

Minutes of the Committee meeting held on 15 September 2021 by MS Teams

Present: Dr Lorna Ramsay (Chair) (LR)
Dr Tara Shivaji (TS)
Kenneth McLean (KMCL)
Professor Abbe Brown (AB)
John Woods (JW)
Martin Walsh (MW)
Dr Angus Ferguson (AF)
Professor Alison McCallum (AMcC)
Professor Colin McCowan (CMcC)
Professor Helen Colhoun (HC)
Martin Bell (MB)
Carole Morris (CM)
Alan Ferrier (Al F)
Penni Rocks (PR) (from 12 noon)

Apologies: Dr George Fernie (GF)
Dr David Felix (DF)
Susan Kerr (Secretariat)

In Attendance: Dr Marian Aldhous (MA)
Phil Dalgleish (PD)

1. Chair's Welcome

The chair welcomed all to the meeting.

- The committee were informed that Dr David Felix has agreed to join the committee as the new representative for NHS Education for Scotland (NES), but was unable to attend this meeting.
- This will be the last meeting for HC as she has come to the end of her time on the committee as a representative of the research community. LR thanked her for all her hard work and contribution and for the 6 month-extension to cover the overlap with the incoming representatives.
- It was also noted that AF and AB have agreed to extend for another six months while the search continues for a replacement lay representative.
- Without GF and DF, the meeting is quorate if AMcC and/or HC represent NHSS through their Honorary NHS contracts. They were happy to do this.

Due to timings of inviting external people to the meeting, the items on the agenda were deliberately taken out of order.

There were no conflicts of interest disclosed.

2. Minutes and Actions from previous HSC-PBPP Committee Meetings

2.1. Minutes of meeting held on 15th June 2021

These were approved as a true record.

2.2. HSC-PBPP Committee Action Log

Two items were outstanding and further discussed:

2.2.1. Action 15-06-21/01: CM to discuss strategies for PBPP Only applications with CMcC and AMcC

This action is still outstanding as the conversation has not yet taken place.

CMcC: an online application form would make the process easier for applicants.

CM: in discussion with RDS that HDRUK are expanding the capability of their form to allow trusted research environments (TRES) to add in their own specific questions. This may allow different forms to align in the future.

AMcC: the more visible the requirements for Scottish applications are, then the easier it is for people to complete the forms and require the bespoke support.

2.2.2. Action 15-06-21/02

This action has been merged with action 06 and requires further discussions between the Operations Group and Roger Halliday.

Actions #01 will be closed and #06 will remain open to be completed.

3. Matters Arising

3.1. Committee personnel update.

The committee still needs one further lay representative and have tried different routes including Young Scot and will continue the process. A representative from NHS Education for Scotland (NES) is now in place.

There are still two vacancies for Caldicott Guardian representatives on the committee, for which it had been hoped they would be filled by representatives from territorial NHS Boards. There is a new Chair for Caldicott Guardian Forum (Dr Tracey Gillies), who has proposed that instead of thinking about NHS Boards as territorial or national boards, that they be thought of as having the functions of patient care vs. patient support. Therefore Public Health Scotland (PHS), NHS National Services Scotland (NSS), NES and Healthcare Improvements Scotland (HIS) are NHS Boards for patient support. All other NHS boards provide direct care for patients, including Scottish Ambulance Service (SAS), the Golden Jubilee National Hospital (GJNH), The State Hospital (TSH) and NHS24, which would be

additional sources to approach people as Caldicott Guardian representatives for the committee.

There was general agreement that this was a sensible way forward.

The patient support boards of PHS, NSS and NES already have representation on the HSC-PBPP committee as they are also data asset holders of the NHSS national datasets, together with the National Records of Scotland (NRS) as the data controller for the NHS Central Register (NHSCR). Currently HIS is also represented as GF is the Caldicott Guardian for HIS.

AMcC has previously worked with SAS and TSH and thought they had helpful perspectives on different patient issues. Those specialist national NHS Board roles also provide a link to the oversight from the Statistics Regulator. There are also Caldicott Guardians in Social Security Scotland and the Mental Welfare Commission.

ACTION 15-09-21 /01: MA to update the HSC-PBPP Terms of Reference
ACTION 15-09-21 /02: LR to follow-up with Tracey Gillies and the Caldicott Guardian forum

3.2. “PBPP Only” applications

A paper was provided which outlined the situation with the “PBPP Only” applications which are no longer supported by eDRIS and the measures put in place to try to mitigate the quality issues raised by them.

A number of comments were made:

- Advice from Caldicott Guardians/IG team always improves the quality of an application so that it goes through the process much more quickly, but is not often sought.
- An online form would need to be able to force people to seek advice if they cannot answer questions to set standards. There is a risk that important things may not go ahead if there is no other route.
- ‘PBPP Only’ applications probably require more information governance (IG) knowledge than eDRIS have, as could cover e.g. NHS operational work, new apps, cross-border applications that only require data from NHS boards. There is a need to push the applicant on questions of data flow, IT security, commercial contracts, Data Sharing Agreements etc. IG support from one NHS board is helpful but not always translatable to the national level and applicants don’t always give the full picture when seeking advice. The previous support from the PHS IG team was good but, currently, is still required for ongoing PHS IG work.
- Some applications are more data-orientated but are just not getting the data through eDRIS and the National Safe Haven (NSH).
- Internal support for applicants may be available within a specific research group that has successfully applied to HSC-PBPP, and sometimes within an institution but this is rarely available across institutions.
- The idea of using a cost recovery model for these applications was generally supported if the applicants were academics and NHS people with funding that would cover this. It would need to be clear at what level this would be set and how would it be administered.

ACTION 15-09-21 /03: LR to raise this with people within PHS

There is advice available on the HSC-PBPP and eDRIS websites. An example HSC-PBPP application from the Tooth Fairy has been written by the panel manager and reviewed by a Tier 1 panel. A couple of changes were suggested and it will then be put on the HSC-PBPP website as an 'approved' application, together with its related Data Protection Impact Assessment (DPIA) and privacy notice. The Information Commissioner had previously used the Tooth Fairy DPIA for training purposes.

ACTION 15-09-21 /04: MA to finalise the Tooth Fairy application and related documents for the HSC-PBPPP website

4. Updates for committee

4.1. Panel Manager Report

This was circulated for information. A few questions were raised about those applications that had been withdrawn: some are withdrawn by the applicant and some by HSC-PBPP because there had been no response from the applicant to the questions raised by the Tier 1 panel for over 3 months. The reasons for the lack of response or the withdrawal is rarely given. Whether the receipt of funding is an issue is unknown.

4.2. Policy Decisions & Case Law Principles

This was unchanged from the previous meeting and was circulated for information. No comments were raised.

4.3. Scottish Government update

PR gave an update from Scottish Government (SG).

COVID vaccinations have been taking priority so there has been a delay in finalising the SG Data Strategy. The Data Strategy has a Working Group consisting of people from COSLA, SG, Data & Intelligence Network, NHS and Local Authority input from Glasgow City Council. The citizen perspective is strewn throughout the strategy. PR will bring update to this to the next meeting.

The Department for Health and Care report will be finalised and published soon.

The Safe Haven accreditation process has been delayed due to ill health.

4.4. Update from HDRUK

CM gave an update on HDRUK.

There is an HDRUK update to PHS from August that can be circulated around the committee.

ACTION 15-09-21 /05: CM to send to MA for circulation

There are a number of ongoing areas of work:

- NSH is still hosting and using health data for COVID19 studies. Now beginning to include non-health data (e.g. Fixed Penalty Notice data from Police Scotland).
- Work is ongoing to try to get lists of data variables in COVID database onto the HDRUK Gateway.
- Information on the medical imaging data is also on the website.
- Data Access Request forms are being formulated and there will be a functionality for the TREs to add specific questions for their requirements.
- CO-CONNECT study to make serology data available to HDR for query is going through HSC-PBPP, with queries from the Tier 1 panel.

For the HDRUK National Core Studies: there is an Outbreak Data Analysis Platform that will host ISARIC and GenoMICC cohort data and other UK-wide data from NHS England and NHS Digital. Data will be accessed via the NSH for health and sensitive data, but the University of Edinburgh platform will be used for the other data, which will give flexibility to analyse genomic data. This will become a UK-wide resource that needs to [be](#) developed and accessed appropriately. Other datasets will be added with the necessary governance in place.

RDS

RDS is working through all the agreements with members and service delivery partners. It will be launched on 30th September at Data Fest. They are formulating a communications launch plan with input from the different communications teams from PHS, NRS and University of Edinburgh.

5. Application matters

Application for discussion and decision: 2122-0071 Colquhoun

This application has been referred to the full committee for discussion with the applicant and decision.

Lead reviewer: TS

The preliminary discussion highlighted the outstanding issues and questions for discussion with the applicant.

LR welcomed Professor Neena Modi (NM) and Richard Colquhoun (RC) from Imperial College, London to the committee.

TS led a helpful discussion with the applicant about the agreed questions.

LR thanked the NM and RC for coming to the committee and thought it had been a very useful discussion and had helped to clarify the outstanding issues about this application.

Post-discussion reflection

After discussion with the applicant the committee thought there were three main decisions required:

- i. Can HSC-PBPP approve the continuance of data submission from NHSScotland in the same way?
- ii. Can HSC-PBPP approve the request to extend the data request to include patient identifiers?
- iii. Can HSC-PBPP approve the request to bypass further scrutiny of the use of the data from NHSScotland?

The committee agreed that data could continue to be sent from NHS Scotland but that there are some good practice approaches that need to be put in place.

The committee did not approve (ii) and (iii) but requested that there would be further constructive discussions with the applicants to ensure that all the concerns have been addressed and to reach a mutually satisfactory outcome.

ACTION 15-09-21 /06: TS and MA to compose a letter for LR to send on behalf of the committee

6. HSC-PBPP Development Slot

Feedback from application 2021-0180 Pell

This application was a COVID application that had previously been approved by the HSC-PBPP COVID Rapid Review panel. It had also been discussed by the committee at its meeting in April as a new study recruitment methodology was being used and for which the committee were keen to gain feedback for learning.

LR welcomed Professor Jill Pell, from the University of Glasgow to the meeting. The application is a study of Long COVID at population level, approaching people who had tested positive or negative for COVID.

The novelty of this study is that these patients will be recruited via SMS Text messaging using the same system as the one that sent out the test results. For this an assessment was required under the Privacy and Electronic Communications Regulations (PECR). This was carried out by the technology company contacting the patients.

Patients were asked to opt-in with e-Consent and are free to withdraw. SG helped with the launch of the study with a press-release and frequently asked questions (FAQs) on the study website. The study will include completion of a questionnaire, record linkage to their medical records and a small sub-group will be interviewed.

From the first batch of invitations (>200,000) there was a 17.8% response rate overall and 26.7% response rate from those who had tested positive for SARS-COV2. This was a similar level to what the study team had hoped. PHS will provide aggregated data on the non-responders, in case they need to adjust for any under-representation of any group. So far, only three have withdrawn from the study. The first batches of invitations were sent in increasing numbers to ensure that the technology didn't fall over. There were some minor changes required to fit with a small screen and smartphone technology.

The study is for 2 years and will continue to recruit patients for all that time. They hope to get the record linkage data soon, so can give some interim results.

LR thanked JP for coming to give feedback and the HSC-PBPP committee would be interested in anything further for information and guidance. The committee are keen to be kept informed and reassured as the study continues.

7. Any other business

No other business was raised.

LR again thanked HC for all her contributions over the years. HC said she was grateful for the insight and learning that membership of this committee had given her.

8. Date of next meeting

The next HSC-PBPP Committee meeting will take place on 16th November 2021.

Actions

Action Reference	Action	Responsible
15-09-21 / 01	Update HSC-PBPP Terms of Reference to reflect the changes to the recruitment of Caldicott Guardian representatives from patient care NHS Boards and not just territorial NHS Boards.	MA
15-09-21 / 02	Recruitment of Caldicott Guardian representatives from these boards to be followed up with the new Chair of the Caldicott Guardian Forum.	LR
15-09-21 / 03	To raise and explore with senior staff of PHS the possibility of using a cost-recovery model for the support received by applicants when completing 'PBPP Only' applications.	LR
15-09-21 / 04	To finalise the Tooth Fairy application and supporting documents and put on the HSC-PBPP website.	MA
15-09-21 / 05	HDRUK update to be made available for circulation around the HSC-PBPP committee.	CM & MA
15-09-21 / 06	A response from the HSC-PBPP committee to be sent to the applicants for application 2122-0071 Colquhoun.	MA /TS / LR