

Minutes

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

28 January 2016

The Dome, New Register House, Edinburgh

Present: Brian Houston (Chair)
Prof Alison McCallum (AMcC)
Dr Angus Ferguson (AF)
Prof Helen Colhoun (HC)
Dr Daniel Beaumont (DB)
Dr Danny McQueen (DMcQ)
Dr Janet Murray (JM)
Dr Harpreet Kohli (HP)
Dr Abbe Brown (AB) (By telephone)
Dr Corri Black (CB) (By telephone)
Dr Hugo Van Woerden (By telephone)
Carole Morris, eDRIS representative (CM)
Ashley Gray, Panel Manager (AG)
Susan Kerr, Secretariat (SK)

Apologies: Mr David Knowles
Mr Gerry Donnelly
Mr Steve Pavis

1. Chair's Welcome

BH welcomed all to the PBPP Committee meeting.

2. Minutes of PBPP Committee meeting dated Thursday 19th November 2015

The minutes from the previous meeting were approved.

3. Ethics and PBPP

CB presented a paper on Ethics and PBPP.

Previously, PAC and Ethics committees had developed an understanding that formed the basis for a shared way of working.



Interim Chair Professor Elizabeth Ireland
Chief Executive Ian Crichton

*NHS National Services Scotland is the common name of the
Common Services Agency for the Scottish Health Service.*

The committee were asked to consider PBPP relationship with ethics with the following:

1. Acknowledge that there is an opportunity to provide greater clarity
2. Consider appendix as a basis from which to develop a process
3. Agree a short life working group
 - 3.1 Review and clarify interim guidance with PBPP and eDRIS
 - 3.2 Establish a short life working group, jointly with ethics committee representatives, to bring a proposal to PBPP with recommendations to clarify, and streamline where possible, the permissions process.

AMcC explained that there is an opportunity for further clarification regarding the transition of studies which have NHS ethical approval in England and the different approaches/ approval routes which are required for Scotland.

CB advised that the first area work should be focused on Scotland with cross-border opportunities to come in at the second level.

HC noted if one of the members of this group were from the National Research Ethics Service (NRES) it would be very helpful.

AG advised that the Tier 1 Panellists have expressed a need for further guidance in respect to the question on the application which relates to ethical approval. Tier 1 seek clarification as to when they should be requesting that the applicant submits their applications to NHS ethics where they have not already done so. AG also explained that the question on the PBPP application does not specifically ask for NHS ethics but refers to an 'ethics committee'.

All agreed and were happy to accept the above recommendations.

4. European Medicines Agency Effectiveness and Pharmacoepidemiology Studies to Support Regulation of medicines

JM circulated 3 papers. The panel were asked to consider the following:

1. Note the approved governance process for individual studies
2. Consider whether applications for individual studies can be prioritised by PBPP
3. If so, agree a process for prioritising individual studies eg applications are considered at first tier 1 panel after referral and time for consideration by tier 2 panel out of committee is reduced.

Timely evidence is key to this proposal. A proportionate governance review of applications will be completed by eDRISLead, PHI Caldicott Guardian, Clinical lead from PHI and an academic from the investigations team who submitted the PAC application. If the outcome of the review indicates that application is required to be submitted to the PBPP for approval then it is proposed this is referred straight to the Tier 2 Out of Committee.

The panel were happy to accept and agree this as an appropriate way forward.

5. Terms of reference

- PBPP
- PBPP Operational Delivery Group
- PBPP/Farr Action Plan

PBPP Terms of Reference

AG reported on the current Terms of Reference for PBPP.

The committee were asked to consider minor changes before these are published on the PBPP website.

JM asked about paragraph 25 regarding how Tier 2 considers samples of applications from Tier 1. The panel agreed this should be in place and should be included in the Terms of Reference. AG agreed to update the document to reflect that this is a process which is carried out by Tier 2.

A discussion took place on the wording within Annex A. After discussion it was agreed that no changes should be made to the current wording.

It was agreed the Terms of Reference need to be published on the PBPP website as soon as possible and AG agreed to action this.

Action AG

PBPP Operational Delivery Group and the PBPP Workplan

CM reported on the PBPP Operational Group terms of reference.

The role of this group is:

- Identify and resolve issues that may affect the smooth running of the PBPP in order to protect the interests of all NHS Boards
- Provide support for the PBPP Panel manager and associated administrative support staff
- Establish and oversee the delivery of a PBPP work plan.

The work plan lays out the opportunities and challenges which the panel has identified or will face within its early stage of operation, and proposes actions to address each.

It was noted that it is very important that the action plan is a central element of the PBPP Operational Group and that the remit for this remains focused to one group.

CM asked if a member of the Committee would like to volunteer to chair the operational group. This individual would be able to provide feedback on the work of the group to the Committee.

AMcC suggested rather than a chair possibly a sponsor could act on behalf of the committee. All agreed this was a good idea.

It was agreed that Dr Janet Murray would be an appropriate person to represent the Tier 2 on the PBPP Operational Group as she is a proposed member in her role as NSS Caldicott Guardian.

6. Generic Questions Submitted to Tier 2 via Tier 1 – Process for Review

AG asked the committee to consider the best way to process and respond to generic questions submitted to Tier 2 by the Tier 1 Panellists.

HC suggested generic questions could be a standard item on the agenda for this committee and decisions made at the committee meetings. HC also suggested that if there is a requirement to respond to a question urgently then it would be appropriate to circulate this via email to Tier 2 Out of Committee members. This was agreed.

7. Panel Manager's update – review of Tier 1 approved / rejected applications.

It was agreed that this update should be circulated with the papers prior to the meeting.

HC stated that she found this very useful but would also like to see numbers of applications which are significantly above target duration. HC also asked if the percentage of applications received which are considered to be research could be provided as this would inform the committee of who the customers are – CM agreed eDRIS can supply this information

Action CM / AG

A discussion took place on amendments to previous applications. It was agreed that AG, Panel Manager can review and approve minor amendments and that these changes do not need to be referred to Tier 1 Panels.

AG advised that the PBPP have developed an amendment acceptance letter to formally acknowledge any changes to approved applications as this brings the Panel in line with other regulatory bodies who have a similar process.

CB commented that this is useful as researchers retain an audit trail of changes throughout the process as well as associated approval documents.

Action AG

A discussion took place on best process to address the back log of applications awaiting review at Tier 1. AG explained that there are 2 NSS Information Governance staff who attend Tier 1 panels on an alternate basis. The time commitment involved for reviewing applications and attending the Panel make it difficult to schedule in others out with the fortnightly meetings. A discussion took place on reviewing more applications at each panel and again the time commitment required. It was agreed that it is possible to review 6 applications at each Tier 1 Panel.

Resources for PBPP

Resources for the PBPP were discussed. It was agreed that more resources for the work required is necessary going forward. In light of the programme of work ahead as well as administration of panel processes there is a concern that the current resource will not be sufficient to sustain this level of movement as the PBPP develops

HC and DMcQ stated that resources for the PBPP is a serious issue which gives rise to concerns on how the PBPP can deliver on all aspects of the process including the development agenda.

CM stated that she has become very involved in the PBPP although this is not her full time job and therefore this resource has not been formally committed financially.

JM suggested the Data Management Board can review resources and the panel agreed that the Chairman should take this forward to this group.

8. AOB

SHELS 4 Programme

AG asked if a member of the committee would like to attend the Shell 4 Programme Public Panel event in March as the PBPP have received a request from Theresa Kirkpatrick. AMcC informed the committee that she attending in October 2015 and found it to be a very interesting.

HC suggested that to invite Sarah Cunningham-Burley as a representative would be a good approach. Sarah is a member of a short-life working group which is looking to address some of the issues around PBPP and Public Engagement and would be able to feedback to the committee. AG agreed to respond to the request and forward to Sarah Cuning-Burley to ask if she wishes to be involved.

Action AG

Cohorts

JM advised that there is a need for further education in the long standing cohort studies, such as Scottish Longitudinal Survey, that are likely to make applications to the Panel and that invitations could be extended for discussion at future Committee meetings.

Training for Tier 1 panellists

Discussions took place on training. It was agreed that this is necessary. It was agreed that an away day for all PBPP members should be arranged.

Action AG/SK

Committee Papers

DMcQ asked for future papers to be linked to the agenda by numbering, SK agreed to do this.

Action SK

Future meetings

It was agreed that the Dome is not the most suitable venue to hold the PBPP committee meetings. BH suggested we hold meetings at the Farr Institute or NHS Lothian. This was agreed and SK agreed to change the venue for the next meeting.

Action SK

9. Date of next meeting

The next meeting will take place on Tuesday 19th April 2016 in meeting room 5.4, 5th Floor, Waverley Gate, Edinburgh.

Proposed agenda items for this meeting should be submitted to the PBPP mailbox by Friday 11th March 2016.