

minutes



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

19 November 2019 at Nine Bioquarter, Edinburgh

- Present:**
- Dr Lorna Ramsay (Interim Chair)
 - Professor Alison McCallum (AM) – part of meeting
 - Dr Maria Rossi (MR)
 - Penni Rocks (PR)
 - Professor Danny McQueen (DM)
 - Dr Steve Pavis (SP) – part of meeting
 - Kenneth McLean (KM)
 - Professor Helen Colhoun (HC)
 - Dr George Fernie GF)
 - Dr Angus Ferguson (AF)
 - Carole Morris (CM)
 - Professor Abbe Brown (AB) – telephone
 - Alan Ferrier (Al F) – telephone
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- Dr Marian Aldhous (MA)
 - Phil Dalglish
 - Susan Kerr
- Apologies:**
- Professor Corri Black
 - Martin Bell
 - Dr Eleanor Anderson

1. Chair's Welcome

LR who is the Medical Director and Caldicott Guardian at NHS National Services Scotland (NSS) welcomed all to the meeting and introduced herself as Interim Chair of PBPP for the foreseeable future.

LR gave a short introduction of her background and current roles: previously deputy Caldicott Guardian in NSS, responsible for NSS PAC Committee, member of CHIAG and Clinical Lead for the national IG Programme through which she established the national Caldicott Guardian Forum. Currently involved in the Digital Health and Care Strategy implementation: Domain B/ Information Governance, Assurance and Cybersecurity which will have an impact on PBPP, Scottish Government (SG) Data Delivery Group (use of Scottish

public sector data to support research and statistics) and member of the Healthcare Data Research UK (HDRUK) Alliance representing NSS.

Introductions then took place around the table.

LR confirmed that Board Chief Executives (BCEs) have agreed that a review of the Public Benefit Privacy Panel (PBPP) should be undertaken. PBPP is accountable to BCEs through its Chair. The Terms of Reference for this review had been sent out prior to the committee meeting, outlining the small core group charged by BCEs to initiate and lead the review.

The purpose of the review is to identify areas whereby the work of the panel could be improved such that both applicants and panel members have an improved experience and the panel effectively delivers against its remit on behalf of NHS Scotland. The review will be cognisant of the broader environment in determining what improvements can be made in the shorter term and making recommendations for longer term changes which align with the evolving context.

HC asked if there are any specific issues which instigated a review?

LR stated that there was not one specific issue, but a number of different things such as a couple of more complex applications and the timescale aspects of decisions. As PBPP has now been functioning for over four years, it was also felt an appropriate time to do a review.

AM asked about external review and if this would be considered? If there is no external review to involve the people who helped set up PBPP in the first place, then this may be a concern to PBPP?

LR confirmed that this will be taken into account.

SP asked if there will be a review of the scope of PBPP or whether it would only be research?

LR stated that, yes, it is good to get a balance over short, medium and longer term and agreed scope will be useful to look at.

DM asked that due to this being the Public Benefit and Privacy panel will there be a public representative on the panel for this review?

LR explained that it is a small executive group at the moment to get things started but this may change as time goes on which will be widened out in time and will definitely not involve just the four people currently on the group.

PR stated that a small executive group is being set up to get a view on things and then possibly they will extend and use PBPP as a discussion panel.

DM stated that he feels strongly about this from the public perception.

LR agreed to share this with the executive group.

KM supports DM and thinks this is very important as no lay representation could be seen as being a negative thing.

LR confirmed that in time, a review with lay members is definitely going to be considered.

The links to other groups are going to be particularly important to influence, inform and helpful to support the work that is happening in the new digital platform. This group will be very useful. HDRUK and Research Data Scotland (RDS) developments need to involve two-way communication so that PBPP needs to be aware of, informing and influencing them, to help steer. The expertise that this group has will help to inform others, particularly with work at UK level, and that the input from this group will be very important. LR confirmed that she is the connection with all these groups.

LR stated that the agenda order would be changed as AM is officially on holiday: AM would speak to Item 2 (minutes of previous committee meeting) and Item 3.9 (update on ORION 4) before leaving. LR thanked AM for attending while on annual leave.

2. Minutes and actions of meeting on 3rd September 2019

It was noted that the first paragraph on page 6 is wrong – there is not a group for Research Data Scotland. This would be the Data Delivery Group which has no Caldicott Guardian representation. There was agreement that there should be Caldicott Guardian representation on the Data Delivery Group. PR to take the message back to the SG that PBPP would like CG representation on the Data Delivery Group.

Action 01: PR

The Data Delivery Group has an IG subgroup which is run by Claire Wainwright.

These changes will be corrected and then the minutes of the meeting held on 03 September 2019 were agreed as an accurate set of minutes.

All actions will be listed at the end of the minutes for future meetings.

Actions from meeting on 3rd September 2019

Page 6 *Action AM Family Nurse Partnership (FNP):* issues now been resolved. AM stated that she was expecting this application to come to the committee for approval today. MA explained that she had only received the updated application to PBPP two days ago, which was then too late to be submitted for today's meeting.

AM stated that her concern was that it had been through a long process and that it was clear that the issues had all been addressed. It has been to the CHI Advisory Group and she thought they were ready to submit it. Re-submission was all about clarity.

LR stated that this application will now go through T1 and hopefully goes through smoothly but if any issues it should then go to T2 for a quick response. Any queries from T1 to go to AM.

Action 02: MA

Page 11 *MA to circulate document for resourcing of the PBPP Committee:* this is to be carried forward to next meeting.

Action 03: MA

Page 12 Actions to be taken forward by the Operations Group

Caldicott Guardian vacancy this would be incorporated into the PBPP review. This would also include the recruitment of not just new younger lay members but younger committee members in general. Some members coming to end of their time, so succession planning will also be addressed in the review.

MR said that we need to consider the Terms of Reference.

LR thinks not to revise them just now, until we know the outcomes of the review.

AM when PBPP started had health and social care remit, if reviewing should we be writing to the Chief Social Work Director now or wait with review?

LR agreed that the review it is a good opportunity to look at specific challenges and looking into Health and Social Care.

GF thinks the alternative individuals is also a way to address some of the issues.

It was agreed that this should go to the Operations Group.

Action 04: Operations Group

HC said that the Conflicts of Interest should also be addressed with some urgency. We need to make provision for academics who have had, for example, an academic collaboration with an applicant in the last two years?

This should also be discussed by the Operations Group.

Action 05: Operations Group

3. Matters arising

3.9 Correspondence regarding 1718-0233 Preiss (ORION-4 study)

AM had previously raised concerns and discussed these with Professor Sir Rory Collins (see correspondence paper).

Discussion was held. It was agreed in principle of the value of the trial and for NHS Scotland to participate. However, it was also agreed that the condition given for this application will be upheld, that the initial contact with the patients should be done from within Scotland.

There is a different consent position in Scotland which requires a greater need to rely on and retain public trust. Lay members expressed strong agreement with this position.

It was proposed that the NHS NSS Scottish Clinical Trials Research Unit to do the initial bulk mailing to eligible individuals and any participants who wish to take part to contact Oxford, who would then take it from there.

It would need to be made clear to potential subjects that there is a central administration for this trial.

All agreed.

Action 06: MA/LR

HC asked that applicants should consider SHARE; SHARE has a list of people who have already consented for their clinical notes to be looked at to see if they are eligible for research, and to be contacted if they are.

It was proposed that there is an evaluation stage – as a proof of concept – where there is a follow up with the patient to review how the process worked and its acceptability. Possible future discussions to be had with SHARE about a mutually beneficial solution.

Action 07: HC/MR

AM left the meeting.

3.1 Provision of Caldicott Guardians for PBPP Committee

To be carried forward under the BCE review of PBPP.

3.2 Accountability lines for PBPP

Accountability is through the Chair to the Board Chief Executives.

3.3 Tier 2 Audit and resourcing PBPP Committee

To be carried forward as part of the BCE review of PBPP.

3.4 Feedback from the Extraordinary meeting

This was addressed in the above discussion regarding the Family Nurse Partnership (FNP).

3.5 Report from ACONF issue

This can now be removed from the agenda and when work concluded CM will give a final update on this.

DM stated that automation can produce errors as humans developing the models can make mistakes.

CM explained that as part of the quality assurance process there are as many checks as possible but it is not a 100% process, of which researchers are aware.

SP suggested that this should be fed back to Roger Halliday and that he should be made aware of challenges around ensuring the quality of linkage and the experience/ learning eDRIS have in this.

AIF is involved in RDS and will emphasise the requirement for data quality in linkage.

3.6 Tier 1 Audit

Before the PBPP workshop in October there were still three responses outstanding, of which two have now been received. However, one response is still outstanding.

MA has written a report and this will be discussed at the PBPP Ops group next week.

Agreed to continue the review with what we have. This report will come to the committee meeting in February 2020.

Action 08: MA

3.7 HDRUK gateway and access to health data

AM, LR and CM attended a roundtable meeting on 14th October 2019.

HDRUK is a UK level group bringing together a number of big charities, health and government groups to pool resources to promote healthcare research across the UK. Andrew Morris is the Director.

The Alliance is a group of collaborating partners – Scottish members are Chief Scientist's Office (CSO); NES Digital Services (NDS) and NHS NSS. It is anticipated other groups will be involved in this from the Scottish perspective through a proposed 'team Scotland' approach. Follow-on meetings are now happening and HDRUK are doing much more work now, e.g. on consistent data standards, what data are available and the quality of the data. CM and eDRIS are involved with the national datasets in relation to metadata.

There are 5 main areas of work - those of most direct relevance to this group relate to governance around access to the data/ approval processes and the means by which data will be made available to others for research. Other workstreams include public engagement.

KM asked if Generation Scotland are involved in this.

KM also asked about machine learning – is it our intention to be involved in developing this? Do we have the computing capacity for us to be involved in this? Through the Safe Havens?

This would all come under the 'Team Scotland' approach with the details still to be worked out. Lot of positive things can come out if this and it is good for Scotland to be involved early on to allow us to influence and inform how this progresses in a way we are comfortable engaging with.

HDRUK will be a standing item on the PBPP committee agenda for updates.

Action 09: MA

HC asked about previous discussion regarding ceding data controllership to the HDRUK Gateways and the Digital Hubs. We need to be very clear where this sits under the digital programme.

HC also asked about commercial access to the data and who controls this? Who assigns value to the data and ensures that the value of getting data comes back to the NHS?

LR stated that the SG Data Delivery Group were looking to develop an agreed Scottish policy around commercial access.

PR stated that a team Scotland approach is good way.

MR felt the presentation from HDRUK was quite IG light.

DM - UK BioBank should not be compromised by their involvement in HDRUK.

SP left the meeting

3.8 Cunningham 1819-0001 Application

HC has a conflict of interest, so did not stay in the room for this discussion.

MR – this application has been approved with 14 agreed conditions and a draft letter has been written. Most of these conditions are straight-forward although some may be more

challenging. The approval is for the data for machine learning, for the first phase of module development.

CM – National Safe Haven is not yet ready for machine learning.

AB asked about the applicant and the time they have been waiting, agreed they have been in the PBPP process for a very long time.

PR asked if PBPP this the correct place to be considering commercial interest. We need more expertise to get the most back from a commercial organisation.

LR stated that what we think is public benefit, we need to make sure the work has value to the people of Scotland.

DM stated that he felt this group does not have the experience.

There was some discussion on the need to know where to go for expertise.

Scottish approach to engagement with commercial companies in terms of growth and economy. In terms of public benefit, this group does have to contribute for the people of Scotland so they are getting something back. Steer from SG about growth of the economy included in public benefit. Benefit has to be explicit, not just 'public will benefit from the new thing that will improve their health'.

AF agreed with the issues but defining public benefit raised concern, as in a lot of applications it's not only Scotland, but it is wider than Scotland.

LR thinks it is correct we should expect a public partner for such applications. This needs to go back to them emphasising that the public partner needs to take on responsibilities of the data controller for the data and ensure that the commercial aspects of the application bring a return of value to Scotland. If they do not have a public partner, then we cannot approve the application.

If the applicant does not identify a territorial Board NHS partner, then MR/LR could offer a meeting with the applicants to talk them through the issues and consider whether NSS could be the NHS partner on behalf of NHSScotland. A final letter to be confirmed and sent to the applicant on behalf of the committee.

Action 10: MR/ LR/ MA

PR left the meeting

4. Standing Items

4.1 Panel Manager Report (October 2019)

For information.

4.2 Policy Decisions & Case Law Principles

For information.

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

To be carried forward when PR is able to lead discussion.

5. Discussion paper: Requirements for “special” applications before they come to PBPP

This paper arises from referred applications NOT coming to committee.

MA stated that we need something on our website or a paper on commercial and machine learning applications: high volume analyses should do some proof of concept work to show that the project will work. If no specific set of hypotheses, then the science needs to be tightened up.

Suggest a pilot study – e.g. using one board’s data to establish hypothesis. This might depend on what the type of application is.

Global discovery – hypothesis-free research (black box – no causal model, but looking for clusters within datasets at higher than average rate).

LR suggested it would be helpful to go through recommendations.

HC asked exactly what do you mean by machine learning?

HC feels the difficulty is to do with the science and not the machine learning point.

Applications not going through scientific peer review.

Discussion took place on machine learning.

We are supposed to see a clear, justified application. A specific application was discussed as an example. Application long, duplication, want everything for apparent fishing expedition. All agreed this application is not approved. No clear scientific validity and not approved.

Initially LR and MA to draft a set of principles of “this is what you need in place before you apply”. Once agreed, these will be placed on the website or in guidance notes. Any comments or suggestions to be sent to MA.

Action 11: All
Action 12: LR /MA

These principles would also be part of the assessment of risk and value, with the formation of a matrix to show this. E.g. High risk and low value (unlikely to be approved) or low risk and high value (likely to be approved). There will be areas in the middle where we will want to have more discussions, require amendments and/ or set conditions. The purpose of this is to help applicants before they apply and to set realistic expectations from the outset. If you wish to participate directly, please let MA know.

6. Accreditation of Safe Havens

This was carried forward – will need clarification from SG.

7. Annual report

Draft final report circulated with committee papers. If anyone wishes to comment, to do so as soon as possible. If no comments are given, then it will be assumed that everyone is happy and the report will be published and circulated.

Action 13: All

8. Any other business

No other business was raised

9. Date of next meeting

The next meeting will take place on Tuesday 4th February 2020 in Nine Bioquarter, Edinburgh.

19 November 2019: Action list

Action No.	Action	Who
19-11-19/ 01	PR to take the message back to the Scottish Government that PBPP would like CG representation on the Data Delivery Group.	PR
19-11-19/ 02	Family Nurse Partnership (FNP) application to go to Tier 1 panel.	MA
19-11-19/ 03	Document for resourcing the Tier 2 committee to be circulated for the committee meeting on 4 th February 2019.	MA
19-11-19/ 04	Operations Group to consider the alternative individuals proposal for Tier 2 committee members.	Ops Gp
19-11-19/ 05	Operations Group to consider the Conflicts of Interest policy for applications coming to PBPP.	Ops Gp
19-11-19/ 06	Consider possible future discussions to be had with SHARE about a mutually beneficial solution.	HC/ MR
19-11-19/ 07	Someone to draft a letter to Professor Sir Rory Collins to outline the alternative process for the ORION-4 study.	MA / LR
19-11-19/ 08	Tier 1 Audit Review to come to next PBPP committee meeting.	MA
19-11-19/ 09	HDRUK to be added as a standing item on the PBPP committee meeting agenda.	MA
19-11-19/ 10	A final letter to be confirmed and sent to the applicant on behalf of the committee.	MR / LR / MA
19-11-19/ 11	Discussion paper on Requirement for “special” applications before they come to PBPP. Any comments to be sent to MA.	ALL
19-11-19/ 12	Principles for these applications to be drawn together from discussion paper.	LR / MA
19-11-19/ 13	Annual Report: any comments to be sent to MA. Otherwise it will be sent to be published as it stands.	ALL