Public Health and Intelligence

minutes

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

18 April 2017

Lord Clerk Room – General Register House, Edinburgh

Present:	Brian Houston (Chair) Prof Alison McCallum (AMcC) Mr Gerry Donnelly (GD) Mr David Knowles (DK) 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:	Dr Hugo van Woerden Dr Angus Ferguson
Observer:	Patricia Ruddy Claire Wainwright

1. Chair's Welcome

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

BH informed the group that Daniel Beaumont is no longer a member of the PBPP Committee and that he plans to write to the Scottish Government regarding his departure.

2. Minutes of PBPP Committee meeting dated 26 January 2017

The minute was approved as a correct record.

3. Matters arising

3.1 Tier 1 Panels

AG reported that there are still concerns relating to the capacity of Tier 1 Panels. The number of applications being reviewed is continuing at 6 applications per panel to attempt to manage the current capacity issues. A quality improvement exercise is scheduled for May and the outcome of this will be discussed by the Operational Group with a view to reporting proposed actions at the meeting in June

3*.2 Quirk Appeal*

SP reported that the appeal decision had been communicated in writing to Professor Ford shortly after the meeting.
JM advised that the examination of parity had been completed and formal notification of the changes to approval had been issued to Mr Lynn. JM noted that Mr Lynn had acknowledged the correspondence and provided the requested list of studies.

3.3 Synthetic Data

JM reported that this work is on-going. JM will continue to communicate on behalf of the Panel and report back updated information when available

Action JM

3.4 New National Data Collections

AMcC reported that she has received a draft paper and returned comments.
An updated paper to reflect the final agreement on New National Data Collections will be circulated for information by KL/JM

Action KL/JM

3. Performance Update

The performance update was circulated for information only.

4. End Point Validation for studies of the safety and efficacy of medicines

JM informed the panel of the privacy risks and practical difficulties in implementing a process for end point validation in studies of drug safety and efficacy.
JM advised that 12 months ago criteria was agreed by a sub group of the Committee which agreed access by research nurses, with recognised Research passports, to complete the necessary work , rather than contacting the clinician via the eDRIS team. However practical issues have been identified such as requests for case notes to be sent to the research team as well as varying degrees of redaction being undertaken locally.
JM asked the group to consider the recommendation to form a SLWG to work through the process and establish guiding principles with all key parties involved.

AMcC advised it would be desirable to have a standardised process across Scotland.

DM stated that he felt that if clinicians do not have the resource then researchers should be granted access. The Research passports enable this and compliance with the agreed routes to access are key.

SP queried if the process was wrong or was the concern based on their compliance with the agreed procedure. If the problem is compliance, then what role or actions can the PBPP take to influence Boards to adopt the principles.

HC stated that agreement and communication is needed with R&D Directors. Research nurse work should be funded directly from the PI and not the responsibility of the NHS Boards

JM agreed that the work should be funded but that Boards need to make the required information available.

CB queried if this issue was specific to pharmacovigilance.

DK stated that principles can be established easily, however Boards are clearly struggling to resource this work and queried if this process would be for all research that requires end points

HC confirmed that this is a process for all regulatory work. There is an immediate safety issue which requires a framework under which resource will be needed. Can a mechanism for release of resources for urgent governance be agreed. It was noted that this work could be useful for more chronic validation.

DM suggested that the Panel retain ownership of the issues as the executive body.

HC explained in line with the remit of the PBPP that a letter of recommendation may be a sensible approach.

AMcC recommended that others are brought into the discussion to work out best practice, workflow and describe the resource that is needed to implement a process. SG involvement also required to ensure that any process can be adequately resourced.

JM also advised that any group should included IG leads.

The Chair agreed that the PBPP will retain ownership of the issue and look to create a SLWG with R&D directors, CSO/SG, IG leads and PBPP to engage in the development of these principles.

AMcC agreed to co ordinate this exercise and report back to the Committee

Action AMcC

5. PBPP Operational Group

5.1 Recruitment update

AG stated that the recruitment process was underway for replacement Caldicott Guardian and also a Public/ Lay representative.

Dr George Fernie from Healthcare Improvement Scotland has expressed interest in joining the Panel in the role of Caldicott Guardian. AG explained that it is hoped an introduction will be arranged between Dr Fernie and the Chair shortly. An invitation will be sent to attend the next Committee meeting in June 2017.

The closing date has now passed and 3 applications have been received for the public/lay representative position. Initially all applications will be reviewed by the Chair and an interview Panel arranged for May/June 2017. AG confirmed that NSS HR are facilitating the process alongside the PBPP team.

JM stated that all 3 candidates may have things to offer the PBPP and suggested having a pool of lay members.

SP suggested that all 3 candidates be invited to attend the next meeting in June to gain a fuller understanding of the workload involved.

It was noted that there are only 2 Public representatives in attendance at this meeting. It was agreed that the PBPP Terms of Reference should be changed from quorum of 3 Public representatives to a quorum 2 Public representatives in attendance at each meeting.

AMcC supported this and agreed panel should be made accessible for all who applied.

DM agreed and advised that a pool of lay representatives would be of benefit to PBPP.

The Panel discussed whether it would be possible to offer all suitable candidates the opportunity to become involved in the Panel if they wish to do so, this should not be limited due to the fact that there is only one vacancy advertised.

It was agreed that interviews will take place. BH will review received applications and AG will proceed to arrange the interview Panel date and membership.

Action AG

5.2 New Application Form

AG circulated the new Application form for information. AG explained that changes have now been finalised but recognised that this is an iterative process so further reviews will be needed in the future. The revised application form is now available on the PBPP website.

HC queried the progress regarding an online application form.

AG advised that this area of development was on hold at the moment due to lack of both staffing and financial resource.

CB enquired regarding the status of integration with the IRAS.

AG confirmed that at the R&D Operational Group meeting in December there had been a discussion regarding the PBPP form and use of IRAS to streamline submissions. Communication had been recently received which indicated that the CSO were moving forward but limited information had been provided in terms of the status of these discussions.

AG and CM agreed to investigate the proposal further and report to the Committee.

Action CM/AG

5.3 PBPP Workshop October 2017

AG reported that the next PBPP Workshop is scheduled to take place on 03 October 2017. A draft agenda will be provided for review at the next meeting in June.

Action AG

5.4 Review of Tier 1 Applications

AG thanked all members for their reviews and participation thus far.
Four applications will be discussed at the Audit workshop taking place on 02 May 2017. The details of the session will be finalised next week and communication issued to those who have confirmed availability to attend.

5.5 International Access to Safe Haven

SP explained that eDRIS and the PBPP are receiving enquiries from researchers who are out with the UK and wish to access data within the National Safe Haven. The paper sets out possible variations in access across the UK, EU and Non EU and provides a recommendation for the Panel to consider.

Following the discussion the Panel agreed that all researchers accessing the National Safe Haven should be required to be 'Approved Researchers' and to follow the existing eDRIS processes and procedures.

It was accepted that UK university employees who are on secondment/visiting other EU universities should be allowed to access data remotely in the normal way. However, this will require them to be able to provide eDRIS with an IP address so that this can be 'white listed'.

EU, EEA and equivalent country (as recognised by the ICO) university employees should be required to be sponsored by a UK university prior to data access. When sponsorship is in place the researcher would be required to provide eDRIS with an IP address so that this can be 'white listed'

Access by Non EU countries to the Safe Haven has not been agreed at this time and CB SP and CM will produce more information on how this access should be controlled and evaluated.

Action CB, SP and CM

6. PBPP Application 1516-0540 McDermaid: '*Radiotype DX: Molecular signatures of radiosensitivity and ipsilateral breast tumour recurrence in breast cancer'*

KL introduced the application and summarised the main concerns on behalf of the Panel

KL explained that this proposal seeks to investigate whether a molecular marker or 'signature' called Radiotype DX, can be validated within a historical Scottish breast cancer trial (Scottish Conservation Trial [SCT]. The application is both commercial and international in nature with collaborations between PFS Genomics, University of Edinburgh and Ontario Institute of Cancer Research. KL highlighted the following principle issues for discussion by the Panel:

- To consider if the commercial aspects of this study meet PBPP principles for unconsented use of patient data.
- To consider if the lack of consent for the new study is justified in view of the acknowledged potential for public benefit, but also the commercial aspects of the study and the transfer of patient samples outside the EU for analysis.
- To consider if the plans for public participation are adequate and any expectations of the panel for feedback from those participation events.
- To consider if the applicant has provided adequate information and assurances around IPR.

SP noted that the public benefit is clear from the science described but raised the issue around the ownership of IP. NHS Scotland is being asked to provide the data to the commercial company/University of Edinburgh and therefore require clarification on where the NHS sits in the partnership and any benefits which will be received by NHS Scotland.

HC summarised that the request seemed to be primarily to agree to the transfer of anonymised, de-identified data to a private company. However queried why the molecular signature could not be imported for analysis and that it was unclear as to why data transfer out with UK is necessary.

Professor David Cameron (DC), Dr Joanne Dunlop (JD) and Ms Tammy Piper (TP) joined the meeting to discuss their application with the Panel and respond to any queries.

DC provided some further background information regarding the purpose of the study to update the SCT with long-term follow up data, and then see if the Radiotype DX test, performed on the breast cancer tissue removed from the patients at the time of their surgery approximately 30 years ago, can help identify those patients who did and did not benefit from the WBRT treatment.

The project will provide over 20 years of follow up data for analysis compared to 5+ years. DC further highlighted that potential benefits to the patients would include a reduction in toxicity with no difference in long term survival.
DC explained that the original trial did not approach subjects for consent to future follow up/research as the standard for informed consent was very different from today. PBPP has been approached to provide permission for the use of unconsented tissue/data in this project.

HC asked if the molecular signature could be imported to Edinburgh and provided information on the Safe Haven standards within Scotland. It was recognised that this standard could not be uniformly applied retrospectively

DC explained that the company advised that the analysis package is large, complex, derived by themselves and may not be able to successfully run on another platform.

JD advised that the Safe Haven would not be able to host the analysis as there is no functionality for genomic data.

CB enquired as to whether the molecular signature could be imported to another area in the University of Edinburgh to support the analysis if the Safe Haven could not accommodate.

AMcC advised that the analysis work to be carried out by Linda Williams will be in a secure environment.

DC confirmed that the company advised this would not be possible.

SP requested clarification on whether NHS could be included as a third equal partner and what the benefits are to the NHS.

DC advised that this project could see a reduction in the clinical work without loss of efficacy and possible reduction in resource costs. Initial discussion had been had with commercial company and the University regarding IP but nothing mandated.

DM asked for clarification regarding the public participation in the proposal to provide the Panel with evidence that a strong body of interest exists. Given that this is unconsented data then public views are required.

JD advised that a focus group is to be held with representatives from various groups to discuss the protocol and dissemination. These will be structured workshops which will look at areas such as consent and international involvement. A report will be submitted to the PBPP.

AB queried whether commercialisation will be discussed.

DC confirmed that the workshop questions were not prescriptive but would expect this area to be discussed. PPI engagement consultants will be facilitating.

DC advised that funding is coming from the company who may then commercialise the tool, however this study could have been granted funded and therefore PBPP have been included earlier due to the nature of the finance arrangements.

HC explained that there is a vast range of expertise available locally to conduct the analysis and queried how the results would be validated
DC confirmed that all data will be sent back to Scotland to replicate the analysis.

TP asked whether the Committee would be happy if the analysis was undertaken by an independent third party in the EU.
DC asked the group what would be the alternatives if the Committee are not happy with the data transfers.

JM explained that the data being requested by the applicants belongs to NHS patients and NHS Scotland are data controllers. The balance of risks between the release of unconsented personal data and IP loss to the company by importing the molecular signature cannot be considered as equal in terms of the potential harm.

The Chair thanked the applicants for their time.

The Panel discussed the application and concluded the following concerns remain which require to be addressed:

- PFS Genomics provides a detailed specification of the technological and analytical requirements for the generation of and testing of prediction characteristics of the molecular signature. This specification should be reviewed by the applicants and an assessment made as to whether this can be provided by the University staff with appropriate IP protection measures taken to protect PFS, and if not why not.
- Further discussion should take place with research partners about the wider ongoing benefits from this project and re-consider how NHS Scotland can be recognised as a partner in those benefits.

KL, SP and HC agreed to prepare questions in relation to the concerns above to be sent to the applicant.

Action KL, SP and HC

7. PBPP Panel Development SLWG: Update

GD updated the Committee on the progress towards merging NHS Scotland PBPP and SG Stats PBPP to simplify and consolidate the current landscape around approval panels.

GD explained that resources to establish this joint panel are being discussed within SG.

In the interim progress to continue with the recruitment of an independent Chair and lay representative SG Stats PBPP is moving forward.

Separately, it was noted that NRS have recently approved the sharing of Census data through the National Safe Haven.

GD will continue to provide progress updates to the Committee when available.

Acton GD

8. Any other business

8.1 BPSU Study

AMcC wished to make the Panel aware that whilst reviewing a recent BPSU project the Confidential Advisory Group had advised that would be unwilling to approve the transfer of patient data to Scotland due to the absence of the IG toolkit. AMcC explained that issue is currently being discussed further and that a resolution which may be proposed/accepted could involve transfer of the data between recognised Safe Havens.

9. Date of next meeting

The next meeting is scheduled to take place on 27 June 2017 in the LCR, General Register House.