage tools have been developed or evaluated using multi-centre data from the NHS.

In light of these difficulties with existing tools, it is necessary to develop another, more specific, triage tool, which will be based on previous efforts. Whilst being simple enough to be applied quickly and consistently during the peak of the pandemic, it should also be complex enough to adjust the decision criteria in order to match demand against capacity and 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.

The SwiFT study thus aims to develop a triage tool to guide immediate policy and practice during the H1N1 swine influenza pandemic in order to deliver the best possible care to critically ill patients. The intention is to develop and implement a UK−wide, real-time high quality clinical database of adult and paediatric patients with confirmed or suspected H1N1 swine influenza referred for critical care. The proposed data collection will allow policy makers within the NHS to assess, in real-time, the burden of severe H1N1 swine influenza and to rapidly respond to escalation in the number of severe cases.

All patients (adult and paediatric) that are referred for critical care, and who would be admitted in "usual" circumstances, and have either confirmed or suspected H1N1 swine influenza, or are refused critical care or receive critical care outside a critical care unit as a direct or indirect result of the pandemic, will be eligible for the study.

Patients will be identified by the direct treating health care teams. Information posters and leaflets will be made available in all participating centres to inform participants and their relatives / friends that the centre is participating in the study, that this does not affect their treatment in any way, and that any participant (or relative / friend on their behalf) is free to withdraw their data from the study at any time without affecting future care.

Patients will not receive any treatment above and beyond what is considered appropriate care by the critical care staff at the hospital.

Patient data, which are routinely collected and recorded in hospital notes, will be abstracted and entered into a secure web portal by local data collection staff and sent to the Intensive Care National Audit and Research Centre (ICNARC) for analysis.

The data will be analysed weekly in order to refine the triage tools, and to provide weekly reports to the Department of Health and to participating centres.

The Committee noted that the proposed study had received approval from the National Information Governance Board for Health and Social Care (NIGB) to process identifiable patient data without consent (under section 251 of the NHS Act 2006). It was acknowledged that this approval meant that under the terms of the Mental Capacity Act (MCA) the proposed study was not considered to be 'intrusive' and consequently the research provisions of the MCA did not apply.

The REC raised a number of queries/concerns in relation to the application and it was agreed that it would be helpful to speak to Dr Harrison (Senior Statistician and Key Investigator / Collaborator on the study), who had attended the meeting to answer any queries in person.

The Chair thanked Dr Harrison for attending the meeting and the following points were raised: -

The Committee noted that four Referee Assessment reports had been provided with the submission and the REC queried to what extent the current application had been changed as a result of the comments raised by these referees.

Dr Harrison explained that the Study Board had considered all of the comments raised by the referees and had addressed some of the issues raised by them (but not all).

The REC questioned the level of service user involvement in the current application.

Dr Harrison informed Members that there were two service user representatives on the study group (both charity trustees on ICNARC's Board of Management and both ex-critical care patients). They would be involved in the progress of the study as it moved forward.

Members noted that the study was described as being non-interventional and confirmation was sought that patients, whose data would be collected as part of the study, would receive only routine clinical care and no additional interventions, i.e. the study would involve only the collection of their data.

Dr Harrison confirmed that this was correct.

Clarification was sought as to how the stated rationale, science and design of the proposed study would inform triage decisions.

Dr Harrison informed Members that the current proposed study would establish a very large database of adult and paediatric patients with confirmed or suspected H1N1 swine influenza who are referred for clinical care. The study would use data from a real-time model and would then test the model and look at refinements. It was intended that the developed models would provide the ability to triage either all patients referred for critical care, or only those patients referred for critical care with confirmed or suspected H1N1 swine influenza.

The Committee noted that approval had been obtained from NIGB for the study team to process patient identifiable information without consent. However, this did not negate the need to provide sufficient information to patients about the study. It was felt that issues around the study were not reflected sufficiently in the study information leaflet

and poster. For example, future limitations in terms of service provision leading to rationing of treatment / resources, and the challenges faced by the NHS.

These concerns would be detailed in writing to the Chief Investigator in the formal letter of response from the North West REC following the meeting.

In addition to the above, it was pointed out that ordinarily, the REC would expect to see a specific named contact at each hospital being included on the information leaflet / poster.

Dr Harrison explained that the study team wished to use a generic information leaflet at all study sites and pointed out that personnel at each site would be aware of the study and would also know who their local contact was in order to direct patients to them if/as required.

The Chair reiterated that it would not be too difficult to include details of the local contact in the information leaflet.

This point was accepted.

The REC questioned whether the information leaflet and poster accurately reflected the aims of the study and in particular the use of the patient data collected to develop triage tools.

Dr Harrison informed Members that the study team would use pre-pandemic data to develop an initial triage model. The Department of Health would then incorporate all patient data (past and ongoing) in order to further develop triage models. He further explained that the current triage model had several limitations not least of which was it's dependence on laboratory data, which was not available for many patients.

The Committee queried whether the two service user representatives on the study group expressed favourable or unfavourable views with regards to the current proposed study.

Dr Harrison confirmed that both service user representatives expressed a favourable view of the current proposed study.

Members sought detail as to the number of patients that would be expected to be unable to consent for themselves through physical or mental incapacity (were consent to be sought).

Dr Harrison provided an estimate of approximately 3% of patients that would be unable to consent for themselves to take part in this study.

The Committee questioned whether the data that would be obtained from the study would be sufficiently sophisticated to enable complex decisions to be made vis-à-vis the development of triage models that would be required in order to 'ration' services.

Dr Harrison pointed out that the study would collect a very large amount of data that would be expected to be sufficient to inform the development of appropriate triage models.

Following on from the above point relating to the possible future rationing of services, the REC expressed concern that the study would not capture information regarding clinical judgement but would only capture physiological patient data.

Dr Harrison informed the REC that the study would collect some data around decisions taken as part of the clinical care received, for example, a decision to discharge a patient due to a shortage of beds etc.

The questioning concluded and Dr Harrison left the meeting.

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Professor R Gulati (Consultant Physician), and Mr R Swindell (Medical Statistician).

Further information or clarification required

Action Points

A. Further to discussion at the meeting, and as stated above, it was agreed that the approval that had been obtained from NIGB for the study team to process patient identifiable information without consent did not negate the need to provide sufficient information to patients about the study. As such it was agreed that the study information leaflet and poster should be amended to more accurately reflect the principal study objective, i.e. the use of patient data to develop triage tools to guide the use of critical care services during the H1N1 swine influenza pandemic. As part of this patients should be informed that the use of triage could prove to be essential in the event that demand for critical care services exceeds available capacity. (Mandatory)

B. Further to discussion at the meeting, and as stated above, the REC would expect to see a specific named contact at each hospital being included on the information leaflet / poster. It was not considered to be sufficient to expect patients to speak to any member of staff in order to obtain information about the local study contact. The Committee appreciates that the study team would wish to use a generic information leaflet /poster at all sites and this would still be possible by means of a blank space on the leaflet / poster for the study site to manually insert details (name, contact number etc.) for their local contact. (Mandatory)

In addition to the above mandatory action points relating to the information leaflet and poster, the North West REC would wish to make a number of comments relating to the proposed study, upon which it respectfully requests that the study team give further consideration (due to the urgent nature of the study, these are suggestions/comments only and approval for the study is not dependent upon a satisfactory response/action): -

- The REC agreed with the concerns raised by a number of the referees regarding possible selection bias in the recruitment of patients into the study and the fact that consideration should be given to the acquisition of data from pre-ICU (intensive care unit) patients.

- The Committee expressed concern with regards to the future introduction of triage models that were likely to be used as rationing tools for healthcare services on the basis of the type of data collected in the current proposed study, i.e. data that takes no account of clinical judgement but focuses solely on physiological data.

- It was pointed out that the introduction of a fixed tool for triage was problematic, as by its very nature, triage must be responsive to the needs of both the service and the patients.

- The Committee supported the view expressed in detail by one of the referees that unless the current swine influenza pandemic is prolonged, the current proposed study is unlikely to result in the production of a scientifically robust and clinically viable triage tool, which

would be made available to, and adopted by clinicians in ICU units across the UK in the future. Furthermore, if future influenza pandemics produce significantly different patterns of morbidity to those produced by the current H1N1 strain, then any tool resulting from the current study would be of limited value.

- The REC felt strongly that the public should be consulted on the use of triage approaches to the allocation of limited critical care resources during the swine influenza pandemic. The rationing of healthcare is an emotive issue and the study team is strongly encouraged to consult the public on the ethical implications of the use of such triage tools (although it is recognised that this would be particularly challenging given the urgency with which the triage tools are to be developed).

When submitting your response to the Committee, please send revised documentation where appropriate underlining the changes you have made and giving revised version numbers and dates.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 16 December 2009.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H1010/58	**Please quote this number on all correspondence**

Yours sincerely

Dr Donal Manning
Chair

Email: noel.graham@northwest.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copies to: -

Ms K Vella
Operations Director
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R&D office for NHS care organisation at lead site: -

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North West Research Ethics Committee

Attendance at Committee meeting on 11 August 2009

Committee Members Present:

Name	*Profession*	*Present*	*Capacity*
Ms Arlene Blanchard	Retired Lecturer / Patient Representative	Yes	Lay
Mr James Bruce	Consultant Paediatric Surgeon	Yes	Expert
Mrs Chris Burgess	Retired Senior Manager - Equal Opportunities Commission	Yes	Lay
Professor Caroline Carlisle	Professor of Education in Nursing and Midwifery – The University of Manchester	Yes	Expert
Dr Sally Furnish	Chartered Clinical Psychologist	Yes	Expert
Professor Ravi S Gulati	Consultant Physician	Yes	Expert
Dr Donal Manning	Consultant Paediatrician	Yes	Expert
Dr Henry C Mwandumba	Consultant Physician	Yes	Expert
Mrs Margaret Norval	Chief Pharmacist	Yes	Expert
Professor Elizabeth Perkins	Director - The Health and Community Care Research Unit - The University of Liverpool	Yes	Lay
Mr Ric Swindell	Medical Statistician	Yes	Expert

Written comments received from:

Name	*Position*
Dr Fiona O'Neill	Medical Sociologist / Bioethicist (Lay)

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Dr Donal Manning
Chair
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25 August 2009

Dear Dr Manning

Re: REC Ref 09/H1010/58 - The Swine Flu Triage (SwiFT) study

Thank you for your letter of 18 August, 2009. I'm sorry that I wasn't able to attend the meeting of the North West Research Ethics Committee (NWREC) on 11 August 2009 to respond directly to the concerns raised. I am, however, very grateful for the Committee's detailed review and comments.

Prior to my response, I think it is important to be explicit about the origins and context for the SwiFT study. Mid-June, ICNARC was contacted by the Department of Health and "encouraged" to respond to a limited (i.e. just us) tender on the development of a prognostic model/clinical decision rule for the triage of patients being considered for critical care – in the light of the impending H1N1 swine influenza pandemic… Following such "encouragement", the SwiFT study proposal was rapidly developed (within 72-hours) and then funded, following rapid peer review.

Though the proposal needed to address the original request to develop a triage tool (described in our protocol in the first objective), I should point out that the investigators are well aware of the issues and limitations of this single model approach, as highlighted by both the NWREC and the original peer reviewers. However, despite these limitations, we, as investigators, do believe that information to guide (and not determine) both local clinical practice and national policy throughout the pandemic is important and possible from the SwiFT study, as planned.

The term "triage tool(s)", used widely throughout the protocol should be regarded, though is not explicitly stated, as any information that the SwiFT study can provide, either from existing or from new SwiFT study data, to guide (and not determine) both local clinical practice and national policy throughout the pandemic.

I write in response, first, to the important comments raised by the Committee and second, to the mandated Action Points.

Comments

The REC agreed with the concerns raised by a number of referees regarding possible selection bias in the recruitment of patients into the study and the fact that consideration should be given to the acquisition of data from pre-ICU (intensive care unit) patients.

The SwiFT study, as you are aware, has two main objectives:

- the development of triage tools using existing data; and
- the establishment of ongoing H1N1 swine influenza pandemic-related data collection to refine any triage tools (developed on the existing data) and, through regular reporting, to guide practice and policy, both locally and nationally.

The above comment refers to the first objective of SwiFT.

With regard to the development of a single overall model to triage patients being considered for critical care, we agree with the NWREC (and the original peer reviewers/referees…) regarding the possible selection bias in the existing data from the Case Mix Programme Database. We have explained this issue, in response to the peer reviewers, to the funders and indicated that we would use our existing, extensive networks to attempt to identify any existing pre-ICU data (we do hold some pre-ICU critical care outreach assessment data at ICNARC which we will use to help to address this bias).

The Case Mix Programme Database, however, may help to identify (from patients who routinely get critical care in a non-pandemic situation) those patients who may be able to be triaged more safely for critical care delivered in an extended critical care area (created as surge capacity) or a non-critical care area (i.e. those receiving only basic respiratory and/or basic cardiovascular organ support etc.) during the pandemic from those who will require major, multiple organ support. The Case Mix Programme Database may also help in planning use of critical care resources by indicating expected duration of critical care required by typical seasonal admissions.

Finally, the planned new SwiFT study data includes data available at the point that patients are referred and assessed as requiring critical care.

The Committee expressed concern with regards to the future introduction of triage models that were likely to be used as rationing tools for healthcare services on the basis of the type of data collected in the current study, i.e. data that takes no account of clinical judgement but focuses solely on physiological data.

We recognise that the SwiFT study will not produce a single triage model to be used to ration critical care services. It is hoped though, that the SwiFT study, using both existing and new SwiFT data, will provide information to guide (and not determine…) optimal use of critical care services throughout the pandemic. My personal history of working with critical care doctors and nurses in the context of risk prediction models for hospital mortality, over the past 22 years, indicates to me that they are used to using such information solely as an adjunct to their clinical judgement.

It was pointed out that the introduction of a fixed tool for triage was problematic, as by its very nature, triage must be responsive to the needs of both the service and the patients.

We agree and the SwiFT study has no intention of providing such a fixed tool.

The Committee supported the view expressed in detail by one of the referees that unless the current swine influenza pandemic is prolonged, the current proposed study is unlikely to result in the production of a scientifically robust and clinically viable triage tool, which would be made available to, and adopted by clinicians in ICU units across the UK in future. Furthermore, if future influenza pandemics produce significantly different patterns of morbidity to those produced by the current H1N1 strain, then any tool resulting from the current study would be of limited value.

These views are rightly related, and noted, to the notion that the SwiFT study will produce a single triage tool. For the reasons outlined above, we do not see this being the case. It is, however, hoped that information derived from the SwiFT study will inform optimal use of critical care services during the pandemic. For example, at this stage, there is little to no collective experience of the characteristics, treatment, outcome, duration of critical care etc. for H1N1 swine influenza cases and the SwiFT study will endeavour to provide these to clinicians, as early as possible, to inform clinical care of these patients.

The REC felt strongly that the public should be consulted on the use of triage approaches to the allocation of limited critical care resources during the swine influenza pandemic. The rationing of healthcare is an emotive issue and the study team is strongly encouraged to consult the public on the ethical implications of the use of such triage tools (although it is recognised that this would be particularly challenging given the urgency with which the triage tools are to be developed).

ICNARC has previously funded and collaborated in research investigating survivors' and family/close friends' experiences of critical care (see: http://www.healthtalkonline.org/Intensive_care/). I am happy to approach the DIPEx research group with a view to addressing this issue, however, as noted by the NWREC, time (and resources) for this are scant. Should the SwiFT study lead to the development of a valid, single overall triage tool, I will ensure that the NWREC's concerns regarding public consultation are conveyed at/to the highest level.

Action Points

I have amended the Patient Information Leaflet and Patient Information Poster both to more accurately reflect the principal study objectives and to ensure that a blank space is available for manual insertion of the details (name/contact number) for the Local Collaborator. We will also ensure that instructions are provided for completion of these details.

Finally, in conclusion, SwiFT is intended to be a responsive, real-time study aiming to support the needs of critically ill patients while taking into account NHS resources for critical care and the likely strain on these NHS resources.

Once again, thank you for the Committee's detailed review and comments.

Yours sincerely

Professor Kathy Rowan
Director

Encs

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02 September 2009

Professor K M Rowan
Director
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Tavistock House
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Dear Professor Rowan

Full title of study:	**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**
REC reference number:	**09/H1010/58**

Thank you for your letter of 25 August 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by Professor R Gulati (Consultant Physician), and Mr R Swindell (Medical Statistician).

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Mental Capacity Act 2005

The committee did not approve this research project for the purposes of the Mental Capacity Act 2005. The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project. The rationale for this is that the proposed study has received approval from the National Information Governance Board for Health and Social Care (NIGB) to process identifiable patient data without consent (under section 251 of the NHS Act 2006). This approval means that under the terms of the Mental Capacity Act (MCA) the proposed study is not considered to be 'intrusive' and consequently the research provisions of the MCA do not apply.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	***Version***	***Date***
Covering Letter - from Professor Kathy Rowan		07 August 2009
Application	IRAS Version 2.3	07 August 2009
Investigator CV - for Professor Kathryn M Rowan		04 August 2009
Protocol	1.3	03 August 2009
Patient Information Poster	1	07 August 2009
Compensation Arrangements: Professional Liability Insurance Certificate - No: A05305/0808		27 August 2008
Letter from Sponsor - from Keryn Vella, Operations Director, ICNARC		04 August 2009
Letter from funder - NIHR Health Technology Assessment programme		27 July 2009
Referees' Reports		
Letter confirming approval from the National Information Governance Board for Health and Social Care (NIGB)		30 July 2009
Spreadsheet of Research Sites		
Response to Request for Further Information: From Professor Kathy Rowan		25 August 2009
Participant Information Sheet: Patient Information Leaflet	3	25 August 2009
Advertisement: Patient Information Poster	3	25 August 2009

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email:

referencegroup@nres.npsa.nhs.uk.

09/H1010/58	**Please quote this number on all correspondence**

Yours sincerely

Dr Donal Manning
Chair

Email: noel.graham@northwest.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copies to:

Ms K Vella
Operations Director
Intensive Care National Audit & Research Centre (ICNARC)
Tavistock House
Tavistock Square
LONDON WC1H 9HR

R&D office for NHS care organisation at lead site: -

Mr S Kelleher
Cambridge University Hospitals NHS Foundation Trust
Research & Development Box 277
Addenbrookes Hospital
Hills Road
CAMBRIDGE
CB2 0QQ

From: Stephen Smye [mailto:S.W.Smye@Leeds.ac.uk]
Sent: 30 July 2009 09:07
To: David Harrison
Subject: Re: SwiFT: follow-up to teleconference

David,

fyi - please see message below, sent yesterday.

best wishes
Steve

"Circulation: CLRN Clinical Directors and Senior Managers
Lead RM&G Managers
P/TCRN Directors and Assistant Directors

C.C. Adeeba Asghar
Stephen Smye
Jonathan Gower
Christine Oxnard
Carolyn Taylor
John Sitzia
Helen Campbell
Swine Flu Coordinating Group

Dear Colleague

Swine Flu Briefing Paper - CRN 4

In line with network plans for expediting the conduct of swine flu research, we are writing to provide an "early warning" of major swine flu studies that will be rolled out nationally across all CLRNs. It is likely that these studies will require set up and NHS permission through CSP throughout August with many starting in early September.

We will be setting up a reporting system to facilitate communication between CLRNs tasked with delivery of these studies and the Coordinating Centre so that we can provide support and assistance. We will provide a weekly summary of the swine flu studies we are expediting through the networks so that networks can be clear which studies to prioritise.

The Swine Flu Triage study (SwiFT): Development of 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.

Chief Investigator: Prof. Kathy Rowan, Intensive Care National Audit and Research Centre (ICNARC)

Study coordinator: Phil Restarick, Intensive Care National Audit and Research Centre (ICNARC)

Lead CLRN: West Anglia.

The study requires data collection for patients with swine flu on Intensive Care Units and national coverage is expected. Whilst details of the data sets (and costs of data collection) are still being developed, it will be very helpful if each CCRN network team reviewed the capacity of the Intensive Care Units to collect this data and, where such capacity is limited, plan to put in place adequate capacity. Many Intensive Care Units already work with ICNARC on similar work as part of ITU audits.

Clearly this is challenging as details of the study and numbers of patients are not clear. However, helpful approaches may include considering

Cover from pool of CLRN research nurses or other appropriate research staff, including data officers
Cover from staff for adjacent CLRN pools of research staff
Cover from staff from adjacent P/TCRN Local Research Networks
Overtime payments for existing staff on ICU
Increasing hours of part-time staff on ICU
Using bank staff

Funding for the data collection exercise will be available from the national contingency if required.

We recognise that any assessment of capacity will simply be an estimate and subject to change in the light of future study details, but it would also be very helpful if you could provide details of the capacity for your network to undertake the data collection by emailing these details direct to Carolyn Taylor at carolyn.l.taylor@nihr.ac.uk. as soon as possible.

As with all of our other Swine Flu correspondence we would be most grateful if you could cascade this information across all of your Clinical Research Networks as appropriate.

Kind regards

Nicki

Gill Thackrah
PA to Dr Nicki Latham, Director of Corporate Affairs
National Institute for Health Research
Clinical Research Network Coordinating Centre (NIHR CRN CC)
Fairbairn House
71 -75 Clarendon Road
Leeds
LS2 9PH

Tel: 0113 343 0437
Fax: 0113 343 2300
Email: gillian.e.thackrah@nihr.ac.uk
www.crncc.nihr.ac.uk

From the Chief Medical Officer
Dr Michael McBride

Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

AN ROINN
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

MÄNNYSTRIE O
Poustie, Resydènter Heisin an Fowk Siccar

Chief Executives, Health & Social Care Trusts

Castle Buildings
Stormont Estate
Belfast BT4 3SQ
Tel: 028 90 520658
Fax: 028 90 520574
Email:michael.mcbride@dhsspsni.gov.uk

Your Ref:
Our Ref:
Date: 25 August 2009

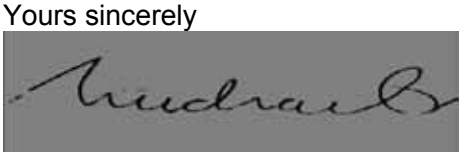
Dear Colleague

ICNARC – SwiFT Study: HOLDING PATIENT IDENTIFIABLE DATA FROM CRITICAL CARE UNITS (N IRELAND) DURING SWINE FLU PANDEMIC

In relation to ICNARC's proposed SwiFT Study, the National Information Governance Board (NIGB) has given approval to hold patient identifiable data from English and Welsh Intensive Care Units. NIGB does not apply to Northern Ireland nor is there equivalent legislation here so patient consent would normally be required before personal data could be contributed to a study.

The issue of contributing information to this study has been considered within DHSSPS. Whilst individual organisations and clinicians can still make their own decisions about whether or not they wish to contribute patient data to the study, it is the view of DHSSPS that Northern Ireland should contribute data as the study is very much in the public interest. It will inform policy and clinical practice both locally and nationally and will deliver benefits for service users here. I would encourage you to support this initiative.

Yours sincerely



DR MICHAEL MCBRIDE
Chief Medical Officer

Scotland A Research Ethics Committee

Secretariat
Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
Telephone 0131 536 9026
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NHS SCOTLAND

0 5 OCT 2009

Professor Kathryn M Rowan
Director
ICNARC
Tavistock House
Tavistock Square
London
WC1H 9HR

Date: 28 September 2009
Your Ref.:
Our Ref.: 09/MRE00/73

Enquiries to: Walter Hunter
Extension: 89026
Direct Line: 0131 536 9026
Email: walter.hunter@lhb.scot.nhs.uk

Dear Professor Rowan

Study title: **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**

REC reference: **09/MRE00/73**

The Scotland A Research Ethics Committee reviewed the above application at the meeting held on 24 September 2009.

Ethical opinion

The Committee questioned if this application was actually primary research rather than service development. It was crucially linked to service delivery. It did not allow for consent to be obtained for adults lacking capacity in Scotland, as required by the Adults with Incapacity (Scotland) Act 2000. The application did not involve any research being undertaken on patients and did not make clear why identifiable information was required. Most of the data were already collected routinely and passed on daily to ICNARC. The Committee wondered if all the participating sites had agreed to participate-they all appeared to be part of CMP in England and Wales and SICSAG in Scotland. The Committee was of the opinion that this was audit linked to service development and delivery rather than research, and therefore did not require ethical approval from an NHS research ethics committee.

The Committee agreed that under the terms of the Research Governance Framework (RGF) this project was considered to be audit and should not be managed as research.

NHS
SCOTLAND

REC reference number: 09/MRE00/73-Please quote this number on all correspondence

Yours sincerely

WALTER HUNTER
Committee Co-ordinator
cc: Keryn Vella
Operations Director
ICARC
Tavistock House
Tavistock Square
London
WC1H 9HR

Dr Donal Manning
Chairman
North West 5 Research Ethics Committee
Haydock Park
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Scotland A Research Ethics Committee

Attendance at Committee meeting on 24 September 2009

Committee Members:

Name	Profession	Notes
Professor K Lees	Consultant Physician/Clinical Pharmacologist (Chairman)	
Dr M Booth	Consultant Anaesthetist (Vice Chairman)	
Professor R Anderson	Consultant in Reproductive Medicine	
Miss R McInnes	Lay	
Mr L Moffat	Consultant Urologist	
Mrs A M Peffer	Lay	
Mrs F Pfab	Statistician	
Dr R Quigley	General Practitioner	
Dr A Richardson	Consultant Clinical Psychologist	
Dr C Selby	Consultant Physician	
Miss F Sloan	Lay	
Mrs M Sweetland	Statistician	
Mrs M Thomson	Lay	
Professor N Webster	Honorary Consultant Anaesthetist	

Apologies

Dr S Gregory	Qualitative Researcher
Mrs A Macpherson	Lay
Canon M McManus	Lay
Dr A Munro	Retired General Practitioner
Mrs W Nganasurian	Lay
Professor J Webster	Consultant Physician/Clinical Pharmacologist

Also in attendance:

Name	Position (or reason for attending)
Mr W Hunter	Senior Committee Co-ordinator
Dr A Bailey	Scientific Officer

Chief Medical Officer and Public Health Directorate

T: 0131-244 2320 F: 0131-244 2285
E: alison.spaull@scotland.gsi.gov.uk

The Scottish Government

Circ to:
CEOs NHS Health Boards
Chairmen of RECs
cc. R&D Directors NHS Health Boards
cc. Directors of R&D networks
cc. Research project leaders (Woolhouse, Simpson, Walsh)

Homecoming Scotland 2009
homecomingscotland2009.com

31 August 2009

Dear Colleague

Commissioned Research Projects on Influenza A(H1N1) Virus

The Scottish Govenrment have been liaising closely with the English group commissioning research on the current influenza outbreak to ensure that the key questions are addressed urgently. Three projects are currently agreed and all are obliged to work to tight timescales if their results are to inform the treatment or prevention of the anticipated over-winter rise in case numbers.

We write to ask you to ensure that these projects are given the priority necessary to secure rapid ethical and other appraisals and prompt responses to requests for information, data, samples or assistance from the research teams listed below

Scottish Govenrment are funding work to establish the level of existing immunity to the H1N1 flu virus in the population through Professor Woolhouse ("*Enhanced influenza surveillance in Scotland*".
Professor Simpson's NIHR-funded study ("V*accine effectiveness in pandemic influenza – primary care- VIPER*") will help inform vaccine usage strategies.
Professor Walsh is co-ordinating Scottish participation in The Swine Flu Triage study (SwiFT). The study requires data collection for patients with swine flu on Intensive Care Units and national coverage is expected. Whilst details of the data sets (and costs of data collection) are still being developed, it will be very helpful if each Health Board reviewed the capacity of the Intensive Care Units to collect this data and, where such capacity is limited, plan to put in place adequate capacity.

If necessary, we expect staff funded from any CSO NHS infrastructure budget to assist these projects as a priority over their normal responsibilities. Such requests will not be unreasonably made.

We appreciate your assistance;
Yours sincerely

Harry Burns *Alison Spaull*

Dr Harry Burns
Chief Medical Officer

Dr Alison Spaull
Director, Chief Scientist office

St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.scotland.gov.uk