**Public Health and Intelligence**

# minutes

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

**NHS Lothian – Waverley Gate, Edinburgh**

**25 September 2018**

**Present:** Brian Houston, Chair
Prof Alison McCallum (AMcC)
Prof Danny McQueen (DM)
Dr George Fernie (GF)
Dr Helen Colhoun (HC)
Dr Kirsty Licence (KL)
Kenneth McLean (KM)
David Knowles (DK)
Prof Corri Black (CB)
Dr Stephen Pavis (SP)
Alan Ferrier (Al F)
Penni Rocks (PR) (part attendance)
Dr Eleanor Anderson (EA) (part attendance)
Dr Angus Ferguson (AF) – T/C
Prof Abbe Brown (AB) – T/C
Carole Morris (CM)
Dr Marian Aldhous (MA)
Phil Dalgleish (PD)
Susan Kerr, Secretariat

**Apologies:** No apologies

## 1. Chair's Welcome and Introductions

BH welcomed Al F from NRS to the Committee.

## 2. Minutes from previous two meetings

Minutes from 26 April 2018 - Approved as a correct record.
Minutes from 26 June 2018- Approved as a correct record.

## 3. Matters Arising

### 3.1 Update/Report from ACONF data issue

CM reported that the data fix has been successfully completed, a full review has now taken place and the Lessons Learned report has been circulated to the attendees. CM is now

creating a final report which will be available for the next PBPP committee meeting and will also be sent to the ACONF Steering committee and NSS IG Team.

### 3.2 Commercial Access to Safe Havens

SP reported that there is still an issue with trying to find out who in the Scottish Government will be taking Commercial Access to Safe Havens forward. A draft paper is currently with the Scottish Government and SP has been in discussions with Charles Weller and CSO/SHIL and will liaise with PR. Commercial access to Safe Havens needs to be part of a wider discussion of commercial access to NHS data. It was felt that the value of NHS data needs to clarified and maximised. Commercial organisations are working with NHS Boards and accessing data and we need to better understand these relationships to develop a national framework. Public opinion and data security also need to be considered and this matter needs to be clarified urgently.
PR agreed but said that lots of ground work is required to find the appropriate balance between access, public benefit and contractual arrangements.
BH agreed to discuss further with PR and with Jason Leitch (at SG).

**Action BH/PR**

### 3.3 New Data Collections (update)

KL gave an update on New Data Collections, explaining that there are different strands. It was agreed that there is already national data collections not sitting within ISD, but in boards and outwith governance structures. Discussions are ongoing as to how to bring these to ISD and will be addressed by NSS ISD Governance.
SP stated that location of data and governance of data are two different things and this is more about governance of data.
It was agreed that this can now be removed from the agenda.

### 3.4 BSUG Update

AMcC explained that all issues have now been addressed with Privacy Impact Assessment. It was agreed this does not need to come back to this committee.

### 3.5 MOU with HFEA

A discussion took place on who would be the appropriate signatory for an MOU. MA explained that Scottish Government do not feel they have responsibility, as there is only dotted-line reporting.
AM suggested the Chief Medical Officer or someone acting centrally on behalf of NHS Scotland.

It was raised that this relates more to the lines of responsibility of PBPP, rather than the signing of an MOU; this MOU is the first test case. This has implications for other issues, e.g. the indemnification of the panel members should they be sued over a panel decision.

## 4. Standing Items

### 4.1 Panel Manager Report

The Panel Manager report was circulated for information only.
AMcC asked for copy of the Audit and performance review slides, CM agreed to circulate these.

**Action CM**

### 4.2 Policy Decisions and Case Law Principles

The Policy Decisions and Case Law Principles document was circulated for information only.

### 4.3 PBPP Resource Scottish Government update, including new Digital Health and Care Strategy board

PR explained that funding has now been agreed and allocated from the Scottish Government to NSS for PBPP for next year. PR also gave an update on the new Digital Health and Care Strategy board and its remit of which Domain B is a review of current Information Governance practices in the health service. A group will be convened shortly to take this forward.

## 5. Application 1718-0257 Whalley

A discussion took place on the issues raised with this application (see Lead Paper).

i. Consent and withdrawal of participants – how do they propose to deal with this?
ii. Scope and scale of data requested and expectations of the original consent.
iii. Role of ethics.
iv. Public Engagement and Participant involvement.
v. Use of Edinburgh University Data Store rather than a Safe Haven.

The applicants were then asked into the meeting for discussion of the above subjects.

i. <u>Consent and Withdrawal</u>
This is a cohort of people with a higher genetic risk of mental health disorders. The study was to monitor this cohort and observe who becomes unwell or not, and then try to determine potential risk factors between groups through data linkage to health records. Those who have actively withdrawn would not be included in the data-linkage or future analyses, but these are few in number. Those who have stopped responding to contact letters will be included as they have not actively withdrawn. The research team have sent letters to participants with updates of the study. In terms of numbers, ~50% have stopped responding to letters and there is a risk of reduced statistical power if these were not included in the data linkage. The data linkage could not have been carried out sooner, as only now are there enough people who have developed illnesses to make the different groups comparable. There was no specific time-frame for the data linkage. The ambiguity in the patient information sheet was because, at the time, grant funding for 5 years had been obtained, but subsequent grant funding for another 5 years had been applied for, but not confirmed.

ii. <u>Scope of Data Requested</u>
Mental health disorders are often related to other morbidities throughout life that are seemingly unrelated. Therefore the scope of the study was expanded to include a wide range of health outcomes. They would like to use the data to investigate the possible co-morbidities or life events in the development of mental health disorders, as well as the genetic and environmental risk factors; hence the requests for SMR06 (cancer) and SMR02 (maternity) data. The applicants felt this is within scope of the study. There has been an amendment to Ethics regarding any relevant physical disorder related to mental health. When asked about the breadth of scope, the applicants said that investigating genes for mental disorders was in scope, whereas investigating genes for, e.g. lung cancer would not be in scope.

iii. <u>Ethics</u>

The applicants were not planning to go back to ethics and are not reporting annually to the REC as the study is closed to recruitment.
The wording of "Brief information" in the consent form for data linkage was in comparison to the extensive amount of information that was gathered during the face-to-face interviews with the participants.

iv. Public Engagement

The cohort members were recruited a long time ago. A number of interim feedback letters have been sent to them, with results and updates, although not for about 5 years. The "End of Study" date has become elusive as more research questions have arisen. Reporting back to participants individually has become more impracticable given the nature of the illness.
There has been a series of public engagement events, through Generation Scotland and cohort 'celebrations'. Information is also disseminated via social media and their website with information for all the research studies. Cohort members bring family members along to the public engagement events. When asked specifically about use of anonymised NHS records, ~95-98% of responses are happy about their use for research, but were much less happy about their use for commercial purposes.
There is a new public website being developed for a new overarching study, under which this study will come, and information on both studies will be placed on that website. Previous participants will be able to access information regarding the study and its ongoing progress.

v. Data storage

Currently the cohort data is stored in the Edinburgh University Data Store and is pseudonymised with the patient identifiers stored elsewhere. The data currently stored there includes a lot of sensitive information, arguably more sensitive than that they are about to receive. The Data Store does not offer the level of security in the same way as a Safe Haven, and is not accredited as such. However, the software in the Safe Haven is not sufficient for the files or the type of analysis that is required. It was agreed that this should be discussed off line with the eDRIS team.

After the applicants had left there was further discussion within the committee. There was consensus that the committee were satisfied with the responses to questions regarding areas i–iv, but that the issue of data storage was still unresolved. The discussion revolved around whether this was a consented study or not: if it was consented the data could be in the Data Store, if it was not consented the data should be in a secure Safe Haven. It was felt that the 'spirit' of consent was backed up by the results of the Public Engagement, where people would be expected to agree with the use of their NHS records for this type of research.

It was agreed that this application will be approved subject to the location of the storage of the data and its security being reviewed.

**6. Actions from the Recommendations from Lessons Learned from Application 1516-0560 – (Radio DX-PFS Genomics)**

The paper identified and documented possible actions arising from the Lessons Learned recommendations from the application process for 1516-0560, for adoption by PBPP. These

were presented in the related paper. The committee discussed up to recommendation 2.3. Due to lack of time, it was agreed that Committee members should send in their comments, particularly with respect to recommendations 2.5, 2.7, 3.3 and 3.4.

KL/MA will then update the table identifying actions to be taken and timelines for these. This will also be discussed further at the PBPP Operational Group.

**Action All**

## 7. Tier 2 PBPP Resources

MA explained that PBPP has been under-resourced at Tier 2, due to the temporary unavailability of one Caldicott Guardian and the resignation of another Caldicott Guardian in mid July. In addition to this not all Lay representatives have been able to respond to requests within the required time-frames. MA explained that although a request for a new CG had gone to the CG forum there had been no volunteers. MA asked if there was any way to release pressure of the current CG members. The paper was to flesh out what expanding the Tier 2 pool might look like.

CB stated the not every board has a CG.
KM discussed collaborative working and what this would look like for the committee.
DK suggested that BH write to the NHS Chief Executives, via Colin Sinclair (NSS Chief Executive) on behalf of the committee and ask that they provide a CG for the committee, as the committee works on the behalf of the NHS Chief Executives.

**Action BH**

## 8. PBPP and CAG Approval: Reciprocal arrangements

PR reported that following on from a meeting with CAG there is now recognition of PBPP approval for UK wide studies where data is travelling between Scotland and England, particularly in relation to the assessment of security arrangements. PR advised that CAG are moving away from IG Toolkit. It is unclear what it will be replaced with at the moment. MA to update guidance accordingly.

**Action PR/MA**

## 9. PBPP Website

PD is in the process of updating the PBPP website. He was hoping that most changes will be implemented by early next year. He asked that any comments or suggestions to be sent to PBPP.

## 10. Any other business

No other business was raised.

## 11. Date of next meeting

The next meeting will take place on 27th November 2018 at the Jury's Inn Edinburgh.

SK agreed to investigate other possible venues and asked how people feel about travelling to the Edinburgh Bioquarter for future meetings.