

**NHS Scotland Public Benefit and Privacy Panel for Health and Social Care
26 June 2018**

NHS Lothian – Waverley Gate, Edinburgh

Present: Prof Alison McCallum (AMcC) – Acting Chair
Dr Angus Ferguson (AF)
Prof Abbe Brown (AB)
Prof Danny McQueen (DM)
Penni Rocks (PR)
Dr Emilia Crighton (EC) – (Part T/C)
Dr Corri Black (CB) – T/C
Dr Stephen Pavis (SP)
Dr George Fernie (GF)
Stuart Law (SL)
Carole Morris (CM)
Dr Marian Aldhous (MA)
Susan Kerr, Secretariat
Dr George Fernie (GF)

Apologies: Brian Houston (BH)
Prof Helen Colhoun (HC)
Kenneth McLean (KM)
David Knowles (DK)

1. Chair's Welcome and Introductions

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

AMcC formally welcomed Carole Morris as a member of the Committee.

2. Aberdeen Children of the 1950s (ACONF) data issue – Urgent Item

CM explained that an issue was reported to the eDRIS team by colleagues in the Grampian Safe Haven (DaSH). This has affected 4 projects.

A resolution is being implemented and discussions have been held between CM and CB as to advising the affected researchers to reassure them that the linkage has been corrected.

An SBAR has been written and amendment requests for each project submitted to this committee to request the addition of personal identifier variables for a specified (short) time period to be viewed only by key individual from each stakeholder group, together with the

Data Manager for DaSH and CM on behalf of eDRIS. These will be reviewed in a secure setting in DASH to confirm the resolution implemented has corrected the linkage.

As this is deviating from standard process, and due to the time-urgency CM and CB ask if this can be approved at this meeting.

SP commented that this is an inherent risk in separation of function – removal of identifiers increases the risk of mis-matching whilst maintaining a high level of privacy.

The committee approved sampling 20% sampling of data sets – as this would be sufficient to confirm that the re-running of the linkage was successful.

Amendment requests agreed. To be signed on behalf of the committee by the Panel Manager.

Minute to be finalised as soon as possible.

Actions:

- Needs to be recorded in NSS PHI Adverse events as, although the incident did not cause a risk to patient privacy, the solution does increase the risk. Applicants will get to see patient identifiable data, albeit for a short space of time in a secure setting and only for 20% sample of the dataset.
- There should be a Lessons Learned session. The report is to be presented at the next PBPP Committee Meeting.
- Steering committee for ACONF to be informed and apology sent.

Actions CM / SP / CB

3. Minutes from the previous meeting on 26th April 2018

3.2 Synthetic Data

SP informed the committee that this was not part of this committee's remit. Synthetic Data is controlled by ISD and the task has therefore been passed to the Head of Profession for Statistics at ISD.

7. Commercial Access to Safe Haven

AB felt that although the minute was accurate that it may be incomplete. AB agreed to look at the wording from previous minutes and send updates to MA.

Action AB / MA

4. Matters Arising

4.1 New Data Collections update

KL and AMcC advised that an update will be circulated with minutes.

4.2 Commercial Access to Safe Haven

SP reported that he has spoken to Charles Weller from Scottish Government regarding commercial engagement. A draft paper is currently with Scottish Government. Charles Weller is lead for commercial research within CSO and runs clinical trial unit with Pharma. Charles Weller could be involved in analysing the commercial benefit before an application comes to PBPP for approval.

SP agreed to liaise with PR with regard to Scottish Government's position on access to data by commercial organisations.

PR and SP agreed to discuss further and report back with the PBPP appropriate role.

Action SP / PR

4.2 HFEA & PBPP Relationship

MA updated the Committee on the HFEA & PBPP Relationship.

The MOU was originally to be signed off by NSS but following further discussion with KL it was felt that this was not the right body as it was a Scotland wide agreement. An MOU is not a legal document so it could be signed off by the Chair of PBPP to formalise the advisory role being provided by the committee regarding HFEA applications from Scottish applicants.

PR suggested MOU should be written whilst further discussion is had as to the appropriate signatory.

Action MA

4.3 GDPR Update

MA informed the committee members that all those involved in Tier 2 Out of committee reviews can keep all applications and paper for their own reference until leaving the committee.

5. Standing Items

5.1 Performance Update – for information

The proportion of applications approved at Tier 1 is increasing due to the input of eDRIS in assisting researchers prior to submission.

MA made the committee aware that time to approval by Tier 2 is on the increase. PR asked if the Performance update could include clocked times for each application.

Action MA

5.2 Policy Decisions and Case Law Principles

A chronology of decision making in respect of the guiding principles and policy of the PBPP is recorded.

5.3 PBPP Resource –Scottish Government update, including new Digital Health and Care Strategy board

Digital Health and Care strategy – SG is looking to find a way to involve stakeholders. Possible workshop to be run at end of August (date to be confirmed). This is for whole strategy not only IG strand. There are wider structures involved for SG in the implementation of the strategy.

CM asked about the Safe haven accreditation process following Daniel Beaumont's departure from Scottish Government.

PR explained that this will continue with the same policy and the contact person is George Irvine at Scottish Government.

SP asked about the process for renewal of accreditation and PR advised she would discuss with colleagues at SG.

Action PR

6. Application 1718-0343 Sharpe

- Applicant unable to attend
- Discussion of issues raised in application

KL proposed looking at this application without the applicant being present as he was unable to attend.

SP sat on the Cancer Innovation Challenge (CIC) Review Board and of the 3 successful Phase 1 projects; only 2 of them will be taken forward to Phase 2. Phase 1 focussed on feasibility of the project. Part of this feasibility is to prove that they can get governance approval..

Applicant has to report back to CIC on feasibility stage by July 2018.

AMcC asked that if CIC people come through to eDRIS expected to be fast tracked. CM responded to say that initially all the projects were using a single NHS Board and this one had approached NHS Lothian but was advised that they couldn't get the data from there so they amended their approach to use national data and apply through PBPP for this.. As we knew the timeline was short to meet the 3 month deadline and that the commercial aspect would automatically refer to Tier 2 it was agreed with the Panel Manager to test a fast track process. However, in future these projects need to allow time to accommodate the standard process unless any change in process is made.

CM noted that as NSS is supporting these challenges they need to discuss how best they can support them given the commercial involvement. And therefore PBPP may also need to give consideration on a national steer for these types of challenges should they require access to national data.

CB asked what the process for governance and peer review within CIC is.

SP advised that peer review is part of the process of CIC along with ISD input as to feasibility, IT security review and that there was public input into the review. It was noted that and eDRIS did do a seminar on information governance to the group but at that time no national data was involved.

AMcC informed the committee that there was lack of acknowledgement of background work that has been done in discussion with NHS Lothian. Original discussions had talked about using renal cancer, which was justified as less heterogeneity than using different cancers with different treatments.

AMcC felt uncomfortable about having to look at all cancers just because machine learning needs a big data set.

DM asked about Public engagement and how to we explain the need for a large volume of data for a feasibility study.

EC said she would not approve the project as the applicant had not fully considered their application in relation to the volume of data for machine learning, the application had not considered ethics or governance sufficiently.

The Committee didn't feel that applicant had fully justified use of large data set, only responding to say that machine learning relies on large datasets.

AMcC suggested using existing datasets already set up, for example, Ian Kunkler's cancer data set and NHS Lothian long standing databases.

It was agreed that more detail was required within the application and that a smaller or local dataset should be used.

As a learning for the Committee it was suggested that a smaller group of people should get together to think about how we address similar applications in the future regarding machine learning.

AF agreed and advised that documents been published on this such as those from The Wellcome Trust and Nuffield Health.

Outcome of the Committee was that the application is not approved. Should the applicant wish to resubmit they need to address following:

- Use smaller, less heterogenic dataset.
- Resubmission of their application after looking at what is already available and then this can be fast tracked straight to T2 Out of Committee.
- Still needs to address issues of IPR and commercialisation.

7. Lessons Learned from Application 1516-0560 (Radio DX-PFS Genomics)

KL reported that she had attended a meeting with the applicants and research team (Prof David Cameron, Prof Ian Kunkler and Tammy Piper), the then PBPP Panel Manager (Ashley Gray), ISD Clinical Trial unit staff supporting the research team (Jo Dunlop and Julie Uttridge) and eDRIS research Co-ordinator for this application (Jackie Caldwell).

Jackie Caldwell was praised as being very helpful throughout this process.

KL summarised on the Lessons Learned:

- Poor communication and lack of clarity
- Timescale and delays
- Policy and process
- Look at Lay member extension in PBPP
- IRAS System
- Research agenda always changing
- Resourcing and support needs to be put into place for the panel

Papers 18-19-13 Lessons Learned and Recommendations provide a summary of the discussion.

SP asked who would do the public engagement.

AMcC suggested that the R&D department have an expert who could facilitate this.

AB suggested that some of the guidance documentation could be updated to reflect the considerations for public engagement.

DM suggested he could be a Lay contact for applicants during application process before submitting.

AMcC explained about the importance of being clear on what is expected regarding public engagement.

EC noted that she cannot commit enough time to applications referred to the T2 Committee due to other work demands.

KL suggested widening to other CGs, the possibility of looking for more lay and professional people for the committee, or widening the number of people on the panel.

KL, MA and CM agreed to take all items discussed and write a response on lessons learned recommendations and answered questions.

Action MA / CM / KL

PBPP Website - CM explained that planning has already started to improve the content of the PBPP web pages. This will include a Hints and tips section.

DM stated that he felt the PBPP profile needs to be raised with possible links to other sites when re-developing website, such as Scottish Health Council, Healthcare Improvement Scotland, major research charities, research funders and research bodies. CM took that on board for their planning.

End of Project reporting has been developed further to include a Public Benefit Impact assessment form. This will be published on the website for each project as it finishes, or reaches a specific milestone for ongoing projects.

8. PBPP Workplan

MA advised that due to limited resources this was slow to progress. To be discussed at next meeting.

9. Data Sharing Agreements and update on BSUG

Comments on DSAs and update on BSUG from AM to sent out with minutes.

10. AOB

No other business was raised.

11. Date of next meeting

The next meeting will take place on 25 September 2018.