

minutes

**NHS Scotland Public Benefit and Privacy Panel for Health and Social Care
24 January 2018**

NHS Lothian - Edinburgh

Present: Prof Alison McCallum (AMcC) Acting Chair
Prof Helen Colhoun (HC)
Dr Stephen Pavis (SP)
Dr Emilia Crighton (EC) by tele conference
Dr Kirsty Licence (KL)
Prof Abbe Brown (AB) by tele conference
Mr Kenneth McLean (KM)
Mr David Knowles (DK)
Prof Danny McQueen (DM)
Carole Morris, eDRIS representative/Acting Panel Manager (CM)
Diane Rennie, eDRIS
Susan Kerr, Secretariat

Apologies: Mr Brian Houston
Dr Janet Murray
Dr Angus Ferguson
Mr Gerry Donnelly
Dr Corri Black
Dr George Fernie
Ashley Gray

1. Chair's Welcome and Introduction

AMcC welcomed all to the PBPP Committee meeting and explained that in the absence of BH she has been asked to chair this meeting.

AMcC sent best wishes to BH with his recovery.

AMcC informed the group that Mr Gerry Donnelly is no longer a member of the PBPP Committee. He advised he will be replaced by Stuart Law, Head of National Health Service Central Register (NHSCR) and Data Linkage

A letter thanking GD for all his work with the Committee is to be sent.
A Letter welcoming Stuart Law to the committee is to be sent.

It was also noted that AG will move into a new role and that her attendance at the Committee meeting in April will be her last. It was noted by NSS Caldicott Guardian that the move will not happen until a replacement has been found and a handover completed.

2. Minutes of the PBPP Committee dated 22 November 2017.

The minute was approved as a correct record.

SK noted changes AMcC has sent, the minute will be updated to reflect these changes.

3. Matters arising from previous minutes

3.1 New National Data Collections

KL explained that further engagement with DPHs was required on the proposal and a high level document produced by KL/AMcC for consideration.

KL agreed to update in response to the views/feedback from DPH at the next meeting.

Action KL/AMcC

3.2 PBPP Workshop Scenario 5

The PBPP Workshop examined a series of potential proposal scenarios to enable active thinking about the functional application of the PBPP Scope as outlined in the Terms of Reference.

There was a general agreement that the current guidance provides sufficient direction in terms of when a PBPP application is required with respect to access across multiple NHS boards or nationally held administrative datasets. However it was agreed that further clarity is necessary with regards to the processing of CHI and the remit of the PBPP in scrutinising these requests.

Scenario 5 has been circulated for comments. This highlights this issue through a real example received by PBPP

The Panel agreed that due to time restrictions it would be sensible to postpone this discussion until the Committee meeting in April 2018.

4. Performance Update

The performance update was circulated for information.

5. Policy Decisions & Case Law Principles

This is an evolving document for information for Tier 1 and Tier 2 Committee members. This document will now be a standing item on the agenda.

AMcC asked if this should also be circulated to the Caldicott Guardians, R&D and the Chief Scientist Office and be made available on the PBPP Website.

HC agreed stating that people need to be more aware of the work of the PBPP.

DM asked if information could be published on the website which gave applicants some insight into those already approved which would help them in completing the application form

CM agreed and explained that plans are in place to do more work on the PBPP website.

It was agreed by all that the Policy Decisions and Case Lay Principles document should be circulated more widely and that publication on the website should be considered.

Action AG

6. PBPP Resource Scottish Government Update

CM explained that funding has been granted to upgrade the Panel Managers post to a band 7 as they recognise the value of the national role and that Scottish Government has agreed to provide additional monies to cover resource to support the Panel Manager.

HC asked about the new system being put in place for web placed PBPP applications and streamline the PBPP process.

CM explained that the HARP system, which is used by other committees such as Ethics is a potential long term solution. This will not be available for another 18 months due to IRAS being re-developed.

AMcC also raised concerns that continued conversations are required with the SG as to resourcing and the accountability issues of this committee

Penni Rocks from Scottish Government has been invited to attend the meeting in April 2018

.

7. Proposal to Approve Synthetic Data (NSS)

SP provided a paper on a process for approving the release of synthetic data.

SP explained that there is an increasing demand for synthetic data based on NHS Scotland national datasets; commonly sought use examples include university teaching, research planning and commercial organisations wishing to understand the type of data and variables that exist.

SP asked the panel if they had any thoughts on the use of Synthpop as a legitimate way to create synthetic versions of NHS datasets for general release, with an initial step of the use of Synthpop being by a senior trusted academic, Prof Dibben, Director of the ADRC-S. Prof Dibben would have accountability during the Synthetic data creation and overseeing the creation of a series of synthetic datasets based on the National NHS datasets which can be released for teaching and research planning purposes without restriction. In addition, eDRIS would create an end user license agreement for when NHS Scotland synthetic data are released.

Discussions took place and it was agreed that there needs to be further work done on:

- Licensing agreements
- How the PBPP Committee look at privacy and confidentiality of synthetic data

- Is there a need for use of safe places for trusted researchers
- Risk Register
- Possibility of a Hacker event
- Legal considerations of the creation/use of synthetic data
- Intellectual Property

KL suggested that this paper to be taken to a meeting on 07 February with Scott Heald from NSS and that SP should also attend this meeting.

KL will report back to AM before the next PBPP meeting in April 2018

Action SP, KL

AM thanked SP for writing this paper.

8. PBPP Application 1516-0560 Kunkler

A letter was received from Professor Kunkler on 18 December 2017 with comments from previous questions raised.

Discussion took place and the committee still had some concerns on:

Unconsented data linkage
Public consultation
Data transfer to commercial entity

HC stated that we have not received many applications for unconsented data for commercial access and use. This is setting a precedent so has to be correct.

The commercial aspect was also a concern and that the discount offered for NHS Scotland was not something this committee could not take into account as not within the remit of the committee.

Professor David Cameron and Professor Ian Kunkler joined the meeting.

HC explained that it appeared that there was a misinterpretation between the parties regarding why the data could not be validated locally and also there was a change in the latest version of the application to that of the original application.

Prof Cameron expressed that the panel had not been clear in its explanation of its concerns at the outset.

It was agreed about the public concern of commercial entities using data and the counter argument in his view is that it is of long term benefit to the health of the population.

HC discussed the need to manage media and publications appropriately to ensure public trust is maintained, and therefore it is important that the Principal Investigator has sight of any media communications to promote the benefits to the public clearly.

The applicants expressed thanks to the committee for this opportunity and left the meeting.

The committee agreed to approve this application with the following conditions:

The Panel would like to note the following points:

- The PBPP grants approvals only in respect of the use of patient data. This approval does not therefore cover other aspects of the governance of this project, such as ethics and tissue governance. These remain the responsibility of the applicant to ensure appropriate approvals are in place.
- As discussed, the panel remains aware of the need to manage media and publications appropriately to ensure public trust is maintained, and therefore it is important that the Principal Investigator has sight of any media communications to promote the benefits to the public clearly.
- In granting approval, the PBPP has taken account of the fact that the work builds on and extends previous research involving a fully consented cohort, although the consent is not deemed to extend specifically to the work approved here.
- The panel welcomes all measures that extend the public benefit of this project beyond the potential direct improvements in care of individual patients.

9. Commercial Access to Safe Havens

SP outlined the current position in relation to the private sector accessing the National Safe Haven. Two issues were highlighted, contracts and public perception.

KL asked if this was seeking direct access without partnership with NHS or Academia. SP commented his preference is in partnership in light of a recently approved application.

HC stated that we need to be aware that as a result of any decision we could receive a high volume of requests from the private sector and asked who will be assigned authority to sign off commercial contracts as she felt this committee is not competent to do this.

Concerns were raised about how this would be managed as it is not clear whether it is within the PBPP remit.

It was agreed that this needs to be escalated to Chief Executives and Scottish Government for their input.

It was noted that in general public attitudes suggests that, whilst the use of anonymised patient data for publicly funded research is generally accepted, attitudes to commercial use of patient data are much more ambivalent.

HC explained there is a need to consider privacy and public benefit, balanced with financial ramifications and this requires more expertise and is not within the remit of this committee.

HC suggested that this paper needs to be looked at by the Chief Executive as this is not our area of expertise.

It was agreed that this is a good starting point and that SP will revise this paper and send to the committee for comments.

AM agreed to then take this forward with Penni Rocks from Scottish Government .

10. PBPP Application 1617-0049 Semple

The committee agreed they are now happy to approve this application.

11. PBPP Application 1617-0265 Flaig

Further to the conditional approval issued by the Committee on 05 October 2017 it was agreed that all conditions applied to the approval have now been satisfied.

Conditions approval letter to be send to the applicant.

12. GDPR Update

The data protection law is changing and from 25 May 2018 all organisations using personal information, in particular Data Controllers and Data Processors, must ensure they comply with the new General Data Protection Regulations (GPDR) and the UK Data Protection Bill, once enacted. Therefore PBPP has an obligation to take steps to maintain compliance where necessary.

CM stated that work with Patricia Ruddy on procedures of PBPP are ongoing and they are looking at changes which will be made to the PBPP documentation ie application form and approval letters etc will be updated in time to be GDPR compliant.

HARP system, which is used by other committees is the long term solution.

AM asked for an updated paper for the next meeting.

Action AG/CM

13. PBPP Amendment Options Paper

The purpose of this paper is to seek agreement from the committee to delegate responsibility to the eDRIS team for approving amendments to approved applications which meet an agreed criteria set against a proportionate level of risk.

Low Risk

It is proposed that the following amendment types are agreed as low risk and can be approved by the eDRIS team with no further review by the Panel Manager. The updated application form would be sent to PBPP and recorded in project file for audit purposes.

- Personnel changes in Sections 1.5-1.6
- Inclusion of derived variables such as age, length of stay, flags
- Changes to exclusion criteria (excluding vulnerable or sensitive populations)
- A prospective update to the approved data extraction period

- Inclusion of variables when eDRIS are undertaking the analysis role for a project

Approved by the Committee.

Medium Risk

It is proposed that the following amendment types are agreed as medium risk and can be approved by the eDRIS team subject to a discussion with the Panel Manager when necessary. If the further review is required then the amendment will be referred to the Panel Manager for assessment.

- Inclusion of a new NSS controlled dataset subject to the following conditions;
 - Data is accessed and analysis within the Safe Haven
 - It is within the scope of the main approved objectives
 - Non sensitive and Non identifiable variables are requested
- Extension of historical time frame for extract
- Change to inclusion criteria which involves non sensitive or vulnerable populations

Full list of data sets to be produced.
CM agreed to do this and pass to KL for approval.

Approved by the Committee.

High /risk

It is proposed that the following amendment types are agreed as high risk and cannot be approved by the eDRIS team and must follow the existing amendments process.

- Changes to the Information Security arrangements (Section 5)
- Changes to the lead/responsible roles 1.1-1.4 (Commercial is a high risk)
- Changes which impact the scope of the proposal
- Requests relating to data originating from the CHI database
- High risk changes to the data flow
- Additional datasets;
 - The data is not NSS controlled
 - where the safe haven is not being used
 - and/or not within the original scope of the proposal
 - and/or includes sensitive or personal identifiable variables

Note – Commercial is a high risk.
Inclusion criteria that involve sensitive or vulnerable

Approved by the Committee

14. Any other business

No other business was raised.

15. Date of next meeting

The next meeting will be held on 26 April 2018 at Waverley Gate, Edinburgh