Public Health and Intelligence

minutes

NHS Scotland Public Benefit and Privacy Panel for Health and Social Care
22 November 2017

FARR - Edinburgh

Present:	Prof Alison McCallum (AMcC) Acting Chair Prof Helen Colhoun (HC) Dr George Fernie (GF) Dr Stephen Pavis (SP) Dr Corri Black (CB) Dr Emilia Crighton (EC) by tele conference Dr Kirsty Licence (KL) Prof Abbe Brown (AB) by tele conference Ashley Gray, Panel Manager (AG) Carole Morris, eDRIS representative (CM) Susan Kerr, Secretariat
Apologies:	Mr Brian Houston Dr Janet Murray Dr Angus Ferguson Mr Kenneth McLean Mr David Knowles Prof Danny McQueen Mr Gerry Donnelly
In attendance:	Patricia Ruddy (PR)

1. Chair's Welcome and Introduction

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

It was noted that due to number of apologies received the composition of the Panel was not quorate and therefore no decisions could be made with regard to business or applications. It was agreed that a teleconference could be arranged to finalise the decisions relating to applications with a quorate number of Panel members should this be required.

AMcC invited introductions from the Panel members and also introduced Patricia Ruddy to the group as observing proceedings and welcomed any input which she may have given her role and expertise as NSS Privacy Advisor.

The following conflicts of interest were noted:

- Item 4 – Professor Corri Black
- Item 6 – Dr Stephen Pavis

AMcC highlighted a number of key developments to the Committee:

- Digital Healthcare Strategy under development by Scottish Government.
- An IG Working Group has been established to take part in a series of workshops which will assist in the development of work streams designed to support the digital healthcare strategy. It was noted that members of the PBPP may be requested to contribute further to this work.
- BH has a meeting scheduled with Andrew Fraser on 29th November to discuss SG & Information Governance matters. BH has also recently met with Penni Rocks and Graham Gault (eHealth Scottish Government) to discuss PBPP resourcing. AMcC commented that it may now be appropriate to write formally to SG to request representation on PBPP to address the requirement of SG policy lead as per ToR as well as ongoing accountability issues.

2. Minutes of PBPP Committee meeting dated

The minute from 13/09/2017 was approved as a correct record

CB queried the time limited approval re 1617-0338 SHARE and how this would be tracked and applicants made aware that permission had lapsed.
AG confirmed this would be picked up via the End of Project Reporting process recently introduced.

The minute from 05/10/2017 was approved as a correct record.

HC asked if further action from her was required in relation to HARP. AG advised no action was required at present and that a teleconference had been arranged for early December.

2. Matters arising

2.1 New National Data Collections

AMcC requested an update on this paper which was previously presented to the PBPP Committee in April 2017.

KL explained that the paper had now been revised with comments from Alison. It was agreed that further engagement with DPH's was required on the proposal and it has been planned to produce a higher level document for this purpose. KL and AMcC will then refine the substantive paper in response to the views/feedback from DPH.

Action KL/AMcC

3. Performance Update

The performance update was circulated for information only.

AG stated that there have been 120 applications with amendments approved as at 31/10/2017and the volume of submissions was resulting in a significant impact on Panel Manager time for review and processing. The majority of amendments fall within the remit of the agreed criteria for delegation to the Panel Manager.

A discussion took place on potential options to reduce the administrative burden and also explore the types of amendments being received.

It was suggested that some changes e.g. personnel could be processed directly by eDRIS, providing the appropriate IG training evidence and other 'approved researcher' criteria has been satisfied.

AG and CM agreed and write an options paper for discussion regarding the current requests and potential powers of delegation to eDRIS/Panel Manger.

Action AG / CM

4. DaSH Scottish Government Accreditation Report

Accreditation of Grampian DaSH report was circulated for information only.

It was agreed that no conflict of interest exists as the PBPP are not undertaking a discussion of the Accreditation process or report.

AMcC commented that SG should advise of time limits of accreditation, when renewal is due and if there have been any concerns noted. PBPP should also be advised when all safe havens have been accredited.

Action Chair

5. PBPP Resource Scottish Government Update

AMcC provided a short update on behalf of BH.

BH met with Penni Rocks and Graham Gault at the Scottish Government to discuss the ongoing resourcing and accountability issues. There has been no immediate solution identified.

Discussions took place and it was agreed that it was appropriate to write again to request a timeframe for resolution.

CM explained that she has a meeting scheduled for next month to meet with both Penni Rocks and Carole Sinclair to discuss the resourcing of PBPP. CM will report back at the next meeting.

Action CM

6. PBPP Application 1617-0049

1617-0049/Semple: Using linked data to follow up longer term outcomes of POPPY trial participants

SP left the meeting room for the duration of this discussion.

AG introduced the application and summarised the main concerns on behalf of lead Panel member Angus Ferguson. It was agreed that George Fernie would assume the lead role for the duration of the meeting and to compose any feedback.

The original POPPY trial (2007) studied the effects of physiotherapy for women with pelvic organ prolapse. Participants were divided into 2 study groups, with members of one group having 5 appointments with a hospital physiotherapist over 16 weeks and being taught exercises which may help reduce prolapse symptoms. Participants signed a consent form for this study which clearly indicated that they could withdraw at any time. They were also asked to consent to limited access to their medical records as part of the research.
The new application seeks to undertake a follow up study, using record linkage to examine longer-term outcomes from this cohort. Participants have not been notified of this study and no consent has been sought for this access.

The main issues identified for discussion were:

- Original consent given by participants does not explicitly cover this new study. By proceeding without consent, participants will not have their right to"withdraw at any time" from the research –be respected. This is an important principle underpinning the social licence for public involvement in medical research.

- A study that sought to follow up with the participants themselves, as well as their records, would seem to be more useful than the proposed linkage-only study – as it would allow assessment of important variables e.g. have the participants continued with the exercises in the intervening period?
- Without the information on participants' individual practice re the exercises (beyond the original study) will the new study be able to arrive at conclusions that are substantial and reliable enough to meet the public interest test.

GF commented that in 2007 the UK landscape regarding consent had evolved and the concept of informed consent was clearly established at this time. The Panel must consider the need to respect this consent given the sensitivities of the topic.
CB highlighted that the applicant had also drawn on the sensitive nature of the topic as justification for not re-consenting.
AB confirmed that consent should not be dismissed lightly and public interest should be robustly demonstrated.
HC queried if the Panel would consider differently if this was a legacy study and consent was given 20+years ago.
CB noted the need for clear public engagement/support in the shift from clinical trial and that as they hold the main dataset the researchers could still identify an individual.
The Panel also agreed it was necessary to establish the scale of effect from the original study as well as the process for study withdrawals.

AMcC welcomed Professor Margaret Maxwell (MM) to the meeting and invited her to provide a short summary of the application.

MM explained this project is part of wider body of work and this proposal is specifically looking into whether the clinical benefits have been sustained from pelvic floor muscle training. Using NHS data it can be seen if there have been further surgeries and present the long term cost-benefit to implement as part NHS routine care.

GF highlighted that the Panel had discussed the benefits of the proposal and would like to clarify the process for those who have withdrawn from the original POPPY study.
MM advised that 16 withdrew from the trial and some participants had indicated they did not wish further contact after conclusion of the trial. MM went on to say that this does not necessarily indicate that those participants would not be willing to be followed up through records. It is important to maintain sufficient numbers for record linkage.

HC wished to confirm that the 16 individuals were completely removed and would not be included in the linkage study.
MM advised that those 16 were removed and were not included in the final numbers.

GF asked for further reassurances in respect to the public engagement activity.
MM explained that there is a public member on the project management group as well as lay members on the Study Steering Group. The lay members are also part of larger interest groups and are supportive of the proposal. There is also funding from the NIHR grant to hold national events to disseminate findings and evidence which will take place in 2018. MM also advised that it is intended to invited participants of a parallel implementation study to attend these events.

GF queried the robustness of anonymisation.
MM explained that the clinical trial data is held by the Clinical Trials Unit and that the consent forms are held by NHAMP unit. The CTU will send the required information to NHS ISD who will then remove identifiers. All analysis will be undertaken in the Safe Haven environment and disclosure checks will be completed. MM also advised that with regards to the potential for low numbers across HBs then the level of geographical access can be flexible to reduce the risk of identification further.

HC wished to know more about the effects of the original study.

MM noted she would have to refer to the Lancet papers but in general there was perceived improved quality of life as well as reduction in stage of prolapse which were of clinical significance.
HC asked what if there was no difference between the groups in subsequent health care utilisation
EC also enquired regarding the possibility of a lack of power and therefore no effect.
MM advised that the research team would need further funding to investigate the ongoing period and whether a refresher course of treatment is necessary to maintain benefit. However evidence of the impact of the initial intervention was required first to make a case to a prospective funder.

AMcC thanked MM for her attendance and contribution to the discussions. AMcC explained to the applicant that no decision would be made on her application during this meeting but that she would receive feedback in due course.

The committee felt broadly positive that some of the key issues had been addressed but concerns remained which required further response by the applicant:

Because of the relatively small sample size and possible attrition from the original study the Panel wish the applicant to undertake a Power Calculation to confirm that any further data will, indeed, result in public benefit. Whilst the aims of this further study appear, in principle, to be laudable, should the numbers be insufficient it would not seem appropriate to proceed further to avoid this being misleading.

The Panel wish confirmation of arrangements for the patients who elect to withdraw from the study although the initial comments that 16 had already done so were reassuring. The concern here is the assertion that there is a right to "withdraw at any time" in the original literature.

As noted above it has been commented that a study that sought to follow up with the participants themselves, as well as their records, would seem to be more useful than the proposed linkage-only study – as it would allow assessment of important variables e.g. have the participants continued with the exercises in the intervening period? The Panel wished to understand the rationale for not including a qualitative element to the project to examine this issue.
It is unclear without the information on participants' individual practice regarding the exercises that the new study will be able to arrive at conclusions that are substantial and reliable enough to meet the public interest test – not just for use of anonymised data without consent, but to justify overriding the original terms of consent for the 2007 POPPY study.

The Panel would request the applicant to expand on the arrangements to improve public participation as the proposed national event was rather vague and we would like to ensure that the women's' focus groups were relevant to those who had suffered pelvic organ prolapse.
It was noted that Professor Maxwell confirmed there would be no attempt by the investigators to identify individuals, reaffirming this point would be appreciated as whilst they would not have access to names and addresses, they would theoretically be identifiable.

GF agreed to prepare the draft response to the applicant. It was suggested that this draft be emailed to Angus Ferguson to confirm he is content, as public representative and lead Panel member, with the direction of questioning prior to feedback to the applicant.
It was confirmed that once responses are received the most appropriate course of action may be to arrange a teleconference with a quorate group to progress the application.

Action GF & AG

7. PBPP Application 1516-0560

PBPP Application 1516-0560 Kunkler (McDermaid): *'Radiotype DX: Molecular signatures of radiosensitivity and ipsilateral breast tumour recurrence in breast cancer'*

KL introduced the application and summarised the background to the study.
The proposal is being considered by the Committee for second review as following initial discussion in April 2017 the applicant was asked to address specific issues in relation to transfer of unconsented patient out with the UK and proposed IP arrangements for NHS Scotland.

The applicants were not present but Jackie Caldwell, eDRIS coordinator was in attendance to support the discussion regarding the applicant responses.

KL noted to the group that the main applicant was now from University of Edinburgh and not NHS NSS
AB commented that the intention regarding shared IP had been made but more is needed regarding how this will work in practice. The agreement will be necessary as arrangements could be complex.

HC stated that the actual transfer of the unconsented sample is suitably covered by a Material Transfer Agreement. Issues centred on the generation of the gene expression and validation of the score. HC reiterated that the score needs to be independently validated and this could be completed by academic researchers/statisticians. HC noted that the arrangements for analysis in the Safe Haven is welcomed as was the inclusion of a much more robust statistical plan.

CB confirmed that she understood the revised data flow diagram (Item 7) but that some of the boxes could be ambiguous in the referral to data being 'released' to PFS genomics.
The Panel agreed that this data flow should be amended to reflect the access arrangements more clearly.

The Panel noted that current PBPP policy does not allow direct access to data by commercial researchers. Although the international access to the safe haven policy had recently been agreed, this was intended to facilitate access to international colleagues through their links with a UK institution.

JC advised that the commercial researchers hold honorary contracts with University of Edinburgh and have completed an approved IG training course.
SP stated that it is important to understand what risk is being mitigated by the honorary contracts – is this one of legal governance/ data security or public perception.

HC returned to the current proposal and said a case had not been made as to why PFS genomics required direct access as opposed to University researchers undertaking the analysis. EC highlighted that the bottom of the diagram suggests further analysis for retraining of the score/signature.

HC noted that this was an addition to the proposal which had not been considered in the previous application. HC advised that the learning of the new signature could potentially be completed by a IGMM researcher.

AB commented that it was unclear what PFS genomics were actually doing.
EC advised that they will complete the omics analysis and have the experience and knowledge to do this.

The Panel agreed that the principle issue was the appropriateness of allowing direct commercial access to unconsented data.
SP noted that the PBPP agreed the current policy and therefore have the power to decide on a new arrangement as the landscape and public appetite changes.
PR commented that honorary contracts are used in different circumstances and across the NHS. The rationale/justification for the contract is stronger in different situations.
HC read out the sections of the safe haven charters relevant to commercial access.
AMcC stated public sounding and wider policy discussions are needed here.

CM suggested that generic commercial access may be a future topic for another meeting.
SP agreed to draft a paper outlining the issues to facilitate further discussion.

Action SP

GF reaffirmed that the applicant had not answered the original query and this was necessary before further discussion could take place.
EC noted concerns remain regarding ownership of the data.
CB requested that is made explicit that the future use of data as mentioned in the application is out with the scope of this proposal and a further application is necessary

After discussion it was agreed that clarification is required from the applicant on the following issues:

- Provision of an assessment of the reasons why the analysis of the clinicopathological dataset within the safe haven cannot be undertaken by University of Edinburgh research collaborators holding full contracts with the University, and why it is essential for PFS Genomics staff (albeit working under Honorary Contracts with the University) to have direct access to the dataset within the safe haven environment.
- Copies of the Honorary Contract terms agreed between the University of Edinburgh and PFS genomics collaborators to be provided
  Updated data flow diagram clearly describing the access and analysis arrangements, once these are finalised
- Acknowledge that the dataset will be used only for the specified study, as described in the protocol and application form, and for no other research unless further approvals are granted

KL will undertake to draft a response to the applicant with assistance from HC

Action KL/HC

8. GDPR May 2018

AG highlighted that as data protection law is changing and from 25 May 2018 all organisations using personal information, in particular Data Controllers and Data Processors, must ensure they comply with the new General Data Protection Regulation (GDPR) and the UK Data Protection Bill, once enacted. Therefore PBPP has an obligation to take steps to maintain compliance where necessary

AG commented that this process will likely involve changes to Panel documentation, website, IG training etc. The PBPP Operational Group will begin scoping the areas which will require attention in the coming weeks to ensure timely adoption of new paperwork.

AG will provide regular progress updates at the upcoming Committee meetings

SP raised the potential impact of GDRP across the Safe Havens and asked if it would be appropriate for him to lead on behalf of all Safe Havens to minimise workload. The Panel agreed this to be a suitable approach.

Action SP

9. PBPP Workshop Scenario 5

The PBPP Workshop examined a series of potential proposal scenarios to facilitate further consideration of how the PBPP Scope, as outlined in the Terms of Reference, was being applied.

There was a general agreement that the current guidance provides sufficient direction in terms of when a PBPP application is required with respect to access across multiple NHS boards or to nationally held administrative datasets. However it was agreed that further clarity is necessary with regards to the processing of CHI and the remit of the PBPP in scrutinising these requests.

AG presented Scenario 5 which highlights this issue in a real time example of a request for access concerning CHI.
The Panel agreed that due to time restrictions and the absence of a number of Committee members that it would be sensible to postpone this discussion until January 2018.

AMcC suggested that the paper is circulated for comment ahead of the next meeting.

Action AG

10. Date of next meeting

The next meeting will be held on 24 January 2018 at Waverley Gate, Edinburgh