Public Health and Intelligence

minutes

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

12 June 2019 at NINE, Edinburgh Bioquarter.

Present: Brian Houston, Chair (BH)
Kenneth McLean (KM)
Eleanor Anderson (EA)
Helen Colhoun (HC) – for part
Maria Rossi (MR)
Danny McQueen (DM)
Carole Morris (CM)
Abbe Brown (AB) T/C
Angus Ferguson (AF) T/C

Marian Aldhous (MA)
Phil Dalgleish
Susan Kerr

Apologies: George Fernie (GF)
Corri Black (CB)
Penni Rocks (PR)
Alan Ferrier (Al F)
Steven Pavis (SP)
Alison McCallum (AM)

1. Chair's welcome and Apologies

The Chair advised that the meeting was not quorate. However, as applicants are on their way, those present agreed to proceed with applications. Detailed notes from the discussion will then be sent out to absent members before final agreement.

There were questions around resourcing and structure of the committee. It was noted that PR has been given the task of taking forward all issues of PBPP and possibility of extending the scope of this group. BH to meet with PR next week.

MR informed the group that both EA and herself were in attendance, because of the lack of Caldicott Guardian representation, but with similar opinions as they share the Caldicott Guardian role from NSS.

Other meeting matters will be carried forward to next meeting in September.

Applications for review

HC stated that with regards to the 1819-0001 Cunningham application she will need to be recused due to a conflict of interest. She will sit out of the room for this one.

HC stated that with regards to the 1718-0233 Preiss application she also has a conflict in that she currently collaborates with Dr Preiss on the LENS retinopathy trial. Therefore, she felt she should probably be recused for this application too.

HC asked whether there should be any sort formality regarding the conflicts of interest policy for committee members and applications that came to committee?

As HC had an item of AOB that she wished to be brought to the committee, it was agreed that this should be done first, and the order of the applications changed, so she that could leave before the discussion of the above two applications.

2. Any other Business

HDRUK

HC stated that UKRI/ MRC have given money to HDR UK to commission "disease focused digital innovation hubs". These hubs would work with NHS to acquire and prepare data for research, with the requirement that data is made available to industry as well as to academia. Hubs will prepare the data. Access to the data will be managed by a "gateway" and this will be run by HDR UK itself. There seemed to be some expectation that Safe Havens would be involved but unclear where eDRIS would fit in. Diabetes colleagues in England want to collaborate with academics in Scotland, but this would mean these Scottish academics committing to passing on the data via a third party into the HDRUK gateway. It is not clear whether the Scottish academics have the authority to do this.

HC stated that she felt there needs to be clarity on this and how where the HDRUK hub and access via the HDRUK gateway fits into NHS Scotland's approval processes. Does PBPP allow secondary use for linked data? This appears to be a big jump for data security from what PBPP provides and what HDR UK seem to be prescribing (Lower standard of security). The deadline for applications was 2nd July 2019. HC felt impossible to get something in place for 2nd July.

KM: what are the risks of going ahead with this and providing data? Was there an application which set precedence in 2016, a case relating to arms length governance of linked data? CM said that there had been one application (Kumari) but this had a clear framework of governance.

Chair: we need to get better picture of what the demand is and then PBPP committee should review.

CM: David Crossman, from the Chief Scientist's Office, is the NHS Scotland rep on HDRUK Alliance. CM to contact him and find out what discussions have been had and report back to the committee.

MR: Scottish Caldicott Guardians are not aware of new suggested arms length body.

AB: we are the body who would decide if this data is available and the privacy risks involved?

NHS logo is on the HDRUK website so we need to know the position

AB stated that we need to make a call to the person in charge. CM stated that this is David Crossman and agreed to get in touch with him to find out more information.

CM and HC off line will get a better understanding of where this stands and then from that PBPP as a group need to take a view of decisions arising.

HC felt need to understand position of Scottish Government and it was agreed to take forward with Penni Rocks and/or Elena Beratabide.
EA requested that someone from the SG to come to the meeting.
It was also agreed that it was necessary to work out how this fits in with Domain B of the Digital Health and Care Strategy. Hopefully PR can provide more information. Chair to contact Penni.

BH, HC and CM to try establish what the position is on behalf on NHS Scotland and let the committee know.

Actions: CM, HC and BH

3. Minutes from previous PBPP committee meeting
The minutes from the previous meeting were agreed.

MR requested that more information is provided if changes made from previous minute. The changes made had been agreed at the previous meeting.

4. Standing Items
4.1 Panel Managers report (June 2019)
For information only.

4.2 Policy Decisions & Case Law Principles
For information only.

4.3 PBPP Resource Scottish Government update, including new Digital Health and Care Strategy
No information provided.

5. Application 1819-0051 Cooper

Lead reviewer: GF (from previous meeting).

It was noted that this application was discussed at the previous committee meeting and comments had been fed back to the applicant.

AM and AF sent in comments, in their absence, for this meeting

This project aims to investigate health and social care inequalities in people with learning disabilities and autism, compared with other people by using Scotland's Census, 2011.

Discussion took place prior to Professor Cooper being invited into the meeting and specific outstanding questions to be addressed to the applicant were listed.

It was agreed that before a final decision was made on this application, that detailed notes would be sent to the committee members not in attendance to allow informed decisions.

HC concerned about reputation of PBPP committee o/a quorate issues (decision made here and circulated to absentees for full approval.

BH welcomed Professor Sally-Anne Cooper and Angela Henderson into the meeting.

The applicants gave a brief presentation to the meeting, addressing the outstanding concerns of the committee.

Professor Cooper stated that there has now been a change to the size of comparison population in data set 1, due to feedback from Stats PBPP and they have revised this approach.
This is now 15% of general population

There was discussion around the questions from the committee.

Professor Cooper did comment that she had found the PBPP process really useful to think through the linkage and variables requested. She also said that she had a very helpful eDRIS coordinator, who had been excellent.

BH thanked both Professor Cooper and Angela Henderson for attending.

Post-presentation Discussion
Most of the fundamental questions had been raised by KM, who was happy with the responses.
Are we happy with the variables and their justification? Yes can see how all relevant.

All happy to approve, with conditions that Stats PBPP approve and updated application with list of variables.

MA agreed to circulate detailed notes to all committee members for full agreement.

Action: MA

6. Application 1819-0236 Campbell

Lead reviewer: EA

There was some discussion as to why this application had come to PBPP in the first place, as this was a service evaluation, but it includes secondary use of NHS data.

Excellence in Care for Nursing and Midwifery programme, which forms part of the government's response to the Vale of Leven Hospital Inquiry Report, covers nursing and midwifery in all hospitals and community services, from A&E to mental health and care of older people to children's services. The aim is that when fully implemented all NHS boards and integrated joint boards will have consistent and robust process and systems for measuring, assuring and reporting on the quality of nursing and midwifery care and practice.

Before the applicant came in, the discussion was focussed on the use of NHS staff data and the information that will be gathered, by whom and whether and how staff know about the use of their data.

BH welcomed Fiona Campbell (applicant), Diane Murray, Scottish Government Deputy Chief Nurse (Information Custodian) and Andrew Moore (Health Improvement Scotland)

The applicants presented slides on the outstanding concerns of the committee.

Governance now sits with new governance board for Excellence in Care (EiC), chaired by Diane Murray.
Scottish Government had made a manifesto promise to introduce the Health and Care staffing Act (2019), which was passed last week. Health and Care staffing Act (2019) now requires health boards to submit data to Healthcare Improvement Scotland.

This application was a validation of indicators of quality, some existing and some being developed, and also includes nursing and midwifery data to truly reflect care levels. There would be an EiC lead in every board.

BH thanked Ms Campbell, Ms Murray and Mr Moore for attending the meeting.

Post-presentation discussion
There was discussion around the implications of the application and the Act.

Data Protection Impact Assessment (DPIA) and data protection notices not yet in place. These need to be in place.

There was a general agreement that those present were happy with this and this application should be approved on condition that the DPIA is signed off by NSS and subject to ratification by the rest of the committee.

There was a further discussion as to why this application came to PBPP? There are lots of other studies and processes doing similar work. NHS NSS needs to use its own internal processes for these types of projects, although the rationale is that this is secondary use of data for management purposes and not direct care.

Although, technically, this does come under the PBPP Terms of Reference but not everything like this should come to PBPP. There is a place for national IG review for national projects, but members were not convinced that PBPP is the right place. This needs to be fed into the IG review.

7. Application 1819-0001 Cunningham

At this point Helen Colhoun left the meeting as she has conflicts of interest with this application and that of Preiss application.

Lead reviewer: GF, but lead by MR in his absence

This application is a program to inform direct patient care using machine learning for using diabetes patient data.

The pre-discussion focussed around the commercialisation of the product and use of data for its development and a there were a number of questions that were still unclear.

BH welcomed the applicants: Dr Scott Cunningham and Dr Debbie Wake to the meeting by telephone; neither were present.

The applicants had sent in a presentation focussing on the outstanding concerns of the committee.

The benefit of the potential product to patients was discussed, as were many questions around the commercialisation of the product.

DPIA would need to be in place.

There was a question as to whether the final product would require a randomised controlled clinical trial under Medical Device regulations. The applicants were seeking advice from the Medical Device Authority, but any such clinical trial would be conducted through Dundee University. This would require separate ethical review.

This PBPP application was for access to the data to develop the product.

The exploitation and commercialisation plans could be made available to PBPP but these are commercially sensitive documents.

BH thanked Dr Cunningham and Dr Wake for telephoning into this meeting.

Post-presentation discussion
The commercialisation opens up a whole wider area for PBPP.

Need guidance from Scottish Government regarding the industrial strategy as the rules around these are not clear.

Exploitation plan seemed balanced – free of charge to Scotland with prospect of sharing of Royalties.
Need to see copy of commercialisation plan, exploitation plan and collaboration agreement so can see if is written down as to what NHS is going to get out of this. Acknowledge that this may not be the final plan. May not be allowed to see the Collaboration agreement, could we ask for an official letter that sets out the return for NHS Scotland?

Machine Learning is still in development – generally and also for this project. Product still under development and will product be used for a RCT? There will need to be some sort of validation of the system, which will be developed by Dundee University.

Ask for documentation and clarifications on:

- Copies of Commercialisation and Exploitation plans
- Collaboration agreement or reassurance that clauses around returns to NHSScotland, not just Royalties, but e.g. free updates for lifetime of product.
- Can they explain further about their plans for commercialisation including outwith Scotland?
- Who owns product once made?
- Who is legally responsible if it goes wrong?
- Who is responsible for technical development / evaluation in future?
- Who is going to do the evaluation?
- Who is will be data controller for the product? Who is Data controller for the data?
- Cyber security?
- Public benefit needs to be further reassured...

When we get the responses, these will be circulated around the whole committee. Those present were minded to proceed subject to the clarifications.

Need to be clear that on receipt of information there is a clear path for approval and without delays. Firm timetable and keep to deadlines. Therefore: Clarifications to applicant – ask for response within week.
Responses to committee and ask for decision within a further week.

Committee was minded to approve, subject to the above clarifications. This was to be communicated to other committee members, but not applicants.

Further issues around commercialisation that need to be pursued at Scottish Government level.

Agreed to ask for clarification and then communicate to rest of committee with a specific time frame, 7 days, with a further 7 days for committee responses. BH requested that responses from the committee should not be delayed.

Action: MA and ALL

8. Application 1718-0233 Preiss

Helen Colhoun had already left the meeting due to Conflict of Interest with this application. Abbe Brown (on phone) also left the meeting.

Lead reviewer: EA

This application revolves around the ORION-4 Trial.
Lowering cholesterol with statin reduces the risk of heart attacks and strokes. This study aims to find out whether inclisiran, given every 6 months for about 5 years, safely reduces the risk of heart attacks and strokes.

Nub of this application is the recruitment method. Instead of recruiting at local level through local care teams, the trial team are asking for patient identifiers and hospital data (ICD codes) indicating that the patient has had a previous cardiovascular event. The trial team will do further screening and then write and invite the patients to the clinic.

For previous studies using this methodology, complaints have been received from patients.

BH welcomed the applicant, Dr David Preiss to the meeting,

Dr Preiss, presented slides addressing the outstanding concerns of the committee.

Only two people can access the patient identifiable information sent to Oxford and these are used to check initial eligibility before sending out invitations. Using this method, invitations are sent to patients from Oxford with appointments with local trial team. Each invitation letter has the local NHS logo and signed by local investigator. The accompanying Information leaflet includes information on how the data was received from the NHS with further links to website. This has been read by lay members and gone through ethical review.

This challenges the “old way” of patient recruitment. Using this approach of invitations without consent gives opportunities for whole population to be involved, rather than just those who attend specific clinics / GPs, who tend to get involved in clinical trials. In addition, this approach is cost effective, as reducing costs of trial will ultimately reduce the costs of the drug once it comes on the market.

BH thanked Dr Preiss for attending the meeting.

Post-presentation discussion
This seems to be an efficient way of recruiting for a large trial and the applicant made the case well. The privacy risk appears to be low and it seems that the opportunity and benefit are outweighing the privacy risk.

But there have been complaints; are these as trivial as the applicant said? The lead for this application would consult with those who still have concerns, to address them.

Action EA/MR/AM

Agreed approval subject to remote approval from other members of this group.

9. Any further other Business

No other business to be discussed

10. Date of next meeting

The next meeting will be held on Tuesday 3 September 2019, Nine Bioquarter, Edinburgh