Public Health and Intelligence

minutes

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

26 January 2017

Lord Clerk Room – General Register House, Edinburgh

Present:
Brian Houston (Chair)
Prof Alison McCallum (AMcC)
Dr Angus Ferguson (AF)
Prof Helen Colhoun (HC)
Prof Danny McQueen (DMcQ)
Dr Stephen Pavis (SP)
Dr Corri Black (CB)
Dr Abbe Brown (AB) by tele conference
Dr Janet Murray (JM)
Carole Morris, eDRIS representative (CM)
Ashley Gray, Panel Manager (AG)
Jenny Scott (JS)
Susan Kerr, Secretariat

Apologies:
Mr Gerry Donnelly
Dr Daniel Beaumont
Dr Harpreet Kholi
Mr David Knowles
Dr Hugo van Woerden

1. Chair's Welcome

BH welcomed all to the PBPP Committee meeting and noted apologies received.

BH informed the Committee that the required quorum of attendees had not been achieved. The ToR states that there must be 7 members of the Committee in attendance, 3 Lay representatives, 1 NSS Caldicott Guardian and 3 other NHS Scotland members.

It was noted that DK had provided comments on a number of agenda items prior to meeting and AB will participate by tele-conference until 11am

It was considered appropriate for CB and HC to be considered NHS Scotland representatives given their NHS contracts.

All agreed that they were happy to proceed but that any decisions in principle should be circulated to the full group for ratification following the meeting.

2. Minutes of PBPP Committee meeting dated 4th October 2016

The minute was approved as a correct record.

3. Performance Update

The performance update was circulated for information only.

SP expressed concerns relating to the capacity of Tier 1 panels and possible backlog of applications waiting up 4-6 weeks for Tier 1 first review.

AG advised that the Panels have temporarily increased the number of applications being reviewed from 5 to 6 applications to manage the current capacity issues.

HC queried if it is necessary for all new applications to be reviewed at Tier 1 panels.
A short discussion took place on the possibility of some types of applications being approved by the Panel Manager. AG noted that this could be explored further but would require the development a set of governance criteria.
It was agreed that this is a priority action to be taken forward by the PBPP Operational Group following the completion of the audit of Tier 1 approved applications (see Item 6a)

AG agreed to report developments at the next Committee meeting in April.

Action AG

4. PBPP Application 1516-0587 Quirk – Appeal

BM welcomed Professor Tamsin Ford and Michael Morton to the meeting
BH explained that the Panel would like the opportunity to discussion the content of the appeal and ask further questions.

Professor Ford explained the background of CAPSS and advised the system has been running successfully for 7 ½ years and BPSU for over 30 years.
The Surveillance unit allows non-burdensome study of rare conditions and events across the country which can be more easily generalised to the general population, which is very beneficial to patient care.

Professor Ford expressed that under the current PBPP approvals that the Chronic Fatigue study is able to proceed with BPSU but must seek separate permission with CAPSS. She further explained that current studies have had to stop collecting data because of the disparity across the two approvals. Professor Ford advised that she felt that the decision was undermining the unit and the research.

Professor Ford queried why BPSU received blanket permission to govern their own projects but this was not reflected in the approval for CAPSS, whose system is the same.
Professor Ford advised that it was desirable to achieve an acceptable solution for both parties.

SP explained the background to the legal basis in Scotland and the role of PBPP in the absence of the Section 251 legal gateway.
Professor Ford advised that the scrutiny of the CAPSS applications is the same as BPSU – two phase process in which applications to HRA and CAG are compulsory.
Michael Morton also added that there is input from clinicians in Scotland on any review / scrutiny of projects occurring in Scotland.

JM explained that the intention is not to undermine or restrict research. JM noted that the BPSU application was the first proposal to be reviewed by the PBPP Panel and that the decision will need to be examined out with this discussion.

Professor Ford explained she would like parity across the systems to be able to advise PI's accordingly. She also stated she did not receive a reply as to whether current projects could continue and she would like to request a decision on that as soon as possible.

HC explained that the information governance landscape is continuously evolving and the Panel aims to agree a solution which will meet all needs but that considerations must be given regarding the use of highly sensitive, unconsented patient data.

Professor Ford advised that data notifications are made through the system. The clinician is then approached to get the identifiable data for the purpose of the study from the clinical academic doing the work and the data is held behind the NHS secure network i.e. N3. Professor Ford explained that this data must be held behind NHS secure network as stipulated in the criteria and outlined in SOPS.

HC advised of the safe haven framework which has been established to ensure unconsented data are held and analysed within a secure environment .
Professor Ford acknowledged BPSU were advised to move to Safe haven set up. However explained that a 10th of the Unit's budget had been used to attend this meeting and so funding for this architecture would not be possible in the short term.

AMcC explained that it is not clear from application all data are held behind the NHS secure network and PBPP need to be sure that the legal basis is sound. PBPP need to be assured that the identity of sensitive/vulnerable patients are controlled and that there may be a need for an additional level of scrutiny for some parts of the population

AF noted there is no lay representation on the CAPSS Committee.
Professor Ford explained that applicants are expected to have PPI on their individual studies and a study without PPI would not proceed to approval.

AF further noted he was impressed with the criteria but queried further on commercial funding and if there are clear processes with the ToR.
Professor Ford advised that there is only one study funded by BUPA and there is no detail currently relating to the process of commercial funding but would be willing to include.

CB queried the process for disclosure control.
Professor Ford explained that during the process of the application there is a discussion with the PI regarding small numbers but don't explicitly request a check of papers

BH thanked the applicants for their attendance and this concluded their participation in the discussion.

JM stated she considers a PBPP application is required for each CAPSS project and the BPSU decision should be revisited. JM suggested those ongoing projects that didn't seek governance are permitted to continue.

HC noted that these studies involve highly identifiable, unconsented data but public benefit is high. HC also suggested that legacy studies should continue however there is a need to recognise that landscape is transitioning. A blanket approval may be possible in future if the architecture for storing and analysing the data is suitable.

SP noted that the removal of identifiers is not anonymization.

CB considers that further work is required in terms of disclosure control and potential approach by commercial organisations. CB also agreed that all individual projects should approach PBPP

SP agreed to draft a formal respond on behalf of the Panel to Professor Ford to advise:

a) Existing studies that are already 'in the field' or at the analysis stage should be allowed to continue using your current arrangements (including the three projects referred to during the discussion). It was not our intention that current studies should be suspended so please accept our apologies for any confusion.
b) All future studies which involve data collected about patients living in Scotland will require approval by the PBPP, prior to any data collection.
c) The Panel will examine other existing arrangement to ensure parity across organisations and studies.

JM, CB, HC and AMc agreed to examine the BPSU decision and consider the appropriate action to be taken to ensure parity between the organisations.

Action SP, CB, HC, JM and AMcC

5. Synthetic Data

Dr Beata Nowok from the University of Edinburgh, Administrative Data Research Centre -Scotland (ADRC-S) presented a paper on Synthetic data.

The purpose of the paper is to seek approval from PBPP for release of non-disclosive entirely synthetic versions of health individual level datasets and to inform PBPP about ongoing research on synthetic data at the ADRC-S.

Synthetic data that replicates the structure and statistical properties of the original dataset without using original content offer a way to enhance the use of confidential microdata. Synthetic data are completely made-up data created by sampling from probability models fitted to the original dataset and therefore they include completely artificial units only

BH thanked Dr Nowok for her attendance and explained the Committee would consider the requests detailed in the paper.

The Panel wish to approve the release of synthetic health variables that are part of approved SLS projects for the purposes of preliminary analysis and the development of analysis code. The Panel note that access to the synthetic extract will be only be released for use outside the safe haven to those accredited researchers who have been granted access to the original data and that only results based on this original data will be disseminated.

The Panel will require additional information in relation to the request to incorporate synthetic data into the *QCummber-envHealth* data platform in order to further assess this application. It was agreed that JM will communicate with Dr Nowok on behalf of the Panel to confirm any additional questions including whether it was important to get a more detailed report in respect to the level of the information governance assessment of risks completed by Mark Elliot.

This request can then be reconsidered by the Committee at a later date.

Any questions should be emailed to JM.

Action JM

6a. Audit and Reporting – Reviewing Tier 1 Approved Applications in 2016

JM explained that it is essential an audit of approved applications is undertaken as a priority and that this paper outlines a proposed review of Tier 1 decisions. JM suggested that the PBPP Committee review a 10% random sample of all applications approved at Tier 1 between January 2016 and December 2016 which would equate to 10 applications.

The Panel consider that this volume of applications per Committee member was very resource intensive particularly for those already participating in Out of Committee referrals.

CB suggested an alternative process which would involve each committee member reviewing a maximum of 4/5 applications from within the 10% random sample. Each member would conduct an independent review of each application in line with Tier 1 proportionate governance criteria review process but would not have sight of the original decision by the T1 Panel. This was agreed as the preferred method.

AG agreed to prepare the application sample for issue and papers would be sent out early February.

AG suggested the possibility of the next committee meeting in April extending into the afternoon to facilitate a discussion of applications in which issues had been identified. The Committee considered it would be desirable to have a separate workshop to include Tier 1 members.

AG agreed to make arrangements for workshop and provisional dates would be circulated.

Action AG

6b Recruitment Process

To recruit new members to the panel as required to fill any vacancies arising on the panel.

This item had been postponed from the meeting in January and therefore Panel members had reviewed the contents of this paper previously.

The recruitment process document was agreed.

6c International Access to Safe Haven

CM asked for guidance from the Committee as to whether requests to access the National Safe Haven from out with the EU should be approved.

Discussions took place and the Committee noted that they are willing to consider international access from out with the EU but require detail relating to the information governance requirements and assurance process for each different type of individuals. At present the positions remains that access to the Safe Haven from out with the EU and EEA is not permitted.

JM, CB and HC agreed to work with CM on refining this detail.

CM agreed to provide an updated paper.

Action CM

7. New National Data Collections

JM asked the Committee to consider the request for new national data collection projects within NSS to be approved internally within NSS without referral to PBPP with the proposed criteria.

Proposals for new data collections that do not meet the criteria will still be considered by PBPP.

JM explained that if this proposal is approved, PHI will provide an annual report to PBPP on all new data or significantly updated national data collections approved by PHI Caldicott Guardians.

The Committee agreed to accept the recommendation subject to discussion between AM and JM

JM and AMcC agreed to discuss this and produce an updated paper to reflect the outcome of any discussion for information only.

Action JM and AMcC

8. Any other business

8.1 Genetic datasets

AMcC asked if genetic data sets could be discussed at the next meeting.

It was agreed that genetic data sets are not part of the remit for the PBPP Committee.

8.2 Capturing decisions

HC asked if there was mechanism for capturing decisions made a this panel
AG confirmed this precedence is documented and information papers which cover key themes have been introduced.

9. Date of next meeting

The next meeting is scheduled to take place on 18/04/2017 in the LCR, General Register House. This meeting will be extended until 2pm.