



Health Research Authority

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16 April 2018

Dr Matthew Snowsill
Emergency Department
Princess Alexandra Hospital
Hamstel Road
Harlow
Essex
CM20 1QX

Dear Dr Snowsill

Application title: Pre-Hospital Emergency Medicine (PHEM) Feedback
CAG reference: 18/CAG/0018

Thank you for your service evaluation application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State (SofS) for Health on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held on 08 February 2018.

Secretary of State for Health and Social Care Approval Decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is conditionally approved, subject to compliance with the standard and specific conditions of approval outlined below.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

This outcome should be read in conjunction with the letter issued on 02 March 2018.

Context

Purpose of Application

This application from the Princess Alexandra Hospital NHS Trust set out the non-research purpose of implementation of a service evaluation system for staff involved in the pre-hospital care of patients. The system would provide staff involved with the pre-hospital care of patients the facility to follow-up on specific cases to facilitate learning, improve clinical judgement, allow an opportunity for reflection, debriefing in particularly difficult or sensitive cases and facilitate improvement in the standard of care provided in the future.

In order to request feedback on a specific patient, the member of staff who had been involved with their pre-hospital care, would be required to complete a request. This would be reviewed by a senior member of their service, who would make a judgement on the appropriateness of the request and the potential educational merit. If the senior colleague supported the request, they would then act as mentor for the junior colleague throughout the debriefing process. The request would then be directed to the main applicant at Princess Alexandra Hospital NHS Trust, who would make a determination around whether the data should be released. If the request is approved, the main applicant, or a member of the team, would access patient records in order to extract the pertinent information required to meet the debrief objectives.

The proposal does not involve the transfer of standard patient identifiers as linkage would be facilitated via the emergency department number; however, upon receipt at the Princess Alexandra Hospital NHS Trust, this data item becomes identifiable as it will be used to identify the patient and the specific hospital presentation in question. The main applicant, who will initially be the only individual undertaking follow-up, will access the full patient record in order to extract information. The data which would be returned to the pre-hospital treating team would not include any items of confidential patient information; however, the specific patient would be identifiable to the individual staff member who had requested follow-up. The pre-hospital clinicians would also be provided with additional clinical and demographic information about the patient and their onward care, which they would not have access to when fulfilling their usual role.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

- Patients presenting to Princess Alexandra Hospital NHS Trust emergency department via pre-hospital care providers, such as ambulances services, air ambulance trusts and British Association for Immediate Care (BASICs), for whom a pre-hospital clinician has requested follow-up detail post hospital admission.
- The potential number of cases cannot be determined as this is a new initiative; however, it is estimated at the outset that there would be 10 cases per week, across all pre-hospital care providers.

The pre-hospital care provider would disclose the emergency department number to the Princess Alexandra Hospital NHS Trust, in order to allow follow-up data to be extracted from the patient's medical record. The applicant would require access to the full medical record in order to extract the specific information which is relevant to the request which has been made from the pre-hospital clinician.

The following items of data would be provided back to the applying pre-hospital care service, for the purposes of assisting with feedback:

- Emergency Department Number – validation and project identifier,
- Age,
- Gender,
- Relevant features of the clinical history, examination, investigations,
- Hospital management and treatment,
- Diagnoses from the Emergency Department and/or on discharge,
- Condition of the patient and destination on discharge, including death and disability,
- Measurement of time which the patient survived (if subsequently deceased, but not date of death – see advice form).

This information will be used to provider the debrief session to the relevant clinician to facilitate learning as per the aims of the service evaluation.

Confidentiality Advice Team Advice

The applicant provided a written response to the CAG's request for further information, as detailed within the previously issued provisionally supported outcome. This was considered by the Confidentiality advice Team.

1. Submit final copies of all patient notification materials, to include the website, email and telephone contact details to facilitate patient objection.

The applicant provided revised posters and a link to the programme website text for information. The poster documents had been updated with website and email links, together with a QR code to make access to the website easier. It was confirmed that posts made via social media channels in relation to the programme would follow the same message as included within the posters.

It was explained that the posters would be situated where the ambulances queue in the corridor while awaiting assessment space to become available, and where the ambulance team bring the patients into for assessment to ensure maximum visibility.

The applicants further advised that the posters may also be adapted or diversified in future depending on advice from the communications teams, logos, colour schemes, new stock pictures of paramedics, alterations to website address etc. but the content and messaging will continue to revolve around explaining the programme to patients.

The applicants confirmed that the website and email provided additional contact channels for patients in order to learn more. This encompassed the patient experience team who handle complaints and patient concerns about the care they receive in order to make the communications pathway as accessible as possible.

The documentation was received and no further queries were raised.

2. Submit a revised application form to include the business address of the main applicant within the contact details section.

The applicant provided the revised document as requested.

The document was received and no further issues were raised.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support Final)

1. Patient and Public Involvement and Engagement – feedback would be required at the time of first annual review around the project evaluation activities which had been undertaken with the patient panel. If the responses given were negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed as satisfactory via direct email from NHS Digital – Princess Alexandra Hospital NHS Trust 01/02/2018, East of England Ambulance Service Trust and Essex and Herts Air Ambulance (report under Essex Air Ambulance) 13/02/2018).**

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the 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. An annual review should be provided no later than **16 April 2019** and preferably 4 weeks before this date.

Reviewed Documents

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised) [Final s251 Application - revised]		03 March 2018
Covering letter on headed paper [Email from Dr Matthew Snowskill]		22 March 2018
GP/consultant information sheets or letters [Supervisor request form PHEM Feedback]	0.1	22 January 2018
GP/consultant information sheets or letters [PHEM Feedback report form to PLMs]	0.1	22 January 2018
GP/consultant information sheets or letters [PHEM Feedback report form to Ambulance supervisors]	0.1	22 January 2018
GP/consultant information sheets or letters [Attender feedback form PHEM Feedback]	0.1	22 January 2018
GP/consultant information sheets or letters [PAH PHEM Feedback Team Members]		
Other [Terms of Service for PHEM Feedback]	0.1	22 January 2018
Other [Patient Panel Feedback]		23 June 2017

Other [EEAST PAH PHEM Feedback Information Sharing Agreement]	1.5	22 May 2017
Patient Information Materials [Poster 2]		
Patient Information Materials [Poster 3]		
Research protocol or project proposal [Data Flow Diagram]		
Research protocol or project proposal [PHEM Feedback database]		
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [Caldicott confirmation letter]		16 June 2017

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

There were *no* declarations of interest in relation to this item.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: HRA.CAG@nhs.net

*Enclosures: List of members who considered application
Standard conditions of approval*

Standard Conditions of Approval

The approval provided by the Secretary of State for Health is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.
4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.
6. Activities are consistent with the Data Protection Act 1998.
7. Audit of data processing by a designated agent is facilitated and supported.
8. The wishes of patients who have withheld or withdrawn their consent are respected.
9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.
10. An annual report is provided no later than 12 months from the date of your final confirmation letter.
11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.